

OPERATOR MANUAL

P/N: MO04444-00ING

SOFTWARE VERSION 21.5

Rev. 4, 12.2016

This manual is valid for the BT analyzers of the series: BT1500 & BT1500i, BT3000Plus, BT3500 & BT3500S and all their derivatives.

The differences among the analyzers are highlighted where necessary.

All general instructions referred to BT1500 include also the BT1500i analyzer. When the BT1500i analyzer has instructions on its own, this is duly explained.



The product is compliant with the essential requirements of the following EC Directives:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical instruments;
- European Community Council Directive 2006/95/CE Concerning on electrical equipment designed for use within certain voltage limits;
- European Community Council Directive 2004/108/CE Electromagnetic Compatibility Directive;

It also conforms to International Standard: IEC 61010-1: 2001; IEC 61010-2-081:200+ A1:2003; IEC 61010-2-101:2002; IEC 61010-2-010:2003 and CEI EN 61326-2-6 (EMC).

The conformity is attested when the equipment is installed in accordance with the conditions outlined in the manual

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IMPORTANT NOTICE ON THE USE OF THE UPS DEVICE

ATTENTION!

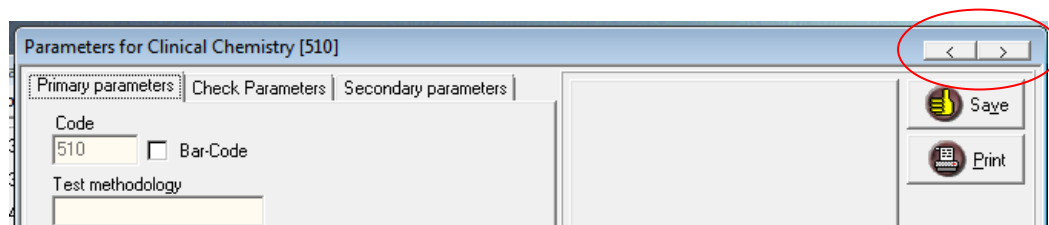
BIOTECNICA INSTRUMENTS ANALYZERS MUST OPERATE ONLY IF CONNECTED TO AN UPS DEVICE.

BIOTECNICA WILL NOT BE RESPONSIBLE FOR ANY DAMAGE TO THE ANALYZER OR INJURY TO PERSONS IF THE ANALYZERS ARE OPERATED WITHOUT THE PROPER CONNECTION TO THE UPS DEVICE OR WITHOUT THE UPS ITSELF.

IMPORTANT NOTICE FOR SYSTEMS WITH EXTERNAL PC

SOME GRAPHICAL ELEMENTS MAY NOT BE VISIBLE BECAUSE OF WINDOWS® 7 OR ABOVE O.S. DEFAULT SETTINGS.

For instance, the arrows in the Parameters page would not be visible:



Please use a standard Theme and font 96 DPI for all Windows® O.S.

INDEX

SECTION I: GENERAL INFORMATION

CHAPTER A	
1. INTRODUCTION	Page: 2
2. BASIC OPERATING PRINCIPLES OF THE ANALYZER	Page: 3
3. SYMBOLS: explanation of the used or applied symbols	Page: 4
4. BRIEF DESCRIPTION OF THE SYSTEM	Page: 9
4.1. Front view of the analyzer	Page: 9
4.2. Rear Panel Controls and Connectors	Page: 11
4.3. Modules	Page: 13
CHAPTER B	
1. INSTALLATION	Page: 2
1.1. Unpacking the Analyzer	Page: 2
1.2. Installation	Page: 4
1.3. Starting the instrument	Page: 8
1.3.1. Turning on the instrument for the first time	Page: 8
1.3.2. Preliminary checks	Page: 9
1.3.3. Used solutions/detergents	Page: 10
CHAPTER C	
1. FUNCTIONS	Page: 2
1.1. Description of the Program Menu	Page: 2
1.2. Operating Principles	Page: 5
1.2.1. Computations	Page: 5
1.2.2. Applied mathematical functions	Page: 7
1.2.3. Initial computation	Page: 9
1.2.4. Optimization techniques for Clinical Chemistry	Page: 9
1.2.5. Methods Description	Page: 10
1.3. Analyses Programming	Page: 15
1.3.1. Creating a New Code	Page: 15
1.3.2. Relation Tests	Page: 16
1.3.3. Primary Analytical Parameters	Page: 17
1.3.4. Check Parameters	Page: 23
1.3.5. Secondary Analytical Parameters	Page: 24
1.3.6. Automatic re-runs	Page: 27
1.4. Controls	Page: 28
1.5. Calibrations	Page: 29
1.6. Creating Profiles	Page: 34
1.7. Creating the Current Analyses' Tray	Page: 35
CHAPTER D	
1. PERFORMANCE AND LIMITS	Page: 2

INDEX

CHAPTER E	
1. OPERATING PROCEDURE	Page: 2
1.1. Turning on procedure	Page: 2
1.2. Reagents: insertion and removal	Page: 2
1.3. Running Standard & Controls (on command or timed)	Page: 5
1.4. Samples	Page: 7
1.5. Work Lists	Page: 13
1.6. Turning off procedure	Page: 17
1.7. Access Password	Page: 18

CHAPTER F	
1. QUALITY CONTROLS	Page: 2
1.1. Inserting/modifying controls	Page: 2
1.2. Data management	Page: 4
1.3. Displaying and processing by lot pairs: Youden graph	Page: 6
1.3.1. Westgard Graph	Page: 7
1.3.2. Daily Chart	Page: 9
1.3.3. Levey-Jennings graph	Page: 10
1.4. Additional Functions	Page: 11
2. POPULATION	Page: 12
2.1. Analysis Selection (How to run a Query)	Page: 13
2.2. Principal statistics formulas used in Population module	Page: 17
2.3. Inserting external analyses	Page: 19
2.4. Other menu functions	Page: 20
3. PATIENTS' ARCHIVE	Page: 22
3.1. Selection (How to run a Query)	Page: 24
3.2. Patients' report	Page: 26
3.3. Printing Reports	Page: 28
3.4. Other menu functions	Page: 30

CHAPTER G	
1. DISPLAYING AND PRINTING RESULTS	Page: 2
1.1. Results per Patient	Page: 3
1.2. Results per Test	Page: 8
1.3. Displaying Real-Time data	Page: 9
1.4. Reaction graphs	Page: 11
1.5. Flags list	Page: 13
1.6. Sorting results in real time	Page: 14

CHAPTER H	
1. ANALYZER TECHNICAL FUNCTIONS	Page: 2
1.1. Service Functions	Page: 2
1.1.1. Analyzer Utilities	Page: 2
1.1.2. Mechanical Calibrations	Page: 4
1.2. Diagnostic Functions	Page: 6

INDEX

2. ANALYZER SETUP	Page: 10
CHAPTER I	
1. BARCODE AND RELATED FUNCTIONS	Page: 2
2. USING THE BARCODE	Page: 2
2.1. Barcode on Samples	Page: 2
2.2. Reagent Barcode	Page: 5
CHAPTER K	
1. VACUUM PUMP SYSTEM INSTALLATION/OPERATION	Page: 2
1.1. Functional characteristics	Page: 2
1.2. System control functions	Page: 3
1.3. Waste container (external)	Page: 3
1.4. Installation & operation	Page: 4
1.5. Maintenance and care	Page: 4
1.6. Trouble-shooting	Page: 4
1.7. Spare parts for maintenance	Page: 5
CHAPTER L	
1. I.S.E. MODULE 2P– BT3000Plus & BT3500 – BT1500i	Page: 2
1.1. Introduction	Page: 2
1.1.1. Contents of the wooden crates: I.S.E.	Page: 4
1.1.2. Applied Mathematical Functions	Page: 4
1.2. Performance And Limits	Page: 5
1.3. I.S.E. Wash and system shut down	Page: 6
1.4. Mechanical Calibrations: I.S.E. Arm	Page: 6
2. Operating the I.S.E. Module	Page: 7
2.1. Parameters	Page: 7
2.2. Programming Standards and Controls	Page: 9
2.3. Replacing and Installing Electrodes	Page: 12
2.4. Preliminary steps before starting the system	Page: 14
2.5. Calibration procedure	Page: 15
2.6. Measuring unknown samples	Page: 17
3. Precautions, maintenance and Troubleshooting	Page: 18
3.1 Precautions for ISE Module usage	Page: 18
3.2. Suggestions for performance maintenance	Page: 19
3.2.1. I.S.E. Maintenance	Page: 20
3.3. Troubleshooting	Page: 23
4. Returning The Analyzer To The Tech. Assistance Service	Page: 29
5. I.S.E. Module Consumables	Page: 31
CHAPTER L1	
1. I.S.E. MODULE-4P – BT3500S	Page: 2
1.1. Introduction	Page: 2
1.1.1. Contents of the wooden crates: I.S.E.	Page: 5

INDEX

1.1.2. Applied Mathematical Functions	Page: 5
1.1.3. Operating principles	Page: 6
1.1.4. Precautions for the I.S.E. Module-4P usage	Page: 7
1.2. Performance And Limits	Page: 9
1.3. Starting the I.S.E. Module-4P	Page: 10
1.4. Analyzer Utilities - I.S.E. Wash and system shut down	Page: 11
1.5. Mechanical Calibrations: I.S.E. Arm	Page: 12
2. Operating the I.S.E. Module-4P	Page: 13
2.1. Parameters	Page: 13
2.2. Programming Standards and Controls	Page: 16
2.3. Replacing and Installing Sensors, Tubes and Pumps	Page: 18
2.4. Preliminary steps before starting the system	Page: 20
2.5. Calibration procedure	Page: 21
2.6. Measuring unknown samples	Page: 22
3. Maintenance and Troubleshooting	Page: 22
3.1. Suggestions for performance maintenance	Page: 22
3.1.1. I.S.E. Maintenance	Page: 23
3.2. Troubleshooting	Page: 25
4. Returning The Analyzer To The Tech. Assistance Service	Page: 27
5. I.S.E. Module-4P Consumables	Page: 29

CHAPTER M

1. WARNINGS AND PRECAUTIONS	Page: 2
1.1. Potential risks during operation and maintenance	Page: 2
1.2. Warnings and precautions	Page: 3
1.3. Waste disposal	Page: 6
1.4. Returning the analyzer to the T.A.S.	Page: 6
1.4.1. Operating Analyzer	Page: 6
1.4.2. Not Operating Analyzer	Page: 7
1.5. Analyzer safe disposal	Page: 8
1.6. Electric and electronic devices disposal	Page: 9

CHAPTER N

1. MAINTENANCE AND CARE	Page: 2
1.1. Preventive maintenance and Extra Wash	Page: 2
1.2. Replacing tubing and accessories	Page: 3
1.2.1. Clinical Chemistry	Page: 3
1.2.2. Extra wash cuvettes	Page: 5
1.2.3. Photometric lamp	Page: 5
1.2.4. Dilutors' piston o-ring	Page: 6
1.3. Cleaning the instrument	Page: 7
2. MALFUNCTIONS	Page: 8
2.1. Troubleshooting	Page: 8
2.2. Screen messages	Page: 9

INDEX

2.2.1. Screen messages - Causes and remedies	Page: 10
2.2.2. Messages requiring technical assistance	Page: 12
2.2.3. Optical system verification messages	Page: 14

CHAPTER 0

1. TECHNICAL SPECIFICATONS	Page: 2
-----------------------------------	----------------

SECTION II: SUPPLEMENTARY INFORMATION

CHAPTER 1

1. ABBREVIATED OPERATING INSTRUCTIONS	Page: 2
1.1. Turning on and preliminary procedures	Page: 3
1.2. Inserting Reagents for Clinical Chemistry	Page: 6
1.3. Analytical calibrations and Controls	Page: 7
1.4. Entering Patients and Work Lists	Page: 10
1.5. Running Tests	Page: 14
1.6. Displaying and Printing Results	Page: 15
1.7. Turning off the analyzer	Page: 19

CHAPTER 2

2. WARRANTY CONDITIONS	Page: 2
• Notes from the manufacturer	Page: 3
• Parts/Instruments Return Authorization	Page: 4

CHAPTER 3

3. ORDERING INFORMATION	Page: 2
3.1. GENERAL TERMS AND CONDITIONS FOR SALE	Page 2
3.2. Consumables for the analyzer	Page: 3

CHAPTER 4

4. SOFTWARE EXTENSION:	Page: 2
Serial communication analyzer <-> Host Computer	Page: 2
4.1. General	Page: 2
4.2. Patient transmission to analyzer	Page: 2
4.3. Results reception	Page: 3
4.4. Calculation of check-sum	Page: 5
4.5. Wiring diagram of interface cable	Page: 6
4.6. Variable communication protocol	Page: 7
4.7. Serial communication test programs	Page: 17
4.7.1. Program Comunica.exe	Page: 17
4.7.2. Program BTPLUS.exe	Page: 17

CHAPTER 5

5. INSTALLATION OF THE OPERATING SYSTEM (OS)	Page: 2
5.1. Installation Of The Operating Program	Page: 3

INDEX

5.1.1 For All Analyzers With Internal Computer	Page: 3
5.1.2. Installation For BT 1500	Page: 4
5.2. Upgrading The BT Analyzers Software	Page: 6

CHAPTER 6	
6. TECHNICAL ASSISTANCE	Page: 2

CHAPTER 7	
7. BIBLIOGRAPHY OF ALLIED SUBJECTS	Page: 2

CHAPTER 8	
8. LIST OF APPLICABLE METHODOLOGIES	Page: 2

ATTENTION: USE OF THE ANALYZER INTERNAL COMPUTER – DOES NOT APPLY TO ANALYZERS WITH EXTERNAL PC

The computer box of BT analyzers is designed for long-term security and reliability and is virtually maintenance-free as long as the user does not install any third-party application programs. If these applications are installed, then they may damage the operating system registry and may also cause disastrous consequence for the computer's hard-drive. Biotechnica Instruments S.p.A. will not be responsible for any damage to the analyzer, its software and data in the hard-disk in case of improper use of the PC box. This includes also: installation of external programs, not properly secure net connections (intranet and internet) and the use of disks without the necessary verification for viruses presence. Biotechnica Instruments S.p.A. will not be responsible for any damage caused by non authorized third parties who may open and alter the PC box configuration.

SECTION I: GENERAL INFORMATION

CHAPTER A: SYSTEM DESCRIPTION

1. INTRODUCTION	2
2. BASIC OPERATING PRINCIPLES OF THE ANALYZER	3
3. SYMBOLS: EXPLANATION OF THE USED OR APPLIED SYMBOLS.....	4
4. BRIEF DESCRIPTION OF THE SYSTEM.....	9
4.1. Front View Of The Analyzer	9
4.2. Rear Panel Controls And Connectors.....	10
4.3. Modules	12

IMPORTANT NOTICE

The introduction of access passwords has been rendered mandatory since 2004 for safeguarding sensitive data (refer to CHAPTER E, paragraph 1.7.).

NOTE:

All pictures in this manual are referred to the BT3000 Plus. Figures may be different for the other analyzers.

1. INTRODUCTION

This instrument is an automatic analyzer for Clinical Chemistry and Immunoturbidimetry, it represents the technological evolution of the T.A.R.G.A. line (“**T**ech**n**ology **A**dvanced **R**andom **G**eneration **A**nalyzer”), manufactured by Biotechnica Instruments S.p.A. Rome, Italy.

The analyzer software is based upon Windows O.S. (Fig. 1). It is easy to learn and offers the operator (thanks to its selective random access) the maximum flexibility in the acquisition and performing of **ROUTINE** and **URGENT** (“**STAT**”, “Single Test Actual Time”) tests on *serum*, *plasma* and *urine*.

Designed for continuous use (*24 hours non-stop*), the analyzer can perform **STANDARDS’ CALIBRATION** and **QUALITY CONTROLS** upon operator’s request or at programmed time intervals. An **AUTODIAGNOSTIC FUNCTION** is built into the operative software, continuously monitors the analyzer system for correct operation.

- Besides clinical chemistry and immunochemistry tests, the BT1500i, BT3000 Plus, BT3500 and BT3500S are equipped for ions determination with the **I.S.E. Module** (Ion Selective Electrodes – BT1500i, BT3000 & BT3500) and the **I.S.E. Module 4P** (BT3500S).
- The methods used are: **End Point**, **Fixed Time**, **Kinetic**, **Initial-Rate (I.R.)**, **Sample Blank type A and B**, **Only Read**, **End Point 2 points**, **Sample Blank (A-b)**, **Sample Blank (B-b)**, **Absolute End Point** and **End Point Starter**. It is possible to store up to **500 different test codes**, plus **Relation Tests** with no limit. In the stored analyses list the operator can generate customized test codes sequence for the reagent tray in use, including the relation tests.
- During analyzer operation, the refrigerated reagents chamber ensures a longer stability of the products in use.
- The positive **barcode** identification of reagents position, reduces the possible error during the positioning of bottles.
- It is possible to perform repetitions (**Re-run**) upon operator's request or automatically (pathological results).
- In case of hyperactive results, the test repetition can be performed with automatic dilution of the sample, as programmed in the parameters page. It is also possible to run tests on already diluted samples, thanks to the automatic data processing function.
- Random positioning of samples and positive barcode identification. The bar-code feature and the connection to the Host Computer allow the system to be fully automated.
- An internal software manages the **QUALITY CONTROL** (statistics of control sera and population) and **PATIENTS’ ARCHIVE** with data display and printouts.

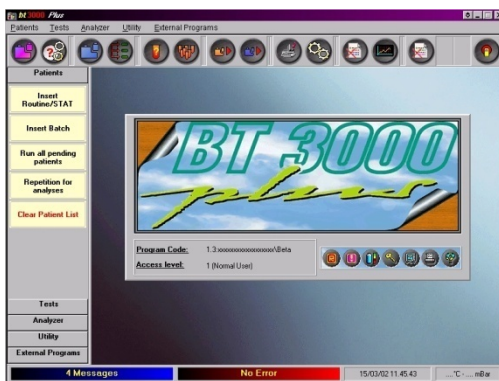


Figure 1

2. BASIC OPERATING PRINCIPLES OF THE ANALYZER

The automatic analyzer is based upon the *spectrophotometry* principles.

The light absorption laws rule the performance of spectrophotometers.

The amount of light radiation that passes through a homogeneous absorbing medium is defined as *transmittance*, T , where:

$$T = I / I_0$$

I_0 = incident light radiation intensity

I = transmitted light radiation intensity

The *absorbance*, A , (or *extinction*, E) is defined as:

$$A = \log (1/T) = \log I_0/I$$

The Lambert-Beer law states the relation between absorbance, concentration of a compound absorbing light and sample thickness:

$$A = \varepsilon c d$$

ε = molar extinction coefficient of the compound absorbing light at a certain wavelength.

c = molar concentration of the compound absorbing light

d = optical path of the radiation into the solution

The absorbing spectrum of a compound is represented by a graph where the absorbed light (= absorbance) is related with the wavelength. For a colored solution, the graph will show one or more absorbance peaks. These may be in the visible part of the spectrum (400-700 nm) as in the ultraviolet (200-400 nm) region.

The analyzer uses a photometric system specially designed by the R&D Dept. of the Biotechnica Instruments S.p.A.

A light beam is sent through a cuvette that contains the solution that has to be read. The exiting light beam is transmitted to a photometer containing 10 interference filters of different wavelengths. The signal is amplified and then processed by the specific electronics and by the computer. The program then makes all the necessary calculations and controls, so that it can finally present the concentration of the compound in the sample and the any irregularities found in the reaction.

The general principle upon which the photometry in clinical chemistry is based is the following: the increasing or the decreasing of the color intensity in a specific solution is proportional to the searched compound concentration. Generally speaking, when a sample is added to a specific reagent, it starts a reaction carried out by specific enzymes or substrates. This reaction causes the increasing (or decreasing) of the solution color inside the cuvette. During the reaction process, the instrument "reads" it by means of its absorbance. The final data processing is done with reference to a calibration or a theoretical factor, so as to give at the end the concentration of the compound into the sample.

The ISE (Ion Selective Electrodes) module, where available, is a device dedicated to the determination in the samples of the electrolytes (see chapter L and L1). This device is defined as ion selective as the used electrodes react with the corresponding ions in accordance with the following Nernst law:

$$E = E_0 + RT/nF \log aM^+$$

aM^+ = M^+ ion activity

E = potential in Volt

E_0 = constant (H^+ electrode redox semi-reaction std potential)

R = gas constant

F = Faraday's constant

T = temperature expressed in Kelvin degrees

n = ion charge

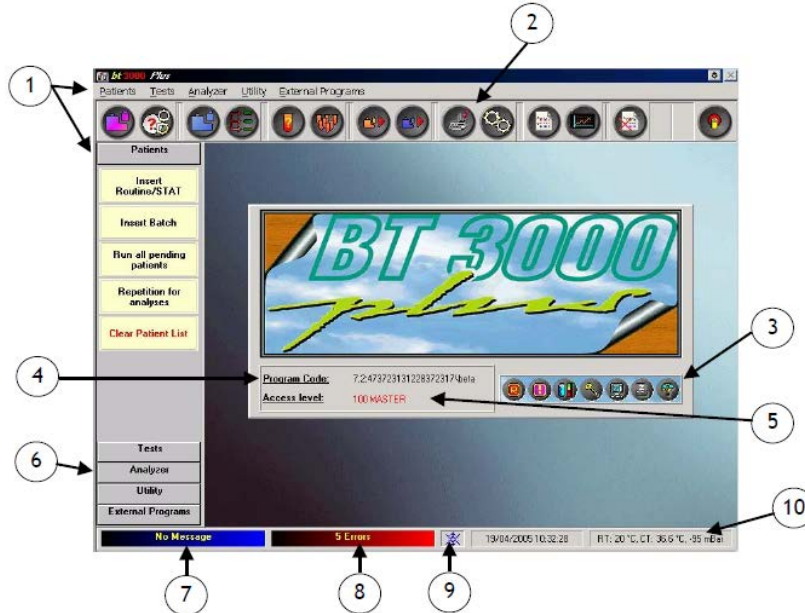
The electrodes life is dependent upon the type of electrodes, the number of sample runs and the routine maintenance procedures outlined in this manual.

3. SYMBOLS: EXPLANATION OF THE USED OR APPLIED SYMBOLS

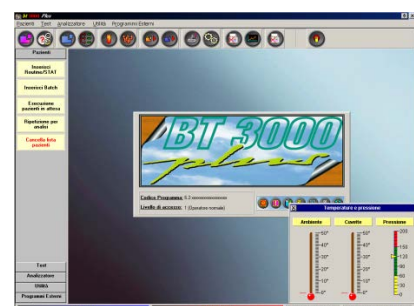
As the analyzer software is based upon Windows, it uses the Windows style, icons, quick commands, function keys and curtain-shaped menus.

Every screen has its own icons and specific menus that will be described hereafter. The full meaning of each command will be explained in the corresponding chapters.

At the start-up, the program will display the following main window:



- ① **Main menu:** each menu generates other commands and/or options
- ② & ③ **Direct access icons:** selecting each icon the relative command is directly activated
- ④ **Program code:** operative program software version
- ⑤ **Access level:** is the access level of the operator: it is password dependent
- ⑥ **Vertical Bar - Commands:** Direct access to function commands
- ⑦ **Messages bar:** clicking here opens a window showing the messages received by the program
- ⑧ **Errors bar:** by clicking here a window is opened showing the errors occurred during the work session.
- ⑨ **Refrigerator Status Indicator**
- ⑩ **Operating Pressure Indicator, Ambient Temperature (RT), Cuvette Temperature (CT)**



SERVICE ICONS BAR



Reset Analyzer (F5)



Stand-by Analyzer (F6)



Displays the Volumes' Status; Used to Insert/Remove Reagents (F10)



Password (F7)



Status Analyzer (F2)



Printer Setup (F4)

FUNCTION ICONS BAR



1 - To Insert New Codes, Parameters, Standards and Controls for all Analyses



2 - To Create the On-Line Reagents' Tray



3 - To Insert Parameters/ Standard and Controls for the On-Line Reagents











4 - To Insert/Modify Profiles



5 - To Insert Routine - View Programmed or In-Run Patients







6 - To Insert Batch

-  **7 - To Run Standards**
-  **8 - To Run Controls**
-  **9 - Analyzer's Utilities**
-  **10 - Mechanical Calibrations**
-  **11 - a) Results Listed per Patient b) Results per test in real time**
-  **12 - No Results**
-  **13 - Reaction Graphs**
-  **14 - Turning off the System**

Simply positioning the cursor on the icons the "hint" will appear (where available), showing a brief description of the icon function. This is followed (when available) by the function key between brackets, which allows for the same function or command as the icon. For example, the hint "Reset (F5)" means that the function key F5 has the same function of the icon. In the same way, in each menu are shown (when available) the quick commands (e.g. "Insert Batch" (Ctrl+B) means that the same function is activated by typing simultaneously on the keyboard the keys "Ctrl" and "B").



















GENERAL ICONS

-  **Cancel** (aborts the programming and closes the window)
-  **Save** (saves the program and closes the window)
-  **Print** (prints the window's contents, i.e. parameters, graphs etc.)
-  Reduces the window to the upper bar where the analyzer's name appears.

An icon representing refrigeration system operation is present in the status bar. The "Refrigerator disabled" state may be necessary if the operator decides not to use the refrigerator for reactions or after a refrigerator operating error generated by the system.















IVD SYMBOLS: PRINTED PACKAGING ITEMS*

		Caution, consult instructions for use	
		<i>In vitro</i> Diagnostic Medical Device	
		Catalog number	
		Manufacturer	 Date of manufacture
		Lot number or Batch code	
		Storage temperature	
		Expiry date	
		Biological hazard	
		Risk symbols	
		CE Logo (Directive 98/79/CE)	
		Caution: Cutting risk	
		Caution: Corrosive substances	
		Caution: Biohazard	
		Caution: Hot surfaces	
		Electrical and electronic devices: collect and dispose separately.	

* Not all symbols are listed here. These are only some examples.

IEC STANDARD SYMBOLS

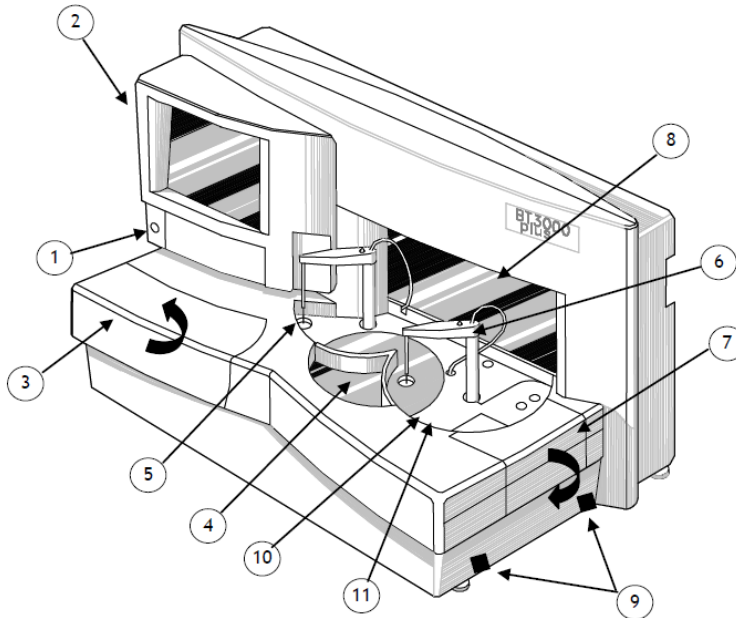
A compilation of the main nameplate and warning symbols used for the IEC standards based on Table 1 of IEC 61010-1 Second Edition.

-  **Direct current**
-  **Alternating current**
-  **Both direct and alternating current**
-  **Earth (ground) Terminal**
-  **Protective earth conductor terminal**
-  **Frame or chassis (ground) terminal**
-  **Equipotentiality**
-  **ON (Main supply)**
-  **OFF (Main supply)**
-  **Equipment protected by double insulation or reinforced insulation**
-  **Caution, risk of electric shock (black on yellow background)**
-  **Caution, refer to accompanying documents (black on yellow background)**

4. BRIEF DESCRIPTION OF THE SYSTEM

4.1. Front View Of The Analyzer

BT3000Plus, BT3500 & BT3500S - Figure 2



- 1 ON/OFF BUTTON FOR COMPUTER
- 2 LCD DISPLAY
- 3 REFRIGERATED REAGENT COMPARTMENT
- 4 SAMPLES TRAY
- 5 SAMPLING ARM FOR CLINICAL CHEMISTRY
- 6 SAMPLING ARM ISE
- 7 ISE MODULE
- 8 FLUIDIC CIRCUIT AND READING STATION
- 9 PUSH-PULL HANDGRIPS
- 10 ISE FUNNEL
- 11 DILUENT BOTTLE

BT1500 & BT1500i- Figure 3



- 3 REFRIGERATED REAGENT COMPARTMENT
- 4 SAMPLES TRAY
- 5 SAMPLING ARM FOR CLINICAL CHEMISTRY
- 6 FLUIDIC CIRCUIT AND READING STATION
- 7 HANDGRIPS
- 8. DILUENT BOTTLE (& I.S.E. FUNNEL only for BT1500 with I.S.E.)
- 9. I.S.E. MODULE (only for BT1500 with I.S.E.)

4.2. Rear Panel Controls And Connectors

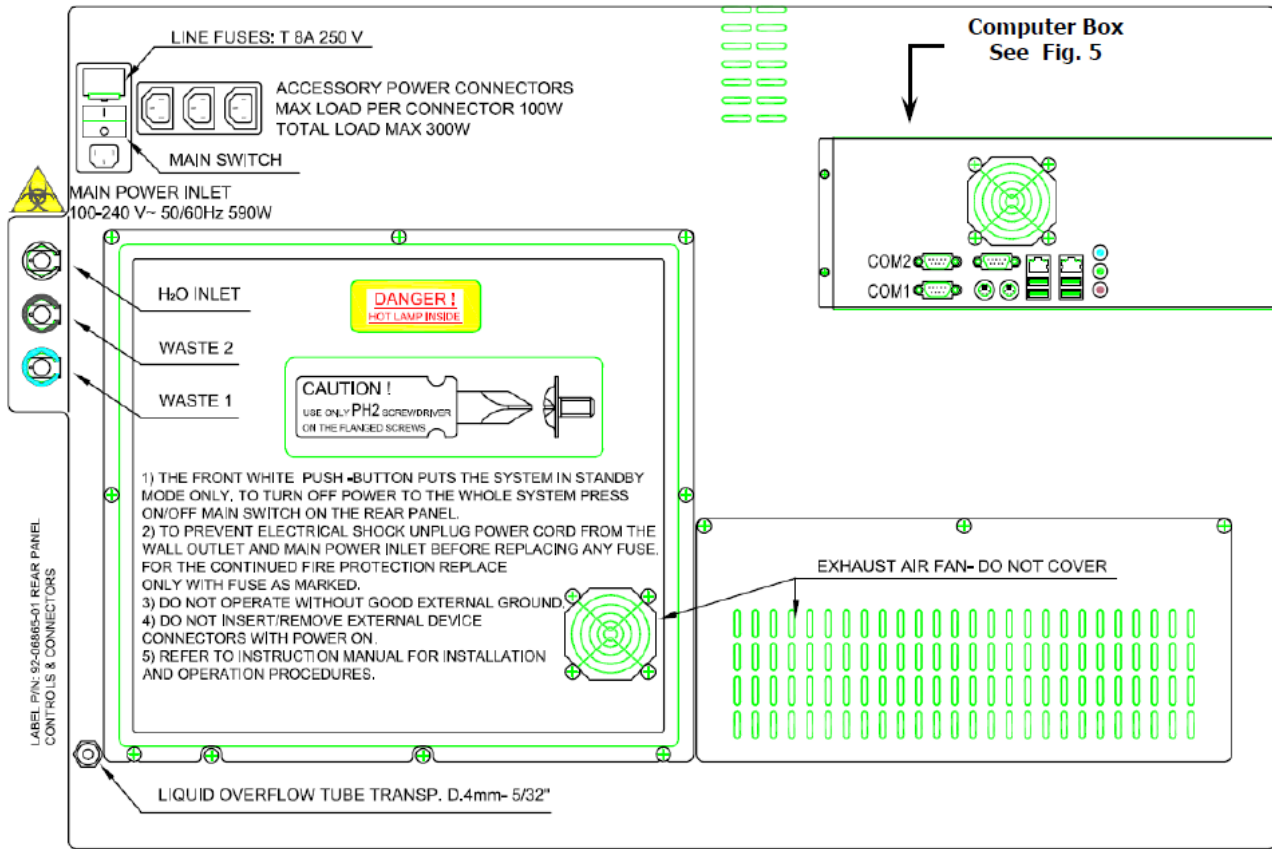


Figure 4 - Rear Panel

IMPORTANT NOTICE:

The illustrated connectors on the Computer Box (Fig. 4 & Fig. 5) may not be the exact representation due to possible design modifications without notice during the life of this manual. For correct configuration of the computer panel, please check the panel of Computer Box on the analyzer rear panel.



Figure 5 - Connectors, Computer Box

Connectors of BT1500 & BT1500i rear panel

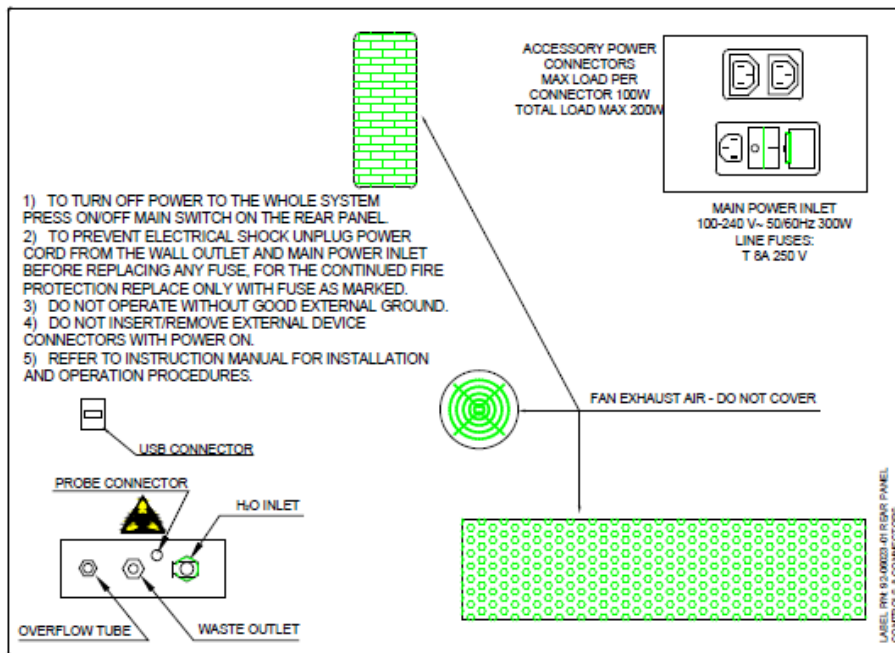


Figure 6

4.3. Modules

The BT analyzers are constructed of a one-piece stainless steel structure. The injection-molded body (in Baydur®) is placed on the chassis to cover the instrument. The following pictures show the modular composition of the instruments. Each module has its own specific function.

BT1500

Modules definition

- **COMPUTER BOX:** it is not present in the BT1500. Consists of LCD Monitor, Touch screen, Main board, Power Supply and peripheral devices.
- **READING STATION MODULE:** comprises cuvette plate, photometer, diluter, reading unit, washing station, H₂O reservoir and electronics.
- **POWER SUPPLY MODULE:** houses the main power supply of the analyzer.
- **REAGENT TRAY MODULE:** is composed of the rotating reagent's tray, the refrigeration chamber, the bar-code reader and the electronics.
- **SAMPLE TRAY MODULE:** is composed of the rotating samples tray, the bar-code reader, the sample tube sensors, the washing wells and the control electronics.
- **SAMPLING ARM:** is composed of a two-axes based mechanical system accommodating sampling needle head with built-in electronics including correct position sensor (Encoder).

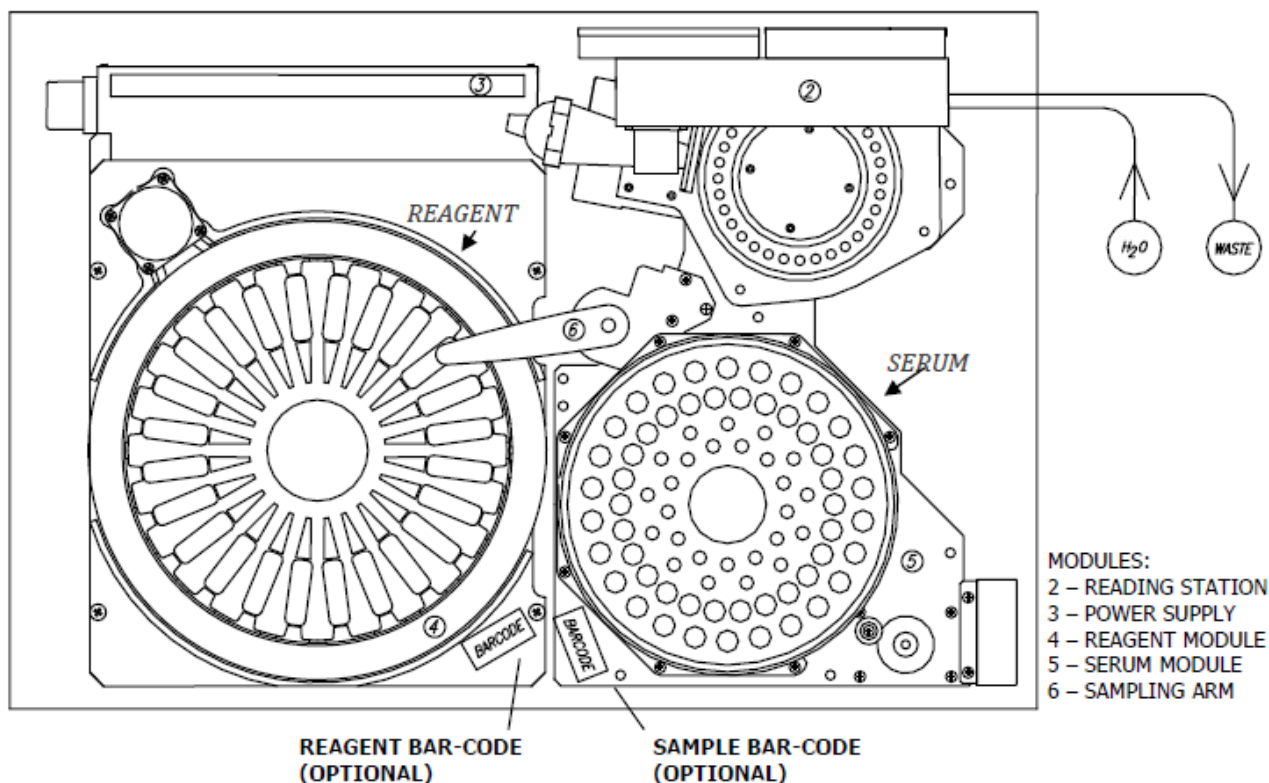


Figure 7 - BT1500 - Modules Arrangement

BT3000 Plus, BT3500 & BT3500S**Modules definition**

- **COMPUTER BOX**: consists of LCD Monitor, Touch screen, Main board, Power Supply and peripheral devices.
- **READING STATION MODULE**: comprises cuvette plate, photometer, diluter, reading unit, washing station, H₂O reservoir and electronics.
- **POWER SUPPLY MODULE**: houses the main power supply of the analyzer.
- **REAGENT TRAY MODULE**: is composed of the rotating reagent's tray, the refrigeration chamber, the bar-code reader and the electronics.
- **SAMPLE TRAY MODULE**: is composed of the rotating samples tray, the bar-code reader, the sample tube sensors, the washing wells and the control electronics.
- **ISE MODULE**: consists of the electrodes panel, hydraulic path and the electronics.
- **SAMPLING ARM (two)**: is composed of a two-axes based mechanical system accommodating sampling needle head with built-in electronics including correct position sensor (Encoder).

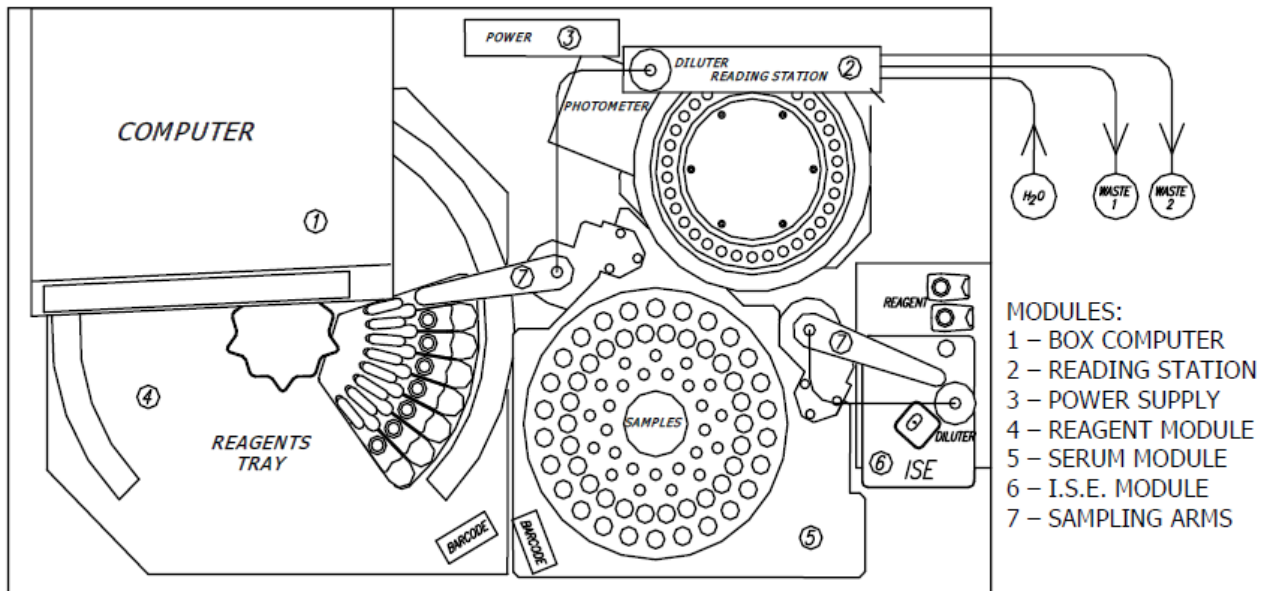


Figure 8 - BT3000 Plus, BT3500 & BT3500S - Modules Arrangement

SECTION I: GENERAL INFORMATION

CHAPTER B: UNPACKING & INSTALLATION

1. INSTALLATION	2
1.1. Unpacking Instructions	2
1.2. Installation	4
1.3. Starting The Instrument	8
1.3.1. Turning On The Instrument For The First Time	8
1.3.2. Preliminary Checks	9
1.3.3. Used solutions/detergents	10

NOTE:

**All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.**

1. INSTALLATION

1.1. Unpacking Instructions

Unpacking the analyzer and the accessories

The crates can be easily opened by applying the lever action, with a large screwdriver, to remove all the spring clips at the base of the crate as shown in the Figure 1. Carefully remove the upper covering. Remove the analyzer and place it on a stable vibration-free surface. Carefully unpack all the accessories and place them in a protected place. Store the empty wooden crate in a safe place for future use.

CAUTION

The analyzer is provided with four integral handgrips (two handgrips for BT1500) located on the left and right sides of the base frame. To lift or move the instrument from one location to another, always use the handgrips. **ATTENTION:** two persons are necessary to move the analyzer.

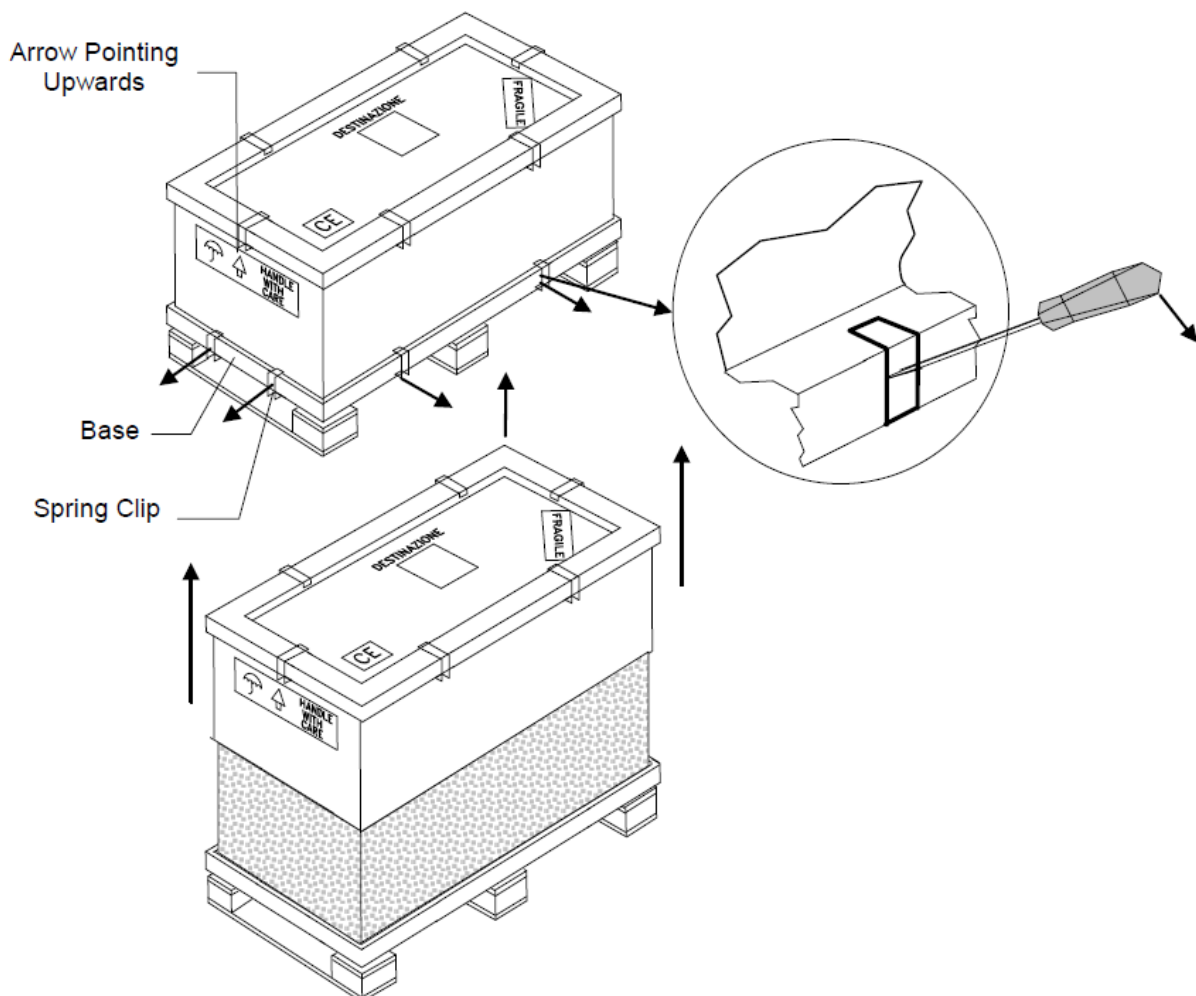


Figure 1

Verification Of the contents of the wooden crates

Verify upon receipt of the analyzer system that all parts are present and intact when opening the wooden crates and packaging. Please use **Mod. 05_28spr**, which is included in the shipment. This document is specific for each analyzer and lists in detail which items are present in the packages. The analyzer and accessories are contained in wooden boxes adequate for the shipment.

Verifying eventual damages occurred during shipment

It is highly recommended to accurately verify the instrument and its accessories for any damages that could have occurred during shipment. In case there is a damage or missing items then please fill out all the sections of the **Mod. 05-35a** in this manual in the **SECTION II, CHAPTER 2 WARRANTY CONDITIONS**. Send it to your nearest sales/service office or directly to Biotechnica Instruments S.p.A. Rome, Italy. After appropriate evaluation, Biotechnica or its branch office will provide the best solution to the problem.

1.2. Installation

The analyzer must be placed on a stable vibration-free-surface, level table or cart. It should be easily accessible to the operator to load samples, consumables, reagents, etc. Ensure that the table can bear the instrument's weight and is large enough for its dimensions (refer to **Chapter O**, paragraph **1. Technical Specifications**). Avoid exposure to direct light, heat, air streams and draught. The instrument's left, right and rear sides must be left free (min. 20 cm from the wall) to ensure the produced heat dispersion and easy tubes and cables connection. Room temperature must not exceed 32°C. We recommend placing on the same table the analyzer and its peripherals (max allowed distance: 1.5 m). The printer can be placed in any location, always taking into consideration the paper feed, the connections with the instrument and the power supply needs. It is very important to place the analyzer away from strong electromagnetic fields, such as centrifuges, electric motors, big refrigerators, X-ray instruments, etc.

The table must be near a wall outlet with earthing and differential switch (life-saving)

The analyzer refrigerator produces water condensation in the reagent chamber. This is important for cooling the reagents in the bottles. In case of too much condensation, wipe it off with a cloth without drying it completely (never do this operation with the analyzer on). The instrument can be leveled by means of the four adjustable feet, to ensure the good drainage of the condensation.

CAUTION

The analyzer is provided with handgrips located on the left and right sides of the base frame. To lift or move the instrument from one location to another, always use the handgrips. For moving the analyzer at least two persons are necessary.

NOTE:

All the components, when present, shown in the following figures may undergo modifications over the time. Therefore, it is recommended to verify them accurately prior to any repair or installation (refer to eventual specific manuals included).

Attention: always verify the shipment check list Mod. 05_28spr, especially for what concerns accessories and peripherals, as not all analyzer's models are supplied with all accessories/peripherals. The following instructions are referred to the analyzers supplied with all accessories and peripherals. In case your analyzer is not supplied with complete equipment, please ignore the instructions related to the accessory/peripheral which is not present.

BT1500 & BT1500i: as far as this analyzer has an external computer, please refer to its instructions for peripherals and electrical connections. The analyzer must be connected to the PC via the USB port located on the left side of the rear panel.

ELECTRICAL CONNECTIONS

Connect main power cable from the instrument to the UPS and connect the latter to the main wall outlet (**Figure 2**). Power circuit should respect current laws and have a good earth connection.

The printer and peripheral devices should be connected to the appropriate accessory power connectors on the analyzer rear panel (adjacent to main power inlet) or directly to the UPS. See **Figure 2**.

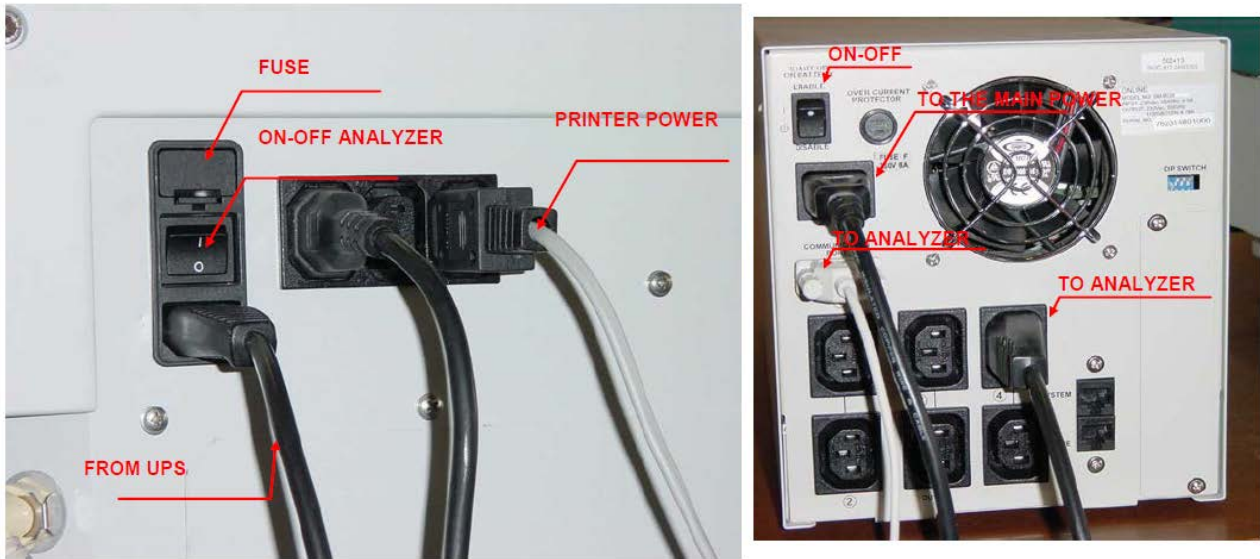


Figure 2

CAUTION! Laser printers must always be connected directly to the main wall outlet, not to the UPS or to the Analyzer.

CONNECTING MOUSE AND KEYBOARD

Keyboard and mouse should be connected to the rear panel of the analyzer respectively to the violet and green connectors where available, or to an USB port. (**Figure 3**).

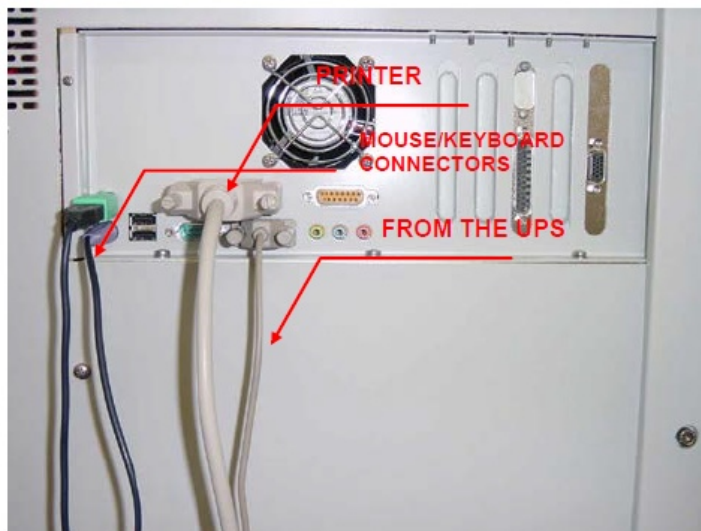


Figure 3

PRINTER: Printer rear view. Refer to **Figure 4** for connections.

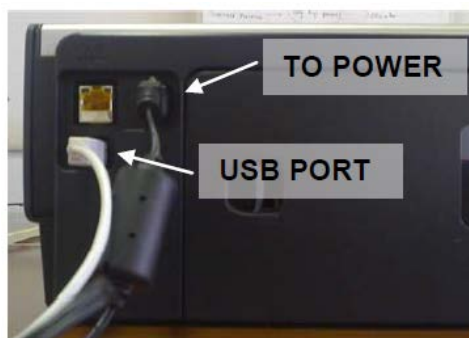


Figure 4

Connect the USB/USB cable to the printer USB port and to one of the USB ports on the rear side of the analyzer. Connect at the same way the power cord, from the printer to one of the power connectors on the analyzer's rear panel (see figure 2).

CAUTION! Laser printers must always be connected directly to the main wall outlet, not to the UPS or to the Analyzer.

FLUIDIC CONNECTIONS

The external fluidic manifold (**Figure 5 – BT1500**) located at the bottom left of the rear panel has three connectors dedicated to H₂O intake, discharge of waste fluids, and a connector for transparent fluid overflow tube. A transparent tube supplies system solution from the external container. The waste probe tube discharges the analyzer waste (flowing from an internal vacuum pump) to the external waste container. In addition, the tubes are fitted with quick-connects having built-in shut-off valves, which in case of disconnection prevents liquid spillage.

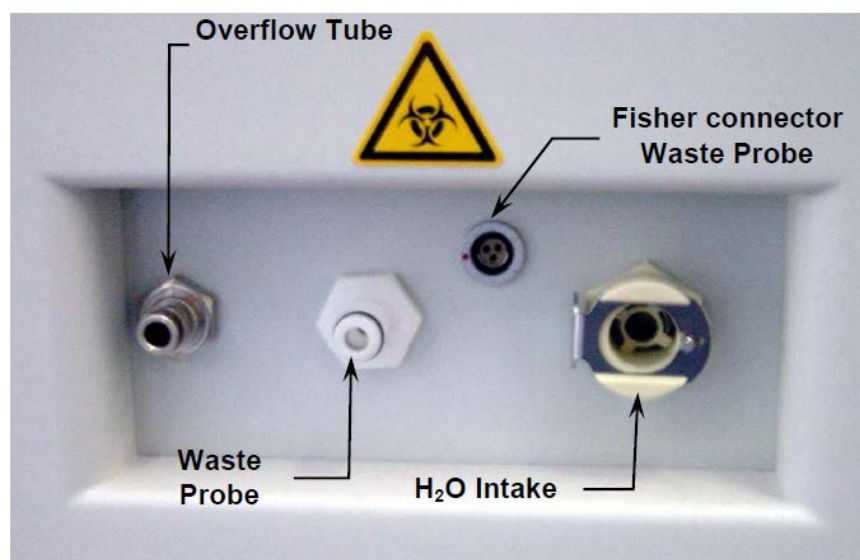


Figure 5 (BT1500)

The transparent tube (**double distilled H₂O plus Surfactant - system solution - 1ml of Surfactant every liter of water, ratio 1/1000**) must be connected to the right connector (**H₂O Intake**). Its other end goes to the external system solution container. Connect the liquid level detector cable (**Fisher connector**) and the drain tube of the waste probe to the middle connector (**Waste Probe**). Insert the waste probe in authorized external waste container (Fig. 7).



For BT3000 Plus, BT3500 & BT3500S, the transparent, black, and blue tubes are fitted with quick-connects having built-in shut-off valves, which in case of disconnection prevents liquid spillage.

The transparent tube (**double distilled H₂O plus Surfactant - system solution - 1ml every liter of water, ratio 1/1000**) must be connected to the upper connector, identified by a white flange. Its other end goes to the external system solution container. The black tube for cuvettes waste fluid must be connected to the middle connector, identified by a black flange. Its other end goes directly into the second input connector of the vacuum pump. The blue tube must be connected to the lowest connector with blue flange on the fluidic manifold. Its other end goes directly into the first input connector of the vacuum pump system. For more info refer to **Chapter K – Vacuum Pump**.

Figure 6

WARNING

- 1) Do not use the internal vacuum pump system with any other fluid source except the analyzer. The unauthorized use may result in serious injury to the user and permanent damage to the vacuum pump system.

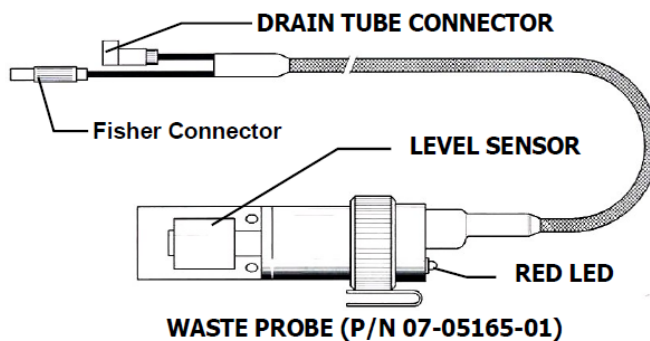


Figure 7

1.3. Starting The Instrument

1.3.1. Turning On The Instrument For The First Time

Turning on procedure for the first time:

- 1) Turn on the UPS device as described in the appropriate supplied manual.
- 2) Power on the printer (refer to the specific manual enclosed).
- 3) To switch on the analyzer, use the main power switch on the rear panel of the instrument. This button activates only the refrigerating system for the reagents, where available. To properly turn on the analyzer system, press once the green push-button placed on the front panel (**Fig. 8**). For what concerns the **BT1500**, **make sure the analyzer is turned on**, verify that the external PC is connected to the analyzer via USB, **then** turn the PC on and then load the analyzer operative program.

CAUTION

Do not press this push-button during analyzer operation, because when pressed it stops the instrument, leaving only the refrigerating system on (refer to **Paragraph 1.6., Chapter E, Turning off procedure**).

The start-up process includes the loading of the operating program (bootstrap) into the memory. At the end of the boot (loading of the operating program), the instrument activates all the devices and performs mechanical, hydraulic and electronic checks. The hydraulic check is represented by a graphical page "Auto Diagnostic" (**Fig. 9**) where the different phases of tests in progress are displayed sequentially. At the end of each test a message "**Passed**" or "**Not Passed**" appears. If all the tests had positive outcome (Passed) then this page automatically disappears. If one of the tests is followed by a message "**Not Passed**" then this indicates that the particular device is not functioning properly. This means that the instrument is not in the condition to perform analytic tests. By performing a manual reset (**F5**), the instrument will repeat the auto-diagnostic cycles in an infinite loop until the problem has been resolved.

- 4) Once turning on procedure has completed (lasting few minutes), wait for the system to warm up. During warm-up phase the temperature indicator flashes on the bottom right of the display until the appropriate temperature is reached. The instrument reaches the steady state after approximately 20 minutes.
- 5) After turning on the system, there is an access password requirement. Refer to Chapter E, paragraph 1.7. ACCESS PASSWORD regarding the utilization of the password.
- 6) Prime the hydraulic circuit using the commands outlined in **Chapter H, paragraph 1.1. Service Functions (Dilutor prime, Wash with water).**

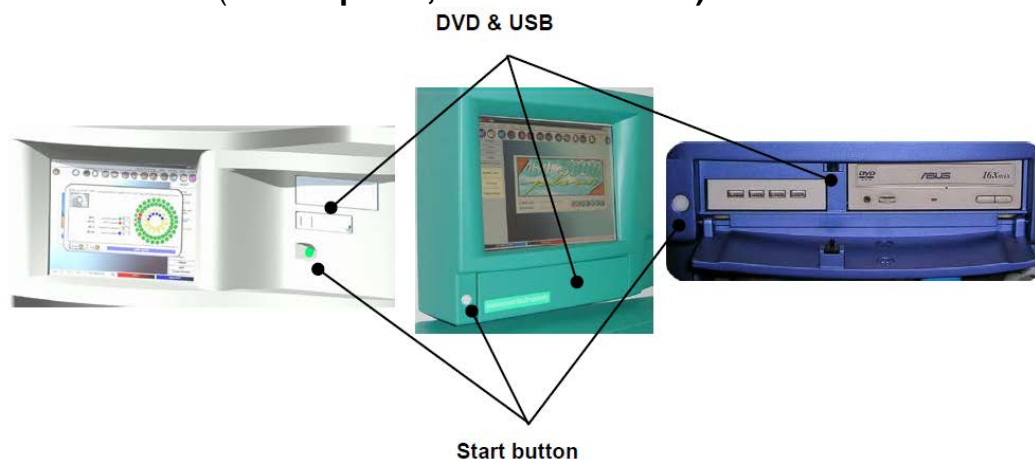


Figure 8

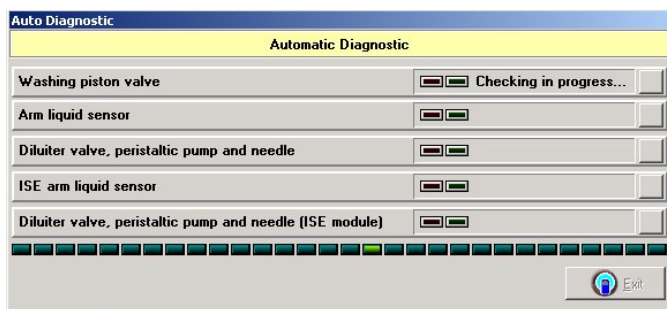


Figure 9

1.3.2. Preliminary Checks

Before using the analyzer, it is recommended to perform the preliminary checks outlined below. Some of these checks should be performed daily and others are periodical.

DESCRIPTIVE TABLE

OPERATIVE CONTROL	PERIODICITY	NOTES
Verify that there is sufficient system solution in the external tank for the needs of the working day. The system solution is prepared by adding to double distilled H₂O the Surfactant - 1ml per liter of water (i.e. ratio 1:1000). See technical specifications regarding double distilled water in the next paragraph.	<u>Daily</u>	(see Sect. II, Chapt. 3 for product codes)
Check that the waste containers are empty or that they are of sufficient capacity for at least containing system solution corresponding to the daily waste liquid volume.	<u>Daily</u>	
Zeroing of the photometer	<u>Twice a day</u>	A reminder message will appear 20 min after start up and then after 6 hours.
Wash the cuvettes with the proper solution (see par. 1.3.3. Used Solutions/Detergents and Sect. II, Chapt. 3 for product codes)	<u>Daily</u>	Before turning off
Extra wash of the cuvettes with proper solution (see par. 1.3.3. Used Solutions/Detergents and Sect. II, Chapt. 3 for product codes)	<u>Weekly</u>	When turning off
Wash I.S.E. module with proper solution	<u>Daily</u>	When turning off

1.3.3. Used solutions/detergents

See also Section II, Chapter 3 for ordering information

- **SYSTEM SOLUTION:** The solution is prepared with 1000ml of double distilled water + 1ml of Surfactant. Carefully read the product instructions. The solution has to be placed in the external dedicated tank. It is used for the system washing of needles and cuvettes during working phases and for the following functions: Wash with water, Zeroing on water, part of the FCC procedure. The external tank should be replaced every time a new solution is prepared, to avoid environmental contamination.

- **CLEANING SOLUTION:** Carefully read the product instructions. The product is ready to use and has to be placed in a 50ml reagent bottle in the reagents tray. The solution is used for the following daily functions: Wash cuvettes, Shut down procedure (shut down wash of the cuvettes). A procedure with messages on the display will guide the Operator to correctly place the solution. The reagent bottle should be replaced every time a new solution is prepared, to avoid environmental contamination.

It is better to close the reagent bottle, remove it from the analyzer and store as indicated in the instructions.

- **WASHING SOLUTIONS:** Carefully read the product instructions. The products are ready to use and have to be placed in 50ml reagent bottles in the reagents tray. The two solutions are used for the following weekly function: Extra Wash Cuvettes. A procedure with messages on the display will guide the Operator to correctly place the solutions. The reagent bottles should be replaced every time a new solution is prepared, to avoid environmental contamination.

The solutions are suitable as acid/basic solutions in the Secondary Analytical Parameters Additional Washes (see Section I, Chapter C, par. 1.3.5.). If the solutions are used as Additional washes, these have to be placed as follows:

BT3500, BT3000Plus, and derivatives: 50ml bottles, in position 39 (acid) & 40 (basic) of the reagents tray

BT1500 and derivatives: in position 24 a 50ml bottle with basic solution matched with a 20ml bottle with acid solution

BT1500 I.S.E.: 50ml bottles, in position 23 (acid) & 24 (basic) of the reagents tray

Always remove the solution bottles from the analyzer and store as indicated in the instructions.

DOUBLE DISTILLED WATER SPECIFICATIONS:

Resistivity: > 5 M Ω /m

Conductivity: < 1 μ S/cm

pH: 6,4

Residual Ions: < 1 μ g/l

SECTION I: GENERAL INFORMATION

CHAPTER C: FUNCTIONS - ANALYSES PROGRAMMING

1. FUNCTIONS.....	2
1.1. Description Of The Program Menu.....	2
1.2. Operating Principles.....	5
1.2.1. Computations	5
1.2.2. Applied Mathematical Functions.....	7
1.2.3. Initial Computation	9
1.2.4. Optimization Techniques For Clinical Chemistry	9
1.2.5. Methods Description – See Also Par. 1.2.1. Computations	10
1.3. ANALYSIS PROGRAMMING	15
1.3.1. Creating A New Code	15
1.3.2. Relation Tests.....	16
1.3.3. Primary Analytical Parameters	17
1.3.4. Check Parameters	23
1.3.5. Secondary Analytical Parameters.....	24
1.3.6. Automatic Re-Runs.....	27
1.4. CONTROLS	28
1.5. CALIBRATIONS.....	29
1.6. CREATING PROFILES	34
1.7. CREATING THE CURRENT ANALYSES TRAY	35

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

1. FUNCTIONS

1.1. Description Of The Program Menu

As already described in the Chapter A, the **BT** instruments are clinical chemistry automated analyzers for performing tests in Routine (programming per patient), Batch (samples per test) and STATs on *serum*, *plasma* and *urine*. The single samples are always accessed in random mode.

Besides the clinical chemistry, it is possible to perform turbidimetry tests (immunochemistry) for specific proteins, pharmaceuticals, drugs abuse and reading of electrolytes (where available, see Chap. L).

Once the program is loaded, the main page appears, where it is possible to enter all the menus. These are available in two variants: the horizontal and the vertical menu bars. Moreover, there is the icon bar that can be used for a rapid access to the most frequently used commands (refer to **Chapter A**, paragraph 3.).

The analyzer provides access to the operating commands in the following three different ways:

- **Menus**
- **Shortcuts**
- **Icons**

Menu: move the cursor on the selected command and click once to access the function.

Shortcuts: the shortcut is a particular combination of the keys: "**Ctrl or Alt + one letter of the function's name**" (ex. "Ctrl+P" or "Alt+A"). It gives a direct access to the requested command. The **Shortcuts** are available for the menu items in **Patients** and **Tests**. These are always enabled, except for the external programs, the diagnostic page, and the parameters' programming pages or in case of errors' notification.

Icons: it is the symbolic representation of a given function. Move the mouse cursor on the desired icon and confirm by a single click to access the function.

The main menu contains five items: **Patients**, **Tests**, **Analyzer**, **Utility** and **External programs**.

Each item has a sub-menu that provides access to additional commands, some of which can also be selected through combination of keys corresponding to the desired shortcut.

Patients Menu

Patients	
I <u>n</u> sert Routine/STAT	Ctrl+P
I <u>n</u> sert Batch	Ctrl+B
R <u>u</u> n all pending patients	Ctrl+R
R <u>e</u> petition for analyses	Ctrl+A
C <u>l</u> ear Patient List	

Insert Routine/STAT, Insert Batch: these items are used to enter samples for Routine/STAT and Batch mode.

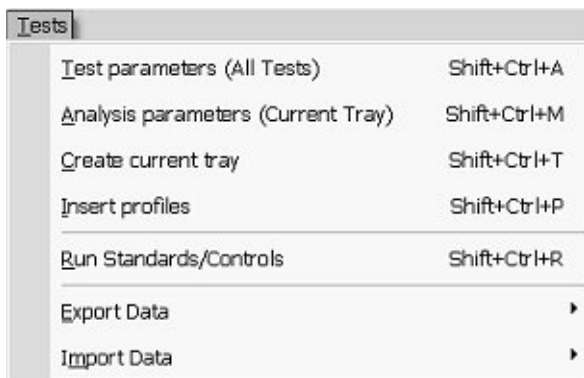
Run all pending patients: Restarts the work list after an interruption.

Repetition for analyses: Selects the repetition by analyses upon operator's request.

Clear Patient List: Deletes the entire memorized patients list. The analyzer will request confirmation before deleting.

Figure 1

Tests Menu



Tests’ parameters (All Tests): It is used for programming and memorizing tests.

Analyses’ parameters (Only In Tray): It provides direct access to the analyses on the current reagents’ tray.

Create current tray: This item is used to create the list of analyses’ in the current reagents tray.

Insert profiles: is used to create the analyses lists (profiles) which can be used for programming patients.

Figure 2

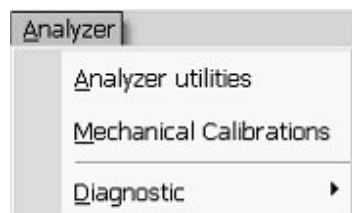
Run Standards/Controls: Activates the procedure for running standard/controls.

Export Data: Copies in any desired location, the analytical parameters. There are two available options: Back-up (for exporting all the analyses) and Single Test (exports a selection of single tests).

Import Data Copies the above-mentioned parameters from any location into the analyzer memory. There are two available options: Restore (will import all parameters) and Single test (imports the exported single tests). The function is allowed only if modify parameters password is given.

NOTE: when a back-up is imported, all data in the global and current analyses trays will be overwritten. When a single parameter is imported, it will be placed in the Global list of analyses. The operator will have then to correctly place it in the Current tray.

Analyzer Menu



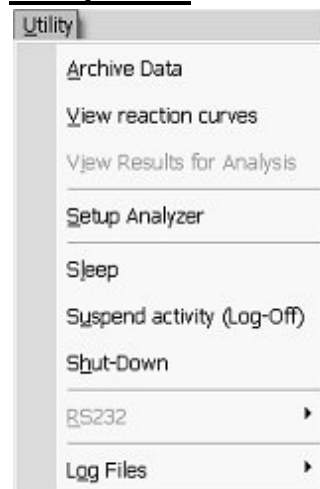
Analyzer’s utilities: provides access to the service procedures of the analyzer.

Mechanical Calibrations: for making adjustments to mechanical devices.

Diagnostic: the technical assistance personnel mainly use this function (see Chapter H).

Figure 3

Utility Menu



Archive Data: this command stores the processed patients’ data into the patients’ archive.

View reaction’s curves: this command displays on a graph the reaction’s curves of tests, with print capability.

View results for Analyses: displays results for test.

Setup Analyzer: it is used to define some system parameters. This command is disabled during analyzer operation. Refer to Setup Analyzer in Chapter H, paragraph 2.

Sleep: this command sets the analyzer to a standby mode, during which the cuvettes are washed (with system solution) and the monitor displays the screensaver. Press the button at the center of the display to exit from the sleep mode. A reset will occur and the analyzer will be immediately ready to operate. This option is useful when the analyzer is not being used for a while, but it must be kept on to resume work immediately.

Figure 4

Note: the analyzer switches automatically to the standby mode when left unused for more than thirty minutes.

Suspend activity (Log-Off): This command is used for programming the power on of the analyzer software on a specific date and hour. A small window will appear on the monitor where the restart time and date can be set. After the programming is confirmed, a guided procedure will lead to the system’s washing procedure (see Chapter H, par. 1.1.1 and Chapter E, par. 1.6) and afterwards the analyzer will suspend its activity. The system will be off except for the reagent refrigeration chamber. Approx 30 min. before the programmed turning on time, the lamp and the cuvettes’ Peltier will be reactivated. At the expiry of programmed time and date the analyzer will exit the suspend mode by performing a system reset. To resume the analyzer activity before the programmed time, click on the left or right mouse button and press the **Exit** button on the window that appears. The system will reset and after approximately 20 minutes warm-up time the analyzer will be ready to operate (refer to Chapter E, paragraph 1.6.).

Shut-Down: to turn off the analyzer, it is important to observe the shutdown procedure (refer to Chapter E, paragraph 1.6.). The program, through a guided procedure, will perform the shutdown wash, and then the computer will turn off leaving only the reagent refrigeration chamber turned on. Press the ON/OFF button on the rear panel to turn also the refrigerator off.

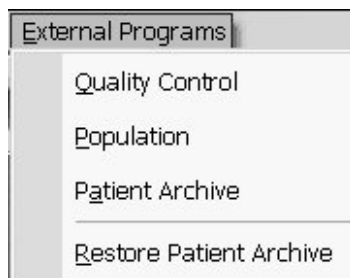
Note: The analyzer’s program will guide the operator through screen messages in the analyzer turning off procedures. The Operator will be invited to place the solutions when needed and to ensure the correct execution of washing procedures. In case the washing procedures are not performed during shutdown, then at the next restarting of the analyzer (and before any samples run) the system will display a message inviting the operator to perform the required washings. Bear in mind that it is not possible to ensure data precision and accuracy if the normal washing and maintenance procedures are not observed.

RS232: This command is active only when the serial communication is enabled (see Analyzer Setup, Chapter H, paragraph 2). It allows the analyzer to send data to the host computer, upon operator’s request.

When the serial port is active, two more commands will appear: **Accept result to be sent** and **Delete result to be sent**. The first one will send the results to the Host computer, the second will delete the results waiting to be send.

Log Files: gives access to the files where the operations performed by the analyzer are stored. This function is divided in two parts: the first part memorizes the performed operations; the second stores the errors and the incorrect procedures. This read-only area is very important for the Technical Assistance/service personnel.

External Programs Menu



The functions in this menu are outlined in the Chapter F.

Figure 5

1.2. Operating Principles

Generally, adding a sample to its reagent determines a chemical reaction (involving enzymes and/or substrates) whose effect is to increase (or decrease) the color and thus the optical density of the solution in the cuvette. As the reaction proceeds, it is "read" by the analyzer in terms of "absorbance" ("A" or "Abs" for absorbance).

As every analyte has its own reagent with its proper characteristics; therefore it becomes necessary to use different methodologies (preparation and reading) based upon different wavelengths for each test. Many tests are based on similar principles, hence they will have in common the method and the wavelength, but not necessarily the incubation and reading times.

To obtain the concentration of an analyte in a sample, the analyzer multiplies the absorbance (or the absorbance delta ΔA = absorbance variation) developed by that sample reaction with a multiplication factor.

Besides some analyses for which a theoretical factor is used, usually the factor is calculated during a calibration. During the calibration the analyzer reads the reaction obtained with a known concentration sample called "standard". The factor is calculated by dividing the known concentration value by the absorbance read for the standard.

For the non-linear analyses (e.g. immunoturbidimetric tests) it is necessary to create an interpolation curve by means of several standards at different concentrations.

1.2.1. Computations

◆ COMPUTING ABSORBANCE (ABS)

End Point

ABS = Mean value of the last points in reading time- second phase - (max 3)
With subtraction of the Blank reagent.

Kinetics

- Linear regression computation
- $ABS = (\text{straight line coefficient}) \times 60 \text{ sec}$

Fixed Time

$ABS = \Delta ABS$ (last reading in second phase – first reading in second phase)

Initial-Rate

- Linear regression computation
- $ABS = \text{Straight line coefficient}$

In case test is unstable:

- Linear regression computation
- Elimination of 49% of the most distant points from the straight line
- ABS re-computation

Sample-Blank (A)

$ABS = \text{Last reading of the second phase} - \text{last reading of the first phase} \times K^*$

* $K = \text{Volumetric factor}$

Sample-Blank (B)

ABS = Last reading of the second phase – last reading of the first phase

End Point 2 Points

If readings are > 3:

- L1 = First reading in incubation time (phase 1)
- L2 = mean value of last three readings (phase 2)

If readings are > 2:

- L1 = First reading in incubation time (phase 1)
- L2 = mean value of last two readings (phase 2)

In the other cases:

- L1 = First reading in incubation time (phase 1)
- L2 = Last reading (phase 2)

$$ABS = L2 - L1$$

Sample-Blank A-b

Blank:	R1 + R2
1 st phase:	R1 + Serum
2 nd phase:	R2
Computation:	(Last Reading 2 nd phase – Last Reading 1 st phase) – blank

Sample-Blank B-b

Blank:	R2
1 st cuvette:	R1 + serum
2 nd cuvette:	R2 + serum
Computation:	(Last Reading 2 nd cuvette – Last Reading 1 st cuvette) – blank

End Point Starter

Dynamic:	As normal End Point with serum starter
1 st phase:	Only reagent (R1 or R1+R2)
2 nd phase:	Serum
Computation:	Last Reading 2 nd phase – Last Reading 1 st phase

Absolute End Point

This method is identical to the End Point but without subtraction of the Blank reagent.

◆ COMPUTING CONCENTRATION VALUE**Fnr**

- If the External Dilution Factor is less than or equal to 1 then ***Fnr = 1***
- In other cases ***Fnr = External Dilution Factor***
- If sample is run with dilution then ***Fnr = External Dilution Factor***

Dynamic Blank Check

If Dynamic Blank is present and test is either a Kinetic, or a Fixed Time, then:

- ***ABS = ABS – Dynamic Blank Value***

If Dynamic Blank is not present and test is an End Point, then:

- **ABS = ABS – Blank Value**
- **ABS = ABS x Fnr**
- If the factor is used, then: **Conc = ABS x Factor**
- Otherwise the concentration is extrapolated from the standard's curve, where:

Fnr : Internal Factor
ABS : Test ABS
Conc : Final concentration

1.2.2. Applied Mathematical Functions

◆ **Correlation Coefficient**

$$CC = \frac{\sum_1^n (T_i - \bar{T})(L_i - \bar{L})}{\sqrt{\sum_1^n (L_i - \bar{L})^2 \sum_1^n (T_i - \bar{T})^2}}$$

where:

n : Number of readings
i : Number of reading (i)
T : Times
L : Readings

◆ **Linear Regression**

$$M = \frac{\sum_1^n (T_i L_i) - n \frac{\sum_1^n (L_i)^2}{n} \frac{\sum_1^n (T_i)^2}{n}}{\sum_1^n (T_i)^2 - \frac{(\sum_1^n T_i)^2}{n}}$$

$$Q = \frac{\frac{\sum_1^n L_i}{n} - \left(\frac{\sum_1^n (T_i L_i) - n \frac{\sum_1^n L_i}{n} \frac{\sum_1^n T_i}{n}}{M} \right)}{M}$$

where:

- M** : Angular coefficient for the line
- Q** : Final point for the line
- n** : Number of readings
- i** : Number of reading (i)
- T** : Times
- L** : Readings

◆ **Distance point-line**

$$D = |Y - MX - Q|$$

where:

- M** : Angular coefficient for the line
- Q** : Final point for the line
- X** : Point Abscissa
- Y** : Point Ordinate

◆ **Distance between two points**

$$Y = \frac{X - x_0}{x_1 - x_0} (y_1 - y_0) + y_0$$

where:

- X** : X axis
- Y** : Y axis
- x₀** : First Point X Axis
- x₁** : Second Point X Axis
- y₀** : First Point Y Axis
- y₁** : Second Point Y Axis

MATHEMATICAL FUNCTIONS FOR CLINICAL CHEMISTRY

◆ **Volumetric factor (used in sample blank A tests)**

$$K = \frac{vS + vR_1}{vS + vR_1 + vR_2}$$

where:

- K** : Volumetric factor
- vS** : Serum volume
- vR₁** : First reagent volume
- vR₂** : Second reagent volume

◆ **I.S.E. Module Functions, see dedicated chapters.**

1.2.3. Initial Computation

The initial computation is important for transforming the microprocessor data into compatible data for the program to generate the single absorbance value, which will be used afterwards for the final absorbance computation.

◆ **Clinical Chemistry**

$$V = \frac{Z - \text{Log} \left(\frac{F_1 - F_{z_1}}{F_2 - F_{z_2}} \right)}{Of} Op$$

where:

- Z** : Zeroing with water
- F₁** : First Filter's Value
- F₂** : Second Filter's Value
- Fz₁** : First Filter's Zero-Value
- Fz₂** : Second Filter's Zero-Value
- Op** : Optical path
- Of** : F.C.C.

1.2.4. Optimization Techniques For Clinical Chemistry

◆ **Searching for the right reading point (for Fixed Time test):**

If the point (P1) is not read exactly at (T₀), then the ABS value for P1 must be extracted with the following procedure:

with N < 3

1. Compute the Regression line $y = mX + q$ from the reading points
2. Search for the point on the line at T₀

with N ≥ 3

1. Compute Best-Fit curve coefficients from the reading points
2. Search for the point on the line at T₀

N = number of points during reading time

◆ **Normalization of reading data (elimination of erroneous readings) (for Kinetics and Initial-Rate tests):**

If more than two points are obtained during reading time, then:

- a. If CC is > 0.99, the procedure stops
- b. If CC is ≤ 0.99:
 1. NN = N / 3
 2. Compute linear regression and store m and q
 3. Compute the first most distant point from the line $y = mX + q$
 4. Trace the point on the line
 5. NN = NN - 1
 6. If NN is > 0 go back to step (2)

where:

- CC** : Correlation Coefficient
- N** : Number of points during reading time
- NN** : Number of points to be traced
- m** : Angular coefficient for the line
- q** : Known line coefficient

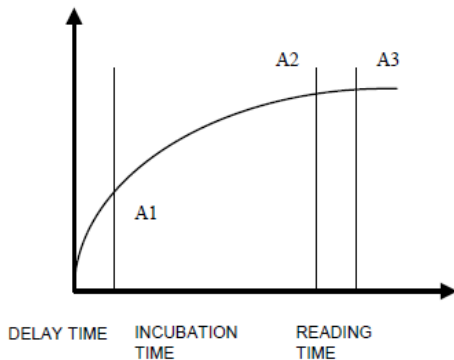
1.2.5. Methods Description – See Also Par. 1.2.1. Computations

End Point

Once the sample has been added to its reagent, a reaction occurs first causing a variation in the solution's color i.e. the absorbance (usually during incubation time), followed by a phase in which the reaction's color is stable, defined as "plateau".

Generally, the absorbance value (A) is read from the first point after the incubation time. This value is then multiplied by the factor computed during calibration, to obtain the concentration of the analyte in the sample.

$$\text{Conc. in sample} = \text{Factor} \times (A3 - \text{Reagent Blank})$$



Absolute End Point

This method is identical to the End Point but without subtraction of the Reagent Blank.

Fixed Time

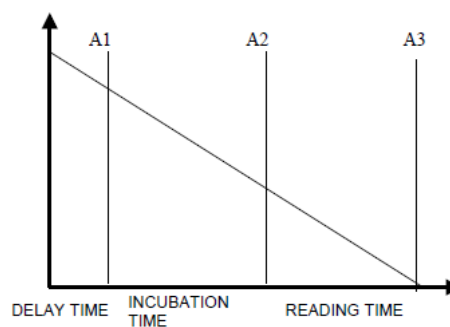
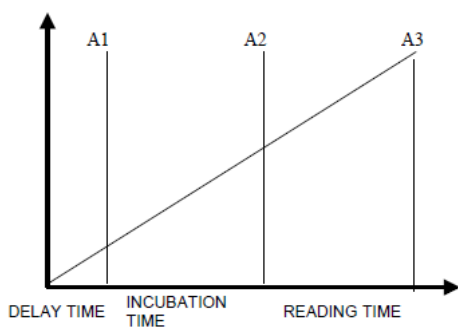
In this type of reaction, there is an increase (or decrease) of the absorbance during both incubation's and reading's phases. However, the slope of the line may not be the same during the two phases. The reaction graph displayed to the user is not always linear, but can also appear as piecewise linear. This is because the graph is obtained by the union of the read points that may not be aligned. A regression line is calculated during both incubation's and reading's phases. These provide the user with information about the correct evolution of the reaction. During reading time, the absorbance delta (ΔA) is also computed, which is used for calculating the final concentration for the analyte in the sample.

It may happen, due to a physical delay, that the instrument does not respect the timing and that tests are read at a different final time from the one set in the parameters. In this case the analyzer performs one more reading, traces the regression line between the last two points, moves to the exact reading time and derives the correct absorbance value from it.

Concentration is calculated by multiplying the absorbance delta (during reading time) by the factor obtained from the calibration:

$$\text{Conc. In Sample} = \text{Factor} \times (A3 - A2)$$

$$(A3 - A2) = \Delta A$$

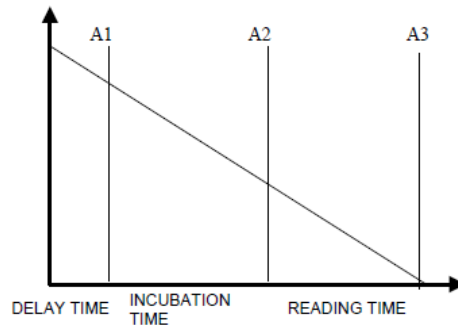
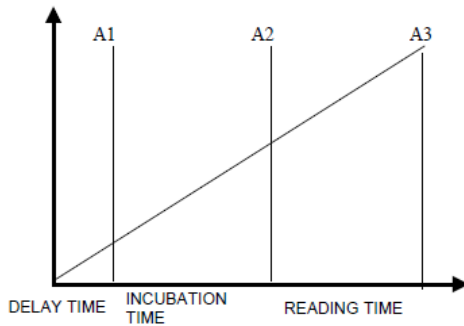


Kinetics

This kind of reaction is very similar to the previous one, with the difference that the reaction and the graph derive both from the computation of two regression lines: one for the incubation phase and the other for the reading phase. These two lines are often the same if the reaction has a good quality. The regression line for the reading phase is then scaled to minutes to compute absorbance delta ($\Delta A/min.$). This value is then multiplied by the factor to compute the concentration of the analyte in the sample:

$Conc. \text{ in Sample} = \text{Factor} (A3 - A2)$

$(A3 - A2) = \Delta A/min.$



Initial Rate (I.R.)

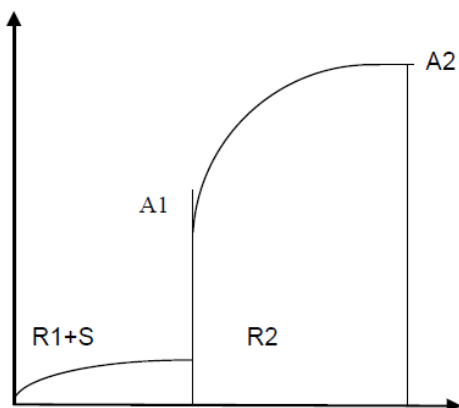
This type of reaction is very similar to the kinetic one. If the initial phase is stable, then it behaves exactly like a kinetic reaction. If the initial phase is unstable, the regression line is computed by eliminating the points outlying it from 49% to 100%. Thus, the calculation is identical to the one for kinetic reaction:

$Conc. \text{ in sample} = \text{Factor} \times (\Delta A/min)$

Sample Blank (A)

This method is used whenever it is required to eliminate the photometric interference of the sample (for example turbid sera) from the reaction. These are double-reagent End Point reactions. The reaction and the computation are performed during two distinct phases: in the first phase (sample blank) the reaction between the first reagent and the sample (R1+S) takes place, while in the second phase the second reagent is added to R1+S (R1+S+R2). The final absorbance used for computing the concentration of the analyte is obtained from the difference in absorbance between the two phases:

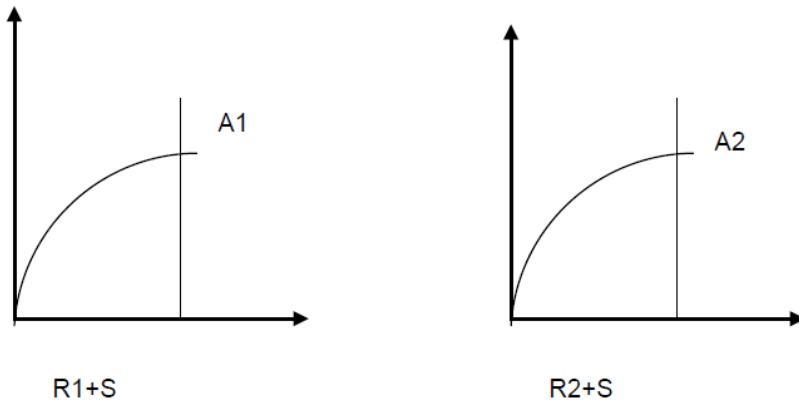
$Conc. \text{ in sample} = \text{Factor} \times [A2 - (A1 \times k)]$



Sample Blank (B)

This kind of reaction is very similar to the previous one. The reaction always occurs in two phases: in the first phase (sample blank) the analyzer reads the final absorbance (A1) of the reaction between the first reagent and the sample (R1+S), in the second phase it reads the final absorbance (A2) of the reaction between the second reagent and the sample (R2+S). The two reactions are distinct and separate, and the sampling in the two phases takes place in two different reading cuvettes. The final absorbance used for computing is obtained from the difference between the two phases:

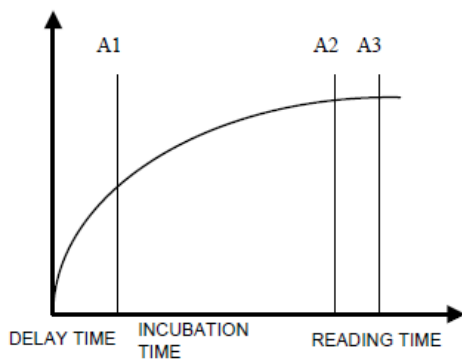
$$\text{Conc. in sample} = \text{Factor} \times (A2 - A1)$$



End Point 2 Points

This method (only for single reagent tests) is used whenever it is required to eliminate from the reaction the interference due to the sample. The absorbance of the first reading in incubation phase is subtracted from the final absorbance:

$$\text{Conc. in Sample} = \text{Factor} \times (A3 - A1)$$



Only Read

This method is used to read in End Point solely the sample, with a reagent blank. It can be used to read an already prepared (manually) solution. The factor for the computation can be either derived from calibration or set by the user:

$$\text{Conc. in Sample} = \text{Factor} \times \text{final A}$$

For all the methods, except for Sample Blank and Only Read, it is possible to work with one or two reagents.

These reagents can be ready to use or concentrated (in this case the analyzer provides automatic dilution). The reagents can be placed in bottles of different volumes (50 ml, 20 ml and 10 ml) and in case of double reagent, the different size bottles are coupled together (e.g. 50 + 50, 50 + 20, 50 + 10, etc.).

The **End Point, Fixed Time, Kinetic** and **I.R.** methods allow, both with single and double reagent, the use of a special feature called **Serum Starter**. Normally, during test runs, the arm samples single or double reagents plus sample. By using the **Serum Starter** function, the reagents are placed into the cuvette **first** and then the sample is placed separately. In this way, the reagents can incubate in the cuvette for the programmed time, before the sample is added which starts the reaction.

The sampling dynamics of the above-mentioned methods are tabulated as follows:

NORMAL SAMPLING PROCEDURE			
Method	Reagent	Blank Reagent	Dynamic
End Point - Fixed Time Kinetic - I.R.	Single	R1	$R1 + S \Rightarrow Ta \Rightarrow L$
Only Read	Single	R1	$S \Rightarrow L$
End Point - Fixed Time Kinetic - I.R.	Double	$R1 + Ta + R2 + Tb$	$R1 + S + Ta + R2 + Tb \Rightarrow L$
End Point - Fixed Time Kinetic - I.R.	Double	$R1 + R2 + Tb$	$R1 + R2 + S + Tb \Rightarrow L$
Sample Blank (A) Sample Blank (A-b)	Double	$R1 + R2$	$R1 + S + Ta \Rightarrow L1 + R2 + Tb \Rightarrow L2$ Sample Blank (L2 - L1)
Sample Blank (B) Sample Blank (B-b)	Double	R2	$R1 + S + Ta \Rightarrow L1 \quad R2 + S + Tb \Rightarrow L2$ Sample Blank (L2 - L1)

Ta and Tb = Incubation times for R1 and R2, L = Reading

SERUM STARTER SAMPLING PROCEDURE			
Method	Reagent	Blank Reagent	Dynamic
End Point - Fixed Time Kinetic - I.R.	Single + S.S.	R1	$R1 + Tr + S \Rightarrow Ts \Rightarrow L$
End Point - Fixed Time Kinetic - I.R.	Double + S.S.	$R1 + Tr + R2 + Tr$	$R1 + Tr + R2 + Tr + S + Ts \Rightarrow L$
End Point - Fixed Time Kinetic - I.R.	Double + S.S.	$R1 + R2 + Tr$	$R1 + R2 + Tr + S + Ts \Rightarrow L$

S.S. = Serum Starter, Tr = Delay Time for R1 and R2, Ts = Serum Incubation Time, L = Reading

The way the **Reagent Blank and the Reaction's Dynamics** are used is tabulated below:

<u>End Point</u>	Reagent blank. Final reaction datum detection (at the end of programmed time for incubation and reading) and concentration's value computation.
<u>Fixed Time</u>	Reagent's reading check. Data detection during programmed reading time, absorbance delta determination (ΔA) and concentration's value computation.
<u>Kinetic</u>	Reagent's reading check. Data detection during programmed reading time, determination of the absorbance delta per minute ($\Delta A/\text{min.}$), processing of the linear regression and computation of the concentration's value.
<u>Initial Rate</u>	Reagent's reading check. Data detection during programmed reading time, determination of the absorbance delta per minute ($\Delta A/\text{min.}$), processing of the linear regression and computation of the concentration's value.

<u>Sample Blank (A)</u>	Reagents' reading only for check (R1+R2); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) adding reagent 2 (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
<u>Sample Blank (A-b)</u>	Blank Reagent (R1+R2); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) adding reagent 2 (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
<u>Sample Blank (B)</u>	Reagent's reading only for check with R2 (Working Reagent); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) with reagent 2 and sample (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
<u>Sample Blank (B-b)</u>	Blank Reagent with R2 (Working Reagent); first phase (sample blank) with reagent 1 and sample (data detection at the end of incubation time 1), second phase (analysis) with reagent 2 and sample (data detection at the end of incubation time 2), absorbance delta determination (ΔA) between first and second phase and concentration's value computation.
<u>Only Read * (End-Point)</u>	Reagent blank. Final reaction data detection (at the end of programmed time for reading) and concentration's value computation.
<u>End Point 2 points</u>	Reagent's reading check. Data detection during programmed reaction time (first datum in incubation time and the last datum in reading time), absorbance delta determination (ΔA) and concentration's value computation.
<u>End Point Absolute</u>	Without Blank Reagent (reading only with reference to H ₂ O). Final reaction data detection (at the end of programmed time for reading) and concentration's value computation. However the Blank is read to verify the reagent.

* During **Only Read (End-Point)** analyses, the analyzer uses the reactive just to prepare the reagent blank. The analysis' procedure requires then to sample at least 220 μ l (for BT1500 & BT3500, BT3500S) or 300 μ l (for the other analyzers) from the final solution in the sample cups and pour it into the cuvettes for the reading phase. Only single reagent use is allowed.

For the **End Point, Kinetic, Fixed Time, Initial-Rate** and **End-Point 2 Point** methods it is possible to use single and double reagent methodologies. The **Only read** method uses only a single reagent, and the **Sample Blank (A) & (B)** methods require exclusively double reagent methodologies.

1.3. ANALYSIS PROGRAMMING

The analyzer can store virtually endless analysis codes (with parameters). There are two different codes' lists: a "global" (**All Tests**) list where all programmed codes are stored, and an "on-line reagents tray" (**Current Tray**) list, where only the codes for the analyses that have their reagent in the tray are stored. Patients, standards and controls can be programmed and performed only for the on-line list.



Figure 6



Figure 7

The analysis programming page can be accessed from the main menu (**Tests**) or from the specific icon that gives direct access (see Chapter A, paragraph 3., icon n°1 in the Function Icons Bar) (**Fig. 6**).

To set out new analyses it is necessary first to create the code (this function is enabled only in the **All Tests**) and then to assign the parameters, the standards and the controls (these are enabled also in the **Current Tray**). To perform any test it is necessary to move its code from the **All Tests** to the **Current Tray** by using the command **Modify Current Tray** (Function Icons Bar, icon n°2). Once the **Current Tray** is created, it will be possible to assign a position to each reagent bottle.

1.3.1. Creating A New Code

Open the analysis programming page and select **New Code**. Enter the test's code and select the **Test Type** among the options showed by clicking on the button "▼". The test type, defines whether the programmed test is a Clinical Chemistry, an I.S.E. (if enabled, refer to **Chapter L and L1**) or a relation test (mathematical computation, refer to paragraph **1.3.2. Relation tests**). Use the button **Save** to memorize the test, or press **Cancel** to exit and abort programming. Any code can be deleted with **Clear Code** or modified with **Rename**. Once a code is set, it is possible to program the analytical parameters (see paragraph **1.3.3.** and the following).

1.3.2. Relation Tests

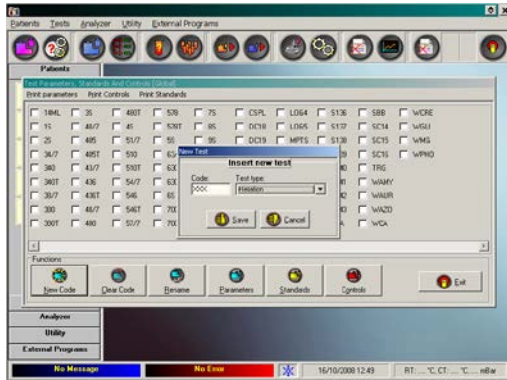


Figure 8

Once the code has been created for the relation test (as shown in **Fig. 8**), it is possible to program its general parameters and the related mathematical function. In the analyses list click on the code (the check symbol ✓ will be displayed), then select **Parameters**.

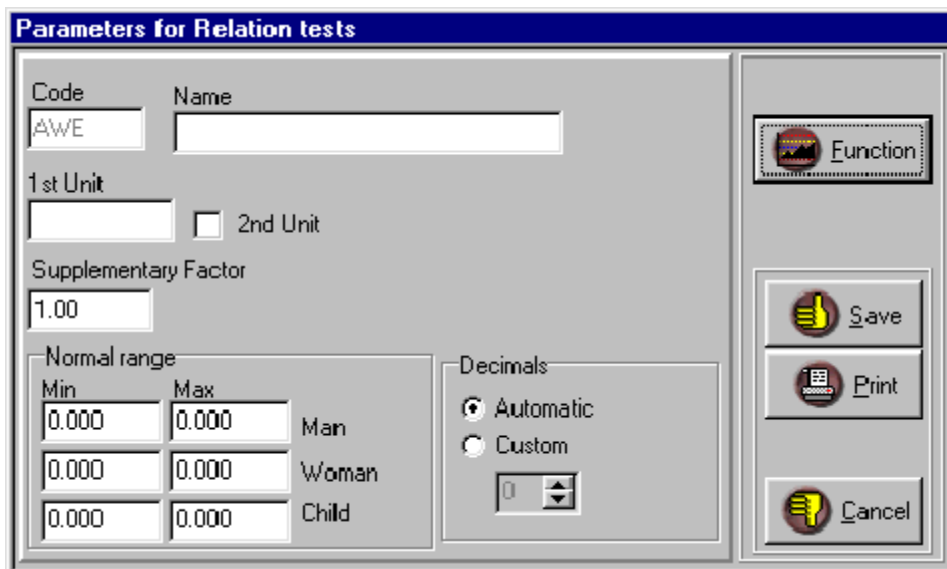


Figure 9

In the parameters window (**fig. 9**) enter the following information:

Name: complete test name

1st Unit: measurement unit. Clicking on the **2nd Unit** it is possible to enter a secondary unit, with its conversion factor (the analyzer will multiply the 1st unit by the given factor).

Supplementary Factor: The result of the mathematical function will be multiplied also by this value. This is simply an additional calculation offered by the analyzer.

Normal Range: insert the min. and max. values of the normal range for male, female and child.

Decimals: it is possible to choose the number of decimals after the point. Leaving the "Automatic" option the analyzer will follow this principle (floating point):

- for values like 0.XXX three decimals
- for values up to 9.XX two decimals
- for values up to 99.X one decimal
- for values over 100 no decimals

To enter the mathematical function select **Function**

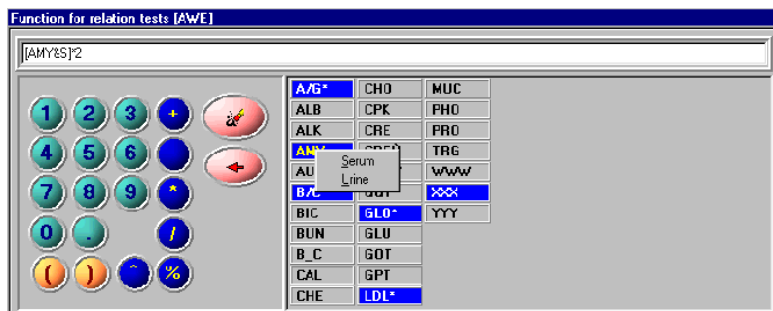


Fig. 10.a

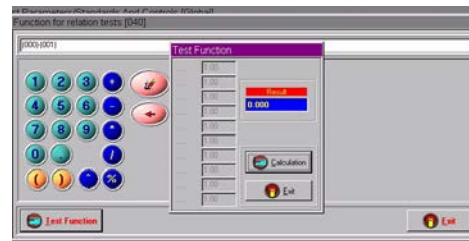


Fig. 10.b

A window divided in two parts will be displayed: one for the calculator and one for the analyses list (current tray), **Fig. 10**. The mathematical function can be composed of simple values and operations or can recall sample results acquired by the analyzer (serum and urine) on other tests (complex function). To enter a simple mathematical function avail yourself of the calculator. To enter a complex function, select the code of the test to be inserted into the function. A small field will appear, where it is possible to select between serum or urine results for that test. Then complete the function with the needed operations. To create more complex functions (involving more than one test's result) it is advisable to use the parenthesis as for all normal mathematical functions. Ex. For the creatinine clearance with urine/24h = 900ml [(urine CRE x urine ml 24/h)/(serum CRE x 1440)] the formula would be: ([CRE&U] * 900) / ([CRE&S] * 1440).

The button **Test Function (Fig. 10.b)** is used for checking the relation test result from the analyzer, based on values given to the tests involved in the function. This option is useful for verifying the correct use of values and parenthesis in the formula.

The other options (**Figure 9**) available are:

Save: saves and exits from the window.

Print: prints parameters.

Cancel: exits without saving.

Note. The relation tests can be inserted into the available analyses' list for the current tray, even if they have no determined reagent position (refer to paragraph 1.7. Modify Current Tray). The result for a relation test can be returned only if both the test itself and all the other analyses involved in the function are present in the current reagent tray.

1.3.3. Primary Analytical Parameters

From the page **All Tests** or **Current Tray** select the desired test code, then move mouse cursor over **Parameters** and click to confirm.

In the displayed page, the analytical parameters for the chosen test are shown: they are divided into **Primary Parameters**, **Secondary Parameters** and **Check Parameters**. By clicking on the > or < buttons it will be possible to go to the next or previous test parameters.



The first screen shows **Primary Parameters**, to display the other screens click on the corresponding tags.

Primary Parameters

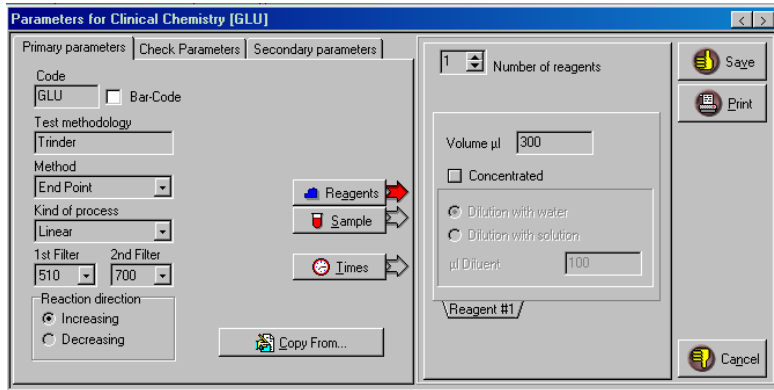


Figure 11

Code: The code of the selected analysis is shown in the text-box. It is not possible to write in this field.

Bar-Code: It is possible to assign a numerical code for positive barcode identification. It enables (if activated in the "Setup Analyzer") bar-code scanning to correctly identify the bottle during reagent's insertion phase.

Test methodology: In this field the reaction principle used for the test can be specified (for example: Jaffè, IFCC, etc.). This option is useful when recalling the tests from the Quality Control archive, in accordance with different principles, during the function **Data Processing**.

Method: This parameter defines the main methodology for the analysis. To program move the cursor over "▼" and select the chosen method. The available methods are detailed in paragraph 1.2.5. of this chapter.

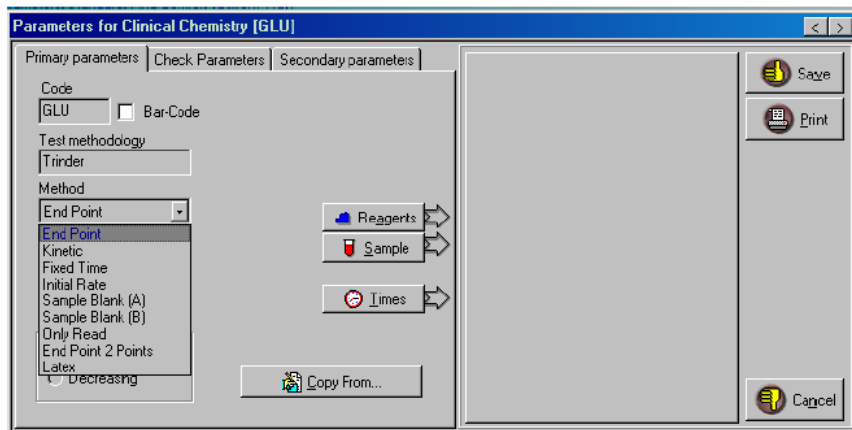


Figure 12

- Available Methods (Fig.13)**
- End Point
 - Kinetic
 - Fixed Time
 - Initial-Rate (I.R.)
 - Sample Blank type (A)
 - Sample Blank type (B)
 - Only Read
 - End Point 2 Points
 - Sample Blank (A-b)
 - Sample Blank (B-b)
 - End Point Starter
 - Absolute End Point

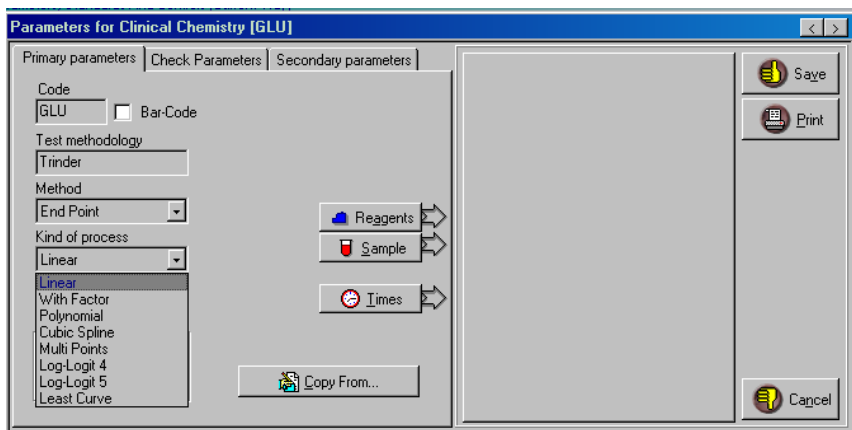


Figure 13

Kind of process: defines the kind of test's calibration: "linear", "with factor" or "with curve". The following choices are available:

linear: This function is used for linear reactions, it requires analytical test calibration to process computing factor.

with factor: It is used for linear reactions whenever the computing factor is known.

with curve: Non-linear tests, distinguished by:

- **Polynomial:** a third degree polynomial function is used. It has a very good approximation, but sometimes it may show anomalies
- **Cubic spline:** the typical cubic interpolation is used. There is a good connection between subsequent point couples. Approximation is perfect on single points, but is not flex point free.
- **Log-Logit 4** and **Log-Logit 5.** It is a logarithmic approximation on four or five points, used for non-linear tests.
- **Multi-point:** Linear interpolating function for several standard concentrations (max 6).
- **Minimum squares:** a second or third degree polynomial interpolation is used. It gives the best approximation to the minimum squares. It is a very simple curve, but sometimes may be distant from the standard points.
- **Line for two points:** Used for linear reactions. It requires analytic calibration of the test. Processes the passing line for two different concentrations. Represents FACTOR (SLOPE) and INTERCEPT (SHIFT).
- **Semi-log:** a second degree curve is used, which is function of the concentration logarithm, and gives the best approximation to the standard points minimum squares. It is asymptotical on the last point, has no flex points and well approximates the standard points. It may be used for highly non linear processes.

FILTER: The operator can select the desired filter value for the **1st Filter** and the **2nd Filter** (reference filter) from the available filter wavelengths: **340, 380, 405, 436, 480, 510, 546, 578, 630, 700 nm (Figures 14 and 15).**

For the tests in **bichromatism**, click on the "**1st Filter**" and select the desired filter value from the cascading window and then go to "**2nd Filter**" and select the desired filter value from its cascading window (1st position has empty field).

For the tests in **monochromatism**, select the desired filter value in the "1st Filter" cascading window. Since the second filter is not used in this test, therefore select the first position (empty field) in the cascading window of "2nd Filter". In this case the analyzer will use a "reference filter" only to stabilize the readings.

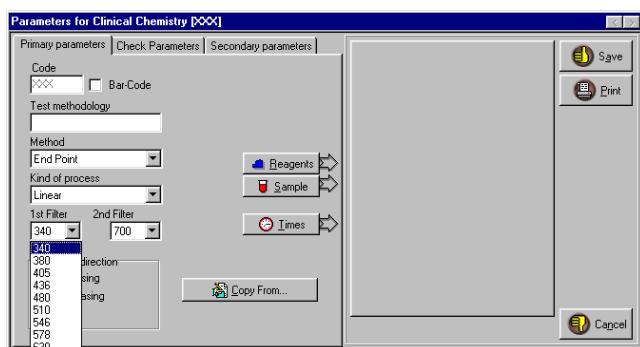


Figure 14

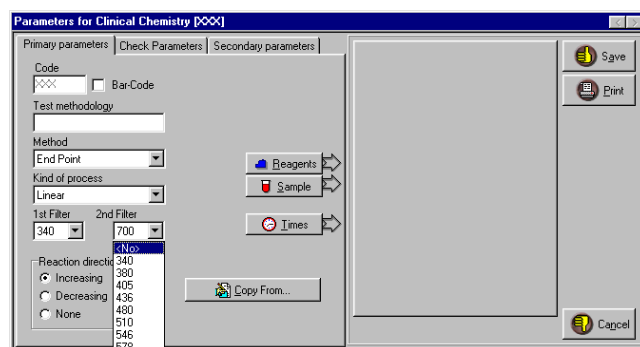


Figure 15

Reaction direction: select the kind of absorbance variation to be checked during reaction. The following choices are available:

- (•) Increasing
- (•) Decreasing
- (•) None

Selecting "**None**" excludes the possibility of controlling the reaction direction, and in addition no control is performed on the flags of ABS Limit and out of range reagents. This function is useful when testing new methods.

Select correct option so that the parameters later described: **Final ABS**, **Initial ABS** and **Reagent Limit** have the necessary reference with reaction progress.

Reagents: click on this button to select the reagents' parameters (**Fig. 16**).

The user can enter the following information:

Number of reagents: Enter the number of reagents the methodology requires, max. 2. Use up/down arrow keys "⬆" or move the cursor directly on the box and enter the value. Insert the volume of each reagent by selecting the corresponding table (Reagent #1 & Reagent #2, see **Fig. 16**) in accordance with number of reagents programmed.

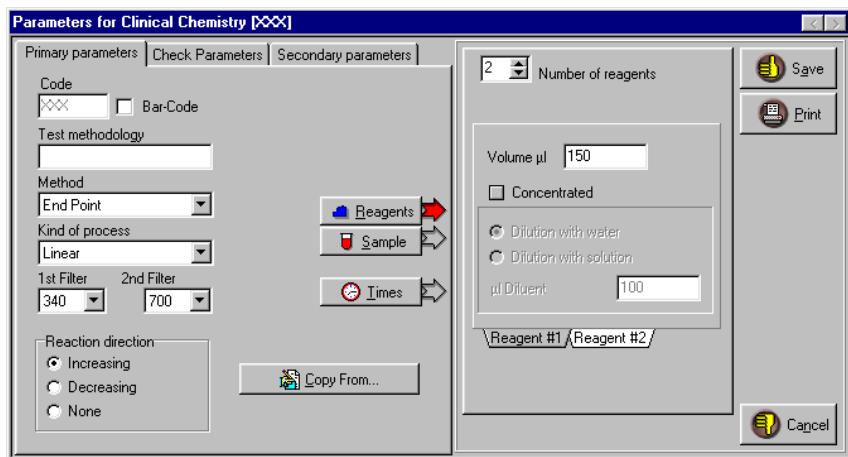


Figure 16

Volume µl: enter the reaction volumes for each reagent expressed in µl selecting the corresponding tag (Reagent #1 and Reagent #2, see **Fig. 16**). Always bear in mind that there are some limits for the final solution (reagent + sample) as well as for sample or reagents. See Table 1 at the end of this paragraph.

Concentrated: this field refers to concentrated reagents. If ready-to-use reagents are used this option should be disabled. If the program for volume of the **Concentrated** is enabled, then insert in the **Volume µl** text box, the volume of the concentrated reagent that the analyzer will withdraw for sampling, select the type of diluent to be used: if double distilled water (system solution) **Dilution with water** or dedicated diluent **Dilution with solution**. Write in the apposite field **µl Diluent** the volume of diluent to be added to the concentrated reagent. For example: for a dilution ratio of 1:3 write 100µl for the concentrated reagent and 200µl for the diluent. The dedicated diluent is considered by the analyzer as a further reagent and will therefore take a position of its own in the reagents' tray. If the diluent is the distilled water, the analyzer will take it from the main reservoir (system solution).

Sample: clicking on the button will open the window where sampling parameters for **Serum** and **Urine** can be programmed (**Fig. 17** and **18**). The **Serum** card is displayed first. To move between the **Serum** and **Urine** cards, click on the desired tag. The user can enter the following information:

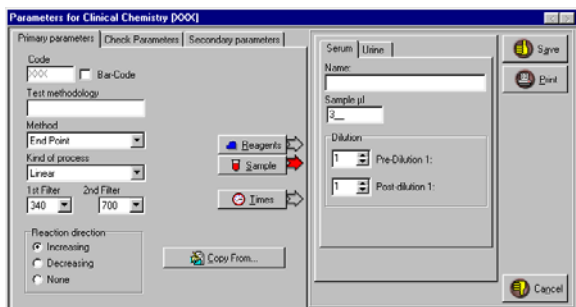


Figure 17

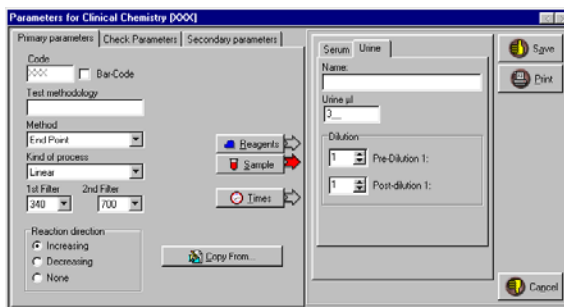


Figure 18

Serum Parameters (Fig. 17)

Name: Enter the complete name. The text written in this field will be used also to identify the test in the report printouts.

Serum µl: Sample volume expressed in µl (see Table 1).

Dilution: In this screen, two fields are available, **Pre-Dilution 1:** (predilution ratio) and **Post-Dilution 1:** (ratio of dilution repetitions). Maximum pre-dilution limit is 1/250. In case both ratios are set, the user can work within this limit, or in case a higher limit is necessary then an external dilution must be performed (refer to chapter E, paragraph 1.4. Samples).

Pre-Dilution 1: Set sample's pre-dilution ratio only if required by the method. Otherwise enter 1, and no predilution will be performed.

Post-Dilution 1: Set the sample's dilution ratio to be used for automatic repetitions of tests, which during the determination have either **Max ABS Delta** or **Final ABS** or **Test Limit** values out of the programmed limits (see ensuing **Control Parameters**). The user can then set an adequate dilution ratio in order to bring the reaction into linearity limits.

Urine Parameters (Fig. 18)

Name: enter the complete name

Urine µl: sample volume expressed in µl (see Table 1).

Dilution: The programming of fields (text boxes) for **Pre-Dilution 1:** and **Post-Dilution 1:**, is identical to the above-mentioned **Serum Parameters**.

ATTENTION: for analyses on urine samples, it is recommended to read the Note on urine parameters at the end of paragraph 1.3.5. Secondary Parameters.

NOTE: for diluting serum samples the analyzer will use the diluent (saline solution) while for urine samples, the analyzer will use bi-distilled water (system solution).

Times: this command allows setting of incubation and reading times. Move the mouse cursor over **Times** command and click to confirm; a form appears on a side of the screen with programmable fields (Fig. 19). The user can then enter the following information:

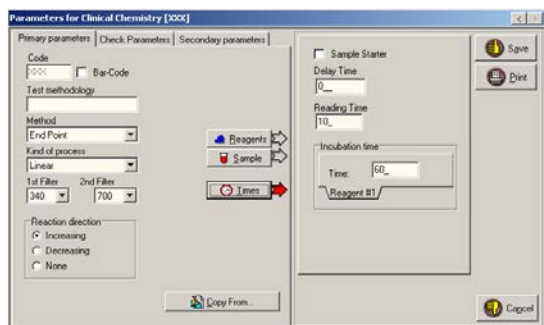


Figure 19

Sample Starter: This parameter, if enabled, allows separate dispensation between sample and reagent. This parameter can be used only for double reagents applications. See also par. 1.2.5. METHODS DESCRIPTION and the note at the end of this paragraph. To enable click on this box to confirm.

Delay Time: Parameter expressed in seconds preceding the incubation time, and it indicates a time gap available for the solution in the cuvette to become stable. During delay time no reading is performed (different from the incubation time) and it is useful in tests with "0" incubation time.

Incubation Time: This parameter expressed in seconds, indicates incubation time for the analysis (reagent and samples dispensed in the cuvettes) as required by the methodology. The possible values range from 0 to 999 seconds. For double-reagent methods, it is possible to enter different incubation times for the first and second reagent originating in different sampling dynamics. During incubation time the analyzer performs reading for capturing in advance the reactions that are out of linearity range (see later **Check Parameters**).

Reading Time: The user must enter the reading time (following the incubation time) in seconds, keeping in mind that the analyzer performs a reading approx every 10 seconds. The possible values range from 0 to 990 s.

Notes on the serum starter

When the serum starter is not activated the analyzer dispenses reagents and sample with different dynamics based on the programming:

Single-reagents: it takes the reagent and serum and dispenses both in the cuvette

Double-reagents: it takes the first reagent and serum and dispenses both in the cuvette; then it takes the second reagent and distributes it in the same cuvette. If the incubation time of the first reactive is zero, it takes both reagents and serum and dispenses everything together in the cuvette.

The method with the serum starter makes it possible instead to take the two reagents (even at different times) and dispense the serum in the cuvette last.

Indicative volumes

	BT3000 Plus	BT1500 BT3500 BT3500S
Min / Max Sample Vol. µl	1 / 100	1.8 / 100
Min / Max Reagent Vol. µl	1 / 470	0.8 / 300
Min / Max volume in cuvette µl	280 / 700	180 / 400
Max diluter volume µl	470	300
Min / Max reaction (reag + sample) µl	300 / 700	180 / 400

Table 1

1.3.4. Check Parameters

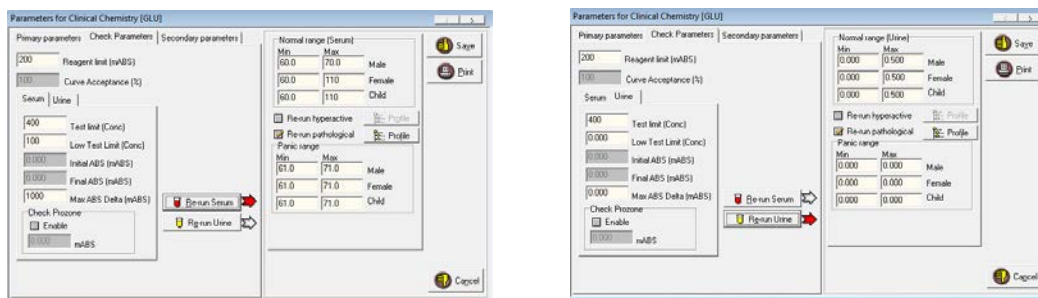


Figure 20

Select the **Check Parameters** table (Fig. 20 and 21). To set a given parameter, move the cursor on its corresponding textbox and click to confirm.

The user can enter the following information:

Reagent limit (mABS): this parameter indicates the limit absorbance (ABS) value that is acceptable for the reagent (maximum for increasing reactions, minimum for decreasing ones) and it is expressed in mABS. If reagent's absorbance is beyond this limit, the analyzer will check the results with **O flag (Reactive out of limit)**. This parameter allows monitoring reagents quality as well as checking any variation from the specific techniques. The parameter is identical for the serum and urine.

Note:

This control has the highest priority on all the other check flags and inhibits the automatic repetition functions. In case of reagent out of limit, the blank will be repeated every time the test is performed in a run.

Curve Acceptance (%): C.C. = Correlation Coefficient. This is only applicable to kinetic type test (fixed time, kinetic and initial rate). The programmable values range from 0% to 100%. This parameter is identical for both serum and urine and indicates the acceptability limit for any data instability that is detected during programmed reading time. If this value is exceeded, the final result will be checked with a **± flag (Unstable Sample – C.C.% greater than assigned value)**.

Test limit (Conc): This parameter is used in all methodologies and it allows verification of the final concentration of the analyses. It represents a threshold value beyond which the analyzer detects an out-of-linearity condition (hyperactivity). With **Re-run hyperactive** check enabled (refer to paragraph 1.3.6. Automatic re-runs), the analyzer will automatically re-run the test, diluting the sample as programmed in the serum parameters, in order to bring the reaction into linearity range. The final result is automatically multiplied by the dilution factor and will be checked with **"I" flag (= Hyperactive Sample – out of Test Limit-)**.

Low detection limit: The Low Test Limit parameter is used in all methodologies and allows for verification of the final concentration of the test. It represents a threshold value below which the analyzer detects an out-of-assay range condition (low limit). Every concentration below the given value will generate an 'L' flag. Results triggering the Low Test Limit are not considered Hyperactive and will not trigger automatic hyperactive sample repeats (if enabled).

Initial ABS (mABS): This parameter is used only for the methods **Kinetics, Fixed Time** and **Initial-Rate**. It is expressed in mABS and defines the limit for the total absorbance (reagent + serum) expected for this test. The first reading of the incubation phase is compared with this value. If the read value is greater than the parameter, the analyzer will consider that as a possible interference of serum in the reaction (for example: lipemic serum), thus marking the final result with **~ flag (= Serum Interference)**.

Final ABS (mABS): this parameter is used only for the methods **Kinetics, Fixed Time** and **Initial-Rate**. It is the last reading of the reaction expressed in mABS; it indicates the limit (upper limit for increasing analyses, lower limit for decreasing ones) beyond which the analyzer detects an out-of-linearity test (hyperactivity).

With **Re-run hyperactive** check enabled (refer to paragraph 1.3.6. **Automatic Re-runs**), the analyzer will automatically re-run the test diluting the sample (refer to Chapter E, paragraph 1.4. **Samples**) in order to bring the reaction into linearity range. The final result is automatically multiplied by the dilution factor and will be checked with **A flag** (= **Hyperactive Sample** – out of final ABS Limit-).

Max ABS Delta (mABS): This parameter expressed in mABS is used in all the methods, except **Only Read**. It represents the maximum Delta (Δ) for the reaction detected during incubation phase. Test is considered out of linearity when this value is surpassed. The analyzer verifies the reaction process during the incubation phase for all the methods. The reaction is prolonged for a period equivalent to 60 seconds for the methods **Kinetics**, **Fixed Time** and **Initial-Rate**.

For the methods in **End Point**, (**End point**, **End Point 2 point**, **End Point Starter**, **Absolute End Point**, **Absolute End Point**, **Sample Blank A and B**, **Sample Blank A-b**, and **Sample Blank B-b**), the reaction is prolonged for a period equivalent to $\frac{1}{4}$ of the incubation time but never less than 20 seconds. The assigned Max ABS Delta is compared with the one calculated at the end of 60 seconds or one-fourth the incubation time, based on the type of test.

With the **Re-run hyperactive** check enabled (refer to paragraph 1.3.6. **Automatic Re-runs**), the analyzer will automatically re-run the test by pre-diluting the sample (see. **Samples**) in order to reenter the reaction into linearity range. The final result is automatically multiplied by the dilution factor and will be checked with **d flag** (= **Hyperactive Sample** – out of Max ABS Delta-).

Check Prozone (mABS): this parameter checks the ABS variation tendency during all processing time of the test. In case of inversion it is likely to be in a Prozone situation. The final result will be checked with **C flag**. This parameter is used for all methods, except for **Only read** and indicates the maximum allowable inversion in the reaction (expressed in mABS). If the prozone flag is activated in a sample, this will be repeated as if it was a hyperactive, if the repetition of hyperactives is enabled. In addition, for an inverse curve flag, the analyzer will also test the prozone.

Re-run serum and Re-run urine: these commands are used to enable automatic repetitions, for more information see paragraph 1.3.6 of this chapter.

Note. The parameters **Test limit**, **Initial ABS**, **Final ABS**, **Max ABS Delta** and **Check Prozone** are different for serum and urine (see **Fig. 19 and 20**).

1.3.5. Secondary Analytical Parameters

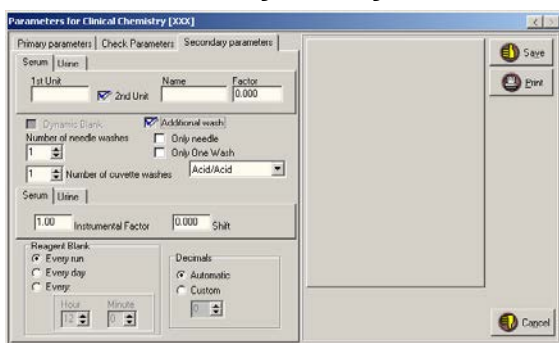


Figure 22

After selecting the **Secondary Parameters** (Figure 22) to program click inside the desired parameter textbox and confirm.

The user can enter the following information:

1st Unit: Enter the measurement unit in this field. Click on the **2nd Unit** to enable it for the second unit of measurement. Instantly a new textbox will appear where the operator can type in the second unit of measurement and the conversion factor between the two units. In case of two units of measurements, the test value is expressed in two results. In the analytical calibrations the **1st Unit** of measurement is used.

1st Unit (Urine): by selecting **Urine** it is possible to enter a specific unit of measurement and then the conversion factor between the unit of measurement expressed in serum and that expressed in urine.

N.B.: always remember that the calibrations are made with the parameters assigned to serum, so this should be taken into account for urine analyses.

The **Factor** field is only for urine and represents a multiplication factor. All the information must be entered in this field, which allows the analyzer to convert the serum units of measurement into those for urine, to convert the diuresis units of measurement and possibly compensate the different volume of urine compared to serum (see the note at the end of the paragraph).

Dynamic Blank: If the parameter is enabled, then the analyzer quantifies and memorizes the photometric drift of the reagent blank by processing only the reagent as sample. After the determination of the Reagent Delta ABS, this value is then subtracted from the Sample ABS value. The value of Reagent Delta ABS is then visualized in the "STANDARD" page adjacent to the absolute value of the reagent. The dynamic blank is only available for the Fixed Time, Kinetics and Sample Blank A tests.

Number of needle washes: With this command the user can set the number of washings (with system solution) to be performed after the dispensing of the reagent used for the test. Normally one washing is sufficient, however in case of highly contaminating tests more washings will be necessary. To set washing numbers (maximum 9 washings) in accordance with the contaminating force of the used product, press the up/down arrow keys "◆" or move the mouse cursor inside the dedicated box and enter directly the value.

Number of cuvette washes: With this command the user can set the number of washings (with system solution) for the cuvette used by the current analysis, before making it available to other tests. In practice, the analyzer verifies and selects from all the cuvettes that have terminated analysis, the one that requires minimum number of washes. Normally only one washing is sufficient, but in the case of very aggressive tests more washings will be necessary. To set washing number (max. 9) required by the contaminating force for the used product, press "◆" or move the mouse cursor over dedicated box and enter directly the value.

Additional washes: allows the operator to enter two additional special washes into the sampling dynamics. These additional washes may be useful when contamination between reagents is found. The two solutions that can be used are described in Chapter B, par. 1.3.3. (see also [Section II, Chapter 3 for ordering information](#)) The additional wash may be for just the sampling needle (check **Only needle**) or it can be for needle and cuvette. In both cases it is possible to select the additional wash to be performed with one (check **Only one wash**) or with two solutions: an acid and a base. The needle and cuvette wash will take place before dispensing the test. The normal water washing of the cuvette with the system solution will still take place, it will then be washed with the (or both) additional solution and then rinsed again with water. In case of double reagents, the needle first wash will take place simultaneously to the cuvette wash.

If there is no additional solution in the reagent bottle, the test result will be marked with the "W" flag and the testing of the single analysis will be aborted.

Reagent Blank Timing: This parameter is used for automatic determination of the ABS value for the reagent. Select, among available choices present in the **Reagent Blank timing** list (see **Fig. 22**), one of the following:

(•) **Every run:** The absorbance determination for the reagent will be performed at every work start-up.

(•) **Every day:** The absorbance determination for the reagent will be performed once a working day (when the first working list of day is started).

(•) **Every:** The absorbance determination for the reagent will be performed at the time intervals as programmed into the **Hour** and **Minute** boxes. For example, setting "02" hour and "00" minutes, determination will be performed every two hours. To set the value, press "◆" or move the mouse cursor inside the dedicated box and enter directly the value.

Decimals: If this parameter is used with the **Custom**, then it sets the number of decimal places that should be used to represent numerical results of the tests. Alternatively, if the decimal places are not programmed **Automatic**, then the analyzer automatically sets the number of decimal places in accordance with "floating point" algorithm.

Instrumental Factor: This function introduces a constant correction of the final data of the executed test. It may be used for making adjustments to test data obtained from analytical methods or different type of instruments. Calculation: final result = value x instrumental factor

Shift: This function introduces a constant quantitative correction of final test data. It may be used for making adjustments to test data obtained through analytical methods or instruments of different types. Calculation: final result = value + shift.

NOTE: When the following parameters are used at the same time: Instrumental factor and Shift (in secondary analytical parameters), External dilution factor and Urine 24/h (in the patient's data), the calculation made by the analyzer will be as follows:

[(test result x External factor x Instrumental factor) + Shift] x Urine 24/h

ATTENTION: if the calculation of the result (with instrumental factor and shift) gives a value less than zero, <NC> (not calculable) will be displayed instead of the result and the associated flag will be **M**: Error in the parameters (instrumental factor and shift): By opportunely correcting the instrumental factor and shift parameters and running the calculation again (with the **Correction** function chap. G par. 1.1) it is possible to convert the <NC> result to a valid number.

NOTE ON THE URINE PARAMETERS

The analyzer always uses the parameters assigned to the serum when it runs the calibrations. It is necessary to bear this in mind when programming analyses on urine.

For tests dedicated solely to urine, it is advisable to program the serum parameters identically to those for urine. In this way the test calibration will be consistent with the urine parameters. For running the tests, urine can be regularly selected as sample, which will allow the use of all the fields assigned to it, both in the parameters and in patient entry (e.g. diuresis).

For tests on serum and urine, since the calibration is made on the serum parameters, it is necessary to take into account all the factors, which permit aligning the serum parameters to the urine ones.

a) Unit of measurement: if the unit for serum is mg/dl and the one for urine must be g/l, the factor will be:

$\frac{mg}{dl}(\text{serum})_correspond_to \frac{gx0.001}{lx0.1}(\text{urine})$, so the factor should be 0.01.

b) Sample volume: if the serum volume is 3µl, and that of the urine is 30µl, the factor will be **0.1***

The total conversion factor for cases a) & b) will be given by 0.01 x 0.1 = 0.001

These factors all go together in the **Factor** field relative to the first urine unit of measurement.

Diuresis: The diuresis field does not have a unit of measurement for greater flexibility, however, to avoid additional calculations, it is advisable to enter the diuresis volume already in the urine units of measurement.

* The factor will be around 0.1, since the exact relation is given by the relation of volumetric factors, however the relation vol. S / vol. U can be used as a good guideline.

OTHER COMMANDS IN THE PARAMETERS PAGE

Save: saves and exits from the window.

Print: prints parameters.

Cancel: exits without saving.

1.3.6. Automatic Re-Runs

The commands **Re-run Serum** and **Re-run Urine** are available (automatic repetition parameters for hyperactive or pathological tests) in the **Check Parameters** table.

To set, move the mouse cursor over the desired command and click to confirm. The following functions are available in the displayed table:

Normal range:	Min. Max. M: }	normal reference values (min. and max.) for male (M), female (F) and children (C).
	Min. Max. F: }	
	Min. Max. C: }	

Re-run hyperactive: It allows automatic re-run for a hyperactive result, with dilution or not of the sample, according to the implemented programming (see par. 1.3.3.). Check the box to confirm and enable. The **Profile** (see below) is automatically enabled when selected.

Re-run pathological: it allows automatic re-run for a pathological test, without sample dilution. Check the box to confirm and enable. The **Panic range** box appears; similar to the **Normal range**, it allows programming the limits beyond which the analyzer performs test re-run. Values in the **Panic range** can be different from those in the **Normal range tests**.

Profile: it is available when automatic (hyperactive/pathological) re-run option is enabled and it allows automatic execution of analyses to be associated to programmed test. To set, move the mouse cursor over **Profile** command and click to confirm. The available analyses list will then appear, select the tests to be associated and store with **Save** command. The analyzer will automatically execute the profile associated to the hyperactive or pathological test.

For non-linear tests, the following fields will also appear:

Re-run out of curve "above": allows automatic re-running of the samples with an absorbance above the calibration curve by applying the same dilution relation required for hyperactive samples. The sample outside the curve is marked with the flag ">" if it is still outside the curve after re-running, the flag will be ">>".

Re-run out of curve "below": allows automatic re-running of samples with an absorbance below the calibration curve. In this case the analyzer applies a different relation between the serum and reactive (the sample volume is doubled) in order to make the absorbance return within the curve limit. The sample outside the curve is marked with the flag "<" if it is still outside the curve after re-running, the flag will be "<<".

GENERAL CONSIDERATIONS ON TEST LIMIT, REACTION LIMIT AND MAX DELTA ABS

These three parameters are used to monitor a likely hyperactive situation in a sample, whether it is serum or urine. With automatic hyperactive samples re-run option enabled, the analyzer produces two results: the first value indicates the specific parameter that has been passed (for example, if Reaction Limit has been passed, the "A" flag is displayed), while the second one indicates what has been detected after repetition. In case the automatic sample's re-run has not been sufficient to restore the reaction within programmed limits, the user can insert a manually pre-diluted sample. For this purpose, a field called "Dilution Factor" has been added to the patient entry page. During check-in or sample's re-run phase, it is possible to set a pre-dilution parameter that will be used by the analyzer when calculating final result. For manually pre-diluted samples, if the result is hyperactive, this will be checked with the appropriate flag, but test won't be automatically re-run.

Note:

Reporting the first and second result when automatically re-running pathological and hyperactive tests: in case of automatic re-run of hyperactive and pathological tests, the analyzer displays and prints in real time a compressed report. The report shows the results obtained from the first and second determination naming them first and second result. However, one should bear in mind that in the patients archive only the second result is stored, the one obtained after the repetition. If printing is set in real time in "report" format (see Setup Chapter H, par. 2), the printed result will only be the second one, just like for the patient archives printing.

1.4. CONTROLS

In the pages **All Tests** and **Current Tray** select desired test code then move the mouse cursor to the command **Controls** and click to confirm. The parameters for the desired test are contained in the displayed page.

The controls are divided into **Known** and **Unknown**, where it is possible to program three levels for each one subdivided in tables:

Known: Level 1, 2, 3

Unknown: Level 1, 2, 3

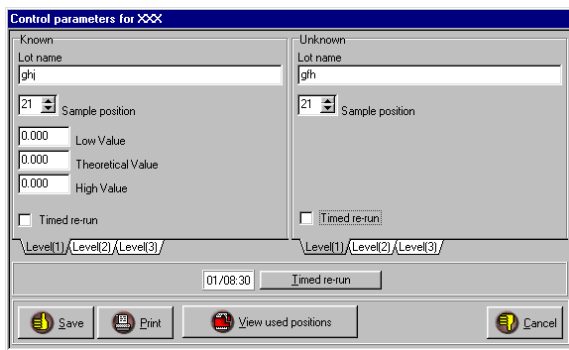


Figure 23

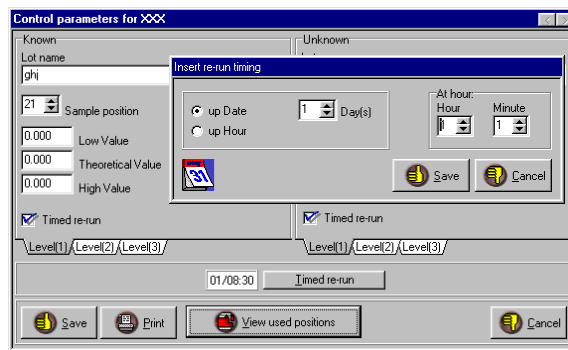


Figure 24

The first displayed tables are **Level 1** for **Known** and **Unknown** controls. To select move onto the desired tag title and click to confirm (Fig. 23).

Known: To program move the cursor over desired boxes and confirm. Enter **Lot name or number**, theoretical value, and low & high limits. Enter **Sample position**, already set to controls in the section **Setup Analyzer** included in the inner ring of samples' tray.

Unknown: Enter **Lot name or number** and **Sample position**. Reserved positions are those already set in the program **Setup Analyzer**, which are shared with known ones.

Timed re-run: is used to program the automatic reminder for repeating controls. It is possible to insert the timer for each single control. Check **Timed re-run** box and then Click **Timed re-run** to display **Insert re-run timing** screen (Figure 24). Here it is possible to enter interval of hours or days for automatic controls run.

upon Date (daily interval): Select the function and set daily interval, then enter test running time (for example 1 08,30 means every day at 08,30 or in any case at start up).

upon Hour (hour interval): Select the function and set the desired hour interval, hours and minutes.

Every day or when the preset time expires, the analyzer will automatically alert the user that there are controls to be run. If reagents and controls are present, then the user can directly confirm to execute the tests.

NOTE: the automatic reminder has to be activated in the **Immediate Controls** page (see Chap. C, par. 1.4)

View used positions: This command displays the test disposition.

NOTE ON TIMED RE-RUN

Timed re-runs of controls or standards may expire while the analyzer is in the standby phase. In this case the expirations will be automatically delayed by 10 minutes.

1.5. CALIBRATIONS Programming

The analytical calibrations that can be run by the analyzer are divided as follows:

Linear and Non Linear

Selection occurs during the programming of the analytical test parameters (refer to paragraph 1.3.3. **Primary Analytical Parameters** and the following) and can be executed on user's request or automatically.

In the pages **All Tests** and **Current Tray** select desired test code then move the mouse cursor to the command **Standard** and click to confirm. The parameters of calibration, execution and verification of the preselected test are shown in the displayed page.

Always bear in mind that the serum parameters will be used for the calibrations, regardless of the sample that is going to be used.

Analyses With Factor

Calibration executed by the analyzer is not required for these tests, but a theoretical factor for calculation needs to be entered. This is a parameter to convert the absorbance values (ABS), determined by the analyzer, in final concentration values. A box appears where it is possible to enter a known factor value, declared in the method, while the reagent ABS value detected by the analyzer is represented at the same time.

Analyses with Linear Calibration

In this type of test the analyzer executes a calibration with a known concentration standard. Based on the absorbance values detected for the standard, the analyzer calculates the factor, which will be used to convert the absorbance values (ABS) of samples to final concentration values. After each new calibration the analyzer calculates and updates the factor. Alternatively, it is possible to directly enter a known value in the **Factor** field.

The following parameters also need to be set.

Figure 25

Range Limit – Minimum and Maximum: in order to verify the validity of the calibration, enter the minimum and maximum limits that the calculated factor must be within. After an out of range value, a warning is given and the previously memorized factor is not changed. If known concentration and absorbance values are available, it is possible to mathematically process the factor using the **Calculation** function key.

NOTE:

The used calibrators or standards must be placed in the positions assigned on the sample tray (bear in mind that the numbering is programmed in the **Analyzer Setup** program, par. 2, chap. H). In linear analysis it is possible to use up to 4 different standard concentrations or execute up to a maximum of 4 repetitions on a single point. It is possible to program the same positions for various analyses if a multi-calibrator is used.

Programming re-runs on a single point (see Fig. 25)

By entering 1 in the **Number of samples** box, the **N. replicates** box automatically appears. Enter the number of replicates to be executed, up to a maximum of four.

A programming box appears for the position and value of the standard concentration, plus other boxes which cannot be programmed related to replicates, for a total equal to the desired number of replicates. The values in the **ABS** boxes are automatically updated during the calibration phase. If known they can be entered by the operator. With this type of programming, the analyzer will execute a maximum of four samplings from the same sample cup, then calculate a factor for each sampling and update the calculation factor using the mean of factors obtained for the replicates.

Programming multiple standards (see Fig. 26)

Enter the number of standards to be used in the **Number of samples** box (maximum of 4). The programming boxes for the positions and concentration values of the standards are automatically displayed in the same quantity. The values in the **ABS** boxes are automatically updated during the calibration phase, if known they can be entered by the operator. With this type of programming, the analyzer will execute a maximum of four samplings of the standard from separate cups with different concentrations, then calculate a factor for each standard and update the calculation factor using the mean of factors obtained for the replicates.

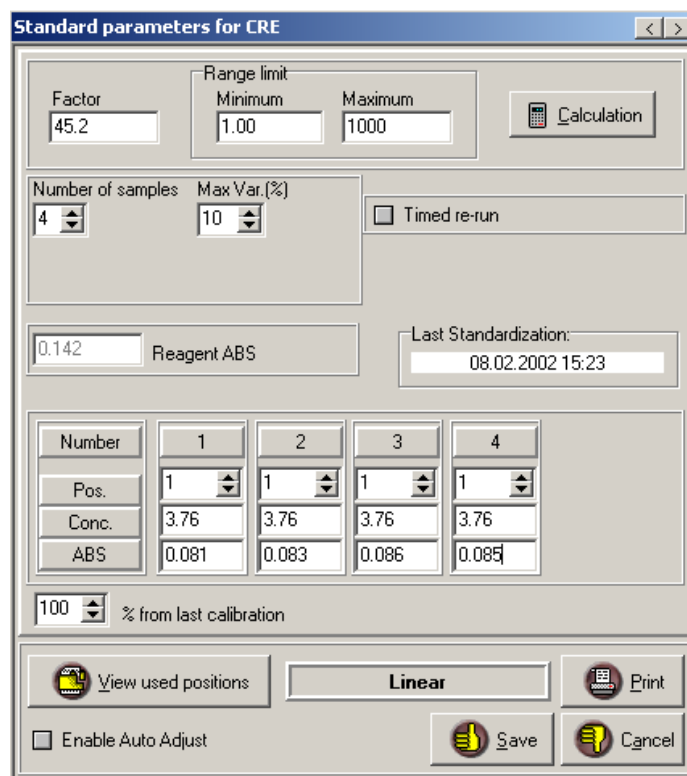


Figure 26

Max Var. (%) (Maximum percentage variation): calibration verification parameter. It represents the acceptable difference (in percentage) among the factors calculated if various standards are used or if replicates are executed on a single point. After a variation above the programmed limit, a warning is given and the previously memorized factor is not changed.

Reagent ABS: each time a reagent blank is executed for the analysis, the measured value is updated in this window. If **Dynamic blank** is enabled (subtraction of the reagent photometric variation, see par. 1.3.3. Primary Analytical Parameters and following paragraphs) the measured reagent ABS value is displayed, plus the variation determined during reading of the blank.

% from last Calibration: parameter which checks the percentage between the executed and previous calibration. It compares the determined factor with the memorized one. After a variation above the programmed limit, a warning is given and the previously memorized factor is not changed.

View used positions: opens a single box to represent the position of tests in relation to the sample tray.

Enable Auto Adjust: this parameter enables or disables automatic modification of the tests results if another calibration is executed when running patients. The user must be enabled to the access level (by password) to modify this parameter.

Last standardization: display box for the date and time of the last test calibration performed. By double clicking on the box it is possible to view the data of the previous calibration, factor, concentrations and absorbance.

Timed re-run: it is used to program the automatic reminder for repeating calibrations. Once the programmed standardization time has elapsed, the analyzer sends a warning message and if the reagents and standards are present, calibration can be directly executed. Enter the standardization time by enabling the check and program the intervals in days and hours:

By Date: select the function for programming the interval days, then indicate the test execution hour (e.g. 1 08.30 means every day at 8:30 or each time the analyzer is turned on).

By Hour: select the function and program the desired time interval, in hours and minutes.

NOTE: the automatic reminder has to be activated in the **Immediate Standards** page (see [Chap. E, par. 1.3](#))

NOTE ON TIMED RE-RUN

Timed re-runs of controls or standards may expire while the analyzer is in the standby phase. In this case the expirations will be automatically delayed by 10 minutes.

Print: command for printing the programmed parameters.

Save: command for memorizing and exiting.

Cancel: program for exiting without memorizing changes.

Analyses with Non Linear calibration (see fig. 27)

Non Linear analyses require from 3 to 6 standards. If the process type is **Multi Point** the number to enter in the **Number of Samples** box varies from a minimum of 2 to a maximum of 6. In the analyses with **Log logit 4 & 5** curve, programming is the same but the required positions are 4 and 5, respectively.

Select the number of standards to be used to construct the curve. The fields for entering the position and concentration of the various standards appear automatically. The values in the **ABS** boxes are automatically updated during the calibration phase, if known they can be entered by the operator. Programming is similar to that for analyses with factor, but here automatic standard dilution is also available.

To use the standard pre-dilution function program the positions of the standards and enter the calibrator concentration (the most concentrated point of the curve) at the first pre-selected position. Then click on the **Automatic Dilution** box. Three new fields will open:

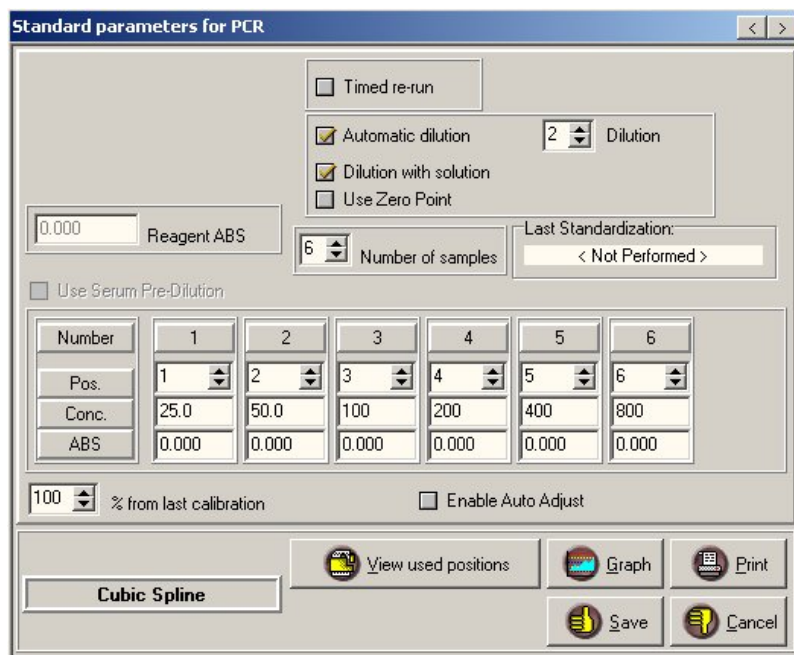


Figure 27

Dilution: sets the dilution relation. The analyzer will automatically calculate and update the scalar concentrations starting from the highest concentration value already present in the fields.

Place the cup with entire standard on the sample tray in the assigned position, plus a number of empty cups equal to the subsequent standards. The serial dilutions used to build the curve will be prepared in these cups.

Dilution with solution: used to select whether to dilute the sample with physiological solution (located in the specific test tube) or with bidistilled water taken from the external tank (system solution).

Use Zero Point: used to automatically reset the concentration of the lowest point of the curve to zero. During the predilution phase of the standards the analyzer will dispense the pre-selected diluent (physiological or water) in this position.

For all the tests with calibration curve, the analyzer will warn the operator if samples (patients) have results above or below the calibration curve with a flag (below curve "<" and above curve ">") next to the result. It is possible to select automatic re-running for samples outside the curve in the control parameters (see par. 1.3.6 Automatic repetitions). When the absorbance of the least concentrated point of the calibration curve (or point with 0.0 concentration) is negative, it will be automatically set to zero, in order to prevent false results, for example concentrations with a minus sign.

The fields **Reagent mABS**, **% from last calibration**, **View used positions**, **Enable auto adjust**, **Timed re-run**, **Print**, **Save** and **Cancel** have the same programming and functions described for linear calibrations.

Last standardization: display box for the date and time of the last test calibration performed.

Use serum Pre-dilution: if in the sample primary parameters (par. 1.3.3.) a pre-dilution ratio has been set, it is possible to perform the standards pre-dilution with the same ratio as for the sample.

Graph: command for displaying the interpolation graph of the memorized curve. The curve and data are represented on the graph display page.

1.6. CREATING PROFILES

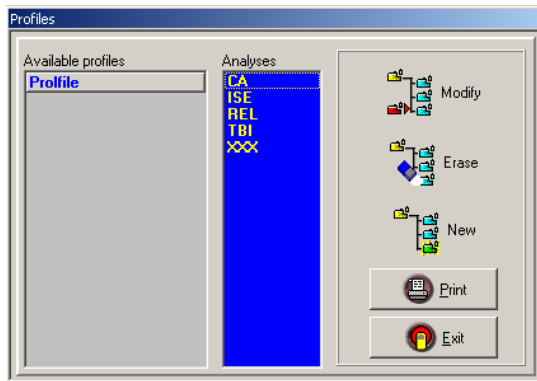


Figure 28

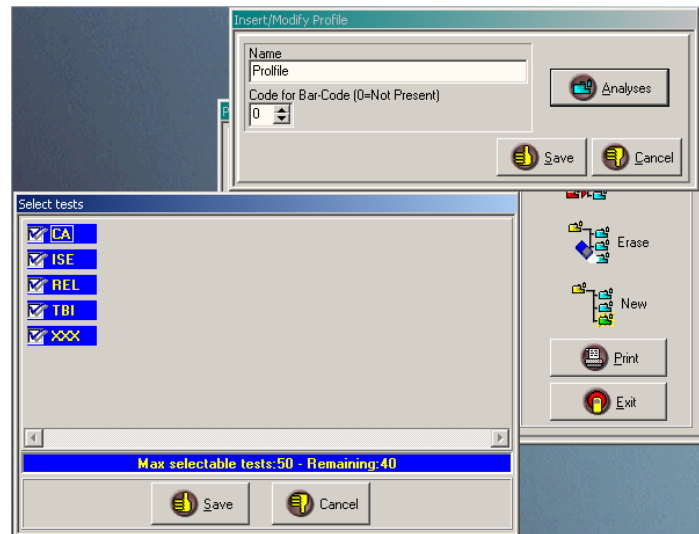


Figure 29

INSERT/MODIFY PROFILES: this function creates/modifies analyses groups, useful when checking-in patients. It can be accessed from **Tests** menu or from the specific icon that allows direct access (**Figure 28**).

It is possible to delete, update and print an already existing profile.

Creating a profile: click over **New** button: the **Profile Name** textbox will appear. Enter the name for the profile and click on **Analyses**: this will open a window where it will be possible to select the analyses for the profile. Click "Save" to store the selected analyses (**Fig. 29**). It is possible to enter in the **Code for Bar-Code** field a numerical code. The analyzer, when reading the bar-code labels of Patients, will recognize it. This code is used for completely computerized acquisition of the analyses assigned to the patient.

To update an existing profile, select it from the list and click on **Modify**, and then proceed as outlined previously. To delete an existing profile, select its name and press **Erase**, confirmation is requested prior to erasing.

Attention: during the patient acquisition, only the analyses present on the tray are displayed for each profile.

1.7. CREATING THE CURRENT ANALYSES TRAY

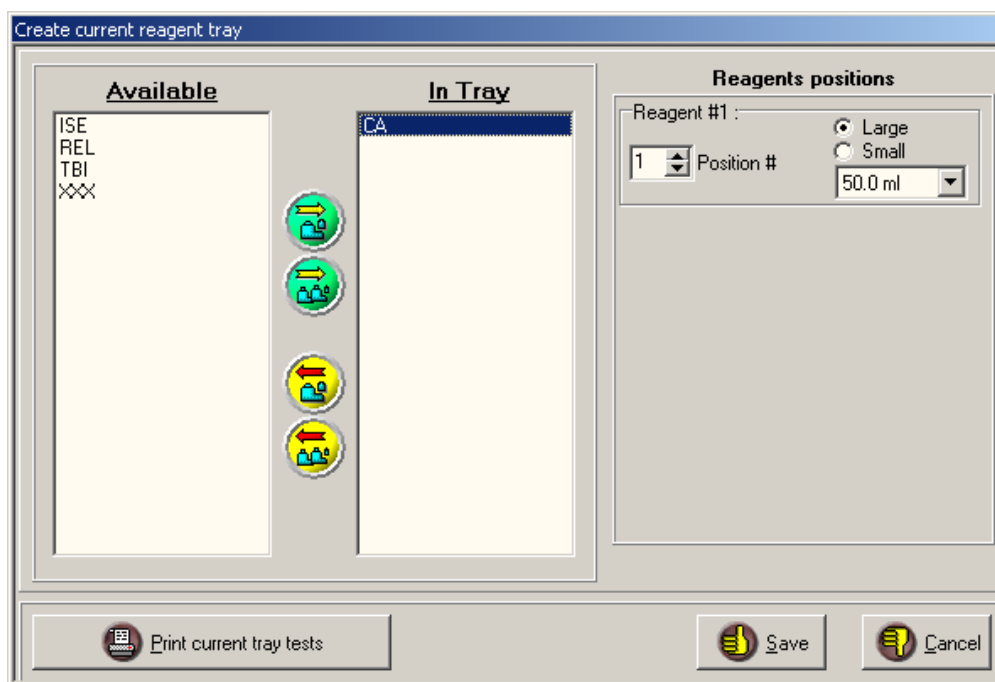


Figure 30

The function **Create/Modify current reagents' tray** creates the list for the reagents placed on the tray. It can be accessed from the **Tests** main menu or from the specific icon that allows direct access.

Into the window (**Fig. 30**) the "All tests" list (**Available**) is displayed and adjacent to it (**In Tray**) the tests for the current tray are listed.

To create the reagents' tray list, select one or more (CTRL+mouse for multiple selections) tests from the left window then transfer them with arrow commands ">" (move single test or selection) or ">>" (move all available tests).

To remove from the current tray list select and transfer codes with commands "<" (single or selection) or "<<" (all available). Once tests are transferred, the analyzer automatically assigns the positions and the type of bottles, but the user can modify both according to his needs.

To modify, select the desired test in "In Tray list" and then move the cursor in **Position #** textbox. Now enter directly the number or use up/down arrow keys "◆" to scroll. Bottle size can be selected by checking • **Large** or • **Small**. There is also a field for selecting the volume of available bottles.

In case of **Double Reagents** or **Concentrated**, to be diluted with solution, positions and bottles' type are displayed for each product. It is possible to use the same reagent position for several analyses.

The creation of the current reagents list is automatic when the Bar-Code option is enabled (refer to **Chapter I**).

The Relation Tests can be entered in the analyses tray. They are placed at end of the generated list and no physical position is assigned to them.

Save: Memorizes data and exits.

Exit: To leave (exit) the program without saving.

Print: To print data in the current tray.

SECTION I: GENERAL INFORMATION

CHAPTER D: PERFORMANCE AND LIMITS

1. PERFORMANCE AND LIMITS	2
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NOTE: for the I.S.E. module specifications, refer to the dedicated chapters (Chapters L/L1)

1. PERFORMANCE AND LIMITS

GENERAL INFO	
Operating Mode:	Random access
Methods:	Tests for Clinical Chemistry and Immune-Chemistry
Test Mode:	Routine, Batch, Emergencies (STAT), Profiles
Tests in memory:	500 single or double- reagent + unlimited Relation Tests
Test Re-runs:	automatic or on demand
Calibrations and Controls:	automatic or on demand
Automatic Profiles:	automatic execution of related profiles or on demand
Quality Control:	3 known levels and 3 unknown levels
Remote diagnostic:	Via Modem (optional)
Maintenance:	Automatic program

TIME REQUIRED TO REACH STEADY STATE	
Ambient conditions:	21 °C R.T., 33% RH
Time required for the analyzer to reach steady state:	20 min.
Time required for refrigerated bottles to reach steady state:	approximately 2 hours

OPERATING AMBIENT TEMPERATURE 18 °C to 32 °C, 10% to 90% RH, Non condensating

PERFORMANCES	BT1500 (1500i)	BT3000 Plus	BT3500/BT3500S
Tests on line:	48 refrigerated reagents + relation test	80 refrigerated reagents + relation test	80 refrigerated reagents + relation test
Measurement:	direct reading of 32 cuvettes in optical glass	direct reading of 34 cuvettes in optical glass	direct reading of 45 cuvettes in optical glass
Samples Tray:	78 total positions; 62 for Samples & STAT, 16 for Standard and Controls	78 total positions 52 for Samples & STAT 26 for Standard and Controls	78 total positions; 62 for Samples & STAT, 16 for Standard and Controls
Sampling arm:	1 for Samples and Reagents	2 for Samples and Reagents	2 for Samples and Reagents
Bar code scanner:	Optional	2 distinct barcode scanners for positive identification of samples and reagents	2 distinct barcode scanners for positive identification of samples and reagents
I.S.E. Module:	Optional, on BT1500i	See Chapter L	See Chapter L for BT3500, BT1500 with I.S.E. and L1 for BT3500S
Sampling cycle:	14.5 seconds	12 seconds	10 seconds
Analytical Throughput:	Up to 250 test/hour	Up to 300 test/hour	Up to 360 test/hour

VOLUMES: WORKING SOLUTIONS		
	BT3000 Plus	BT1500 (1500i) BT3500 - BT3500S
Min / Max Sample Vol. µl	1 / 100	1.8 / 100
Min / Max Reagent Vol. µl	1 / 470	0.8 / 300
Min / Max volume in cuvette µl	280 / 700	180 / 400
Max diluter volume µl	470	300
Min / Max reaction (reag + sample) µl	300 / 700	180 / 400

RESIDUAL VOLUMES OF REAGENTS BOTTLES	
80 ml BOTTLES:	2 ml
50 ml BOTTLES:	1.5 ml
20 ml BOTTLES:	0.6 ml
10 ml BOTTLES:	0.6 ml

UTILITY EXECUTION TIMES				
	BT3000 PLUS	TIME	USED SYSTEM SOL. (approx)	USED DEDICATED SOL. (approx)
Wash with water	5'		200ml	
Wash cuvettes	8'		250ml	25ml
Extra wash cuvettes	21'		860ml	25ml + 25ml
Zeroing on water	6'		200ml	
Sleep mode wash	5'		200ml	
FCC Function	15'		300ml	15ml
Cuvette single wash			6ml (5ml to 8.2ml)	
Needle single wash			2ml	
Consumption per test			8ml	

	BT3500/ BT3500S	TIME	USED SYSTEM SOL. (approx)	USED DEDICATED SOL. (approx)
Wash with water	5'		200ml	
Wash cuvettes	7'		250ml	19ml
Extra wash cuvettes	21'		720ml	19ml + 19ml
Zeroing on water	6'		200ml	
Sleep mode wash	5'		200ml	
FCC Function	15'		300ml	15ml
Cuvette single wash			5ml (3.7ml to 6ml)	
Needle single wash			2ml	
Consumption per test			7ml	

	BT1500	TIME	USED SYSTEM SOL. (approx)	USED DEDICATED SOL. (approx)
Wash with water	6'		140ml	
Wash cuvettes	6'		230ml	14ml
Extra wash cuvettes	18'		380ml	14ml + 14ml
Zeroing on water	8'		140ml	
Sleep mode wash	6'		140ml	
FCC Function	15'		300ml	10ml
Cuvette single wash			3.5ml (3.1ml to 6.1ml)	
Needle single wash			2ml	
Consumption per test			5.5ml	

NOTE: stated times and liquid consumptions should be considered only as indicative as they may vary in different conditions. A variation of ±20% in liquid consumption should be considered as normal.

Operating Limits

The instrument cannot guarantee the preceding performance specs in the following conditions:

- 1) Ambient conditions beyond the specified range.
- 2) Use of non-conformant clinical chemistry products such as washing/detergent/cleaning/surfactant solutions, distilled water, and etc.
- 3) Maintenance schedule and expiry date ignored.
- 4) Use of non-original spare parts and consumables.

The manufacturer does not guarantee the correct instrument performances in case of implementation of unanticipated methodologies. Consult your nearest sales/service office or factory for the use of different methodologies.

SECTION I: GENERAL INFORMATION

CHAPTER E: OPERATING PROCEDURE

1. OPERATING PROCEDURE	2
1.1. Turning On Procedure	2
1.2. Reagents: Insertion And Removal	2
1.3. Running Standards & Controls (On Demand Or Timed)	5
1.4. Samples	7
1.5. Work Lists	13
1.6. Turning Off Procedure	17
1.6.1. Long-term Turning Off Procedure	18
1.7. Access Password	18

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

1. OPERATING PROCEDURE

1.1. Turning On Procedure

Turn on the analyzer by pressing on/off switch on the rear panel (refer to Chapter B, paragraph 1.3. **Starting the instrument.** This operation turns on only the refrigerating system for the reagents. To properly turn on the analyzer, momentarily press the pushbutton located inside the panel at the right side of the LCD display (**Chapter B, Figure 11**). Remember that if the same pushbutton is pressed again, it turns off the analyzer. Turning off the program in this way may permanently damage it. After this initial phase of power on, it will be necessary to enter the password (see paragraph 1.7. **ACCESS PASSWORD** in this chapter). After the turning on procedure (lasting approx. 1 minute), allow the analyzer to warm-up. The instrument is ready for use after about 20 minutes, when the temperature in the cuvettes tray has reached the proper value and the photometric lamp is stable. At this point the analyzer will require a zeroing of the photometer. It is advisable to execute the photometer zeroing every time it is requested by the analyzer i.e. every six hours. **It is not advisable to keep the analyzer ON for more than one month as this may cause problems with Windows internal counters.**

1.2. Reagents: Insertion And Removal

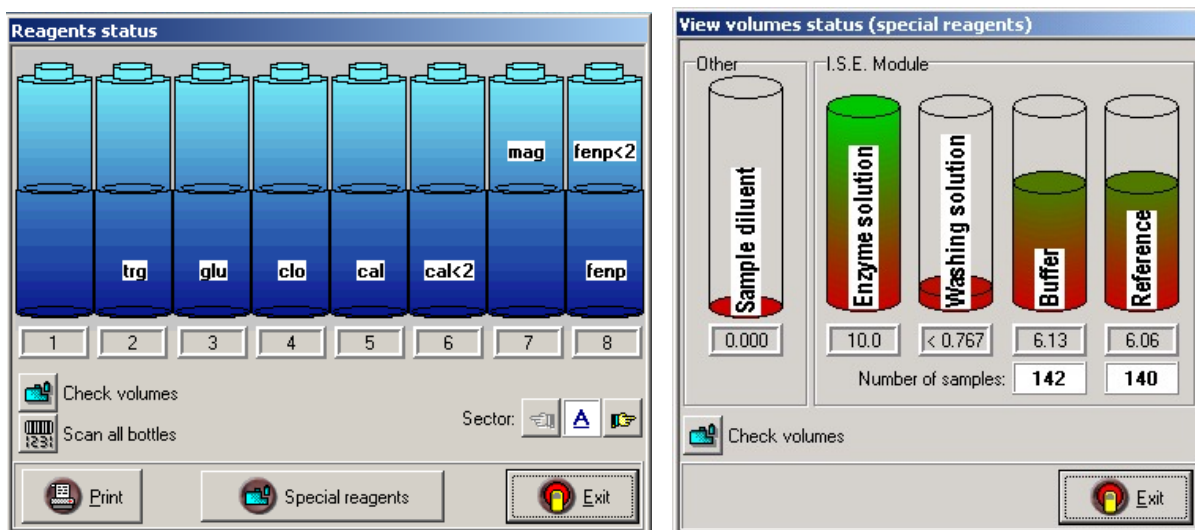


Figure 1

This function is accessed either by pressing F10 key or by clicking on the specific icon. It helps the user to correctly position the reagent bottles, as programmed in the current tray.

The reagent tray is divided into sectors, identified by the letters A, B and C for BT1500, while for BT3000 Plus and BT3500/BT3500S, the letters are A, B, C, D and E. Each sector has 8 positions. The screen displays the representation of 8+8 bottles (Figure 1). The analysis codes of large bottles are displayed on the lower positions, while the upper positions indicate the codes used for small bottles. By clicking on the Special reagents, the diluent and I.S.E. , where available, reagents volume status are displayed.

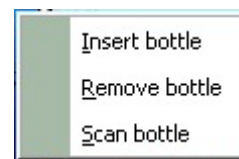
The symbols + or XXX<2 can be displayed inside the code boxes (fields). The symbol + indicates that the position is used for more than one analysis, while the symbol XXX<2 indicates the position of second bottle pertaining to the double-reagent analyses.

In the field SECTOR the belonging group is shown, and the default choice is "A". To change group click on the left and right hand buttons.

ATTENTION: FOR THE USER SAFETY, NEVER ATTEMPT TO OPEN THE SAMPLES AND REAGENTS COVERS WITHOUT USING THE PROPER SOFTWARE-GUIDED PROCEDURE.

Single bottle (available in alla analyzers):

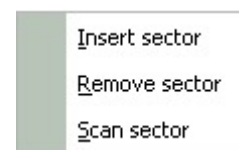
Right-click over analysis code. A combo box asks the user to choose between "Insert bottle" or "Remove Bottle". After the choice has been made, the analyzer will correctly position the tray to match with the arrow at the base of the tray itself. The verification of fluid volume contained in the bottle is associated only with the insertion procedure.



With the barcode option enabled, identification is correctly achieved through the automatic scan of the barcode on the inserted bottle. The same function can be performed on command, by activating the "Scan bottle" command, near the insertion and removal commands.

Whole sector (available only in BT3000Plus and BT3500/BT3500S analyzers):

Right-click over the "SECTOR" field. A combo box asks the user to choose between sector's insertion "Insert sector" or removal "Remove sector". After the choice has been made, the analyzer will correctly position the whole sector for insertion or removal. The verification of fluid volume contained in the bottles is associated with the sector insertion procedure. With bar-code option enabled, identification is correctly achieved through the automatic scan of the bar code of the inserted bottles. The same function can also be performed on command through "Scan sector", near the sector insertion and removal commands.



NOTE: if the bar-code function on reagents is not enabled, when using the "Remove" option (both for single bottle and for Sector), no functional control is performed: the existing volume and test code are not removed from the view volumes window.

In case the bar-code on reagents is enabled, when removing a reagent with the "Remove" function, the analyzer will perform a scan of the position (or the sector) to verify that the reagent has been removed. When closing the View volumes status window, the analyzer will perform a second verification scanning and then will move the removed test code from the on-line tray to the global list.

Check volumes

This option checks, on user's demand, the volume contained in all the bottles that are placed on the tray. Click with mouse on this command to confirm.

Scan all bottles

Enabled only when barcode option is on. It automatically performs the correct identification of all bottles' positions. Move cursor to this command and click.

Special reagents: command for checking the volumes of reagents and washing solutions for the I.S.E. module plus the diluent solution for the samples. With the **Check volumes** command the analyzer checks the volume contained in all the bottles. By clicking with the right mouse button, a window opens with the **Insert bottle** and **Check volumes** command, similar to those explained above (see Fig. 1).

Print: Performs a printout of the reagents status, with volumes and positions.

Volume's information

By clicking on the each analysis code, the volume of the reagent contained in the bottle is displayed as well as the number of tests that can be performed with it (Figure 2). For various tests in the same position, they will be listed individually. The count of the executable tests is made by single analysis, as if it was present alone in that given position. The Real samples field refers to the maximum number of samples which can be executed for the test when one of the reagents has a lower volume than the other. In this case the reagent with the lower volume determines the maximum number of samples that can really be executed.

Analyses	Volume (ml)	Num. Samples	Max Samples
YYY 2*	0.000	0	0

Exit

Figure 2

1.3. Running Standards & Controls (On Demand Or Timed)

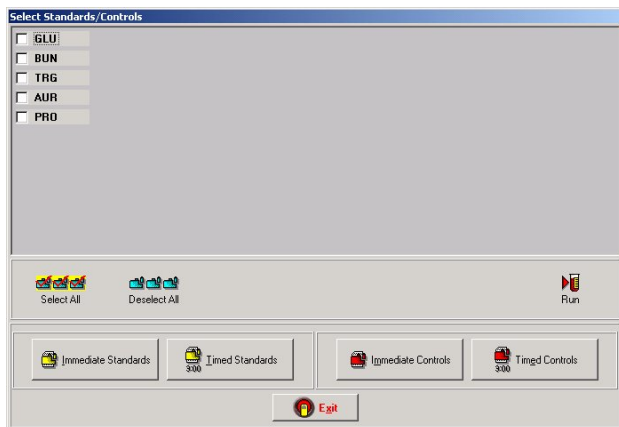


Figure 3

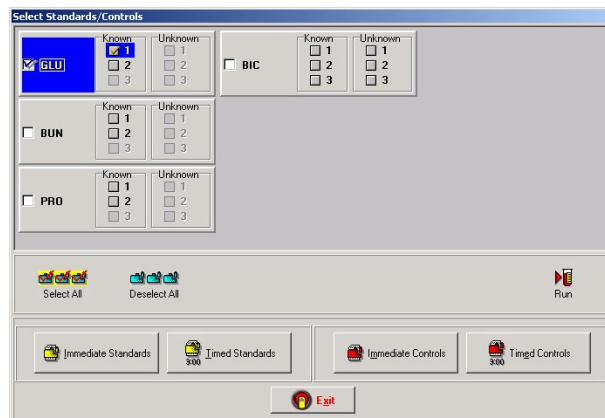


Figure 4

The **Run Standards** and **Run Controls** functions are available from the **Tests** main menu or through the specific icons that allow direct access.

The displayed analysis codes belong to the list generated in the **Current tray** list. Only codes with programming, even if incomplete, are displayed on the controls page. In this case the un-programmed levels will be displayed, even if not enabled. The entire list of tests, with programmed standard parameters, present in the current tray is displayed for the standards (with the exception of relation tests).

RUNNING STANDARDS

Standards' calibration can be run either on command or automatically at pre-determined time intervals (refer to **Chapter C**, paragraph **1.5. Calibrations**). Both choices can coexist. The commands are **Immediate Standards** and **Timed Standards (Fig. 3)**.

Immediate Standards: Once the button is clicked a list of codes appears, select the desired tests and run by pressing Run. With Select All or Deselect All commands, it is possible to select or deselect the whole list. A message will ask the user whether the calibration standards are already present in the tray or not. If the samples are already present, click Yes and calibration procedure will automatically start. Otherwise, if calibration samples aren't already placed on the tray, click No; in this case a procedure will guide the user through samples' insertion. By clicking over sample's position, the tray moves itself to accommodate cup's insertion. Once the necessary cups have been inserted, it is possible to run the calibration.

Timed Standards: Only the codes with programmed times are enabled. After selection of tests, the calibrations can be run. In this case, the interval of the automatic calibration starts when tests are run. In case the calibrations aren't run, then the time count of calibration's interval starts from the moment the selection was made. Once the automatic calibration time has elapsed a message appears on the screen asking the operator if the tests need to be run. If the standards and reagents are on the tray answer yes. At this point the automatic calibration time restarts.

If the message is not answered or a negative answer is given, the calibration time count starts again. The previous calibration remains in the memory. If the timing expires while the analyzer is in standby, it will be automatically moved 10 minutes forward.

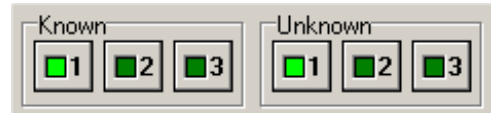
RUNNING CONTROLS

Controls Sera can be run on command or automatically, according to programmed time intervals (refer to **Chapter C**, paragraph **1.4. Controls**). The two modes can coexist. Commands are **Immediate Controls** and **Timed Controls** (Fig. 4).

Immediate Controls:

Clicking this button generates a list of codes. With **Select All** or **Deselect All** commands, it is possible to select or deselect the whole list.

The single levels for each type of control can be selected at the same time for all the tests present, by clicking on the relative button, which will change color from dark green to light green.



Select the desired tests and run by pressing **Run**.

A message will ask the user whether the control samples are already present in the tray or not. If samples are already present, click **Yes** and run will automatically start. Otherwise, if controls samples aren't already placed on the tray, click **No**; in this case a guided procedure is presented for samples' insertion. By clicking over sample's position, the tray moves itself to accommodate cup's insertion. After the insertion of necessary cups, run the controls.

Timer-driven Controls:

Only the codes with programmed times are enabled.

When the listed tests are selected the controls can be executed, in this case the automatic execution time interval starts from when the test begins, if the controls are not executed the execution time count starts from when the selection is carried out. When the automatic execution time has elapsed a message appears on the screen asking the operator if the tests need to be executed. If the operator answers yes, it checks for the presence of the controls and reagents and starts the tray.

If the message is not answered or a negative answer is given, the control time count starts again. If the timing expires while the analyzer is in standby, it will be automatically moved 10 minutes forward.

Standards, Controls and Patients Run

The analyzer allows the associated running of standards, controls and patients. The standards can be processed before, during or after patients' run. These three options provide the analyzer with maximum operating flexibility.

To run the calibrations during the patients determinations, proceed as described above. The analyzer will calculate the factors for the calibrations being run and update the result page in real time (by patient). If no errors occur in the calibrations, the results of the next patients will be calculated with the new factors at the end of the calibrations. The results of the patients before the calibrations will be calculated with the previous factors. When finished working it is possible to recalculate all the results based on the last executed calibration, again if there have not been any errors. This function is available on the result page in real time for patients (see Ch. G, par. 1. **Displaying and printing results**).

Press the **Correction** button and select the correction with standard. This way all the results will be recalculated based on the last calibration.

NOTE:

In case of analytical errors during calibrations, the analyzer displays the error type and conserves the previous validated calibrations in the analyzer memory.

1.4. Samples

Entering Samples (Routine, STAT, Controls and Batch)

Samples can be entered with **Insert Routine/STAT** or with **Insert Batch**. These can be accessed from **Patients** main menu or from dedicated icons. Select **Exit** to leave the program. The represented analyses codes pertain to the list generated in the **Create current tray**.

Insert Routine/STAT: The following options are available in this page **Global Insert/View Patients** (Figure 5):

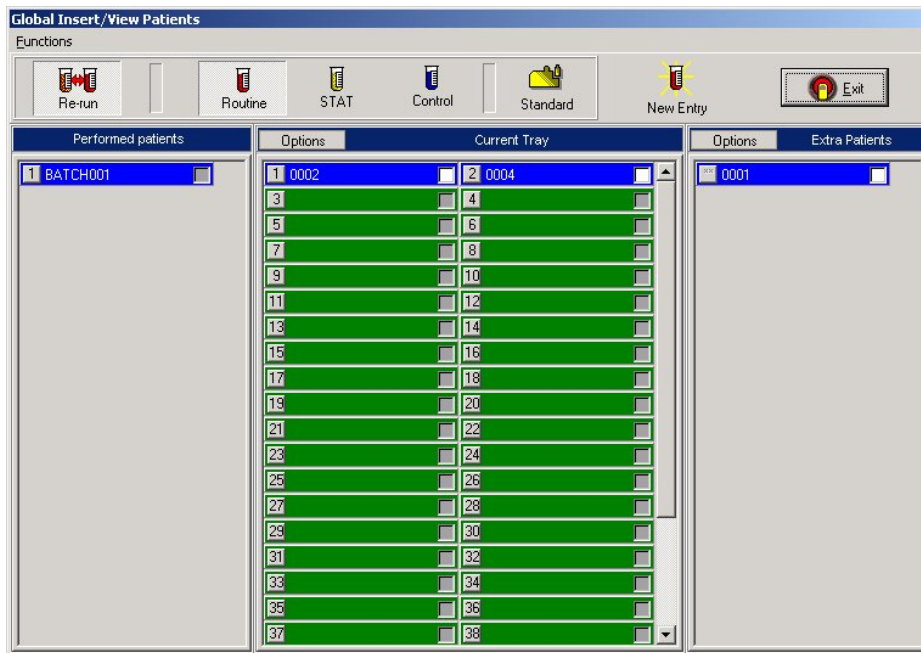


Figure 5

NOTE:
Point the cursor on the desired option and click to confirm.

Re-run: allows tests which have been run and not archived to be re-run (repetitions) on user's demand. See also **Performed Patients List** in par. 1.5 Work lists.

Routine: Default display of Patient positions.

STAT: Displays STAT (**S**ingle **T**est in **A**ctual **T**ime, i.e. urgent positions) positions.

Control: Displays Control positions.

Standard: Displays Calibrators positions.

New Entry: Enables data entry procedure for Routine, STAT and Controls.

Extra Patients: Displays the list of patients with no assigned position. Patients selected in the work-list may be moved here ("Options" menu, "Send to extra patients" command) and then back.

Exit: To leave program

New Entry Routine:

After the selection of **Routine** followed by confirmation through command **New Entry**, the patients acquisition frame is displayed (**Figure 6**). The programmed patient can be executed immediately or saved for later use. The programming fields and the functions are outlined below:

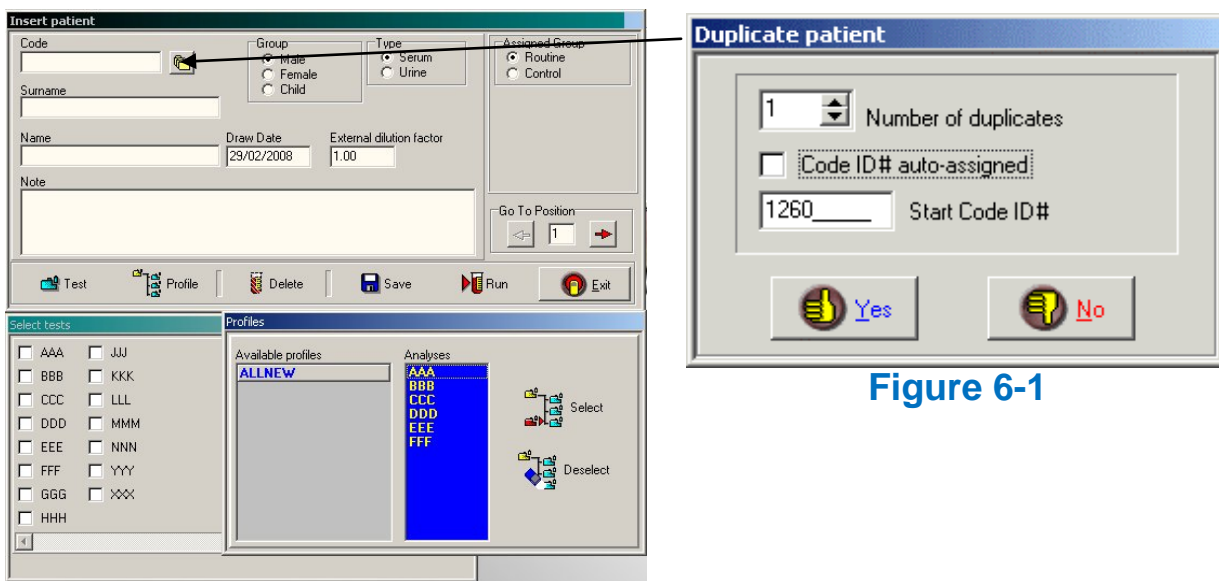


Figure 6

Figure 6-1

Group: Select the group (Man, Woman, Child) for correct reference with normal values range.

Type: It is default set to **Serum**. The sample type (Serum or Urines) is selected here. If **Urine is selected, then** the volume of diuresis (in the 24h) is requested. This is required for processing data acquired with automatic calculation on 24 hours. If this processing is not required then leave the value at zero "0".

Assigned Group (Routine or CTRL Routine): The default setting is **Routine**. It is used for selecting the category (Patient or Control Serum) during sample programming. Selecting **CTRL Routine** the type (**Known or Unknown**) and levels (**Level 1, 2, 3**) must be specified.

NOTE:

With this type of acquisition, the controls belonging to the stored Q.C. will use the positions assigned to routine patients, not the dedicated ones.

Position: Displays the first free position from the available positions. To modify this field use horizontal arrows $\leftarrow \rightarrow$ or type in the desired position. Do not modify to accept.

Code: It is the identification number assigned by the user to the patient. The user can also enter the code of a patient saved in the work list, even if in execution. In this case, a message asks the user to confirm patient's data cloning. In case of affirmative response, all the data relevant to the patient is instantly displayed and is linked to the current position. The cloning of a patient's code allows the user to obtain one report in case different samples are used. If this option is not used, then separate reports are obtained.

Duplicate patient: By clicking on the icon, it is possible to create a worklist with the same profile (**Autobatch**) or else a list with sequential codes. When the patients are entered using the duplication method, their codes may be assigned by the analyzer, or it may be a progressive number. In the case of progressive number, the operator must enter the first code to be used.

Surname, Name: Enter patient's personal data.

Draw Date: System date is automatically displayed. To modify, move mouse cursor on textbox, click and edit.

Note: Additional information to be added to the report.

External Dilution Factor: By default set to "1". It allows analysis determination on externally diluted samples. Enter in this field the external dilution factor ratio used in sample preparation. Final result is multiplied by the inserted ratio.

CAUTION!

IN THIS CASE THE PRE AND POST DILUTION FACTORS OF TEST PARAMETERS WILL NOT BE TAKEN INTO CONSIDERATION.

NOTE:

If a hyper-activity parameter value is surpassed (indicated by an appropriate flag) during determinations of externally diluted samples, the Automatic Re-run is not performed.

Test: Generates the Analysis List. Select each analysis to be performed on the sample.

Profiles, Select/Deselect Tests

Profile: The stored Profiles list (Fig. 7) is displayed through this command (refer to Chapter. C, paragraph 1.6. Creating Profiles). Two acquisition modes are available. The first one requires a double-click on profile’s name. The second mode, after choosing the profile with one click, requires confirmation by activating Select.

The analyses programmed in this way can be modified. To add or remove tests, it is necessary to enter in the screen "Select tests" and confirm by clicking on the textboxes. With "Deselect", it is possible to delete an already selected profile.

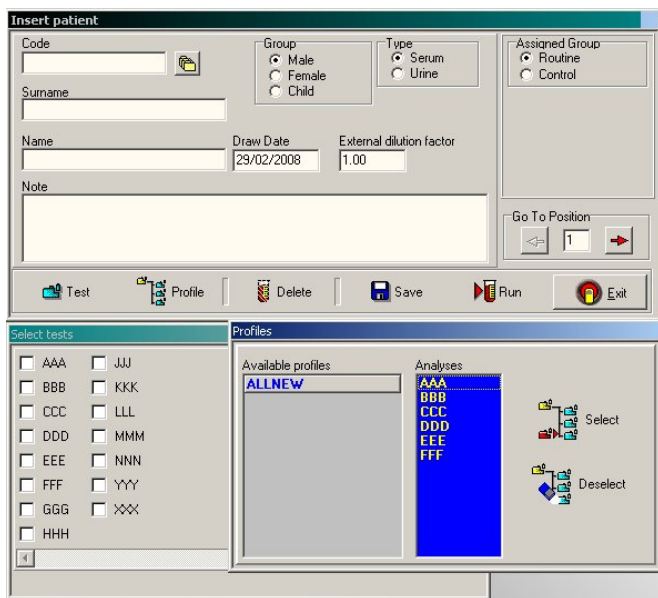


Figure 7

Delete: Cancels the programmed patient or the analyses of an already programmed (and saved) patient. Confirmation is requested.

Save: Saves patient’s data and the associated analyses. With this command test execution is delayed.

NOTE:

In the routine programming, it is possible to acquire a greater number of patients than the available number of positions in samples’ tray. All the patients acquired with no associated position are saved and displayed in the extra patients list and can be transferred to the main list on user’s demand (refer to paragraph 1.5. Work Lists).

Run: This command immediately starts the execution of the programmed patient. The sample plate adjusts itself to match the position assigned to the patient, and a blinking red LED indicates the position for inserting cup or primary tube. If patient code is missing or no analyses have been selected then this command cannot be activated.

New Entry/STAT:

After the selection of **STAT** followed by confirmation through **New Entry**, the STAT acquisition frame is displayed (**Figure 8**). Bear in mind that the tray positions reserved for emergencies are the ones assigned in the **Analyzer Setup (Chapter H, paragraph 2.)**. An appropriate screen message alerts the user when a wrong position number is entered. Patients acquired as "STAT" can be saved as described in "Routine", but if sent for execution, they are analyzed immediately with highest priority.

All the acquired patients with no assigned position are saved and displayed in the temporary list **Extra Patients (STAT)**, from where they can be transferred back to the work-list on user's demand (refer to paragraph 1.5. **Work Lists**).

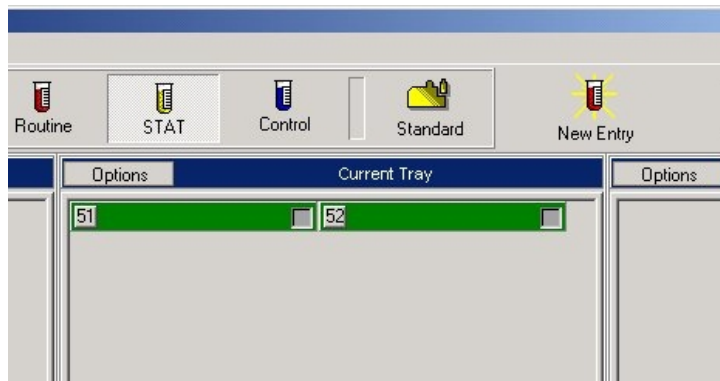


Figure 8

New Entry/Controls:

Once the icon "Controls" is selected, the list of control positions is displayed (**Fig. 9**). Controls acquisition frame is displayed by activating **New Entry** command or with a click on a given position. A window identical to the one displayed in **Routine** appears but without the patient fields. Bear in mind that the tray positions reserved for controls are the ones assigned in the **Analyzer Setup (Chapter H, paragraph 2.)**. An appropriate screen message alerts the user when a wrong position number is entered. Patients acquired as "Controls" can be saved as described in "Routine", and are executed afterwards. All the acquired controls without assigned position are saved and displayed in the temporary list **Extra Patients (Control)**, from where they can be transferred on user's demand (refer to paragraph 1.5. **Work Lists**).



Figure 9

Insert Batch:

In this page (**Figure 10**) select the desired analysis code and associate sample positions with it. Analysis list and routine numerations are displayed. The **Select** command (located next to the tray positions) automatically enables all the positions entered in the fields **From** and **To**, and the **Deselect** disables them all. Click on the check boxes to enable or disable a test. After entering one or more analysis code, enable test run and start working phase by pressing **Run**. The enabled sera positions are highlighted in red, while the analyses codes in blue. Press **Exit** to terminate and leave.

This check-in procedure is simplified as it doesn't require patients data entry and doesn't make any distinction between serum and urine. In the report, A progressive numerical identification is automatically assigned to the report, for example Batch # xx.

NOTE:

Even if the programming is based on analyses, the analyzer processing is always patient selective.

ATTENTION: when programming a batch, it is necessary to be sure that all the selected positions are free and not already programmed in the routine work-list. When "Run" is selected, the analyzer will ask confirm that the positions are free.

"Are you sure that the selected positions are all available?"

Answering "Yes", the batch will be run, answering "No", the run will be aborted in order to allow the operator to verify if the positions in the routine work-list are available or not.

If the operator runs a batch in which some of the selected positions are not available, the analyzer will skip on those positions and will keep the already programmed patients (in the same status these were before running the batch). The positions of the batch that have been skipped will not be considered at all, as if these were not programmed from the beginning.

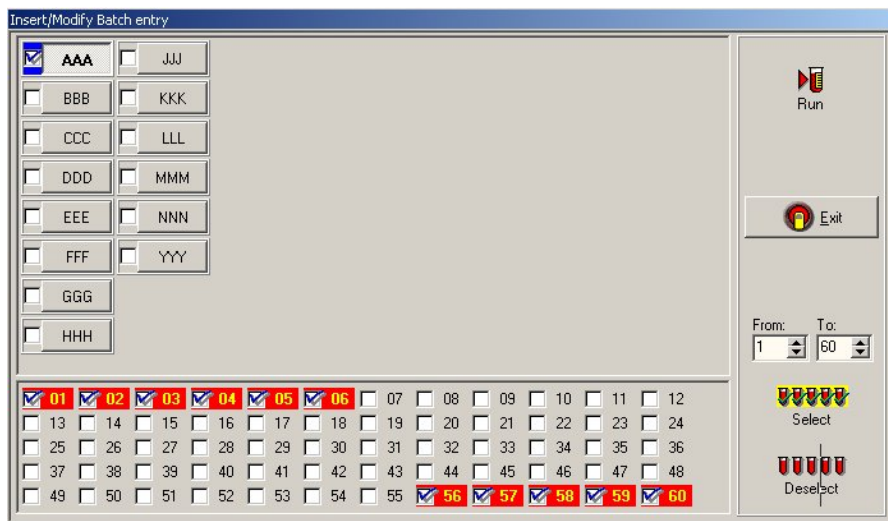


Figure 10

1.5. Work Lists

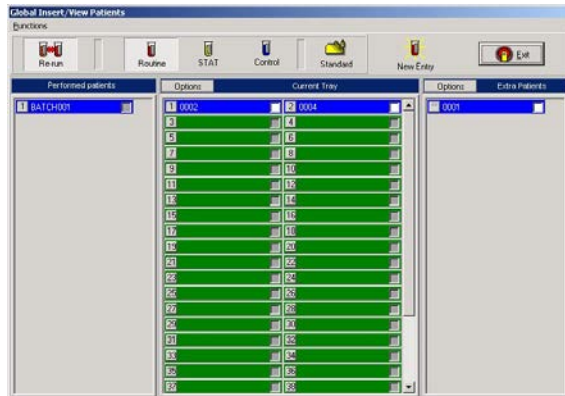


Figure 11

The Work Lists can be accessed through the menu "Patients" → "Insert Routine/STAT" or directly using its proper icon. The screen displays the "Current Tray (Routine)" in the center and the "Extra Patients (Routine)" on the right. During the working phase, it may be useful to display also the "Re-run" worklist.

Click on the **Routine**, **STAT**, **Control** and **Standard** buttons to view the corresponding work lists. For "Control" and "STAT", as for the patients, the screen displays the "Current Tray (Routine)" list and the "Extra Patients (Routine)" list. It is

possible to run controls and calibrators even during the determination of patients. The work-lists show the position number and test code. Positions are color-coded:

Current Tray (Routine) Work-list

- **Green Position**: position available on the tray
- **Blue Position**: programmed sample in stand-by (not running)
- **Red Position**: sample is running (performing tests)
- **White Code**: programmed samples not yet started
- **White Code**: sample testing begun, but no results available
- **Yellow Code**: sample testing begun and some results available under the Performed Patients worklist
- **Yellow Code**: repeated sample on stand-by.
- **Yellow Code**: repeated sample testing begun no results available
- **Yellow Code**: sample with added on tests on stand-by
- **Yellow Code**: sample with added on tests in run
- **Yellow Code**: cloned sample ID code on stand-by

Performed Patients Work-list

- **Blue Position**: all tests results within the set reference range
- **Red Position**: one or more results are outside the set reference range
- **Yellow Position**: insufficient serum or reagent
- **White Code**: samples results complete and all are within set reference range.
- **Yellow Code**: one or more result is available and within set reference range; repeat sample or additional tests added being tested.
- **Yellow Code**: sample testing begun and one or more result is outside set reference range.
- **White Code**: sample results complete and one or more result is outside set reference range.

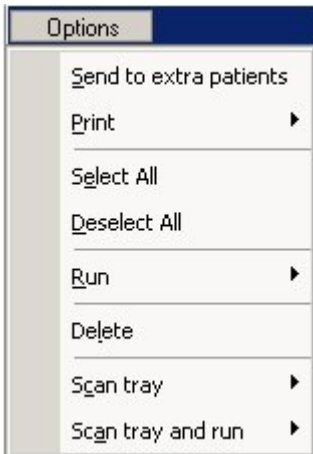
The samples located in the Extra Patients List are graphically indicated in blue.

Work Lists are used to display the entered patients' codes or to verify the samples' state on the tray (**Fig. 11**)

Routine Tray List:

Inside this list it is possible to view in real-time the actual situation. The user, by clicking on an active position, enables the Registry situation with information on selected code and analyses. It is possible to modify if the sample is not being run. It is possible to enter new data by just clicking on a vacant position. During tray processing, as the samples are analyzed, the positions that were previously occupied become vacant (green).

Options: The "Options" menu is available in the **Current Tray** (Routine, STAT and Controls). It displays the following commands (Figure 11):



Send to extra patients: The selected patients are removed from current samples tray list for placement on **Extra Patients List**. Selection can be done by checking the appropriate boxes. Use "Select All" to select the whole list and "Deselect All" to deselect.

Print: Prints the partial (for selected items) or total samples list.

Select All: Automatically selects the whole list.

Deselect All: Automatically deselects the whole list.

Run: Work start command. If single patients or the whole list is selected, a message asks if the samples have been inserted. If the answer is affirmative, the analyzer automatically starts processing. In case of a negative answer, a guided procedure will assist the user to insert the samples. Confirming with cursor on the corresponding line performs the selection of the sample to be inserted. After the insertion of all the samples, activate "Run".

Delete: Removes selected or all the patients. Confirmation is required.

In case the serum barcode is enabled in the Options menu, then two additional commands are automatically added (Controls are excluded). The two commands are Scan Tray and Scan Tray and Run. Both commands allow further selection: All and Single Position.

Scan tray: Allows positive identification and saves present samples on the tray. It is subdivided into the following two functions:

All: The tray performs a rotation scan to make a positive identification, and saves all the samples (codes) in the sera tray.

Single Position: Allows positive identification and saving of only one single code. The analyzer requests the desired position and the tray accordingly positions itself for sample's insertion. Makes one rotation for reading the present code.

Scan tray and run: Performs reading rotation as before, but runs the tests immediately.

NOTE:

In patients' bar-code printing protocols it is possible to add **Profile Number**, which provides total automation in patient acquisition (refer to Chapter C, paragraph 1.6. Creating Profiles and Chapter I, paragraph 1. Bar-code and related functions).

During bar-code reading, the analyzer provides a list of likely errors that occurred. In this case the reading can be repeated by re-activating the command.

Extra Patients: It displays the acquired patients that haven't been inserted in the run list. The user by clicking on an active position enables Registry Situation with selected code and analyses information. It is possible to modify it.

Options: The "Options" menu allows the following functions:

Send to Current Tray: The selected patients are removed from **Extra Patients List** for placement on current samples tray list. The patients will be placed in the free positions starting from the first available. Use **Select all** or **Deselect all** commands to select or deselect the whole list. It is also possible to "drag and drop" single patients to the current tray in any available position.

Print: Prints the selected or total samples list.

Delete: Removes selected or all the patients. Confirmation is required.

Performed Patients List: This list displays the codes and positions for the completed patients that are available for repetition. The user, by double-clicking on an active code, enables patient's information page with assigned analyses and relevant results, while by clicking on a given analysis code, the reaction graph is presented.

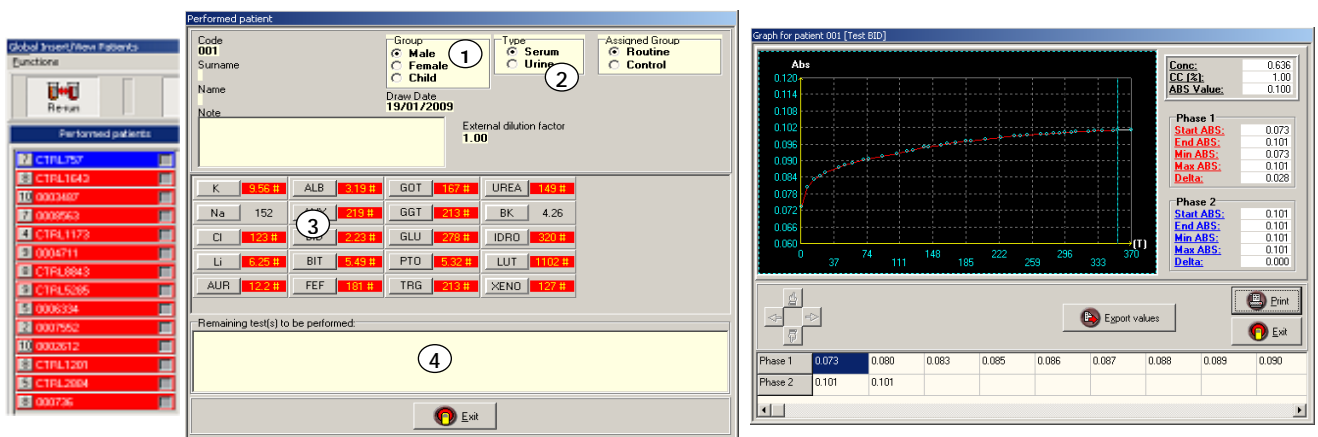


Figure 12

In the Performed patient window the following information are displayed:

- ① group which the sample belongs to.
- ② sample type.
- ③ already performed tests (the test graph can be displayed by clicking on the test code).
- ④ remaining tests (to be performed).

To re-run, the desired patient code must be transferred to Current Tray List and then run again. Confirm with a single click on the position number, confirmation is requested before transferring. If the answer is positive, then the screen "Select Repetition Position" is displayed. If available the previously used position is shown otherwise the first vacant position is presented, modify if necessary. Once the position is confirmed or modified, Registry Situation with related analysis is presented. Deselect the analysis that should not be repeated, add new tests if needed. Once programming has been terminated confirm with command "Run" to run the sample or "Save" for memorizing.

NOTE:

Confirmation is requested in all the patients' work lists, to perform Codes Transfer Commands. The analyzer verifies the availability of positions in the samples tray list and eventually prompts the user about the impossibility to complete the task.

Standards List:

Activation of **Standard** button displays a list (**Fig. 13**) of Calibrator Positions **Current Tray (Standards)**. This list is in a read-only format.

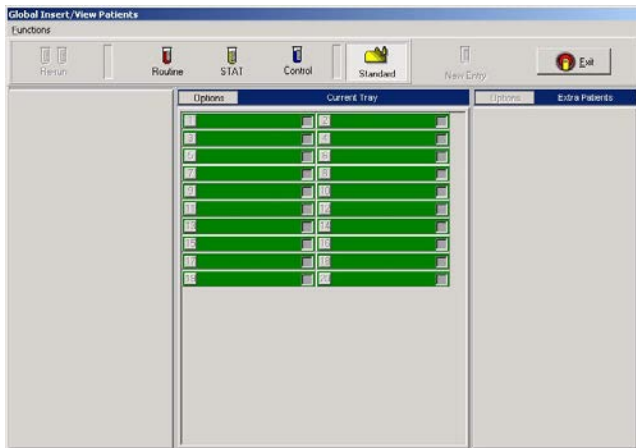


Figure 13

Global Insert/View patients

The "Functions" menu in the "Global Insert/View patients" (fig 14) bar provides access to the following commands:

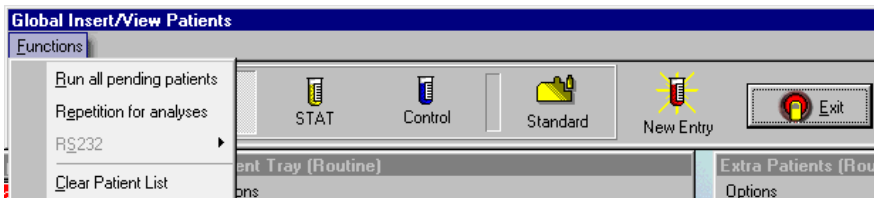


Figure 14

◆ **Run All Pending Patients:**

A sole command for running the already acquired patients and the partially processed patients (because of an interruption during tests execution). The analyzer will continue to process suspended patients. Confirmation is required.

◆ **Repetition for Analyses:**

This command re-runs test for samples. First the selection of the desired analyses codes is required and then the confirmation. The analyzer automatically searches for the samples which had already undergone determination of selected analytes, and performs the newly assigned work list and then updates patient reports with new data obtained from the repetition.

◆ **RS 232:**

This function is used for transferring data from the analyzer to the host computer. Data transfer can be automatic if enabled in the Setup. If it is not enabled, then the data transfer occurs on user's request through the command **Accept Result to be sent**. Confirmation is required. The function **Delete Result to be sent** allows deletion of the data to be sent to the host computer; confirmation is required (see also **Chapter H**, paragraph **2. Analyzer Setup**).

◆ **Clear Patients' List:**

This command allows deletion of the previously acquired patients list. Confirmation is required. It deletes the whole list.

1.6. Turning Off Procedure

To turn off the instrument, the **SHUT DOWN** procedure must be performed. In this way the instrument is definitely turned off, except for the refrigerator for the reagents. The shut down procedure proposes the wash of the cuvettes with appropriate washing solution before turning off. The analyzer indicates the position where the appropriate solution should be inserted (see also Chapter B, par. 1.3.3. and Chapter H, paragraph 1.1.1). As regards the ISE Module, please refer to Chapter L, par. 1.3. and Chapter L1, par. 1.4.

NOTE: if cuvettes are not properly washed at the shut-down, at the following start up the analyzer will ask for the cuvettes extra wash . Performing the normal cuvettes wash will not prevent the analyzer from warning again that the extra wash is needed.

Conditions are:

- a. If no test has been performed before the shut-down, at the following start-up of the program, no wash message will appear.
- b. If no test has been performed before the shut-down and the shut-down wash has been started but it did not complete correctly, then at the following start-up of the program, the analyzer will warn the operator that the preceding wash was not correctly completed.
- c. If tests have been performed and the shut-down wash was not performed, at the following start-up of the program, the analyzer will ask for the Extra wash cuvettes and will warn the operator that the preceding wash was not correctly completed.

NOTES:

- 1) Having performed a test: it means having performed either a single test with reagents and sample or any procedure involving colored solutions, such as the FCC.
- 2) The analyzer asks for the Extra wash cuvettes as it does not know how long the solutions were left inside the cuvettes before washing them.

The analyzer provides two other modes for interrupting its operativity:

1) SLEEP-MODE

This mode can be manually activated, or it starts automatically when the instrument is left inactive for more than 30 minutes. The **Sleep-Mode** automatically performs the wash and fill up of the cuvettes with system solution and remains idle (waiting for user's commands for immediate operation).

2) LOG-OFF

The "Log-Off" mode represents a partial turning off of the analyzer. It disables some devices: halogen lamp of the photometer, cuvettes thermostat and drive motors. This mode is used for energy saving.

The Log-Off mode is utilized for programming automatic turning on at a desired date and time. The instrument will remain in a stand-by condition and it will automatically turn on 30 minutes before the programmed time. The turning on in anticipation allows the analyzer to reach steady state thus allowing immediate operation at the programmed time.

To exit ahead of time from a suspended activity, click on the left or right mouse button and press the **Exit** button on the window that appears. However, in this case it is necessary to wait for the devices to become operational.

NOTE

It is not advisable to keep the analyzer ON for more than one month as this may cause problems with Windows internal counters.

CAUTION!

If the SHUT DOWN procedure has not been observed, then do not ever stop the analyzer by turning off the main switch. This may cause irreparable loss of data in the archives and damages to the operative program.

1.6.1. Long-term Turning Off Procedure

If the analyzer has to be turned off for more than three days, it is advisable to perform one of the following procedures instead of the normal shut-down procedure, followed by an Empty fluidics.

- perform an Extra wash cuvettes
- perform a Wash cuvettes followed by a Wash and fill-up with system solution

At the end of these procedures, run an Empty Fluidics procedure, then turn off the analyzer and take care to put in place all covers (reagents tray cover, samples tray cover, cuvettes cover). Unplug the analyzer and disconnect all peripherals, disconnect the UPS and turn it OFF, cover the analyzer with a suitable cloth.

This procedure will leave the cuvettes and the hydraulic circuits dry and clean.

1.7. Access Password

To comply with the European law on privacy (processing of sensitive data) enacted with Italian Legislative Decree no. 196 of 30/6/2003 passwords have been implemented for the analyzer. This makes it possible to keep a record of the activity of each authorized operator. To have access to the analyzer program, a sequence of USERNAME and PASSWORD needs to be entered.

When the analyzer is installed or first used, the Administrator or lab manager must assign each operator with a Username and password combination, associated with his own access level to the program.

The first window that appears is dedicated to the Administrator (a manager who takes care of archiving as well as password management of the users who have access to the analyzer).

The Administrator needs to enter the following in the Username field: ADMIN

The Administrator needs to enter the following in the Password field: Administrator

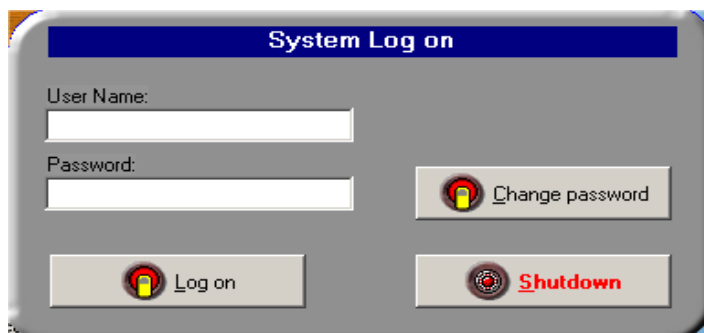


Figure 15

After pressing the Logon button, a window will open where the Administrator enters his new personal password.



Figure 16

The Administrator password does not have an expiration date, while those assigned to operators need to be renewed every three months.

Do not forget the Username and Password sequence. If this happens, the Administrator will have to delete the operator profile and create a new one. If the Administrator forgets his own password, it will be necessary to delete the entire list of passwords using an external special program. If necessary, submit a request to the Technical Assistance Service.

Once access to the password entry page is obtained, the Administrator must assign each operator with his Username and Password combination. Press on **New User**. A window opens for typing the Username and password and confirming the password. Next, the Administrator needs to assign the access level allowed for the individual operator.

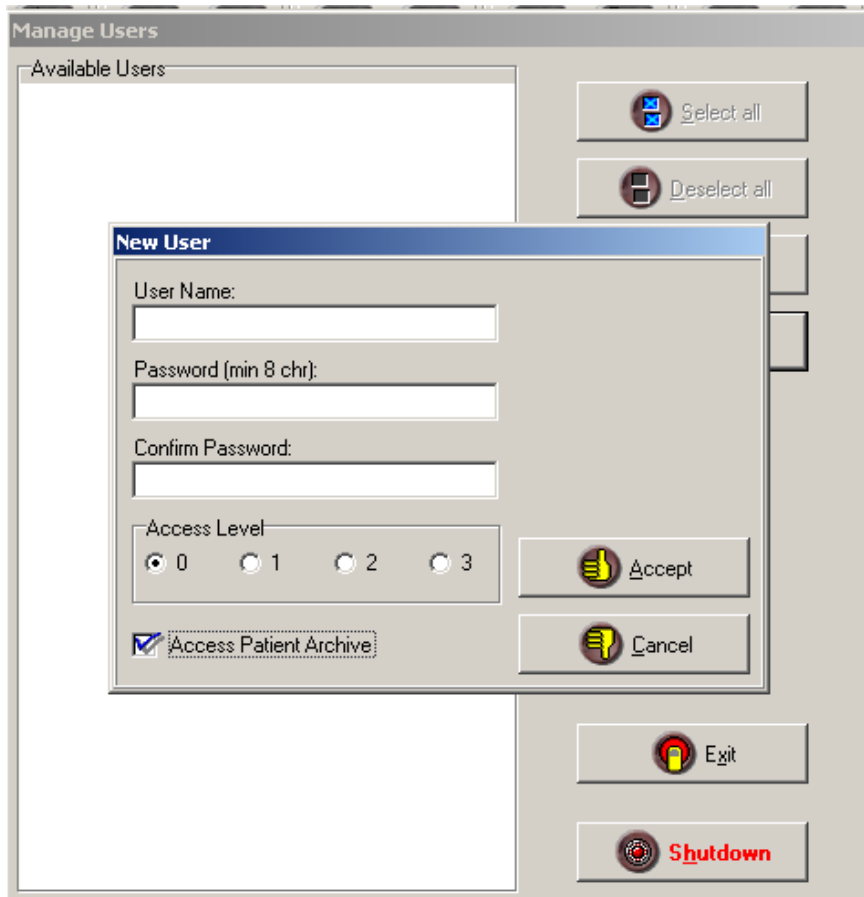


Figure 17

Each level allows access to normal analyzer operations (acquisition and running of patient lists, Calibrations, Q.C. program and Population, etc.) plus some specific functions that would otherwise not be available. Access to the patient archive is allowed by putting a check in the specific box.

L0: NO PASSWORD REQUIRED	
Modify Parameters	Not allowed
Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Not allowed
View Patients Archive	Not allowed
Modify Values In Patients Archive	Not allowed
Special Functions in General Diagnostic	Not allowed

L1: WITH PASSWORD	
Modify Parameters	Not allowed
Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Allowed
View Patients Archive	Allowed if operator is authorized
Modify Values In Patients Archive	Allowed
Special Functions in General Diagnostic	Not allowed
L2: WITH PASSWORD	
Modify Parameters	Allowed
Import/Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Not allowed
View Patients Archive	Allowed if operator is authorized
Modify Values In Patients Archive	Not allowed
Special Functions in General Diagnostic	Not allowed
L3: WITH PASSWORD	
Modify Parameters	Not allowed
Export Parameters	Allowed
Create Tray	Allowed
Adjust Function	Not allowed
View Patients Archive	Not allowed
Modify Values In Patients Archive	Not allowed
Special Functions in General Diagnostic	Allowed

To be able to allow a user to have an access level other than 0 it is necessary to know the system password that allows access to the same level. This is requested after selecting a level.

The system passwords can be changed in the analyzer Setup. Access is only allowed to the third level.

ATTENTION: if the new system passwords are forgotten, it is necessary to format the hard disk and reinstall the program. In this case any unsaved data will be lost. Biotechnica shall not be held liable for system passwords that are changed by the user.

NOTE: the users password **MUST** be at least of eight characters. It is advisable to use alpha-numeric passwords. Avoid using 8-times repeated characters such as YYYYYYYY or 33333333.

It is advisable to test the password every time a new password is programmed.

SECTION I: GENERAL INFORMATION

CHAPTER F: QC, POPULATION, PATIENTS ARCHIVE

1. QUALITY CONTROLS	2
1.1. Inserting/Modifying Controls	2
1.2. Data Management	4
1.3. Displaying & Processing By Lot Pairs: Youden Graph	6
1.3.1. Westgard Graph.....	7
1.3.2. Daily Chart Graph.....	9
1.3.3. Levey-Jennings graph.....	10
1.4. ADDITIONAL FUNCTIONS	11
2. POPULATION	12
2.1. Analysis Selection (How To Run A Query)	13
2.2. Principal Statistics Formulas Used In Population	17
2.3. Inserting External Analyses	18
2.4. Other Menu Functions	19
3. PATIENTS ARCHIVE	21
3.1. Selection (How to run a Query)	23
3.2. Patients Report	25
3.3. Printing Reports	27
3.4. Other Menu Functions	29

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

1. QUALITY CONTROLS

This is an external program used to enter, change and process quality controls. The program can process data from the analyzer (controls run in routine or dedicated positions) and from other instruments (with the **Insert / Modify Data** function).

NB: due to the large dimensions that the archive can reach, it is advisable to run a backup at regular intervals, even monthly.

It is advisable to use the “Export Data” function in the FILE menu to export the archive in CSV or Fixed length format (see par 2.4 OTHER MENU FUNCTIONS).

Once the archive is saved into a different location, please delete the internal archive to avoid the archive itself to crash.



The program is composed of three separate sections:

- ◆ **Insert/Modify controls**
 - ◆ **Data Management**
 - ◆ **Youden graph**
- plus some Additional functions

Figure 1

1.1. Inserting/Modifying Controls

It makes possible to process data obtained **externally** at the analyzer. It requests a series of information used to statistically process the inserted values. Press the **Insert Modify Data** button.

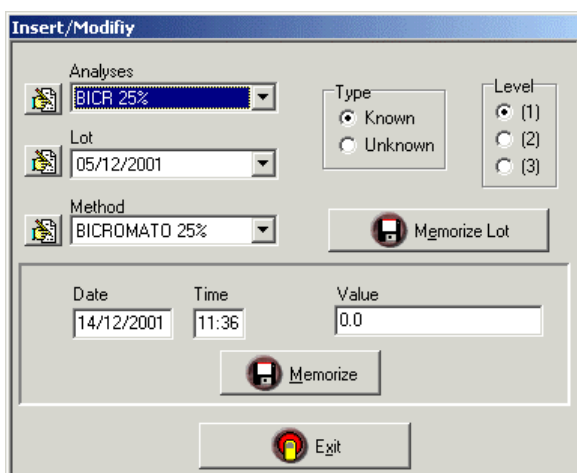


Figure 2

To enter a new name in the Analyses, Lot and Method field, click on the



To confirm and close the window, press MEMORIZE.

Analyses: insert a name for analysis or select one from the existing list.

Lot: insert the lot number or select one from the existing list.

Method: insert a method or select one from the existing list.

Type: select if the control is a known or unknown type.

Level: select the level to assign to the values.

Then press the **Memorize Lot** button: a window will open for inserting the central control value and relative acceptability range.

After providing all the necessary data for unequivocal identification of the control data, the values can be inserted by pressing the **Memorize** button. The date and time proposed by the analyzer can be changed if necessary.

Once data insertion is finished, close the window in figure 2. At this point statistical processing of the data becomes available.

Data inserted manually will be managed exactly like the data from the analyzer (control execution).

1.2. Data Management

Used to display and process data.

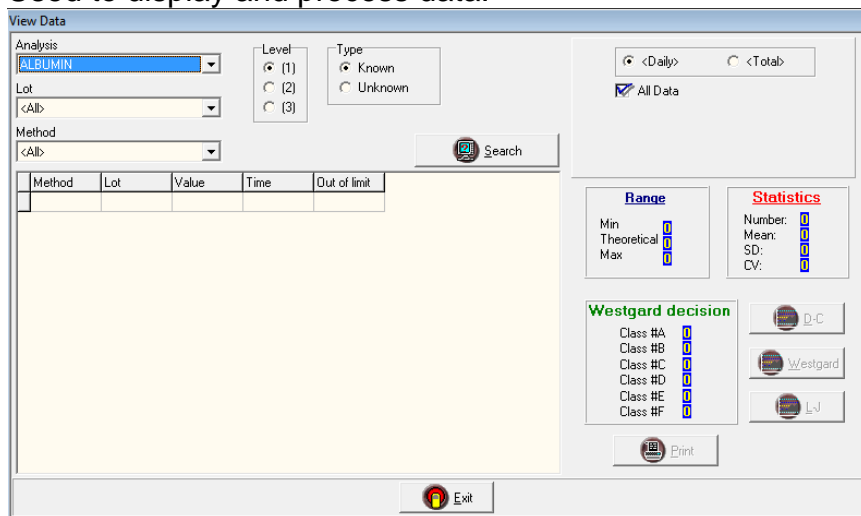


Figure 3

To obtain data processing it is necessary to provide the analyzer with all the information related to the control: **Analysis, Lot, Method, Control type – Known/Unknown – and Level.**

If the **All** option is left in the **Lot** and **Method** fields, the search will be done for all the lots and all the methods relative to the test selected in the **Analyses** field. In this condition the **Range** and Westgard **Decision** values will not be displayed (fig. 3-1).

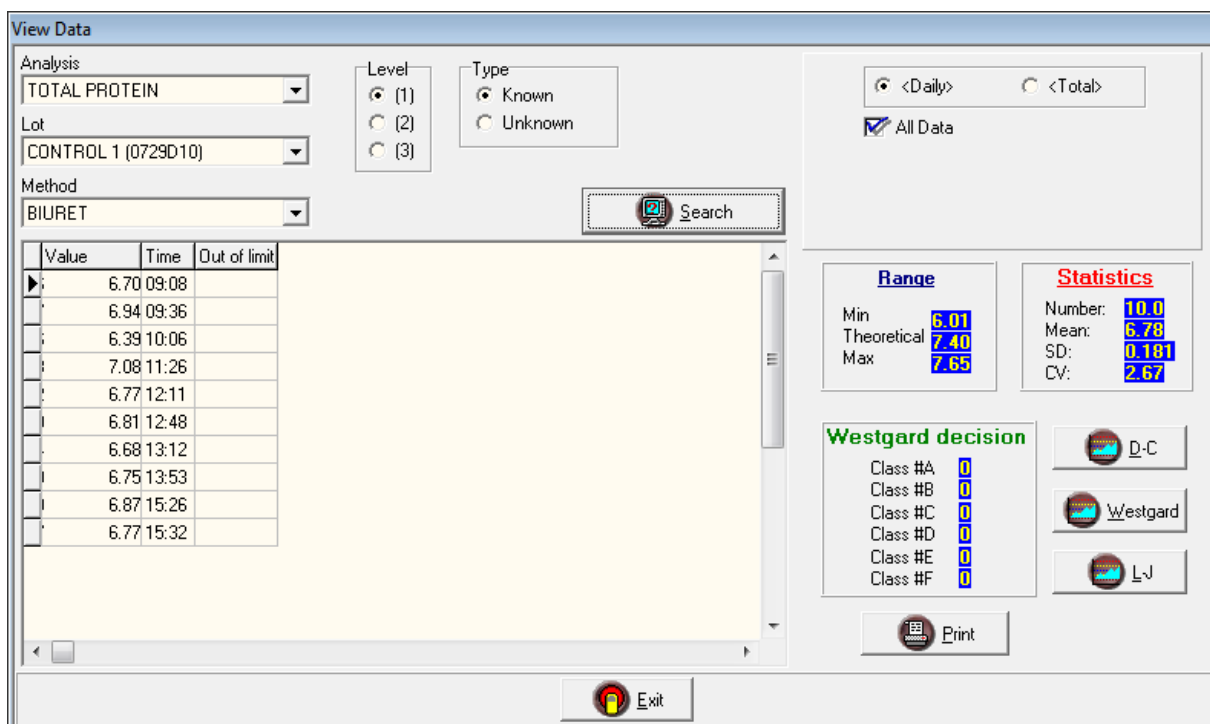
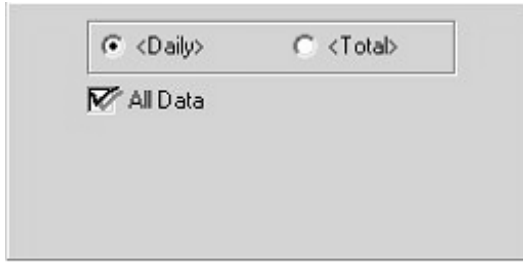


Figure 3-1

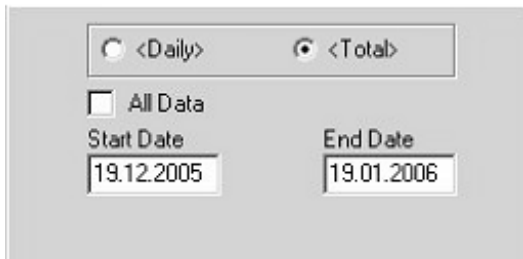
Data searches can be run for a single date (**Daily**) or for an interval of dates (**Total**).



It is possible to select **All data** for both the Daily Q.C. and for the Total. In this case no additional range will be requested to further narrow the search field.



If only data for a precise time period in a work day are going to be processed, it is possible to disable the check on the **All data** field. At this point the analyzer proposes a date and time range. Enter the values within which to run the search.



If data for a precise time period in days are going to be processed, it is possible to disable the check on the **All data** field. At this point the analyzer proposes a start and end date for the search. Enter the values within which to run the search.

Make all the selections necessary for processing the data, then press the **Search** button. The results will be displayed as shown in figure 3. The data are ordered by date and time. Out of range controls are indicated with an asterisk. The asterisk is used also when there is only one control lot, but the lot is not selected. In this case the lot range is not displayed, but the controls out of range are flagged. To delete a record, it must be first selected with the left mouse button, then it can be deleted by pressing the right mouse button. This is possible only if the search is Daily and not Total.

When the search is run on unknown controls the range and Westgard classes are not displayed.

Deleting data: see fig. 3 and 3-1. After having performed a daily query, it is possible to delete one or more control values. To delete a control, first highlight it, then right click on it and confirm.

1.3. Displaying & Processing By Lot Pairs: Youden Graph

After selecting the key parameters **Analyses**, **Lot**, **Method**, **Type (Known/Unknown)** and **Level**, data processing and visualization is performed. The controls are ordered by date and only in case of known controls the **Out of limit** condition is indicated. Refer to Figure 4. This function relates two different levels for the same lot displaying distribution of controls within the limits of lots.

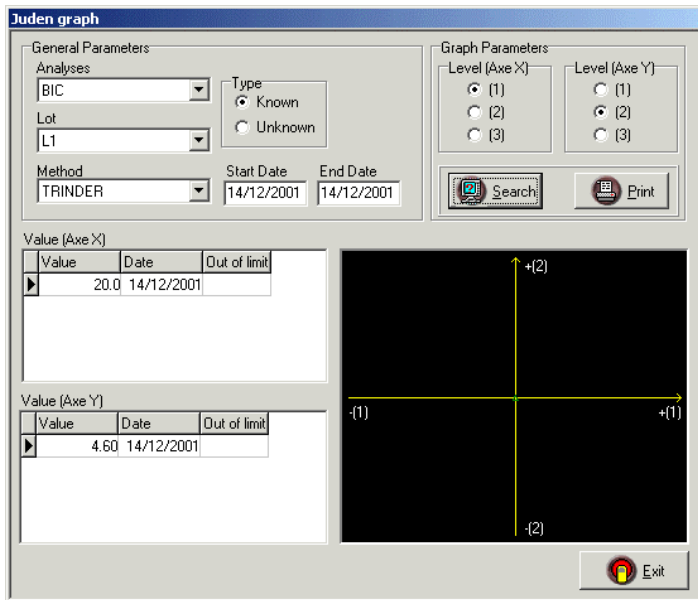


Figure 4

By clicking over a value plotted on the graph, the information relating the pair of values will be displayed.

1.3.1. Westgard Graph

The Westgard graph provides a global vision of a given lot by plotting data on a diagram having the origin at 0 line representing the lot mean value, calculated as $(\text{lot min} + \text{lot max})/2$, which usually corresponds to the lot theoretical value. As division, are reported values such as $\text{Mean} \pm 1S$ $\pm 3S$ (see Westgard table in Figure 5). All data within the given range will be displayed with a green triangle while the out of range data will be plotted using red squares. The two red lines indicate the lot limits low and high.

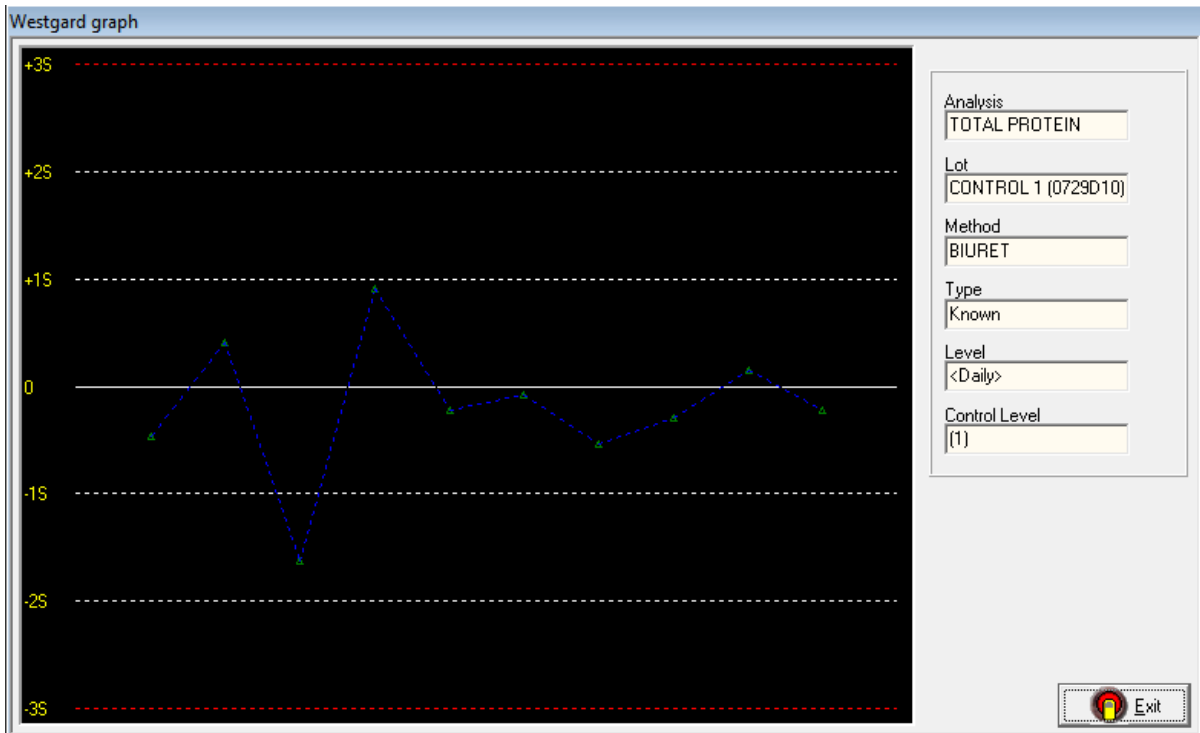


Figure 5

By clicking the mouse over a given value in the graph, its information will be displayed (fig. 6).

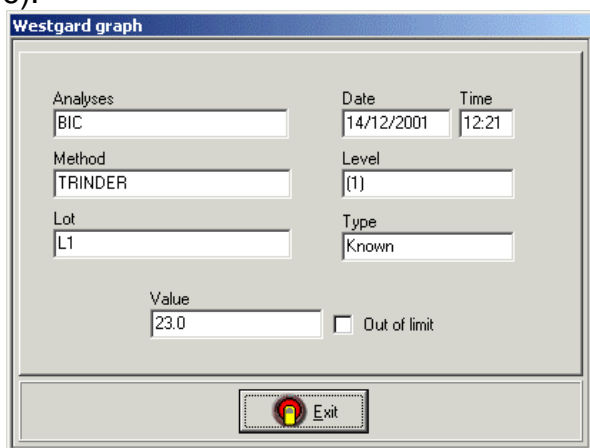
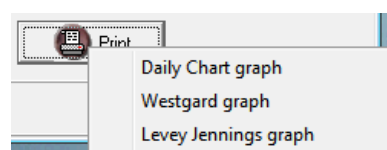


Figure 6

Click on the "Print" button to print the graph.



Westgard's Decision

It is a procedure for classifying values of a **Known** lot taken into consideration for processing.

Mean: mean between the maximum and minimum lot value

S: (Maximum lot value – Minimum lot value) / 6

The following procedure is observed for classification:

- Class A (1-2S):** One result exceeds Mean by +/- 2S.
- Class B (1-3S):** One result exceeds Mean by +/- 3S.
- Class C (2-2S):** Two consecutive results exceed mean by 2S in the same direction.
- Class D (R-4S):** Difference between two consecutive results is higher than 4S and at least one result exceeds mean by +/- 2S.
- Class E (4-1S):** Four consecutive results exceed mean by more than 1S in the same direction and at least one result exceeds mean by +/-2S.
- Class F (10x):** Ten consecutive results are all in the same direction of the mean value and at least one result exceeds the mean by +/- 2S.

Classes are controlled from F to A. The classes are mutually exclusive, that is, if a given value is mapped to one class then it can't be part of another class.

Example:

2 E classes means that **5** consecutive results exceed Mean by more than 1S in the same direction and at least one result exceeds mean by +/-2S; alternatively two groups of 4 consecutive results exceed the mean by more than 1S in the same direction and at least one result exceeds mean by +/-2S.

1.3.2. Daily Chart Graph

The "Daily Chart graph" provides a global vision of a given lot, plotting data on a diagram having the origin represented by the actual mean (not by the theoretical value) of the same lot and as divisions values such as Mean+Standard Deviation*1, Mean+Standard Deviation*2 to Mean+Standard Deviation*4. In addition the red dashed lines indicate the upper and lower limits of the lot. All data within the range will be represented by a green triangle, while the out of range data will be plotted using red squares.

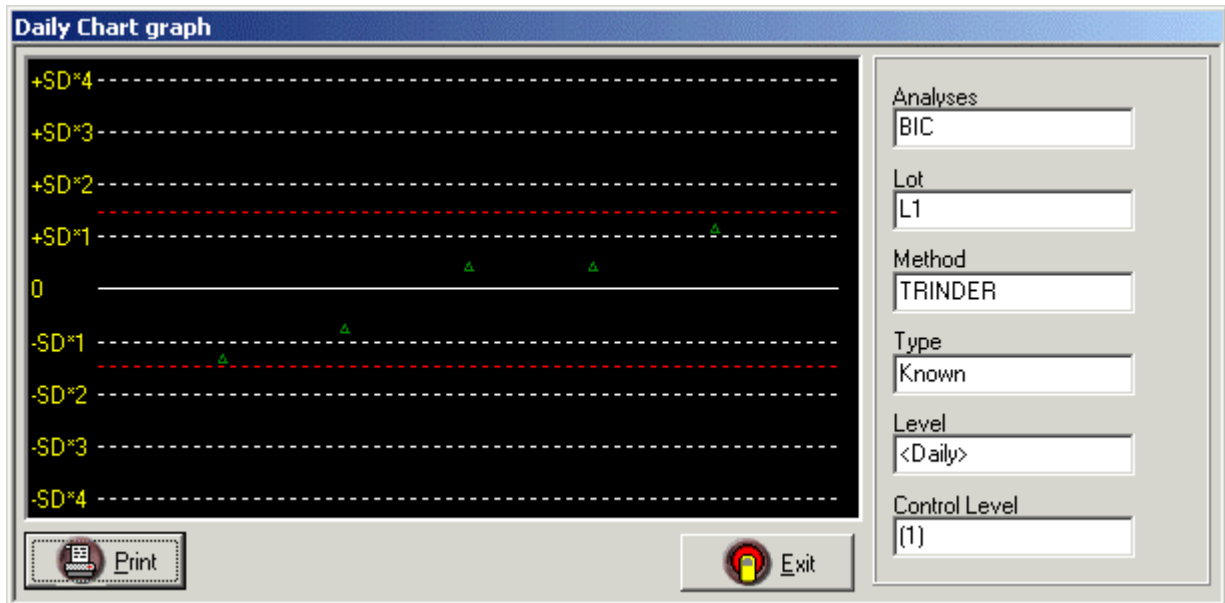


Figure 7

By clicking the mouse over a given value in the graphic, its information will be displayed. Click "Print" to print the graph.

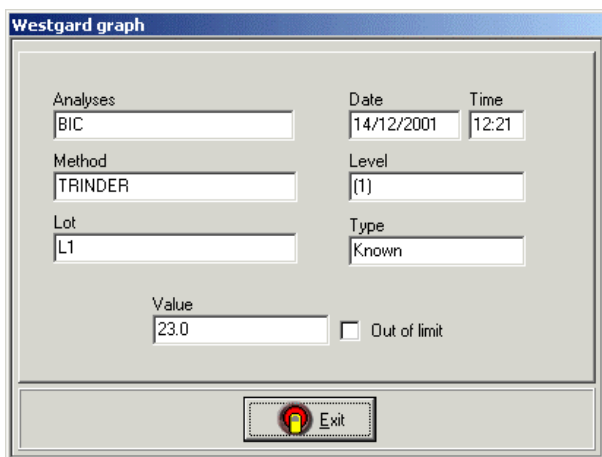


Figure 7-1

1.3.3. Levey-Jennings graph

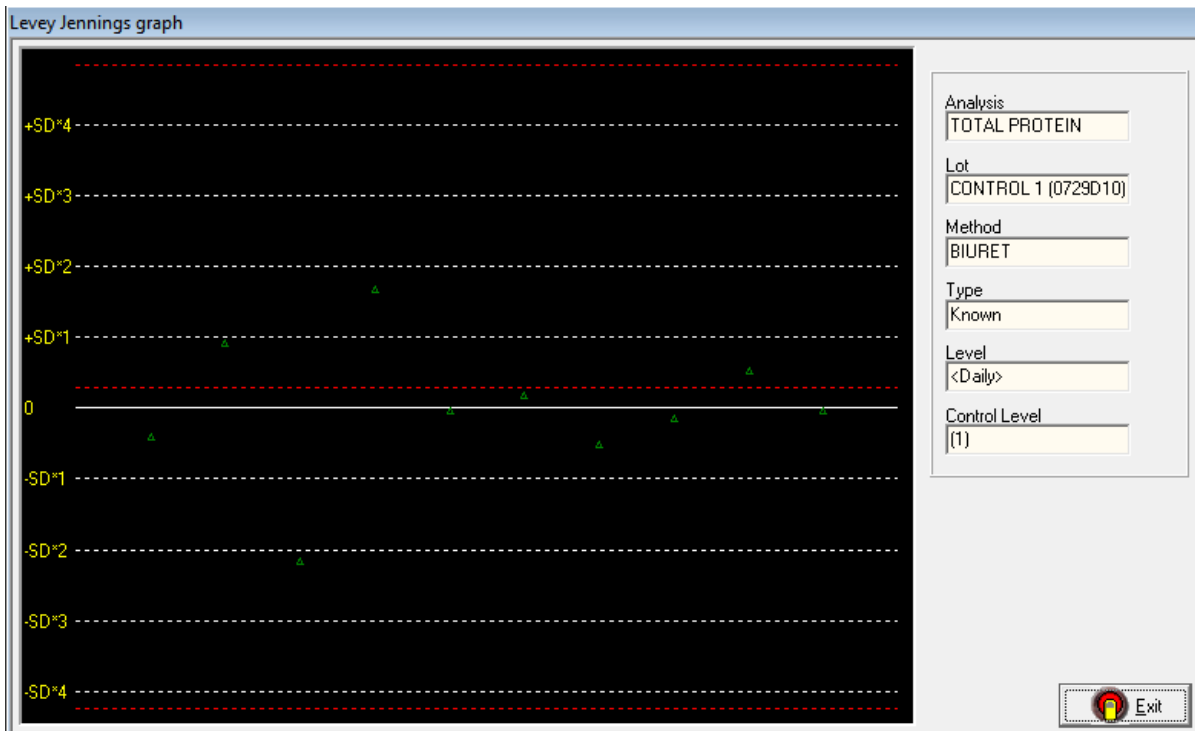


Figure 8

The Levey-Jennings graph provides a global vision of a given lot, plotting data on a diagram having the following information represented all together in the same graph:

- Mean: calculated controls mean (continuous line in the center)
- Control Lot mean value (red dashed line in the center)
- calculated standard deviations intervals (white dashed lines)
- Control Lot Minimum and Maximum values (red dashed lines at the extremes)

All data within the range will be represented by a green triangle, while the out of range data will be plotted using red squares.

The Levey-Jennings graph displays the same information as the Daily Chart, with the addition of the Control lot Mean value. In this graph the query can be for one single lot at a time only and is not available for unknown controls.

Click on the **Print** button to print the graph.

1.4. ADDITIONAL FUNCTIONS

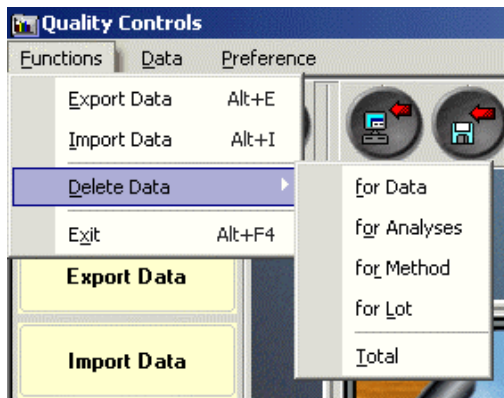


Figure 9

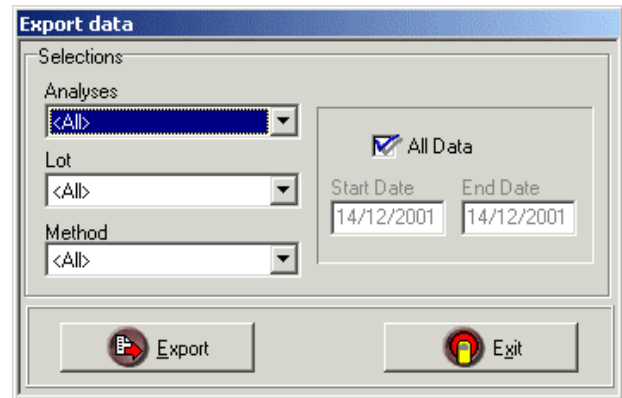


Figure 10

The **FUNCTIONS** menu contains the following:

Export Data: Saves memorized quality controls by selecting a particular "Method", "Analyses", "Lot", and "Date". If "All" is selected in the above-mentioned fields then all controls will be memorized. Refer to Figure 10. It is also possible to export the QC data in CSV (comma separated values) or Fixed length formats, compatible both with Word or Excel kind applicatives.

NOTE: the use of this function is very important to have constantly updated archives in a hard disk different from the analyzer's.

Once the *.csv or *.txt file has been created, it can be opened with Excel or Word. First open the appropriate program (both programs will open both kind of files, but the easier way is to use Excel for *.csv and Word for *.txt files). Then select "Open file" and in the "open" window, select in the field "File of type": "all files - *.*". Click twice on the file you want to open.

Import Data: Overwrites the actual stored data with the imported data. **CAUTION:** It is not possible to restore overwritten data.

Delete Data: it is possible to delete records in the archive by **Date, Method, Analyses, Lot** or erase the whole archive (Figure 9). **CAUTION:** It is not possible to restore deleted data in the previous "Delete Data" command.

- **Reindex Data-Base:** function used to reorder the **Quality Controls** archive.
- **Close:** closes the Q.C. program.

The **DATA** menu contains the functions explained in the paragraphs above.

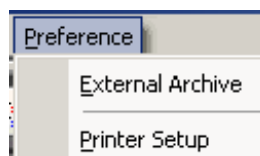
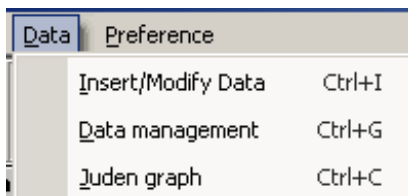


Figure 11

The **PREFERENCE** menu (fig. 11) contains the following:

External archive: used to view and print the quality controls memorized on the hard disk or on a floppy disk. A window opens where the position for opening the archive can be selected.

Printer Setup: used to set up the printer (heading, footnotes, etc.)

2. POPULATION

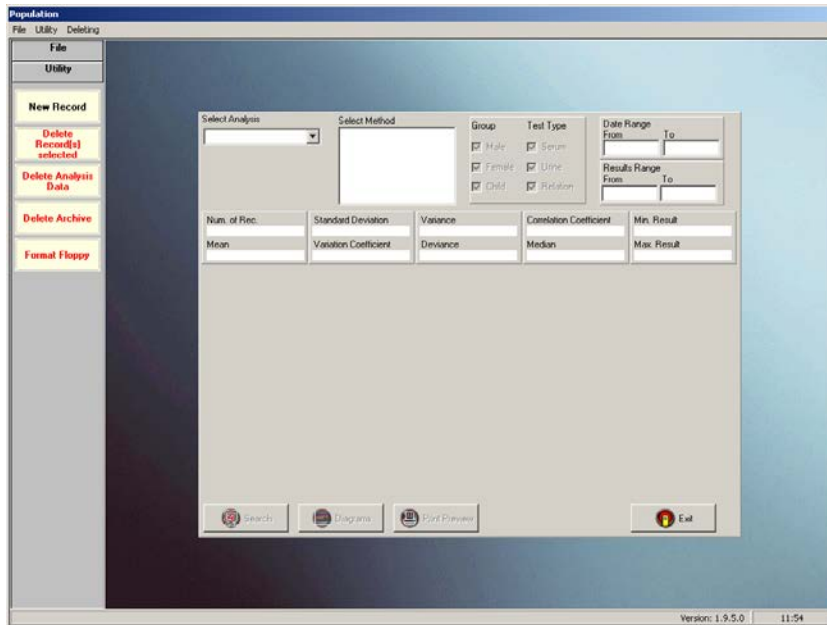


Figure 12

The Population module manages and displays graphs as well as data, and computes statistics on data of all the analyses performed by the instrument.

N.B.: due to the large dimensions that the archive can reach, it is advisable to run a backup at regular intervals, even monthly. It is advisable to use the “Export Data” function in the FILE menu to export the archive in CSV or Fixed length format (see par 2.4 OTHER MENU FUNCTIONS). Once the archive is saved into a different location, please delete the internal archive to avoid the archive itself to crash.

The main functions are:

- Display and data acquisition from updated analyses file.
- Update internal archives.
- Generate dynamic query that allows to sort and display data by analysis, analytical method, results' range, group, type and date.
- Statistical operations: display number of run tests, mean calculation, standard deviation, variation & correlation coefficients, variance, deviance, angular coefficient and known term of the minimum square line.
- Display data graphs: Trender (data with fitting line), L. Jennings, histograms with base zero and statistical (mean value represents the base).
- Printout of total and partial data, graphs, and statistics.

Moreover the program has the following built-in secondary functions:

- Total and partial "Back-Up" and "Restore" (selected by date and/or group and/or type and/or method and/or by results' range) functions.
- Total "Restore" function appends (adds) data to the existing archive.
- Printer setup.
- Deletion of the whole population archive.
- Addition of external tests for storing in the memory results belonging to different analyses than those performed by the analyzer: these results will be saved in the archive thus allowing data display and statistics generation.

2.1. Analysis Selection (How To Run A Query)

Figure 13

To perform any query it is necessary to select an analysis from the **Select Analysis** list (**Fig. 13**). Once selected all existing methods associated to the analysis (**Select Method**) are displayed. It is possible to select among the available methods by clicking on the check box. One can simultaneously enable the search for one or more groups "Group" (Man, Woman, Child) or **Test Type (Serum, Urine, Relation)**. Moreover it is possible to limit search within two dates (**Date range**) or according to a given data range (**Results range**). Once the all query criteria have been selected, press the **Search** button to display the data and statistics referred to it (**Fig. 14**). This page shows the statistical processing for the query. They are also present on the pages for graphic processing (Diagrams)

Num. of Rec.	Standard Deviation	Variance	Correlation Coefficient	Min. Result
8	0.885	0.785	0.035	103.0
Mean	Variation Coefficient	Deviance	Median	Max. Result
103.8	0.854 %	5.500	103.5	105.0

Method	Result	Date	Group	Test Type
Mdc	103.0	11/01/2006	Male	Serum
Mdc	104.0	11/01/2006	Male	Serum
Mdc	105.0	11/01/2006	Male	Serum
Mdc	104.0	11/01/2006	Male	Serum
Mdc	103.0	11/01/2006	Male	Serum
Mdc	103.0	11/01/2006	Male	Serum
Mdc	105.0	11/01/2006	Male	Serum
Mdc	103.0	11/01/2006	Male	Serum

The statistical data presented for the query include:

- ✓ **Number of selected records**
- ✓ **Mean**
- ✓ **Standard Deviation**
- ✓ **Variation coefficient**
- ✓ **Variance**
- ✓ **Deviance**
- ✓ **Correlation coefficient**
- ✓ **Median**
- ✓ **Minimum result**
- ✓ **Maximum result**

Figure 14

The query data can be printed (**Print Preview**) in three different formats:

- **Only values**
- **Only statistics**
- **Values and statistics**

Once the selection is made the print preview page opens. To print, press the printer icon.

By pressing on the **Diagrams** button, a series of possible graphics processing is proposed for the executed query (**Fig 15**).

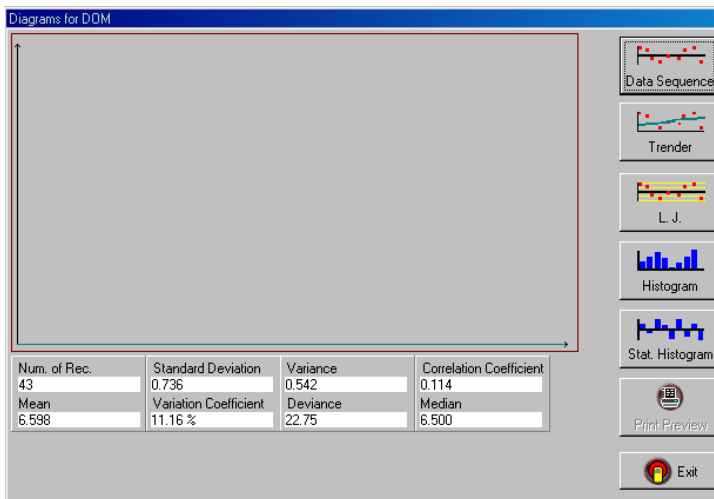
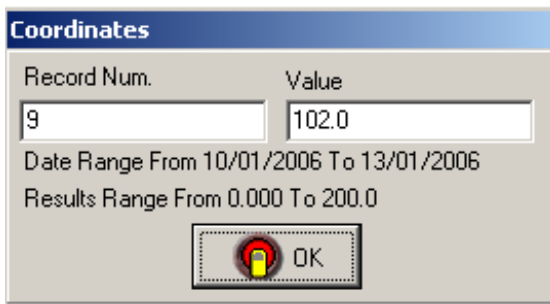


Figure 15

By clicking on one of the keys related to diagrams it is possible to view one of the graphs listed below.



In all available diagrams, by double-clicking the mouse on a given plotted point, information about its coordinates (position and value) is shown. The specific criteria used for the query are also described, if present.

Data Sequence Graph

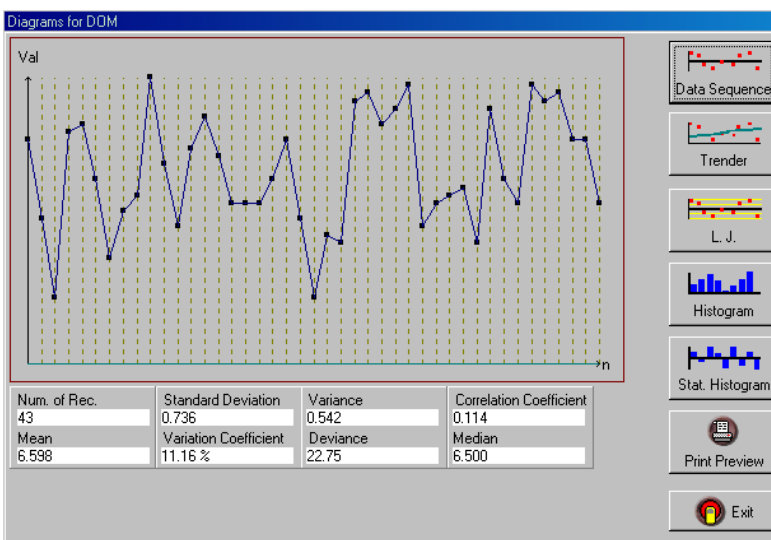


Figure 16

By clicking on **Data Sequence (Fig.16)** key, the data sequence is displayed.

Trender Graph

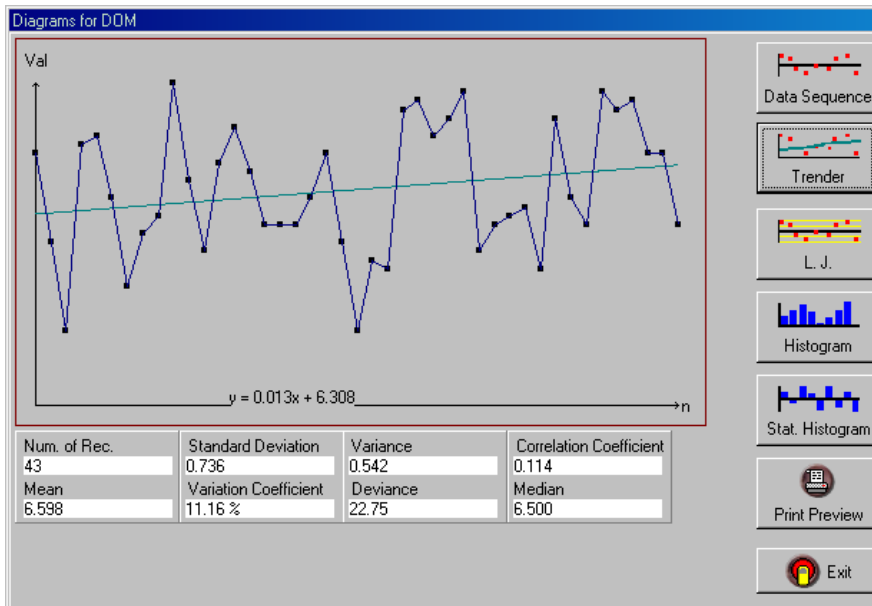


Figure 17

By clicking on Trender button, data sequence is displayed together with its related minimum square line (Fig. 17); in the lower part of the graph the equation for the line is shown.

L. Jennings Graph

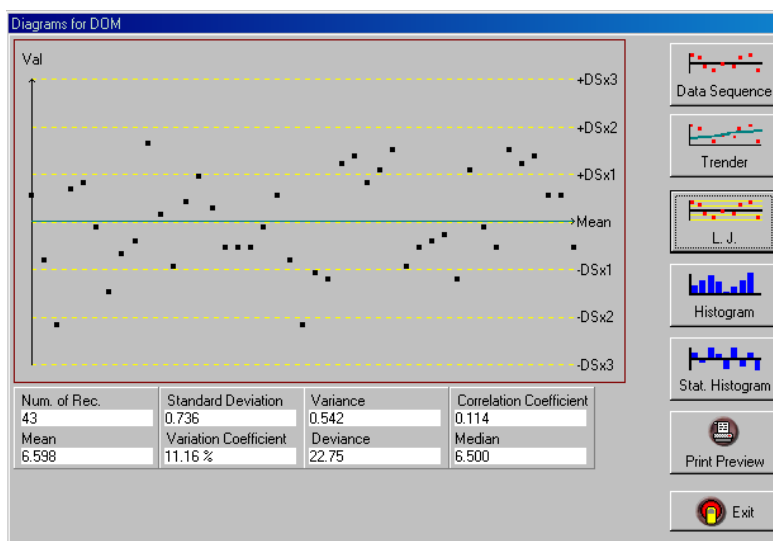


Figure 18

By clicking on **L. Jennings** button, L. Jennings graph is displayed for the selected data (Fig. 18).

Histogram Graph

By clicking on **Histogram** button, the histogram for the selected data is displayed (**Fig. 19**).

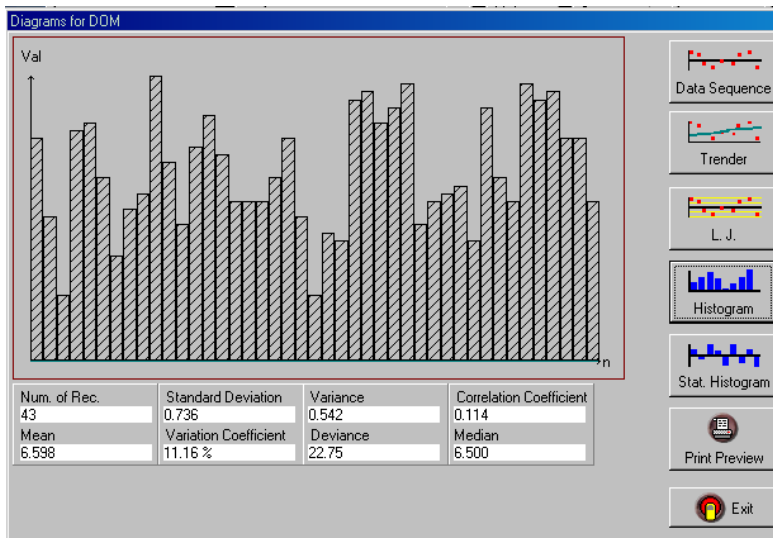


Figure 19

Statistic Histogram Graph

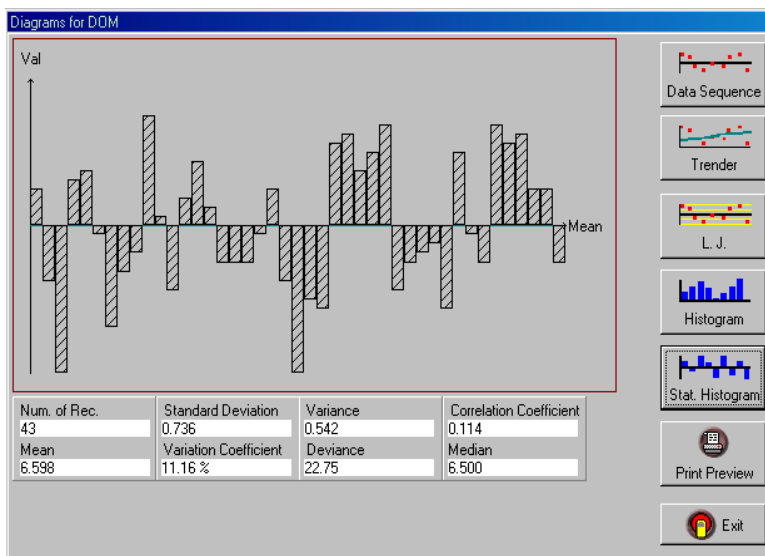


Figure 20

By clicking on **Statistic Histogram** button, the histogram for the selected data with respect to the mean value is displayed. (**Fig. 20**).

2.2. Principal Statistics Formulas Used In Population

◆ **Mean:**

\bar{X} : $X_1 \dots X_n$ selected elements; being "n" the number of elements:

$$\bar{X} = \frac{X_1 + X_2 + \dots + X_n}{n}$$

◆ **Standard Deviation:**

SD: is a quantity that measures the spread of data across its mean value. If data is mostly located near the mean SD assumes a small value, otherwise a large value indicates large data spread.

$$DS = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1}}$$

◆ **Variation coefficient:**

CV%: is computed as the ratio between mean square error and arithmetic mean. CV% is a relative quantity and independent from the measurement unit used.

$$CV = \frac{DS * 100}{\bar{X}}$$

◆ **Minimum square line $y = ax + b$**

Where:

$$a = \frac{\sum XY - n \sum x \sum y}{\sum X^2 - n(\sum X)^2}$$

$$b = \sum Y - a \sum x$$

◆ **Correlation Coefficient:**

$$CC = \frac{\sum [(Y - \bar{Y}) * (X - \bar{X})]}{\sqrt{\sum (X - \bar{X}) * (Y - \bar{Y})}}$$

◆ **Variance:**

$$V = \frac{\sum X^2 - \frac{[\sum X * \sum X]^2}{n}}{n-1}$$

◆ **Deviance:**

$$D = \sum X^2 - \frac{(\sum X)^2}{n}$$

Median:

The **Median** for an ordered set of data is the central value or the arithmetic mean of the two central values, depending on the fact that the number of elements in the set be odd or even. In particular the median for N odd elements, is the $X[(N+1)/2]$ th element.

Example.: given the following 9 elements set
 1, 2, 2, 17, 21, 34, 34, 34, 67

$$\text{Median} = [X (N+2)]/2 = X[(9+1)/2] = X[5] = 21$$

median is 21, the fifth element.

The median for N even elements, is the $\{ X(N/2) + X[(N+2)/2] \}/2$ element.

Ex.: be given the following 8 elements set

1, 2, 12, 24, 26, 45, 45, 46
 $\{X[4]+X[5]\}/2 = (24+26)/2 = 25$

median is 25.

By comparing the median and the arithmetical mean, one can assume the existence of a measurement error or an asymmetry in the distribution function, in case these two quantities differ greatly.

2.3. Inserting External Analyses

Press on the **New Record** in the **Utility** menu.

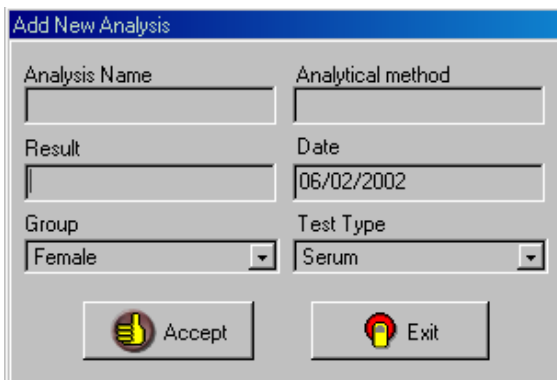


Figure 21

It is possible to store in the analyzer’s memory results of other analyses not performed by the analyzer. These data will be saved into the archive and it will be possible to display statistics as well as analyses results.

The input screen (**Fig. 21**) shows the following fields:

Analysis Name, Analytical Method, Result, Date, Group and Test Type.

To insert a series of consecutive values for the new analysis, the results field should be programmed last. Then enter the results by pressing **Enter** on the keyboard (or the **Accept** button) to confirm each value.

By pressing the **Exit** key the external analysis insertion window closes and the entered data become available for statistical processing.

Data entry is case sensitive, meaning that an analysis name written in capital letters (YOU) is different from the one written in lower case letters (you) and is different from the one written with initial upper case letter (You).

2.4. Other Menu Functions

The main menu contains three items, each of which has different commands. The most useful are also displayed in the navigation bar (Fig. 22)

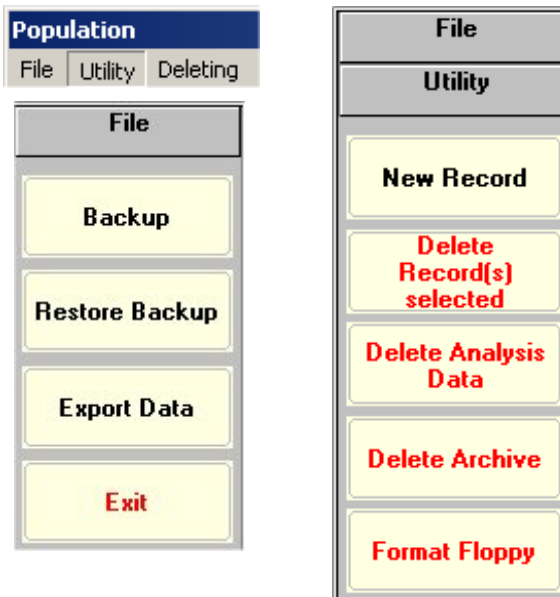


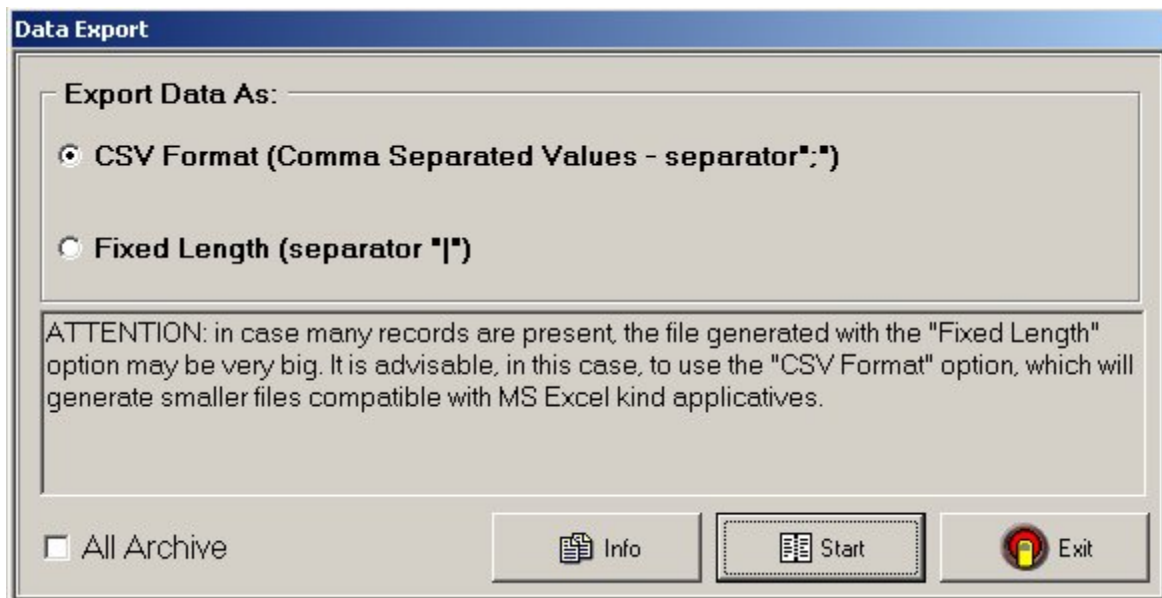
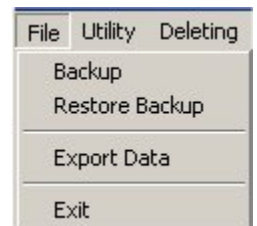
Figure 22

FILE MENU

Backup: creates a backup copy of the executed query. The backup copy can be saved on a floppy disk or the hard disk.

Restore Backup: used to restore the backup copy to its original position.

Export Data: this function allows exporting data in CSV (comma separated values) or Fixed length formats, compatible both with Word or Excel kind applicatives.



It is possible to export the whole archive (select **All archive**) or a query. To export a single query, it is first necessary to perform the query and then to click on the Export data option.

NOTE: the use of this function is very important to have constantly updated archives in a hard disk different from the analyzer's.

Once the *.csv or *.txt file has been created, it can be opened with Excel or Word. First open the appropriate program (both programs will open both kind of files, but the easier way is to use Excel for *.csv and Word for *.txt files). Then select "Open file" and in the "open" window, select in the field "File of type": "all files - *.*". Click twice on the file you want to open.

Exit: exits the application.

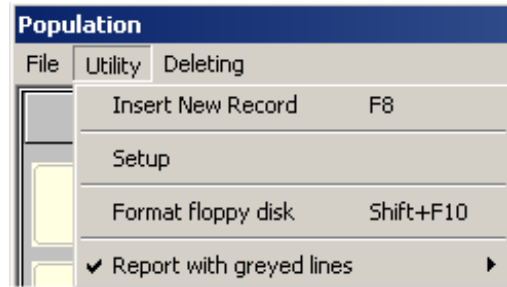
UTILITY MENU

Insert new Record: see the paragraph above (par. 2.3 and fig. 21)

Setup: opens the printer setup window (see also Ch. H Analyzer Setup, par. 2)

Format floppy disk: used to format a floppy disk.

Report with grayed lines: used to select whether to print the reports in "easy reading" format. Easy reading printing contains light gray lines alternated with lines the color of the paper.

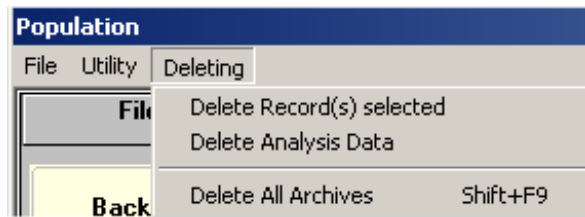


DELETING MENU

Delete Record(s) selected: it is possible to highlight several values in a query by holding down the CTRL key while selecting various results with the mouse cursor. These values can be deleted with this command.

Delete analysis data: deletes all the data related to the selected analysis and executed query. Selected analysis data that is not part of the query will be preserved.

Delete all archives: completely deletes the population archives.

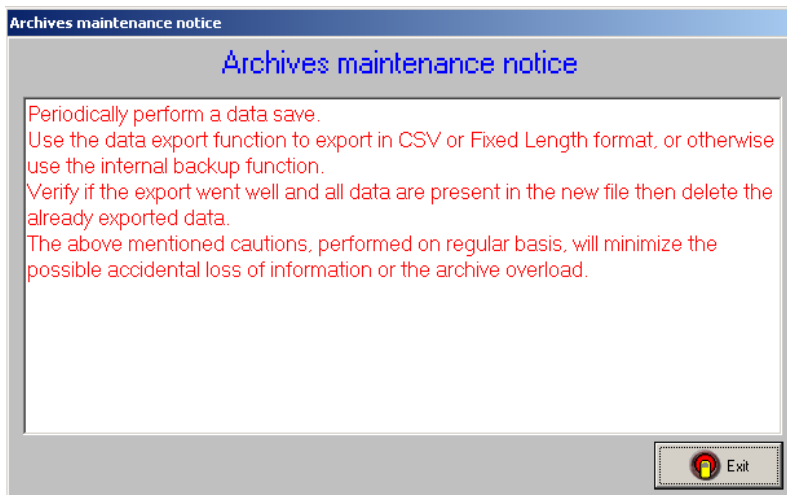


3. PATIENTS ARCHIVE

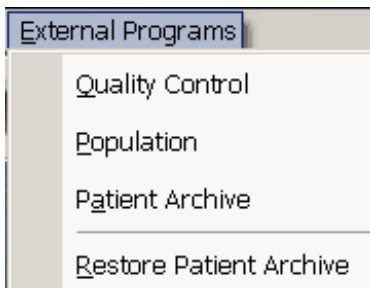
The “Patients Archive” module displays patients’ information and allows report printing.
N.B.: due to the large dimensions that the archive can reach, it is advisable to run a backup at regular intervals, even monthly.

It is advisable to use the “Export Data” function in the FILE menu to export the archive in CSV or Fixed length format (see par 2.4 OTHER MENU FUNCTIONS). Once the archive is saved into a different location, please delete the internal archive to avoid the archive itself to crash.

An automatic maintenance has been added to the Patients Archive in order to avoid archive crash due to data overload. At periodical intervals, depending on the size of the Archive, the following maintenance message will appear.

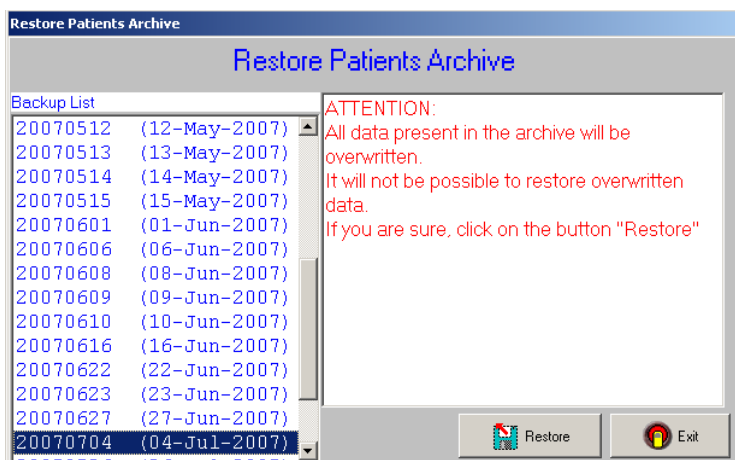


In case of Archive crash, it will be possible to restore one of the automatically performed backups.



Go to the External Programs menu, and select Restore Patients Archive.

The following window will appear. Select the file date you wish to restore and click on the Restore button. Pay careful attention: overwritten data can not be restored.



PATIENTS ARCHIVE

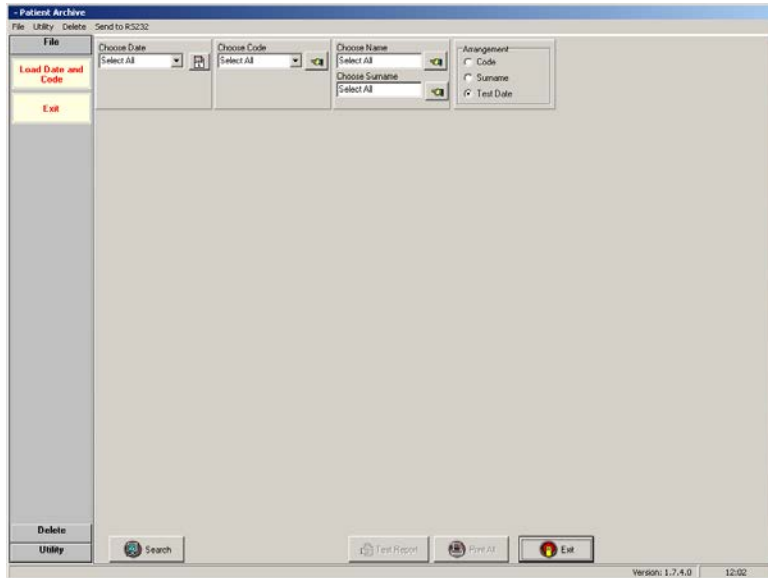


Figure 23

Its main features are:

- ◆ Displaying as well as data acquisition from updated analysis file.
- ◆ Internal archives update.
- ◆ Internal and external archives display.
- ◆ Modifying values;
- ◆ Dynamic query that allows sorting, ordering and displaying data by date range, code, patient's name/surname,.

The program also contains other complementary functions:

- ◆ Archive backup;
- ◆ Printer set-up
- ◆ Deleting analysis file, query or the entire archive
- ◆ Floppy disk formatting

3.1. Selection (How to run a Query)

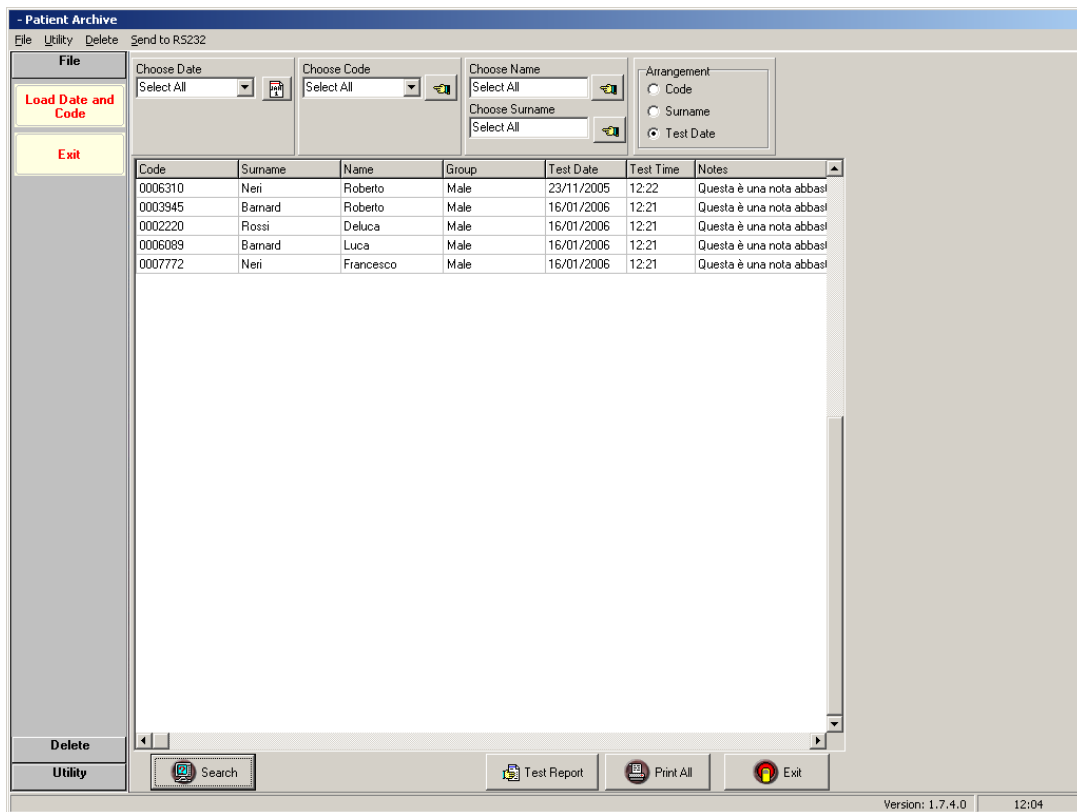


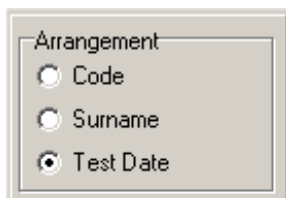
Figure 24

To run a query it is possible to specify various query criteria (Fig. 24) such as:

- ◆ Tests date range;
- ◆ Analysis code range;
- ◆ Name;
- ◆ Surname;
- ◆ Arrangement by code, surname, test date.

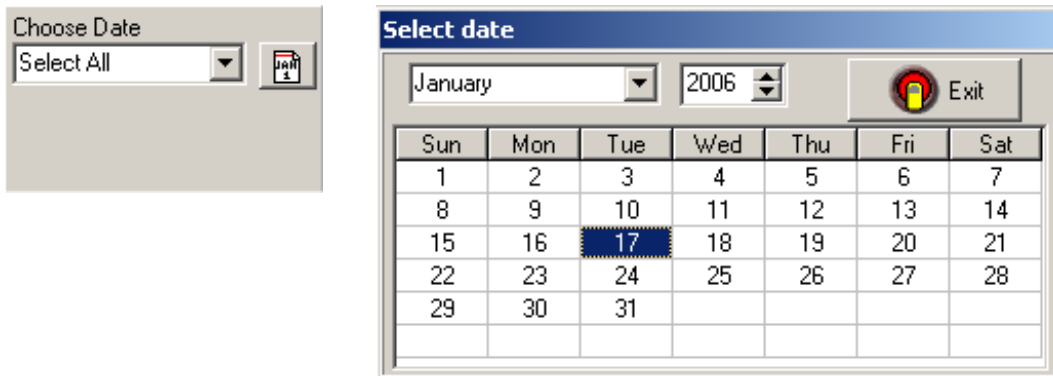
Select all is displayed by default in the fields. In this case, by pressing the **Search** button all the data present in the archive will be displayed.

Patients will be ordered by **Test Date** as long as the operator does not want to order by **Code** or **Surname**.



Choose date:

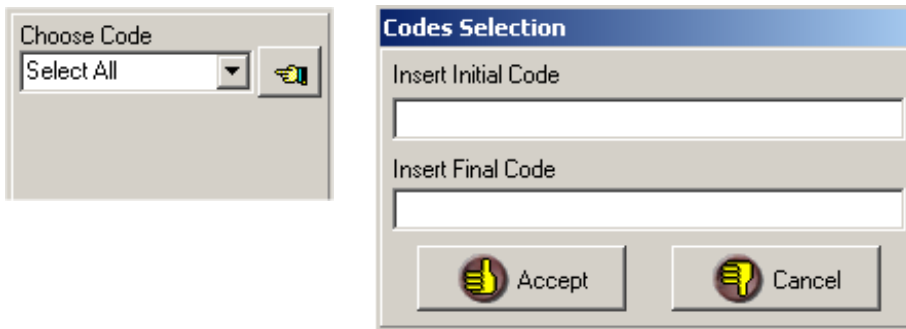
Clicking on the icon next to the editing window "Choose Date" for selection of tests date, it is possible to select the desired date range for search (query). It is possible to select the initial and final date with simple clicks in the window (shown at the left). Click on "exit" to save and close the frame. Press ESC to abort.



Choose code

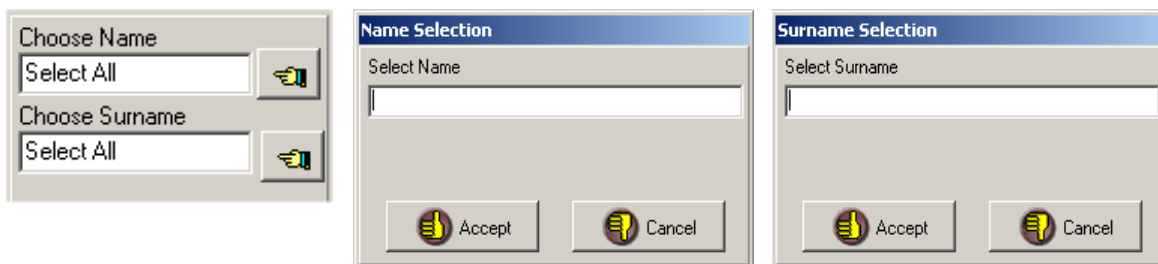
It is possible to enter the information regarding the search range for desired analyses codes by clicking on the icon (hand) next to "Choose Codes". The search is case sensitive, meaning that the system distinguishes the capital letters (Upper case letters) from the small letters (lower case letters).

Clicking on the button "Accept" will save the values entered in the editing fields "Insert Initial Code" and "Insert Final Code". Pressing of "Cancel" will cancel the operation of the codes selection.



Choose Name/Surname

Click on the "hand" icon corresponding to "Choose Name" or "Choose Surname" to open the "Name Selection" window for searching by name or surname. Write name or surname in the dedicated field and click "Accept" to save the search or click "Cancel" to abort the operation. The search is case sensitive.



Once the search criteria have been fixed, click on **Search** button. The patients' data page will be displayed as in fig. 24.

3.2. Patients Report

By clicking with the right button of the mouse on one of the records (Fig. 25) it is possible to select one of the functions described below.

Code	Surname	Name	Group	Test Date	Test Time	Notes
0006310	Neri	Roberto	Male	23/11/2005	12:22	Questa è una nota abbast
0003945	Barnard	Roberto	Male	16/01/2006	12:21	Questa è una nota abbast
0002220	Rossi	Deluca	Male		12:21	Questa è una nota abbast
0006089	Barnard	Luca	Male		12:21	Questa è una nota abbast
0007772	Neri	Francesco	Male	10/01/2006	12:21	Questa è una nota abbast

Figure 25

View Analyses: this can also be accessed with a double click and is used to display the information related to the selected patient (Fig. 26)

Info Record: displays the position of the selected record inside the executed query.

Quick Print: immediately prints the report for the selected patient.

View Analyses

Results for 16/01/2006 - Code "0003945"

Surname	Name	Date	Group
Barnard	Roberto	16/01/2006	Male

Notes
Questa è una nota abbastanza lunga

Analysis	Method	Unit	Result	Flag	Min	Max
Glucosio	Color	mg/L	20.34	*	45.00	119.
RAT	XXXXX	mg/L	13.41		10.00	29.0
BID	Color	UI/dl	52.68	*	56.00	116.
Bilirubina	Color	mg/dl	*	30.00	102.
Glicemia	Color	UI/dl	42.25		30.00	84.0
Lipasi	XXXXX	UI/l	7.660	*	22.00	54.0
PRV	Color	mg/dl	*	34.00	71.0

Send to RS232 Print Preview Previous Next Exit

Figure 26

With the keys **Previous** and **Next** it is possible to scroll the entire patients list.

Send to RS232: sends the results to the Host Computer (when enabled)

Print Preview: opens the print preview of the patient's report.

In addition to the list of "Analysis" of selected code, the following informations are displayed: name, surname, test date, group, measurement unit, flags (an asterix identifies tests with flags; see flag page below), Min - Max range, and notes.

There is a possibility to change the analysis results by right-clicking with mouse on the relative line and selecting the option "Modify Value" (fig. 27). In the first field the "Old Value" of the result is shown, while in the second field "New Value" it is possible to insert the modified result. In case a wrong value is entered, then a screen message will alert the user to repeat the operation. Please pay careful attention to the correct entry of the decimal separator.

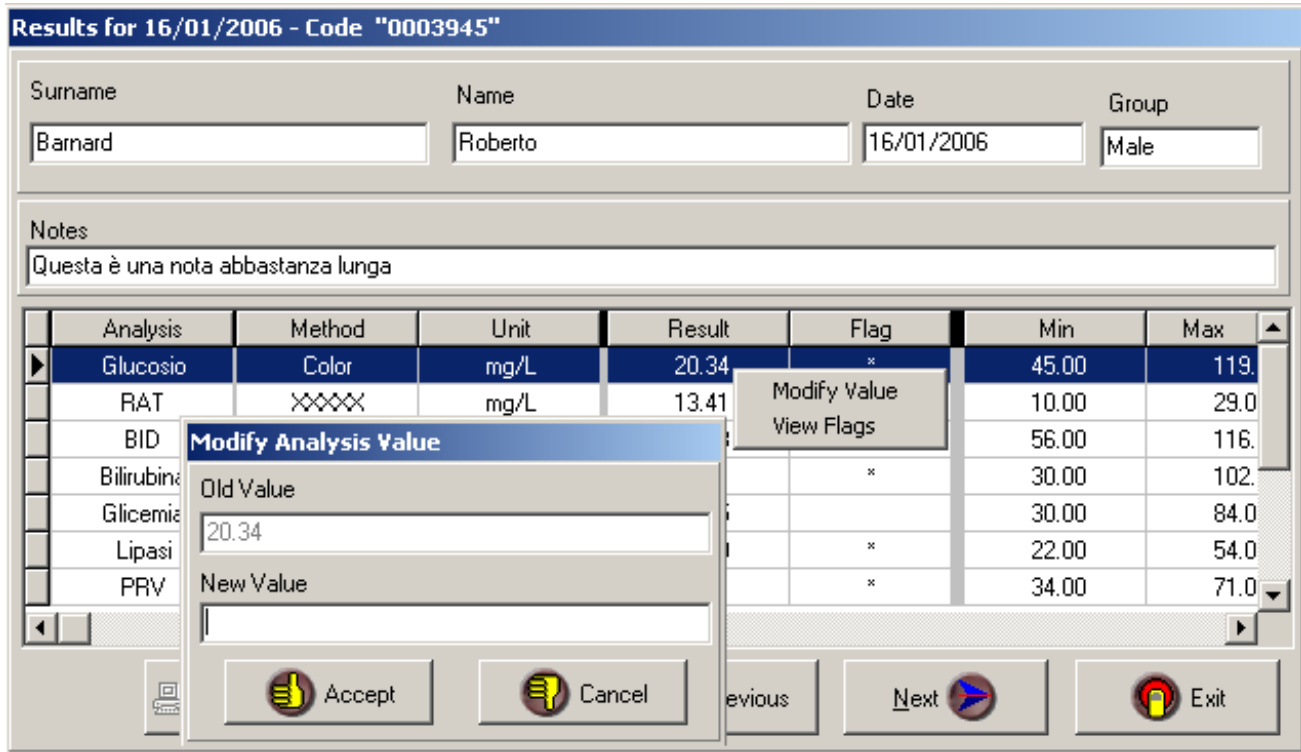
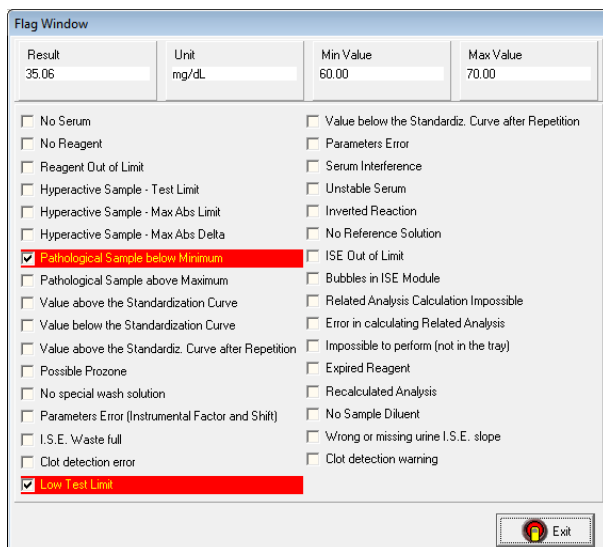


Figure 27

N.B.: the possibility of accessing the Patients' Archive module and modifying the analysis values is controlled by password and thus only accessible to authorized personnel.

See also Chapter E, Paragraph 1.7 Access Password.



It is also possible to view the analysis flags by selecting the **View flags** option (Fig. 27) or with a double click on the analysis line (Fig. 28).

For more information on the meaning of the flags see Chapter G, paragraph 1.5.

Figure 28

3.3. Printing Reports

The **Print All** button in figure 24 is used for quick access to a print window with some options.

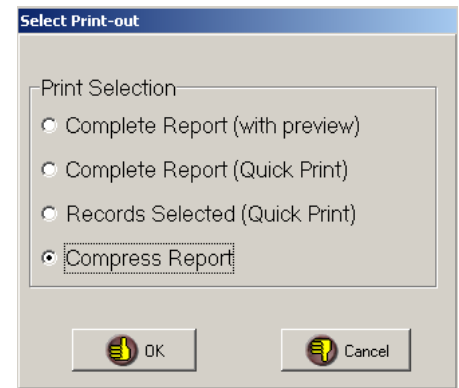
Complete Report (with preview): this option will allow printing of all patients' reports matching with the search criteria. A printing preview will be displayed.

The operator will start the actual printing of reports by for single patient.

Complete Report (Quick print): this option will allow printing of all patients' reports matching with the search criteria. Printing is immediate, with no preview.

Records Selected (Quick print): if only one or a few patients are selected, it will be possible from here to print only these reports

These three kinds of printings will produce reports as shown in Fig. 29.



Patient Archive					
Code: 30002 (Male)		Test Date: 23/04/2009			
Surname:		Name:			
Notes:					
Analysis	Method	Result	<small>(Result 2nd unit)</small>	Range	<small>(Range 2nd unit)</small>
ACIDO URICO DIALAB	TRINDER	4.748	mg/dl	3.400 - 7.000	
BILIRUBINA DIRETTA	J.Grof.mod.	0.734	mg/dl	0.100 - 0.300	
BILIRUBINA TOT.	J.Grof.mod.	1.317	mg/dl	0.500 - 1.200	
COLESTEROLO DIALAB	TRINDER	95.34	mg/dl	140.0 - 220.0	
D-CREATININA	JAFFE	1.065	mg/dl	0.800 - 1.400	
FERENE DIALAB 2	FERENE	135.9	µg/dl	40.00 - 150.0	
GLUCOSIO DIALAB	ColorimetricoGOD-PA	91.63	mg/dl	60.00 - 110.0	
D-GOT	IFCC	42.75	U/l	0.000 - 40.00	
D-GPT	U/l	42.79	U/l	0.000 - 46.00	
PROTEINE TOTALI	Biureto	6.417	g/dl	6.600 - 8.800	
TRIGLICERIDI DIALAB	TRINDER	99.55	mg/dl	60.00 - 160.0	
D-UREA	U.V.	40.46	mg/dl	10.00 - 50.00	
ALBUMINA 4L	BCG	5.072	g/dl	3.500 - 5.500	
GGT	Szasz	41.57	U/L	0.000 - 50.00	

Figure 29

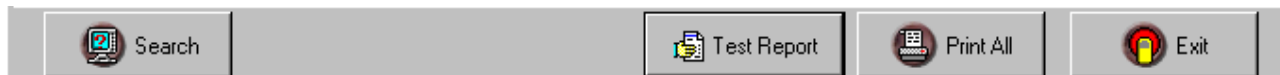
In this kind of printout, all patient data are shown, followed by the analyses list with analytical method, result (with flags) and normal range.

Compress Report, will produce a different kind of report, where only analyses are listed, with no reference to the pertinent patient. A printing preview will be displayed (Fig. 30).

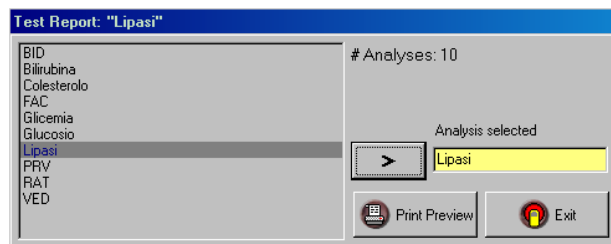
Lipasi	<Color>	(M) <NC> UI/dl	24.00 - 86.00
Bilirubina	<Color>	(M) <NC> UI/l	16.00 - 68.00
Glicemia	<Trinder>	(M) <NC> UI/l	31.00 - 83.50
FAC	<Jundrassik>	60.91 UI/l	53.00 - 99.50
Colesterolo	<XXX>	48.50 mg/L	32.00 - 101.0
Glucosio	<XXXXX>	(M) <NC> mg/L	57.00 - 108.5
BID	<Jundrassik>	(M) <NC> mg/dl	56.00 - 132.0
RAT	<Jundrassik>	98.88 mg/L	52.00 - 108.0
Glicemia	<XXX>	53.51 mg/dl	18.00 - 72.00
Bilirubina	<Jundrassik>	(M) <NC> mg/dl	25.00 - 63.50

Figure 30

There is another type of printing by test option in the main window of the Patient Archive (Fig. 24):



Test Report: from here it is possible to select one of the available tests and to print the corresponding results (Fig. 31 and 32)



Select the test, move it into the **Analysis Selected** field with > and click on **Print preview**

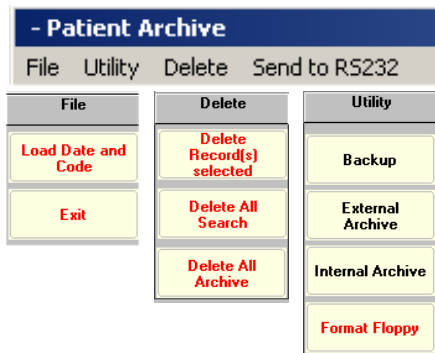
Figure 31

All results matching with the search criteria are displayed.

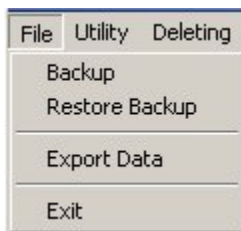
Patient Archive						
Analysis Values: "BILIRUBINA DIRETTA"						
Date From "23/04/2009" To "23/04/2009"			Code: Select All			
Surname: Select All			Name: Select All			
Date	Value	Code	Group	Test Type	Method	
23/04/2009	(+) 0.733 mg/dl	30001	Male	Serum	J.Grof.mod.	
23/04/2009	(+) 0.734 mg/dl	30002	Male	Serum	J.Grof.mod.	
23/04/2009	(+) 0.746 mg/dl	30003	Male	Serum	J.Grof.mod.	
23/04/2009	(+) 0.864 mg/dl	30004	Male	Serum	J.Grof.mod.	
23/04/2009	(+) 0.751 mg/dl	30005	Male	Serum	J.Grof.mod.	
23/04/2009	(+) 0.757 mg/dl	30006	Male	Serum	J.Grof.mod.	
23/04/2009	(+) 0.752 mg/dl	30007	Male	Serum	J.Grof.mod.	

Figure 32

3.4. Other Menu Functions



Other menus are available with relative command in the main page of the Patient Archive (Fig. 23), some of these are also present in the navigation bar.

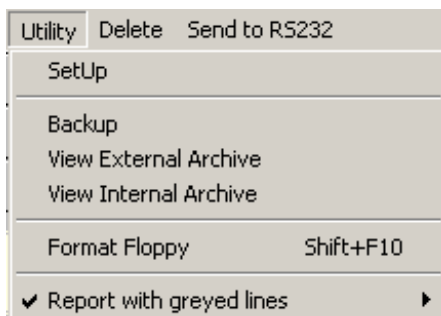


FILE

Load Date and Code: used to load the date for the test execution dates and patients codes so that they are available in the query criteria "scroll-box" (par. 3.1.).

Export Data: has the same function as in the Population archive: see par 2.4 OTHER MENU FUNCTIONS

Exit: is used to close the Patients Archive program.



UTILITY

SetUp: opens the printer setup.

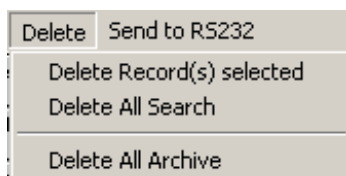
Backup: creates a backup copy of the selected search, without deleting files from the HD. To create the backup it is necessary to first perform a search, then select a location for the backup files.

View External Archive: click on this button, select the location where the backup files are and then press the search button to view data.

View Internal Archive: press this button to go back to the internal archive after having viewed an external backup file.

Format Floppy: it is used to format a floppy disk.

Report with grayed lines: used to select whether to print the reports in "easy reading" format. Easy reading printing contains light gray lines alternated with lines the color of the paper.

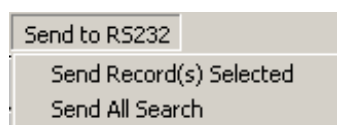


DELETE

Delete Records Selected: Allows deletion of only the randomly selected records.

Delete All Search: it deletes the whole performed search.

Delete All Archive: it deletes the whole archive.



SEND TO RS232

Send Records Selected: sends randomly selected records to the host computer.

Send All Search: sends the whole performed search to the host computer.

SECTION I: GENERAL INFORMATION

CHAPTER G: DISPLAYING AND PRINTING RESULTS

1. DISPLAYING AND PRINTING RESULTS	2
1.1. Results Per Patient.....	3
1.2. Results Per Test.....	8
1.3. Displaying Real-Time Data.....	9
1.4. Reaction Graphs.....	11
1.5. Flags List.....	13
1.6. Sorting Results In Real Time	14

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

1. DISPLAYING AND PRINTING RESULTS

The representation of the test results can be accessed through the specific icons (Fig. 1) for the two available options: “View results for sample” (results will be displayed for patient) and “View results in real time” (results will be displayed as the single tests are read).

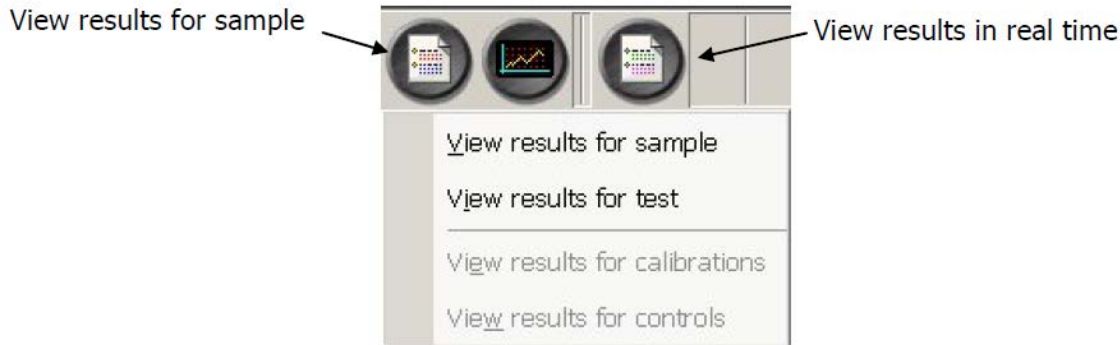


Figure 1

By clicking on the icon for **View results for sample** the operator has the possibility of viewing the results **by sample** or **by test** (Fig. 1).

In the first case the patient data are displayed together with all the analyses run on that sample. In the second case the results of performed tests are displayed, grouped by analysis.

Moreover it is possible to view the results for the calibrations or the controls in the dedicated RT pages.

Results		Info Flags	
#19 STD003 (Standard) (20/01/2009 16:16)			
ISEB>K		+14.60	mV (4.40 -10.2)
ISEB>Na		-12.50	mV (-18.8 -6.34)
ISEB>Cl		+10.30	mV (33.5 +23.2)
ISEB>Li		+13.70	mV (-65.9 -79.7)
#20 STD004 (Standard) (20/01/2009 16:19)			
ISEB>K		+0.439	mV (-11.5 -11.9)
ISEB>Na		+0.944	mV (-6.19 -7.13)
ISEB>Cl		-0.973	mV (23.1 +24.0)
ISEB>Li		-0.620	mV (-81.0 -80.4)
#19 STD005 (Standard) (20/01/2009 16:20)			
ISEB>K		+15.10	mV (4.69 -10.5)
ISEB>Na		-12.40	mV (-19.1 -6.69)
ISEB>Cl		+10.40	mV (33.7 +23.2)
ISEB>Li		+14.20	mV (-65.1 -79.4)
#1 STD002 (Standard) (20/01/2009 16:16)			
ACIDO URICO	<ENZ COLORIMETRICO>	5.20	mg/dl (0.146)
ACIDO URICO	<ENZ COLORIMETRICO>	5.20	mg/dl (0.146)
ACIDO URICO	<ENZ COLORIMETRICO>	5.20	mg/dl (0.147)
BILIRUBINA TOTALE	<JENDRASS-GROF>	5.10	mg/dl (0.355)
BILIRUBINA TOTALE	<JENDRASS-GROF>	5.10	mg/dl (0.359)
BILIRUBINA TOTALE	<JENDRASS-GROF>	5.10	mg/dl (0.369)
BILIRUBINA DIRETTA	<JENDRASS-GROF>	2.20	mg/dl (0.318)
BILIRUBINA DIRETTA	<JENDRASS-GROF>	2.20	mg/dl (0.407)
BILIRUBINA DIRETTA	<JENDRASS-GROF>	2.20	mg/dl (0.325)
FERRO	<COLORIMETRICO>	195	ug/dl (0.108)
FERRO	<COLORIMETRICO>	195	ug/dl (0.106)
FERRO	<COLORIMETRICO>	195	ug/dl (0.106)
#20 STD006 (Standard) (20/01/2009 16:23)			

Results		Info Flags	
#15 CTRL002 (20/01/2009 16:47)			
ISEB>K (Serum)		8.23	mEq/l (+11.50 mV) 5.88 - 7.02
ISEB>Na (Serum)		141	mEq/l (+1.700 mV) 129 - 157
ISEB>Cl (Serum)		113	mEq/l (-1.800 mV) 109 - 133
ISEB>Li (Serum)		5.22	mEq/l (+15.60 mV) 2.30 - 2.92
GGT	<SAZES>	196	UI/l (0.132) 165 - 237
ALFA AMILASI	<CNF G2>	191	UI/l (0.063) 164 - 236
UREA	<UV>	130	mg/dl (0.402) 121 - 169
GLUCOSIO	<GOD-POD>	264	mg/dl (0.916) 219 - 293
ACIDO URICO	<ENZ COLORIMETRICO>	11.2	mg/dl (0.315) 9.50 - 12.9
G.O.T.	<IFCC>	153	UI/l (0.087) 116 - 168
TRIGLICERIDI	<GOD-POD>	202	mg/dl (0.263) 169 - 233
BILIRUBINA DIRETTA	<JENDRASS-GROF>	2.35	mg/dl (0.369) 1.97 - 2.83
BILIRUBINA TOTALE	<JENDRASS-GROF>	5.79	mg/dl (0.410) 4.44 - 6.40
ALBUMINA	<BCD>	3.10	g/dl (0.192) 2.61 - 3.75
FERRO	<COLORIMETRICO>	168	ug/dl (0.092) 141 - 201
PROTEINE TOTALI	<COLORIMET BIURETO>	4.72	g/dl (0.186) 4.33 - 5.55
Betkellio		3.91	UI/l 2.00 - 8.00
Iscopeno		302	nmol/l 100 - 200
Lutesio		941	°/sett 200 - 600
Xenon		116	mg/ren 15.0 - 40.0
#11 CTRL003 (20/01/2009 16:53)			
ISEB>K (Serum)		3.08	mEq/l (-2.470 mV)
ISEB>Na (Serum)		126	mEq/l (-1.240 mV)
ISEB>Cl (Serum)		80.3	mEq/l (+3.200 mV)
ISEB>Li (Serum)		1.69	mEq/l (+6.460 mV)
GGT	<SAZES>	39.7	UI/l (0.035)
ALFA AMILASI	<CNF G2>	36.9	UI/l (0.025)
UREA	<UV>	94.9	mg/dl (0.131)
GLUCOSIO	<GOD-POD>	85.9	mg/dl (0.333)
ACIDO URICO	<ENZ COLORIMETRICO>	4.74	mg/dl (0.133)
G.O.T.	<IFCC>	40.2	UI/l (0.023)
TRIGLICERIDI	<GOD-POD>	118	mg/dl (0.154)
BILIRUBINA DIRETTA	<JENDRASS-GROF>	0.654	mg/dl (0.098)
BILIRUBINA TOTALE	<JENDRASS-GROF>	1.39	mg/dl (0.098)
ALBUMINA	<BCD>	5.06	g/dl (0.313)
FERRO	<COLORIMETRICO>	129	ug/dl (0.070)
PROTEINE TOTALI	<COLORIMET BIURETO>	6.22	g/dl (0.244)
Deckellio		5.64	UI/l
Iscopeno		130	nmol/l
Lutesio		305	°/sett
Xenon		26.7	mg/ren
#14 CTRL001 <1234> (20/01/2009 17:04)			

Figure 2

<NC> WRITTEN INSTEAD OF THE RESULT

The paragraphs below (for example see fig. 4 or fig. 8) display the result pages in real time. It is possible to read <NC> “not calculable” in place of the value. This refers to values that cannot be calculated for one of the following reasons:

- no serum
- no reagent
- no washing solution
- no diluent
- no solution (I.S.E.)
- incorrect parameters
- expired reagent
- inverse curve

<NC> results can normally be archived (only in the patient archive) with the other results (see Ch. H, par. 2. Analyzer Setup) or they can be stored in the work lists to let the operator re-run the sample as soon as possible. In this case, the patient with the <NC> result will be regularly archived and a copy will be left in the work lists.

<NC> only appears on the result page in real time, it will be replaced by a series of dots “...” in the patient archive.

1.1. Results Per Patient

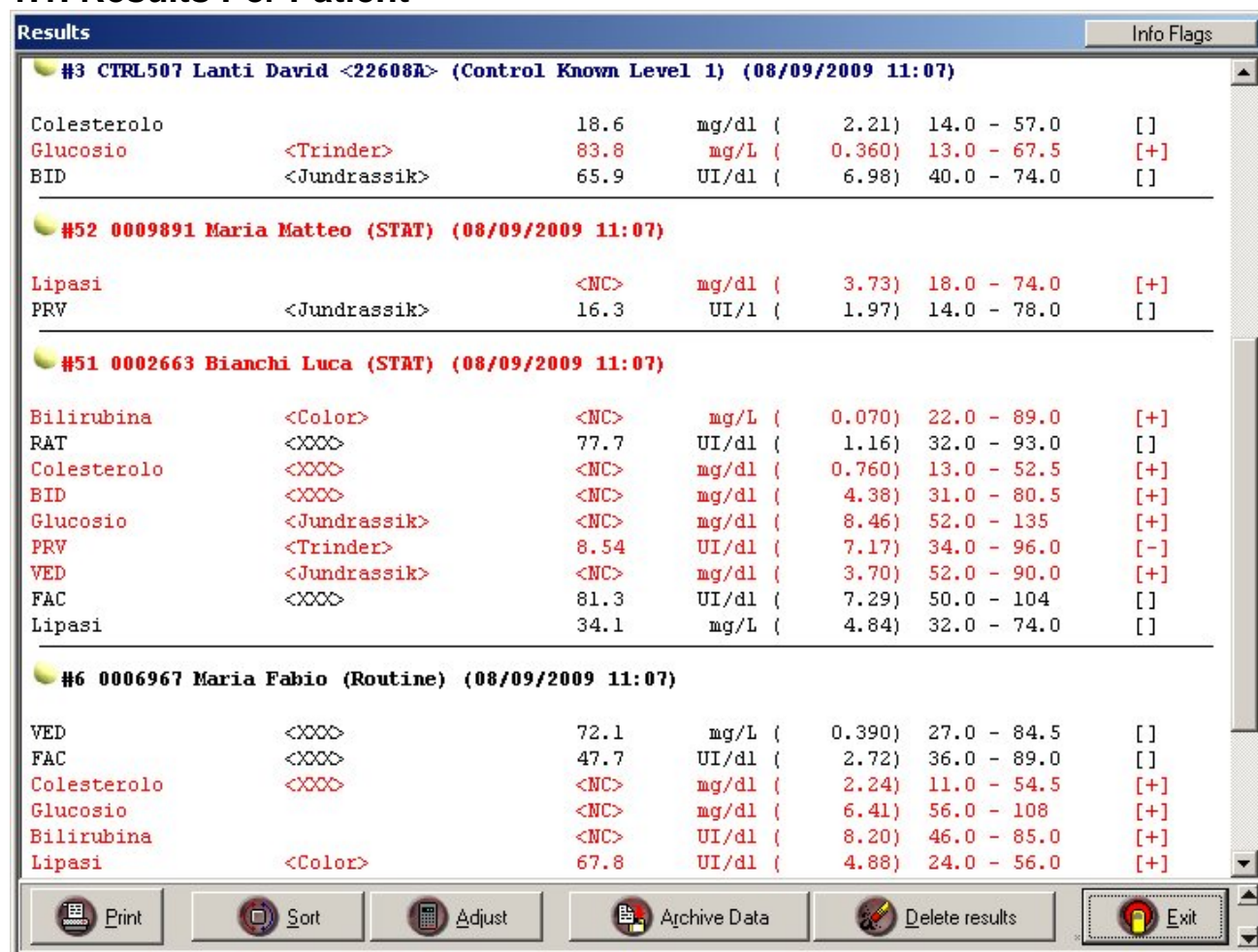


Figure 3



The "Patient's" data display page is shown in **Figure 3**. It can be accessed through the specific icon (Fig. 1).

In this area information related to calibrations is represented, like the values of calculated factors or any types of errors that occurred during execution.

If there is no data the page appears blank. A color code makes it possible to quickly identify the information:

- red text: presence of flags in at least one test of the sample
- blue text: controls
- green text: calibrations
- black text: no anomaly in the test or the entire sample

It is a brief representation of data and allows visualization of results of patient in execution as the tasks for the single patients are completed.

Once the results are archived, the information present in this page will no longer be available.

The following information are displayed for each sample:

- a) Sample Position (#XX)** Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.
- b) Sample Code** For Patients (Routine and STAT) it is assigned at check-in. For STD and Batch it is automatically assigned. It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph 1. "Quality Controls").
- c) Surname, Name** Patient's personal data.
- d) Sample Type** The relationship of Sample to one of the groups: Routine, STAT, CTRL or STD is indicated between brackets.
- e) Date and time** Indicated when (date and time) the sample was performed.
- f) Results** The results of test attributed to patients are represented with:

FAC	<Color>	38.1	mg/L (1.57)	53.0 - 102	[-]
VED	<Trinder>	19.7	mg/L (0.910)	17.0 - 67.5	[]

- full name of the analysis
 - execution method
 - result
 - unit of measurement
 - absorbance read (between parenthesis)
 - range of normal values
 - any flags (between brackets – see also par. 1.5)
- For automatic re-runs the values of the first and second determination are represented.

INFO FLAGS

In both types of result displays (per patient and in real time) an **Info Flags** button is available on the upper right.



It provides access to a page where the flags are listed, with a short explanation of the meaning of each one (Fig. 4).

Flag	Information
S	No Serum
R	No Reagent
W	No Additional Wash Solution
O	Reagent Out Of Limit
I	Hyperactive Sample (Test Limit)
A	Hyperactive Sample (Final ABS)
d	Hyperactive Sample (Max ABS Delta)
-	Pathological Sample (Below)
+	Pathological Sample (Above)
<	Sample Out Of Calibration Curve (Below)
>	Sample Out Of Calibration Curve (Above)
<<	Sample Out Of Calibration Curve (Below - After Automatic Repetition)
>>	Sample Out Of Calibration Curve (Above - After Automatic Repetition)
P	Not Enough Data To Calculate The Result
~	Sample Interference (Initial ABS)
±	Unstable Sample (Curve Acceptance)
!	Invalid Reaction Direction
r	No Serum Diluent
D	ISE Unstable
B	Bubbles in ISE
?	Impossible To Calculate A Relation Test (Not Enough Data)
X	Impossible To Calculate A Relation Test (Negative Value)
T	Test Is Not In The Current Tray
C	Positive Prozone Check
N	Reagent Expired
E	Recalculated Test
M	Error in the parameters (Instrumental Factor and Shift)
Z	Clot detection <ERROR>
z	Clot detection <Warning>
L	Low Test Limit

At the bottom of the 'Info Flags' window, there is an 'Exit' button with a red circular icon containing a white 'X'.

Figure 4

ADDITIONAL COMMANDS

The following commands are available in the data display page (fig. 3):



PRINT: Print command. It allows two options: Normal print-out (will print the pages as they are displayed i.e. samples will be printed sequentially) or Printout for sample (will print one single patient for each page). However, this is not a print-out in report format.

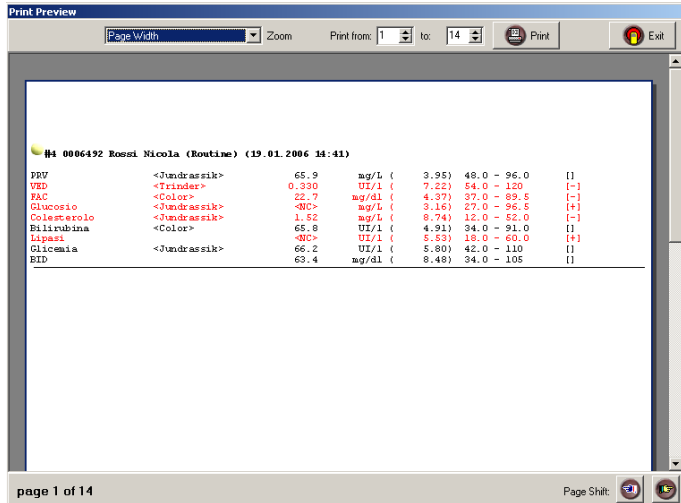
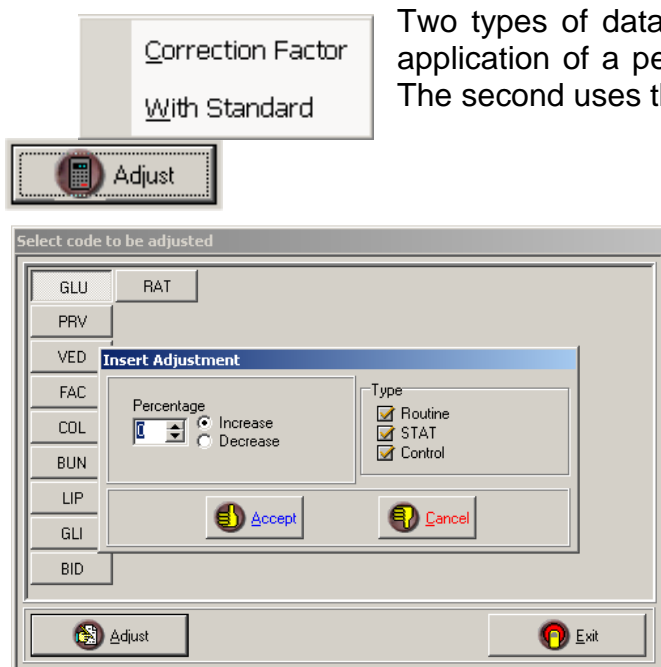


Figure 5

A print preview will be displayed (Fig. 5) where it is possible to select which and how many pages to print.

SORT: Data sorting command. This function is enabled only at the end of working session. The real-time data are displayed in random order as the analyzer returns them. The "Sort" command allows sorting based on the criteria selected in the Setup dedicated page (see par. 1.6 in this chapter).

ADJUST: Data reprocessing command. This function is enabled only at the end of working sessions. For patients re-run manually only the last result will be recalculated. The correction is made starting with the absorbance memorized for the single test.



Two types of data re-processing are possible. The first allows application of a percentage correction in increase or decrease. The second uses the last valid calibration as reference.

When recalculating the percentage or **Correction factor** (Fig. 6) a window is presented for selecting the test to recalculate, then by pressing the **Adjust** button, a mask appears for inserting the recalculation percentage (increase or decrease) and the type of sample to apply it to (routine, STAT and/or control). The maximum percentage allowed (both increase and decrease) is 50%. By clicking on **Accept** the analyzer will make the adjustment.

Figure 6

In the correction **With standard** the analyzer runs the recalculation starting from the absorbance memorized for the test, thus the various analytical parameters and the last valid calibration are taken into consideration. In this case, if the instrumental factor and shift have been set in the analytical parameters, they will be used in calculating the new value.

N.B.: If a recalculation result returns a value of 1,000,000 or higher, **<NC>**, not calculable will be shown instead of the result. If the returned result is negative, the **M** flag will be assigned: error in the parameters (instrumental factor and shift).

NB: In the correction With standard, **I.S.E. and Relation Tests results will not be recalculated.**

The **E** flag (recalculated value) will be assigned to all tests that undergo recalculation.

Use of the correction functions is only for operators authorized with a specific password (see chap. E, par. 1.7 Access Password).

ARCHIVE DATA saves all the data present on the page on the hard disk. After archiving, the data will be available, based on type, in the three external programs: Quality Control, Population and Patient archive. Archive data also includes the deletion of the data from the visualization pages (per patients and in real time) as well as reaction graphs. Therefore, it is a good idea to print any pertinent graphs before archiving data.

DELETE RESULTS deletes all the data from the visualization pages (per patients and in real time) as well as the page of reaction graphs. The data cannot be recovered.

EXIT: closes the page and returns to the main program, without modifying the data.

1.2. Results Per Test

Test ID	Result	Unit	Measurement	Normal Range	Flags
#51 0009629	<NC>	mg/dl	(3.50)	48.0 - 99.0	[+]
#52 0003772	8.46	UI/dl	(7.98)	40.0 - 114	[-]
#52 0004873	<NC>	mg/dl	(1.37)	22.0 - 54.0	[+]
#3 0005468	<NC>	UI/l	(6.79)	46.0 - 95.0	[+]
#7 CTRL9932	<NC>	UI/l	(3.87)	11.0 - 47.5	[+]
#51 0002675	63.9	mg/dl	(3.07)	13.0 - 72.5	[]
GLU (Glucosio)					
#52 0003772	<NC>	mg/L	(7.65)	13.0 - 35.5	[+]
#3 CTRL507	83.8	mg/L	(0.360)	13.0 - 67.5	[+]
#51 0002663	<NC>	mg/dl	(8.46)	52.0 - 135	[+]
#6 0006967	<NC>	mg/dl	(6.41)	56.0 - 108	[+]
#5 0004657	38.0	UI/dl	(4.96)	12.0 - 45.0	[]
#3 0005468	19.8	mg/L	(7.18)	13.0 - 35.5	[]
#7 CTRL9932	<NC>	UI/l	(1.25)	27.0 - 72.5	[+]
#51 0002675	<NC>	mg/dl	(7.71)	11.0 - 52.5	[+]
LIP (Lipasi)					
#52 0003772	2.22	UI/dl	(8.35)	30.0 - 87.0	[-]
#52 0009891	<NC>	mg/dl	(3.73)	18.0 - 74.0	[+]
#51 0002663	34.1	mg/L	(4.84)	32.0 - 74.0	[]
#6 0006967	67.8	UI/dl	(4.88)	24.0 - 56.0	[+]
#52 0003795	<NC>	mg/dl	(2.45)	47.0 - 130	[+]
#3 0005468	<NC>	mg/dl	(4.92)	10.0 - 42.0	[+]
#7 CTRL9932	<NC>	mg/dl	(9.95)	59.0 - 132	[+]
PRV					
#51 0009629	78.5	UI/l	(0.020)	57.0 - 137	[]
#52 0003772	22.6	mg/dl	(4.36)	29.0 - 92.5	[-]
#52 0009891	16.3	UI/l	(1.97)	14.0 - 78.0	[]
#51 0002663	8.54	UI/dl	(7.17)	34.0 - 96.0	[-]
#5 0004657	26.2	mg/dl	(8.97)	47.0 - 114	[-]
#52 0003795	<NC>	UI/dl	(5.42)	27.0 - 98.5	[+]
#2 0002725	<NC>	mg/dl	(9.73)	35.0 - 89.5	[+]
#3 0005468	49.2	mg/dl	(1.58)	34.0 - 106	[]
RAT					
#52 0003772	83.7	mg/L	(7.44)	12.0 - 77.0	[+]
#51 0002663	77.7	UI/dl	(1.16)	32.0 - 93.0	[]
#5 0004657	<NC>	UI/dl	(3.45)	36.0 - 101	[+]
#8 0004127	<NC>	mg/L	(3.38)	44.0 - 117	[+]
#3 0005468	<NC>	mg/dl	(9.77)	21.0 - 44.5	[+]
VED					
#51 0002663	<NC>	mg/dl	(3.70)	52.0 - 90.0	[+]
#6 0006967	72.1	mg/L	(0.390)	27.0 - 84.5	[]
#5 0004657	<NC>	mg/dl	(9.49)	51.0 - 95.5	[+]
#2 0002725	<NC>	UI/dl	(1.76)	48.0 - 106	[+]
#3 0005468	<NC>	UI/l	(4.18)	38.0 - 99.0	[+]
#7 CTRL9932	<NC>	UI/dl	(0.690)	54.0 - 113	[+]

Figure 7

After the end of programmed task, the results can be viewed per **Test**. The test Results display page is shown in **Figure 7**.

The following information is displayed for each single test:

- a) **Code and test name** The displayed code is the same read on the list of tests, while the full name between parenthesis is the one assigned by the operator in the analytical parameters (chap. C, par. 1.3.3.).
- b) **Sample Position (#XX)** Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.
- c) **Sample Code** For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.
- e) **Results** The results of test attributed to patients are represented with:
 - result
 - unit of measurement
 - absorbance read (between parenthesis)
 - range of normal values
 - any flags (between brackets – see also par. 1.5)

The following commands are available in the results display page:



PRINT: used to print the contents of the window. This is not a print-out in “report” format. A print preview will be displayed (Fig. 6) where it is possible to select which and how many pages to print.

EXIT: closes the page and returns to the main program, without modifying the data.

A window is also available on this page (**Info flag** button – see par. 1.1.) with information relative to the flags associated to the results.

PRINT-OUTS IN REPORT FORMAT

From the visualization pages mentioned in this chapter it is not possible to obtain print-outs for patients in report format. For more information on these type of print-outs, see chap. F par. 1.6 and chap. H, par. 2.).

1.3. Displaying Real-Time Data

Results					
#51 0003216	RAT	41.7	UI/dl (2.98)	47.0 - 83.5	[-]
#51 0003216	BID <Color>	55.1	mg/L (1.21)	44.0 - 82.0	[]
#51 0003216	Lipasi	66.3	mg/dl (4.11)	58.0 - 97.0	[]
#51 0003216	FAC	7.39	mg/L (7.88)	43.0 - 85.5	[-]
#51 0003216	PRV	62.6	UI/l (7.58)	29.0 - 72.5	[]
#51 0003216	Glicemia <XXX>	59.1	mg/L (3.70)	41.0 - 83.5	[]
#51 0003216	Bilirubina <Jundrassik>	24.7	UI/l (6.23)	59.0 - 147	[-]
#51 0003216	VED	54.7	UI/l (2.66)	41.0 - 94.5	[]
#51 0003216	Colesterolo <XXX>	41.5	mg/L (0.200)	40.0 - 112	[]
#51 0003216	Glucosio <XXX>	99.6	mg/L (8.22)	48.0 - 102	[]
#6 CTRL2011	BID <XXX>	57.3	UI/l (1.05)	38.0 - 106	[]
#6 CTRL2011					

Figure 8

This page can be accessed through the specific icon (fig. 1). The data shown (Figure 8) refer to the results obtained by the analyzer in real time, i.e. as the tests are completed. For this reason the results of tests with a shorter incubation and reading time may appear first even if they belong to later patients. The results are not sorted in any way, not per patient, not for type of test. When no data is present this page is empty. The data display is synthetic.

Once the results are archived, the information present in this page will no longer be available. The results of tests associated to flags are shown in red.

The following information are displayed for each single test:

- a) **Sample Position (#XX)** Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.
- b) **Sample Code** For Patients (Routine and STAT) it is assigned at check-in. For STD and Batch it is automatically assigned. It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph 1. “**Quality Controls**”).
- c) **Date and time** The date and time the test was run is between parenthesis.
- d) **Results** The results of test attributed to patients are represented with:

#1 0007685 (20.01.2006 09:36)						
VED	<Color>	<NC>	mg/dl (9.98)	33.0 - 77.5	[+]

#1 0007685 (20.01.2006 09:36)						
Colesterolo	<Color>	49.8	UI/dl (0.180)	40.0 - 106	[]

- full name of the analysis
 - execution method
 - result
 - unit of measurement
 - absorbance read (between parenthesis)
 - range of normal values
 - any flags (between brackets – see also par. 1.5)
- For automatic re-runs the values of the first and second determination are represented.

1.4. Reaction Graphs

This function can be accessed through the specific icon. It is used for displaying and eventually printing the graphs of the analyses. The page that opens displays the first available graph.

IMPORTANT: The graphic pages are available only after test runs and prior to data archival (par. 1.1.).

Graphs are divided into two parts by two dashed orthogonal axes. On the left part there is the incubation time graph, while on the right there is the reading time graph (Fig. 9).

On the right of the window, there are two frames containing the information concerning the absorbance determined during the two phases (incubation and reading times), Each division in the Time axis is approx 10secs.

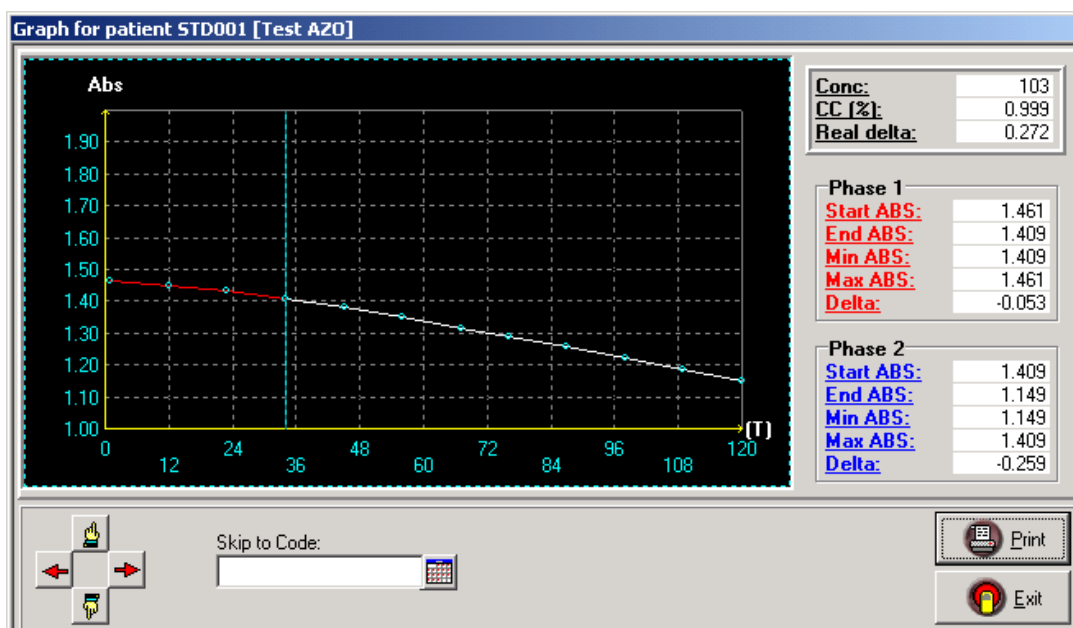
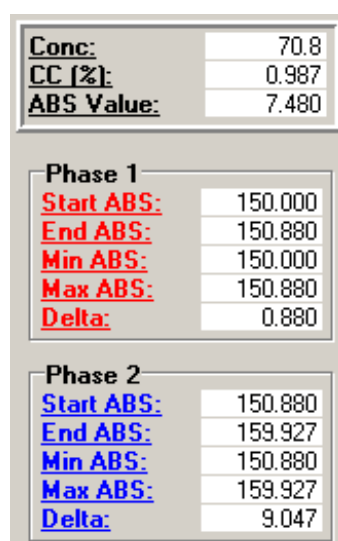


Figure 9



The following information is reported on the graph page (Fig. 9).

Conc: shows the test result.

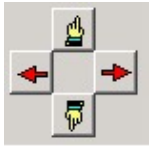
CC%: shows the correlation coefficient compared to the test regression rate.

ABS Value: shows the test absorbance value.

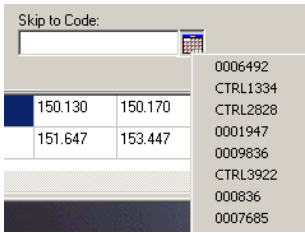
Phase1: corresponds to the incubation phase for almost all the tests, with the exception of tests in two phases (such as sample blank). It shows the absorbance data detected by the analyzer during the test: start, end, minimum and maximum absorbance and the delta between the start and end absorbance.

Phase 2: corresponds to the reading phase or the second phase. The rest of the information is the same as phase 1.

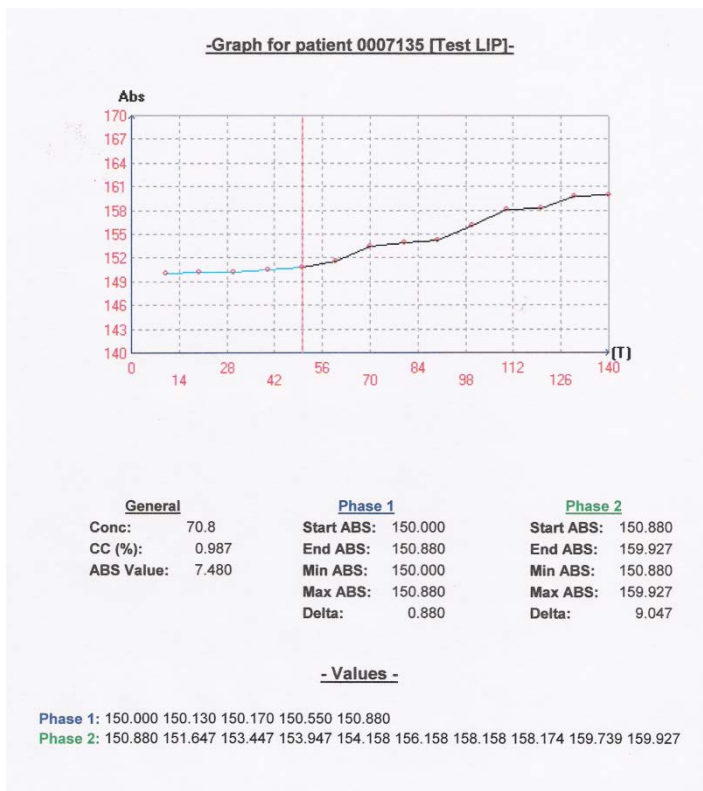
N.B.: The absorbance values read per single point in each phase are shown at the bottom, under the graph. This data can be exported into a file by pressing the **Export Values** button.



Using the up/down hand keys the user scrolls through different patients, while using left/right arrow keys, the different graphs for a single patient are shown (Figure 9).



By selecting an identification code, among the available in the “Skip to code” field, it is possible to go directly to the single patient.



Print: used to print the displayed graph. By accepting to print also the data, all the absorbances corresponding to the reading points will be printed, otherwise only the information in the first part of the graph will be printed.

<- Absorbances of single points.

EXIT: closes the page and returns to the main program.

1.5. Flags List

The analyzer uses flag symbols to properly check analyses result. These symbols are printed adjacent to the result.

The following priority exists for the flags indicating hyperactivity:

I (Test Limit),

A (Reaction Limit)

d (Max ABS Delta)

The flags and their meanings are tabulated below:

FLAG	MEANING
+	Pathological above range
-	Pathological below range
I	Hyperactive sample (Test Limit exceeded)
d	Hyperactive sample (Max. ABS Delta surpassed)
A	Hyperactive sample (Reaction Limit exceeded)
L	Sample below the reagent detection capability (below Low detection limit)
O	Reagent Out of Limit
!	Inverse Reaction
S	Serum missing
R	Reagent missing
r	Dilution reagent missing (for diluting samples)
~	Serum interference
P	Errors in Parameters
±	Unstable sample (C.C. % greater than assigned value)
>	Sample above Calibration curve
>>	Sample above Calibration curve after repetition
<	Sample below Calibration curve
<<	Sample below Calibration curve after repetition
	No Error: result to be accepted
?	Impossible to calculate Relation Test, due to missing data (no Serum or Reagent)
X	Error in Relation Test (negative result)
C	Probable Prozone Effect (Prozone Check value exceeded)
T	Result processing impossible: analysis is not resident on the tray
N	Reagent expired - result set to 0 (zero), if the barcode is used
E	The test result has been recalculated
M	Error in the parameters (instrumental factor and shift)
W	Either one or both of the additional washing solutions is missing
	Only when Clot detection is available/active
Z	Clot detection <ERROR> - A clot has been detected.
z	Clot detection <Warning> - Possible clot detected.
	Only for BT3500S
U	Wrong or missing urine ISE slope
w	ISE waste full

Note:

In report printing from patients' archive, all flags are replaced by the generic symbol * (asterisk).

In the patients archive active flags will be highlighted in red and will have the check in the corresponding box.



1.6. Sorting Results In Real Time

In the following chapter (chap.H), in the Setup section, it is explained how to get to the sorting page for the results in real time. It is possible to select the options as in the following picture.

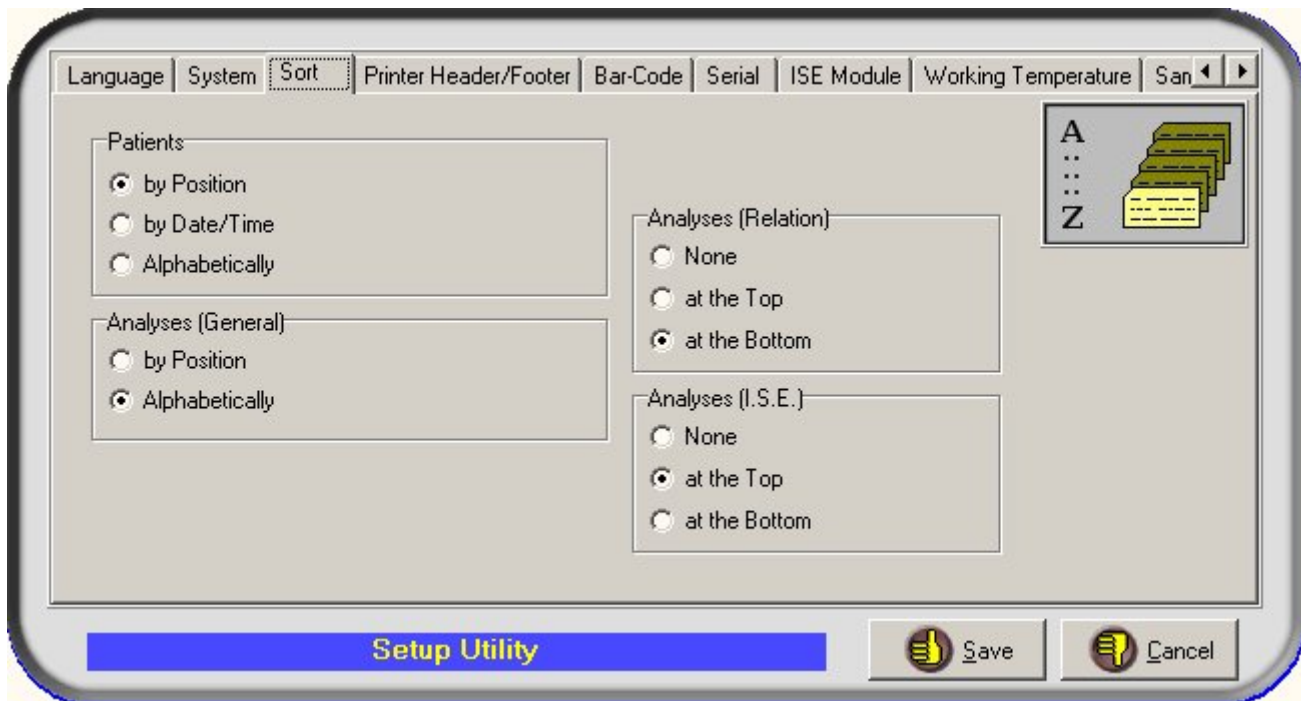


Figure 10

It is necessary first to select the desired options in the Setup and save. In the real time results page then, select the Sort button to arrange the results on the base of the selection performed in the Setup. The same arrangement will be performed both for the RT results and for the calibrations & controls dedicated pages.

Depending on the selection, the results in the real time page will be sorted as follows.

PATIENTS	ANALYSES	RELATION	I.S.E.	SORTED AS
BY POSITION	BY POSITION	None	None	ANALYSES – RELATION – I.S.E.
		At the bottom	None	ANALYSES – RELATION – I.S.E.
		None	At the bottom	ANALYSES – RELATION – I.S.E.
		At the bottom	At the bottom	ANALYSES – RELATION – I.S.E.
		At the top	At the top	I.S.E. – RELATION – ANALYSES
		At the top	At the bottom	RELATION – ANALYSES – I.S.E.
		At the top	None	RELATION – ANALYSES – I.S.E.
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION
		None	At the top	I.S.E. – ANALYSES – RELATION
	ALPHABETICALLY	None	None	ANALYSES, RELATION & I.S.E. all in alphabetical order
		At the bottom	None	ANALYSES and I.S.E. in alphabetical order - relation in alphabetical order
		None	At the bottom	ANALYSES and RELATION in alphabetical order – I.S.E.
		At the bottom	At the bottom	ANALYSES - RELATION – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	At the top	I.S.E. – RELATION – ANALYSES (ANALYSES & RELATION in alphabetical order)
		At the top	At the bottom	RELATION – ANALYSES – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	None	RELATION – ANALYSES & I.S.E. in alphabetical order
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION (ANALYSES & RELATION in alphabetical order)
		None	At the top	I.S.E. – ANALYSES & RELATION (ANALYSES & RELATION in alphabetical order)

Calibrations are sorted by position (on the tray), controls ran in the routine positions are listed before the controls ran from the dedicated positions.Both are sorted by position.

PATIENTS	ANALYSES	RELATION	I.S.E.	SORTED AS
BY DATE/HOUR	BY POSITION	None	None	ANALYSES – RELATION – I.S.E.
		At the bottom	None	ANALYSES – RELATION – I.S.E.
		None	At the bottom	ANALYSES – RELATION – I.S.E.
		At the bottom	At the bottom	ANALYSES – RELATION – I.S.E.
		At the top	At the top	I.S.E. – RELATION – ANALYSES
		At the top	At the bottom	RELATION – ANALYSES – I.S.E.
		At the top	None	RELATION – ANALYSES – I.S.E.
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION
		None	At the top	I.S.E. – ANALYSES – RELATION
	ALPHABETICALLY	None	None	ANALYSES, RELATION & I.S.E. in alphabetical order
		At the bottom	None	ANALYSES & I.S.E. in alphabetical order - RELATION in alphabetical order
		None	At the bottom	ANALYSES & RELATION in alphabetical order – I.S.E.
		At the bottom	At the bottom	ANALYSES - RELATION – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	At the top	I.S.E. – RELATION – ANALYSES (ANALYSES & RELATION in alphabetical order)
		At the top	At the bottom	RELATION – ANALYSES – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	None	RELATION – ANALYSES & I.S.E. in alphabetical order
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION (ANALYSES & RELATION in alphabetical order)
		None	At the top	I.S.E. – ANALYSES & RELATION (ANALYSES & RELATION in alphabetical order)

In the RT page, are listed: calibrations,- analyses – controls. Calibrations and controls are sorted by date/hour

PATIENTS	ANALYSES	RELATION	I.S.E.	SORTED AS
ALPHABETICALLY	BY POSITION	None	None	ANALYSES – RELATION – I.S.E.
		At the bottom	None	ANALYSES – RELATION – I.S.E.
		None	At the bottom	ANALYSES – RELATION – I.S.E.
		At the bottom	At the bottom	ANALYSES – RELATION – I.S.E.
		At the top	At the top	I.S.E. – RELATION – ANALYSES
		At the top	At the bottom	RELATION – ANALYSES – I.S.E.
		At the top	None	RELATION – ANALYSES – I.S.E.
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION
		None	At the top	I.S.E. – ANALYSES – RELATION
	ALPHABETICALLY	None	None	ANALYSES, RELATION & I.S.E. in alphabetical order
		At the bottom	None	ANALYSES & I.S.E. in alphabetical order – RELATION in alphabetical order
		None	At the bottom	ANALYSES & RELATION in alphabetical order – I.S.E.
		At the bottom	At the bottom	ANALYSES - RELATION – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	At the top	I.S.E. – RELATION – ANALYSES (ANALYSES & RELATION in alphabetical order)
		At the top	At the bottom	RELATION – ANALYSES – I.S.E. (ANALYSES & RELATION in alphabetical order)
		At the top	None	RELATION – ANALYSES & I.S.E. in alphabetical order
		At the bottom	At the top	I.S.E. – ANALYSES – RELATION (ANALYSES & RELATION in alphabetical order)
		None	At the top	I.S.E. – ANALYSES & RELATION (ANALYSES & RELATION in alphabetical order)

In the RT page, are listed: calibrations,- analyses – controls. Calibrations and controls are sorted alphabetically .

SECTION I: GENERAL INFORMATION

CHAPTER H: ANALYZER TECHNICAL FUNCTIONS/SETUP

1. ANALYZER TECHNICAL FUNCTIONS.....	2
1.1. Service Functions.....	2
1.1.1. Analyzer Utilities	2
1.1.2. Mechanical Calibrations.....	4
1.2. Diagnostic Functions	6
2. ANALYZER SETUP	10

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

1. ANALYZER TECHNICAL FUNCTIONS

1.1. Service Functions

The analyzer has dedicated commands to allow **Service** and **Diagnostic** operations. The **Service** functions are divided into **Analyzer Utilities** and **Mechanical Calibrations**.

These functions are accessed from Analyzer’s main menu or through the appropriate direct access icons.

The commands are available in the form of buttons. To access a function just push a button.

The **Exit** button on both pages closes the window and saves any settings.

The **Analyzer Utilities** include items (FCC Calculation, Lamp Setup, Temperature Test and Empty Fluidics) normally dedicated to technical assistance personnel. These functions should not be used unless they have been suggested by qualified personnel. Just like for the other parts of the program or analyzer, these functions must be used according to the intended use established by the manufacturer, failure to do so will result in warranty invalidation.

1.1.1. Analyzer Utilities



Direct Access Icon

Figure 1

To activate any of the following commands click on the corresponding button (**Figure 1**):

Wash with water: washes, with the system solution (bidistilled water and surfactant) the cuvettes and leaves them filled with system solution. This function is recommended when a work session has ended and the analyzer is not going to be used again immediately. However, after 20 minutes of inactivity, the analyzer goes into standby and automatically washes the cuvettes.

Wash cuvettes: is used for complete washing of the needles and reading cuvettes. Once the command is given, a guiding message appears asking to insert the bottle (50ml bottle in pos. 24 for BT1500 – 50ml bottle in pos. 40 for BT3000 Plus and BT3500/BT3500S) containing the dedicated solution in the indicated position. The analyzer will wash the cuvettes with system solution, then will fill them with the proper solution (from the reagents tray) and will leave the solution in the cuvettes. This function must be used at the end of the day if the analyzer is not turned off. The shut-down procedure (guided washing function at the shut-down) uses the same washing procedure already explained. See also Chapter B, par. 1.3.3. for the solutions description and Section II, Chapter 3 for ordering information.

Extra wash cuvettes: is used for complete washing of the needles and reading cuvettes with two dedicated solutions: one basic and one acid. Once the command is given, a guided procedure appears asking to insert the bottles in the indicated positions (for BT1500: acid solution in a 50ml bottle in pos. 23 and basic solution in a 50ml bottle in pos. 24; for BT3000 Plus and BT3500/BT3500S: acid solution in a 50ml bottle in pos. 39 and basic solution in a 50ml bottle in pos. 40). The analyzer will wash the cuvettes with system solution, then will fill them with the proper solutions (from the reagents tray, basic solution first, followed by a wash cycle with system solution and then acid solution). At the end the analyzer will fill the cuvettes with system solution and will leave it in the cuvettes.

This wash is necessary at least once a week or if the analyzer returns inconsistent results for no apparent reason. This wash will reset the Diagnostic page maintenance counter. See also Chapter B, par. 1.3.3. for the solutions description and Section II, Chapter 3 for ordering information.

Dilutor prime: Performs a filling-up cycle with system solution of the hydraulic circuit and sampling system.

I.S.E. module prime: Fills up the fluidic circuit of the I.S.E. module (where available).

Extra wash I.S.E. Module: see Chapter L, par. 1.3. For BT3500S, see chapter L1, par. 1.4.

For all I.S.E. functions refer to the dedicated chapters. For 1500 I.S.E., refer to chapter L.

Zeroing on water: Performs photometer zeroing with system solution. This procedure can be performed either on request or automatically. In this second case, when the zeroing time has elapsed the analyzer will propose a message on the screen requesting zeroing.

When the analyzer is first turned on each day, it waits for the reaching of the steady state (stabilization of the Peltier temperature and lamp), then it requests the photometer zeroing. It is important to remember that zeroing is necessary to avoid any drift of the photometer zero.

Check volumes: The analyzer checks the volumes of reagents present in the reagent tray. These volumes are updated in the corresponding window **Reagents status** for the reagents insertion procedure (**F10** key).

Volumes calibration: used to allow the analyzer to create references used as a basis for determining the volume of reagents in the bottles and serum holder cups. A message will appear to guide the operator. Follow the instructions and place the empty containers in the correct positions. The bottles/cups are automatically filled with system solution according to an internal procedure.

F.C.C. calculation: This procedure is for calculating the optical correction factor for the reading cuvettes. A screen message invites to insert a bottle with appropriate solution (supplied by Biotecnica – ask the Technical Assistance Service) into the reagents tray. Generally this solution has an absorbance in the range between 0.500 and 1.0 Abs (read at 340 - 700nm). The analyzer guides the user through the procedure. This function is password protected.

It is performed only when one or more cuvettes are replaced or after a thorough service is performed on the instrument computer (e.g. hard disk substitution) where correction factors may be lost.

Lamp Setup: this function is only necessary after the photometric lamp has been changed. It is used to align the new lamp to preset internal values. It also carries out photometer zeroing at the same time. It is advisable that only technical assistance personnel use this function.

Temperature test: Verifies thermostatic temperature of the reading cuvettes plate. For a correct measurement it is important that the thermometer of low temperature absorbance (miniature probe tip) is used. The measurement cuvette should be filled with 300 to 400µl of system solution (between 200µl and 300µl for BT1500 & BT3500/BT3500S). It is also important that the measurements are taken approximately 20 minutes after the instrument has reached the steady state.

Empty Fluidics: This command completely empties the fluidic circuit. It is to be used exclusively as preliminary operation for maintenance or eventual moving of the instrument.

NOTE: if one of the analyzer functions is active, remember not to make modifications in the Setup program. This will cause a reset of the analyzer thus terminating the activated function.

1.1.2. Mechanical Calibrations

This function allows mechanical centering and adjustments for the different positions of the sampling arm, cuvettes plate, sample plate and reagents tray. Bear in mind that the analyzers are already factory-calibrated and a new adjustment is seldom necessary. To perform calibrations, move the mouse cursor on the desired function and click to confirm: the [-] Dec. and [+] Inc. command keys will be enabled on the screen, which determine the movement of the selected object either clockwise or counterclockwise, step by step. The [*] Test key lowers and lifts the sampling needle or the wash piston to check centering.

NOTE:

It is highly recommended to calibrate the trays (Sample/Reagent/Cuvette) first and then the positions of sampling arm. In addition the sampling needle must be centered on the required positions.



Figure 2

The **Calibrations** menu is subdivided into three columns: **Clinical Chemistry Arm, I.S.E. Arm and Tray** as shown in **Figure 2**.

NOTE: bear in mind that only BT3000 Plus and BT3500/BT3500S systems have two diluters and two sampling arms. The the I.S.E. Module is present in the previously mentioned analyzers and in the BT1500 as optional.

The following commands are available:



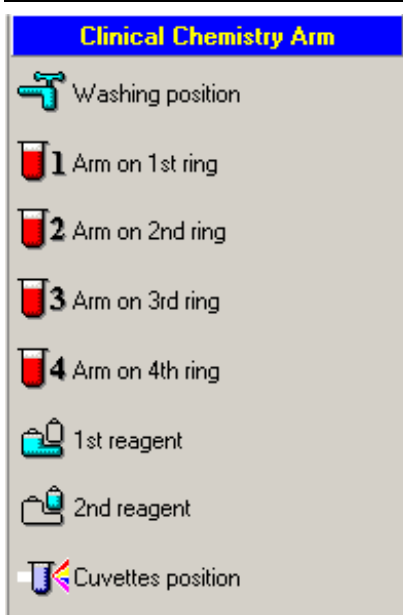
TRAY

Sample tray: centers the tray so that the arm is centered on the first position of the serum tray.

Reagents tray: It is recommended to insert a large reagent bottle matched with small bottle into position #4 prior to the calibration. By activating this command the reagents tray moves and puts position #4 below the hole for the first reagent. Center the bottle for the first reagent in this position. It is suggested to check also the position for the second reagent.

Cuvettes tray: The washing piston must be centered on the cuvette. Check correct centering through the piston up/down movement using the command (*) **Test**.

CLINICAL CHEMISTRY ARM



Washing position: Arm remains on the washing position upon which it must be centered.

Arm on 1st ring: The sampling arm moves to position #1 of the 1st ring (outer circle). Insert an empty cup into the tray to better observe the position. Center the sampling needle on the cup using the needle lower function [*] **Test** to better visualize the position.

Arm on 2nd ring: The sampling arm moves to the first position of the 2nd ring.

Arm on 3rd ring: The sampling arm moves to the first position of the 3rd ring.

Arm on 4th ring: The sampling arm moves to the first position of the 4th ring.

Note: the first position for each ring is: #1, #27, #1 & #14 for BT3000 Plus. It is: #1, #27, #53 & #4 for BT1500 and BT3500/BT3500S

1st reagent: the sampling arm moves to the appropriate hole on the instrument's top for accessing 1st reagent. Before starting the calibration a big bottle matched with a small one must be inserted in position n° 4. Center the sampling needle on the neck of the bottle.

2nd reagent: The sampling arm moves to the position for the second reagent corresponding to the appropriate hole for accessing small reagent bottle on the instrument's top. It is recommended to calibrate the reagent tray prior to calibrating the sampling arm.

Cuvettes position: The sampling arm moves over cuvettes tray. The sampling needle must be centered on the cuvette.

ISE ARM

The first five items and the **Cuvettes position (I.S.E.)** are the same as the corresponding button of the Clinical Chemistry Arm, see them for more information.

Arm on diluent: centers the I.S.E. arm above the tube containing the physiological solution for diluting the samples.

Arm on funnel: the I.S.E. arm moves above the I.S.E. mixing funnel. Center the sampling needle at the hole at the bottom of the funnel. It is very important that the needle is centered in this position to prevent it from touching the funnel walls during mixing.

For more info, see chapter L, par. 1.4 and for BT3500S see chapter L1.

1.2. Diagnostic Functions

Diagnostic pages are accessible only from Analyzer's main menu (**Fig. 3**). The **Diagnostic** functions are partially reserved for approved service personnel only. Therefore the access to some of the functions is password protected.

It contains the following options: **Show F.C.C.**, **Show Optical Transmission**, **Show Diagnostic** and **General Diagnostic**.

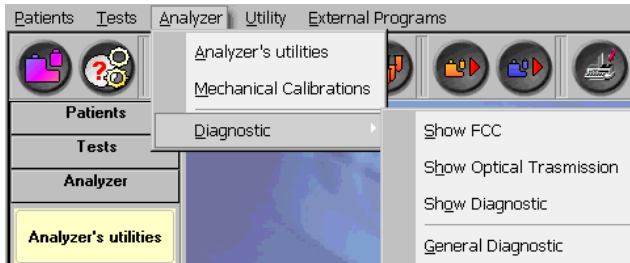


Figure 3

Show F.C.C.: It shows the optical correction factor calculated for all the reading cuvettes. For each cuvette, the mABS and the F.C.C. values (**Figure 4**) are reported. It also indicates the cuvettes with correction factor exceeding the preset limits ($\pm 3\%$). It is possible to print this page.

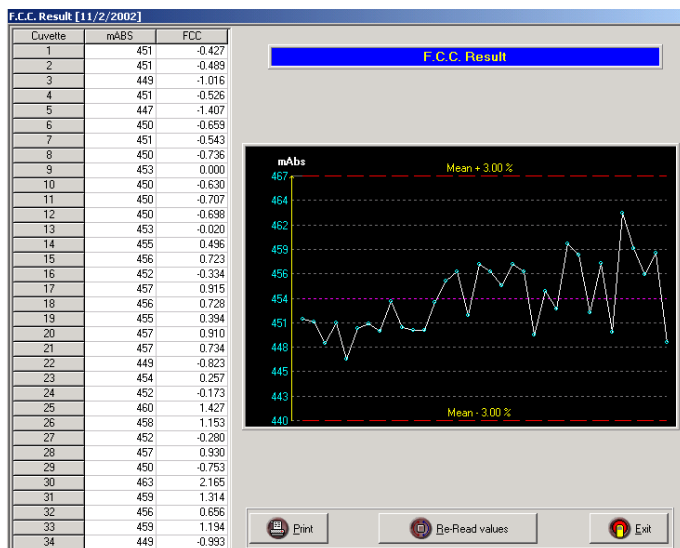


Figure 4

Cuvette	Percentage	Out
1	100.0	
2	100.0	
3	100.0	
4	100.0	
5	100.0	
6	100.0	
7	100.0	
8	100.0	
9	100.0	
10	100.0	
11	100.0	
12	100.0	
13	100.0	
14	100.0	
15	100.0	
16	100.0	
17	100.0	
18	100.0	
19	100.0	
20	100.0	
21	100.0	
22	100.0	
23	100.0	
24	100.0	
25	100.0	
26	100.0	
27	100.0	
28	100.0	
29	100.0	
30	100.0	
31	100.0	

Figure 5

Show Optical Transmission: After each photometric zeroing, it indicates the percentage transparency of the cuvettes. The cuvettes with poor transparency are highlighted (Figure 5). If the optical transmission of a cuvette falls below a specific percentage (40% less than the mean of the calculated O.T.), the analyzer will eliminate it and will work with one less cuvette. If it becomes necessary to eliminate four or more cuvettes, the analyzer generates an alarm and will not allow work to continue. It is possible to continue to work with three damaged cuvettes.

Optical transmission of the cuvettes tends to decrease due to a series of factors, including lamp performance, opaque cuvettes etc.

Show Diagnostic: it shows the status of the various parts of the system that should be replaced regularly. This page shows the consumable parts, life cycles, remaining cycles and the possible replacement date (Figure 6). When at the analyzer start up, the message **There are the following obligations in diagnostic**, appears, it means that the indicated item has to be replaced or an action has to be undertaken. In the **Show Diagnostic** page there will be one or more red lines corresponding to the parts needing replacement (refer to **Chapter N**). Once the required maintenance has been performed, reset the internal counters of the analyzer, by clicking on the single voice described in the table on the right side.

Based on how the analyzer is used, the cycles may come to an end before the dates or vice versa. However, the maintenance requested by the analyzer should be carried out, even if the actual workload has been light. This guarantees perfect operation of the analyzer. If the analyzer has not been used for some time, it is advisable to replace the tube kits and possibly the seals, since they can deteriorate even if not used.

Phase	Life cycles	Remaining cycles	Replacement date
Kit: Tubes and Peristaltic Pump	150000	150000	7/15/2010
Kit: Tubes ISE Module			7/15/2010
Extra wash cuvettes			7/2/2009
I.S.E. Peristaltic Pumps	150000	150000	7/15/2010
I.S.E. Sensors: Cl, Li			10/15/2009
I.S.E. Sensors: K			1/15/2010
I.S.E. Sensors: Na, Ref			7/15/2010
Photometric Lamp (hours)	1500	1500	
Dilutor's Piston Seal	300000	300000	7/15/2010

Figure 6

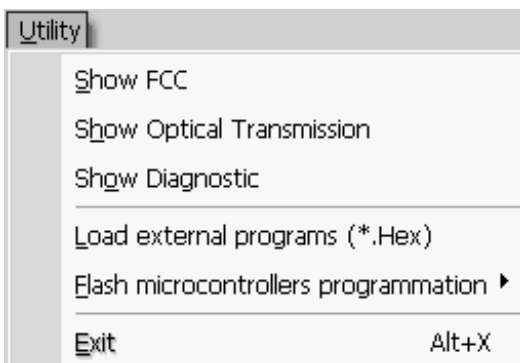
ATTENTION: the maintenance page shown in figure 6 is only an example. Check the consumable parts mentioned in the analyzer program, the cycles and replacement dates on the analyzer. Bear in mind that the replacement dates indicated on the maintenance page are a guideline as they are calculated on an average work day that may not reflect the needs of each lab.

General Diagnostic: This function is reserved for the Technical Assistance personnel for diagnosing problems that cause analyzer malfunction. There is free access to most of this program. However, the use of this program without the proper supervision of approved technical personnel, is under user's responsibility. Therefore it is highly recommended that the operator is assisted by the specialized technical personnel when using this program.

This page verifies the operation of the following devices and the operating phases:

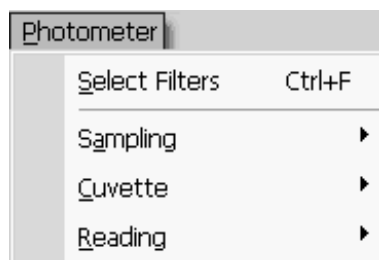
- 1) Photometer stability and operation.
- 2) Hydraulic functions: sampling, washing, and emptying of cuvettes.
- 3) ISE Module operation (where available).
- 4) Barcode operation and programming.
- 5) Stress program.

The **Diagnostic** page has four menus.



Utility: contains the same items previously explained at the beginning of the paragraph, plus the **Exit** command to close the diagnostic program.

Load external programs and Flash microcontroller programming are options dedicated only to the Technical Assistance personnel, and may not appear at all in the menu.



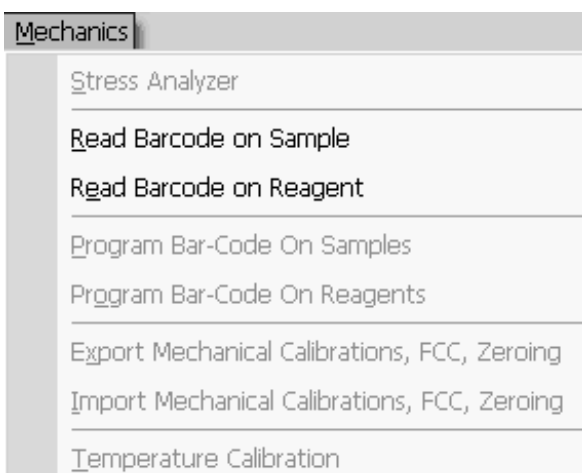
Photometer: is used to check the sampling and the readings executed by the photometer.

Select filters: used to select the filters for executing the reading.

Sampling: used to select whether to run a normal sampling or to use the serum as starter.

Cuvette: used to empty or fill a cuvette as selected by the operator. It runs a wash and fill cycle for the cuvettes.

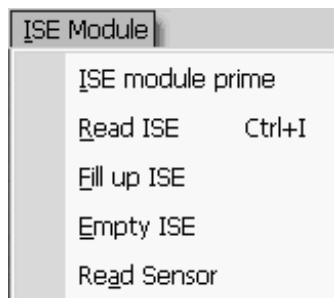
Reading: used for reading the zero on filters, zeroing on water and reading (in mV and mAbs) of the contents of the cuvettes.



Mechanics: the items in this menu are not available. All the commands are only available with third level access (Technical Assistance). Only read barcode on reagent and serum is available to operators.

Export / Import Mechanical Calibrations: the calibrations in the Diagnostic section can now be exported into a support different from the floppy.

Only for BT3000 Plus, BT3500/BT3500S and BT1500 with I.S.E.



I.S.E. Module: all the items in this menu are available. It is possible to run the I.S.E. module prime, read channels in mV, fill up I.S.E. hydraulic circuit with reference solution, empty I.S.E. and read the bubble sensor.

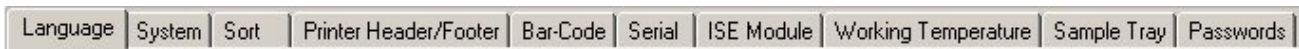
It is not advisable to use the commands in the **Diagnostic** program without the assistance of qualified personnel.

2. ANALYZER SETUP

This command is used for entering additional information on the various controls of the system. It can be accessed through the **Utility** ⇒ **Setup Analyzer** in the main menu. It is disabled during working sessions of the analyzer.

NOTE: if one of the analyzer functions is active, remember not to make modifications in the Setup program. This will cause a reset of the analyzer thus terminating the activated function.

By clicking on the **Setup Analyzer** command a screen displays various programmable items. Point the cursor on the desired title and click to confirm. After setup is done, click **Save** to save changes or **Cancel** to leave the program without saving (bear in mind that setup is an external program and must be closed once changes are made). It is highly recommended that operations in the setup program are performed by specialized personnel. It is advisable to keep track of the modifications made to the setup and the effects they can have on analyzer operation to avoid problems later on.



LANGUAGE: on this page (**Figure 7**) it is possible to select the language (for example English or Italian) from those available.

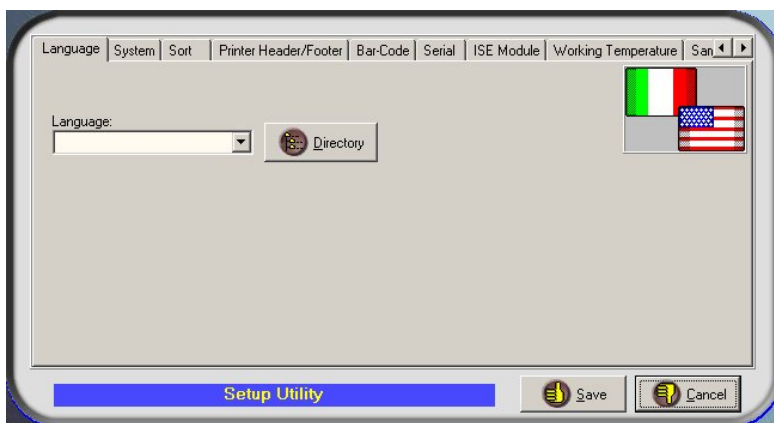
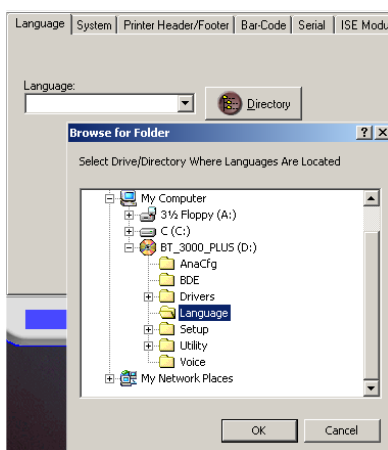


Figure 7

If there are no languages on the list they need to be installed. To view all the available languages, insert the installation disk of the operating program in the CD reader, then press the **Browse the Folder** button and browse the disk contents until finding the Language folder and click on **OK** (fig. 7-1).



The Setup program will load the languages in an internal directory of the analyzer, then it will be possible to select the desired language from those available in the scroll box.

Figure 7-1

SYSTEM: In this page it is possible to modify the following options (**Figure 8**):

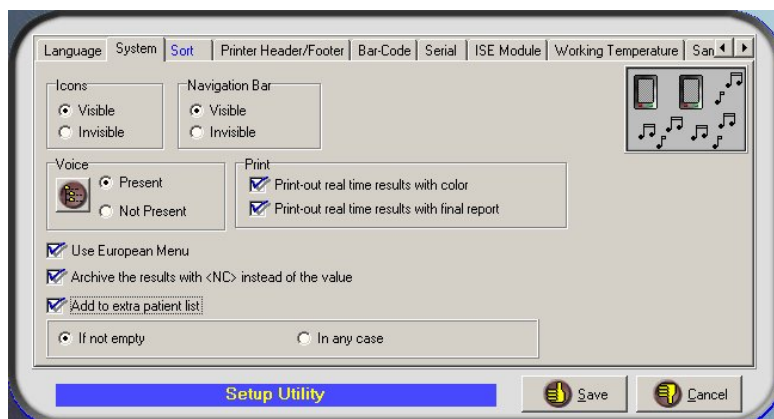


Figure 8

Icons: It enables or disables the displaying of the icons on top of the screen.

Navigation Bar: It enables or disables the displaying of the navigation bar on the left side of the screen.

Voice: it enables or disables vocal function (vocal messages). By clicking on the icon a mask appears for selecting and controlling the audio (reproduction speed and volume).

Use European Menu: If disabled, it changes the menu bar as well as the operating functions from European mode to the ones exclusively dedicated to USA mode.

NOTE: The USA operating modes are not outlined in the present manual.

Print-out real time results with color: When enabled, the real time print-out will be in colors, otherwise it will be in black and white. Bear in mind that in this way, the identification at glance of results associated to flags in printouts is lost, as they are normally printed in red.

Print-out real time results with final report: When enabled, it provides test results per patient in real time print-out in report format. However, remember that if it is necessary to execute a re-run, a new print-out would be obtained. This option may be costly in terms of paper and may cause confusion as there may be several reports printed for the same sample.

Archive the results with <NC> instead of the value: used to archive all the results, including those marked as not calculable in the Patient Archive. If this is not enabled, the results marked with <NC> will not be archived and they will be left on the work list to allow for re-running them (see Ch. G, par. 1. and Ch. F, par. 3.2.)

Add to extra patient list: during the patient programming phase in Routine, it is possible to have the analyzer memorize the patients directly on the extra patients list, instead of the normal work list (see Ch. E, par. 1.5. Work lists). This option is divided into: **If not empty** and **In any case**. In the first case, the patients are saved in the additional list only if it contains at least one other patient. **In any case:** the patients are saved directly on the extra patients list.

N.B.: The patients are transferred to the extra patients list only if the acquisition is via the **New Entry** button, and not by clicking directly on a free position on the sample tray (see Ch. E, par. 1.4.).

This option may be useful in cases where all patients are being programmed, before actually receiving the samples. As the samples are received the patients are moved from the extra patients list to the routine list and the work is started.

SORT: allows the operator to select the way to arrange the results in the real time results page. Select the desired combination of options and save. See also chapter G, par. 1.6.

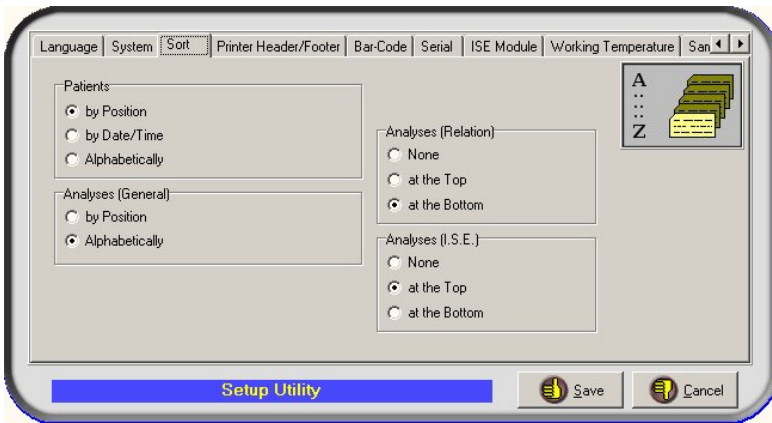


Figure 9

PRINTER HEADER/FOOTER: Customizes the printouts generated by the analyzer in the **Patient Archive, Population** and Quality Control Utilities (Figure 10). Two editable fields are displayed for programming of **HEADER & FOOTER**. Characters can be formatted (**B** for bold, **U** for underline, **I** for italic) as needed. Text format, font type, size and text color are also available. To print a test page click **Test** button.

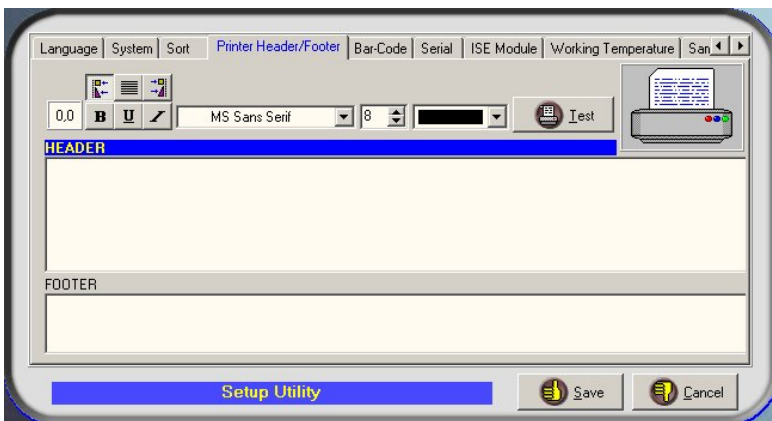


Figure 10

BAR-CODE: Enables bar-code scanning option (**Figure 11**). Confirm **Present** to enable it or **Not Present** to disable it. With bar-code enabled, further options are: **On Samples** and **On Reagents** (or just one of the two). The bar-code is optional on the BT1500.

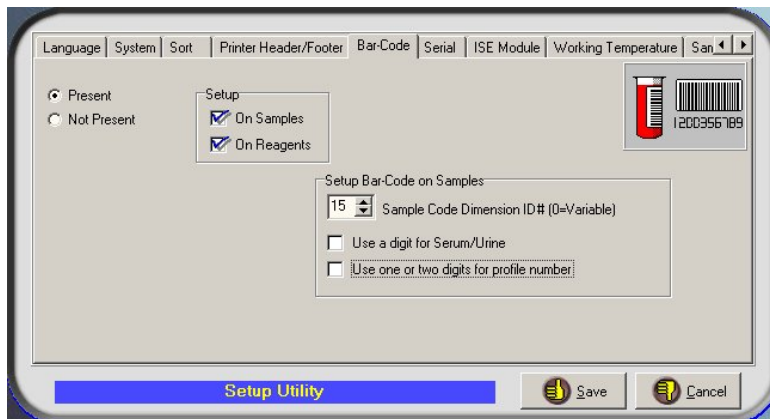


Figure 11

Setup Bar-code on Samples: This function customizes the contents of the patient code reported on the bar-coded label.

Dimension Sample Code: This field is used to define the number of characters dedicated to the patient code. If set to zero, the code length is variable (codes with a number of characters between 1 and 13 are accepted automatically). If as an example 10 is entered, then the patient code must have ten characters.

Use a digit for Serum/Urine: If enabled it is possible to use one character to automatically identify the type of sample (Serum/Urine) undergoing test.

Use one or two digits for profile number: When enabled it is possible to use one or two characters to identify automatically the profile number assigned during profiles programming (refer to **Chapter C**, paragraph 1.6., **Creating Profiles**).

SERIAL: Enables communication with host computer (**Figure 12**).

Two communication ways are available: the **RS232** standard or the **TCP/IP**. Both use the same communication protocol (internal or variable), with the same control characters (STX, ACK, EOT).

NOTE: for analyzers with external PC: only if the OS is Windows10, when changing from TCP/IP to Serial or vice-versa, it is advisable to turn the PC and the analyzer OFF and ON again to avoid possible problems with the OS.

Check **Present** to enable or **Not Present** to disable. Once the communication port is enabled, the **Parameters** functions will be enabled too.

Select the type of communication between Serial and TCP/IP.

TCP/IP Protocol: the default communication port is 8888. It can be set (by the technical assistance personnel with their password) in the setup. If the communication port is changed, it will be necessary to turn the analyzer (or the external PC) off and then on to activate the new port.

The TCP/IP protocol version used is version 4 (not version 6)

In the installation disk there are two programs (under the directory Utility) that can be used for testing the TCP/IP communication. One is TestTCPIP.exe and works under Windows, the other is TCPIPHost.exe and simulates a host computer under Windows.

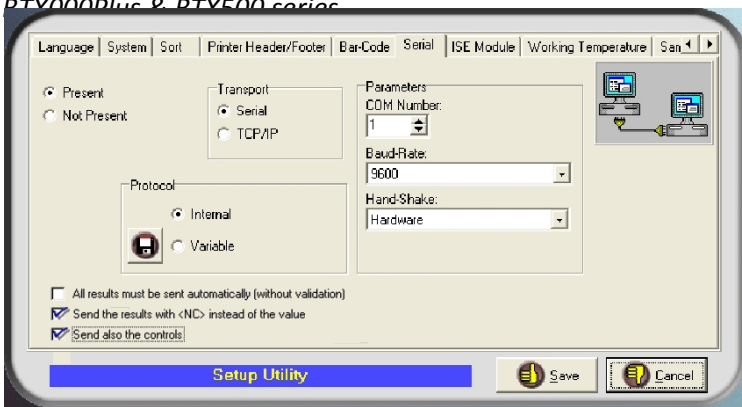
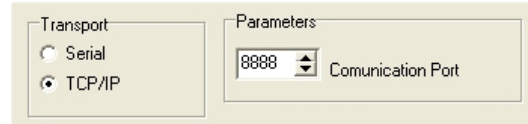


Figure 12



Serial: COM Number: Sets the serial port number (for example COM 1, COM 2 etc.)

Baud-Rate: Sets data transmission speed between the analyzer and the host computer. Click ▼ to view all the possible transmission speeds. To select, click on the desired value.

Hand-Shake: Enables Data Flow Control to be used during data transmission. Click ▼ to view the available options. To select, click on the desired option.

Protocol: it is possible to use the internal communication protocol or a variable protocol. When choosing the variable protocol, it will be possible to set the protocol options by clicking on the dedicated icon. Only expert operators should set the variable protocol (see **Chapter 4, Section II, paragraph 4.2**).

All results must be sent automatically (without validation): When this option is enabled, all results from the analyzer are sent automatically and immediately to the host computer. If the option is not enabled, then the operator decides when to send the data (see **Chapter C, paragraph 1.1. Description of the program Menu**). Analyzer will display the following options for sending patients to the host computer: accept results to be sent or delete results to be sent (see **Chapter. E, paragraph 1.5. WORK LISTS**).

Send the results with <NC> instead of the value: by selecting this option the non-calculable results will also be sent to the Host Computer, if the option is not enabled the <NC> results will not be sent to the Host Computer and will be deleted. In this case the <NC> results that are not archived and are on the work lists can be run again by the analyzer and if there are valid results, they will then be sent to the Host computer.

Send also the controls: with this option also the quality controls will be sent to the host computer by means of the communication.

I.S.E. MODULE: Only available in BT3000 Plus, BT3500/BT3500S and BT1500 with I.S.E.. Activates the ISE module (**Figure 13**). Check Present to activate or Not Present to deactivate. When the ISE module is disabled, all relevant menu options will be disabled too or not visible at all.

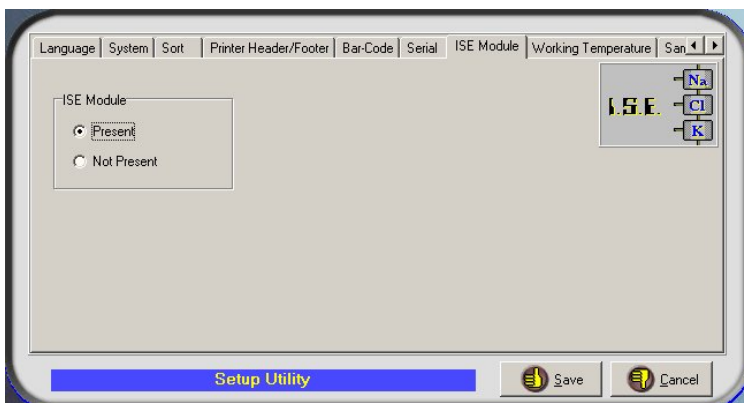


Figure 13

WORKING TEMPERATURE: Sets working temperature for reading cuvettes and activates the refrigerator for the reagents. Click to select the desired temperature among the available (**Figure 14**).

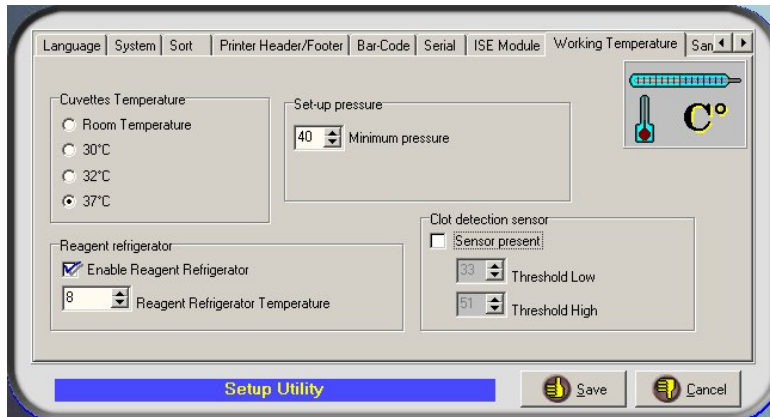


Figure 14

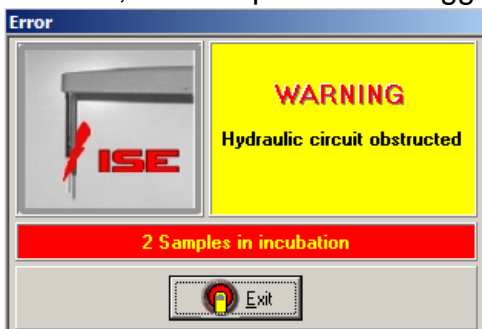
- Room Temperature
- 30°C
- 32°C
- 37°C

By selecting **Room temperature** bear in mind that when this is very high the temperature of the solution in the cuvettes will be high as well. The same thing is true even if the selected temperature is **37°C**, but the room temperature is 40°C, for example. The heating elements of the cuvette tray are able to heat but not cool if the room temperature is higher than the programmed temperature.

Enable Reagent Refrigerator: If not selected, it excludes the reagent refrigeration.

Clot detection sensor: Only available in **BT3500/BT3500S**. The clot detection sensor is used to verify whether there are total or partial occlusions in the sampling needle, due to proteins or else. It can be enabled or disabled. There are two thresholds, one high and one low, which values are set by default for the normal working conditions encountered in labs. It is possible to modify these values in case the used samples show, for instance, a higher density and therefore the system gives continuous errors.

If a clot is detected and the sampling arm is obstructed, the sampling for that patient is aborted, the sample will be flagged with the Z flag: Clot detection <ERROR>. The analyzer



then goes into the washing well and performs a prime to verify that the clot has been washed away. If yes it goes ahead with the sampling of the next patient, if not, it gives a fatal error. The Clot fatal error is a fatal error that prevents the analyzer from proceeding with its normal work. The samples already fully dispensed and in incubation will be completed (as happens with the Low pressure or No water alarms): a countdown will appear to show how many samples are in incubation. By pressing 'Exit' before the countdown has reached

zero, the remaining samples in incubation will be lost.

To avoid the peristaltic pump generated pressure to possibly damage the clot sensor, following a clot, the needle will go into the washing well, then the analyzer will verify that the sensor isn't saturated. In case of saturated sensor, a fatal error will be given, to prevent the pump from rotating.

A warning message of probable needle occlusion or hydraulic error will be given too. At the following reset, the error condition will be deleted, but the base reading of the sensor will give again the error if the obstruction is not removed. In this case a new warning will be given stating the sensor is defective and it will be deactivated ('Clot sensor does not work. The sensor will be disabled ...!'). Perform 4/5 diluter primes to remove the clot from the needle, then run a false patient using distilled water as sample to verify that the clot is not present anymore. If the washing procedure has not been enough to clean the needle from the clot, it will be necessary to unscrew the needle and clean it mechanically with the Cleaning tool for arm needle (see also Chapt. N, par 1.2.1. Clinical Chemistry).

If there is a possible obstruction of the sampling arm, the analyzer will go ahead sampling, but the results for that will be flagged with the z flag: Clot detection <Warning>

The clot sensor also detects malfunctioning of the hydraulic circuit, including bubbles and detached tubes that cause a sudden drop in the hydraulic circuit pressure. In case this happens, the analyzer will immediately stop working and will display a proper warning message (Error on Arm hydraulic circuit...!)

Once an air bubble has entered into the hydraulic circuit, there is no way to fill the hydraulic circuit again without having the error message. It will be necessary to disable the clot sensor and perform some diluter prime or to turn the analyzer off and on again.

SAMPLES' TRAY: Customizes samples' tray (**Figure 15**). Here it is possible to change the number of positions dedicated to the samples of **Routine**, **STAT**, **Standards** and **Controls**.

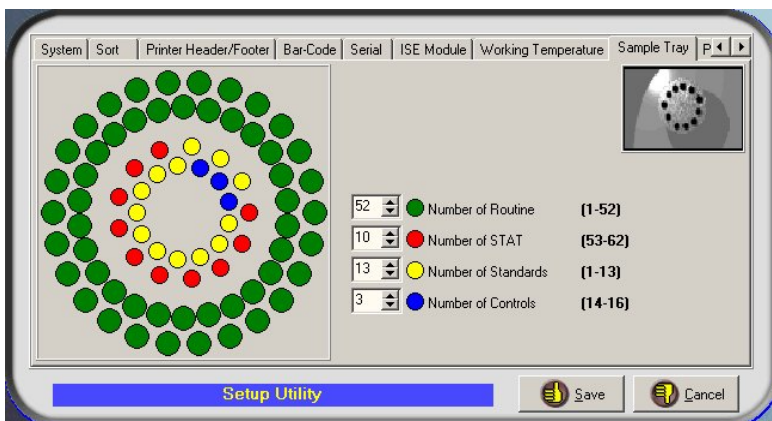


Figure 15

Customizes samples' tray (**Figure 15**). Here it is possible to change the number of positions dedicated to the samples of **Routine**, **STAT**, **Standards** and **Controls**.

Routine and STAT positions are included in the two outermost rings with progressive numeration from **1 to 52**. Standard and Controls positions are in the innermost rings with progressive numeration from **1 to 26**. It is not possible to exclude one typology to advantage of the other one. The minimum number of assignable positions is **1** for the Routine, STAT and Standards; and **3** for the Controls.

Click up/down arrows to increase/decrease the number of dedicated positions, or write the desired number into the textbox. The analyzer will automatically upgrade the positions for the second item of the pair every time the first one is changed.

Only for BT1500 & BT3500/BT3500S: Routine and STAT samples share the dedicated positions from number **1 to 62**. The two outermost rings with progressive numeration from 1 to 52 allow placing of primary tubes or cups. The positions from 53 to 61 will allow only cups. Standard and Controls shared positions are in the innermost rings with progressive numeration from **1 to 16** and allow placing of cups only.

PASSWORDS: on this page (**Figure 16**) it is possible to insert new passwords instead of the internal system ones. It is not advisable to change these passwords, since if they are forgotten or lost it will no longer be possible to access the system.

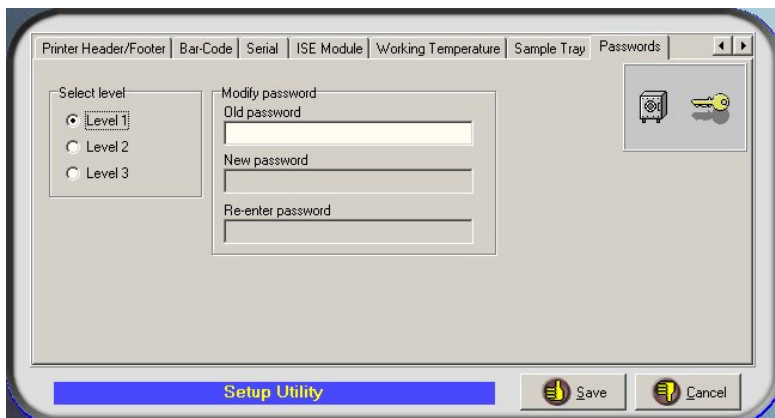


Figure 16

ATTENTION: when writing any of the passwords in one of the three appropriate field, it is necessary to confirm it by pressing Enter. This will also enable the following writing field. If the procedure is correct, the analyzer will display a message confirming that the password has been changed.

SECTION I: GENERAL INFORMATION

CHAPTER I: BAR-CODE & RELATED FUNCTIONS

1. BAR-CODE AND RELATED FUNCTIONS.....	2
2. USING THE BAR-CODE.....	2
2.1. Barcode On Samples	2
2.2 Reagent Barcode.....	5

NOTE:

**All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.**

1. BAR-CODE AND RELATED FUNCTIONS

The software for the analyzer allows independent enabling (and disabling) for bar-code scanning on Samples and Reagents (refer to **Chapter H**, paragraph 2. “**Analyzer Setup**”). The enabling of barcode scanning on samples visualizes specific commands in the program (refer to **Chapter E**, paragraph 1.5. “**Work Lists**”).

The analyzer uses as format a numeric code of max 13 digits (for example EAN 13). If the used format has a lesser digits, then the information space is reduced in the labels printing protocol. In fact it is not possible to add profiles number, serum and urine identification and besides the number of available characters for patient code are also reduced.

2. USING THE BAR-CODE

2.1. Barcode On Samples

Entering Patients

Tests to be run can be acquired from the Host Computer, from those stored after manual input (refer to **Chapter E**, paragraph 1.4. “**Samples**”) and through barcode scanning using the “**Profile**” utility (refer to **Chapter C**, paragraph 1.6. “**Creating Profiles**”).

Manual programming: the patient is programmed manually (code and analyses), then his position on the sample tray is checked by barcode reading. In this case the samples can be inserted randomly on the tray, since the barcode reader will assign the position on the tray to the patient corresponding to each code read which has the same ID code.

Programming via Host Computer: The patient is programmed (code and analyses) on the Host Computer and transferred to the analyzer. The position on the sample tray is checked by barcode reading as described above.

Programming with Profiles function: this can be used with manual programming and programming via Host Computer. In this case when the barcode is created, the desired profile code also needs to be inserted (already assigned as described in chap. C, par. 1.6. **Create Profiles**). When the barcode is read the profile is automatically assigned to the read code. Once the patients are acquired it is possible to add or remove analyses. The samples can be randomly inserted in the sample tray and the barcode reader will assign the position.

Entering patients with and without bar-code on the same tray

Patients with barcode and those without can be run together. Patients without barcode must be inserted exactly into the positions assigned during programming. Patients with bar-code can be freely placed in any of the free position with no need to respect the assigned position number.

Bar-code Notes and Example

The bar-code on samples length and meaning can be programmed in the Setup program at the bar-code page.

The maximum number of digits that can be assigned to a sample is 15, depending also from the type of bar-code used.

See the following examples.

EXAMPLE 1

Patient ID# of digits: 10	With one digit for serum or urine: no	With two digits for profile: no
1234567890		
PRINTED CODE:	1234567890	TOTAL 10 CHARACTERS

EXAMPLE 2

Patient ID# of digits: 10	With one digit for serum or urine: yes	With two digits for profile: no
1234567890	1	
PRINTED CODE:	12345678901	TOTAL 11 CHARACTERS

EXAMPLE 3

Patient ID# of digits: 10	With one digit for serum or urine: yes	With two digits for profile: yes
1234567890	1	99
PRINTED CODE:	1234567890199	TOTAL 13 CHARACTERS

If in the Setup the number of digits for the patient ID is set to 15 and the printed code is of 10 characters, the analyzer will consider as ID# the 10 printed numbers.

If in the Setup the number of digits for the patient ID is set to 13 and the printed code is of 10 characters, the analyzer will consider as ID# the 10 printed numbers.

If in the Setup the number of digits for the patient ID is set to 13 (serum/urine digit and profile number are active) and the printed code is of 13 characters, the analyzer will not consider the digits for serum/urine and for profile number as it is expecting the patient ID to be of 13 digits. The patient ID always has the priority on the following numbers.

EAN13

If the bar-code used is an **EAN13**, the sample bar-code can be programmed as follows.

NOTE: with the EAN13 there are some limitations: the first number must not be 0; the actual number of digits is 12 as the last digit is the checksum **X** (automatically created).

EXAMPLE 1

Patient ID# of digits: 12	With one digit for serum or urine: no	With two digits for profile: no
123456789012		
PRINTED CODE:	123456789012X	TOTAL 13 CHARACTERS

EXAMPLE 2

Patient ID# of digits: 11	With one digit for serum or urine: yes	With two digits for profile: no
12345678901	0	
PRINTED CODE:	12345678901X	TOTAL 13 CHARACTERS

EXAMPLE 3

Patient ID# of digits: 9	With one digit for serum or urine: yes	With two digits for profile: yes
123456789	1	99
PRINTED CODE:	123456789199X	TOTAL 13 CHARACTERS

ANOMALIES IN BARCODE READING

There are some cases where the analyzer automatically makes modifications to the work lists acquired by barcode.

- **two identical barcodes are read in two different positions:** the analyzer deletes both codes since it has no way of knowing which one is incorrect. Thus, new programming becomes necessary.

- **a patient without a barcode and one with a barcode are found in the same position:** when the barcode is read the analyzer detects a sample with a barcode in a position where another patient was programmed without a barcode. The sample with barcode remains in the assigned position, while the patient without barcode is moved to the additional list (see chap. E, par. 1.5. **Work lists**).

Additional Information regarding types of barcodes:

The barcode scanner located inside the analyzer has the possibility of memorizing from one to six different codes in its flash ram memory.

At present the following codes are default set in the flash ram memory of the barcode scanner module:

Ean13, Code39, Codabar, Interleave 2 of 5 (6); Interleave 2 of 5 (8); Interleave 2 of 5 (10).

The scanner automatically detects the presence of one of the preceding codes on the barcode label.

Other codes can be programmed upon request. They are available in blocks of six and are uploaded by USB pen.

Some of these codes available upon request include:

2/5 INTERLEAVED, CODE 39, CODE 39 FULL ASCII, CODABAR, CODE 128, EAN 128, CODE 93, PLESSEY, PHARMACODE, ALL EAN/UPC, EAN 13, EAN 8, UPC A, UPC E, EAN 13 ADDON 2, EAN 8 ADDON 2, UPC A ADDON 2, UPC E ADDON 2, EAN 13 ADDON 5, EAN 8 ADDON 5, UPC A ADDON 5, UPC E ADDON 5, EAN/UPC w/o ADDON, EAN/UPC ADDON 2, EAN/UPC ADDON 5, EAN/UPC ADDON N

Suggested dimensions for the labels:

Although the analyzer is equipped with a high quality barcode scanner, the labels of improper dimensions or defective labels may not be read. For correct readings the barcode label should be properly centered on the tube and should have a height between 2 cm and 3.7 cm. The barcode on the label should be completely visible after the tube has been inserted into the sample plate. It must not be partially covered on the top and the bottom. If the tube is partially covered by barcode, then the tube must be positioned in such a way that the barcode is facing outwards of the sample plate.

2.2 Reagent Barcode

The main objective of the reagent bottle barcode is the positive identification of the bottle to avoid position error. Moreover, upon request, a special program makes it possible to “close” the analyzer making it possible to use just reagents with barcode, introducing a series of additional controls.

However the barcode can be used only with specific labels produced by the manufacturer of the reagents.

At the installation of the instrument can be configured in the following three different modes of operation, in agreement between the manufacturer of the analyzer, the reagent supplier and the client:

- 1) Use of reagent bottles without barcode, independent use.
- 2) Use of reagent bottles with barcode (analysis code), only for positive identification of the bottle.
- 3) Use of reagent bottles with complex barcode, use of reagents bound by purchasing agreement.

This mode allows for a barcode with customized reading key. The instrument doesn't accept bottles having unknown and incoherent barcode labels, thus preventing the execution of the tests. The applied algorithm provides for: analysis code, bottle type, test type (single or double), reagent lot and expiration date. The improper modification of any one of these parameters invalidates its applicability. There is also a built-in prevention against refilling of previously identified bottle.

NOTE:

Exclusively the General Director of the company manufacturing the analyzer releases additional information.

“Check volumes”

This command allows measurement of the volume of the reagent bottles (refer to **Chapter E**, paragraph 1.2. “**Reagents: insertion and removal**”). With reagent barcode enabled, it is also possible to check the actual position of all the bottles in tray.

At the end of the reagent scanning, the analyzer sorts codes disposition and provides a list of all the errors found during reading phase. In case of detected anomalies, the procedure can be repeated once the problems have been solved. Every time a new reagent bottle is inserted, the analyzer will read the inserted codes.

When removing a reagent with the "Remove" function, the analyzer will perform a scan of the position to verify that the reagent has been removed. When closing the View volumes status window, the analyzer will perform a second verification scanning and then will move the removed test code from the on-line tray to the global list (see also Cap. E, page 3).

SECTION I: GENERAL INFORMATION

CHAPTER K: VACUUM PUMP SYSTEM

1. VACUUM PUMP SYSTEM INSTALLATION/OPERATION	2
1.1. Functional Characteristics	2
1.2. System Control Functions	3
1.3. Waste Container (External)	3
1.4. Installation & Operation	4
1.5. Maintenance And Care	4
1.6. Trouble-Shooting	4
1.7. Spare Parts For Maintenance	5

NOTE:

The present chapter applies only to BT3000 Plus, BT3500 and BT3500S analyzers, which have an external vacuum system.

1. VACUUM PUMP SYSTEM INSTALLATION/OPERATION

1.1. Functional Characteristics

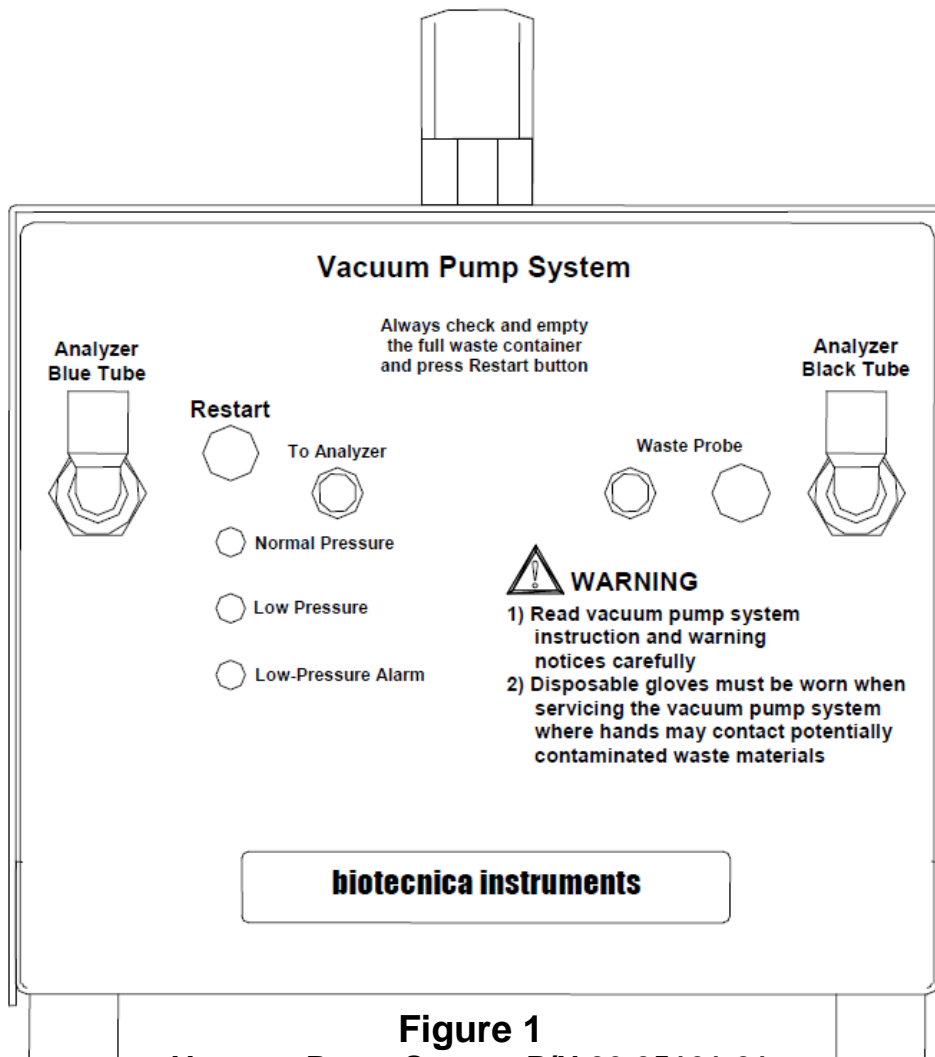


Figure 1
Vacuum Pump System P/N 06-05161-01

This silent and compact vacuum pump system has been specifically designed for use with this analyzers. It provides for an automatic and safe collection of waste liquids from analyzer’s reaction cuvettes and sampling needle washing into the external waste disposal container in lab environment. The system consists of a metallic cabinet containing two membrane pumps controlled by a microprocessor, electronics, and the electrical and fluidic connections to the analyzer. The microprocessor manages three main functions: pressure measurement, waste container full check, and pump shutdown. The waste discharge has the following pathway (course):

- A) The liquids aspirated by the pumps from the needle washing funnels (bowls) and the cuvettes washing through the two tubes (Blue and Black tubes) respectively are transferred to an internal waste chamber (made of transparent Pyrex). From here, the waste fluid is ejected to the external waste container through the waste probe equipped with liquid level sensor.
- B) Whenever the external waste container is full, the waste liquid level sensor activates an audio/visual alarm that alerts the operator and instantly shuts down the pumps.

1.2. System Control Functions

Pressure: Three LEDs on the front panel indicate the system vacuum level.

Green LED: Normal operating vacuum level (approximately –60 millibar).

Yellow LED: Low vacuum level (below 30 millibar).

Red LED: Vacuum level lower than –15 millibar

Simultaneous lighting of Green, Yellow, and Red LEDs: Indicate high vacuum level (higher than –150 millibar).

All LEDs turned off: Pumps disabled.

The green LED indicates that the system is functioning properly.

The yellow LED may indicate an operating limit condition, still satisfactory but signaling the beginning of vacuum level deterioration. The red LED indicates vacuum level failure due to various reasons.

The simultaneous lighting of Green, Yellow, and Red LEDs indicate excessive vacuum level probably caused by an occluded waste probe tube (from the vacuum pump system to the external waste container). If this condition occurs sporadically during washing then it must be considered normal.

All LEDs turned off condition is reached when the standby time (2 minutes) terminates without resetting the system (pumps disabled). In this case, the green LED of the Restart button flashes in quick successions.

1.3. Waste Container (External)

The waste probe is placed into the external waste container to transfer liquid ejected from the waste pumps into the container. For safety reasons the waste probe is equipped with a liquid level sensor, which is activated when the external waste container is full. In this condition, the liquid level sensor transmits the signal to the microprocessor, thus putting the system in standby mode. In addition, the vacuum pump system generates an intermittent audible alarm and the red LED on top of the waste probe is lit. During the standby (lasting approximately 2 minutes) the waste fluid flow is deviated through a three-way solenoid valve into the internal waste chamber, thus continuing the waste aspiration function transitorily but the fluid flow to the external waste container is stopped. The purpose of this momentary deviation is to avoid any spillage during the transfer of the waste probe from one waste container to another empty container. After emptying or substituting the external waste container press Restart button on the vacuum pump system front panel to continue the operating procedure and reset the alarm. If the preceding step is not taken, after 2 minutes the system will enter in the alarm condition by turning off the aspiration pumps of the vacuum pump system. Simultaneously the analyzer enters the standby mode and a corresponding warning message LOW PRESSURE appears on the screen.

NOTE:

The liquid level sensor is magnetically actuated reed switch make and break type.

1.4. Installation & Operation

- 1) Connect the Blue and Black waste tubes from the right side of the analyzer to the appropriate quick connect on the vacuum pump cabinet front panel (Fig.1).
- 2) Connect the Waste Probe electric cable (liquid level detector) and the drain tube of to the vacuum pump cabinet front panel (Fig.1 and Fig.3).
- 3) Insert the Waste Probes in authorized external waste container.
- 4) Plug the power cord set to power inlet on the rear of vacuum pump cabinet and then into one of the accessory power connectors on the analyzer rear panel.
- 5) Now the system is fully installed and ready for operation.
- 6) Switch on the analyzer. The vacuum pump will start running

NOTE:

The vacuum pump system power inlet on the rear has no ON/OFF switch. The system turns ON and OFF simultaneously with the analyzer. The vacuum Pump System is equipped with a universal power supply of 100 to 240 Volt AC, 50/60 Hz similar to the power supply of the analyzer.

1.5. Maintenance And Care

This compact pump system is virtually maintenance-free and offers continuous duty collection of waste liquids outside the analyzer. Does not require inconvenient peristaltic pump cartridge and filter changes. The theoretical operating life of the pumps is between 4000 to 5000 hours, after that the service technician should substitute the pumps.

WARNING

- a) **DISPOSABLE GLOVES MUST BE WORN WHEN SERVICING THE VACUUM PUMP SYSTEM WHERE HANDS MAY CONTACT POTENTIALLY CONTAMINATED WASTE MATERIALS.**
- b) **THE SAFE DISPOSAL OF THE WASTE MATERIALS IS THE RESPONSIBILITY OF THE USER. INSURE THAT THE DISPOSAL OF WASTE CONTAINER FLUIDS IS DONE ACCORDING TO ALL APPLICABLE LAWS AND REGULATIONS.**

1.6. Trouble-Shooting

TROUBLE-SHOOTING GUIDE	
SYMPTOMS	CORRECTIVE ACTIONS
The vacuum pump is silent and Restart green LED not lit.	a) No power to the system. Power cord disconnected. Connect the power cord. b) Blown fuse/s. Replace with appropriate fuses as marked.
Audible alarm of intermittent frequency, some flashing LEDs and the instrument in standby mode.	Indicates vacuum level variation due to leakage in the hydraulic circuit connection/s. Ensure that the waste tubes (blue and black tubes connecting vacuum pump to the analyzer) are firmly connected. During the analyzer operation, this phenomenon may be considered normal, as there may be sudden variations in the vacuum level during emptying of the reading cuvettes.

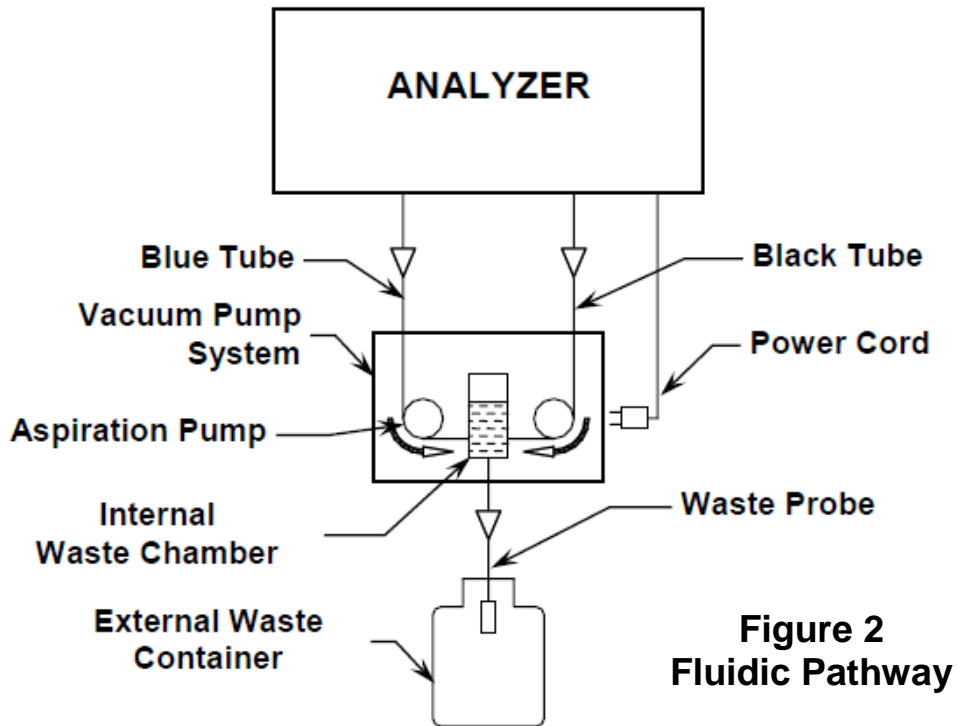


Figure 2
Fluidic Pathway

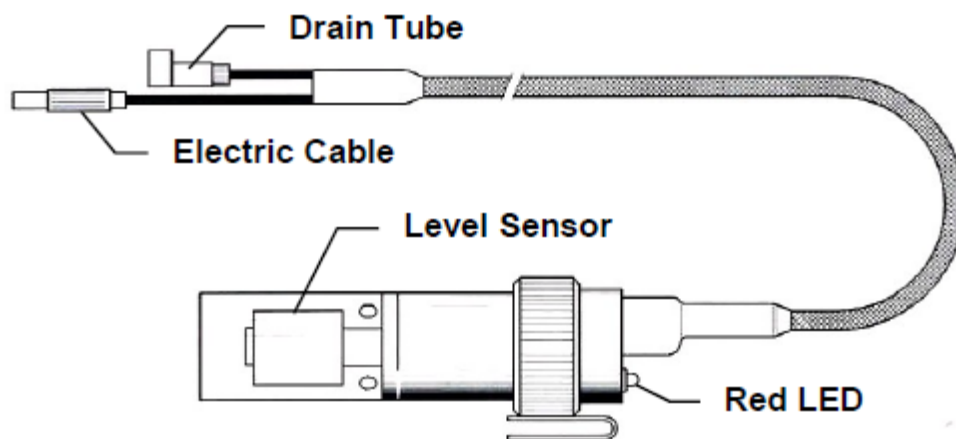


Figure 3
Waste Probe (P/N 07-05165-01)

1.7. Spare Parts For Maintenance

The following is listing of spare parts, which are available for field replacement:

PART NO.	DESCRIPTION
06-05161-01	VACUUM PUMP SYSTEM (COMPLETE) FOR THE ANALYZER
07-05165-01	WASTE PROBE
330.6338	FUSE 250 VOLT, 0.5 AT
330.6400	MAIN POWER SUPPLY CORDSET

SECTION I: GENERAL INFORMATION

CHAPTER L: I.S.E. MODULE 2P

BT3000 PLUS & BT3500 –BT1500i

1. ISE MODULE	2
1.1. Introduction	2
1.1.1. Contents Of The Wooden Crates	4
1.1.2. Applied Mathematical Functions.....	4
1.2. Performance And Limits I.S.E. Module	5
1.3. Analyzer utilities - I.S.E. Wash and system shut down.....	6
1.4. Mechanical Calibrations: I.S.E. Arm	6
2. OPERATING THE I.S.E. MODULE	7
2.1. Parameters	7
2.2. Programming Standards And Controls.....	9
2.3. Replacing And Installing Electrodes	12
2.4. Preliminary Steps Before Starting The System.....	14
2.5. Calibration Procedure.....	15
2.6. Measuring Unknown Samples	17
3. PRECAUTIONS, MAINTENANCE AND TROUBLESHOOTING	18
3.1. Precautions For Ise Module Usage.....	18
3.2. Suggestions For Performance Maintenance.	19
3.2.1. I.S.E. Maintenance	20
3.3. Troubleshooting.....	22
4. RETURNING THE ANALYZER TO THE TECHNICAL ASSISTANCE SERVICE	28
5. ISE MODULE CONSUMABLES	30

NOTE:

**All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.**

1. ISE MODULE

1.1. Introduction

In addition to the Clinical Chemistry and Immune-chemistry tests, the BT analyzers allow tests for the Na⁺, K⁺, Cl⁻ and CO₂ ions with ion selective electrodes (ISE module) with indirect potentiometry method.

The device consists of a reading module with a partially dedicated sampling arm and therefore can be considered as a stand-alone module of the instrument.

The system is called Ion Selective as the electrodes used respond to their respective ions in accordance with the Nernst equation:

$$E = E_0 + RT/nF \log aM^+$$

aM⁺ = M⁺ ion activity

E = observed potential in Volts

E₀ = constant (standard potential for a redox semi-reaction referred to hydrogen electrode)

R = gases' constant

F = Faraday's constant

T = temperature in Kelvin degrees

n = ion's charge

In the indirect potentiometry, standards and samples are prediluted before the reading. This is automatically performed by the analyzer.

The prediluted sample is then dispensed into the I.S.E. funnel (or bowl), from where it flows through the electrodes and then through the ground electrode to the waste.

Each reading is alternated with a baseline reading.

In the 1500 with I.S.E., while the samples or the baseline flow through the electrodes, the reference solution (diluted) flows through the reference electrode.

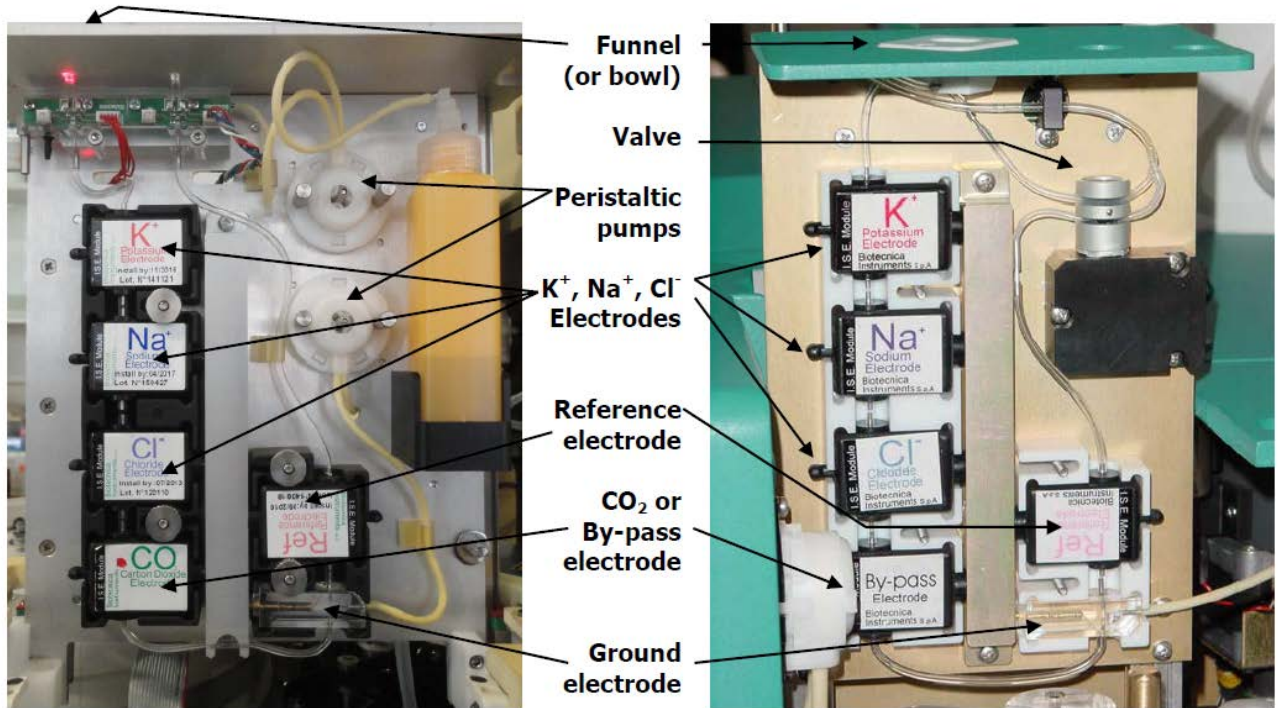
In BT3000 and BT3500 analyzers the buffer and baseline concentrated solutions are located in the dedicated reagents holder inside the I.S.E. unit (see figure 9). In the BT1500 with I.S.E., the buffer and baseline concentrated solutions are located in the reagents tray (see figure 9-1), while the diluted reference solution is located on the I.S.E. panel, next to the electrodes (see figure 7-1 & 8-1). The bubble sensors indicate to the system when there are bubbles in the liquid path or there is no more solution left.

It is highly recommended to carefully read this chapter before using the system. The user should also keep in mind that all the ISE components must be maintained in optimal operating conditions to ensure precise and accurate determination of results.

The correct use by the well-qualified personnel, assures quality test results as well as a longer duration of the electrodes. Lifetime for electrodes is about 1 year for sodium and reference, 3 months for potassium, chloride and carbon dioxide.

However, the electrodes lifetime depends upon the number of samples determined, and the observation of routine maintenance at proper intervals.

For a correct use of the system, the user must observe some basic functions such as initial restoring for electrodes conditioning, calibrations repeated every 4 hours or at any temperature variation that is greater than 3°C and at the substitution of working solutions (Buffer & Reference). When turning off the analyzer it is necessary to perform a washing procedure with appropriate detergent solutions.



BT1500i

BT3000Plus & BT3500

This chapter gives some operating suggestions and GLP to help assure precision and accuracy of the system.

The ISE module is located inside the right side of the analyzer. The ISE reagents are positioned near the ISE module and are accessible through an appropriate panel. The module can be removed by opening the panel and extracting it upwards (all fluidic tubes must be disconnected before ISE module removal).

ATTENTION: when the I.S.E. module is removed the related sampling arm no longer works. If the I.S.E. module is not going to be used, it should be disabled from the Setup (chap. H).

1.1.1. Contents Of The Wooden Crates

In the small wooden create there are the items listed in **Mod. 05_28spr**, which is included in the shipment.

1.1.2. Applied Mathematical Functions

◆ COMPUTING THE SLOPE

$$S_i = \frac{(mV_h - BL_h) - (mV_l - BL_l)}{\text{Log} \left(\frac{C_h + BSF}{C_l + BSF} \right)}$$

where:

- S** : Slope
- i** : Electrodes
- BSF** : Base Line Factor
- mV_h** : mV High Standard
- mV_l** : mV Low Standard
- BL_h** : Base Line High Standard
- BL_l** : Base Line Low Standard
- C_h** : High Standard Concentration
- C_l** : Low Standard Concentration

◆ COMPUTING THE RESULT

$$\text{Conc} = \left((Cs_l + BSF) \cdot 10^{\left(\frac{(mV_i - BL_i) - (mVs_l - BLs_l)}{S_i} \right)} \right) - BSF$$

where:

- S** : Slope
- i** : Electrode
- BSF** : Base Line Factor
- mV_i** : mV Electrode
- mVs_l** : mV Low Standard
- BL_i** : Base Line Electrode
- BLs_l** : Base Line Low Standard
- Cs_l** : Low Standard Concentration

1.2. Performance And Limits I.S.E. Module

Method:	Indirect potentiometry	
Number of electrodes:	4 plus Reference Electrode	
Analytes:	K ⁺ , Na ⁺ , Cl ⁻ and CO ₂ (By-Pass)	
Analytical throughput:	up to 190 tests/h (K ⁺ , Na ⁺ , Cl ⁻ and CO ₂)	
Analytical throughput BT1500:	up to 200 tests/h (K ⁺ , Na ⁺ , Cl ⁻ and CO ₂)	
Reagents:	Buffer and Reference Solution (concentrated)	
Sample Type:	Serum, Urine (whole)	
Sample Volume:	BT3000 Plus:30µl BT3500: 23µl BT1500i: 23µl	
Concentrated Reagents Dilution:	1/9 with H ₂ O (automatically)	
Dilution of Serum/ Buffer:	1/14 (automatically)	
Precision on Serum test:	± 1% for K ⁺ & Na ⁺ , ± 2% for Cl ⁻ , ± 3% for CO ₂	
Precision on Urine test:	± 2% for K ⁺ , Na ⁺ and Cl ⁻	
Linearity for Serum test:	Na=50-200mEq/L K=1-20mEq/L Cl =50-400mEq/L CO ₂ =10-45mEq/L	
Linearity for Urine test:	Na=20-400mEq/L K =2-200mEq/L Cl =40-400mEq/L	
<u>Accuracy for Serum test:</u>		
Intra Run Serum (N°20 samples):	Na ⁺ and K ⁺	C. V. < 1%
	Cl ⁻	C. V. < 2%
	CO ₂	C. V. < 5%
Inter Run Serum (N°20 samples):	Na ⁺ and K ⁺	C. V. < 2%
	Cl ⁻	C. V. < 2.5%
	CO ₂	C. V. < 5%
<u>Accuracy for Urine test:</u>		
Intra Run Urine (20 samples):	Na ⁺ , K ⁺ and Cl ⁻ C. V. < 2%	
Infra Run Urine (20 samples):	Na ⁺ , K ⁺ and Cl ⁻ C. V. < 2.5%	
Life expectancy for electrodes:	Na ⁺ and Reference Electrode	12 months
	K ⁺	3 months
	Cl ⁻ & CO ₂	3 months

WORKING SOLUTIONS

BT3000 Plus

Concentrated Buffer Solution:	45 µl + 350 µl (H ₂ O) approx
Concentrated Reference Solution:	45 µl + 350 µl (H ₂ O) approx
Sample Volume:	30 µl
Concentrated Buffer 10 ml:	200 tests approx
Concentrated Reference Solution 10 ml:	200 tests approx

BT3500

Concentrated Buffer Solution:	34 µl + 280 µl (H ₂ O) approx
Concentrated Reference Solution:	34 µl + 280 µl (H ₂ O) approx
Sample Volume:	23 µl
Concentrated Buffer 10 ml:	290 tests approx
Concentrated Reference Solution 10 ml:	275 tests approx

BT1500i

Concentrated Buffer Solution:	34 µl + 280 µl (H ₂ O) approx per sample
Concentrated Reference Solution:	34 µl + 280 µl (H ₂ O) approx per sample
Diluted Reference solution	100µl approx per sample
Sample Volume:	23 µl
Concentrated Buffer 10 ml:	290 tests approx
Concentrated Reference Solution 10 ml:	275 tests approx
Diluted Reference Solution 50ml:	300 test approx

***Note: the diluted reference solution flows at every function, reset included, so the actual consumption may be different from the declared approx consumption.**

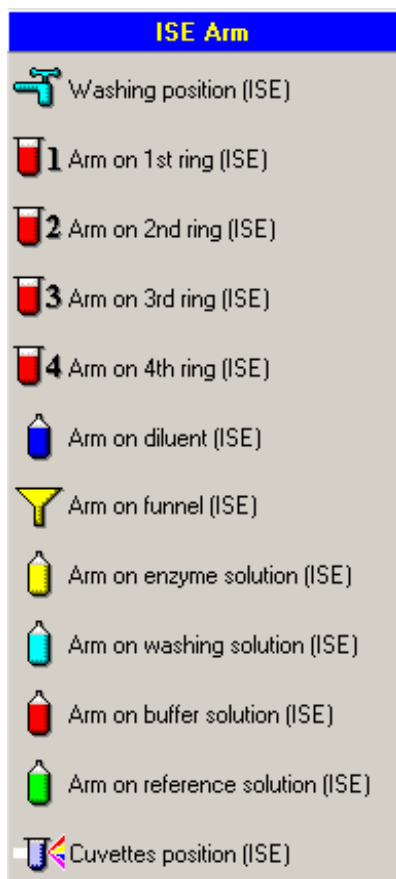
1.3. Analyzer utilities - I.S.E. Wash and system shut down

Wash I.S.E. Module: It is used for a complete extra wash with appropriate solutions (ISE Cleaning Solution and Enzymatic Solution) of the fluidic circuit of the ISE module. This washing procedure must be run daily, at the end of the day. This is to guarantee correct maintenance of the electrodes. Like wash cuvettes this procedure can be run when the analyzer is shut off (using the guided shut down procedure) or at the end of the day if the analyzer is not shut off.

NOTE: when the Cl electrode is not in use, the analyzer does not perform the enzyme wash at the shut-down, but only the normal I.S.E. wash.

1.4. Mechanical Calibrations: I.S.E. Arm

The first five items and the **Cuvettes position (I.S.E.)** are the same as the corresponding button of the Clinical Chemistry Arm, see Chapter H, par. 1.1.2. for more information.



The BT1500i, having only one arm, must be adjusted only on the **Arm on funnel** and **Arm on diluent** positions, as all the other positions can be adjusted in the dedicated paragraph (par. 1.1.2 of Chapter H).

Arm on diluent: centers the I.S.E. arm above the tube containing the physiological solution for diluting the samples.

Arm on funnel: the I.S.E. arm moves above the I.S.E. mixing funnel. Center the sampling needle at the hole at the bottom of the funnel. It is very important that the needle is centered in this position to prevent it from touching the funnel walls during mixing.

Arm on enzyme solution [ISE]: The sampling arm moves on to the appropriate hole corresponding to the enzyme solution, in the instrument's top.

Arm on washing solution [ISE]: Same as above, but for the washing solution.

Arm on buffer solution [ISE]: Same as above, but for the buffer solution

Arm on reference solution [ISE]: Same as above, but for the reference solution

2. OPERATING THE I.S.E. MODULE

2.1. Parameters

Go to the **Global list** or the **Current Tray list** select **ISE**, and then click **Parameters** to display the screen showing analytical parameters: **General Parameters**, **Serum's Parameters**, and **Urine's Parameters**.

N.B.: the I.S.E. parameters have been optimized for this analyzer. The parameter fields marked with an asterisk should not be modified. Biotechnica Instruments S.p.A. shall not be held liable for unreliable results if the I.S.E. parameters are changed.

The **General Parameters** is displayed first (Figure 1), to access the other parameters click on the corresponding tags.

GENERAL PARAMETERS: In this page it is possible to program the general parameters for the ISE. The I.S.E. module test parameters are preset and should not be modified because the I.S.E. module has been designed to operate best with the parameters supplied by Biotechnica. The description and use of the parameters is very similar for what is described for clinical chemical parameters, see that section for more information.

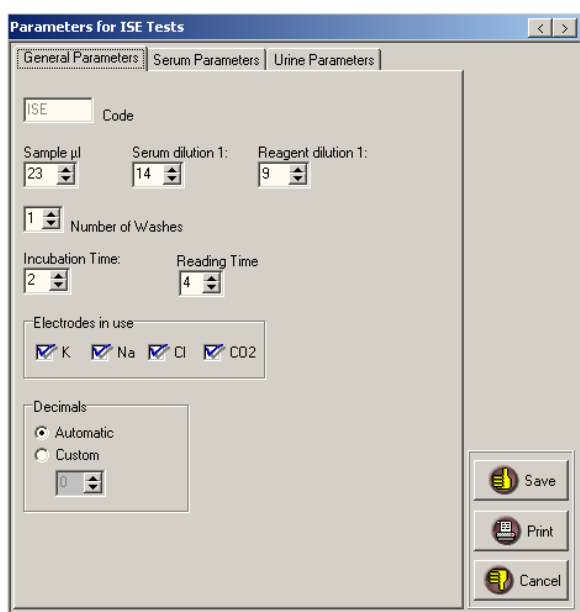


Figure 1

***Sample µl:** Sample volume expressed in µl, default value is 30µl for BT3000 Plus, 23 µl for BT3500 and for BT1500i.

***Serum dilution 1:** Sets dilution ratio between sample and reagent, default value is set at 14.

***Reagent dilution 1:** Sets dilution ratio for concentrated reagent, default value is 9. Using this parameter the analyzer prepares (dilutes) the working reagents such as Reference (Baseline) Solution and Buffer Solution, which are CONCENTRATED.

1st Unit: Enter value in the corresponding field and enable **2nd Unit** to enter a second value and instantly a new textbox appears where the user can enter the second unit and the second unit's conversion factor. In case of double units, the test values are expressed with two results. In analytical calibrations, the first measurement unit

is used.

Number of Washes: Normally one wash is usually sufficient. To set a different number of washes (maximum 9) use up/down arrow keys \blacktriangle or enter the value directly into the box. This option allows the user to set the number of washes that will be run at the end of dispensing the reagent used for the programmed test.

***Incubation Time:** Incubation time expressed in seconds, default value is 2 seconds.

***Reading Time:** Analysis' reading time, expressed in seconds, default value is set at 4seconds.

Decimals: For setting the number of decimal digits in test results (**Automatic** or **Custom**). If a value is not specified, then the analyzer automatically assigns number of decimal digits using the Floating point algorithm.

Electrodes in use (K Na Cl CO2): Click the check boxes to select the electrodes to be used among those available here. This command selects or deselects electrode. When an electrode By-pass is used it is necessary to deselect the electrode which is not used to prevent continuous errors during calibration. If the selection of electrodes being used is modified, it is necessary to repeat the calibration.

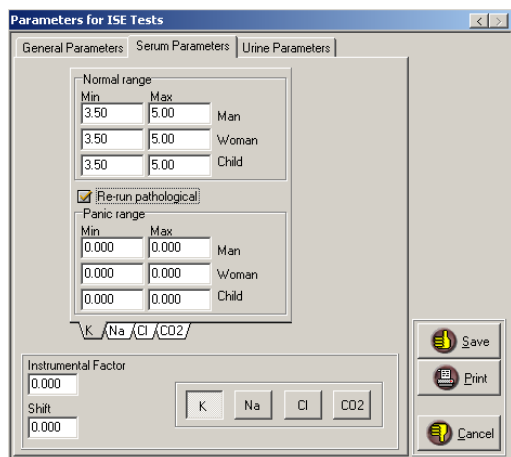


Figure 2

SERUM'S PARAMETERS: Here it is possible to assign the **Normal range** (Figure 2) for each electrode and, if needed the panic range for pathological repetition. The programming of the normal range values for Man, Woman and Child is assigned specifically to each electrode. To assign the normal (and panic) range to each electrode, click corresponding tag.

To visualize the Panic range, click **Re-run pathological** checkbox. If Re-run pathological option is selected, the analyzer will repeat all pathological results outside the given range.

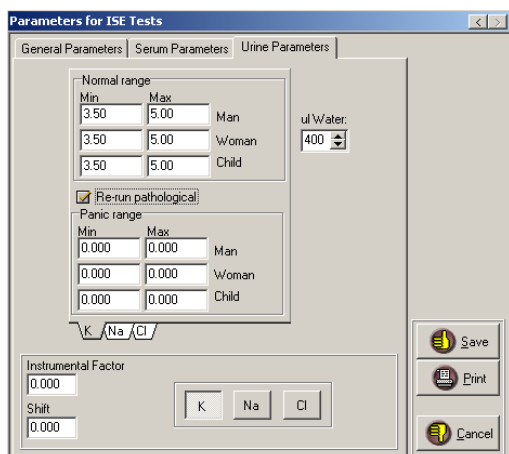


Figure 3

URINE'S PARAMETERS: In addition to the same functions as the Serum's Parameters, it also has the **µl Water** field (Figure 3). This is used for entering the volume in µl of water that must be used for washing the hydraulic circuit at the end of a test determination.

Note: The **CO₂** electrode is automatically excluded in Urine's parameters (it does not appear even if it is present in the electrodes in use).

The Instrumental factor and Shift fields are available for both serum and urine, separated by single electrode.

Instrumental factor: introduces a correction of the final datum of the executed test; it can be used to adjust the data of the executed test with different types or analytical methods or instruments. Calculation: final result = value x instrumental factor.

Shift: the function introduces a quantitative correction of the final datum of the executed test; it can be used to adjust the data of the executed test with different types or analytical methods or instruments. Calculation: final result = value + shift.

NOTE: When the following parameters are used at the same time: Instrumental factor and Shift, External dilution factor and Urine 24/h (in the patient's data), the calculation made by the analyzer will be as follows:

$$[(\text{obtained result} \times \text{External dilution factor} \times \text{Instrumental factor}) + \text{Shift}] \times \text{Urine 24/h}$$

At the end of programming press the **Save** button to save the inserted data, otherwise press **Cancel**.

2.2. Programming Standards And Controls

INSERTING STANDARDS: Go to the **Global list** or the **Current Tray list**. Select **ISE**, and then click **Standards** to display the **Standard parameters for ISE** (Figure 4). Standards programming (automatic or on request) follows the same procedure of Clinical Chemistry (Chapter C, paragraph 1.5. Calibrations). For system calibration, two known standards (Low and High) are required.

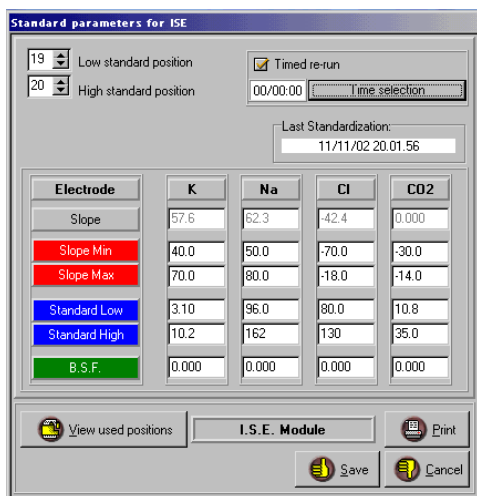


Figure 4

The Calibration parameters of the module and the relevant slopes calculated for each electrode are displayed together. Here it is possible to set an automatic standardization timer and assign two positions for low and high standards (same as clinical chemistry procedure outlined in Chapter C, paragraph 1.5.).

Low standard position and **High standard position:** write in these fields or select with up/down arrow keys \blacktriangle the positions for I.S.E. calibrators.

Timed re-run: It is possible to program automatic execution of calibration using this parameter. The analyzer will issue a warning message when the

programmed standardization ends. If the reagents and standards are present, then one can directly perform the calibration. Insert the standardization time by enabling Time selection and program the corresponding field. One can enter interval of hours or days in this field.

Last Standardization: The time and date of last test positive calibration are shown here.

Electrode	K	Na	Cl	CO2
Slope	57.6	62.3	-42.4	0.000

Slope: After each calibration, the calculated values for the slopes are updated in these fields.

Calculated slope values must be within the indicated ranges.

Slope Min	40.0	50.0	-70.0	-30.0
Slope Max	70.0	80.0	-18.0	-14.0

Slope Min / Max: By double-clicking the textboxes, slope ranges are individually set for

each electrode. Refer to test methodology for correct values. The slope values are important for verifying a correct calibration and the electrodes status. When a slope is out of range, it will probably mean that the electrode must be replaced.

Standard Low	3.10	96.0	80.0	10.8
Standard High	10.2	162	130	35.0

Standard Low/High: Double clicking in the appropriate fields it is possible to program the

concentration values of the two standards for each electrode. Every time standards are changed, the set points must be changed as well. Refer to the kit insert or to the standards label for the correct values.

B.S.F.	0.000	0.000	0.000	0.000
--------	-------	-------	-------	-------

BSF: This parameter is a Base Line Factor and is used for Cl and

CO₂. It must be set to 5. It is a linearity correction factor.

View used positions: This command shows all the positions used by standards.

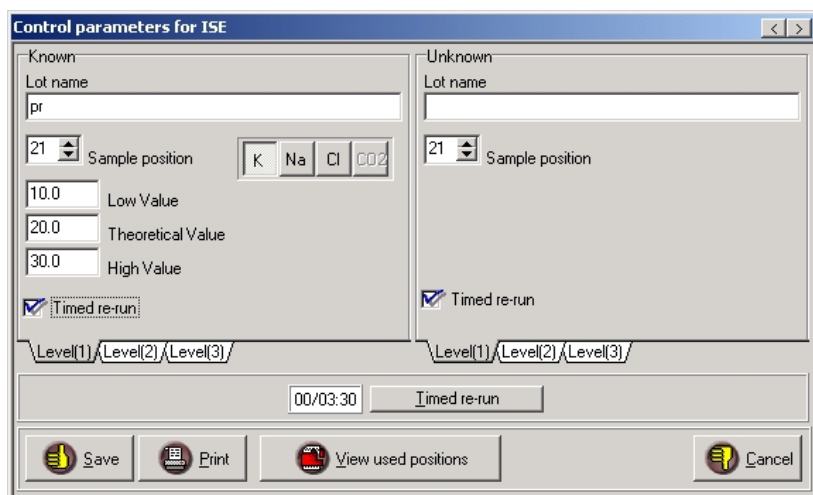


Figure 5

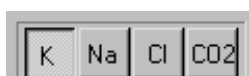
INSERTING CONTROLS

Go to the **Global list** or the **Current Tray list**. Select **ISE**, and then click **Controls** to display the **Controls parameters for ISE (Figure 5)**. The Controls programming (automatic or on request) follows the identical procedure of Clinical Chemistry (**Chapter C, paragraph 1.4. Controls**). Selection of a single electrode is required prior to controls programming.

Use the command **Save** for memorizing data, **Cancel** for leaving the program without saving changes, and **Print** for hard copy printout.

The displayed page is divided into two parts, one for the **Known** controls and the other for the **Unknown** controls (**Figure 5**). The opening page is default set to **Level (1)** controls. To set parameters for Level 2 and 3, click corresponding tabs.

KNOWN CONTROLS



Known Controls: Select the electrode, prior to entering the control's range values.

Lot Name: Enter a name or a lot number.

Sample position: Enter the sample's physical position on the plate. The reserved sample positions are located in the inner circles of the sample plate and are dedicated to calibrators and controls. The numerical positions on the sample plate correspond to those established in the Setup Analyzer (refer to Chapter H, paragraph 2. Setup Analyzer).

Low value: Enter the lower value for the control's range.

Theoretical Value: Enter the theoretical value for the control.

High value: Enter the higher value for the control's range.

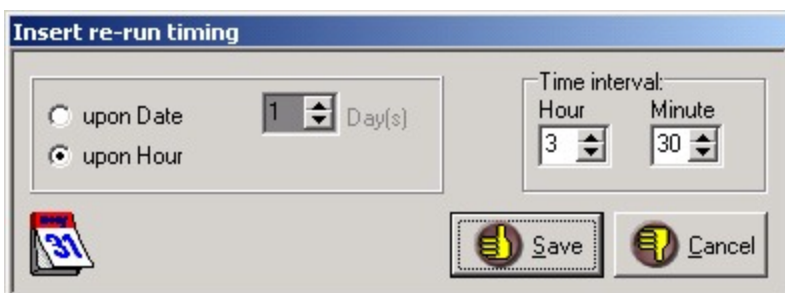


Figure 6

Timed re-run: This parameter allows programming of automatic execution of controls. It is possible to insert automatic execution time for each single control. Check **Timed re-run** box and then Click **Timed re-run** (just above the **View used positions**) to display **Insert re-run timing** screen (**Figure 6**).

Here one can enter interval of hours or days (refer to Chapter C, paragraph 1.4.) for automatic controls run.

upon Date (daily interval): Select the function and set daily interval, then enter test running time (for example 1 08,30 means every day at 08,30 or in any case at start up).

upon Hour (hour interval): Select the function and set the desired hour interval, hours and minutes.

Every day or when the preset time expires, the analyzer will automatically alert the user that there are controls to be run. If reagents and controls are present, then the user can directly confirm to execute the tests.

View used positions: This command displays the test disposition.

NOTE: Enter the same parameters also for Level 2 and 3 controls.

UNKNOWN CONTROLS

The only parameters to be set are the lot name or number, the sample position on the sample tray and the timed re-run for each level. Reserved positions are located in the inner circle of the sample plate and are dedicated to the calibrators and controls. The numerical positions on the sample plate correspond to those already set in the program **Setup Analyzer** (refer to Chapter H, paragraph 2. Setup Analyzer).

After programming all the parameters, save parameters by clicking **Save** button. Click **Print** for hardcopy printout of control parameters.

2.3. Replacing And Installing Electrodes

The analyzer is supplied with the electrodes already installed in the ISE module.
 To replace or install the electrodes the **analyzer must be turned off** and then the following steps must be observed:

WARNING

Do not touch with bare hands the small metallic tubes of the electrodes, the contacts of electrodes, or the sensor electronics, in order to avoid electrostatic discharges that may cause permanent damage or system malfunction.

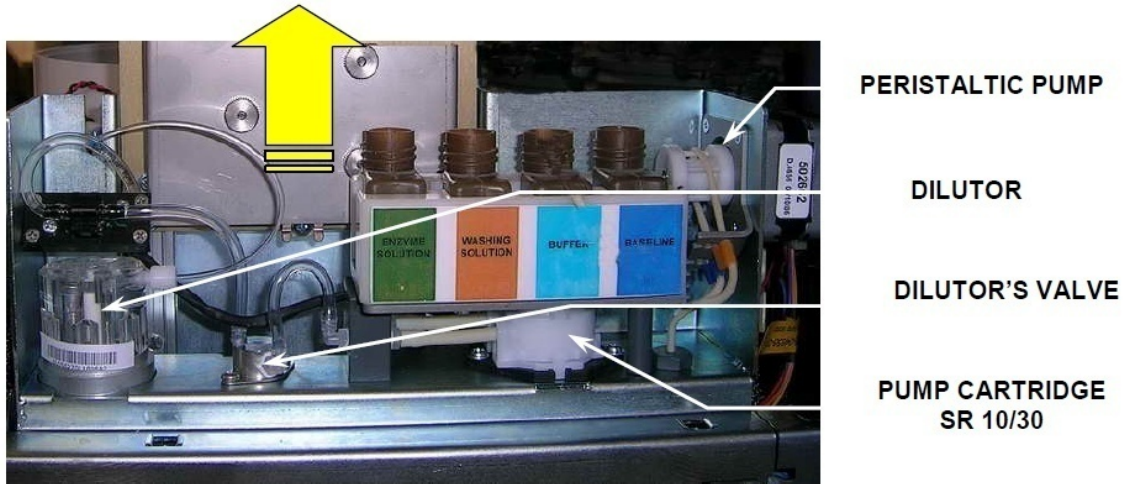


Figure 7



BT1500i

To extract the module, use the handle and lift it up until it automatically locks. Push down to insert the panel back in place.

Figure 7-1

1. Before installing or replacing electrodes, remove the ISE module as shown in **Figure 7** and **Figure 7-1** (BT1500) and unscrew the thumbscrews securing the metallic shield.
2. Disconnect the tubes **2, 3, 4, 5** and **6** (**Figure 8**) from the electrodes. Remove the housing containing measurement electrodes (K, Na, Cl, By-pass or CO₂) by gently moving leftwards (**Figure 8**). Remove the housing containing Reference and Ground electrodes by carefully moving it rightwards. Keep these housings in vertical position when electrodes are present.
3. Disconnect the tubes **2, 3, 4, 5** and **6** (**Figure 8-1** – BT1500) from the electrodes and follow instructions as at point 2.
4. Carefully remove the electrodes from their respective housings by gently pressing on the backside. Always maintain the electrodes stack in vertical position.
5. It is recommended to immediately disconnect the first electrode (K) from the next one, especially when CO₂ is present.
6. Replace the defective electrodes with new ones.
7. Reassemble the electrodes stack and place it into its housing.
8. Position the housing with the measurement electrodes on the ISE panel, and gently press fit to the right into the appropriate connecting pins of the detection electronics.
9. Carefully fit the housing with Ref & Ground electrodes by gently pushing to the left into the pins of the detection electronics.
10. Reconnect tubes **2, 3, 4, 5** and **6**.
11. Secure the metallic shield using the thumbscrews.
12. Insert ISE module into its appropriate slot.

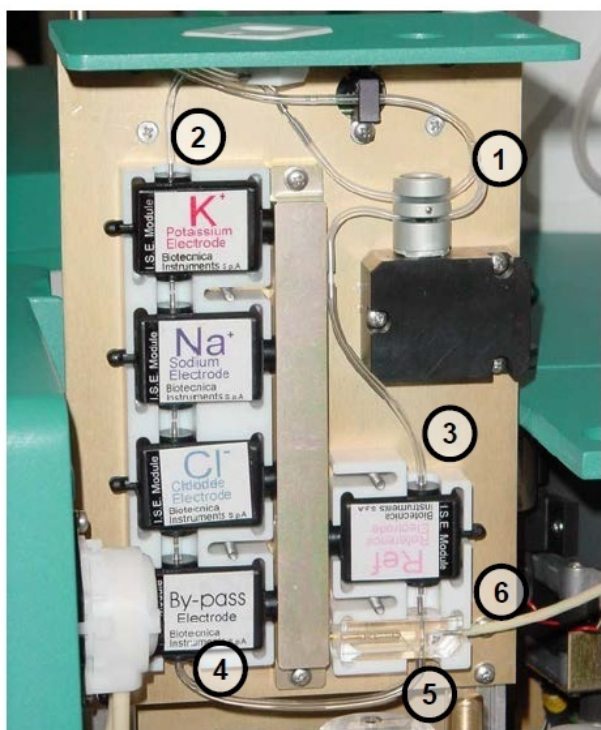


Figure 8

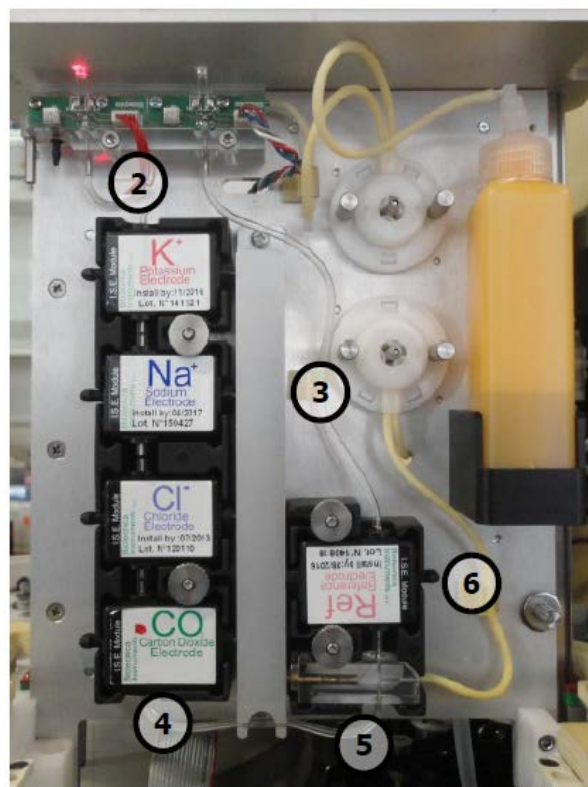


Figure 8-1

2.4. Preliminary Steps Before Starting The System

This procedure is necessary when installing the system or after replacing the electrodes. For normal operating functions, observe the following procedure:

- a) Place the working solutions in their respective lodgings (**Figure 9; for BT 1500 8-1 - reference solution - and 9-1 – buffer and baseline**).
- b) Make sure that the contents of the working solutions are sufficient for the necessary workload.

Caution

This verification of volumes (for necessary workload) is highly recommended. Whenever reference (present only on BT1500), baseline or buffer solutions are changed, a new calibration of the system must be performed.

- c) Run **Prime I.S.E.** (refer to **Chapter H**, paragraph 1.1.1.) and repeat it for at least three times.

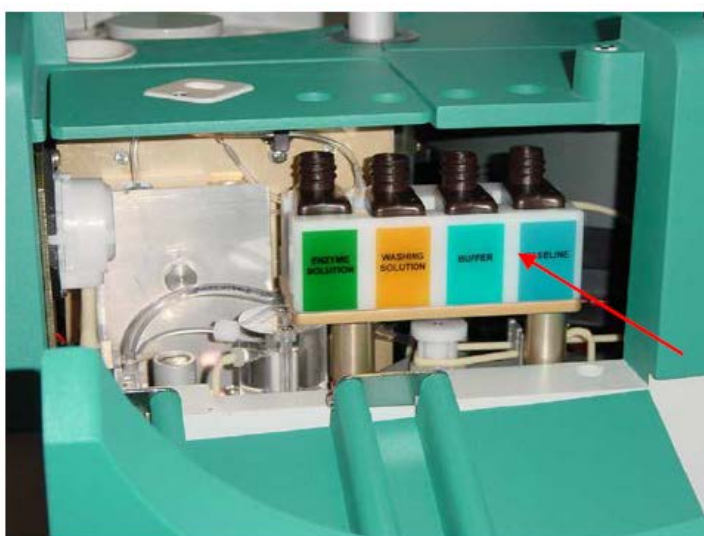


Figure 9

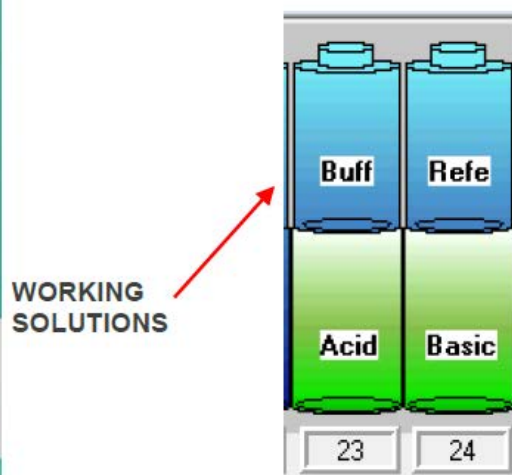


Figure 9-1

NOTES: if the device has just been installed, the electrodes have been replaced or if the I.S.E. module has not been used for some time, various system primes should be run. Wait around 30 minutes before using the I.S.E. module to let the electrodes be conditioned by prior passage of the reference solution.

d) Verify that programmed values for the standards (high level/low level) correspond to the used lot. Programming is performed as shown in **Figure 4**, where the values for two standards must be entered for the calculation of slope during the calibration.

e) To reduce the risk of contamination of reference (present only on BT1500), baseline and buffer solutions through ambient air, it is suggested to remove and close the bottles at the end of daily working sessions. Remember to open and replace these bottles at the beginning of every new working session.

The ISE module should be considered by the user as an ordinary test for Clinical Chemistry requiring a programming of its own for standards and controls. Calibration should be performed every four hours and it is essential for precise and accurate results. In addition, it is recommended to execute repeated calibrations until a stable slope value is obtained.

2.5. Calibration Procedure

Standards are automatically diluted with buffer solution with a ratio of 1:14. The mixed product is aspirated into the electrodes through the peristaltic pump. After an incubation period, the reading is performed.

At the end of calibration phase, the slope is calculated in accordance with **Nernst** equation:

$$\text{Slope (s)} = \Delta E / (\log \text{STD high} - \log \text{STD low})$$

where ΔE = difference in mV between STD high and STD low

After calibrating each electrode, optimal slopes are obtained which should be within the following acceptance range:

	<u>Optimal slopes</u>		<u>Range of slopes</u>
K:	53 / 58.5 mV	K	40 / 70 mV
Na:	54 / 60 mV	Na	50 / 80 mV
Cl:	-57 / -43 mV	Cl	-70 / -18 mV

NOTE:

In addition to the acquired slopes values, it is important to observe also the potential of the standards **mV STD Low** and **mV STD High** in the calibration printout.

In the optimal conditions, these values can be reproduced quite easily with slight variations around nominal value. The potential of the standards in association with the obtained slope values, are useful for evaluation of a correct calibration. When electrodes are not efficient, for example, when poor or no maintenance has been performed, or in case of contamination or degradation of the working solutions (Reference (present only in BT1500), Buffer, Baseline, or STD), the potential values vary considerably. This results in erroneous slopes indicating that the operating conditions are not optimal. However, in some cases, the potentials have incorrect values, but the slopes are apparently acceptable. Be cautious with this situation as the precision and accuracy of tests results will be affected by an incorrect calibration.

#19 STD001 (Standard) (2/1/2006 12:37:59 PM)				
ISE>K	-9.78	mV	(61.6 71.4)	[]
ISE>Na	-12.3	mV	(-16.8 -4.53)	[]
ISE>Cl	9.37	mV	(-298 -307)	[]
ISE>CO2	1.82	mV	(-348 -350)	[]
#20 STD002 (Standard) (2/1/2006 12:37:59 PM)				
ISE>K	22.2	mV	(94.0 71.8)	[]
ISE>Na	4.07	mV	(-0.62 -4.69)	[]
ISE>Cl	-1.82	mV	(-308 -306)	[]
ISE>CO2	-11.2	mV	(-361 -350)	[]
Standardization for ISE performed!				
New Slopes = K	: 61.2			
Na	: 64.4			
Cl	: -50.2			
CO2	: -26.3			

The potential values are related to standards, thus by changing standard's lot with another, the different potentials will be observed with the same slope values. To optimize system performance it is fundamental that both the slope and potential values are always around established levels.

In case the slope values are out of range, an on-screen error message is displayed, even if there is an incorrect response from only one electrode. A check is also performed on the slopes reproducibility. The values obtained during current calibration are compared to the values of previous calibration. An error message appears during calibration if there is a variation greater than 3% for K and Na, 5% for Cl and 8% for CO₂.

Each standard measurement is followed by a baseline measurement. The baseline is a reference solution used for compensating any eventual drift of the system.

IMPORTANT NOTICE

- a) After an incorrect calibration or in case of a calibration beyond the preset limits, the analyzer automatically performs a new calibration with up to 3 calibrations maximum.
- b) Once the calibration standards are poured into the sampling cups, they are stable for no longer than 15 minutes. If calibrations, for any reason, last longer than this time, it is necessary to replace standards with fresh ones and repeat the calibration. The bottles containing buffer and reference solutions must be placed on the analyzer (open bottles - at room temperature) at least 30 minutes before operating phases begin and to allow for equilibrium with ambient temperature and with the carbon dioxide (CO₂) level in the air. If the thermal equilibrium is not reached, then the phenomena of drift effects and erroneous results can occur, while a lack of equilibrium with CO₂ may provide higher results for the latter test.

NOTE:

If slopes and potentials are constantly out-of-range, this indicates that the electrodes are exhausted, or there is an aspiration error in the baseline (or also reference in BT1500) solution in the reference electrode, or the working solutions (buffer, baseline, reference in BT1500, STD) are contaminated or degraded. In case of contamination or degradation, replace in sequence the buffer solution, then the reference/baseline solution and at last the standard. Whenever a product is replaced, repeat the calibration procedure. In the other cases such as exhausted electrodes or a baseline aspiration error in the reference electrode, refer to the Troubleshooting guide.

2.6. Measuring Unknown Samples

After a correct calibration, the samples are determined, which are prepared and read in similar manner to standards: dilution 1:14, aspiration into the electrodes, potential reading, and the reference (baseline) aspiration. The samples are calculated applying **Nernst** equation:

$$E - E_0 = s \log (C_x / C_{Std})$$

Considering the fact that the system requires a calibration, the measurement method is defined as comparative.

ISE tests are programmed in the same way as any other analysis of clinical chemistry.

Precision and accuracy errors when determining samples

NOTE:

In case of errors during samples determination, please follow indications outlined in the Troubleshooting guide.

Determined results can be associated to a flag that indicates eventual problems occurred during measurement.

The presence of **D** flag near a result, relevant to one or more electrodes, indicates drift during sample reading, i.e. the drift has exceeded $\pm 2\text{mV}$ and thus the electrode may be unstable.

The flag **R** near the results indicates the absence of reagents.

The flag **B** adjacent to results indicates the presence of air (bubbles) in the hydraulic circuit during the transfer of the sample into the electrodes.

The sign **<NC>** in place of the results, indicates abnormal values (for example 9999999,999) or erroneous values (ex. No sample or reagent). Abnormal values may result from an interruption of the liquid flow into the electrodes during the test reading phases.

3. PRECAUTIONS, MAINTENANCE AND TROUBLESHOOTING

3.1. Precautions For ISE Module Usage

- ◆ The ambient conditions play an important role in the correct use of the ISE module. Room temperature must be between 20°C and 26°C
- ◆ If the room temperature varies (even by 2°C or 3°C) during a working day, then it will be necessary to repeat the calibration of the ISE module just before running tests to avoid errors during next readings.
- ◆ It is suggested to insert the bottle containing buffer solution (open bottle - at room temperature) in the reagent tray at least 30 minutes before operating phases begin and to allow for equilibrium with ambient temperature and with the carbon dioxide (CO₂) level in the atmosphere. If the thermal equilibrium is not reached, then the phenomenon of drift and erroneous results may occur, while a lack of equilibrium with CO₂ may provide higher result values for the latter test.

NOTE:

ISE Module should be calibrated only after the above-mentioned equilibrium has been reached.

- ◆ When using the chemical standards, bear in mind that they are altered by air exposition. Therefore, it is recommended to fill the cups $\frac{3}{4}$ full (to minimize evaporation effect) and run the calibration immediately afterwards and then discard the remaining standard. In any case, do not leave standards exposed to air for longer than 15 minutes.
- ◆ It is recommended to run the standardization twice a day, in the morning and in the afternoon or in any case every four hours. To ensure a successful calibration, repeat it up to three times and verify if the results are stable. Standards and samples should be at room temperature before they can be used.
- ◆ Bear in mind that also the samples are altered if exposed to air for more than 30 minutes.
- ◆ The buffer bottle must always be closed (in case only a few samples per day are performed) after the ISE determinations, as the CO₂ in the solution degrades when exposed to air. If CO₂ slope should drop below 15, then replace the buffer solution and calibrate again. If the slope is still low even with a new buffer, then replace the electrode.
- ◆ If one of the two solutions, buffer or reference, is replaced, then the calibration should be performed again to avoid possible incorrect results.
- ◆ If the electrodes are removed for any reason, then carefully note down the electrodes sequence positions. The potassium electrode (K) must be immediately detached (by disconnecting tube) from the next electrode (Na) in the stack and maintained in vertical position, because even a small reflux of liquid from Cl and CO₂ electrodes can destroy it.
- ◆ The electrodes should be washed every day. This makes the electrodes more stable and guarantees a longer life.
- ◆ If only a few samples are run during the day, all the bottles containing I.S.E. solution should be closed (the enzymatic solution needs to be put in the refrigerator), in order to minimize contamination and evaporation.

3.2. Suggestions For Performance Maintenance.

To eliminate any problems during ISE operation, observe the following suggestions:

Before a long period of system's inactivity, proceed as follows:

- a) Perform an ISE wash (refer to **Chapter H**, paragraph 1.1.1.), even if no ISE determination has been performed.
- b) Run **Prime I.S.E.** and repeat it three times (refer to **Chapter H**, paragraph 1.1.1.).
- c) At the end of this operation, release **tube 6 (Figure 8)** from the peristaltic pump and remove the tubes 1 from the valve to avoid sticking and collapsing of tubes.

NOTE: In case the ISE module has the **Cl** and **CO₂** electrodes, then also disconnect the tube 2 connected to **K** electrode (see **Figure 8**).

After a long period of system's inactivity, perform the following:

- a) Connect tube 6 to the peristaltic pump, insert tubing 1 into the valve and connect the tube 2 to **K** electrode.
- b) Run **Prime I.S.E.** and repeat this procedure for three times (refer to **Chapter H**, paragraph 1.1.1.).

CAUTION: refer to the Troubleshooting guide in case of problems during system restoring.

The analyzer alerts the operator in the following situations:

- a) Every 24 hours the analyzer will ask for the ISE wash.
- b) In case more than 150 ISE tests have been performed, then the ISE washing will be prompted.
- c) If more than 300 ISE tests have been performed, then the preceding ISE washing message will be supplemented by an additional prompt requiring the cleaning of Chloride electrode.

Turning off the system equipped with ISE Module

During turning off procedure, the analyzer requests whether the cuvettes and the ISE Module should be washed (with Cleaning Solution and Enzymatic Solution). In case of an affirmative response, the analyzer will wash both cuvettes and electrodes, otherwise it is possible to wash the cuvettes only.

NOTE: It is important to wash electrodes everyday. This makes the electrodes more stable and prolongs their life. If the I.S.E. module is not going to be used any longer, run a complete wash. It is not necessary to repeat the wash after this until the I.S.E. module is used again.

3.2.1. I.S.E. Maintenance

PROGRAMMED MAINTENANCE

Item	Replacement
Kit tubes and peristaltic pump	Every 150000 cycles or 6 months
Kit tubes I.S.E. module	Every 3/6 months
Potassium electrode (K)	Every 3 months
Sodium electrode (Na)	Every 12 months
Chloride electrode (Cl)	Every 3 months
Carbon dioxide electrode (CO ₂)	Every 3 months
Reference electrode (Ref)	Every 12 months

The above mentioned items replacement may change as the analyzer system improves. Refer to the analyzer maintenance dedicated page (Menu Analyzer → Diagnostic → General Diagnostic).
 Note: the Kit tubes and peristaltic pump items are contained into the BT3000 Plus Six month maintenance kit, in the BT3500 Six month maintenance kit and in the BT1500 Annual Maintenance Kit. The other items are contained in the following dedicated kits (ref to Fig. 10).

BT3000 PLUS: QUARTERLY MAINTENANCE KIT		
ITEM	QTY	DESCRIPTION
1	1	REF - K Tube Manifold
5	1	Interconnection Tube for GND/Bypass OR CO2 Electrode
6	1	ISE Pump Tube

BT3500: QUARTERLY MAINTENANCE KIT		
ITEM	QTY	DESCRIPTION
1	1	REF - K Tube Manifold
5	1	Interconnection Tube for GND/Bypass OR CO2 Electrode
6	1	I.S.E.-Pump Tube

BT1500i: SIX-MONTHS MAINTENANCE KIT		
ITEM	QTY	DESCRIPTION
1	1	Sampling tube
2	1	Ref cartridge
3	1	Waste cartridge
4	1	Interconnection K- sample bubble sensor tube
5	1	Interconnection GND – Bypass/CO2 Electrode tube
6	1	Reference tube

MAINTENANCE: BT3000Plus&BT3500 (refer to Fig. 10)

- To access the ISE Module, remove the plastic lodging for the reagents. Slide up the ISE electrodes panel to have an easy access to disconnect the waste tube connecting peristaltic pump to the ISE Module.
- Replace the Y-shaped tubing set (ref. 1) by first inserting the single tube end into the bubble sensor, and then connect it to the funnel located above. Insert the remaining two tube attachments into the appropriate slots (K tube in the upper slot and the REF tube in the lower slot) of the valve and then correctly connect their ends to the REF and K electrodes as shown in the figure. Verify correct tubing placement in the valve.
- Replace the I.S.E.-peristaltic pump tube (ref. 6) by connecting one end to the ground electrode, then around the pump head, and the other end to the waste liquid connector as illustrated. Then clip the tube holders to the tightener support. Do not stretch the tube, or it may be malfunctioning.

- Connect interconnection tube (ref. 5) to the CO2 electrode (or By-pass) and the ground electrode.
- Replace peristaltic pump cartridge (ref. 7) remove both ends of the peristaltic pump tubing from the diluter manifold. Squeeze the locking catches and remove the defective cartridge. Place the new cartridge on the drive shaft and gently press to snap-fit. Carefully attach the pump tubing to both fittings in the diluter manifold.
- Replace tube (ref. 8) connecting the peristaltic pump through valve to the dilutor.
- Carefully lower the ISE electrodes panel back into place ensuring that the tube (ref. 6) is free and not pinched or crushed by the panel.

After replacing tubes and accessories, turn on the analyzer. Insert the plastic lodging with the reagent bottles containing appropriate products and run a few times the function Dilutor prime and Prime I.S.E. (refer to Chapter. H, paragraph 1.1.1.) to prime the hydraulic circuit.

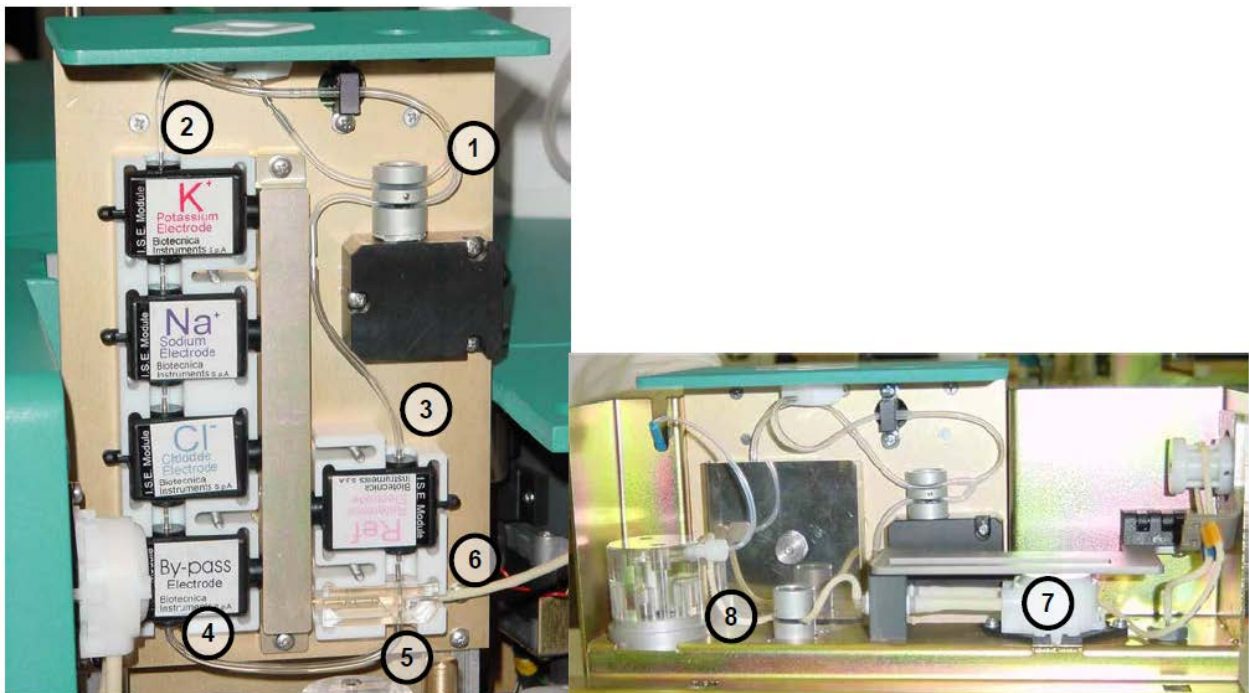


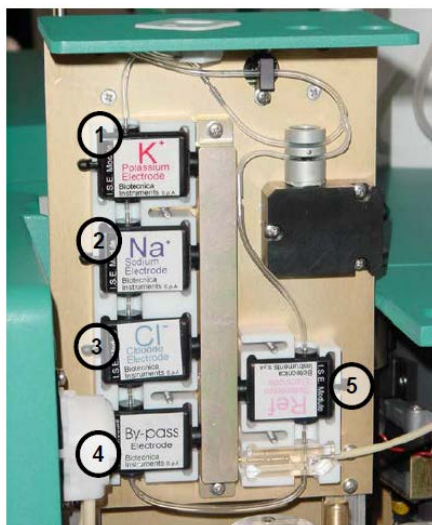
Figure 10

BT3000 PLUS: QUARTERLY MAINTENANCE KIT		
ITEM	QTY	DESCRIPTION
1	1	REF - K Tube Manifold
5	1	Interconnection Tube for GND/Bypass OR CO2 Electrode
6	1	ISE Pump Tube

BT3500: QUARTERLY MAINTENANCE KIT		
ITEM	QTY	DESCRIPTION
1	1	REF - K Tube Manifold
5	1	Interconnection Tube for GND/Bypass OR CO2 Electrode
6	1	I.S.E.-Pump Tube

I.S.E. ELECTRODES: BT3000PLUS&BT3500

The by-pass electrode, sometimes present in the place of another electrode not in use, does not require maintenance.



Ref.	El.	Description
1	K	Potassium electrode
2	Na	Sodium electrode
3	Cl	Chloride electrode
4	CO2	Carbon dioxide electrode
4	ByP	By-Pass electrode
5	Ref	Reference electrode

Figure 10-1

MAINTENANCE: BT1500 with I.S.E. (refer to Fig. 11)

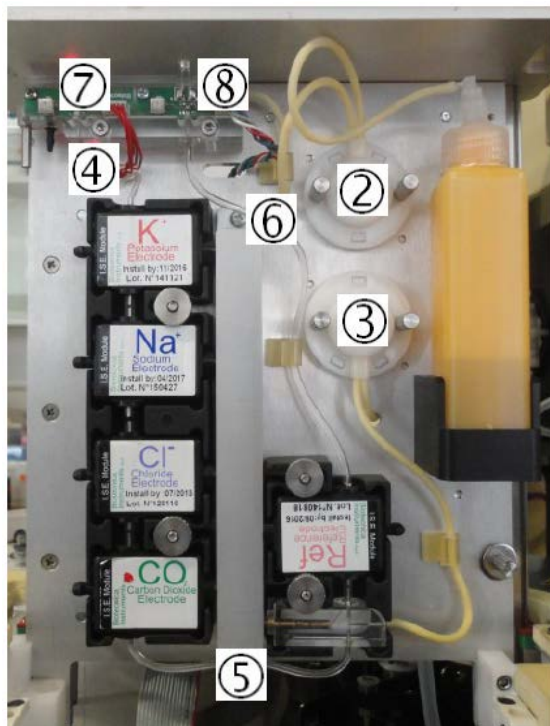


Figure 11

To access the ISE Module, slide up the ISE electrodes panel.

All tubes can be easily removed by pulling them out of their nipples. Peristaltic pumps can be removed by unscrewing the thumb-screws that fix them to the module; keep thumb-screws in a safe place as they will be necessary for fixing the new pumps. Replace tubes/peristaltic pumps one by one to avoid errors or confusing parts. The following instructions concern the replacement of the parts, as the removal is easy and it has been explained above.

- Replace the reference tube (ref. 6) by first inserting one end into the reference bubble sensor (ref. 8) and then connect the other end to the reference electrode. Position the tube into the clip to keep it in place.
- Replace the Interconnection K- sample bubble sensor tube (ref. 4) by inserting its ends in the K electrode and the sample bubble sensor nipples.
- Replace the reference peristaltic pump and its tubes (ref. 2) by inserting the shorter tube end into the reference bubble sensor nipple (ref. 8) and the longer tube end fully into the reference bottle, until it touches the bottle bottom.

- Replace the waste peristaltic pump and its tubes (ref. 3) by inserting the shorter tube end into the hole in the panel and then into its nipple into the waste collector on the rear of the panel; insert the longer tube end into the ground electrode nipple.
- Connect the interconnection tube (ref. 5) to the CO2 electrode (or By-pass) and the ground electrode.

- Carefully lower the I.S.E. electrodes panel back into place ensuring that all tubes are free and not pinched or crushed by the panel.

BT1500i: SIX-MONTHS MAINTENANCE KIT		
ITEM	QTY	DESCRIPTION
1	1	Sampling tube
2	1	Ref cartridge
3	1	Waste cartridge
4	1	Interconnection K- sample bubble sensor tube
5	1	Interconnection GND – Bypass/CO2 Electrode tube
6	1	Reference tube



To replace the sampling tube, remove the cuvettes cover and the sampling tube cover by unscrewing the thumb-screw and lifting it upwards freeing it from the retaining magnets (ref. 1 in Figure 11-1). Then detach the sampling tube from its rubber connector to the I.S.E. panel (Figure 11-2) and remove the funnel with the tube (ref. 9 in Figure 11-2).

Figure 11-1

Disconnect the I.S.E. sampling tube from the funnel.

In this occasion it may be a good idea to clean the funnel by washing it with double distilled water and a clean piece of cloth. Then rinse it with double distilled water. Connect the new sampling tube to the funnel and to its rubber connector on the I.S.E. panel. Place the I.S.E. sampling tube cover back in place, using the magnets and the thumb-screw to fix it in its position. Take care to put all the sampling tube inside the cover.

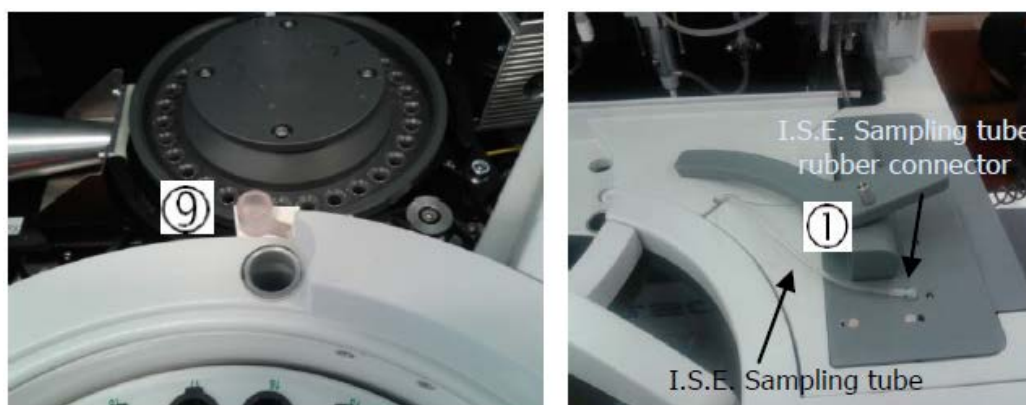


Figure 11-2

After replacing tubes and accessories, turn on the analyzer and run a few times the function Dilutor prime and Prime I.S.E. (refer to Chapter. H, paragraph 1.1.1.) to prime the hydraulic circuit.

3.3. Troubleshooting

If the routine maintenance is performed regularly, the ISE module functions correctly. The most common problems encountered in the ISE Module are as follows:

- a) Calibration errors.
- b) Unreliable sample results with flags.
- c) Error messages of air bubbles.

a) **CALIBRATION ERRORS**

The causes may be due to various reasons and can be diagnosed through close examination of mV values of slopes.

Typical values of calibration potentials in mV:

K	std low = -8 mV std high = +22 mV	difference 30 mV (slope 57 mV)
Na	std low = -10 mV std high = + 5 mV	difference 15mV (slope 63 mV)
Cl	std low = +6 mV std high = -4 mV	difference 10mV (slope 50 mV)
CO₂	std low = +4 mV std high = - 6 mV	difference 10mV (slope 32 mV)

The above-mentioned values are indicative and may deviate due to the wear and tear of the electrodes.

A positional error or an incorrect concentration of reagents may determine a considerable variation of potentials and slopes.

The mV values (in brackets) in the calibrations printout can give additional indications, which are useful for the diagnostics.

For example:

Std low	-8mV	(-208 -200)
Std high	+22mV	(-178 -200)

One can observe in the above example the Baseline value (-200), which must be always included between two Std values. In fact the value -200 is between the two values -208 and -178.

Various combinations of error

a) Inversion of Buffer / Baseline

Considerable increase of potentials (up to 100mV), decrement of slopes.

b) Insertion of identical reagents: Buffer / Buffer or Baseline / Baseline.

The potentials are almost within norms but there is considerable decrement of slopes.

In the above items a) and b), the Baseline values shown in the preceding example shall not be coherent.

Obstructions caused by proteins in electrodes Cl & CO₂

When running 150-200 I.S.E. samples per day, the Cl & CO₂ electrodes may be periodically obstructed. In this case, one observes an increase in the slopes of K & Na, and decrement in the slopes of Cl & CO₂. Follow the instructions for the cleaning of electrodes.

A similar error may also be caused by a partially occluded Ground electrode. Generally, the obstructions in the ground electrode are caused by the foreign matter and not by protein. Carefully observe the cleaning procedures as outlined in the Figures 10 and 11 on the ensuing pages.

NOTE:

A prolonged obstruction of the Cl electrode may progressively obstruct the electrodes below it (CO₂ and Bypass). For cleaning these electrodes, use syringe for the CO₂ and the cleaning tool on the Bypass as shown in the Figure 11.

b) BAD RESULTS OF SAMPLES:

Generally, this phenomenon occurs during sampling but it may take place afterwards. Observe the above-mentioned diagnostic procedures.

c) ERROR MESSAGES, AIR BUBBLES, FLAGS

During a calibration or a run an error message Air bubbles may appear. The error may be momentary and not appear afterwards. In this case, it means a casual formation of bubbles.

The bubble error in the I.S.E. is managed as follows:

- a. If the bubble error occurs during the prime, the analyzer should give the bubble error warning, all the following I.S.E. samples will have to be flagged with B and will have <NC> instead of the result.
- b. If the bubble error occurs during the sampling, while reading the baseline, the analyzer should display the bubble error message, should stop sampling and should give all the following I.S.E. samples results as <NC>, with flag B.
- c. In case bubbles are detected while reading a sample, the warning message should be displayed. The sample will be flagged with B and will have <NC> instead of the I.S.E. result. The analyzer will go ahead with the following samples.

If the bubble error persists then it may be due to problems of hydraulic nature.

- a) ISE funnel takes long time to empty. It may be caused by defective or worn peristaltic pump for draining or an obstruction in the electrodes stack. Repair or replace.
- b) Prime operation failure. The Prime also calibrates the bubble sensor. Check that prime is performed properly.
- c) Collapsed tube in the ISE valve. The Baseline solution doesn't enter the Reference electrode and the funnel doesn't empty. The Reference electrode is filled during the prime. Check and correct.
- d)

Results with flag D

During the reading, the flag D on one or more electrodes indicates a drift of potential greater than 2 mV. The phenomenon may be determined by one of the following causes:

- Defective electrode.
- Electrode to be reconditioned.
- Partial occlusion of the electrode.
- Incorrect reagents.
- No washing after a consistent run.
- Correlation with general problems already explained.

Screen Messages - Causes And Remedies

NO SPECIAL REAGENTS	
<p>NO I.S.E. BUFFER SOLUTION NO I.S.E. REFERENCE SOLUTION</p>	<p>The error message NO ISE BUFFER SOLUTION / NO ISE REFERENCE SOLUTION is displayed when the analyzer detects the absence of ISE buffer solution or reference solution needed for programmed tests. Immediately after this message the ISE sampling is interrupted. Insert new buffer / reference and perform a new I.S.E. calibration. It is possible to repeat interrupted tests using the Re-run option (Chapter E, paragraph 1.5).</p>
<p>NO I.S.E. WASHING SOLUTION</p>	<p>The error message NO ISE WASHING SOLUTION is displayed when the analyzer detects through a built-in liquid sensor the absence of ISE washing solution and instantly the ISE sampling is interrupted. To restart washing insert new washing solution bottle.</p>

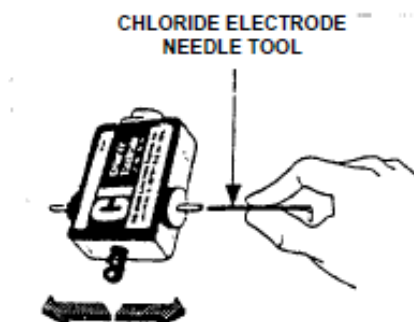
NOTICE

It is often possible to extend the life of a chloride electrode by using the supplied **CHLORIDE ELECTRODE NEEDLE TOOL P/N 03254**.

1. Grasp the NEEDLE TOOL as shown. Gently insert the tip of the needle tool into either end of electrode. Keeping your fingers off the opposite end of electrode, slowly but firmly push the needle straight through the electrode's inner core until the needle tip appears at the other end of the electrode (be careful not to bend the needle inside the electrode). Wipe off any debris on the needle tip and gently pull the needle back out of the electrode. Wipe off the needle and remove any debris or moisture from the electrode surface. Repeat on the other side of the electrode and until the needle tool tip is perfectly clean when exiting from the electrode.
2. Reinstall the electrode into the electrode housing in the correct order.
3. Install the electrode housing into the ISE. Connect tubing and prime the ISE module completely. If the electrode's performance does not improve, contact your local Technical Support.

WARNING

NEEDLE TOOL can damage all other electrodes (K, Na, CO2, REF). Do not use!



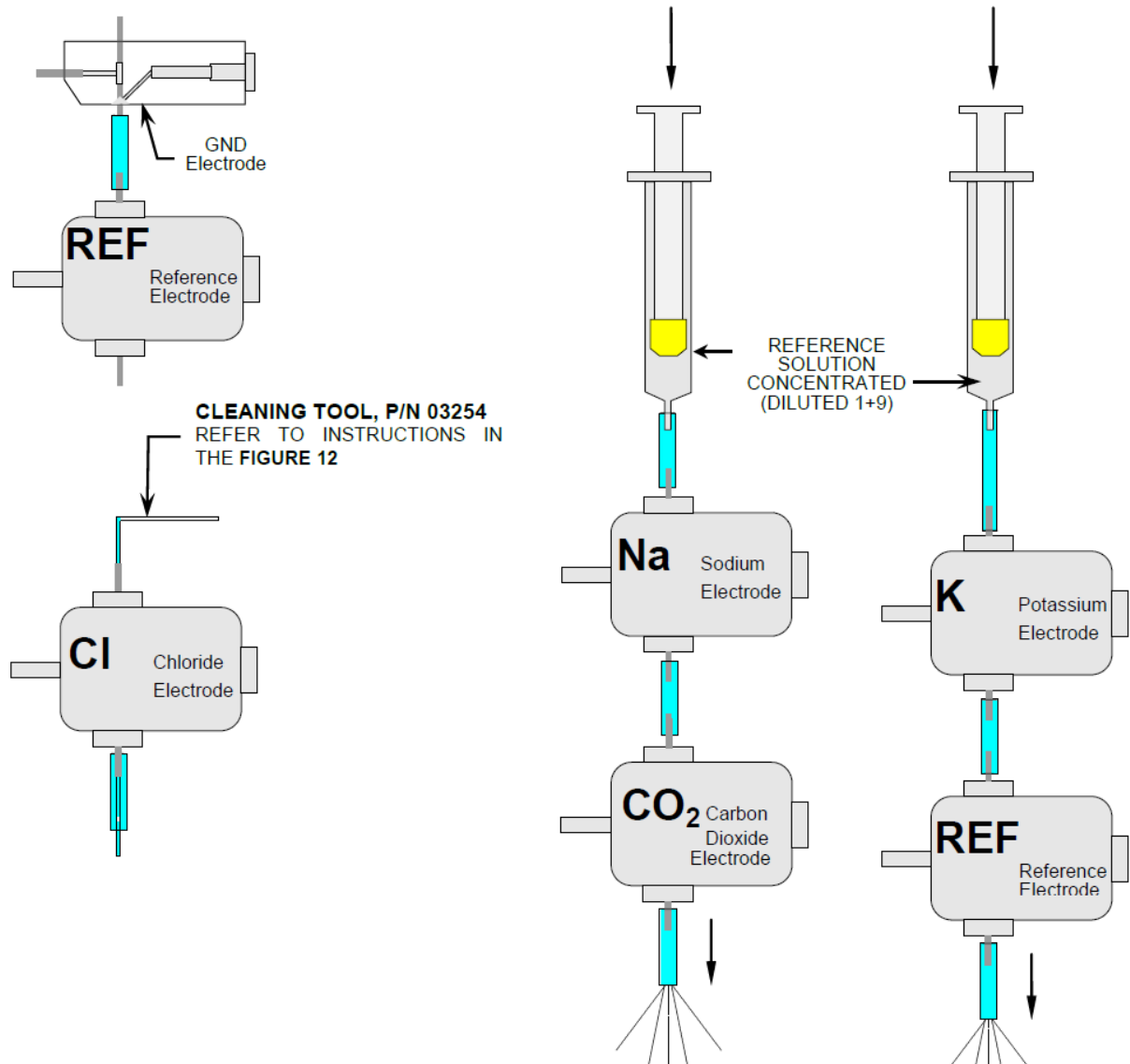
Chloride Electrode Cleaning Procedure

Figure 12

ISE ELECTRODES CLEANING PROCEDURE

NOTE:

FOR CONVENIENCE SAKE, IT IS IMPORTANT TO DETACH THESE ELECTRODES IN SMALL GROUPS FROM THE REST TO AVOID POSSIBLE ACCIDENTAL DAMAGE WHEN HANDLING A LONG STRING OF ELECTRODES. OBSERVE THE CLEANING PROCEDURE OUTLINED HERE FOR OTHER ELECTRODES.



CLEANING PROCEDURE

1. Carefully insert the tip of 5ml - 10 ml syringe filled with appropriate solution onto the top duct of electrode assembly as shown.
2. Inject solution until all the solution is forced through interconnecting bores of the electrodes and flows out from the bottom electrode, thus thoroughly removing any contamination.

WARNING

- a. PUSH THE PLUNGER ONLY TO EJECT THE SOLUTION. DO NOT PULL THE PLUNGER TO ASPIRATE THE SOLUTION INSIDE ELECTRODES. THIS WILL CAUSE IRREPARABLE DAMAGE AND CONTAMINATION TO THE POTASSIUM ELECTRODE WITH Cl OR CO₂ PARTICLES.
- b. DO NOT USE PLASTIC STRING FOR CLEANING THE REFERENCE OR Na ELECTRODES AS IT MAY DAMAGE THE ELECTRODES INTERNALLY

Figure 13

4. RETURNING THE ANALYZER TO THE TECHNICAL ASSISTANCE SERVICE

FOR MORE INFO REFER TO CHAPTER M

Operating Analyzer

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Put a suitable decontaminant (e.g. HCl 1N hydrochloric acid diluted at 3%) in a reagent bottle and place it in position no. 40 for BT3000 Plus & BT3500.
3. Prepare a bottle of enzymatic solution for washing the I.S.E. and place it together with the other I.S.E. solutions in the specific housing.
4. Start a cuvette (Analyzer Utilities menu – Wash cuvettes) and I.S.E. (Analyzer Utilities menu – Wash I.S.E.) wash cycle.
5. Wait five minutes after the washes have finished and then remove the decontaminant bottle from the reagent tray and put the I.S.E. enzymatic solution back in the refrigerator. Remove all the other bottles of I.S.E. solutions.
6. Run a normal wash cycle with water (Analyzer Utilities – Wash with water).
7. Empty the hydraulic circuit (from the Analyzer Utilities menu - Empty fluidics).
8. Shut down the analyzer.
9. Clean off the entire sample tray with decontaminant and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.

For assistance at the Lab: in addition to the above, disconnect the waste tubes from the instrument and clean an area with decontaminant which is large enough for the Technician to work.

Analyzer Safe Disposal

When the instrument is no longer useable or needs to be decommissioned, follow the procedure below, bearing in mind that any part of the analyzer may come into contact, even accidentally, with potentially infected samples: therefore set up adequate protection using the necessary individual protection devices.

Be very careful of any splashing of residual decontaminant when disconnecting the various tubes or touching the various parts of the hydraulic system, after decontamination.

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Empty the hydraulic circuit (from the Analyzer Utilities menu: empty fluidics).
3. Remove the water tube from the external container and put it in a container with at least one liter of suitable disinfectant or decontaminant (e.g. hydrochloric acid HCl 1N diluted at 3%). Put disinfectant also in the four empty bottles in place of I.S.E. solutions and in a bottle in position 40 for BT3000 Plus & BT3500 of the reagent tray.
4. Fill the hydraulic circuit again by running a reset and a series of prime of the clinical chemical diluter and the diluter of the I.S.E.
5. Run a wash of the cuvettes and I.S.E. (from the Analyzer Utilities menu - Wash with water and Wash I.S.E.)
6. Wait five minutes. Remove the disinfectant from the container and from the I.S.E. bottles and replace it with water. Put the water tube back in the container which has just been filled.

7. Run a wash of the cuvettes and I.S.E. again, and then empty the hydraulic circuit again.
8. Shut down the analyzer.
9. Remove all the cords connecting the UPS to the mains and peripheral devices from the analyzer.
10. Remove all the cables connecting the peripheral devices (keyboard, mouse, wireless connector, printer and UPS).
11. Carefully clean off the entire sample tray with decontaminant (hydrochloric acid HCl 1N diluted at 3%) and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.
12. Carefully clean the peripheral devices using a clean cloth and a disinfectant.
13. Remove the waste tubes from the analyzer and the vacuum system.
14. Remove the vacuum system discharge probe and soak it for five minutes in disinfectant (HCl 1N diluted at 3%). Then rinse it in water.
15. Remove all the tubes which are part of the washing, distribution and sampling hydraulic circuit and the I.S.E. circuit. Remove the I.S.E. electrodes as well.
16. Sort the material from decommissioning the instrument so that they can be recycled or disposed of as special waste in accordance with local laws.

If the analyzer is going to be returned to the Distributor, make sure all the removal parts of the system are bagged and separated after decontamination so that they can be disposed of as special waste.

5. ISE MODULE CONSUMABLES

PRODUCT	PART NO.	SIZE
COMMON PRODUCTS		
I.S.E. Low Calibrator	943	2x20 ml
I.S.E. High Calibrator	944	2x20 ml
I.S.E. Starter Kit (Consists of: 943, 944, 947A, 947B, 947C, 947D)	947	1
I.S.E. Buffer (concentrated)	947A	3x10 ml
I.S.E. Reference (concentrated)	947B	3x10 ml
I.S.E. Washing Solution	947C	3x10 ml
I.S.E. Enzymatic Solution	947D	3x10 ml
By-Pass Electrode	662.0709	1
Reference Electrode	662.0710	1
Sodium Electrode (Na)	662.0711	1
Potassium Electrode (K)	662.0712	1
Chloride Electrode (Cl)	662.0713	1
Carbon Dioxide Electrode (CO ₂)	662.0716	1
Cleaning tool for Chloride Electrode	03254	1
BT3000 Plus		
BT3000 PLUS Quarterly maintenance kit	11-05338-01	1
BT3500		
BT3500 Quarterly maintenance kit	11-05668-01	1
BT1500 w/I.S.E.		
I.S.E. Reference solution	948	2x125
BT1500 I.S.E. Six-Monthly Maintenance Kit	11-07281-01	1

SECTION I: GENERAL INFORMATION

CHAPTER L1: I.S.E. MODULE 4-P

ONLY FOR BT3500S

1. I.S.E. MODULE-4P	2
1.1. Introduction	2
1.1.1. Contents Of The Wooden Crates	5
1.1.2. Applied Mathematical Functions.....	5
1.1.3. Operating Principles	6
1.1.4. Precautions For I.S.E. Module-4P Usage.....	7
1.2. Performance And Limits - I.S.E. Module-4P	9
1.3. Starting The I.S.E. Module-4P	10
1.4. Analyzer Utilities - I.S.E. Wash And System Shut Down	11
1.5. Mechanical Calibrations: I.S.E.	12
2. OPERATING THE I.S.E. MODULE-4P	13
2.1. Parameters	13
2.2. Programming Standards And Controls.....	16
2.3. Replacing And Installing Sensors, Tubes And Pumps.....	18
2.4. Preliminary Steps Before Starting The System.....	20
2.5. Calibration Procedure.....	21
2.6. Measuring Unknown Samples	22
3. MAINTENANCE AND TROUBLESHOOTING	22
3.1. Suggestions For Performance Maintenance.	22
3.1.1. I.S.E. Maintenance (Six Monthly Kit I.S.E. 4P Code 11-06227-01)	23
3.2. Troubleshooting	25
4. RETURNING THE ANALYZER TO THE TECHNICAL ASSISTANCE SERVICE	27
5. I.S.E. MODULE-4P CONSUMABLES	29

1. I.S.E. MODULE-4P

1.1. Introduction

In addition to the Clinical Chemistry and Immune-chemistry tests, the analyzers equipped with the I.S.E. Module-4P, allow also tests for the Na, K, Cl and Li ions with ion selective sensors (I.S.E. Module-4P).

The system is called Ion Selective as the sensors used respond to their respective ions in accordance with the Nernst equation:

$$E = E_0 + RT/nF \log aM^+$$

aM^+ = M^+ ion activity

E = observed potential in Volts

E_0 = constant (standard potential for a redox semi-reaction referred to hydrogen sensor)

R = gases' constant

F = Faraday's constant

T = temperature in Kelvin degrees

n = ion's charge

It is highly recommended to carefully read this chapter before using the system. The user should also keep in mind that all the I.S.E. components must be maintained in optimal operating conditions to ensure precise and accurate determination of results.

The correct use by the well-qualified personnel, assures quality test results as well as a longer duration of the sensors.

However, the sensors lifetime depends upon the number of samples determined, and the observation of routine maintenance at proper intervals.

For a correct use of the system, the user must observe some basic functions such as initial restoring for sensors conditioning, calibrations repeated every 4 hours or at any temperature variation that is greater than 3°C and at the substitution of working solutions. Once a week it is necessary to perform a washing procedure with appropriate solution. This chapter gives some operating suggestions and GLP to help assure precision and accuracy of the system.

The I.S.E. Module-4P (Figure 1) is located inside the right side of the analyzer. The analyzer can process the I.S.E. samples both with direct and indirect potentiometry methods.

The I.S.E. reagents are: reference solution, A solution (standard 2), B solution (standard 1), sample diluent solution and standard C. There is also a washing solution (Na conditioning solution).

The sensors stack can be removed by opening the side panel and extracting it.

ATTENTION: if the I.S.E. Module-4P is not going to be used, it should be disabled from the Setup (chap. H).

Schematic description of the I.S.E. Module-4P (figure 1).

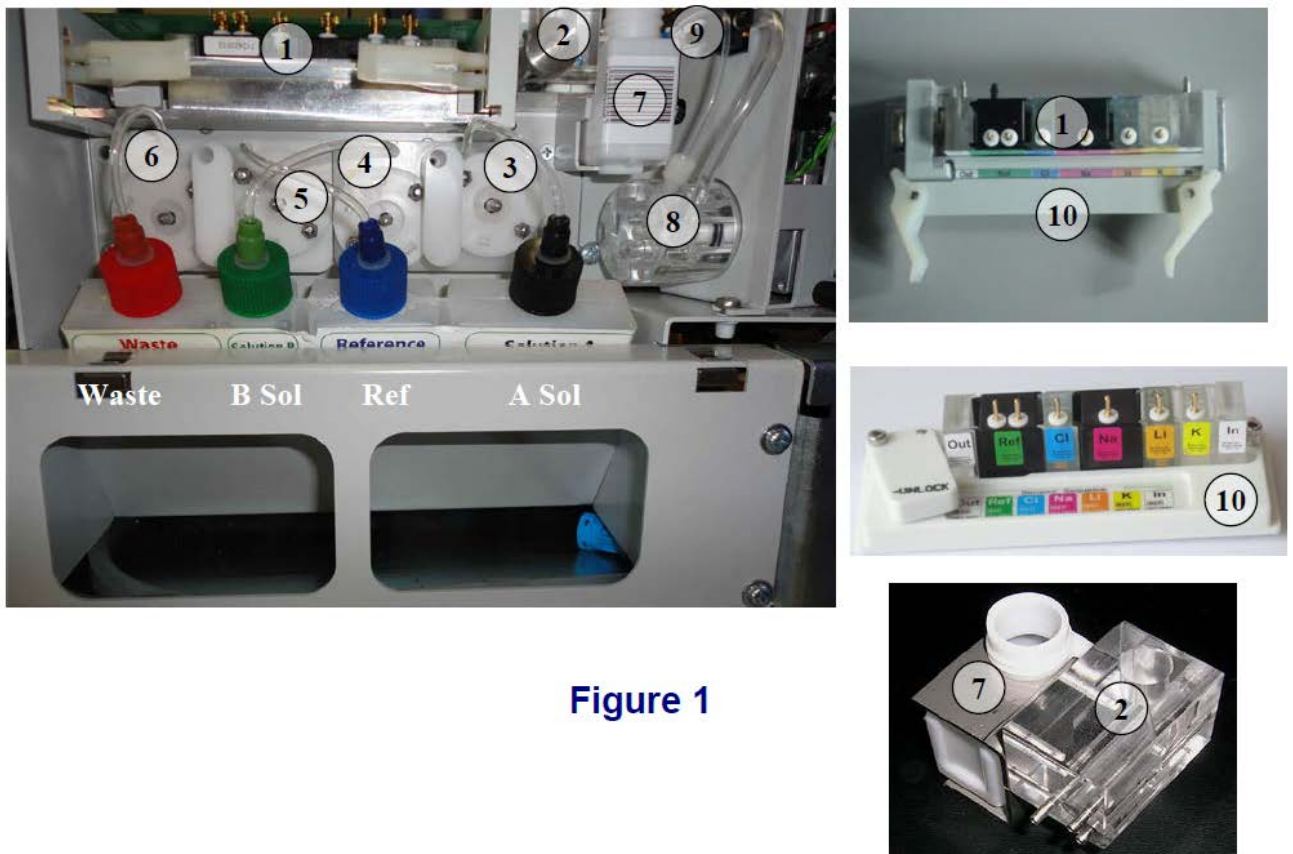


Figure 1

REF	DESCRIPTION
1	Sensors stack (inlet, K, Li, Na, Cl, Ref, outlet)
2	Mixing chamber
3	A solution tube and peristaltic pump
4	B solution tube and peristaltic pump
5	Reference solution tube (to Ref. sensor) and peristaltic pump
6	Waste tube and peristaltic pump
7	Sample diluent bottle
8	Diluter
9	Clot sensor
10	I.S.E. slide

Description of the I.S.E. slide (figure 2)

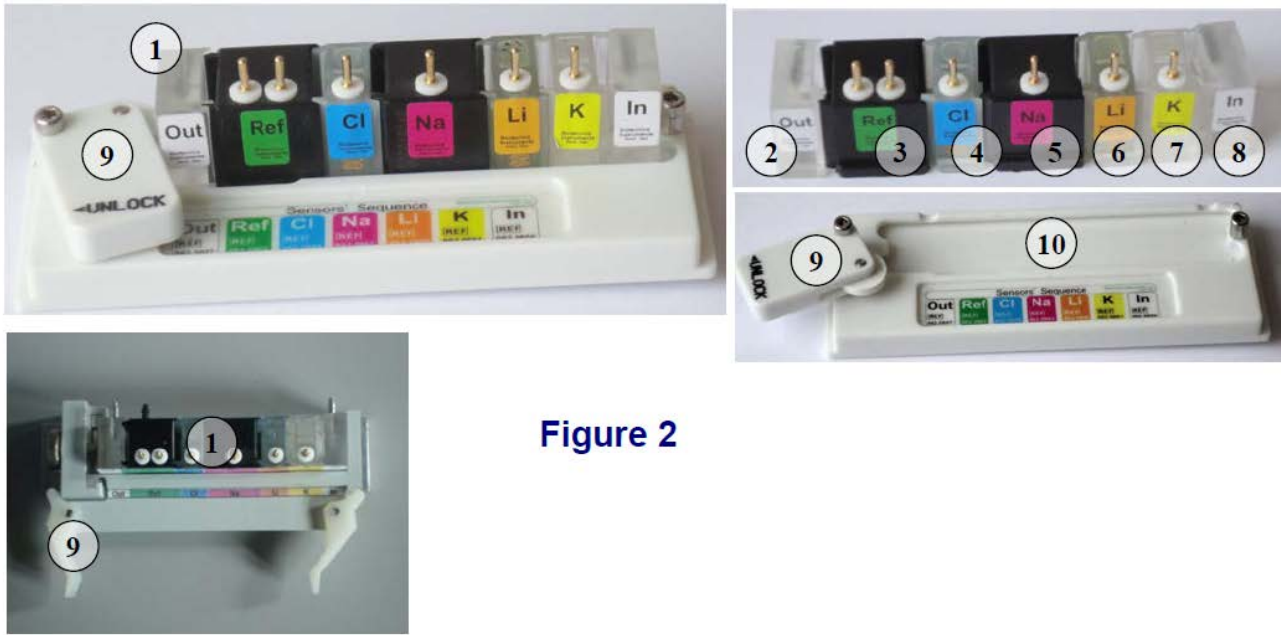


Figure 2

Some analyzers have the slide with one clip, while other analyzers have the two clips slide. The two type of slides are fully compatible and interchangeable.

REF	DESCRIPTION
1	Sensors stack (inlet, K, Li, Na, Cl, Ref, outlet)
2	Outlet sensor
3	Reference sensor
4	Chloride sensor
5	Sodium sensor
6	Lithium sensor
7	Potassium sensor
8	Inlet sensor
9	I.S.E. slide retaining clip
10	I.S.E. slide

1.1.1. Contents Of The Wooden Crates

In the small wooden create there are the items listed in **Mod. 05_28spr**, which is included in the shipment.

1.1.2. Applied Mathematical Functions

◆ COMPUTING THE SLOPE

$$S = \frac{(mVs_b - mVs_A)}{\text{Log}\left(\frac{Cs_b + H}{Cs_A + L}\right)}$$

where:

- S** : Slope
- mVs_b** : mV standard B, subtracted of its baseline value
- mVs_A** : mV standard A, subtracted of its baseline value
- Cs_b** : B standard concentration
- Cs_A** : A standard concentration

H and L are posed = 0 for all sensors but lithium.

For lithium sensors H and L will be:

$$H = \frac{Cb[Na]}{K[Na]} + \frac{Cb[K]}{K[K]}$$

$$L = \frac{CA[Na]}{K[Na]} + \frac{CA[K]}{K[K]}$$

where:

- Cb[Na]**: is the B concentration in the sodium sensor
- Cb[K]**: is the B concentration in the potassium sensor
- CA[Na]**: is the A concentration in the sodium sensor
- CA[K]**: is the A concentration in the potassium sensor
- K[Na]**: is the constant for sodium
- K[K]**: is the constant for potassium

◆ COMPUTING THE RESULT

$$Conc = \left(-H + (CsA + L) \cdot 10^{\left(\frac{(mVc - mVsA)}{S} \right)} \right)$$

where:

mVc : sample's mV, subtracted of its baseline value

mVsA: mV standard A, subtracted of its baseline value, read during the calibration

CsA : A standard concentration

S : Slope

H and L are posed = 0 for all sensors but lithium.

For lithium sensors H and L will be:

$$L = \frac{CA[Na]}{K[Na]} + \frac{CA[K]}{K[K]}$$

$$H = \frac{C[Na]}{K[Na]} + \frac{C[K]}{K[K]}$$

where:

C[Na]: is the sample concentration – newly calculated - in the sodium sensor

C[K]: is the sample concentration – newly calculated - in the potassium sensor

CA[Na]: is the A concentration in the sodium sensor

CA[K]: is the A concentration in the potassium sensor

K[Na]: is the constant for sodium

K[K]: is the constant for potassium

1.1.3. Operating Principles

The I.S.E. Module-4P can use both the direct or indirect potentiometry method, as desired by the operator. The direct potentiometry means a work method without the dilution of samples, while the indirect potentiometry means a work method where samples are diluted before the reading. The choice of the work method will be at the discretion of the user who opts for the one or the other method evaluating the performance of methods and their relative limits.

The Direct Potentiometry: theoretically it should be the most accurate method due to the exclusion of errors generated by the process of dilution and mixing, but it has a limit as it uses a relatively large quantity of sample.

The Indirect Potentiometry: on the contrary this method can work with a minimum sample volume. The sampling system provides the dilution of sample in the desired ratio using the sample diluent solution.

Reagent Volumes

Bear in mind that the volumes consumption is linked to the aging of the peristaltic pumps, therefore the below listed volumes must be considered as average.

An example of the used volumes is illustrated in the following table.

μl	Sol. A	Reference	Sol. B	Std C	Sample diluent
1 Cal. S	591	120	180		
1 Cal. S & U	1016	210	180	180	
1 Sample S (220 μl)	728	180			
10 Sample S	3581	960			
1 Sample U (diluted 1:3)	771	150			60 μl urine + 120 μl diluent
10 Sample U (diluted 1:3)	4011	960			1200 μl diluent
1 Prime	280	280	180		

1.1.4. Precautions For I.S.E. Module-4P Usage

SPECIAL CAUTION FOR THE WASTE CONTAINER

The reagent pack is composed of four bottles. One of these is for the I.S.E. waste.

It is of outmost importance to pay great attention to the volume of wasted liquids in the waste bottle. The reagent pack is calibrated in order to have the waste filled approx when the working solutions are almost empty. In any case the wasted liquids volume depends also on the samples. It is **strongly** suggested to verify often the volume in the waste bottle to avoid spillage and the consequent possible contamination of the pack and its seat.

WASTE ALARM

The I.S.E. WASTE volume is monitored by the software. When the volume reaches approx 88% of the container, the analyzer will warn the operator with a dedicated message. After the first message, other messages will be displayed while the waste volume increases. When the volume in the waste reaches 99% of the container, the analyzer will stop performing other I.S.E. functions and will ask the operator to replace the reagent pack.

In this error condition the analyzer will not allow to run I.S.E. primes or Na conditioning (in both cases the analyzer will display the error message and will ask to replace the I.S.E. pack. If the pack is not replaced, the functions will be aborted).

In the same error condition, calibration and patients will be started and immediately ended, giving slopes=0 and "w" flag for calibrations, for patients, results will be <NC> and flag "w".

The analyzer gives an approximated value of the waste in the Info Volumes window (function key F10 – Special reagents), see also [par. 1.4. Analyzer utilities](#) – I.S.E. wash and system shut down.

EMPTY PROCEDURE FOR I.S.E. MODULE-4P

In case it is necessary to rinse and empty the I.S.E. liquid path (maintenance, long periods of inactivity, etc) it is strongly recommended to perform the following procedure. Perform an I.S.E. Prime by using distilled water instead of the solutions. For this purpose it is possible to use an empty reagent pack (supplied with the analyzer) filled with bi-distilled water. Alternatively it is possible to leave the reagents pack in place (for the wasted liquid – approx 400 μl for the two primes as described hereafter) and to use two containers filled with bi-distilled water: insert the Ref tube in one container and the A & B solution tubes in the other. Perform an I.S.E. Prime, then remove the water from the containers and perform again an I.S.E. Prime to leave the tubes empty (place some adsorbing paper underneath the reference tube). Now it is possible to remove all containers and the reagents pack. This procedure will wash perfectly the entire hydraulic circuit and finally leave it empty. The successive activation of the I.S.E. Module-4P will require a Prime I.S.E. and the "Na conditioning" procedure. Remember to replace the reagents pack and to place the colored caps with draw tubes on the bottles.

Before operating this system, be sure to read the operator manual thoroughly and carefully. Afterwards, keep it handy for future reference

- ◆ Use only Biotecnica reagents, washing/conditioning solutions, maintenance kits.
- ◆ Never remove the sensors while the analyzer is working. This may cause malfunctioning of the system.
- ◆ The ambient conditions play an important role in the correct use of the I.S.E. Module-4P. Room temperature must be between 20°C and 26°C, and the humidity between 35% and 75%.
- ◆ If the room temperature varies (even by 2°C or 3°C) during a working day, then it will be necessary to repeat the calibration of the I.S.E. Module-4P just before running tests to avoid errors during next readings.
- ◆ It is suggested to insert the solutions (at room temperature) at least 30 minutes before operating phases begin. If the thermal equilibrium is not reached, then the phenomenon of drift and erroneous results may occur.

NOTE:

I.S.E. Module-4P should be calibrated only after the above-mentioned equilibrium has been reached.

- ◆ It is recommended to run the standardization twice a day, in the morning and in the afternoon or in any case every four hours. Standards and samples should be at room temperature before they can be used.
- ◆ Bear in mind that the samples are altered if exposed to air for more than 30 minutes.
- ◆ If the solutions are replaced, then the calibration should be performed again to avoid possible incorrect results.
- ◆ If the sensors are removed for any reason, then carefully note down the sensors sequence positions.
- ◆ The sensors should be washed (Na conditioning solution) on regular basis once a week. This makes the sensors more stable and guarantees a longer life
- ◆ A repeated conditioning of the sensors may be necessary in the following conditions:
 - more than 100 samples are performed each day
 - a period of inactivity of two or more days. After a week-end it is suggested to perform a sensors' conditioning on Monday.
- ◆ Randomly it may be necessary to perform a conditioning of the sensors in case the Na slope should suddenly fall (ex. from 55 to 30). This may be due to a variation in the sensor's pH. The conditioning solution can solve this problem.
- ◆ The necessity of repeated conditioning procedures may indicate a general problem with reagents/samples/sensors that may require further investigations.

1.2. Performance And Limits - I.S.E. Module-4P

Number of sensors:	4 plus Reference Sensor
Analytes:	K ⁺ , Na ⁺ , Cl ⁻ and Li
Method:	Direct or indirect potentiometry
Analytical throughput:	Up to 240 tests/hour (K ⁺ , Na ⁺ , Cl ⁻ and Li)
Sample Type:	Serum, Urine (diluted)
Sample Volume:	See table 1, par. 2.1.
Machine I.S.E. cycle:	60" in direct and 72" in indirect
Serum measurement range:	Na : from 60 mEq/l to 350 mEq/l K: from 2 mEq/l to 20 mEq/l Cl: from 50 mEq/l to 250 mEq/l Li: from 0 mEq/l to 4 mEq/l
Reagent autonomy:	> 220 tests.

Precision				
Direct		Indirect		
	Serum	Urine	Serum	Urine
K	± 1.5 %	± 2 %	± 2 %	± 2.5 %
Na	± 1.5 %	± 2 %	± 2 %	± 2.5 %
Cl	± 2 %	± 2 %	± 2 %	± 2.5 %
Li	± 3 %		± 3 %	

Linearity		
	Serum	Urine
K	2 - 10 mEq/l	10 - 300 mEq/l
Na	60 - 200 mEq/l	10 - 300 mEq/l
Cl	60 - 200 mEq/l	20 - 300 mEq/l
Li	0 - 4.0 mEq/l	

Accuracy							
Direct		Indirect		Direct		Indirect	
Intra-run (C.V.)				Inter-run (C.V.)			
	Serum	Urine	Serum	Urine	Serum	Urine	Urine
K	< 1.5 %	< 2 %	< 1.5 %	< 2 %	< 3 %	< 2.5 %	< 2.5 %
Na	< 1.5 %	< 2 %	< 1.5 %	< 2 %	< 2.5 %	< 2.5 %	< 2.5 %
Cl	< 2 %	< 2 %	< 2 %	< 2 %	< 2.5 %	< 2.5 %	< 2.5 %
Li	< 3 %		< 3 %		< 5 %		< 5 %

1.3. Starting The I.S.E. Module-4P

After passing all the first power-on procedures, it is possible to initialize I.S.E. Module-4P.

PRIME ISE: once the reagent pack has been inserted, press I.S.E. prime. The peristaltic pumps R, A and B will begin to aspirate the Reference (which will be emptied first), the STD A and the STD B solutions respectively until their presence is detected by the dedicated bubble sensors. It is important that the Prime I.S.E. is performed every time, when you insert a new reagent pack. However it is important to note that I.S.E. Prime is automatically performed prior to a calibration or a test run, if the instrument has been just switched on.

The module can now initiate to execute its functions starting with the calibration.

CALIBRATION: It is performed aspirating the standard B followed by the standard A, which is aspirated a first time for washing, then a second time for the reading. The slope is then calculated. This process can be repeated up to 3 times so that the slope is repetitive at least once and within the predefined limit values. In case of calibration also for urine, a third standard, named standard C has to be placed on the samples tray. The standard C will be aspirated, dispensed into the funnel and used for the urine slope calculation in combination with the standard A.

The concentration values of standards are generally always the same (standard 1/2 or standard B/A): K = 10/4 Na = 60/140 Cl= 46/114 Li= 5/0,5 expressed in mEq/l. However check the insert in the package for declared values. The standard C concentration is usually K = 100 and Na = 30mEq/l.

The concentrations of the standards used for calibration are titled with the protocol of NIST, which is not always used by everyone. For this reason the values of samples and control sera may not be the expected values.

SAMPLE ANALYSIS: the determination of a sample is always followed up by a reading phase of standard A (used as baseline). The sample is dispensed into the funnel by the sampling arm directly with the direct potentiometry method. In the indirect potentiometry method the sampling arm picks up the sample diluent + sample and dispenses into the funnel (mixing chamber) for successive mixing.

RECONDITIONING OF THE Na SENSOR. The Na sensor requires reconditioning of its proper pH value. The reconditioning procedure is simple and rapid and a specific solution "Na conditioning solution" has to be used which is provided. When to perform: usually once a week or when one notices a sharp decline of the Na Slope, beyond 6 mV. In practice the Na Slope descends a couple of mV per day, but it is also dependent upon the number of tests executed. The function of Na reconditioning is in the Utility menu under the title "Na Reconditioning". The procedure consists in placing a serum cup with at least 500µl of Na conditioning solution in the serum plate in the position indicated on the displayed message and then press start. This procedure will last for approximately 4 minutes (after the aspiration of the Na solution into the sensors, the analyzer will wait for approx 3 min) and ends with the release of the solution A into the sensors. Then it is suggested to run a calibration (slope).

WASTE CONTAINER. The volume of the Waste container may not be sufficient to contain all the discharges if there are many Urine tests. In fact the volume of urine tests is larger than the serum tests. It is advisable to verify often the volume in the waste container (see also [Change I.S.E. pack in par. 1.4. ANALYZER UTILITIES](#))

REFRESH CYCLE: The refresh operation maintains the sensors and the hydraulic circuit. This operation is for avoiding stagnation of fluids in the tubing and sensors due to the potential formation of crystals. Refresh is activated every 4 hours releasing small amounts of Sol. A and reference solution in the sensors. The volumes consumed every 4 hours are approximately 25µl of Reference solution and 60µl of Sol. A. The refresh is not activated during testing, but every 4 hours of I.S.E. inactivity. The refresh is activated automatically also when the instrument is in sleep mode or after a shut-down, unless the power switch is turned off.

Temporary removal of the ISE Module for maintenance

It is of utmost importance to maintain the hydraulic efficiency because the circuit is susceptible to obstructions caused by the highly saline solutions, especially the Reference solution tends to crystal formation. For this reason it is very important, when the instrument must remain inactive for more than 5 days, to run a washing with distilled water of the hydraulic circuit of the sensors. It is therefore strongly recommended to perform an I.S.E. Prime by using distilled water instead of the solutions (see the correct procedure at par. 1.1.4., line EMPTY PROCEDURE FOR I.S.E. MODULE-4P). Remember to close the reagents pack with the original caps.

1.4. Analyzer Utilities - I.S.E. Wash And System Shut Down

The shut down procedure proposes the wash of the cuvettes with appropriate cleaning solution before turning off (see chapter E, par. 1.6. TURNING OFF PROCEDURE). The analyzer indicates the position where the solution should be inserted for the cuvettes washing. As regards the I.S.E. Module-4P, the Na conditioning procedure provides a wash of the I.S.E. module, but it is not necessary at the shut-down. The Na conditioning must be performed every time it is necessary and at least once a week.

NOTE: if the analyzer is never turned off, it will automatically refresh the sensors with the baseline (A solution) and the reference every four hours (only during the sleep or the suspend activity modes). Make sure that there are enough solutions in the bottles.

I.S.E. prime: the manual I.S.E. prime will empty the reference tube and then fill up the I.S.E. tubes. This procedure may be repeated up to seven times if the liquid does not reach the bubbles sensor.

Sodium Reconditioning: It is used for a complete wash with appropriate solution (Na Conditioning Solution) of the fluidic circuit of the I.S.E. Module-4P. This is to guarantee correct maintenance of the sensors.

The dedicated solution must be placed in the samples' tray – an on-screen message will guide the operator.



Change I.S.E. pack: the analyzer monitors the I.S.E. waste volume, which is updated in the Info volumes window (F10). When the waste reaches the 88%, the analyzer will display a warning message. To replace the I.S.E. pack and restart the volume counter, press this button and then confirm. After this operation an I.S.E. prime and an I.S.E. calibration will be mandatory. If the analyzer will go on working after the warning message, the I.S.E. waste will reach the max allowed percentage, blocking the I.S.E. functions as explained below.

NOTE ON THE I.S.E. WASTE WARNINGS:

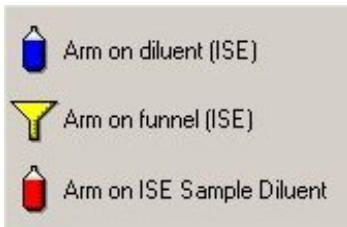
When the I.S.E. waste is full, the analyzer will not allow the operator to perform I.S.E. functions. If the operator selects an I.S.E. prime or an Na conditioning, the analyzer will warn that the I.S.E. waste is full and will ask to replace the pack. In case of positive answer, the operator will have to replace the pack, in case of negative answer, the selected function will be aborted and an error message will be displayed.

If a calibration or a run (with I.S.E. tests) are selected, the analyzer will start the procedure, but it will interrupt it immediately. The calibration will give an error, the slopes will be set to zero and it will be flagged with "w" (I.S.E. waste full). The I.S.E. tests present in the run will not be performed, the result will be <NC> and it will be flagged with "w".

1.5. Mechanical Calibrations: I.S.E.

The mechanical calibration of the arm on I.S.E. follows the same rules already seen for the arm mechanical calibrations, see Chapter H, par. 1.1.2.

The following two functions are directly linked to the arm positioning on the I.S.E. side.



Arm on funnel: the I.S.E. arm moves above the I.S.E. mixing funnel. Center the sampling needle on the funnel. It is very important that the needle is centered in this position to prevent it from touching the funnel walls during mixing.

Arm on diluent: centers the I.S.E. arm above the tube containing the physiological solution for diluting the samples.

Arm on I.S.E. sample diluent: center the I.S.E. arm above the sample diluent bottle located inside the I.S.E. module, next to the funnel.

2. OPERATING THE I.S.E. MODULE-4P

2.1. Parameters

Go to the Global list (Figure 3) or the Current Tray list. Select I.S.E., and then click Parameters to display the screen showing analytical parameters for the I.S.E.: General Parameters, Serum's Parameters, and Urine's Parameters. The General Parameters is displayed first (Figure 4), to access the other parameters click on the corresponding tags.

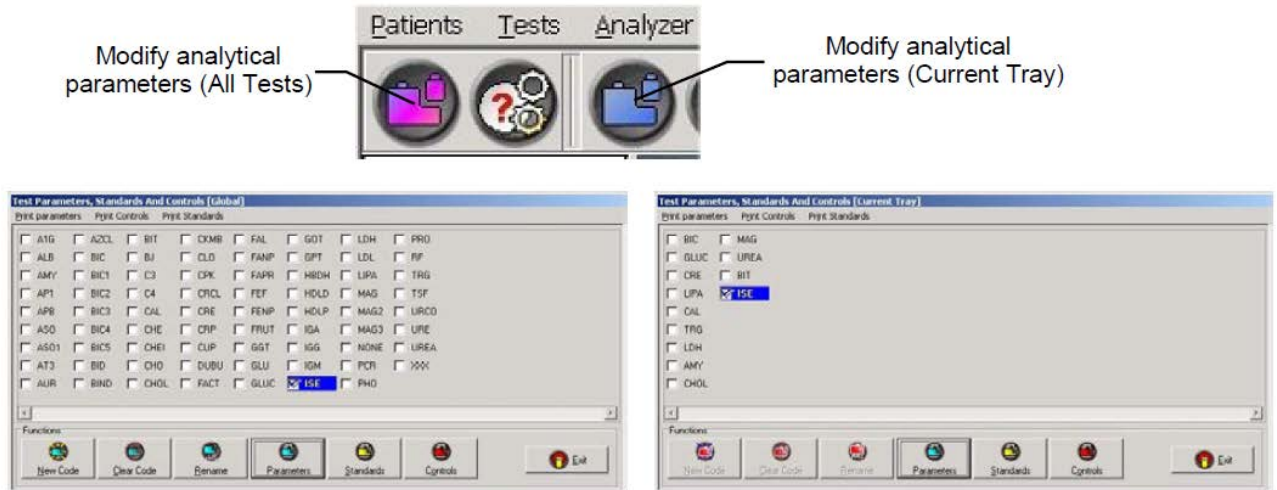


Figure 3

GENERAL PARAMETERS: In this page it is possible to program the general parameters for the I.S.E.

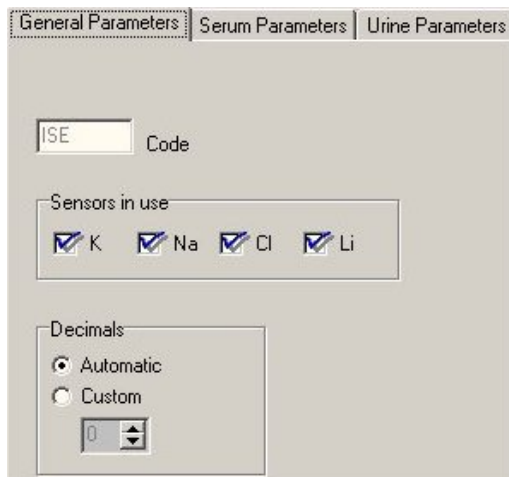


Figure 4

Sensors in use (K Na Cl Li): Click the check boxes to select the sensors to be used among those available here. This command selects or deselects sensor. When an sensor is not used it is necessary to deselect the sensor to prevent continuous errors during calibration. If the selection of sensors being used is modified, it is necessary to repeat the calibration.

Decimals: For setting the number of decimal digits in test results (**Automatic** or **Custom**). If a value is not specified, then the analyzer automatically assigns number of decimal digits using the Floating point algorithm.

NOTE: the analytical parameters have been optimized by Biotechnica Instruments for this I.S.E. module. The suggested optimized parameters are listed in Table 1.

Both serum and urine samples may be run whole or diluted, with the limitations specified in Table 2.

SERUM & URINE PARAMETERS: Here it is possible to set the analytical parameters for running serum or urine samples with the I.S.E. The parameter fields are the same for serum and urine. The lower part of the window, containing the normal range, the instrumental factor, etc, is different for every sensor, therefore it must be filled for potassium, for sodium, for chloride and lithium separately. Between serum and urine, the only difference is that in the urine window there is not the page dedicated to the lithium parameters.

Sample µl: write here the sample volume expressed in µl that the analyzer will take from the cup.

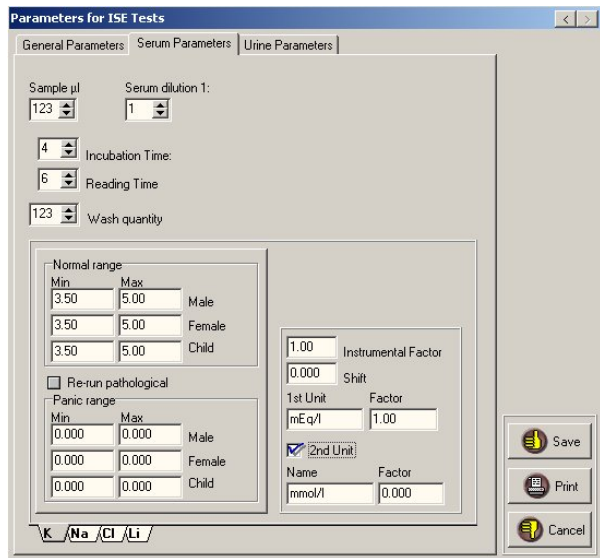


Figure 5

Serum dilution 1: sets dilution ratio between sample and sample diluent.

Incubation Time: incubation time expressed in seconds, suggested value is 4 seconds.

Reading Time: analysis' reading time, expressed in seconds, suggested value is set at 6 seconds.

Wash quantity: this is used for entering the volume in µl of A solution that must be used for washing the hydraulic circuit at the end of a test determination. The suggested wash volume corresponds to the total sample volume used.

Then it is possible to assign the **Normal range** (Figure 5) for each sensor and, if needed the panic range for pathological repetition. The programming of the normal range values for Man, Woman and Child is assigned specifically to each sensor. To assign the normal (and panic) range to each sensor, click corresponding tag. Click **Re-run pathological** checkbox to let the analyzer repeat all pathological results outside the given range.

Instrumental factor: introduces a correction of the final datum of the executed test; it can be used to adjust the data of the test with different types or analytical methods or instruments. Calculation: final result = value x instrumental factor.

Shift: the function introduces a quantitative correction of the final datum of the executed test; it can be used to adjust the data of the test with different types or analytical methods or instruments. Calculation: final result = value + shift.

1st Unit: Enter value in the corresponding field and enable **2nd Unit** to enter a second value and instantly a new textbox appears where the user can enter the second unit and the second unit's conversion factor. In case of double units, the test results are expressed with two values. In analytical calibrations, the first measurement unit is used.

Factor: in case the standards are expressed with a different unit, it is possible to enter here the conversion factor between the first unit and the standard's unit.

The following are the suggested parameters - **Table 1**

	DIRECT POTENTIOMETRY		INDIRECT POTENTIOMETRY	
	Serum	Not available	Serum	Urine
Sample volume µl	123	---	90	60
Sample dilution 1:	1	---	2	3
Incubation time	4	---	4	4
Reading time	6	---	6	6
Wash quantity	123		180	180

Parameters Limits - Table 2

	DIRECT POTENTIOMETRY		INDIRECT POTENTIOMETRY	
	Serum	Urine	Serum	Urine
Min sample volume	123	180	24	32
Max sample volume	320	320		
Dilution range 1:	1	1	Up to 5	Up to 10
Min total volume	120	120	120	120
Max total volume	320	320	320	320

The above mentioned limits are only indicative, as it is not advisable to use the direct potentiometry with undiluted urines, as well as it is not advisable to use very small sample volumes (24µl and 32µl) in the indirect potentiometry.

URINES: bear in mind that urines must be collected in the 24h before being analyzed. Biotechnica suggests to dilute the 24h urines 1:3 with the sample diluent.

Note: The Li sensor is automatically excluded in Urine's parameters (it does not appear even if it is present in the sensors in use).

At the end of programming press the **Save** button to save the inserted data, otherwise press **Cancel**.

NOTE: When the following parameters are used at the same time: Instrumental factor and Shift, External dilution factor and Urine 24/h (in the patient's data), the calculation made by the analyzer will be as follows:

$[(\text{obtained result} \times \text{External dilution factor} \times \text{Instrumental factor}) + \text{Shift}] \times \text{Urine 24/h}$

2.2. Programming Standards And Controls

INSERTING STANDARDS: as explained for parameters (Figure 2 & 3), select I.S.E., and then click Standards to display the Standard parameters page (Figure 6 & 7). Standards programming (automatic or on request) follows the same procedure seen for Clinical Chemistry. For serum calibration, two known standards are required, for urine calibration three standards are required.

Timed re-run: see the same function in Controls.

Use urine calibration: select the check-box in case the calibration is required for running both serum and urine samples. In this case the standard C is necessary and it must be placed on the samples tray, in a position among the available for standards.

ATTENTION: this checkbox enables the reading of urine samples with the dedicated slopes. If not enabled, the urine samples will be erroneously read with the serum-calculated slopes.

Position standard C: select here the position among the standards where to place the urine standard.

Last Standardization: The time and date of last test positive calibration are shown here. There are two pages: one for serum calibration and one for urine calibration.

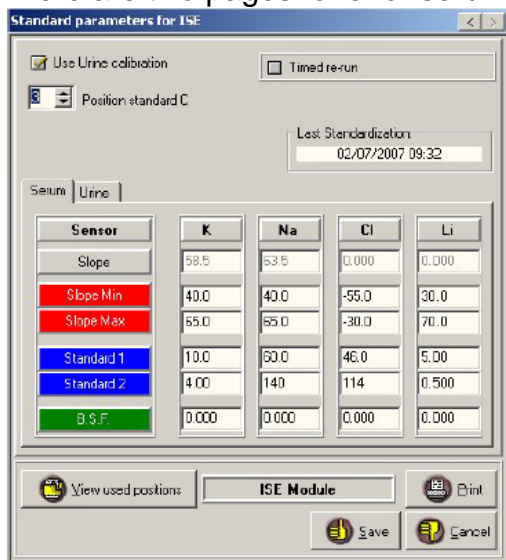


Figure 6

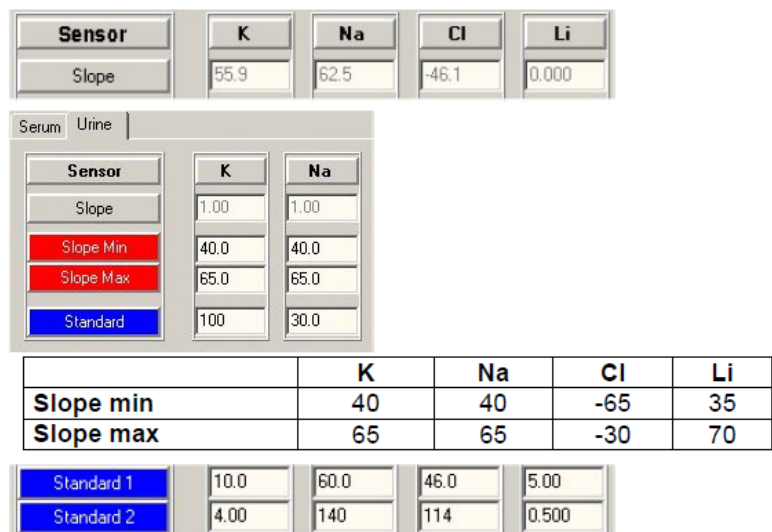


Figure 7

Slope: After each calibration, the calculated values for the slopes are updated in these fields. Calculated slope values must be within the indicated ranges.

Slope Min / Max: By double-clicking the textboxes, slope ranges are individually set for each sensor. Refer to test methodology for correct values. The slope values are important for verifying a correct calibration and the sensors status. When a slope is out of range, it will probably mean that the sensor must be replaced.

Standard 1 / 2: Double clicking in the appropriate fields it is possible to program the concentration values of the two standards for each sensor. Every time standards are changed, the set points must be changed as well. Refer to the kit insert or to the standards label for the correct values. When calibrating also for urine, a third standard name "C" must be given, for potassium and sodium, in the urine dedicated page.

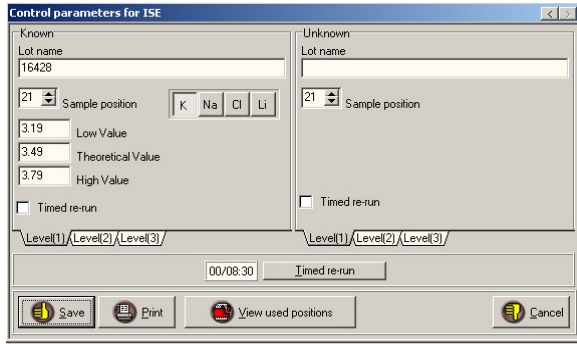
IMPORTANT NOTICE: always remember that standard 1 corresponds to the B solution and standard 2 corresponds to the A solution.

BSF: This parameter is a Base Line Factor used as linearity correction factor, in case of need.

View used positions: This command shows all the positions used by standards.

INSERTING CONTROLS

Go to the analyses list , select **I.S.E.**, and then click **Controls** to display the **Controls parameters**



for I.S.E. (Figure 8). The Controls programming (automatic or on request) follows the identical procedure of Clinical Chemistry (Chapter C, paragraph 1.4. Controls). Selection of a single sensor is required prior to controls programming. Use the command **Save** for memorizing data, **Cancel** for leaving the program without saving changes, and **Print** for hard copy printout.

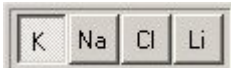
Figure 8

The displayed page is divided into two parts, one for the **Known** controls and the other for the **Unknown** controls (Figure 8). The opening page is default set to **Level (1)** controls. To set parameters for Level 2 and 3, click corresponding tabs.

KNOWN CONTROLS

Known Controls: Select the sensor.

Lot Name: Enter a name or a lot number.



Sample position: Enter the sample's physical position on the plate. The reserved sample positions are located in the inner circles of the sample plate and are dedicated to calibrators and controls. The numerical positions on the sample plate correspond to those established in the Setup Analyzer (refer to Chapter H, paragraph 2. Setup Analyzer).

Low value: Enter the lower value for the control's range.

Theoretical Value: Enter the theoretical value for the control.

High value: Enter the higher value for the control's range.

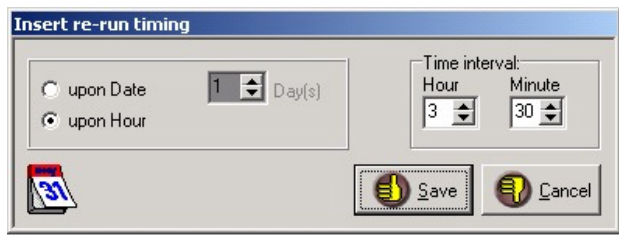


Figure 9

Timed re-run: to program the automatic reminder for repeating controls. It is possible to insert the timer for each single control. Check **Timed re-run** box and then Click **Timed re-run** (just above the View used positions) to display Insert re-run timing screen (Figure 9). Here it is possible to enter interval of hours or days (refer to Chapter C, paragraph 1.4.) for automatic controls run.

Every day or when the preset time expires, the analyzer will automatically alert the user that there are controls to be run.

The automatic reminder has to be activated in the **Immediate Controls** page (see Chap. E, par. 1.3)

View used positions: This command displays the test disposition.

NOTE: Enter the same parameters also for Level 2 and 3 controls.

UNKNOWN CONTROLS

The only parameters to be set are the lot name or number, the sample position on the sample tray and the timed re-run for each level. Reserved positions are located in the inner circle of the sample plate and are dedicated to the calibrators and controls. The numerical positions on the sample plate correspond to those already set in the program **Setup Analyzer** (refer to Chapter H, paragraph 2. Setup Analyzer).

After programming all the parameters, save parameters by clicking **Save** button. Click **Print** for hardcopy printout of control parameters.

2.3. Replacing And Installing Sensors, Tubes And Pumps.

The analyzer is shipped with all I.S.E. accessories in separated envelopes. Before using the I.S.E. Module-4P it will be necessary to install all parts. See the following instructions for replacing/installing parts. The I.S.E. sensors are shipped in single sealed bags. The peristaltic pumps are shipped with the corresponding tubes with silicon connector already in place. The colored caps, with their draw tubes are placed in a smaller bag. The sensors' slide is placed in a separated bag.

SENSORS

To replace or install the sensors the **analyzer must be turned off** and then the following steps must be observed. Make sure all not necessary items are removed from inside the I.S.E. Module-4P (protective labels or other items).

WARNING

Do not touch with bare hands the metallic pins of the sensors, or the sensor electronics, in order to avoid electrostatic discharges that may cause system malfunctioning for several hours.

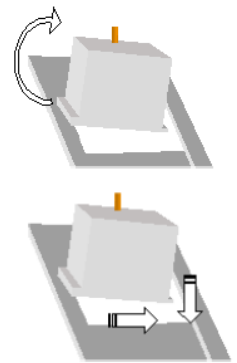


Figure 10

REF	DESCRIPTION
1	Sensors stack (inlet, K, Li, Na, Cl, Ref, outlet)
2	Outlet sensor
3	Reference sensor
4	Chloride sensor
5	Sodium sensor
6	Lithium sensor
7	Potassium sensor
8	Inlet sensor
9	I.S.E. slide retaining clip
10	I.S.E. slide

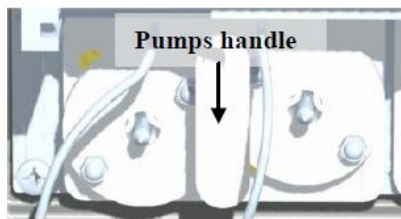
1. Before installing/replacing the sensors, make sure the I.S.E. hydraulic circuit is empty. Perform an I.S.E. prime after having removed the tubes ①, ② and ③ of Figure 11, from their caps.
2. Remove the sensors support sliding it out of its grooves.
3. Unlock the retaining clip ⑨ by rotating it clockwise.

The slide offers an enlargement to allow the sensors extraction. This enlargement corresponds to the Ref sensor position. To remove the sensors, first extract the Ref, by lifting its front side, then all other sensors, by sliding them to the Ref position and then extracting them as done for the Ref. To insert the sensors, use the Ref position and insert every sensor using the same procedure seen for the removal, but inverted. Introduce the back of the sensor into the slide groove and then insert the front. Start from the Inlet, then K, Li, Na and Cl. Let the sensors slide to their final positions. Then enter the Outlet sensor and fully slide it to the left, as in Figure 10. The Ref must be the last one inserted.



4. Install or remove and replace the sensors as necessary.
5. Pay attention to the correct order of the sensors in the stack.
6. Place the retaining clip ⑨ back to block the sensors.
7. The sensors stack can be placed back into the module, by inserting it into the dedicated slot. Make sure that the slide is correctly in place and fully pushed inside.
8. Close the side panel. After these operations, it may be advisable to run some I.S.E. primes.

PERISTALTIC PUMPS



The pumps assy is fixed with a thumb-screw to the panel. Remove the screw, then pull the pumps handle and the whole assy will be removed. Place a new pumps assy by inserting the two pump axes in the holes at the center of the pumps, then push the assy panel in place and fix it again with its screw.

TUBES

Once the peristaltic pumps have been replaced/installed, all four solutions tubes will be free, having at the end the colored rubber connectors. Take the colored caps with draw tubes. Insert every colored rubber connector into the nipple on the corresponding colored cap, matching colors. Place the reagents pack into the analyzer and simply screw the colored caps into their respective bottles. Pay attention to correctly insert the draw tubes into the bottles when closing them. The A solution has black rubber and cap, the B solution has green rubber and cap, the reference solution has blue rubber and cap, while the waste has red rubber and cap. On the reagents pack label, the solutions are identified by the same colors.



Figure 11

2.4. Preliminary Steps Before Starting The System

This procedure is necessary when installing the system or after replacing the sensors

- a) Place the reagents pack in its lodging. The sample diluent solution is placed it into a 20ml bottle in a dedicated position (see figure 1) near the mixing chamber (funnel).
- b) Make sure that the contents of the reagents pack is sufficient for the necessary workload.

Caution: this verification of volumes (for necessary workload) is highly recommended. Whenever the solutions are changed, a new calibration of the system must be performed.

- c) Run **Prime I.S.E.** and repeat it for at least three times.

NOTES: if the device has just been installed, the sensors have been replaced or if the I.S.E. Module-4P has not been used for some time, various system primes should be run. Wait around 10 minutes before using the I.S.E. Module-4P to let the sensors be conditioned by prior passage of the solutions.

- d) Verify that programmed values for the standards (solution A/solution B) correspond to the used lot. Programming is performed as shown in **Figure 7**, where the values for two standards must be entered for the calculation of slope during the calibration.

- e) to avoid contamination and evaporation of the sample diluent solution, it is advisable to close the bottle when the I.S.E. is not used, especially if only a few samples are run each day.

The I.S.E. Module-4P should be considered by the user as an ordinary test for Clinical Chemistry requiring a programming of its own for standards and controls. Calibration should be performed every four hours and it is essential for precise and accurate results. In addition, it is recommended to execute repeated calibrations until a stable slope value is obtained.

2.5. Calibration Procedure

Standards are aspirated into the sensors through the peristaltic pump. After an incubation period, the reading is performed.

At the end of calibration phase, the slope is calculated in accordance with **Nernst** equation:

$$\text{Slope (s)} = \Delta E / (\log \text{STD high} - \log \text{STD low})$$

where ΔE = difference in mV between STD high and STD low

After calibrating each sensor, optimal slopes are obtained which should be within the following acceptance range:

	<u>Range of slopes</u>
K:	40 / 65 mV
Na:	40 / 65 mV
Cl:	-55 / -30 mV
Li:	30 / 70 mV

NOTE:

In addition to the acquired slopes values, it is important to observe also the potential of the standards in the calibration printout (see also par 3.3 troubleshooting).

In the optimal conditions, these values can be reproduced quite easily with slight variations around nominal value. The potential of the standards in association with the obtained slope values, are useful for evaluation of a correct calibration. When sensors are not efficient, for example, when poor or no maintenance has been performed, or in case of contamination or degradation of the working solutions (Sample diluent, Solution A, Reference or STD), the potential values vary considerably. This results in erroneous slopes indicating that the operating conditions are not optimal. However, in some cases, the potentials have incorrect values, but the slopes are apparently acceptable. Be cautious with this situation as the precision and accuracy of tests results will be affected by an incorrect calibration.

The potential values are related to standards, thus by changing standard's lot with another concentration, the different potentials will be observed with the same slope values. To optimize system performance it is fundamental that both the slope and potential values are always around established levels.

In case the slope values are out of range, an on-screen error message is displayed, even if there is an incorrect response from only one sensor. A check is also performed on the slopes reproducibility. The values obtained during current calibration are compared to the values of previous calibration. An error message appears during serum calibration if there is a variation greater than 3% for K and Na, 5% for Cl and 8% for Li. For serum & urine calibration the K and Na slopes are acceptable if the variation is within 4%. A further control is performed with an internal algorithm to verify if the serum and urine calibration are consistent. In this case the acceptable limits are :

$$-20\% < \text{K slope} < +10\% \quad -10\% < \text{Na slope} < +10\%$$

After an incorrect calibration or in case of a calibration beyond the preset limits, the analyzer automatically performs a new calibration, with up to 3 calibrations maximum.

NOTE:

If slopes and potentials are constantly out-of-range, this indicates that the sensors are exhausted, or there is an aspiration error of the reference solution in the reference sensor or the working solutions are contaminated or degraded. In case of contamination or degradation, replace the solutions and repeat the calibration procedure. In the other cases such as exhausted sensors or a reference aspiration error in the reference sensor, refer to the Troubleshooting guide.

2.6. Measuring Unknown Samples

After a correct calibration, the samples are determined, which are prepared and read in similar manner to standards: aspiration into the sensors, potential reading, and the reference aspiration. The samples are calculated applying **Nernst** equation:

$$E - E_0 = s \log (C_x / C_{Std})$$

Considering the fact that the system requires a calibration, the measurement method is defined as comparative.

I.S.E. tests are programmed in the same way as any other analysis of clinical chemistry.

Precision and accuracy errors when determining samples

NOTE:

In case of errors during samples determination, please follow indications outlined in the Troubleshooting guide.

Determined results can be associated to a flag that indicates eventual problems occurred during measurement.

The presence of **D** flag near a result, relevant to one or more sensors, indicates drift during sample reading, i.e. the drift has exceeded $\pm 2\text{mV}$ and thus the sensor may be unstable.

The flag **R** near the results indicates the absence of reagents.

The flag **B** adjacent to results indicates the presence of air (bubbles) in the hydraulic circuit during the transfer of the sample into the sensors.

The sign **<NC>** in place of the results, indicates abnormal values (for example 9999999,999) or erroneous values (ex. No sample or reagent). Abnormal values may result from an interruption of the liquid flow into the sensors during the test reading phases.

3. MAINTENANCE AND TROUBLESHOOTING

3.1. Suggestions For Performance Maintenance.

To eliminate any problems during I.S.E. operation, observe the following suggestions:

Before a long period of system's inactivity, proceed as follows:

- a) Perform an Na conditioning even if no I.S.E. determination has been performed.
- b) It is very important that when the instrument must remain inactive for more than 5 days to run a washing with distilled water of the hydraulic circuit of the sensors. It is therefore strongly recommended to perform an I.S.E. Prime by using distilled water as described in paragraph 1.1.4. at the voice EMPTY PROCEDURE FOR I.S.E. MODULE-4P. This procedure will wash perfectly the entire hydraulic circuit and finally leave it empty. The successive activation of the ISE module will require a Prime ISE and the "Na conditioning" procedure. Remember to replace the original reagents pack and to place the colored caps with draw tubes on the bottles

After a long period of system's inactivity, perform the following:

- a) Run Prime I.S.E. and repeat this procedure for three times, perform an "Na conditioning" procedure

CAUTION: refer to the Troubleshooting guide in case of problems during system restoring.

3.1.1. I.S.E. Maintenance (Six Monthly Kit I.S.E. 4P Code 11-06227-01)

The I.S.E. maintenance involves the sensors as well as the peristaltic pumps with their tubes, connectors and caps. Make sure that the I.S.E. liquid path is empty. Disconnect the rubber connectors from their caps, place some adsorbing paper underneath the rubber connectors and start an I.S.E. prime. Remove the paper and turn the analyzer off.

I.S.E. peristaltic pumps and tubes

Six monthly I.S.E. Maintenance Kit (Code 11-06227-01)		
Pos.	Q.Ty	Description
1	1	Waste and reference peristaltic pumps + tubes with red and blue rubber connectors + red and blue caps with draw tubes.
2	1	A & B solutions peristaltic pumps + tubes with black and green rubber connectors + black and green caps with draw tubes.

In the replacement kit there are two couples of pumps, the tubes with the colored rubber, the colored caps with their draw tubes.

Disconnect the colored rubber connectors from the caps and remove the reagents pack. The pumps assy is fixed with a knob to the panel. Remove the knob, then pull the pumps handle and the whole panel will be removed. Place a new pumps panel by inserting the two pump axes in the holes at the center of the pumps, then push the panel in place and fix it again with its knob.



Figure 12

Remove the old colored caps with draw tubes from the reagent pack and replace them with the new ones, following the correct color code. Place the reagent pack back in place. Insert every rubber connector into the corresponding colored cap as shown in the above picture.

CAUTION: the peristaltic pumps must always be well fixed to the back panel by means of the knob, to avoid the pump axe to slide causing reagent errors.

I.S.E. Sensors

The I.S.E. sensors maintenance consists in the replacement of the sensors as follows:

- K: every 6 months
- Na: every 12 months
- Cl: every 3 months
- Li: every 3 months
- Ref: every 12 months

If a large amount of tests are performed daily, it might be necessary to replace the sensors more often.

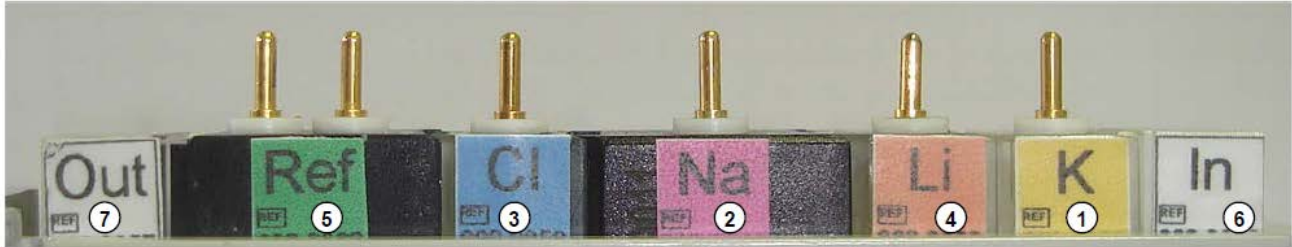


Figure 13

For replacing the sensors, follow the instructions in par. 2.3.

In the normal maintenance is also necessary to wash the sensors weekly with the Na conditioning solution (see Sodium reconditioning at par. 1.4.).

Ref.	Sensor.	Description
1	K	Potassium sensor
2	Na	Sodium sensor
3	Cl	Chloride sensor
4	Li	Lithium sensor
5	Ref	Reference sensor
6	Inlet	Inlet (to the sensors)
7	Outlet	Outlet (to the waste)

3.2. Troubleshooting

If the routine maintenance is performed regularly, the I.S.E. Module-4P functions correctly. The most common problems encountered in the I.S.E. Module-4P are as follows:

- a) Calibration errors.
- b) Unreliable sample results with flags.
- c) Error messages of air bubbles.
- d) Occlusions in the I.S.E. bowl (funnel)

a) CALIBRATION ERRORS

The causes may be due to various reasons and can be diagnosed through close examination of mV values of slopes.

Typical values of calibration potentials in mV for new sensors and fresh reagents:

K around 22 mV

Na around -19 mV

Cl around 19 mV

Li around 26 mV

The above-mentioned values are indicative and may deviate due to the aging of the sensors.

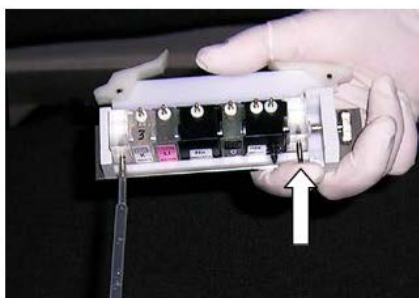
See also point d).

b) UNRELIABLE SAMPLE RESULTS WITH FLAGS

This problem may be determined by one of the following causes:

- Defective sensor. Check and replace.
- Sensor to be reconditioned. Perform an Na conditioning.
- Contaminated reagents. Replace.
- No washing after a consistent run. Perform an Na conditioning.
- Air in the hydraulic system. Inspect the sampling tube for possible leaks.
- Sampling imprecision due to reagent or sample residues on the external surface of the needle, with consequent contamination during preparation. Remove Needle and clean externally using gauze soaked with alcohol.

- Partial occlusion of the sensor. Check there are no occlusions in the sensors stack. To



perform this operation always wear protective devices (gloves, glasses, etc). Remove the sensors stack. Load a syringe with A solution, remove the needle and insert the supplied rubber in its place. Connect the rubber to the Ref sensor. Keep closed one of the nipples of the In or Out sensors with a finger and push the solution through the sensors. The solution should flow and exit from the open metallic nipple. If the solution does not flow correctly, open the sensors stack and inspect the sensors singularly.

- Partial occlusion of the needle: remove the needle and clean it internally with the supplied tool.

Results with flag D

During the reading, the flag D on one or more sensors indicates a drift of potential greater than 2 mV.

Results with flag R

The flag R indicates no reference or baseline solutions. Verify if there is enough reference solution in bottle. Verify the A solution bottle residual volume. Replace if necessary.

c) ERROR MESSAGES, AIR BUBBLES, FLAGS

During a calibration or a run an error message Air bubbles may appear. The error may be momentary and not appear afterwards. In this case, it means a casual formation of bubbles. The bubble error in the I.S.E. is managed as follows:

- a. If the bubble error occurs during the prime, the analyzer should give the prime error warning, all the following I.S.E. samples will have to be flagged with R and will have <NC> instead of the result.
- b. if the bubble error occurs during the sampling, while reading the baseline, the analyzer should display the bubble error message, should stop sampling and should give all the following I.S.E. samples results as <NC>, with flag B.
- c. In case bubbles are detected while reading a sample, the warning message should be displayed. The sample will be flagged with B and will have <NC> instead of the I.S.E. result. The analyzer will go ahead with the following samples.

If the bubble error persists then it may be due to problems of hydraulic nature.

d) I.S.E. BOWL (FUNNEL)

The I.S.E. funnel takes long time to empty. It may be caused by defective or worn peristaltic pump for draining or an obstruction in the sensors stack. Repair or replace.

When running many serum samples it may happen an occlusion in the I.S.E. bowl, causing many calibration errors. In this case it is enough to remove the bowl (unscrew it from the support) and wash it with water and a clean piece of cloth. Rinse with distilled water and place it back into its seat fixing with the screw.

In case one or more of the above error conditions appears and it is not possible to solve the problem, it will be necessary to call the technical assistance.

Screen Messages - Causes And Remedies

NO SPECIAL REAGENTS	
NO I.S.E. SAMPLE DILUENT SOLUTION NO I.S.E. REFERENCE SOLUTION	The error message NO I.S.E. SAMPLE DILUENT SOLUTION / NO I.S.E. REFERENCE SOLUTION is displayed when the analyzer detects the absence of I.S.E. sample diluent solution or reference solution needed for programmed tests. Immediately after this message the I.S.E. sampling is interrupted. Samples will be flagged with R and <NC> instead of the result. Insert new sample diluent / reference and perform a new I.S.E. calibration.
NO I.S.E. WASHING SOLUTION I.S.E. WASH FAILED	The error message NO I.S.E. WASHING SOLUTION or I.S.E. WASH FAILED is displayed when the analyzer detects through a built-in liquid sensor the absence of I.S.E. washing solution (Na conditioning).

4. RETURNING THE ANALYZER TO THE TECHNICAL ASSISTANCE SERVICE

FOR MORE INFO REFER TO CHAPTER M, PAR. 1.4.

Operating Analyzer

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Put a suitable decontaminant (e.g. HCl 1N hydrochloric acid diluted at 3%) in a reagent bottle and place it in position no. 40.
3. Start a cuvette (Analyzer Utilities menu – Wash cuvettes) and I.S.E. (Analyzer Utilities menu – Sodium reconditioning) wash cycle.
4. Wait five minutes after the washes have finished and then remove the decontaminant bottle from the reagent tray.
5. Run a normal wash cycle with system solution (Analyzer Utilities – Wash with water).
6. Empty the hydraulic circuit (from the Analyzer Utilities menu - Empty fluidics).
7. Shut down the analyzer.
8. Clean off the entire sample tray with decontaminant and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.

For assistance at the Lab: in addition to the above, disconnect the waste tubes from the instrument and clean an area with decontaminant which is large enough for the Technician to work.

Analyzer Safe Disposal

When the instrument is no longer useable or needs to be decommissioned, follow the procedure below, bearing in mind that any part of the analyzer may come into contact, even accidentally, with potentially infected samples: therefore set up adequate protection using the necessary individual protection devices.

Be very careful of any splashing of residual decontaminant when disconnecting the various tubes or touching the various parts of the hydraulic system, after decontamination.

ATTENTION: this procedure will damage the I.S.E. sensors, after the procedure discharge the sensors.

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Empty the hydraulic circuit (from the Analyzer Utilities menu: empty fluidics).
3. Remove the water tube from the external container and put it in a container with at least one liter of suitable disinfectant or decontaminant (e.g. hydrochloric acid HCl 1N diluted at 3%). Put disinfectant also in the I.S.E. bottle and in a bottle in position 40 of the reagent tray.
4. Fill the hydraulic circuit again by running a reset and a series of prime of the clinical chemical diluter and the diluter of the I.S.E.
5. Run a wash of the cuvettes. Wait five minutes. Remove the disinfectant from the container and from the I.S.E. bottles and replace it with water. Put the water tube back in the container which has just been filled.

7. Run a wash of the cuvettes again, and then empty the hydraulic circuit again.
8. Shut down the analyzer.
9. Remove all the cords connecting the UPS to the mains and peripheral devices from the analyzer.
10. Remove all the cables connecting the peripheral devices (keyboard, mouse, wireless connector, printer and UPS).
11. Carefully clean off the entire sample tray with decontaminant (hydrochloric acid HCl 1N diluted at 3%) and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.
12. Carefully clean the peripheral devices using a clean cloth and a disinfectant.
13. Remove the waste tubes from the analyzer and the vacuum system.
14. Remove the vacuum system discharge probe and soak it for five minutes in disinfectant (HCl 1N diluted at 3%). Then rinse it in water.
15. Remove all the tubes which are part of the washing, distribution and sampling hydraulic circuit and the I.S.E. circuit. Remove the I.S.E. sensors as well.
16. Sort the material from decommissioning the instrument so that they can be recycled or disposed of as special waste in accordance with local laws.

If the analyzer is going to be returned to the Distributor, make sure all the removal parts of the system are bagged and separated after decontamination so that they can be disposed of as special waste.

5. I.S.E. MODULE-4P CONSUMABLES

PRODUCT	PART NO.
Kit Bio I.S.E. Direct #BT3500S	933
Consists of:	
4x I.S.E. solution A/baseline	
4x I.S.E. solution B	
4x I.S.E. Reference solution	
1x Na conditioning solution	
I.S.E. Urine Standard	936
I.S.E. Sample Diluent	935
Potassium Sensor:	961
Lithium Sensor:	963
Sodium Sensor:	960
Chloride Sensor:	962
Reference Sensor:	964
Inlet Sensor	662.0856
Outlet Sensor	662.0857
Spacer sensor	662.0858
Kit I.S.E. 4P	11-06227-01
Consists of:	
Blue colored cap + draw tube assy	
Green colored cap + draw tube assy	
Black colored cap + draw tube assy	
Red colored cap	
Peristaltic pump cartridge (two pairs)	
Empty reagent pack	08-06268-01

SECTION I: GENERAL INFORMATION

CHAPTER M: WARNINGS & PRECAUTIONS

1. WARNINGS AND PRECAUTIONS	2
1.1. Potential Risks During Operation And Maintenance	2
1.2. Warnings And Precautions	3
1.3. Waste Disposal	6
1.4. Returning The Analyzer To The Technical Assistance Service	6
1.4.1. Operating Analyzer.....	6
1.4.2. Not Operating Analyzer.....	7
1.5. Analyzer Safe Disposal	8
1.6. Electric And Electronic Devices Disposal	9

ATTENTION: USE OF THE ANALYZER INTERNAL COMPUTER – DOES NOT APPLY TO ANALYZERS WITH EXTERNAL PC

The computer box of BT analyzers is designed for long-term security and reliability and is virtually maintenance-free as long as the user does not install any third-party application programs. If these applications are installed, then they may damage the operating system registry and may also cause disastrous consequence for the computer's hard-drive. Biotechnica Instruments S.p.A. will not be responsible for any damage to the analyzer, its software and data in the hard-disk in case of improper use of the PC box. This includes also: installation of external programs, not properly secure net connections (intranet and internet) and the use of disks without the necessary verification for viruses presence. Biotechnica Instruments S.p.A. will not be responsible for any damage caused by non authorized third parties who may open and alter the PC box configuration.

1. WARNINGS AND PRECAUTIONS

1.1. Potential Risks During Operation And Maintenance

▪ USE

Although the BT analyzer system uses high performance components, which provide a high degree of safety, it is essential that the user takes the usual precautions to safeguard himself and to ensure a safe working environment.

Biotechnica Instruments S.p.A. only guarantees the workmanship and materials of its products. It is the duty of the user to take care of safe operation and no amount of warnings can take place of such care.

As regards the moving parts in the analyzer, these have been appropriately protected to avoid any potential risks to the user, and for proper instrument operation and safety. However, it is highly recommended to exercise extreme care during analyzer operation and especially when working close to the devices.

To avoid accidental contamination, use suitable guards and/or personal protection, such as overall and gloves. When handling reagents, it is advisable to observe good laboratory practice (GLP) rules.

Chemicals, serum samples and reagents must be handled with extreme caution. Patient samples may be biologically hazardous. The reagents or any other substances that may enter in contact with samples should be treated in the same way as samples themselves.

The materials of human origin, such as control sera, are tested for the detection of HbsAg, anti-HCV anti-HIV-1 anti-HIV-2 antibodies. Even if the result is negative, as no known analytical method can exclude any infection's risk with certainty therefore these materials must be considered as potentially infective and thus must be handled with extreme caution. The reagents and any other substance entering in contact with samples must be treated in the same way. The reagents must be manipulated (before, during and after the use) by qualified personnel familiar with their characteristics in order to safeguard the user as well as the quality of the reagent itself.

▪ MAINTENANCE

- It is of extreme importance that the instrument is fully turned off and the power cord unplugged from the wall outlet to safely perform any maintenance or service procedure.
- During maintenance procedures (see "**Chapter L, "Maintenance"**"), the safety and warning precautions must be observed as outlined in the preceding paragraph.
- The exterior of the analyzer casing may be cleaned periodically to remove dust grease and other contamination. It is not necessary to clean the inside. Use soft cloth dampened with a mild solution of neutral detergent with water.
- The owner shall be responsible for maintenance of the analyzer. Wear or damage caused by lack of normal maintenance or by misuse of the analyzer shall not be considered as defective workmanship and material.

1.2. Warnings And Precautions

The following warnings will aid the user to provide adequate safeguards to assure safe trouble-free performance:

1. BEFORE OPERATING THIS SYSTEM, BE SURE TO READ THE OPERATOR MANUAL THOROUGHLY AND CAREFULLY. AFTERWARDS, KEEP IT HANDY FOR FUTURE REFERENCE.
2. TAKE SPECIAL CARE TO FOLLOW THE WARNINGS AND CAUTIONS INDICATED ON THE SYSTEM REAR PANEL AS WELL AS IN THE OPERATOR MANUAL.
3. SYSTEM'S USE SHOULD BE RESTRICTED TO LAB'S QUALIFIED PERSONNEL ONLY.
4. SLOTS AND OPENINGS IN THE CASE, BACK PANEL, AND BOTTOM ARE PROVIDED FOR VENTILATION. THIS ENSURES RELIABLE OPERATION OF THE SYSTEM AND TO PROTECT IT FROM OVERHEATING. DO NOT BLOCK OR COVER THESE OPENINGS.
5. BEFORE USING THE SYSTEM, CHECK THAT THE VOLTAGE ON THE REAR PANEL LABEL MATCHES THE LOCAL LINE VOLTAGE.
6. TO GUARANTEE SAFETY THE SYSTEM MUST BE PROPERLY GROUNDED. THE WIRES IN THE MAINS POWER CORDSET ARE COLORED IN ACCORDANCE WITH THE FOLLOWING CODES:

GREEN AND YELLOW:	EARTH
BLUE:	NEUTRAL
BROWN:	LIVE

IN CASE OF DOUBTS CONTACT THE NEAREST QUALIFIED ELECTRICIAN.

7. REPLACE FUSE AS MARKED (see Chapter N, "Maintenance"). PRIOR TO THE REMOVAL OF ANY FUSE, TURN POWER OFF AND UNPLUG THE CORDSET FROM THE WALL.
8. UNDER NO CIRCUMSTANCES IS THIS INSTRUMENT CASE TO BE OPENED. THIS INSTRUMENT IS NOT USER SERVICEABLE. DANGEROUS HIGH VOLTAGES INSIDE THIS INSTRUMENT CASE. IN EVENT OF DIFFICULTY, PLEASE NOTIFY YOUR DEALER FOR PROMPT SERVICE.
9. FOR OPERATING SAFETY, DO NOT INSTALL THE SYSTEM IN A LOCATION WHERE IT WILL BE EXPOSED TO HEATING EQUIPMENT OR RADIATORS, DIRECT SUN LIGHT, OR ANY OTHER SOURCE OF EXTREMELY HIGH TEMPERATURES.
10. DO NOT OPERATE THE SYSTEM IN THE PRESENCE OF FLAMMABLE FLUIDS OR GASEOUS ATMOSPHERE, DISINFECTING AGENTS, CLEANING AGENTS, ETC., DUE TO POSSIBLE FIRE OR EXPLOSION.
11. DO NOT KINK, BEND, LAY OBJECT ON, OR OTHERWISE DAMAGE OR RESTRICT CABLES AND TUBES.
12. BE SURE THAT THE POWER SWITCH ON THE BACK PANEL OF SYSTEM IS OFF WHEN PLUGGING IN, OR REMOVING THE POWER CORDSET FROM A WALL OUTLET.
13. TURN OFF THE MAINS POWER SWITCH ON THE REAR PANEL WHENEVER THE SYSTEM IS NOT IN USE. THIS PREVENTS DAMAGES DUE TO SURGE IN THE MAINS POWER.

14. DO NOT ATTEMPT TO ALTER THE SHAPE OF ANY PART OF THE SYSTEM.
15. IF THE SYSTEM IS NOT OPERATING PROPERLY AND THE TROUBLE-SHOOTING SECTION (refer to Chapter N, "Maintenance") DOES NOT PROVIDE A SATISFACTORY SOLUTION TO THE PROBLEM, THEN DO NOT USE THE SYSTEM UNTIL THE DEFECTS ARE REMEDIED.
16. INSPECT ALL ACCESSORIES AND SYSTEM CORDS. DO NOT USE IF DAMAGE CAN BE SEEN SUCH AS CUT INSULATION OR OUTER COVERING, FRAYED OR BROKEN WIRES, CORRODED OR BROKEN CONNECTORS ETC.
17. TO REDUCE THE RISK OF FIRE OR ELECTRIC SHOCK, DO NOT ALLOW FLUIDS OR ANY FOREIGN OBJECT TO ENTER THE SYSTEM. WIPE OFF SPILLS IMMEDIATELY.
18. DO NOT USE BENZENE, THINNER, ANY KIND OF SOLVENTS, OR ABRASIVE DETERGENTS TO CLEAN THE CASE. CLEAN WITH SOFT DUSTING CLOTH DAMPENED WITH DISTILLED WATER. IF NECESSARY USE ONLY NEUTRAL DETERGENT.
19. DO NOT STICK OBJECTS OF ANY KIND INTO THE SYSTEM THROUGH BACK PANEL OR CASE SLOTS AS THEY MAY TOUCH DANGEROUS VOLTAGE POINTS OR SHORT OUT PARTS THAT COULD RESULT IN FIRE OR ELECTRIC SHOCK.
20. INSTALL THE SYSTEM IN SUCH A WAY THAT ADEQUATE VENTILATION IS PROVIDED ALL AROUND TO PROPERLY DISSIPATE THE HEAT.
21. USE ONLY ORIGINAL BIOTECNICA'S TUBING REPLACEMENTS. DO NOT USE CONVENTIONAL TUBING. THIS WILL CAUSE MALFUNCTION OF THE SYSTEM.
22. MAKE SURE ALL FLUID LINES ARE FREE OF KINKS, NICKS, SHARP BENDS, PUNCTURES, OR OCCLUSIONS BEFORE INSTALLING ON SYSTEM.
23. DO NOT TWIST THE PERISTALTIC PUMP TUBING WHEN PLACING IN THE RACEWAY OF THE PUMP ROLLER.
24. RELEASE THE PERISTALTIC PUMP TUBING WHENEVER THE SYSTEM IS UNUSED FOR A PERIOD OF TIME LONGER THAN 36 HOURS.

CAUTION

THE HYDRAULIC CIRCUIT SHOULD BE FULLY DISCHARGED AND THE WATER RESERVOIR DISCONNECTED FROM THE CIRCUIT PRIOR TO RELEASING THE TUBES FROM THE VALVES. IF THESE STEPS ARE NOT TAKEN, SERIOUS DAMAGE MAY BE CAUSED TO THE ANALYZER.

25. THE HALOGEN LAMP MUST BE REPLACED SOME MINUTES AFTER THE INSTRUMENT HAS BEEN TURNED OFF AND POWER CORD UNPLUGGED (refer to Chapter N, "Maintenance").
26. ALWAYS ALLOW THE BURNT OUT LAMP TO COOL DOWN BEFORE HANDLING OR ATTEMPTING REPLACEMENT.
27. NEVER TOUCH THE LAMP OR THE REFLECTOR WITH BARE FINGERS. USE A RAG WHEN CHANGING.
28. IF THE LAMP IS TOUCHED INADVERTENTLY DURING INSTALLATION, CLEAN THE LAMP OR REFLECTOR WITH ALCOHOL AND DRY WITH A CLEAN, SOFT CLOTH BEFORE BURNING. CONTAMINATION OF THE LAMP OR REFLECTOR MAY REDUCE LAMP PERFORMANCE.

29. THIS LAMP (WHEN LIT) EMITS UV (ULTRAVIOLET) RADIATION. PROLONGED EXPOSURE TO THIS LAMP MAY CAUSE SKIN AND EYE IRRITATION.
30. THE ANALYZER SYSTEM MUST NOT BE DISMANTLED OR REPAIRED BY ANYONE WHO HAS NOT BEEN QUALIFIED BY THE MANUFACTURER. INCORRECT WORK MAY CAUSE FIRE OR IRREPARABLE DAMAGE TO THE SYSTEM.
31. DO NOT OVERLOAD ACCESSORIES POWER OUTLETS AND EXTENSION CORDS AS THIS CAN RESULT IN FIRE OR ELECTRIC SHOCK.
32. DO NOT PLACE THE SYSTEM ON AN UNSTABLE CART, STAND, OR TABLE; THE SYSTEM MAY FALL, CAUSING SERIOUS INJURY TO USER, AND SERIOUS DAMAGE TO THE APPLIANCE. PLACE THE SYSTEM ON A STABLE, VIBRATION-FREE, LEVEL TABLE OR CART.
33. USE ONLY SECURE POWER SOURCE TO PROTECT THE ANALYZER SYSTEM AGAINST POWER SURGES. DISCONNECT TEMPORARILY THE ANALYZER POWER CORD FROM THE WALL OUTLET IN CASE OF BAD ATMOSPHERIC CONDITIONS.
34. DO NOT OIL ANY PART OF THE SYSTEM.
35. EMPTY WASTE CONTAINERS WHENEVER THEY ARE FULL. ENSURE THAT THE CONTAINER LIDS ARE SCREWED ON TIGHTLY TO PREVENT LEAKAGE OR DISPERSION INTO THE ENVIRONMENT.
36. THE SAFE DISPOSAL OF THE ANALYZER WASTE MATERIAL WITH MINIMAL ENVIRONMENTAL IMPACT IS THE RESPONSIBILITY OF THE USER AND WILL HAVE TO MEET THE LOCAL LAWS AND DISPOSITIONS.
37. DO NOT ATTEMPT TO REMOVE ANY PANELS OR COVERINGS OF THE ANALYZER SYSTEM WHILE THE SYSTEM IS IN OPERATION.
38. AFTER OPERATION/SERVICING, COVER THE SYSTEM WITH A PROTECTIVE PLASTIC OR CLOTH SHEET.
39. DO NOT USE SOFTWARE DISKS OF UNKNOWN ORIGIN IN THE ANALYZER COMPUTER AS THEY MAY INTRODUCE VIRUSES.
40. DO NOT USE THE COMPUTER OF THE ANALYZER FOR ANY OTHER PURPOSE THAN THE ONE FOR WHICH IT IS DESIGNED FOR.
41. BE PARTICULARLY CAUTIOUS THAT NO PARTS OF YOUR BODY (e.g. FINGERS HAIR, ETC.) OR LOOSE OBJECTS (e.g. CABLES, TUBING, ETC.) CAN BE TRAPPED BY ANY MOVING OR ROTATING PARTS (e.g. SAMPLING ARM, PLATES, WASHER MODULE, PUMP ROLLERS ETC.) OF THE ANALYZER SYSTEM.

NOTE:

- a) *The careful observation of the proceeding warnings should result in a long and satisfactory performance. If the above-mentioned notices are not fully observed, then any form of warranty is no longer valid and Biotecnica Instruments S.p.A. will not be responsible for any subsequent damage or loss. (see Section II, 2 "Warranty Conditions").*
- b) *The information in this manual is based upon the hardware and software currently in use. Biotecnica Instruments S.p.A. reserves the right to make software and hardware changes or improvements for product enhancement without notice and without imposing any obligation upon itself to install these changes or improvements on its products previously manufactured.*

1.3. Waste Disposal

- To ensure environment health and safety, it is recommended not to discard the used consumables, waste liquids or disposable maintenance kits into the environment.
- Insure that the disposal of waste material is done according to all applicable laws and regulations.

1.4. Returning The Analyzer To The Technical Assistance Service

The Technical Service Assistance (S.A.T.) may intervene locally, at the Lab, or at Biotechnica Instruments S.p.A. for analyzers returned for repair.

In all cases it is necessary to decontaminate the analyzer and its parts to protect the health of technical assistance employees.

To decontaminate the analyzer follow the procedure below, bearing in mind that any part of the analyzer may come into contact, even accidentally, with potentially infected samples: therefore set up adequate protection using the necessary individual protection devices.

Be very careful of any splashing of residual decontaminant when disconnecting the various tubes or touching the various parts of the hydraulic system, after decontamination.

The procedure described below is not considered to be complete and any other action taken by the Lab to ensure the safety of Biotechnica's technicians is appreciated.

1.4.1. Operating Analyzer

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. **To properly decontaminate the I.S.E. module, where present, refer to chapter L, par. 4.**
3. Put a suitable decontaminant (e.g. HCl 1N hydrochloric acid diluted at 3%) in a reagent bottle and place it in position n°. 40 for BT3000 Plus and BT3500/BT3500S or in position 24 for BT1500.
4. Start a cuvette (Analyzer Utilities menu – Wash cuvettes) wash cycle.
5. Wait five minutes after the washes have finished and then remove the decontaminant bottle from the reagent tray.
6. Run a normal wash cycle with system solution (Analyzer Utilities – Wash with water).
7. Empty the hydraulic circuit (from the Analyzer Utilities menu - Empty fluidics).
8. Shut down the analyzer.
9. Clean off the entire sample tray with decontaminant and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.

For assistance at the Lab: in addition to the above, disconnect the waste tubes from the instrument and clean an area with decontaminant which is large enough for the Technician to work.

For shipping the analyzer to Biotecnica:

In addition to the instructions seen above, carry out the following:

1. Disconnect the waste tubes from the instrument.
2. Disconnect the water tube from the instrument, wind it up and put it in a bag.
3. Push the sampling needles all the way into their wash wells.
4. Put the cuvette and serum cover trays back in their places.
5. Make sure that all moveable parts are secured tightly.
6. Decontaminate the vacuum system, where present, and make sure there is no residual fluid.
7. Decontaminate the vacuum system discharge probe by soaking it for five minutes in HCl 1N diluted at 3%.
8. Wind up the waste tubes and put them in a tightly shut bag.
9. Pack up the peripheral devices and analyzer in their original packing.

1.4.2. Not Operating Analyzer

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. Clean off the entire sample tray with decontaminant (hydrochloric acid HCl 1N diluted at 3%) and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.
3. Unscrew the sampling needles from their arms and soak them for five minutes in decontaminant and then rinse them with water and put them aside or screw them back into place.
4. Decontaminate the vacuum system, where present, and make sure there is no residual fluid.
5. Decontaminate the vacuum system discharge probe by soaking it for five minutes in HCl 1N diluted at 3%.
6. Make sure the cuvettes are empty and then fill them manually with the decontaminant solution. After five minutes remove the solution and replace it with bidistilled water.

For assistance at the Lab: in addition to the above, disconnect the waste tubes from the instrument and clean an area with decontaminant which is large enough for the Technician to work.

For shipping the analyzer to Biotecnica:

In addition to the instructions seen above, carry out the following:

1. Disconnect the waste tubes from the instrument.
2. Disconnect the water tube from the instrument, wind it up and put it in a bag.
3. Push the decontaminated sampling needles all the way into their wash wells.
4. Put the cuvette and serum cover trays back in their places.
5. Make sure that all moveable parts are secured tightly.
6. Wind up the decontaminated waste tubes and put them in a tightly shut bag.
7. Make sure the cuvettes are empty.
8. Make sure there is no residual liquid in the hydraulic circuit or any other part of the instrument.
9. Pack up the peripheral devices and analyzer in their original packing.

1.5. Analyzer Safe Disposal

When the instrument is no longer useable or needs to be decommissioned, follow the procedure below, bearing in mind that any part of the analyzer may come into contact, even accidentally, with potentially infected samples: therefore set up adequate protection using the necessary individual protection devices.

Be very careful of any splashing of residual decontaminant when disconnecting the various tubes or touching the various parts of the hydraulic system, after decontamination.

Note: this procedure will make the I.S.E. electrodes unusable anymore.

1. Remove all the consumable parts, still present, from the analyzer (sample cups, test tubes, reagent bottles etc.).
2. **To properly decontaminate the I.S.E. module, refer to chapter L, par. 4.**
3. Empty the hydraulic circuit (from the Analyzer Utilities menu: empty fluidics).
4. Remove the water tube from the external container and put it in a container with at least one liter of suitable disinfectant or decontaminant (e.g. hydrochloric acid HCl 1N diluted at 3%). Put disinfectant also in a bottle in position 40 of the reagent tray for BT3000 Plus and BT3500/BT3500S or in position 24 for BT1500.
5. Fill the hydraulic circuit again by running a reset and a series of prime of the clinical chemical diluter and the diluter of the I.S.E, if present.
6. Run a wash of the cuvettes and the I.S.E. module.
7. Wait five minutes. Remove the disinfectant from all the containers and replace it with water. Put the water tube back in the container which has just been filled.
8. Run a wash of the cuvettes and I.S.E. again, and then empty the hydraulic circuit again.
9. Shut down the analyzer.
10. Remove all the cords connecting the UPS to the mains and peripheral devices from the analyzer.
11. Remove all the cables connecting the peripheral devices (keyboard, mouse, wireless connector, printer and UPS).
12. Carefully clean off the entire sample tray with decontaminant (hydrochloric acid HCl 1N diluted at 3%) and a clean cloth, as well as its housing and all the accessible surfaces of the analyzer.
13. Carefully clean the peripheral devices using a clean cloth and a disinfectant.
14. Remove the waste tubes from the analyzer and the vacuum system, if present.
15. Remove the vacuum system discharge probe and soak it for five minutes in disinfectant (HCl 1N diluted at 3%). Then rinse it in water.
16. Remove all the tubes which are part of the washing, distribution and sampling hydraulic circuit and the I.S.E. circuit. Remove the I.S.E. electrodes as well.
17. Sort the material from decommissioning the instrument so that they can be recycled or disposed of as special waste in accordance with local laws.

If the analyzer is going to be returned to the Distributor, make sure all the removal parts of the system are bagged and separated after decontamination so that they can be disposed of as special waste.

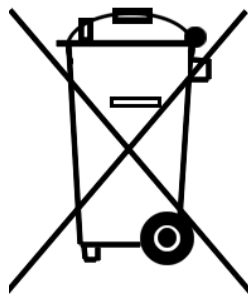
1.6. Electric And Electronic Devices Disposal

ATTENTION:

Waste Electrical and Electronic Equipment, called WEEE must be disposed of in accordance with **European Directive 2012/19/EU and 2011/65/UE**.

The points below provide some instructions related to disposal of WEEE, however we recommend consulting the aforesaid Legislative Decree for additional information.

1. WEEE must not be disposed of as urban waste, it must be recycled.
2. Municipalities guarantee operation, access and suitability for recycling systems for WEEE, so that end users and distributors can return to collection centers all waste produced within their territories, at no cost.
3. WEEE can be returned to the distributor when new equipment is purchased, without prejudice the provisions of Legislative Decree 151/05.
4. The distributor has the obligation to take the WEEE, however pick up may be refused when there is a risk of contamination of personnel assigned to this job.
5. The presence of hazardous substances in electrical and electronic equipment requires separate disposal due to the potential effects on the environment and humans. Improper use of the same equipment or its parts may be potentially hazardous.
6. The symbol that indicate separate disposal of electrical and electronic equipment is a trash container on wheels with a cross over it as indicated below: the symbol is printed in a visible, readable and indelible manner



Editor's note: The picture is only for the purposes of example: see the printed version in the Italian Official Gazette no. 175 of 29-7-2005

7. Legislative Decree 151/05 includes a list of fines for illegal disposal of WEEE.

NOTE:

The manufacturer shall not be held liable for any failure to comply with regulations regarded to delivery of the instrument to third parties. Check the pertinent lists at specialized waste disposal centers.

Constraint: It is left to the responsible laboratory organization to determine whether electric and electronic components are contaminated or not. If contaminated, treat them in the same way as the instrument and analyzer, before disposal.

For more information about disposal of your product, please contact your city office, waste disposal service.

SECTION I: GENERAL INFORMATION

CHAPTER N: MAINTENANCE & TROUBLESHOOTING

1. MAINTENANCE AND CARE	2
1.1. Preventive Maintenance And Extra Wash	2
1.2. Replacing Tubing And Accessories	3
1.2.1. Clinical Chemistry	3
1.2.2. Extra Wash Cuvettes	5
1.2.3. Photometric Lamp.....	5
1.2.4. Dilutors' Piston o-ring.....	6
1.3. Cleaning Of The Instrument	7
2. MALFUNCTIONS	8
2.1. Troubleshooting	8
2.2. SCREEN MESSAGES	10
2.2.1. Screen Messages - Causes And Remedies	10
2.2.2. Screen Messages Requiring Technical Assistance	12
2.2.3. Optical System Verification Messages.....	14

NOTE:

**All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.**

1. MAINTENANCE AND CARE

1.1. Preventive Maintenance And Extra Wash

EXTRA WASH

This function is similar to the daily one but run with two detergents. This operation is requested by the instrument on a weekly basis. See paragraph 1.2.2. The extra wash helps guarantee efficiency and long life for the reading cuvettes.

Exercise extreme care to ensure that the system is regularly provided with proper maintenance and care to avoid any problems and malfunctions, which can potentially generate erroneous results. This will give longest life at lowest overall cost.

The maintenance is normally performed at regular intervals or whenever the operating conditions dictate it. The analyzer stores the number of run tests and a built-in maintenance software automatically alerts the operator through on-screen messages whenever any part needs attention or replacement. Failure to follow proper maintenance and replacement procedures may result in system malfunction.

The software programmed maintenance does not exonerate the user from neglecting any unexpected problems.

For the reasons just mentioned, we recommend that the operator follows the suggestions below:

The following simple steps serve as practical guidelines in establishing your care and maintenance program:

- 1) Replace the worn out component soon after the on-screen message from the maintenance software has been displayed (**Figure 1 “Show Diagnostic”**). To access this function refer to chapter H.
- 2) Any consumable part showing signs of wear or damage should be immediately replaced, even if the appropriate on-screen message is not already displayed.
- 3) Use only original Biotecnica parts. Do not replace defective parts with non-original parts as this will cause malfunctioning of the analyzer. In case of any doubt, contact the Biotecnica Instruments S.p.A. or nearest service center.
- 4) Use only bi-distilled water for the washes performed during working phases.
- 5) Use only Biotecnica Instruments S.p.A. approved solutions for the routine washing procedures and at the end of working session.
- 6) During routine maintenance, exercise extreme caution to avoid any contamination. When replacing tubing, needle, or handling waste container etc. accidental contact with potentially contaminating liquid is possible. For individual safety, use suitable protective garments, such as overalls and gloves (refer to **Chapter K**, paragraph 1.1. “**Potential risks during use and maintenance**”).



Figure 1

The components that are most subject to wear are the fluidic tubing used in the valves, the peristaltic pump cartridges and the photometric lamp.

The hydraulic circuit items, not mentioned in the maintenance table, should be considered as non-consumable and should be replaced only by the qualified technical personal during service.

1.2. Replacing Tubing And Accessories

CAUTION:

- a) Completely empty hydraulic circuit, using the program outlined in the **Chapter H**, paragraph 1.1. **Empty Fluidics** and wait until this operation terminates.
- b) Always make sure that the mains power switch on the instrument is turned off and the power cord is unplugged from the wall outlet before performing any maintenance procedure.

The following figures show the position and indication of components to be replaced. The maintenance kits include all that is needed for the ordinary maintenance of the analyzer. **For the I.S.E. module maintenance, refer to chapter L, paragraph 3.2.1.**

Phase	
Kit: Tubes and Peristaltic Pump	See paragraph 1.2.1.
Extra wash cuvettes	See paragraph 1.2.2.
Photometric Lamp (hours)	See paragraph 1.2.3.
Dilutor's Piston Seal	See paragraph 1.2.4.

PROGRAMMED MAINTENANCE

Item	Replacement
Kit tubes and peristaltic pump	Every 150000 cycles or 6 months
Kit tubes I.S.E. module	Every 6 months
Photometric lamp	Every 1500 hours of use
Dilutor's piston seal	Every 300000 cycles or 12 months

The above mentioned items replacement may change as the analyzer system improves. Refer to the analyzer maintenance dedicated page (Menu Analyzer → Diagnostic → General Diagnostic).

1.2.1. Clinical Chemistry

- Peristaltic pump cartridge (ref. 4 fig 2): remove both ends of the peristaltic pump tubing from the diluter manifold. Squeeze the locking catches and remove the defective cartridge. Place the new cartridge on the drive shaft and gently press to snap-fit. Carefully attach the pump tubing to both fittings in the diluter manifold.
- Tube for valves (ref. 1 fig 2): detach valve tube and discard it. Carefully attach ends of valve tubing to appropriate fittings (Figure 2).
- Aspiration tube for washing module (ref. 2 fig 2): detach defective tube and replace with new aspiration tube.
- H₂O tube for washing module (ref. 3 fig 2): remove and discard the old tubing. It is possible that a small quantity of distilled water will flow out of the water reservoir. Immediately dry it after the tube replacement. Carefully attach the ends to the valve and to the appropriate fittings of the water reservoir and the washer.
- Tubular filter for water container (263 μ) (ref. 5 fig 2): maintenance includes annual replacement (or if the filter is completely clogged).
- Sampling arm: maintenance of the sampling arm includes annual replacement (or if the device does not work correctly) of the sampling needle (ref. 6 fig 2). To replace the needle, loosen and remove retaining nut with needle from the needle holder. Clean or substitute with new needle. Then gently push in needle into the needle holder until fully seated and screw it gently back into the needle holder.

Note: the reading cuvettes are also part of the reading station, but they do not need to be replaced unless it is impossible to wash them correctly or they break. If they need to be replaced contact the Technical Assistance Service.

The annual maintenance kit corresponds to the “Tube and Peristaltic Pump Kit” on the Diagnostic page (fig. 1)

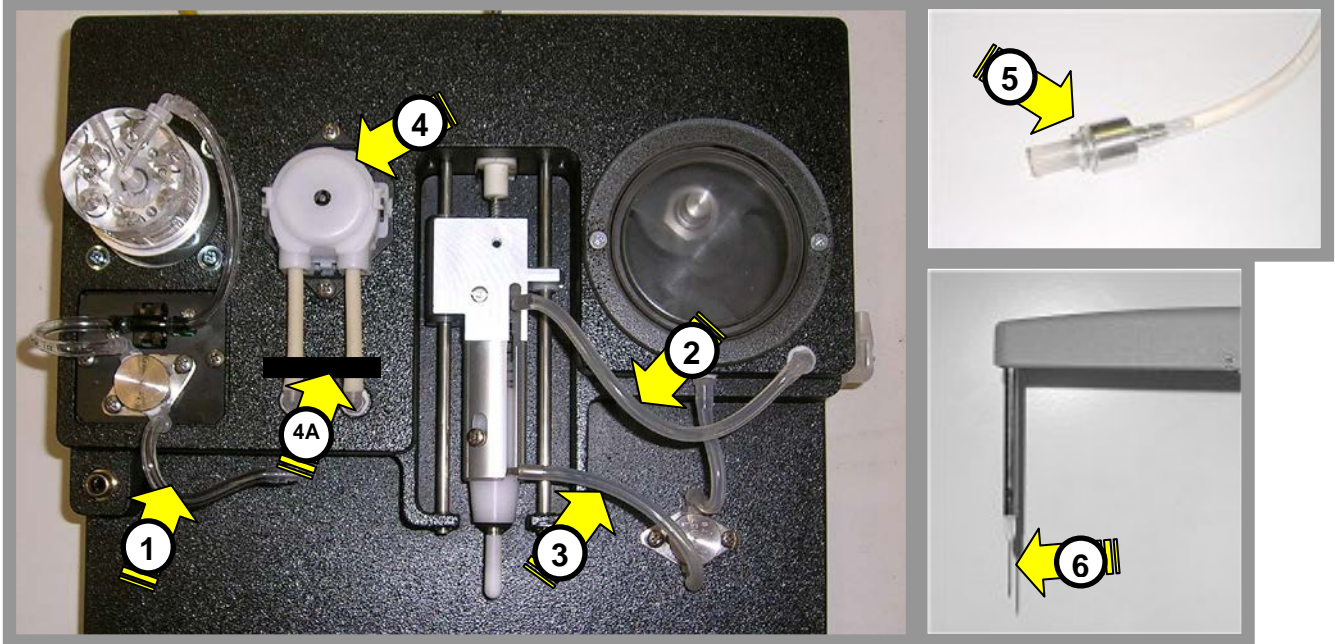


Figure 2

BT3000 PLUS: SIX MONTH MAINTENANCE KIT (CODE 11-05337-01)		
ITEM	QTY	DESCRIPTION
1	1	Diluter/Valve Tube
1A	1	Diluter/Valve Tube I.S.E. (see chapter L)
2	1	Aspiration Tube for Washing Module
3	1	H ₂ O Tube for Washing Module
4	2	Peristaltic Pump Cartridge
4A	1	Peristaltic Pump Tray
8	1	Tubular Filter for Water Container
9	2	Sampling Needle

BT3500: SIX MONTH MAINTENANCE KIT (CODE 11-05669-01)		
BT3500S : SIX MONTH MAINTENANCE KIT (CODE 11-6230-01)		
BT1500: ANNUAL MAINTENANCE KIT (CODE 11-06050-01)		
ITEM	QTY BT3500 / BT3500S / BT1500	DESCRIPTION
1		Diluter/Valve Tube - Does not need any maintenance
2	1 / 1 / 1	Aspiration Tube for Washing Module
3	1 / 1 / 1	H ₂ O Tube for Washing Module
4	2 / 1 / 1	Peristaltic Pump Cartridge
4A	1 / 1 / 1	Peristaltic Pump Tray
5	1 / 1 / 1	Tubular Filter for Water Container
6	2 / 2 / 1	Sampling Needle

1.2.2. Extra Wash Cuvettes



This is requested by the analyzer on a weekly basis.

Insert the bottles with dedicated solutions (see Sect. II, Chapt.3, par. 3.2. Consumables For BT Analyzers) in the position indicated in the message and activate the command.

It is highly advisable to run this operation any time the efficiency of the cuvettes is questionable. A progressive accumulation of contaminants in the cuvettes may lead to serious release problems when running tests.

Analyzer Utilities menu

Figure 3

1.2.3. Photometric Lamp

The analyzer controls the Halogen lamp condition, and it should be replaced as advised by the maintenance program or when there is a faulty operation. The analyzer verifies lamp efficiency and stability, and alerts the user through appropriate messages in case of fault.

Precautions for handling the halogen lamp:

- Turn off power and remove the power cord from the wall outlet before servicing. The replacement of the Halogen lamp can be done by the removal of the rear panel, or by sliding the transparent shutter on the front panel and then removing the access cover from the deck **Figure 4**.
- Always allow the burnt out lamp to cool down.
- Never touch the reflector or the lamp with bare fingers. Use a rag when changing.
- If the lamp is touched inadvertently during installation, clean the lamp or reflector with alcohol and dry with a clean, soft cloth before burning. Contamination of the lamp or reflector may reduce lamp performance.
- It is recommended to initially burn the new lamp for about 30 minutes before analyzer operation.
- Release the lamp assembly by gently sliding downwards and remove the burnt out lamp.
- Insert a new halogen lamp fully into the socket. It is recommended to slightly press both of the lamp retaining spring clips before fitting the lamp.
- Slide the lamp assembly onto the light cone and orient the lamp socket in the vertical position as shown in the **Figure 4**

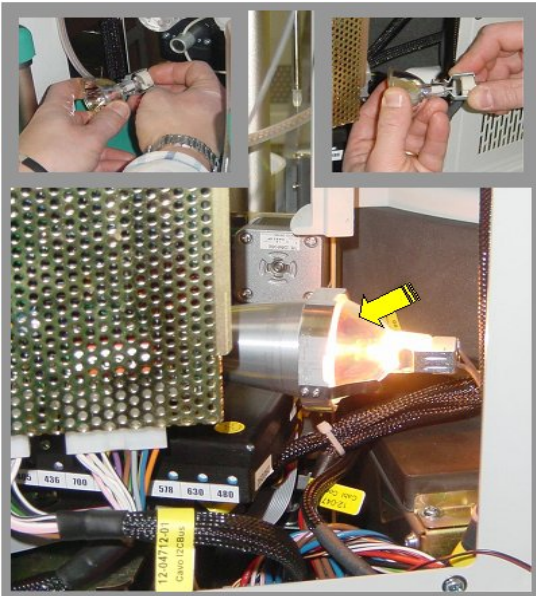
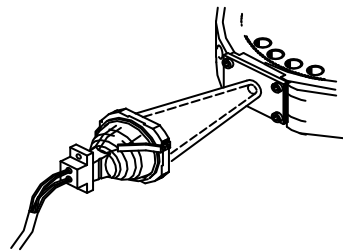


Figure 4



1.2.4. Dilutors' Piston o-ring

The dilutor o-ring needs to be replaced as advised by the maintenance program. Since this replacement operation is very difficult it is advisable to ask for intervention from the Technical assistance service.



BT dilutors maintenance consists in the o-ring replacement and greasing of the stepping motor lead screw. In the kit there are the o-ring and grease necessary for one dilutor.

For the sole BT3500/BT3500S it is only necessary to replace the o-ring, without greasing the lead screw. See section II, chapter 3 for consumables list.

Figure 5

Code	Description	
11-05283-01	Dilutor piston o-ring kit (contains what is necessary for one dilutor)	BT3000 Plus
330.5741	Ring-flon for diluter piston	BT3500/BT3500S & BT1500

1.3. Cleaning Of The Instrument

It is a Good Laboratory Practice (GLP) to maintain the instrument in optimal operating conditions. The instrument should be fully turned off and the power cord unplugged from the wall outlet prior to performing any cleaning procedure. Always wear suitable protective devices such as protective gloves, protective glasses, white coat, etc.

The exterior of the analyzer casing may be cleaned periodically to remove dust, grease and other contamination. Use soft dusting cloth dampened with distilled water or a mild solution of detergent with water. Do not use alcohol, solvents, or abrasives.

Use appropriate soft lint less cloth or tissues for LCD Display cleaning. Clean gently and avoid excessive rubbing to prevent damage to the LCD surface. Do not use any liquid that may damage the invisible matrix of the touch screen.

Protective gloves and laboratory coats/gowns should be worn to prevent contamination when cleaning the inside of the reagent chamber or serum plate chamber because of liquid contaminants. Use appropriate disinfectant for the thorough cleaning and elimination of biological residues.

Clean the cuvettes thoroughly with approved solutions (see Sect. II, Chapt.3, par. 3.2. Consumables For BT Analyzers).

Immediately eliminate any traces of serum drops or liquid contaminants using appropriate disinfectant to avoid difficulties associated with removal of dry and tenacious contaminations.

2. MALFUNCTIONS

2.1. Troubleshooting

The risk of encountering system malfunctions is very low if the routine care and maintenance procedure (outlined in the previous chapter) and the instructions in the operating manual are strictly observed. Refer to the troubleshooting guide below and the subsequent text regarding symptoms and corrective actions.

The instrument or one of its peripheral devices does not turn on

Verify that the UPS group is turned on, the electrical cables are correctly connected and check the fuses. If fuses need replacement then observe the following procedure:

- 1) Turn off the instrument by pressing the main switch on the rear panel and unplug power cord.
- 2) Extract the fuse-holder (located above the main switch on the rear panel) by gently opening the latch with a tool. Discard the old fuses and replace with new fuses, which match the selected voltage rating indicated on the rear panel label. Insert the fuse-holder into the compartment and push until its latch snaps back into the position (see Figure 3, Chapter B).

Results are invalid or cannot be reproduced due to residues in the dilutor.

- 1) Disconnect dilutor tubes
- 2) Remove the two mounting screws on the transparent dilutor chamber and clean the piston with soft lint less cloth dampened with alcohol. Rinse the chamber and reassemble. Connect the tubes to appropriate ports.

Results are invalid or cannot be reproduced due to air in the sampling system.

Sampling imprecision due to the presence of air in the hydraulic circuit. Probably caused by the clogged tubular filter in the external water container:

- Check, replace **Filter** if necessary (ref. 5 Fig. 2).

Sampling imprecision due to deteriorated tube in the dilutor valve:

- Inspect and replace **Tube** (ref. 1 Fig. 2).

Sampling imprecision due to reagent or sample residues in the sampling tube or in the needle:

- Inspect and replace **Peristaltic Pump Cartridge** (ref. 4 Fig. 2).
- Check and replace the **Sampling Needle** (ref. 6 Fig. 2).
- Check and replace the **Sampling Tube**. To be replaced by qualified service technician only.

Sampling imprecision due to reagent or sample residues on the external surface of the needle, with consequent contamination during preparation:

- Remove **Needle** and clean externally using gauze soaked with alcohol (ref. 6 Fig. 2).
- Check the efficiency of built-in devices for needle cleaning. In case of vacuum pump malfunction or if there are any obstructions in the cleaning devices, contact immediately the nearest Biotechnica sales/service office.

Results are imprecise due to insufficient cleaning or drying of the reading cuvettes.

Vacuum pump malfunction or occluded washing piston.

- BT1500: In case of vacuum pump malfunction or if there are any obstructions in the washing piston, contact immediately the nearest Biotechnica sales/service office. Check sampling/washing hydraulic circuit for leaks, which may affect system performance
- BT3000 Plus & BT3500/BT3500S: In case of vacuum pump malfunction refer to items in VACUUM PUMP SYSTEM chapter K. If the problem with vacuum pump still persists or if there are any obstructions in the washing piston, contact immediately the nearest Biotechnica sales/service office.

NOTE:

Check sampling/washing hydraulic circuit for leaks, which may affect system performance.

Invalid results or results cannot be reproduced.

Defective or burnt-out lamp.

Inspect and replace the lamp, refer to par. 1.2.3 in this chapter.

Invalid results or results cannot be reproduced without any evident reason.

Perform all maintenance procedures and check all possible causes described earlier in this chapter.

2.2. SCREEN MESSAGES

2.2.1. Screen Messages - Causes And Remedies

The BT analyzers software has a built in Auto-diagnostic function, which is enabled during normal working sessions. This function allows verification of any system malfunction or lacking of any solution necessary for running the tests.

In presence of any system malfunction, an appropriate message is displayed on the screen indicating the type of error and the suggested solution. The system stops until the causes of error are eliminated and then the operation can be resumed from where it stopped.

When anything necessary for test run is lacking (for example reagent or sample) an appropriate message is displayed on the screen, sampling procedure for the missing element is interrupted while the analyzer continues with the next working phases.

<p>SAMPLE IS MISSING</p> <p>NO ROUTINE #XX NO STAT #XX NO STANDARD #XX NO CONTROL #XX</p>	<p>The error "SAMPLE IS MISSING" is displayed when the analyzer detects the absence of sample through a built-in liquid sensor. It is subdivided into NO ROUTINE, NO STAT, NO STANDARD, NO CONTROL. After this message the sampling of the missing sample is interrupted. It is possible to run remaining tests using the rerun commands (Chapter E, paragraph 1.5) after the problem is solved.</p>
<p>REAGENT IS MISSING</p> <p>NO REAGENT XXX POSITION XX</p>	<p>The error "REAGENT IS MISSING" is displayed when the analyzer detects the absence of reagent needed for test run. After this message the sampling of the missing reagent is interrupted. It is possible to run remaining tests using the rerun commands (Chapter E, paragraph 1.5) after the problem is solved.</p>
<p>NO SAMPLE DILUENT</p>	<p>The error message "NO SAMPLE DILUENT" is displayed when the analyzer detects the absence of sample diluent solution. The testing of samples to be prediluted is interrupted. To solve the problem add fresh diluent solution and re-run the sample (Chapter E, paragraph 1.5).</p>
<p>NO I.S.E. SOLUTIONS</p>	<p>See Chapter L, par. 3.3</p>
<p>VACUUM SYSTEM:</p> <p>- WARNING -</p> <p>LOW PRESSURE</p>	<p>BT1500 This message appears when the vacuum pump inside the analyzer has lost efficiency and the vacuum level is below -40 mbar. It is possible to continue the tests if the vacuum level is -35 mbar and by setting the minimum threshold in the setup to -20 mbar. If the problem persists contact nearest sales service department. After resolving the problem, the analyzer can be restarted and continue testing from where it stopped.</p> <p>The message "-WARNING- LOW PRESSURE" may also appear when waste liquid container is full. Empty or replace it.</p> <p>BT3000 Plus & BT3500/BT3500S The message -WARNING- LOW PRESSURE may</p>

	<p>also appear when waste liquid container is full. See chapter K in this manual</p> <p>Operative steps sequence in case of alarm: <u>First alarm on (slow intermittent beeps) and the waste probe LED is lit.</u> External waste container full. Empty or replace it and press RESTART button (Green) to continue the operating procedure and to reset the alarm.</p> <p><u>Second alarm on (rapid intermittent beeps) with the LED on the waste probe lit.</u> The external waste container and the internal waste chambers are full. The vacuum system stops itself, the analyzer interrupts working phases and displays the message Low pressure.... Empty or replace the waste container and press the green RESTART button on the vacuum pump cabinet to continue the operating procedure and to reset the alarm.</p> <p>If the audible alarm is still activated, it means that the peristaltic pump for draining is not efficient and that the internal waste chamber is still full. The vacuum system stops itself, the analyzer interrupts working phases and displays the message Low pressure.... Consult your nearest sales/service office regarding repair. After resolving the problem, the analyzer can be restarted and continue testing from where it stopped (see Chapter E, paragraph 1.5., line 'Run all pending patients').</p> <p>The message "-WARNING- LOW PRESSURE" may also appear when waste liquid container is full. Empty or replace it.</p>
<p align="center">- WARNING - NO WATER</p>	<p>The message "No Water ..." appears when system solution does not reach the analyzer because the external water container is empty or defective loading pump. When this message is displayed, the sampling procedure for programmed tests is stopped. Fill the external water container to continue the tests. Check, replace if necessary, the tubular filter on the intake tube inside the water tank (par. 1.2.1. and ref. 5 Fig. 2). The analyzer will start working from where it stopped (see Chapter E, paragraph 1.5. , line 'Run all pending patients'). If the error message persists, because of defective loading pump, contact the approved technical assistance.</p>
<p align="center">THERE ARE THE FOLLOWING OBLIGATIONS IN DIAGNOSTIC: EXTRA WASH</p>	<p>The message is displayed during normal working sessions seven days after the last Extra wash was performed. Execute an Extra wash procedure. This message does not stop test execution, but it is not possible to guarantee correct results if an effective Extra Wash is not performed. The extra wash message is displayed also if the analyzer is turned off without washing the cuvettes with the correct daily procedure.</p>

2.2.2. Screen Messages Requiring Technical Assistance

SCREEN MESSAGE	CAUSES & REMEDIES
<p align="center">ERROR RESETTING SAMPLE TRAY</p>	<p>This message stops the execution of programmed tests. The message is generated by an incorrect home position of the sample tray. This error can be caused either by an absence of sample tray, or defective position sensor. In case of a wrong positioning or absence of sample tray, correctly position the sample tray in its chamber and then press “F5” (“Reset”) key to restore correct analyzer operation. In case of defective position sensor contact qualified technical assistance to solve the problem.</p>
<p align="center">ERROR RESETTING REAGENT TRAY</p>	<p>This message stops the execution of programmed tests. The message is activated by an incorrect zero positioning of the reagent tray. This error can be caused either by an incorrect placement of reagents tray into the analyzer or by a defective position sensor. Verify and correctly place the reagents tray and then press “F5” (“Reset”) key to restore correct analyzer operation. In case of defective position sensor contact qualified technical assistance to solve the problem.</p>
<p align="center">ERROR RESETTING DILUTOR</p>	<p>This message stops the execution of programmed tests. The message is generated by an incorrect zero positioning of the dilutor piston. This error can be caused either by an excessive piston friction or a defective position sensor. In the event of friction it is sufficient to disassemble and clean the piston with a soft cloth dampened with alcohol, reassemble and then press “F5” (“Reset”) key to restore correct analyzer operation. In case of defective position sensor contact approved technical assistance to solve the problem.</p>
<p align="center">ERROR RESETTING CUVETTE TRAY</p>	<p>This message stops the execution of programmed tests. The message is generated by a position sensor error of the cuvette tray. Press “F5” (“Reset”) key to try to restore the correct operation of the analyzer. If this does not solve the problem, then it will be necessary the to contact approved technical assistance.</p>

SCREEN MESSAGE	CAUSES & REMEDIES
<p>ERROR RESETTING ARM (HORIZONTAL)</p> <p>ERROR RESETTING I.S.E. ARM (HORIZONTAL)</p>	<p>This message stops the execution of programmed tests. The message is generated by a defective position sensor of the arm. Press “F5” (“Reset”) key to restore the correct analyzer operation. If the problem persists, then contact approved technical assistance.</p>
<p>ERROR RESETTING ARM (VERTICAL)</p> <p>ERROR RESETTING ARM I.S.E. (VERTICAL)</p>	<p>This message stops the execution of programmed tests. The message is generated by an error during up/down motion the sampling needle. This error may be caused by a deformed needle, obstructions (i.e. improper placing of the reagent bottles) or a defective position sensor. If the needle is deformed, replace it. As regards obstructions, just place the bottles correctly. Afterwards press “F5” (“Reset”) key to restore correct analyzer operation. In case of defective position sensor, contact approved technical assistance.</p>
<p>ERROR RESETTING WASHING STATION</p>	<p>This message stops the execution of programmed tests. A defective position sensor of the washer module generates this message. Press “F5” (“Reset”) key to restore correct analyzer operation. If the message persists, contact approved technical assistance.</p>
<p>IMPOSSIBLE TO RESET ANALYZER</p>	<p>The message “Impossible to reset analyzer” indicates a system error. It does not allow the continuing of working phases. Restart the system computer by pressing the start button. If the message persists, contact approved technical assistance.</p>
<p>SYNCH ERROR</p>	<p>The message “Synch error” indicates a system error. It does not allow the continuing of working phases. Restart the system computer by pressing the start button. If the message persists, contact approved technical assistance.</p>
<p>SYSTEM BLOCKED CALL ASSISTANCE</p>	<p>The message “System blocked” indicates a total blockage of the system. Restart the system computer by pressing the start button. If the message persists, contact approved technical assistance.</p>

2.2.3. Optical System Verification Messages

ERROR MESSAGE	CAUSES & REMEDIES
<p align="center">- WARNING - LAMP PROBABLY OFF</p>	<p>The message is displayed after a photometric zeroing, when the analyzer detects that the optical system has a lower efficiency than the minimum value stored. When this message is displayed it is not possible to continue sampling tests. Replace photometric lamp (see par. 1.2.3 in this chapter) and perform Photometric Zeroing (refer to Chapter H paragraph 1.1.1.). In case the error message still persists, contact approved technical assistance.</p>
<p align="center">- WARNING - LAMP PROBABLY EXHAUSTED</p>	<p>The message is displayed after a photometric zeroing, when the analyzer detects that the optical system has at 340nm a lower efficiency than the minimum value stored. The sampling tests are not stopped after this message. It is necessary to replace the lamp (see par. 1.2.3 in this chapter) and repeat the “Photometer zeroing” command (refer to Chapter H paragraph 1.1.1.). If after observing these steps, the message no longer appears, then it is possible to continue testing. In case the error message still persists, contact approved technical assistance.</p>
<p align="center">ERROR IN OPTICAL GROUP</p>	<p>The message is displayed after resetting the analyzer and indicates an optical group malfunction. Contact approved technical assistance.</p>
<p align="center">CUVETTES TRANSMISSION OUT OF LIMITS</p>	<p>The message is displayed after a photometric zeroing, when the analyzer detects optically unusable cuvettes. After this message the unused cuvettes (up to a max. of three) are rejected by the analyzer that continues to work with the remaining ones. An “Extra wash” should be run followed by a new “Photometer zeroing”.</p> <p>If more than three cuvettes are unused operation is stopped and intervention of the specialized technical personnel is required.</p>

IMPORTANT NOTICE:

The above-mentioned messages are only a partial representation of all the possible warnings that the analyzer may output to the user. In case of any messages that are not covered here or are not clear, please contact Technical Assistance Dept. at Biotechnica Instruments S.p.A.

SECTION I: GENERAL INFORMATION

CHAPTER 0: TECHNICAL SPECIFICATONS

1. TECHNICAL SPECIFICATIONS.....2

NOTE:
Specifications are subject to change without notice

1. TECHNICAL SPECIFICATIONS

CUVETTE OPERATING TEMPERATURE

Programmable Temperatures: room temperature, 30°C, 32 °C, or 37 °C
 Precision: ± 0,2°C
 Accuracy: ± 0,2°C
 Temperature Monitoring Device based on Peltier Effect

REAGENT CHAMBER TEMPERATURE

Nominal Temperature: Between 5°C and 15°C Approx. (depending upon the setting)
 Temperature Monitoring Device based on Peltier Effect

OPERATING AMBIENT TEMPERATURE 18 °C to 32 °C, 10% to 90% RH, Non condensating

DILUTORS

Dilutors Type: Biotechnica Dilutor

TECHNICAL SPECIFICATIONS

BT3000 Plus

BT1500 BT3500&BT3500S

Max Volume:	470 µl	340 µl
Linearity F.S.:	± 0.1% F.S. (Full Scale)	± 0.1% F.S. (Full Scale)
Accuracy at 3 µl:	± 3%	± 1%
Accuracy (Full Scale):	±1% from 10 µl to 470 µl	± 1% from 10 µl to 340 µl
Reproducibility	± 0.7% at 3 µl; ± 0.6% at >3 µl	± 0.7% at 3 µl; ± 0.6% at >3 µl
Average Life:	3 million operating cycles	1 million operating cycles
Maintenance:	Every 300,000 operating cycles (O-ring seal replacement)	Every 300,000 operating cycles (O-ring seal replacement)

PHOTOMETER

Optical System Solid state photometry, (patented by Biotechnica Instruments S.p.A.)
 Detectors 10 UV/VIS photodiodes + reference channel

PRECISION AND ACCURACY

Spectral Response: 340, 380, 405, 436, 480, 510, 546 578, 630, 700 nm
 Bandwidth: ± 5 nm max
 Photometric precision: ± 1% from 0 to 2.000 O.D., ± 2.5% at 2-3 O.D.
 Photometric Sensitivity: ± 0.001 ABS
 Drift: ± 0.005 ABS/h (steady state)
 Optical path: 7 mm for BT3000 Plus
 5.9 mm for BT1500 & BT3500/BT3500S
 Photometric Lamp: Tungsten Halogen Lamp with Dichroic Reflector
 Beam Angle: 9°
 Power: 35 Watts
 Input voltage: 12 VDC
 Avg Rated Life: Approximately 2000 hours

NOTE: For optimal result the lamp can be used for about 1,500 hours.
 The long-term use will result in the gradual deterioration of the UV emission.

ANALYZER POWER REQUIREMENTS

	BT1500	BT3000 Plus	BT3500&BT3500S
Universal Input:	100 / 240 V~	100 / 240 V~	100 / 240 V~
	50-60 Hz	50-60 Hz	50-60 Hz
Power:	300 Watt	590 Watt	590 Watt

PFC Unit (Power Factor Correction) included.

VACUUM PUMP POWER REQUIREMENTS P/N 06-05161-01

	BT3000 Plus	BT3500&BT3500S
Input:	100 / 240 V~, 50-60 Hz	100 / 240 V~, 50-60 Hz
Power:	40 Watts	40 Watts

PRINTER POWER REQUIREMENTS

Universal Input: 100 / 240 V~, 50-60 Hz
 Power: 50 Watts

UPS

Input: 220 V~, 50-60 Hz (110 V~ on request)
 Output: 220 V~, 50-60 Hz (110 V~ on request)
 Power: 1100 VA (710 Watts)

DATA MANAGEMENT (Except for BT1500)

Computer	≥ CPU Intel ≥ 1.6 GHz or more, IBM compatible
DVD	≥ 16X
Hard disk	>100 Gb
Monitor	Color LCD 12" with integrated touchscreen
Interface	RS232 Bidirectional + USB + LAN + VGA
Printer	Ink-jet Color IBM compatible or other
Mouse & keyboard	IBM Compatible (International)
External Modem	Optional
Error Messages	Visible

EXTERNAL PC MINIMUM REQUIREMENTS FOR BT1500

Operative system: In English	Windows 2000® Professional Windows XP Professional Windows Vista Professional Windows 7 Professional
Computer:	IBM compatible
Processor:	Pentium Dual core duo
RAM:	1Gb (2Gb for Windows Vista)
Video:	SVGA or compatible, 32K colors
Display:	Color min. resolution 800x600
Mouse:	Serial, PS2 or USB, 2+1 buttons
Host communication:	RS232 or LAN (TCP/IP)
USB:	1, version 2.0 for communication with the analyzer
Parallel port:	1, if the printer has a parallel port
Printer:	Windows compatible (the printer <u>must</u> be installed on the PC before installing the operative software) Deskjet, Inkjet or Laser
CD ROM:	DVD reader
HD:	5Gb free
Note: use a standard theme for all the windows and font 96 DPI.	

DIMENSIONS & WEIGHT	BT1500	BT3000 Plus	BT3500&BT3500S
Instrument	53 Kg (116lb)	95 Kg (210lb)	95 Kg (210lb)
Instrument dimensions	L=78cm (30.7") D=58cm (22.8") H=51cm (20")	L=100cm (39.4") D=58cm (22.8") H=68cm (26.7")	L=100cm (39.4") D=58cm (22.8") H=68cm (26.7")

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This instrument has passed all tests related to Electromagnetic Compatibility (EMC), and Safety requirements for electrical equipment for measurement, control, and laboratory use performed by the OCE Lab (EMC & Electrical Safety Compliance Test Laboratory), Ministry of Communication - Italy accredited EMC certification body, No. 051 of 21 October 1998. Certificate's documentation is available on request. This analyzer is in conformity with the following normative/standards:

EN 61326: EMC

EN 61010-1: ELECTRICAL SAFETY

NOTE:

- 1 As regards the technical specifications for the system "instrumentation + reagent" used in the applications of kit, these are the responsibility of kit's manufacturer and will be stated in the applications (refer to the instructions accompanying the kits).
- 2 The analyzer BT PLUS does not require (after sales) any routine electrical or mechanical readjustments. There are mechanical and electronic adjustments performed by the manufacturer (Biotecnica Instruments S.p.A.) during assembly and quality controls. These adjustments may be performed again in case required by a particular technical service and in any case are at the discretion of the authorized technical personnel only. However, It is highly recommended to check the system periodically to prevent any faults or malfunction of the analyzer.

SECTION II: ADDITIONAL INFORMATION

CHAPTER 1: ABBREVIATED OPERATING INSTRUCTIONS

1. ABBREVIATED OPERATING INSTRUCTIONS.....	2
1.1. Turning On And Preliminary Procedures.....	3
1.2. Inserting Reagents For Clinical Chemistry.....	6
1.3. Analytical Calibrations And Controls.....	7
1.4. Entering Patients And Work Lists	10
1.5. Running Tests	14
1.6. Displaying And Printing Results.....	15
1.7. Turning Off The Analyzer	19

FOREWORD

This quick guide gives a global view of the system operation by outlining the sequence of fundamental operating phases. It is highly recommended to carefully read the whole manual in order to have a deeper knowledge of each argument.

ATTENTION: USE OF THE ANALYZER INTERNAL COMPUTER – DOES NOT APPLY TO ANALYZERS WITH EXTERNAL PC

The computer box of BT analyzers and by-products is designed for long-term security and reliability and is virtually maintenance-free as long as the user does not install any third-party application programs. If these applications are installed, then they may damage the operating system registry and may also cause disastrous consequence for the computer's hard-drive. Biotechnica Instruments S.p.A. will not be responsible for any damage to the analyzer, its software and data in the hard-disk in case of improper use of the PC box. This includes also: installation of external programs, not properly secure net connections (intranet and internet) and the use of disks without the necessary verification for viruses presence. Biotechnica Instruments S.p.A. will not be responsible for any damage caused by non authorized third parties who may open and alter the PC box configuration.

NOTE:

**All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.**

1. ABBREVIATED OPERATING INSTRUCTIONS

The BT instruments are automatic analyzers for clinical chemistry, immunochemistry analyses, and, where available, for electrolytes determination through Ion Selective Electrodes (**I.S.E. Module**).

The analyzer can be divided into the following two distinct operative parts:

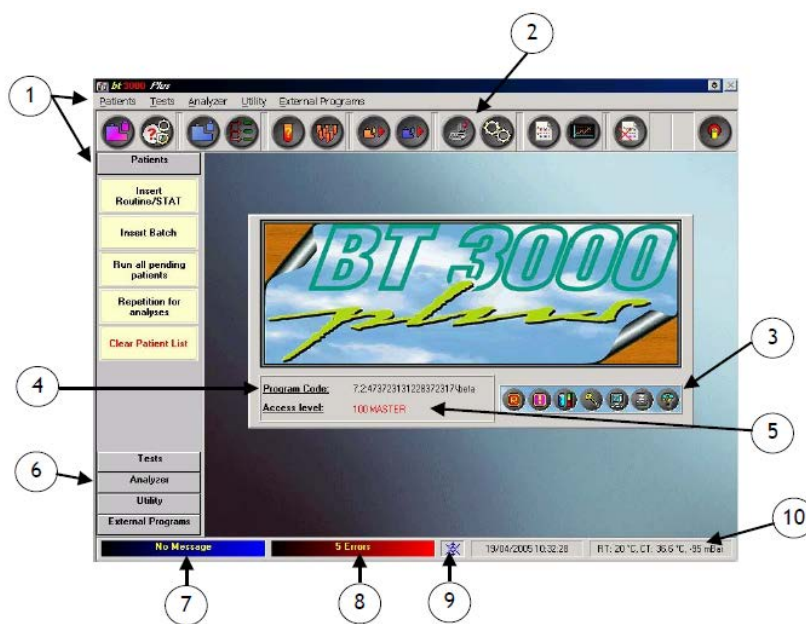
- a) **Sampling Unit:** It prepares for tests the samples and single or double reagent.
- b) **Reading Unit:** Cuvette plate with integral automatic washing system.

SYMBOLS

As the BT analyzers software runs under Windows, it uses the same philosophy with windows, icons, quick commands, function keys and curtain-shaped menus.

Every window has its own icons and specific menus that will be described hereafter. The full meaning of each command will be explained in the corresponding chapters.

At the start-up the program will display the following main window:



- ① **Main menu:** each menu generates other commands and/or options
- ② & ③ **Direct access icons:** selecting each icon the relative command is directly activated
- ④ **Software version:** operative program version
- ⑤ **Access level:** is the access level of the operator: it is password dependent
- ⑥ **Vertical Bar - Commands:** Direct access to function commands
- ⑦ **Messages bar:** clicking here opens a window showing the messages received by the program
- ⑧ **Errors bar:** by clicking here a window is opened showing the errors occurred during the work session
- ⑨ **Refrigerator Status Indicator**
- ⑩ **Operating Pressure Indicator, Ambient Temperature (RT), Cuvette Temperature (CT)**

1.1. Turning On And Preliminary Procedures

Turning on procedure for the first time:

- 1) Turn on the UPS device as described in the appropriate supplied manual.
- 2) Power on the printer (refer to the specific manual enclosed).
- 3) To switch on the analyzer, use the main power switch on the rear panel of the instrument. This button activates only the refrigerating system for the reagents. To properly turn on the analyzer system, momentarily press the green push-button placed on the front panel (Fig. 1). For what concerns the **BT1500**, verify first that the external PC is connected to the analyzer via USB, then turn the PC on and load the analyzer operative program.

CAUTION

Do not press this push-button during analyzer operation, because when pressed it stops the instrument, leaving only the refrigerating system on (refer to Paragraph 1.6., Chapter E, Turning off procedure).

- 4) Once turning on procedure has completed (lasting few minutes), wait for the system to warm up. During warm-up phase the temperature indicator flashes on the bottom right of the display until the appropriate temperature is reached. The instrument reaches the steady state after approximately 20 minutes.

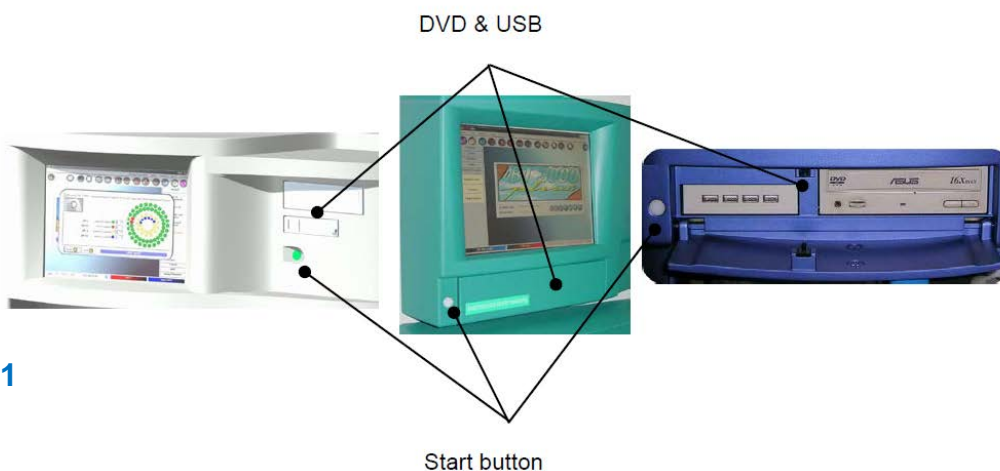


Figure 1

- 5) Verify the presence of the system solution (at least for the daily needs). It consists of bi-distilled H₂O plus Surfactant (1ml/l of water - ratio 1/1000 – see Sect. II, Chapt. 3 for product codes).
- 6) Verify that waste liquid container is empty or at least has the capacity to contain the quantity of liquid produced during the working day.

NOTE:

It is important to observe steps 5) and 6) to ensure a continuous operation of the analyzer without interruptions.

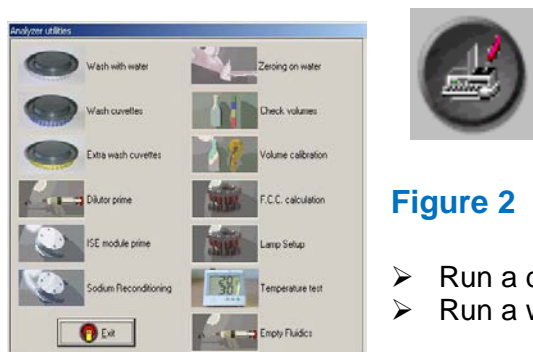


Figure 2

- Run a dilutor prime by the command **Dilutor prime** (Fig. 2).
- Run a wash by the command **Wash with water**.

SERVICE ICONS BAR



Reset Analyzer (F5)



Stand-by Analyzer (F6)



Displays the Volumes' Status; Used to Insert/Remove Reagents (F10)



Password (F7)



Status Analyzer (F2)



Printer Setup (F4)

FUNCTION ICONS BAR



1 - To Insert New Codes, Parameters, Standards and Controls for all Analyses



2 - To Create the On-Line Reagents' Tray



3 - To Insert Parameters/ Standard and Controls for the On-Line Reagents











4 - To Insert/Modify Profiles



5 - To Insert Routine - View Programmed or In-Run Patients



6 - To Insert Batch

-  **7 - To Run Standards**
-  **8 - To Run Controls**
-  **9 - Analyzer's Utilities**
-  **10 - Mechanical Calibrations**
-  **11 - a) Results Listed per Patient b) Results per test in real time**
-  **12 - No Results**
-  **13 - Reaction Graphs**
-  **14 - Turning off the System**

Simply positioning the cursor on the icons the hint will appear (where available), showing a brief description of the icon function. This is followed (when available) by the function key between brackets, which allows for the same function or command as the icon. For example, the hint Reset (F5) means that the function key F5 has the same function of the icon. In the same way, in each menu are shown (when available) the quick commands (e.g. Insert Batch (Ctrl+B) means that the same function is activated by typing simultaneously on the keyboard the keys Ctrl and B).

GENERAL ICONS



Cancel (aborts the programming and closes the window)



Save (saves the program and closes the window)

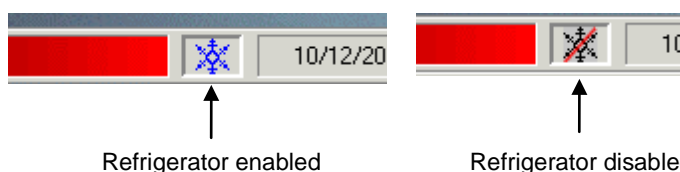


Print (prints the window's contents, i.e. parameters, graphs etc.)



Reduces the window to the upper bar where the analyzer's name appears.

An icon representing refrigeration system operation has been added to the status bar in the main menu. The Refrigerator disabled state may be necessary if the operator decides not to use the refrigerator for reactions or after a refrigeration operating error generated by the system.



1.2. Inserting Reagents For Clinical Chemistry



Direct Access

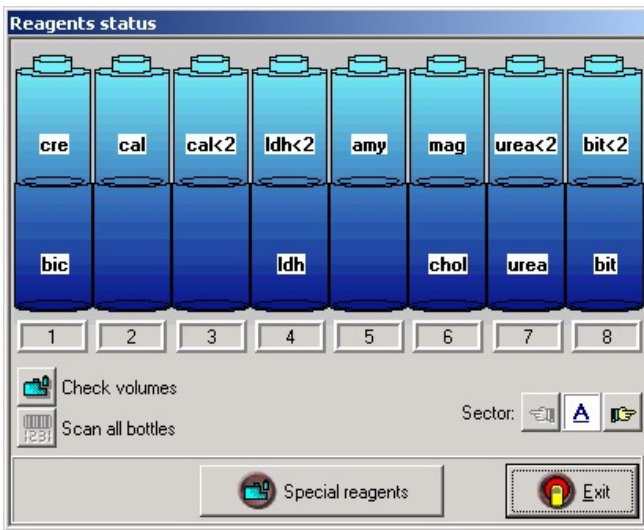


Figure 3

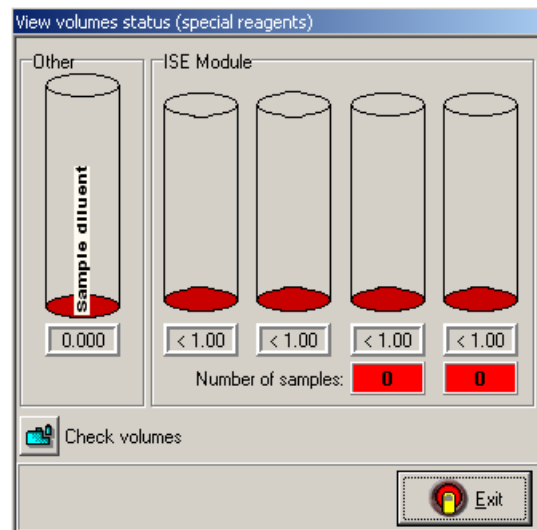


Figure 4

This function is accessed either by pressing F10 key or by clicking on the specific icon. It helps the user to correctly position the reagent bottles, as programmed in the current tray.

The reagent tray is divided into sectors, identified by the letters A, B and C for BT1500, while for BT3000 Plus and BT3500/BT3500S, the letters are A, B, C, D and E. Each sector has 8 positions. The screen displays the representation of 8+8 bottles (**Figure 3**). The analysis codes that use large bottles are displayed in the lower positions, while the codes using small bottles are displayed in the upper positions. The reagents volume status for the **I.S.E.** Module and the sample diluent are illustrated in the **Figure 4**. The insertion of reagents in the reagent tray for clinical chemistry, and in the **I.S.E.** Module is explained below.

Single bottle: Right-click over analysis code. Choose between bottle's insertion or removal. The analyzer will correctly position the tray to match with the arrow at the base of the tray itself. With bar-code option enabled, identification is correctly accomplished through the automatic scan of the bar code on the inserted bottle. The same function can be performed on demand, by activating the Scan Bottle command (near the insertion/removal commands). **Figure 5**

Whole sector: Right-click on the SECTOR field. Choose between bottle's insertion or removal. The analyzer will correctly position the whole sector for insertion or removal. With bar-code option enabled, identification is correctly achieved through the automatic scan of the bar code for the inserted bottles. The same function can be performed on demand through Scan Sector (near the sector insertion/removal commands).

In both cases, after insertion of the reagents, the analyzer will run a control of the volume of the liquid present. **Figure 5**

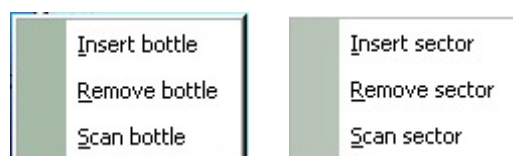


Figure 5

NOTE: when using the Remove option, no functional control is performed: the existing volume and test code are not removed.

1.3. Analytical Calibrations And Controls

CALIBRATIONS

The analytical calibrations that can be run by the analyzer are divided as follows: **With Factor**, **Linear** and **Non Linear**. The selection occurs during the programming of the analytical test parameters (refer to **Chapter C**, paragraph 1.3.3. **Primary Analytical Parameters**) and can be executed on user's request or automatically.

Linear and With factor analyses

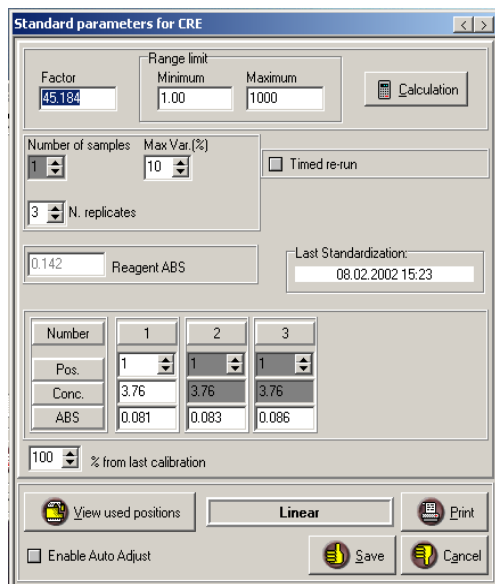


Figure 6

Factor: This parameter converts absorbance (ABS) values detected by the analyzer into final concentration values. When a theoretical factor is used (i.e. With Factor methodologies), enter in this field the known factor. The analyzer, when calibrating, calculates and updates the factor value.

Range limit: In order to verify calibration's validity, enter the Minimum and Maximum range in which the factor must be included. If an out-of-limit factor is detected, a message informs the user and the previously stored value is not modified.

Calibrators or standards used must be placed into dedicated positions on the samples' tray. It is possible to use up to 4 different standard concentrations or run up to 4 repetitions on a single title (and position) in the linear analyses.

Programming replicates on a single title

Enter 1 into the **Number of samples**, then enter the **N. replicates** (up to 4 max). Select the actual position (**Pos.**) on the tray for the replicated standard and then the concentration (**Conc.**). The values are automatically updated in the ABS boxes during the calibration and the factor will be automatically calculated.

Programming several standards

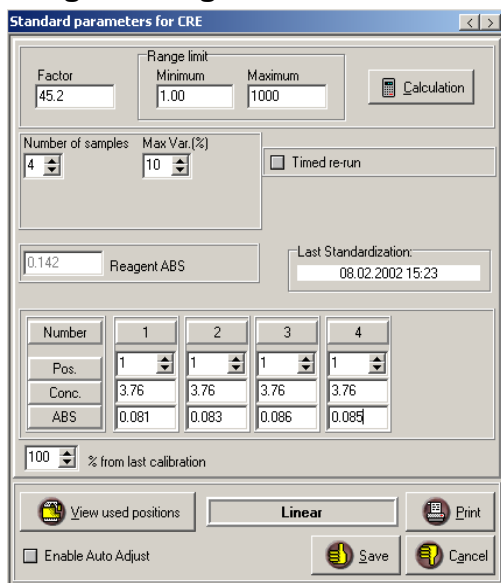


Figure 6-1

Enter the number of standards to be used in the **Number of samples** textbox. Enter the actual positions (**Pos.**) on the tray for each standard and then the concentrations (**Conc.**). The values are automatically updated in the ABS boxes during the calibration and the factor will be automatically calculated.

Calibration parameters

Max Var. (%) (Maximum percentage variation): This parameter is for verifying percentage variation. It represents the acceptable difference between the ABS values calculated for the different calibration points, in case more calibrators are used or repetitions are performed on a single title. When an out-of-limit variation occurs, a message informs the user and the calibration will not be stored (the previous positive calibration will remain in memory).

Reagent mABS: It is a read-only field and it is updated every time the blank reagent is performed.

% from last calibration: It is a percentage check made between current and previous calibration. It compares the newly determined ABS with already stored data. If the programmed limit is surpassed, then a message informs the user and the previous positive calibration will remain intact in memory.

Automatic adjust: It is a password-protected parameter that enables or disables automatic modification of test results in case of an additional calibration run during patients' execution.

Last Standardization: This field displays date and time for the last stored positive calibration. By double-clicking over the date textbox it is possible to display the previous calibration parameters.

Save: This command saves data and then closes the window.

Non Linear analyses: These tests require from 3 to 6 standards. Enter the number of standards to be used in the **Number of Samples field**. Enter the actual positions (**Pos.**) on the tray for each standard and then the related concentrations (**Conc.**). The values are automatically updated during calibration into the **ABS** boxes.

To use standards pre-dilution function, enable the **Automatic Dilution**. It is then possible to select whether dilution must be performed with water (system solution) or physiological solution (**Dilution with solution**). In the **Dilution** field enter the required dilution ratio. If automatic dilution is not required, then appropriate concentration of the corresponding standard must be entered in the each concentration field.

Graph: This command displays the graph of the stored interpolation curve. In the graphic display page, data and curve are displayed together and can be printed.

CONTROLS

The controls are divided into **Known** and **Unknown**, where it is possible to program three levels for each one subdivided in tables:

Known: Level 1, 2, 3

Unknown: Level 1, 2, 3

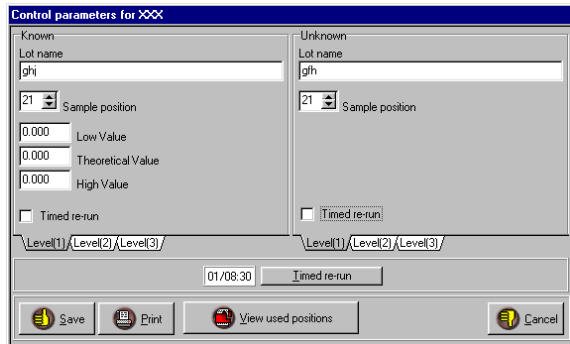


Figure 7

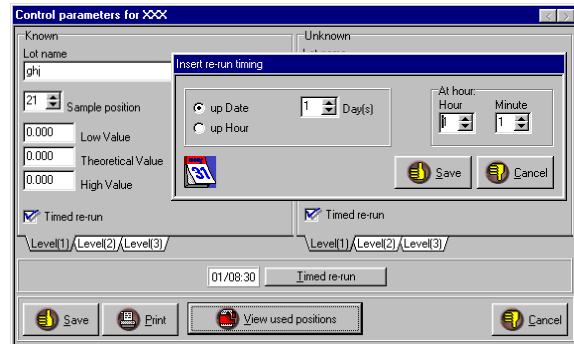


Figure 8

Known: Enter lot name or number, mean value, and min & max limits. Enter tray's position, already set to controls in the section **Setup Analyzer** included in the inner ring of samples' tray.

Unknown: Enter lot name or number and tray's positions. Reserved positions are those already set in the program **Setup Analyzer**, which are shared with known ones.

RUNNING STANDARDS AND CONTROLS

The functions **Run Standards** and **Run Controls** can be accessed from Tests main menu or through the specific icons that allow direct access (**Fig. 9 and 10**).

The displayed analysis codes pertain to the list generated in the **Current tray**. To run standards and controls, select the desired tests and then click on the **Run button**. To leave program press Exit.



Run Standards
Direct access icon



Run Controls
Direct access icon

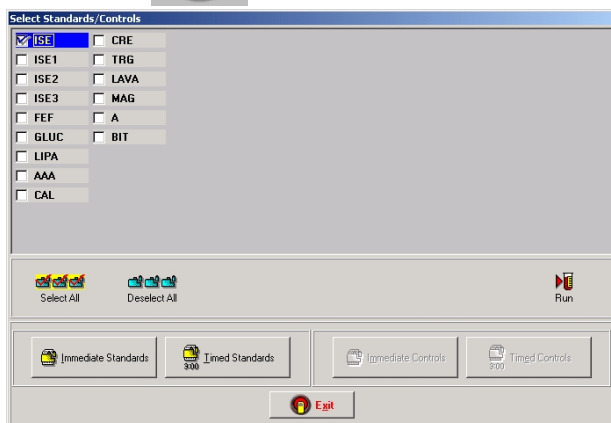


Figure 9

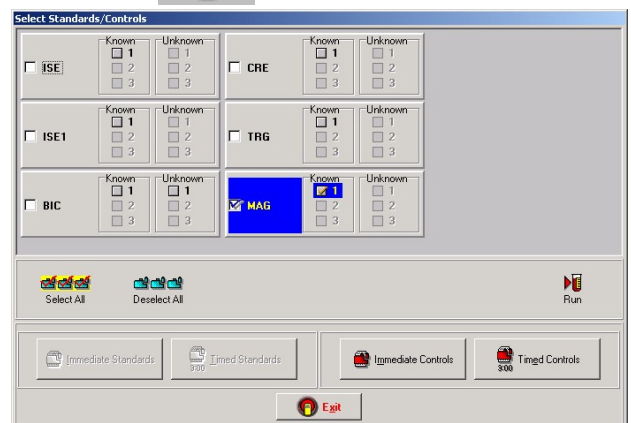


Figure 10

1.4. Entering Patients And Work Lists

Entering Samples (Routine, STAT, Controls and Batch)

Samples can be entered with **Insert Routine/STAT** or with **Insert Batch**. These can be accessed from **Patients** main menu or through appropriate direct access icons. Select **Exit** to leave the program. The represented analyses codes pertain to the list generated in the **Create current tray**.

Entering Patients: The options outlined below are available in this page **Global Insert/View Patients** (Figure 11). Point the cursor on the desired option and click to confirm. To leave program press Exit.

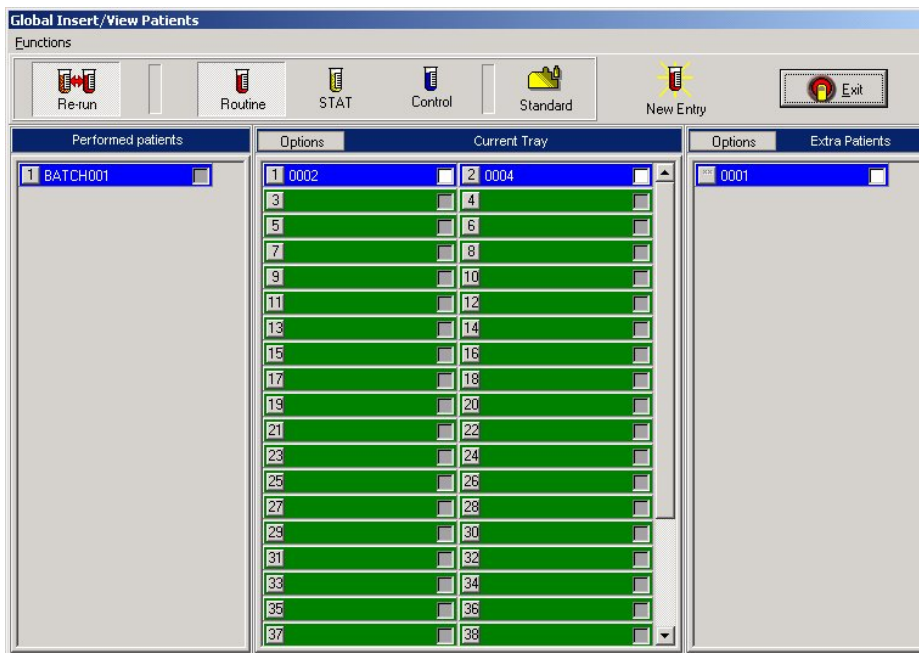


Figure 11

Re-run: allows tests re-run (repetitions) on user’s demand.

Routine: Default displays of Patient positions

STAT: Displays STAT (**S**ingle **T**est in **A**ctual **T**ime, i.e. urgent positions) positions.

Control: Displays Control positions.

Standard: Displays Calibrator positions.

New Entry: Displays window for entering data of Routine, STAT and Control samples.

Extra Patients: Displays the list of patients with no assigned position. Patients selected in the work-list may be moved here (Options menu, Send to extra patients command) and then back.

Exit: To leave program

Example of entering samples

New Entry Routine:

Figure 12

After the selection of **Routine** followed by confirmation through command **New Entry**, the patients acquisition frame is displayed (**Figure 12**). The programmed patient can be executed immediately or saved for later use. The programming fields and the functions are outlined below:

Code: It is the identification number assigned by the user to the patient. It is possible to assign an already given code thus creating a clone of the patient. The cloning of a patient's code allows the user to obtain one report in case different samples are used. If this option is not used, then separate reports are obtained.

It is also possible to create multiple **duplicates** of the same patient, where the codes will be automatically assigned and identified by the name Autobatch. These will have individual reports.

Surname, Name: Enter patient's personal data.

Date: enter the test date.

Notes: enter additional notes.

External Dilution Factor: By default set to 1. It allows analysis determination on externally diluted samples. Enter in this field the external dilution factor ratio used in sample preparation. Final result is multiplied by the inserted external dilution factor.

Group: Select the group (Man, Woman, Child) for correct reference with normal values range.

Type: It is default set to **Serum**. The sample type (Serum or Urines) is selected here. If **Urine** is selected, then the volume of diuresis is requested.

Assigned Group (Routine or CTRL Routine): The default setting is **Routine**. It is used for selecting the category (Patient or Control Serum) during sample programming. Selecting **CTRL Routine** the type (**Known or Unknown**) and levels (**Level 1, 2, 3**) must be specified.

Position: Displays the assigned position on the sample tray.

Test: Generates the Analysis List. Select each analysis to be performed on the sample.

Profile: Select the desired profile among the available. The analyses programmed in this way can be modified. To add or remove tests, it is necessary to enter in the screen Select tests and confirm by clicking on the textboxes. With Deselect it is possible to delete an already selected profile.

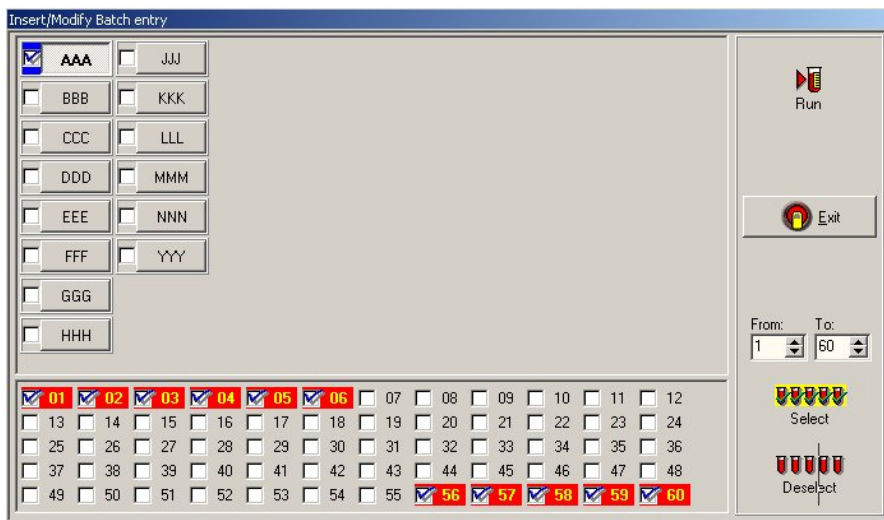
Save: Saves patient's data and the associated analyses. With this command test execution is delayed.

NOTE:

In the routine programming, it is possible to acquire a greater number of patients than the available number of positions in samples' tray. All the patients acquired with no associated position are saved and displayed in the extra patients list and can be transferred to the main list on user's demand (refer to paragraph 1.5. Work Lists).

Run: This command immediately starts the execution of the programmed patient. The sample plate adjusts itself to match the position assigned to the patient, and a blinking red LED indicates the position for inserting cup or primary tube.

Entering samples in Batch



Direct access icon

Figure 13

Batch Entry: Click test code, then click each desired position (selected positions are highlighted in red). Finally click on the checkbox by the code to activate the programmed batch. Select the **Run** button to perform the patients. Refer to Figure 13.

Work Lists

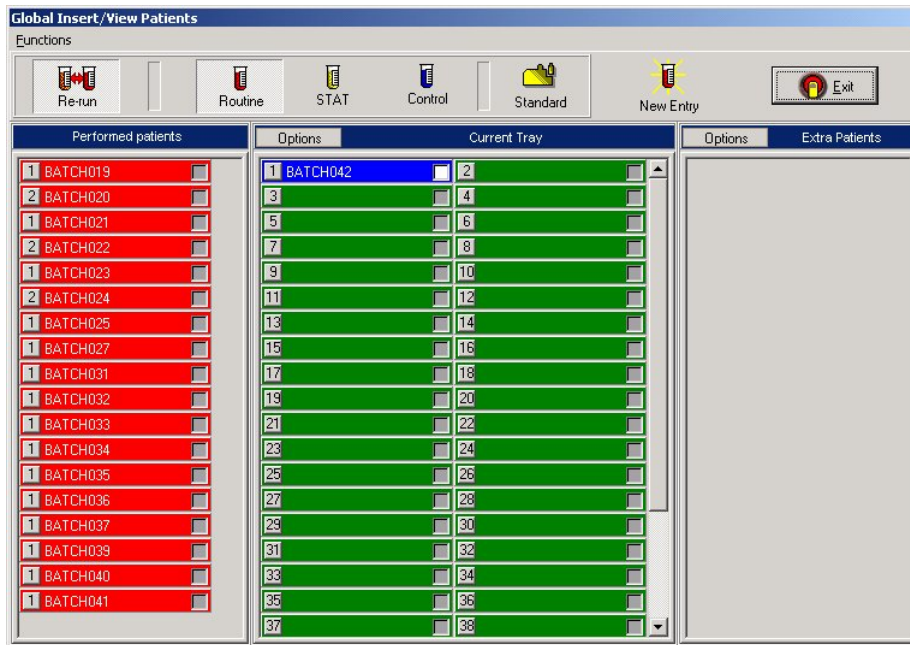


Figure 14

Work Lists (**Figure 14**) are used to display the patient codes or to verify the status of the samples in the tray together with the situation of Routines, STAT, Controls and Calibrators. The Work Lists can be accessed through the menu **Patients** → **Insert Routine/STAT** or using its direct access icon. The screen displays the **Current Tray (Routine)** in the center and the **Extra Patients (Routine)** on the right. During the working phase, the **Re-run** is also shown.

Click on the **STAT**, **Controls** and **Standard** buttons to view their worklists. For each the Current Tray and the Extra Patients lists will be displayed. It is possible to perform patients while running calibrations.

1.5. Running Tests

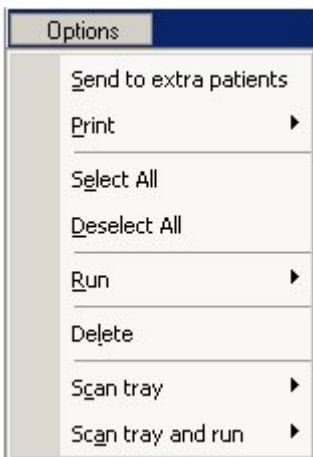
Once the data has been entered, insert the samples into the tray (**Figure 15**) and then place the tray into the analyzer (**Figure 16**).



Figure 15



Figure 16



Options:

The Options menu is available in the **Current Tray** (Routine, STAT and Controls). It displays the following commands:

Send to extra patients:

The selected patients are removed from current samples tray list for placement on **Extra Patients List**. Selection can be done by checking the appropriate boxes.

Print:

Prints the partial (for selected items) or total samples list.

Select All:

Automatically selects the whole list.

Deselect All:

Automatically deselects the whole list.

Run: Work start command. If single patients or the whole list are selected, a message asks if the samples have been inserted. If the answer is affirmative, the analyzer automatically starts processing. In case of a negative answer, a guided procedure will assist the user to insert the samples. The selection of the sample to be inserted is performed by confirming with cursor on the corresponding line. Use Select All to select the whole list and Deselect All to deselect it but in this case confirmation is required. After the insertion of all the samples, activate Run

Delete: Removes selected or all the patients. Confirmation is required.

Scan tray – Scan tray and run: performs a reading of the samples' tray and updates the patients worklist. Selecting "scan and run" the analyzer will read the samples' tray and start the patients run.

1.6. Displaying And Printing Results

Displaying Patients Results

The representation of the test results can be accessed through the specific icon (shown on the right) for the two available options: **View results for sample** (results will be displayed for patient) and **View results for test** (results will be displayed for test).

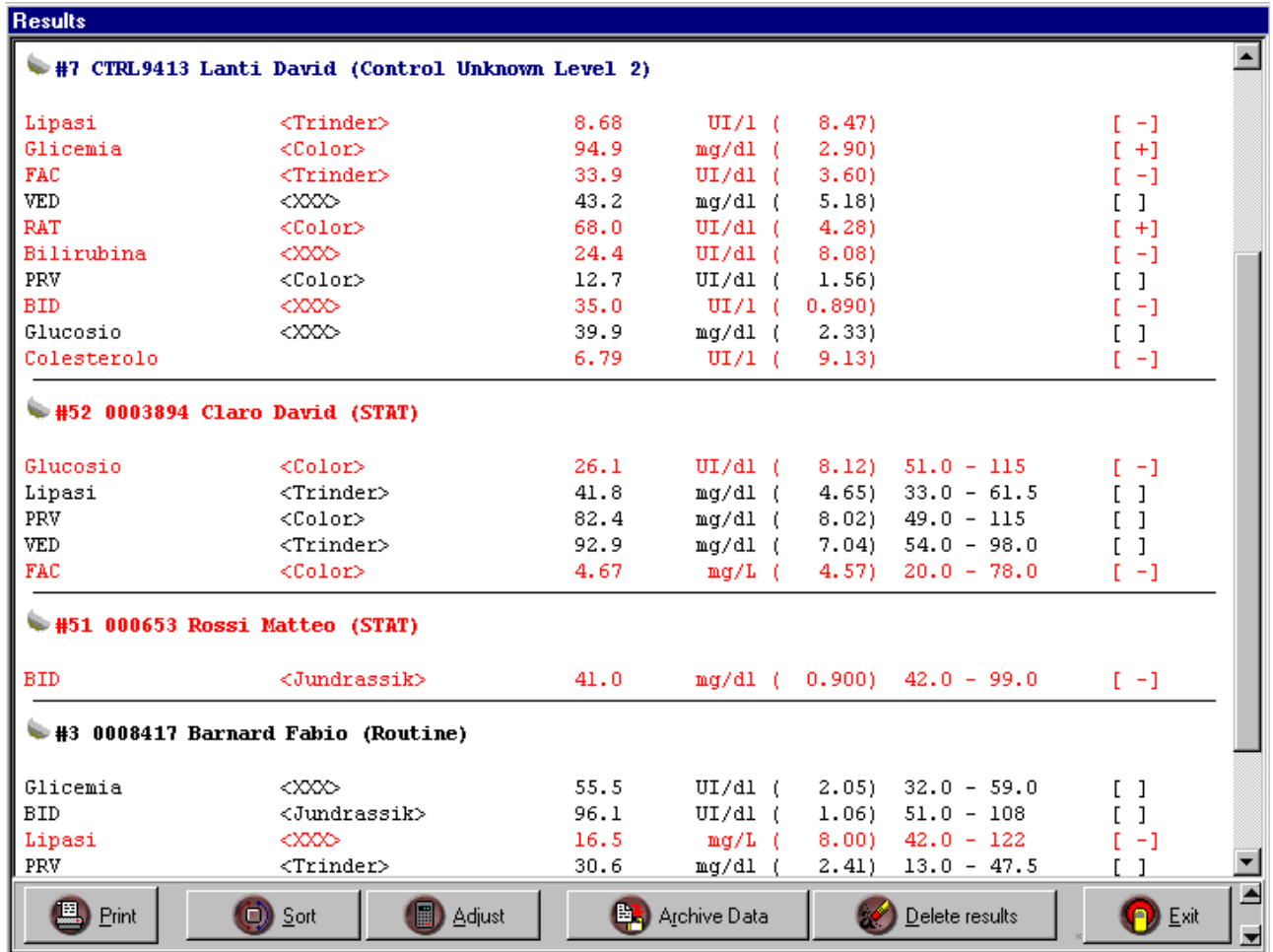


Figure 17

The Patient's data display page is shown in **Figure 17**. It can be accessed through the specific icon (shown on the right). It is a brief representation of data and allows visualization of results of patient in execution as the tasks for the single patients are completed. Once the results are archived, the information present in this page will no longer be available.



In this area information related to calibrations is represented, such as the values of calculated factors or any types of errors that occurred during execution.

If there is no data the page appears blank. A color code makes it possible to quickly identify the information:

- red text: presence of flags in at least one test of the sample
- blue text: controls
- green text: calibrations
- black text: no anomaly in the test or the entire sample

The following information are displayed for each sample:

- a) Sample Position (#XX)** Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.
- b) Sample Code** For Patients (Routine and STAT) it is assigned at check-in.
For STD and Batch it is automatically assigned.
It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph 1. “**Quality Controls**”).
- c) Surname, Name** Patient’s personal data.
- d) Sample Type** The relationship of Sample to one of the groups: Routine, STAT, CTRL or STD is indicated between brackets.
- e) Results** The results of test attributed to patients are represented with:

FAC	<Color>	38.1	mg/L (1.57)	53.0 - 102	[-]
VED	<Trinder>	19.7	mg/L (0.910)	17.0 - 67.5	[]

- full name of the analysis
 - execution method
 - result
 - unit of measurement
 - absorbance read (between parenthesis)
 - range of normal values
 - any flags (between brackets – see also par. 1.5)
- For automatic re-runs the values of the first and second determination are represented.

The following commands are available in the data display page:



Print: Print command. If enabled, it prints the entire contents of the data display page. However, this is not a print-out in report format.

Sort: Data sorting command. This function is enabled only at the end of working session. The real-time data are displayed in test execution order. The Sort command allows sorting based in the following criteria, in this order: date, time, position on tray. The controls are places last and the calibrations first.

Adjust: Data re-processing command. This function is enabled only at the end of working sessions. For patients re-run manually only the last result will be recalculated. The correction is made starting with the absorbance memorized for the single test. After confirming the command and selection of the desired analysis, two data re-processing modes are available. The first mode allows a positive or negative percentage correction and the second mode uses the latest valid calibration

Archive Data: This command saves data into the patients archive.

Delete Results: deletes all the data from the visualization pages (per patients and in real time) as well as the page of reaction graphs.

Exit: Exits from data display page.

INFO FLAGS

In both types of result displays (per patient and in real time) an **Info Flags** button is available on the upper right.

It provides access to a page where the flags are located, with a short explanation of the meaning of each one.

RESULTS PER TEST

Test ID	Value	Unit	Reference Range	Flag
#51 0009629	<HC>	mg/dl (3.50)	48.0 - 99.0	[+]
#52 0003772	8.46	UI/dl (7.98)	40.0 - 114	[-]
#52 0004873	<HC>	mg/dl (1.37)	22.0 - 54.0	[+]
#3 0005468	<HC>	UI/l (6.79)	46.0 - 95.0	[+]
#7 CTRL9932	<HC>	UI/l (3.07)	11.0 - 47.5	[+]
#51 0002675	63.9	mg/dl (3.07)	13.0 - 72.5	[]
GLU (Glucosio)				
#52 0003772	<HC>	mg/L (7.65)	13.0 - 35.5	[+]
#3 CTRL507	83.8	mg/L (0.360)	13.0 - 67.5	[+]
#51 0002663	<HC>	mg/dl (8.46)	52.0 - 135	[+]
#6 0006967	<HC>	mg/dl (6.41)	56.0 - 108	[+]
#5 0004657	36.0	UI/dl (4.96)	12.0 - 45.0	[]
#3 0005468	19.8	mg/L (7.18)	13.0 - 35.5	[]
#7 CTRL9932	<HC>	UI/l (1.25)	27.0 - 72.5	[+]
#51 0002675	<HC>	mg/dl (7.71)	11.0 - 52.5	[+]
LIP (Lipasi)				
#52 0003772	2.22	UI/dl (8.35)	30.0 - 87.0	[-]
#52 0009891	<HC>	mg/dl (3.73)	18.0 - 74.0	[+]
#51 0002663	34.1	mg/L (4.84)	32.0 - 74.0	[]
#6 0006967	67.8	UI/dl (4.88)	24.0 - 56.0	[+]
#52 0003795	<HC>	mg/dl (2.45)	47.0 - 130	[+]
#3 0005468	<HC>	mg/dl (4.92)	10.0 - 42.0	[+]
#7 CTRL9932	<HC>	mg/dl (9.95)	59.0 - 132	[+]
PRV				
#51 0009629	78.5	UI/l (0.020)	57.0 - 137	[]
#52 0003772	22.6	mg/dl (4.36)	29.0 - 92.5	[-]
#52 0009891	16.3	UI/l (1.97)	14.0 - 78.0	[]
#51 0002663	8.54	UI/dl (7.17)	34.0 - 96.0	[-]
#5 0004657	26.2	mg/dl (8.97)	47.0 - 114	[-]
#52 0003795	<HC>	UI/dl (5.42)	27.0 - 98.5	[+]
#2 0002725	<HC>	mg/dl (9.73)	35.0 - 89.5	[+]
#3 0005468	49.2	mg/dl (1.58)	34.0 - 106	[]
RAT				
#52 0003772	83.7	mg/L (7.44)	12.0 - 77.0	[+]
#51 0002663	77.7	UI/dl (1.16)	32.0 - 93.0	[]
#5 0004657	<HC>	UI/dl (3.45)	36.0 - 101	[+]
#6 0004127	<HC>	mg/L (3.38)	44.0 - 117	[+]
#3 0005468	<HC>	mg/dl (9.77)	21.0 - 44.5	[+]
VED				
#51 0002663	<HC>	mg/dl (3.70)	52.0 - 90.0	[+]
#6 0006967	72.1	mg/L (0.390)	27.0 - 84.5	[]
#5 0004657	<HC>	mg/dl (9.49)	51.0 - 95.5	[+]
#2 0002725	<HC>	UI/dl (1.76)	48.0 - 106	[+]
#3 0005468	<HC>	UI/l (4.18)	38.0 - 99.0	[+]
#7 CTRL9932	<HC>	UI/dl (0.690)	54.0 - 113	[+]

Figure 18

After the end of programmed task, the results can be viewed per **Test**. The test Results display page is shown in **Figure 18**. Test results with flags are highlighted in red. The following information is displayed for each single test:

- a) **Code and test name** The displayed code is the same read on the list of tests, while the full name between parenthesis is the one assigned by the operator in the analytical parameters (chap. C, par. 1.3.3.).
- b) **Sample Position (#XX)** Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.
- c) **Sample Code** For Patients (Routine and STAT) it is assigned at check-in. For STD and Batch it is automatically assigned.
- e) **Results** The results of test attributed to patients are represented with:
 - result
 - unit of measurement
 - absorbance read (between parenthesis)
 - range of normal values
 - any flags (between brackets – see also par. 1.5)

The following commands are available in the results display page:

PRINT: used to print the contents of the window. This is not a print-out in report format. A print preview will be displayed where it is possible to select which and how many pages to print.

EXIT: closes the page and returns to the main program, without modifying the data.

DISPLAYING REAL-TIME DATA

Results					
#51 0003216	RAT	41.7	UI/dl (2.98)	47.0 - 83.5	[-]
#51 0003216	BID <Color>	55.1	mg/L (1.21)	44.0 - 82.0	[]
#51 0003216	Lipasi	66.3	mg/dl (4.11)	58.0 - 97.0	[]
#51 0003216	FAC	7.39	mg/L (7.88)	43.0 - 85.5	[-]
#51 0003216	PRV	62.6	UI/l (7.58)	29.0 - 72.5	[]
#51 0003216	Glicemia <XXX>	59.1	mg/L (3.70)	41.0 - 83.5	[]
#51 0003216	Bilirubina <Jundrassik>	24.7	UI/l (6.23)	59.0 - 147	[-]
#51 0003216	VED	54.7	UI/l (2.66)	41.0 - 94.5	[]
#51 0003216	Colesterolo <XXX>	41.5	mg/L (0.200)	40.0 - 112	[]
#51 0003216	Glucosio <XXX>	99.6	mg/L (8.22)	48.0 - 102	[]
#6 CTRL2011	BID <XXX>	57.3	UI/l (1.05)	38.0 - 106	[]
#6 CTRL2011					

Figure 19

The data shown refer to the results obtained by the analyzer in real time (fig. 19), i.e. as the tests are completed. The results are not sorted in any way, not per patient, not for type of test. The data display is synthetic. The results of tests associated to flags are shown in red.

Once the results are archived, the information present in this page will no longer be available.

The following information is displayed for each single test:

- a) **Sample Position (#XX)** Progressive number as programmed in the Setup dedicated page for **Routine** and **STAT**.
Progressive number as programmed in the Setup dedicated page for **STD** and **CTRL**.
- b) **Sample Code** For Patients (Routine and STAT) it is assigned at check-in. For STD and Batch it is automatically assigned. It is automatically assigned for CTRL, but can be assigned by the user during input. The relevant group level is also indicated (see **Chapter F**, paragraph 1. “Quality Controls”).
- c) **Date and time** The date and time the test was run is between parenthesis.
- d) **Results** The results of test attributed to patients are represented with:
 - full name of the analysis
 - execution method
 - result
 - unit of measurement
 - absorbance read (between parenthesis)
 - range of normal values
 - any flags (between brackets – see also par. 1.5)
 For automatic re-runs the values of the first and second determination are represented.

A window is also available on this page (**Info flag**) with information relative to the flags associated to the results. The Print and Exit buttons are also present, their functions have already been described in the previous paragraph.

1.7. Turning Off The Analyzer

To turn off the instrument, the **SHUT DOWN** procedure must be observed. In this way the instrument is turned off, except for the reagent refrigerator. The shut down procedure proposes the wash of the cuvettes with appropriate dedicated solutions (see Sect. II, Chapt.3, par. 3.2. Consumables For BT Analyzers) before turning off. The analyzer indicates the position where the dedicated solutions should be inserted for the cuvettes washing (see also **Chapter. C**, paragraph 1.1.). As regards the I.S.E. Module, please refer to Chapter L, par. 1.3.

There are two additional modes for interrupting analyzer operation:

1) SLEEP-MODE

This mode can be manually activated, or it starts automatically when the instrument is left inactive for more than 30 minutes. The Sleep-Mode automatically performs the wash and fill up of the cuvettes with system solution and remains idle (waiting for user's commands for immediate operation).

2) LOG-OFF

The Log-Off mode represents a partial turning off of the analyzer. It disables some devices: halogen lamp of the photometer, cuvettes thermostat and drive motors. This mode is used for energy saving. The Log-Off mode is utilized for programming automatic turning on at a desired date and time. The instrument will remain in a stand-by condition and it will automatically turn on 30 minutes before the programmed time. The turning on in anticipation (30 minutes before the programmed time) allows the analyzer to reach steady state thus allowing immediate operation at the programmed time.

To exit ahead of time from a suspended activity, click on the left or right mouse button and press the Exit button on the window that appears. However, in this case it is necessary to wait for the devices to become operational (around 20 minutes).

CAUTION!

- a) **Do not ever stop the analyzer by turning off the main switch prior to performing the correct SHUT DOWN procedure.**
- b) **Improper shutdown may cause loss of data and programs and will necessitate reinstallation of the operating software.**

SECTION II: ADDITIONAL INFORMATION

CHAPTER 2: WARRANTY CONDITIONS

SECTION II: ADDITIONAL INFORMATION

2. WARRANTY CONDITIONS 2
NOTES FROM THE MANUFACTURER 3

2. WARRANTY CONDITIONS

- Biotecnica Instruments S.p.A., after having accurately tested this analyzer, guarantees the instrument for 1 (one) year starting from invoice or goods delivery.
- The warranty includes the repairing and the replacement for free of the faulty parts due to wrong manufacturing. Warranty is not extended to the normally consumable parts of the system.
- The warranty is not valid in case of improper use, negligence, improper or lack of maintenance and cleaning, tampering or repairing by third parties not authorized by Biotecnica Instruments S.p.A. and in any case when the cause cannot be stated as original manufacturing fault.
- The costs of shipment and transport to Biotecnica Instruments S.p.A. for repair or substitution, and the risks deriving from this is the responsibility of the buyer, including all the costs of onsite technical service at client's location (transport, board and lodging) as well.
- If the stated defects will result to be out of warranty limits, the buyer will pay repair or replacement costs.
- Biotecnica Instruments S.p.A. is not responsible for any unforeseen technical problem that might occur. If the requested technical assistance is outside the terms of warranty a charge will be made to the customer as per current rates in force.
- Biotecnica Instruments S.p.A. is an internationally known for its high quality standards in production. Biotecnica Instruments S.p.A. is thus responsible for providing to the customer clear and effective information for use of its products, including all the precautions and warnings for a secure and risk-free use.
- Service personnel must also refer to the warnings and cautions notices in this manual. It is the duty of the service engineer of Biotecnica to instruct the customer's personnel to take all necessary precautions during repair and handling of products.
- Biotecnica Instruments S.p.A. is not responsible for any damage that may be caused directly or indirectly to persons or things due to a lack of observance of all the warnings and cautions outlined in the user's manual, and concerning the warnings and cautions during the different working phases of the instrument (see chap. M). Direct, indirect, incidental, special, moral damages as well as other damages of any type (including, with no limitation, those deriving from profit's loss, business interruption or information loss) cannot be ascribed to Biotecnica Instruments S.p.A. even in the case in which the possibility of the event had been explicitly stated.

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NOTES FROM THE MANUFACTURER

- The Biotechnica Instruments S.p.A. reserves the right to revise this manual without notice, for any reason. This includes but is not limited to, utilization of advance in the state-of-the-art and changes thereof. Product enhancement resulting from our continuing quality improvement effort may necessitate changes in specifications without notice. This fact doesn't oblige the company to inform its actual customers because the information included in the present manual refers to state of the product when shipped, thus no warranty about notification of future changes is given.
- The information contained in this manual is proprietary with "Biotechnica Instruments S.p.A.". Reproduction of any part or whole may only be performed with written permission from "Biotechnica Instruments S.p.A.".



Parts / Instruments Return Authorization

DATE: ____/____/____

From:			
To: Technical Assistance – Export Manager			
Client information			
Instrument model:		Serial number:	
Defective part			
Part description:			
Code:		Serial number:	
Bar-code number:		Quantity:	
Under warranty: Yes <input type="checkbox"/>	No <input type="checkbox"/>	Invoice number:	Date:
Description of the problem:			
<i>Request for:</i>			
Repair <input type="checkbox"/>	Exchange <input type="checkbox"/>	Quotation <input type="checkbox"/>	Urgent <input type="checkbox"/>
Name:		Signature:	
Biotechnica Instruments response			
Return authorization number:		Date:	
/ 20__			
<i>Approved:</i> Yes <input type="checkbox"/> No <input type="checkbox"/>			
Repair <input type="checkbox"/>	Exchange <input type="checkbox"/>	Destroy <input type="checkbox"/>	Quotation: <input type="checkbox"/>
Note:			
Approved by: Technical Assistance Dept.		Signature:	
Checked by: Quality Assurance Manager		Signature:	

NOTE: No parts or instruments will be accepted for repair or replacement without a Return Authorization number that can be obtained from Biotechnica Instruments S.p.A. Fax this Return Authorization form to +39 06 410 3079 to the attention of Technical Assistance/Export Manager, who will then evaluate and issue a Return Authorization number.

WARRANTY EXTRACT: Biotechnica Instruments S.p.A. warrants its instruments to be free from defective parts and workmanship for a period of one (1) year from the date of purchase. Liability under this warranty is expressly limited to repair or replacement of defective parts at the option of Biotechnica Instruments S.p.A. This warranty does not cover the results of misuse, accident or abuse of any parts of its instruments which have been repaired, tampered with or altered by anyone other than personnel authorized by Biotechnica Instruments S.p.A. This warranty does not apply to fluid handling devices, consumables or reagents.

Products returned to Biotechnica Instruments S.p.A. for repair or replacement shall be sent with transportation prepaid. If found not to be defective under the terms of warranty, a charge will be made for repair or replacement and freight costs will be at customer's expense.

SECTION II: ADDITIONAL INFORMATION

CHAPTER 3: ORDERING INFORMATION

3. ORDERING INFORMATION.....2
3.1. General Terms And Conditions For Sale.....2
3.2. Consumables For BT Analyzers.....3

3. ORDERING INFORMATION

For technical or ordering assistance start with our convenient ordering check list located in the ensuing paragraph **3.2**. For further assistance, don't hesitate to call the Biotechnica Instruments S.p.A. or your local sales/representative office.

To obtain accessories/spare parts, address order or enquiry to your Biotechnica Instruments S.p.A. sales/service representative or to Biotechnica Instruments S.p.A. and supply the following Information:

- a) **Instrument Model and Serial Number**
- b) **Quantity of parts desired**
- c) **Part Number**
- d) **Description**

Biotechnica Instruments S.p.A.

Via Licenza, 18

00155 - Rome (ITALY)

Phone: +39 06 411 2316 Fax: +39 06 410 3079

E-mail: bt@biotechnica.it

NOTE:

DUE TO IMPROVEMENTS IN DESIGN AND/OR SPECIFICATIONS, SOME PRODUCTS MAY DIFFER SLIGHTLY FROM THE PREVIOUS DESCRIPTION.

For the I.S.E. module orders, refer to the I.S.E. chapter dedicated paragraph.

3.1. General Terms And Conditions For Sale

ORDERS: All telephone or written orders placed by the customer are considered a binding contract created with the Company, when a written order acceptance has been sent by the Company or the ordered goods have been shipped. For orders with a value over Euro 250,00, the goods include the packing cases. All prices listed exclude VAT and all similar taxes and the purchaser will be liable for such taxes if applicable.

SHIPMENTS: In accordance with the general provisions of law, the goods are shipped at the customer's risk even where shipped carriage free.

The goods with cold storage temperature between 2 - 8° are shipped at controlled temperature.

CLAIMS: Any claims must be made within 10 days from the receipt of goods.

JURISDICTION: For any judicial contest, legal venue for both parties is Rome (Italy).

For additional information please visit our website at the following URL:
www.biotechnica.it

3.2. Consumables For BT Analyzers

COMMON PRODUCTS

	PART NO.	SIZE
Surfactant	392T	2x50 ml
Cleaning Solution	395C	1x1000ml
Washing Solution	395W	2x100ml
Fuse RVT 8A, 250 Volt (for Analyzer)	330.6342B	1
Power Cord (for analyzer)	330.6391	1
Power Cord (for peripheral devices)	330.6400	1
Peristaltic Pump Cartridge	11-05209-01	1
Halogen Lamp 12V/35W for Photometer	330.9321	1
Tubular Filter for H ₂ O container	330.9614	1
5 lt Cubitainer	660.4002	1
Cleaning Tool for Arm Needle	662.0629A	1
10 lt Cubitainer	662.1010	1
Sampling Needle	662.1011	1
Sample Cup 2 ml	667.1040	1 (min. 1000)
Reagent Bottle 50 ml (white)	667.1084	1
Reagent Bottle 20 ml (white)	667.1085	1
Reagent Bottle 10 ml (white)	667.1086	1
Reagent bottle cap	667.1075	1
BT1500	PART NO.	SIZE
Annual Maintenance Kit	11-06050-01	1
10 ml Test-tube	667.1081	1
Dilutor Ring Flon Φ 5mm	330.5741	1
BT1500 I.S.E. Six-Monthly Maintenance Kit	11-07281-01	1
BT3000 PLUS	PART NO.	SIZE
Reagent Bottle 80 ml (white)	667.1083	1
Quarterly I.S.E. Maintenance Kit	11-05338-01	1
Six-Monthly Maintenance Kit	11-05337-01	1
Dilutor piston o-ring kit (contains the necessary for one dilutor)	11-05283-01	1
Fuse RVT 0.5A, 250 Volt (for Vac Pump P/N 06-05161-01)	330.6338	1
BT3500	PART NO.	SIZE
Reagent Bottle 80 ml (white)	667.1083	1
Quarterly I.S.E. Maintenance Kit	11-05668-01	1
Six-Monthly Maintenance Kit	11-05669-01	1
Dilutor Ring Flon Φ 5mm	330.5741	1
Fuse RVT 0.5A, 250 Volt (for Vac Pump P/N 06-05161-01)	330.6338	1
BT3500S	PART NO.	SIZE
Reagent Bottle 80 ml (white)	667.1083	1
Six-Monthly Kit I.S.E. 4P Maintenance	11-06227-01	1
Six-Monthly Maintenance Kit	11-06230-01	1
Dilutor Ring Flon Φ 5mm	330.5741	1
Fuse RVT 0.5A, 250 Volt (for Vac Pump P/N 06-05161-01)	330.6338	1

SECTION II: ADDITIONAL INFORMATION

CHAPTER 4: SERIAL COMMUNICATION

4. SOFTWARE - SERIAL COMMUNICATION:	2
BT ANALYZER <-> HOST COMPUTER	2
4.1. GENERAL	2
4.2. PATIENT TRANSMISSION TO BT ANALYZER	2
4.3. RESULTS RECEPTION	3
4.4. CALCULATION OF CHECK-SUM	5
4.5. WIRING DIAGRAM OF INTERFACE CABLE	6
4.6. VARIABLE COMMUNICATION PROTOCOL	7
4.7. SERIAL COMMUNICATION TEST PROGRAMS	16
4.7.1. Program COMUNICA.EXE:.....	16
4.7.2. Program BTPLUS.EXE:	17

Important Notice:

Any modification to the Variable Serial Protocol is restricted to qualified personnel only. The Biotechnica Instruments S.p.A. guaranties the correct performance of the internal serial protocol. The responsibility for any malfunction arising out of any modifications to the scripts of the Variable Serial Protocol rests with the customer.

WARNING

This information regards the setting up of the barcode for sample tubes identification. The reading of the sample barcode label has the same progression as patient code.

For example: Once a patient code of 15 characters has been entered, then a code of 8 characters followed by 7 empty spaces to reach the 15 characters is sent.

The code read on the barcode label must have the same sequence 8 + 7 for correct detection.

IMPORTANT NOTICE ON DATA TRANSMISSION (from version 14.0)

Any character below the "space" (value 32 decimal or 0x20 hexadecimal – the "space" is not included) at the beginning or at the end of a patient code will be deleted. In this way it will be possible to have a patient code shorter than 15 characters, without being obliged to use the variable protocol. In case, after eliminating these characters, the resulting patient code is empty, it will automatically be changed into '{0}'

4. SOFTWARE - SERIAL COMMUNICATION: BT ANALYZER <-> HOST COMPUTER

4.1. GENERAL

The analyzer allows bi-directional communication through RS 232C serial connection with any host computer.

For the transport please refer to the Setup dedicated paragraph (Chapt. H).

The particular feature of the dialog is that it is always the host computer, which initiates the communication for either transmitting patient list or for receiving the results.

To initiate any communication the host computer will have to send to analyzer the character STX (0x02) and expect the character ACK (0x06) as a response. At this point the host computer will send data to the analyzer and terminate the communication by sending the character EOT (0x04).

It is important to remember that any communication is followed by a response from the analyzer.

It must be noted that if the parameter to be transmitted is shorter in length than the length requirement of the communication protocol than a space must be added before or after. For example the analysis have length 4, therefore to send a code GLY one must add a space after to reach the length of 4 characters.

4.2. PATIENT TRANSMISSION TO BT ANALYZER

- ▶ Start communication with sequence STX<->ACK.....
- ▶ Send patient code..... (15 characters)
- ▶ Send list type for patient insertion..... ("T" for Routine or "R" for STAT)
- ▶ Send type of serum..... ("S" for Serum or "U" for Urine)
- ▶ Send if the patient is a clone..... ("Y" for Yes or "N" for No)
- ▶ Transmit position of cup..... ("00" unknown)
- ▶ Send number of tests to be executed..... (from "01" to "99")
- ▶ Send codes of tests to be performed..... (4 characters)
- ▶ Send Check-Sum..... (3 characters)
- ▶ Send end transmission character EOT.....
- ▶ Wait for response from the analyzer..... (2 characters)

If the communication is successful then the analyzer responds with character "Y" followed by a byte, which identifies the position where patient has been inserted. In case the communication was unsuccessful, then the analyzer responds with "N" followed by a byte identifying the type of error. The possible errors generated by the analyzer in response to the invalid insertion of patient are as follows:

- 0x01 Check-Sum Error
- 0x02 Unknown Command
- 0x03 Routine/STAT field Error
- 0x04 Serum/Urine field Error
- 0x05 Clone Yes/No field Error
- 0x06 Cup position Error
- 0x07 Number of Analysis field Error
- 0x08 Wrong Number of Test
- 0x09 Position already in execution
- 0x0A Cloning impossible
- 0x0B Code duplicated
- 0x0C One or more analysis not present in the analyzer
- 0x0D One or more analysis not present in the current plate
- 0x0E Too many analysis for the patient
- 0x0F Constant data not valid
- 0x10 Variable data not valid
- 0x11 Variable data in analysis not valid.
- 0x12 No patient to repeat
- 0x13 The serum field in the patient to be repeated is different from the memorized one
- 0x14 Patient to be repeated, but the list is already full

- 0x15 Patient to be repeated, but the list is different
- 0x16 The assigned position is already in use
- 0x17 Already existing or performed patient, it is not a clone and belongs to a supplementary (extra) list
- 0x18 Already performed patient, but no repetitions or clones are active

For example to send a patient with code 00000000000001, serum type and with analysis GLY, BUN and CHO onto the STATS list, then one must send the following sequence of characters (excluding initial sequence STX<->ACK):

00000000000001RSN0003GLU BUN CHO 142<EOT>

Where:

- 00000000000001**..... Patient code
- R**..... Identifies STATS list
- S**..... Identifies the type of patient (in this case: Serum)
- N**..... Identifies that the patient is not a clone
- 00**..... Unknown position (the analyzer will insert the patient in a convenient position)
- 03**..... Identifies the number of test to be executed.
- GLY, BUN, CHO**..... Test codes (observe the space after each code to reach the 4 characters limit)
- 142**..... Identifies the Check-Sum
- <EOT>**..... This character ends communication

4.3. RESULTS RECEPTION

There are three commands for receiving reports from the analyzer:

- R**..... Reception of next available report
- L**..... Reception of the last report sent (in case of reception problems)
- A**..... Reception of the first available report (in case one desires to receive again all the reports)

The commands R, L, and A require standard communication or the procedure STX<->ACK and the character EOT to end communication.

As a response to one of these three commands the analyzer sends the requested report (if available) or the character NAK (0x15) if there is no report to be sent. It must be borne in mind that after a run test the reports are not immediately available for transmission as these need validation. To do this, go to Utility menu, RS232 and enable the option "Accept result to be sent". This operation must always be performed after each run test or groups of run test.

There is also an additional option for performing validation operation automatically. Go to Setup of the analyzer (Menu Utility, Setup Analyzer), go to the Serial (fourth from the left) and enable the option "All results must be sent automatically (without validation)" at the bottom of the page.

In case of positive response to the request for a report the analyzer will transmit the data which will have a different format, depending on the selection made in the **Send also the controls** option (enabled or disabled - see chapt. 10 Setup, par. 2, **Serial** tag).

Data transmitted with the Send Controls option disabled:

Patient code.	15 characters
List type.	"T" for Routine or "R" for STATS
Sample type	"S" for Serum or "U" for Urine
Number of reports	3 characters
<u>For each report:</u>	
Analysis code	4 characters
Result	7 characters
Check-Sum	3 characters
<EOT>	

The following is an example of eventual response to the data sent in "Sending a patient to BT ":

0000000000000001RS003GLU 000.000BUN 0010.10CHO 00100.0253<EOT>

<u>Where:</u>	
0000000000000001	Patient code
R	Identifies STATS list
S	Identifies the type of patient (in this case: Serum)
003	Identifies number of reports
GLU	First test code
000.000	GLU test result
BUN	Second test code
0010.10	BUN test result
CHO	Third test code
00100.0	CHO test result
253	Identifies the Check-Sum
<EOT>	This character ends communication

Data transmitted with the Send Controls option enabled:

Patient code.	15 characters
List type.	"T" for Routine or "R" for STATs
Sample type	"S" for Serum or "U" for Urine
Control sample	"Y" for control or "N" for normal sample
Known control	"K" for Known or "U" for Unknown
Control level	3 characters
Control lot number	20 characters
Number of reports	3 characters

For each report:

Analysis code	4 characters
Result	7 characters
Check-Sum	3 characters
<EOT>	

Note: when sending a sample which is not a control, the control lines (fields) will have the following values:

Control Sample	"N"
Known control	"K"
Control level	"001"
Control lot number	" "

The possible answer to the patient sent in paragraph 4.2 would be:

000000000000001RSNK001 003GLI 000.000BUN 0010.10COL 00100.0063<EOT>

Where:

000000000000001	Patient code
R	Identifies STATS list
S	Identifies the type of patient (in this case: Serum)
N	The sample is not a quality control
K	Type of control: known
001	Control level 1
	Control lot number empty (20 spaces)
003	Identifies number of reports
GLU	First test code
000.000	GLU test result
BUN	Second test code
0010.10	BUN test result
CHO	Third test code
00100.0	CHO test result
063	Identifies the Check-Sum
<EOT>	This character ends communication

4.4. CALCULATION OF CHECK-SUM

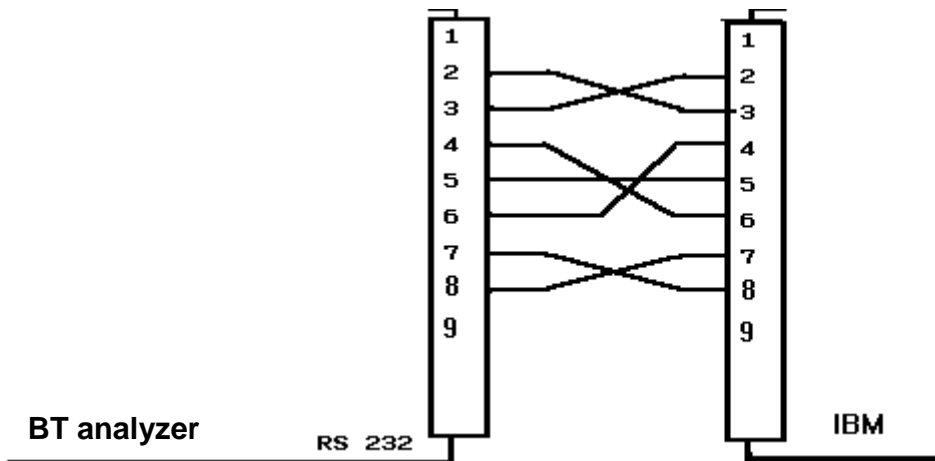
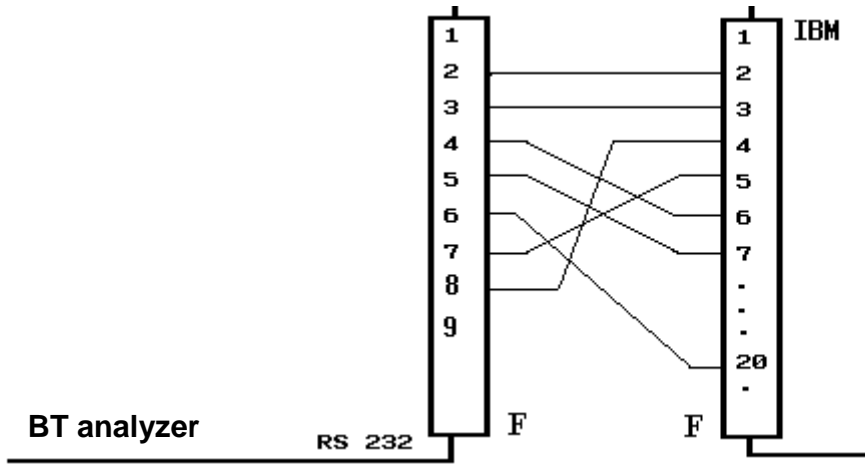
This procedure calculates a Control code in accordance with the transmitted or received data. An algebraic sum of ASCII values of all the sent characters is executed. For example the character "A" has ASCII value 65 - 0x41.

Consequently the module 256 of the found value is executed (balance of dividing the value by 256). This is the Check-Sum to be sent.

IMPORTANT NOTE FOR VARIABLE COMMUNICATION PROTOCOL

THE TERMINATING CHARACTERS OF VARIABLE LENGTH STRINGS DO NOT ENTER INTO THE CHECKSUM CALCULATION

4.5. WIRING DIAGRAM OF INTERFACE CABLE



4.6. VARIABLE COMMUNICATION PROTOCOL

Introduction

The variable serial protocol has been designed to provide the user with possibility to personalize the transmitted and received data from the analyzer.

ATTENTION: WHEN A VARIABLE COMMUNICATION PROTOCOL IS CREATED OR MODIFIED (BOTH IN TRANSMITTING AND/OR RECEIVING), IT IS ABSOLUTELY NECESSARY TO SAVE BOTH TRANSMITTING AND RECEIVING SCRIPS AND TO COMPILE AGAIN BOTH OF THEM, EVEN THOU ONLY ONE HAS BEEN MODIFIED.

THE DEFAULT SCRIPTS ARE SIMILAR TO THOSE OF THE STANDARD SERIAL PROTOCOL, BUT PLEASE NOTE THAT THE CHARACTER USED TO SET THE TYPE OF LIST IS DIFFERENT BETWEEN THE TWO PROTOCOLS. IN THE STANDARD INTERNAL PROTOCOL, THE CHARACTER "T" IDENTIFIES THE ROUTINE LIST AND "R" IDENTIFIES THE URGENT SAMPLES LIST. IN THE VARIABLE PROTOCOL, THE CHARACTER "R" IDENTIFIES THE ROUTINE LIST AND "S" IDENTIFIES THE URGENT SAMPLES LIST.

The user can transmit or receive in addition to preset data (patient code, analysis code, results etc.), also the simple text strings and/or characters in order to meet the personal requirements.

Not only the user can decide to send or receive numerical information (for example number of tests) not as single byte but as a preset numerical string or vice versa.

For example the user can decide to receive something like:

```
"Initiate analysis data"  
<Analysis data true and typical>  
"End analysis data"
```

Where the phrases "Initiate analysis data" and "End analysis data" do not refer to any preset data by the analyzer but serve only for monitoring communication process (can be useful for inserting specific markers on those programs which obtain information from text files).

It is obvious that the protocol of initiation and end of communication, the commands for the request of report, and the analyzer responses in case of error or success remain identical to the usual preset serial communication.

NOTE:

- a) If a check-sum is omitted in a communication then the analyzer will not control it.
- b) The following numbers have been used to represent the error codes relevant to sending a patient to the analyzer as regards the parameters not part of the standard serial communication:

0x0F	Data (constant) sent to a TAG #Char, #String or #Stringn does not fall within the possible values range
0x10	Data (variable) sent to a TAG #Char, #String or #Stringn is not valid
0x11	An analysis variable is outside the SET BEGIN/END relative to the analysis

Notes regarding Scripts

A script is a text document. Each one of the single commands must each reside in a different line and be complete. In other words a single command cannot be divided into more lines.

String 'Name' | \$10 -> *Valid line*

String 'Name' | \$10 **char** 'A' -> *Invalid line*

String 'Name'
 | \$10 -> *Invalid Command*

An editor for writing, modifications, saving and compiling of one or more scripts is accessible inside the program (setup function). In any case it is possible to write a script with any text editor (DOS or Windows) like Notepad of Windows or the EDITOR of the DOS. It is not possible to import documents written with UNIX as the characters used for going to the next line are different from the ones used by the DOS or Windows.

CAUTION!

If one wants to use the script stored in a removable disk (for example floppy disk) then it will be necessary to copy it on the hard disk.

TYPE OF DATA

Character: Identifies a single character, can pass as printable character (enclosed between single apostrophes), as decimal ASCII value (followed by symbol \$) or else hexadecimal ASCII value (followed by **0x**).

If for example we want to identify the character **A** (decimal value **65** or hexadecimal value **41**) then we can write '**A**', **\$65** or **0x41**.

String: Identifies a sequence of printable characters enclosed in single apostrophes, for example: '**this is a string**'.

Comment: Identifies a portion of text (preceded by a character ; which will not be compiled but will serve as note only for the programmer.

Variables: These are particular sequence of characters preceded by the symbol #, which will be used by the program for storing internal information (patient code, analysis name and etc.), refer to "TABLE 1 - TRANSMISSION/RECEPTION".

There are also variables for direct uses, which allow for identification of any character below ASCII 32 (space) to facilitate the writing of the script (for example, one can use the variable **#EOT** to identify the character **\$4**), see "TABLE 2 - INTERNAL VARIABLES".

SCRIPT FUNCTIONS

String: Identifies a string of variable length ending with a particular character.

Syntax:

String <string>|<Terminator>

Where

<String> Transmit/receive string

<Terminator> End character

Note:

It is not possible to use the variables like parameter <Terminator>

Example:

String 'Hello Word'|\$0

String 'My String'|'@'

String #Variable1|0x10

Stringn: Identifies a string of fixed length

Syntax:

Stringn <String>|<Length>

Where

<String> Transmit/receive string

<Length> String length

Note:

If the length of the text strings is less than the data length then a series of spaces will be added on the right to reach the data preset length. In case the text string is longer than the data length then the string end will be cut off to match the data length.

If the length of the numerical values is less than the data length then a series of characters '0' will be added to the left to reach the preset data dimension. In case the length of the numerical values string is longer than the data length then the string will be truncated to match the data length.

It is not possible to use variables as parameter <Length>.

Example:

Stringn 'Hello Word'|\$40

Stringn #Variable1|0x10

Char: Identifies a single character (or single byte)

Syntax:

Char <Character>

Example:

Char 'H'

Char \$20

Char 0x10

Char #STX

Set: Identifies the beginning and the end of the group of repetitive commands

Syntax

Set Begin<Name of group>

Begin repetitive group

Set End<Name of group>

End repetitive group

Note:

Actually the **ANALYSESDATA** is the unique SET present, which identifies the analysis in transmission/reception.

Only one command **SET BEGIN** and one command **SET END** can be present in a script.

A script must always contain the command **SET**.

The variable **PATIENTNUMBERTEST** must be present before the command **SET**.

COMPILATION ERRORS

One or more errors due to incorrect script writing or the system error may show up during compilation of a script. The compiler shows the error code, the description of error, and the line where it has been detected.

The following table shows the error codes, description, and the possible causes:

Error Code	Description	Possible Causes
1	Unknown command	An invalid command has been inserted in the commands of script.
2	A string request	A string as first parameter for String or Stringn command has not been inserted.
3	A number request	A string like parameter <lunghezza - length> of command Stringn has been inserted.
4	Invalid number format	Inserted invalid decimal or hexadecimal number.
5	Excessive data	a) Inserted more than two parameters for command String or Stringn. b) Inserted more than one parameter for the command Char or Set.
6	Invalid data	A string for command Char has been inserted.
7	String Terminator Request	The end (') character of a string not found.
8	Too little data	a) Inserted less than two parameters for command String or Stringn. b) No parameter inserted for command Char or Set.
9	Invalid String Length	The string length for Stringn command is less than 0 or more than 128.
10	Empty string	a) An empty string inserted for the command String or Stringn. b) Inserted a character identified as "
11	Unknown variable	a) Tried to transfer an invalid variable in the list of internal variables. b) Tried to use a transmission variable in the script of reception or vice versa.
12	Damaged file	Hard disk error. Contact Sales/Service.
13	Unknown file	Internal error. Probably damaged program. Reinstall the program. If the problem persists contact sales/service.
14	Incorrect identifier in the SET command	a) The text SET BEGIN or SET END not written. b) A different value from ANALYSEDATA transferred as <Group name> for the SET command.
15	Damaged exit file	Hard disk error. Contact sales/service.
16	SET command not closed	The SET END not inserted in the script.
17	Too many SET commands	More than one SET BEGIN command inserted.
18	SET command not found	The SET BEGIN command not found in the script.
19	Incorrect variable for SET command	A different value from ANALYSEDATA transferred as <Group name> for the SET command.
20	Variable not found before the SET command	The highlighted variable required in the script before the SET BEGIN command.
21	The variable must be String type	The highlighted variable must be String type, not Char
22	Already occupied position	An already occupied position on the plate has been entered
23	Patient exists but in different lists	An already existing code (or already executed) on the plate has been entered, but the list is different.
24	Patient executed but no repetition	An already processed code has been entered without indicating a repetition or a clone.

TABEL 1 – TRANSMISSION

The following variables are used for the transmission of a report from analyzer to the host computer:

Variable	Usage	Type of valid data
PATIENTCODE	Patient Code	String
PATIENTNAME	Patient Name	String
PATIENTSURNAME	Patient Surname	String
PATIENTGROUP	Group ⁽¹⁾	String Character
PATIENTLISTTYPE	List ⁽²⁾	String Character
PATIENTTYPE	Method Type ⁽³⁾	String Character
PATIENTNOTE	Descriptive Note	String
PATIENTNUMBERTEST	Number of Results	String Character
CHECKSUM	Check-Sum	String Character
ANALYSESCODE	Analysis Code	String
ANALYSENAME	Analysis name	String
ANALYSESTYPE	Analysis Type ⁽⁴⁾	String Character
ANALYSESCONCENTRATION1	1st Concentration	String
ANALYSESCONCENTRATION2	2nd Concentration	String
ANALYSESFLAGS1	Flag 1st Result	String
ANALYSESFLAGS2	Flag 2nd Result	String
ANALYSESMINVALUE	Minimum Value	String
ANALYSESMAXVALUE	Maximum Value	String
ANALYSESUM1	1st Unit of Measurement	String
ANALYSESUM2	2nd unit of measurement	String
ANALYSESUMFACTOR	Unit Factor	String
ANALYSES2RESULT	Does the 2nd result exists? ⁽⁵⁾	String Character
ANALYSESSERUMTYPE	Method Type ⁽³⁾	String Character
ANALYSESURINE24H	Urine in 24/h	String
ISCONTROL	Identifies if it is a QC ⁽⁶⁾	String Character
CONTROLTYPE	Known or Unknown control ⁽⁷⁾	String Character
CONTROLLEVEL	Control level	String Character
CONTROLLOTNAME	Control lot number	String

⁽¹⁾ Identifies Male, Female or Child (Select one of these):

- 'M' : Male
- 'F' : Female
- 'C' : Child

⁽²⁾ Identifies Routine or STAT (Select one of these):

- 'R' : Routine
- 'S' : STAT

Transmitting patient from archive will always have identifier of Routine.

⁽³⁾ Identifies Serum or Urine (Select one of these):

- 'S' : Serum
- 'U' : Urine

⁽⁴⁾ Identifies Clinical Chemistry, or Relation Analysis (Select one of these):

- 'C' : Clinical Chemistry
- 'R' : Relation Analysis

⁽⁵⁾ Identifies if the 2nd result exists or not (Select one of these):

- 'Y' : 2nd result exists
- 'N' : 2nd result does not exist

- If only the final result is desired then always refer to variables pertaining to 2nd result.
- In case of the absence of 2nd result then its variables will have the same values of the 1st result.

⁽⁶⁾ Identifies if it is a quality control or a sample (only one of these)

- 'Y' : Quality control
- 'N' : Normal sample

⁽⁷⁾ Identifies if it is a Known or an Unknown quality control

- 'K' : Known control
- 'U' : Unknown control

TABLE 1 – RECEPTION

The following variables are used for reception of a patient by the analyzer:

Variable	Usage	Type of valid data
PATIENTCODE	Patient Code	String
PATIENTNAME	Patient Name	String
PATIENTSURNAME	Patient Surname	String
PATIENTLISTTYPE	List ⁽¹⁾	String Character
PATIENTGROUP	Group ⁽²⁾	String Character
PATIENTTYPE	Method Type ⁽³⁾	String Character
PATIENTURINE24H	Urine in 24/h	String
PATIENTNOTE	Descriptive Note	String
PATIENTISCONTROL	If the patient is a control ⁽⁴⁾	String Character
PATIENTCONTROLKNOK	If it is a known control ⁽⁵⁾	String Character
PATIENTCONTROLLEVEL	Control Level ⁽⁶⁾	String Character
PATIENTCLONE	If it is a clone ⁽⁷⁾	String Character
PATIENTCUPPOSITION	Vial (Cup) position ⁽⁸⁾	String Character
PATIENTNUMBERTEST	Number of test	String Character
CHECKSUM	Check-Sum	String Character
ANALYSESCODE	Analysis Code	String

⁽¹⁾ Identifies Routine or STAT (Select only one of these):

- \$0 : Routine
- \$1 : STAT
- '0' : Routine
- '1' : STAT
- 'R' : Routine
- 'S' : STAT
- 'ROUTINE' : Routine
- 'STAT' : STAT

⁽²⁾ Identifies Male, Female or Child (Select only one of these):

- \$0 : Male
- \$1 : Female
- \$2 : Child
- '0' : Male
- '1' : Female
- '2' : Child
- 'M' : Male
- 'F' : Female
- 'C' : Child
- 'MAN' : Male
- 'FEMALE' : Female
- 'CHILD' : Child

⁽³⁾ Identifies Serum or Urine (Select only one of these):

- \$0 : SERUM
- \$1 : URINE
- '0' : SERUM
- '1' : URINE
- 'S' : SERUM
- 'U' : URINE
- 'SERUM' : SERUM
- 'URINE' : URINE

⁽⁴⁾ Identifies a Control or a Sample (Select only one of these):

\$0 : Sample
 \$1 : Control
 '0' : Sample
 '1' : Control
 'N' : Sample
 'Y' : Control
 'S' : Sample
 'C' : Control
 'NO' : Sample
 'YES' : Control
 'SAMPLE' : Sample
 'CONTROL' : Control

⁽⁵⁾ Identifies a Known or Unknown Control (Select only one of these):

\$0 : Unknown
 \$1 : Known
 '0' : Unknown
 '1' : Known
 'N' : Unknown
 'Y' : Known
 'U' : Unknown
 'K' : Known
 'NO' : Unknown
 'YES' : Known
 'UNKNOWN' : Unknown
 'KNOW' : Known

⁽⁶⁾ Identifies Control Level (Select only one of these):

\$1 : Level 1
 \$2 : Level 2
 \$3 : Level 3
 '1' : Level 1
 '2' : Level 2
 '3' : Level 3
 'L' : Level 1
 'N' : Level 2
 'A' : Level 3
 'LOW' : Level 1
 'NORMAL' : Level 2
 'ABNORMAL' : Level 3

⁽⁷⁾ Identifies if it is a Clone (Select only one of these):

\$0 : Normal
 \$1 : Clone
 '0' : Normal
 '1' : Clone
 'N' : Normal
 'Y' : Clone
 'NOCLONE' : Normal
 'CLONE' : Clone

⁽⁸⁾ If this field has value 0, the position is automatically assigned by the analyzer

Note:

It is not possible to repeat the patient if:

- 1. It is not present among the executed patients**
- 2. No free position exists on the plate**
- 3. The patient has already been inserted in the current list**
- 4. The lists of execution are different**
- 5. The Serum/Urine field is different**
- 6. It is also selected as clone**

TABEL 2 – INTERNAL VARIABLES

Variables	Decimal	Hexadecimal
NUL	\$00	0x00
SOH	\$01	0x01
STX	\$02	0x02
ETX	\$03	0x03
EOT	\$04	0x04
ENQ	\$05	0x05
ACK	\$06	0x06
BEL	\$07	0x07
BS	\$08	0x08
TAB	\$09	0x09
LF	\$10	0x0A
VF	\$11	0x0B
FF	\$12	0x0C
CR	\$13	0x0D
SO	\$14	0x0E
SI	\$15	0x0F
DLE	\$16	0x10
DC1	\$17	0x11
DC2	\$18	0x12
DC3	\$19	0x13
DC4	\$20	0x14
NAK	\$21	0x15
SYN	\$22	0x16
ETB	\$23	0x17
CAN	\$24	0x18
EM	\$25	0x19
SUB	\$26	0x1A
ESC	\$27	0x1B
FS	\$28	0x1C
GS	\$29	0x1D
RS	\$30	0x1E
US	\$31	0x1F

SCRIPT EXAMPLES

The examples outlined here are the transformation in script of the standard routine of the patient reception by the analyzer.

Stringn #PatientCode|\$15
Char #PatientListType
Char #PatientType
Char #PatientClone
Stringn #PatientCupPosition|\$2
Stringn #PatientNumberTest|\$2

Set #BeginAnalysesData
Stringn #AnalysesCode|\$4
Set #EndAnalysesData

Stringn #Checksum|\$3

The following are the details of the above Scripts:

Stringn #PatientCode|\$15
 Patient Code of fixed length equal to 15 characters

Char #PatientListType
 Type of list (Routine/STAT) as single character

Char #PatientType
 Serum type (Serum/Urine) as single character

Char #PatientClone
 Identifies if the patient is or is not a clone (single character)

Stringn #PatientCupPosition|\$2
 Position of serum cup (string of fixed length equal to 2 characters)

Stringn #PatientNumberTest|\$2
 Number of tests to be executed (string of fixed length equal to 2 characters)

Set #BeginAnalysesData
 Beginning of analysis codes

Stringn #AnalysesCode|\$4
 An analysis code of fixed length equal to 4 characters. It must be entered for each type of test as per qty indicated in the #PatientNumberTest.

Set #EndAnalysesData
 End of analysis codes

Stringn #Checksum|\$3
 Check-Sum (transferred as a string of fixed length equal to 3 characters)

The following examples are the transformation in script of the standard routine for the transmission of a report by the analyzer to the host computer:

```
Stringn #PatientCode|$15
Char    #PatientType
stringn #PatientNumberTest|$3

Set     #BeginAnalysesData
Stringn #AnalysesCode|$04
Stringn #AnalysesConcentration2|$7
Set     #EndAnalysesData

Stringn #Checksum|$3
```

The details of the above scripts are as follows:

Stringn #PatientCode|\$15
Patient Code of fixed length equal to 15 characters

Char #PatientType
Serum type (Serum/Urine) as single character

stringn #PatientNumberTest|\$3
Number of results to be sent (a string of fixed length equal to 3 characters)

Set #BeginAnalysesData
Beginning of zone repeated for the number of results to be sent (see **#PatientNumberTest**)

Stringn #AnalysesCode|\$04
An analysis code of fixed length equal to 4 characters

Stringn #AnalysesConcentration2|\$7
Concentration referred to the analysis code as per **#AnalysesCode** (a string of fixed length equal to 7 characters)

Set #EndAnalysesData
End of zone repeated for the number of results to be sent

Stringn #Checksum|\$3
Check-Sum (transferred as a string of fixed length equal to 3 characters)

4.7. SERIAL COMMUNICATION TEST PROGRAMS

4.7.1. Program COMUNICA.EXE:

It is a simple communication program for sending command characters to the analyzer and receive any response.

At the start the only input to the program is the number of the communication port (from 1 to 4).

A blue screen divided into two sections is displayed. In the upper section the characters coming from the analyzer are displayed, while the lower section displays the characters sent to the analyzer.

The only special keys used are F1 to clear the screen and F10 for exiting the program.

The special characters (with values less than 32) are displayed in ASCII notations along with their values.

For example the Character EOT - value 4 - will be shown as EOT (4).

To send a special character (with values less than 32 or higher than 124) it is necessary to keep pressed the ALT key and simultaneously to write the value of the character to be sent using numerical keys. For example to send EOT it is necessary to keep the ALT key pressed and simultaneously enter the value 4 through the numerical key and then release the ALT key.

4.7.2. Program BTPLUS.EXE:

It is a simple communication program that simulates the host computer. At the start it is necessary to identify the number of communication port (from 1 to 4) and the desired procedure (Transmission or Reception).

In case the Transmission is selected the program will ask for patient code (from 1 to 15 characters), the test number (from 1 to 9) and the relevant analysis code for each test (for example: BUN).

It is a good practice to use the same analysis codes, which the analyzer has memorized in the plate actually in use, if otherwise then an error will result in the transmission phase.

Now the program will execute an initialization procedure of communication with the analyzer, will send patient data and wait for the outcome of transmission.

At the end the screen will display the outcome of the operation or show the position number of the plate where the patient has been inserted or explanation of error code sent by the instrument (for example: Patient Code Duplicated).

If the Reception procedure is selected, then the program will begin initialization of communication with analyzer, will ask for data of the next report ready for serial dispatch and show data of relevant downloaded report.

If there are no reports to be received, then a relevant message will be displayed.

Every time the program waits for a response from the analyzer, in case of problem it is possible to abort the current operation by simply pressing the Esc (Escape) key.

NOTE:

The program BTPLUS.EXE works only with the internal serial protocol. The option "Send controls" in the Setup must be disabled.

Both the programs must reside in the computer connected serially to the analyzer through appropriate cable indicated in the Operators Manual.

The computer must be an IBM compatible equipped with DOS operative system: Windows 95, Windows 98, or Windows 2000. The operating systems such as MAC, UNIX, Windows ME or XP are not supported.

Since the programs operate in DOS ambience, therefore in case the Windows operating system is used then it will be necessary to open a DOS shell (the command Prompts of MS-DOS is found in the menu Programs, Accessories - accessed through the Start button on the bottom left of the screen).

Both the programs use serial port with the following setups:

Baude-Rate	9600
Stop-Bits	1
Parity	None
Hand-shake	Hardware

IMPORTANT NOTICE: These two programs are in the installation disk under Utility folder.

SECTION II: ADDITIONAL INFORMATION

CHAPTER 5: INSTALLATION OF THE OPERATING SYSTEM

5. INSTALLATION OF THE OPERATING SYSTEM (OS)	2
5.1. Installation Of The Operating Program	3
5.1.1 For All Analyzers With Internal Computer	3
5.1.2. Installation For BT 1500.....	4
5.2. Upgrading The BT Analyzers Software	6

NOTE:

All pictures in this manual are referred to the BT3000 Plus.
Figures may be different for the other analyzers.

5. INSTALLATION OF THE OPERATING SYSTEM (OS)

CAUTION!

INSTALLATION OF THE OPERATING SYSTEM MUST BE DONE BY EXPERT PERSONNEL, AND ONLY IN CASE THE OS HAS TO BE RE-INSTALLED EX-NOVO. BEFORE STARTING ANY SOFTWARE INSTALLATION PROCEDURE, CONTACT THE AUTHORIZED TECHNICAL PERSONNEL ONLY.

The installation of the O.S. is performed by means of the Image Disk supplied with the analyzer.

Before restoring the image disk on BT Plus analyzers the following procedure can be used to save and restore the system data, including private data (Patients Archive):

- PO-07116-01 Saving and restoring of data and parameters of the analyzer when using the image disk

The procedure needs a working analyzer computer box (Window™ O.S must be running).

An USB memory is required with enough free space for the incoming data: usually a 4 GB memory is more than sufficient, however big Archives may need bigger USB data memory support.

Depending on the O.S. present on the analyzer and on the PC system characteristics, a different installation procedure might be necessary.

For this reason, please contact your Technical Assistance Service.

Keep at hand the following information:

- analyzer model
- analyzer serial number
- installed software
- analyzer configuration (printable from the External programs menu, with third level password)
- latest Technical Assistance Report

THE PRINTER MUST BE INSTALLED BEFORE THE OPERATIVE PROGRAM!

Open the Printers window (“Start” button, “Settings”, “Printers”) and click on “New Printer”, then follow instructions. Otherwise, insert the printer’s installation disk into the driver and follow the printer’s setup instructions.

5.1. Installation Of The Operating Program

5.1.1 For All Analyzers With Internal Computer

Insert the CD-ROM containing the operating program of the BT analyzers in the CD-ROM drive.



The following screen appears:

Click **“LAUNCH SETUP”**.

Now the installation procedure begins, which will guide the user during operating program installation.



Click **“NEXT”**.

The installation procedure automatically checks the communication port (**COM**) used for communication with the 552. In case the communication port not found (cable disconnected, no processor, etc.), the following screen **"Select communication port"** will appear:

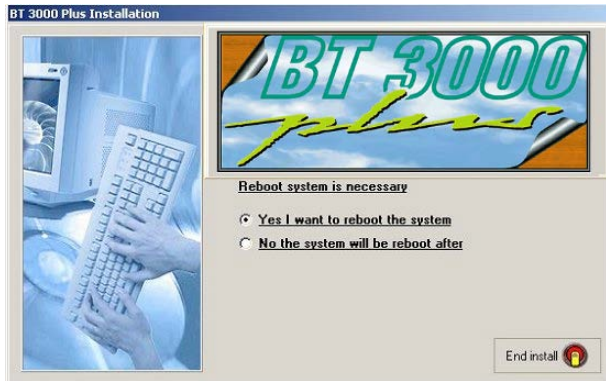


Here the operator will manually select the Com port used for communication (normally **"Com4"** is utilized).

Select **Com4** and click **“Accept”**. Now the installation of operating programs begins.

CAUTION:

DO NOT INTERRUPT THE ONGOING INSTALLATION, UNLESS FOR SERIOUS REASONS.



After the termination of previous phase, a message **"Setup has finished installing BT Plus on your computer"** will be displayed:

Click **"Finish"**.

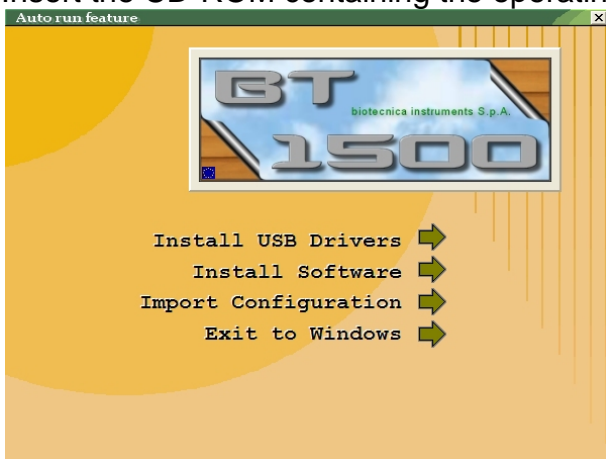
Now a screen with various options for **"End installation"** (with restart or without restart of the system) is displayed.

In case of the new installation, select **"Yes, I want to restart my computer now"** (first option).

Now the operating program has been installed correctly in the system.

5.1.2. Installation For BT 1500

Insert the CD-ROM containing the operating program of the analyzer in the CD-ROM drive.



The following screen appears:

Install USB Drivers

Installs the drivers of the USB module for communication with the analyzer.

This operation is necessary only if the PC is totally new (not for those supplied by the manufacturer together with the analyzer) and it **MUST** be performed before the installation of the operative program.

Install Software

Installs the operative program software.

Import Configuration

Restores the analyzer configuration supplied by the manufacturer on an external device (USB pendrive). This operation is necessary only if the PC is totally new (not for those supplied by the manufacturer together with the analyzer).

Exit to Windows

Terminates the installation program and goes back to Windows. If one of the preceding functions has been successfully performed, the program will ask if the operator wants to re-boot the PC.

Note:

The autorun module will not automatically close at the end of one of the above mentioned functions, to allow the operator to perform all the necessary operations before re-booting the PC.

Click **“Install software”**.

Now the installation procedure begins, which will guide the user during operating program installation.



Click **“NEXT”**.

The installation procedure automatically checks the communication port (**COM**) used for communication with the 552. In case the communication port not found (cable disconnected, no processor, etc.), the following screen **“Select communication port”** will appear:

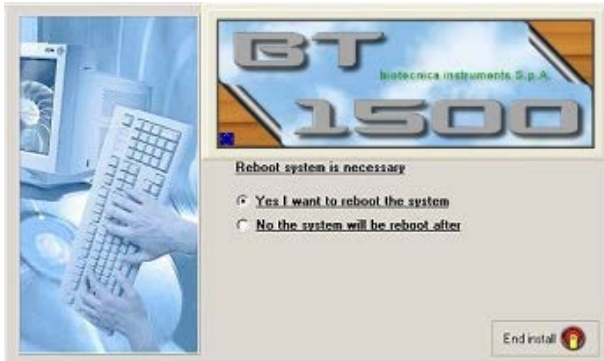


Here the operator will manually select the Com port used for communication (normally **“Com4”** is utilized).

Select **Com4** and click **“Accept”**. Now the installation of operating programs begins.

CAUTION:

DO NOT INTERRUPT THE ONGOING INSTALLATION, UNLESS FOR SERIOUS REASONS.



After the end of this phase, before re-booting the system, it is possible to perform one of the other operations described before.

Once finished, select **"Yes, I want to restart my computer now"**.

Now the operating program has been installed correctly in the system.

NOTES:

Whichever PC or operative system you have, the next instructions must be followed.

- stand-by: the energy saving mode **must** be disabled
- the UAC must be disabled (except Windows XP)
- the access to the operative system must always be in administrator mode
- Windows firewall must be disabled
- system characters must be in standard format (96 dpi)
- System desktop theme must be the Standard Theme
- the energy saving stand by mode due to the closing of the PC cover must be disabled

5.2. Upgrading The BT Analyzers Software

Proceed with installation as for a new instrument (see preceding paragraphs)

SECTION II: ADDITIONAL INFORMATION

CHAPTER 6: TECHNICAL ASSISTANCE

6. TECHNICAL ASSISTANCE.....2

6. TECHNICAL ASSISTANCE

In case of need for the Technical Assistance Service, before calling Biotecnica, please make sure that the following information is available:

- analyzer model
- serial number
- program code (at the center of the main screen)
- analyzer configuration (printable from the External programs menu, with third level password)

For operative and applications problems, make sure all possible information is available (in addition to the above mentioned), such as:

- analytical parameters printout
- calibration parameters printout
- calibration results in RT printout
- calibration reaction graphs printout
- samples reaction graphs printout
- real time pages printout
- possible errors or messages from the analyzer printout

Please do not return any equipment or part of the system to Biotecnica before discussing your problem with an authorized technical assistance representative or Biotecnica own technical assistance. The Technical Assistance Service at Biotecnica Instruments S.p.A. will provide a Return Authorization Number for the **Parts/Instruments Return Authorization module** available in Section II, chapter 2.

Reference numbers for Biotecnica Instruments S.p.A. Technical Assistance Service:

✉ BIOTECNICA INSTRUMENTS S.p.A.
Via Licenza, 18
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 [**www.biotecnica.it**](http://www.biotecnica.it)

SECTION II: ADDITIONAL INFORMATION

CHAPTER 7: BIBLIOGRAPHY

7. BIBLIOGRAPHY OF ALLIED SUBJECTS2

NOTE:

The following bibliography is given to supplement this manual, whose scope as an operator manual permits only the mention or brief explanation of some subjects.

7. BIBLIOGRAPHY OF ALLIED SUBJECTS

- ◆ **Burtis C.A., Ashwood E.R.: “Tietz Textbook of Clinical Chemistry” IInd Ed. W.B. Saunders Company, 1994**
- ◆ **Press W.H., Flannery B.P., Teukolsky S.A., Vetterling W.T.: “Numerical Recipes” - The Art Of Scientific Computing -, Cambridge Univ. Press, 1986**
- ◆ **International Standard: IEC 61010-1: 2001; IEC 61010-2-081:200+ A1:2003; IEC 61010-2-101:2002; IEC 61010-2-010:2003**
- ◆ **International Standard CEI EN 61326-2-6 (EMC).**
- ◆ **Directive 98/79/EC on in vitro diagnostic medical devices (1998)**
- ◆ **2011/65/UE: Restriction of the use of certain hazardous substances in electrical and electronic equipment**
- ◆ **Decreto Legislativo 30 giugno 2003, n. 196 Codice in materia di protezione dei Dati Personali (Privacy and sensitive data dispositions).**
- ◆ **EN ISO 18113-1:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)**
- ◆ **EN ISO 18113-3:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)**
- ◆ **Directive 2012/19/EU**

SECTION II: ADDITIONAL INFORMATION

CHAPTER 8: APPLICATIVE METHODOLOGIES

8. LIST OF APPLICABLE METHODOLOGIES	2
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8. LIST OF APPLICABLE METHODOLOGIES

Some examples of available applicable methodologies are resident in the analyzer's hard disk.

Updated Biotechnica applications are available inside each reagent kit.

For further details on the applied methodologies, please address to the following e-mail:

bt@biotechnica.it