HumaCount 30^{TS} / HumaCount 80^{TS}

| **User Manual**

CE

Cat No. 16420/801

Human

Diagnostics Worldwide

REVISION LIST OF THE MANUAL

Rev. /DATE.	REVISION DESCRIPTION
01/2015-04	First edition
02/2015-06	Special symbols added
03/2015-12	Addition of Saftey Notes and Bar Codes

SYSTEM VERSION

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SERVICE UND SUPPORT

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1 SAFETY INSTRUCTIONS

1.1 Introduction

This manual is considered part of the instrument and must be available to the operator and the maintenance personnel. For accurate installation, use and maintenance, please read the following instructions carefully.

In order to avoid damage to the instrument or personal injury, carefully read the "GENERAL SAFETY WARNINGS", describing the appropriate operating procedures. Please contact your HUMAN authorised local Technical Service in the event of instrument failure or other difficulties with the instrument.

This manual is for both types of instruments, the HumaCount 30^{TS} and Huma-Count 80^{TS}. All screens which are equal on both instruments are not shown for both types of instruments, but only for HumaCount 30^{TS}.

If a chapter/table or screen is only for one analyzer type, it is marked in the title and explanations. If it is applicable for both instruments it will be named Huma-Count 30^{TS}/ HumaCount 80^{TS}.

! **This manual is for both types of instruments, HumaCount 30^{TS} and HumaCount 80^{TS}.**

1.2 User Warranty

HUMAN warrants that instruments sold by one of its authorised representatives shall be free of any defect in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item within this warranty period at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability to replace any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer's instructions, altered in any way not specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.

1.3 Intended Use of the Instrument

The instrument must be used for its intended purpose (see paragraph 2). It must be operated in perfect technical conditions, by qualified personnel, in such working conditions and maintained as described in this manual, in the GENERAL SAFETY WARNINGS. This manual contains instructions for qualified professional operators.

IVD

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1.4 General Safety Warnings

Use only chemical reagents and accessories specified and supplied by HUMAN and/or mentioned in this manual. Place the product so that it has proper ventilation.

The instrument should be installed on a flat, stationary working surface, that is free of vibrations.

Do not operate in area with excessive dust.

Operate at temperature and at a humidity level in accordance with the specifications listed in this manual.

Do not operate this instrument with covers and panels removed.

Use only the power cord specified for this product, with the grounding conductor of the power cord connected to earth ground.

Use only the fuse type and rating specified by the manufacturer for this instrument.

The use of fuses with improper ratings may pose electrical and fire hazards.

To avoid fire or shock hazard, observe all ratings and markings on the instrument.

Do not power the instrument in environments that are potentially explosive or at risk of fire.

Prior to cleaning and/or performing maintenance on the instrument, switch off the instrument and remove the power cord.

Only cleaning materials described in this manual may be used, as other materials may damage parts. It is recommended to always wear protective clothing and eye protection while using this instrument.

All warning symbols that appear in this manual must be carefully observed.

The peripheral connectors on the HumaCount 30TS and HumaCount 80TS are SELV (safety extra low voltage) connectors. Only connect approved external devices that are SELV rated to the instrument to avoid the risk of electrical shock.

Based on the performed risk analysis it's guaranteed that the trained user doesn't need further operator action in case of residual risk as long as the operator works according to the user manual and takes care of the warning labels.

After maintenance or service procedure it's mandatory for the user to check the service report where the trained service representative ensures that the instrument's safety level is not decreased.

1.5 Disposal Management Concept

The applicable local regulations governing disposal must be observed. It is the user's responsibility to arrange for proper disposal of the individual components. All parts which may contain potentially infectious materials must be disinfected by suitable, validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal must be carefully observed. The instruments and electronic accessories (without batteries, power packs etc.) must be disposed of according to the applicable local regulations for the disposal of electronic components.
Batteries, power packs and similar power sources must be removed from electric/electronic parts and disposed of in accordance with applicable local regulations.

1.6 Biohazard Warning

Analytical instruments for in vitro diagnostic application involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious.
The „BIOHAZARD" warning label must be affixed to the instrument prior to first use with biological material!

FIGURE 1

Biological Hazard Symbol

1.7 Instrument Disinfection

Before performing any servicing on the instrument it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. Decontamination must be performed by authorised well-trained personnel, and in observance of all necessary safety precautions.

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1.8 Who should use this manual

This user's manual is intended for clinical laboratory professionals using the The HumaCount 30^{TS}/HumaCount 80^{TS} automated hematology analyzer. This manual includes information about the operation and user interface of the analyzer, and also describes daily routine maintenance requirements to keep your analyzer functioning properly.

Please, go through this manual before operating the analyzer.

1.9 Special Symbols used in this Manual and on the Analyzer

TABLE 1

Label	Meaning	Explanation
	Biohazard	Blood samples and analyzer waste are potentially infectious materials. Please, handle them accordingly.
	Corrosive	Reagents may cause corrosion or skin irritation.
	Warning	General warning of possible hazard conditions.
	Sharp needle warning	The sampling needle may be a hazard to the operator.

1.10 General Precautions

Please, read this section carefully before operating the analyzer.

TABLE 2

	The sampling needle and other components inside the analyzer may cause injury, or can get damaged if handled incorrectly. Only certified personnel should open the covers. Running samples with opened cover is not recommended due to the risk of possible injury. Always wear safety gloves while performing maintenance actions.
	The analyzer should be moved holding the analyzer in an upright position.
	Make sure to retain the original packaging material for safe transportation and storage in the future.
	To prepare the analyzer for shipping, storage or extended periods of inactivity, please drain the reagents (run Preparing for shipment procedure) and repackage it in its original packaging. Do not expose the HumaCount 30^{TS}/HumaCount 80^{TS} to direct sunlight, extreme temperature or humidity over 80%.

The analyzer operates with chemically and biologically active reagents. Physical contact with these reagents should be avoided. Please read reagent descriptions and MSDS carefully for possible emergency actions.

To ensure reliable operation and reliable results:
- Only human blood samples should be analyzed.
- Only genuine Human reagents should be used.
- Required user maintenance should be performed as detailed in this
- manual.
- Only Human certified service personnel should perform service
  actions.
- Only genuine Human service materials and spare parts should be
  used.

Only Human certified service personnel that have successfully completed the HumaCount 30^{TS}/HumaCount 80^{TS} Service Training program are qualified to service the HumaCount 30^{TS}/HumaCount 80^{TS} analyzer.

Before operating the HumaCount 30^{TS}/HumaCount 80^{TS} analyzer, all operators should complete a HumaCount 30^{TS}/HumaCount 80^{TS} Operator Training program. This program is offered by certified service personnel of HumaCount 30^{TS}/HumaCount 80^{TS}.

Replacement materials or spare parts (tubes, valves, etc.) which might have been in contact with human blood or reagents should be handled as a potentially biologically hazardous and chemically dangerous material. All applicable laws and regulations must be observed in the handling and disposal of these materials.

HumaCount 30^{TS}/HumaCount 80^{TS} is designed for laboratory operation. Mobile operation is not supported. Operate it within the ambient temperature range described in section 2.2.2.

This IVD equipment complies with the emission and immunity requirements described in relevant part of the IEC 61326 series.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Electromagnetic environment should be evaluated prior to operation of the device.

This analyzer contains electronic components. Please handle electronic waste adhering to local or federal regulations.

Waste contains poisonous substances (because of chemical content) and human origin substances meaning biohazard. These substances are representing potential danger to environment. For this reason, safe handling of the waste liquid is very important.

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2 SYSTEM DESCRIPTION

The HumaCount 30^TS/HumaCount 80^TS are fully automated 3-part differential cell counters designed for in vitro diagnostic use, developed for small clinics and point-of-care lab offices.

2.1 The Instrument

The HumaCount 30^TS/HumaCount 80^TS are fully automated, bench-top hematology cell counters. They implement the so-called Coulter-method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells.

The analyzer features a color graphical display module with large touch screen. The software allows sending results to an external printer (via USB port), or to the 58 mm built-in thermal printer module.

Its internal memory is capable of storing 10000 records with full histograms, and individual patient data. QC measurements are also stored in separate database. The software operating the instrument is easy to upgrade using a USB pen-drive. The instrument allows connecting to a host computer for uploading records stored in the memory through a USB B (slave) port. Archiving and restoring of records to and from USB pen-drive is also possible.

! If the equipment is used in a manner different from which the manufacturer specified, the protection provided by the equipment may be impaired. Misuse of equipment or use other than its intended purpose will invalidate conditions of warranty. The accuracy and precision may also be impaired.

2.1.1 PATIENT TESTING

The HumaCount 30^TS can process 30 samples, the HumaCount 80^TS processes 80 samples per hour in 3-part WBC differential mode. Samples can have individual sample data, and additional parameters.

You can print results to an external or to the built-in printer. The user can customize the report format.

The analyzer determines the following 22 hematology parameters, including 3-part WBC differential, from a 25 µl whole blood sample:

WBC	total white blood cell count
LYM	lymphocytes count
MID	mid-sized cell count
GRA	granulocytes count
LYM%	lymphocytes percentage
MID%	mid-sized cell percentage
GRA%	granulocytes percentage
HGB	hemoglobin concentration
RBC	red blood cell count
HCT	hematocrit

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MCV	mean corpuscular volume
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
RDWcv	red cell distribution width (CV) = coefficient of variation
RDWsd	red cell distribution width (SD) = standard deviation
PLT	platelet count
PCT	platelet percentage
MPV	mean platelet volume
PDWcv	platelet distribution width (CV)= coefficient of variation
PDWsd	platelet distribution width (SD) = standard deviation
P-LCC	platelet large cell concentration ▷
P-LCR	platelet large cell ratio ▷

▷ Research parameters only

RDW and PDW parameters have two forms of representation: CV and SD.
Both parameters describe the distribution width, but from different aspects.
User can select the units to use for displaying RDW and PDW parameters.

2.1.2 REAGENTS

Use only reagents supplied by HUMAN with the analyzer, otherwise accuracy cannot be guaranteed.

HC-DILUENT (Cat.No. 17400/11)	Isotonic saline solution, used to dilute whole blood samples and to rinse the fluidic system between measuring procedures.
HC-LYSE (Cat.No. 17400/22)	Creates hemolysate for 3-part WBC differential and for total WBC and HGB.
HC-CLEANER (Cat.No. 17400/31)	For cleaning process of the fluidics
HC-Control (Cat.No. 17400/40)	Stabilized blood cell control
HC-Calibrator (Cat.No. 17400/50)	Stabilized blood cell calibrator

2.1.2.1 Safety Notes
REF 17400/22 HC-Lyse CF

Hazard statements
H412 Harmful to aquatic life long lasting effects.

Precautionary statements
P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local/regional/national/
international regulations.
vPvB: 9036-19-5 Polyethylene glycol octylphenyl ether

REF 17400/31 HC-Lyse CF
vPvB: 9036-19-5 Polyethylene glycol octylphenyl ether
After inhalation: Supply fresh air; consult doctor in case of complaints.
After eye contact: Rinse opened eye for several minutes under running water.
For further details see safety data sheet.

2.1.2.2 Dangerous components
REF 17400/22 HC-Lyse CF
CAS: 1119-94-4 Dodecyltrimethylammoniumbromid 2,7%

REF 17400/31 HC-Lyse CF

vPvB: 9036-19-5 Polyethylene glycol octylphenyl ether 0,8%
Aquatic Chronic 2, H411, Acute Tox. 4, H302, Eye Irrit. 2, H319
After eye contact: Rinse opened eye for several minutes under running water.
For further details see safety data sheet.

2.1.3 TECHNICAL OPERATION
As the cell counter is a fully automated instrument, operating requires minimal
training or technical support. Operator interaction is reduced to the following:
-   Perform a Blank Measurement in case the instrument is not used for a spe-
    cific time
-   Enter sample and/or patient data
-   Insert the sample to be analyzed into the sample holder
-   Print results either one-by-one, or in groups by selecting records from the
    database.
-   Perform simple weekly maintenance, as described later in this descrip-
    tion (4.8.2).

2.1.4 CALIBRATION
The HumaCount 30^{TS}/HumaCount 80^{TS} arrive to your laboratory factory-calibrat-
ed and ready to use. However, calibration needs updating whenever you find
that the results have slightly changed, or a different or new control material is

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used. With each control material you receive for the instrument, you will find a control sheet listing the parameters the instrument should match. Perform these calibrations as explained in a later chapter (4.9).

2.2 Unpacking and Installation

This chapter provides instructions for the unpacking and installation of Huma-Count 30^TS/HumaCount 80^TS hematology analyzers. The procedures described below must be followed correctly to ensure proper operation and service. Please carefully read and follow all instructions in this User's Manual before operating the analyzer.

This hematology analyzer is a precision instrument: Handle with care. Dropping or other improper handling of the instrument will disturb calibrated mechanic and electronic components and/or cause damage.

Carefully remove the analyzer from the shipping carton. Inspect the instrument for any visible signs of damage incurred during shipping. Would you find any damage, file a claim with the carrier or your distributor immediately. Check the accessories received against the packing list. Contact Service if anything is missing.

Place the instrument on a firm work surface in the designated work area, near an appropriate AC electrical outlet. The power outlet connection MUST be grounded (see also 2.2.2 – Environmental factors).

! **Always handle the instrument with care.**

! **Prior to initial operation, allow the instrument to reach room temperature (approx. 2 hours).**
Rapid temperature changes in an operating unit can lead to water condensation, which may damage electronic parts, and cause malfunction.

! **Before making connections: Make sure that all power is in "OFF" state before connections (printer, external keyboard) are made. Carefully read all literature accompanying the instrument and its accessories. Pay particular attention to the operating procedures for the external printer.**

! **Do not switch on the analyzer before connecting external power supply to it and to the AC outlet, as well as before connecting an external printer or a keyboard to the analyzer.**

Keyboard and external printer:
Attach the keyboard cable to one of the USB A ports on the back of the instrument. Attach both ends of the printer cable to the appropriate ports on the printer and HumaCount 30^TS/HumaCount 80^TS. Attach the AC adapter to the printer (if required) and plug it into an AC outlet.

Host Computer:
The instrument has a built-in USB B port that allows connection to a host computer. You can export results, including histograms. USB B I/O settings are located in Settings menu.
For installation instructions for communication, please, contact Service.

Power supply:
Connect the power supply to the instrument. Attach power cord outlet to the external power supply of HumaCount 30^TS/HumaCount 80^TS and plug the other end into a properly grounded AC outlet.

Reagent Containers:

Place the reagent containers near the instrument, to an accessible location. Do not place the containers to a higher position than that of HumaCount 30^TS/HumaCount 80^TS because would a tube come off its connector, the fluids spill out. Use the supplied connecting tubes and special bottle caps. Be sure that the color on each tube and cap match. You can, for example, place the reagent containers below the desk the analyzer is installed on, as the instrument has sufficient power to draw the liquids from a lower location.

All containers should be left open (do not block the small air vent hole on the special container caps) in order to provide free airflow.

! Reagents may cause corrosion and skin irritation. If any of liquids leaked to cover of analyzer or the furniture, wipe it off immediately. In case of skin contact, rinse the liquid with plenty of water.

FIGURE 2

Human
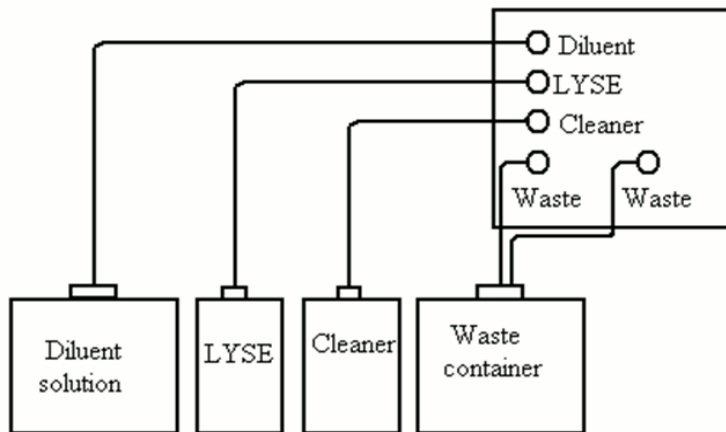
2.2.1 CONNECT REAGENTS

HumaCount 30^{TS}/HumaCount 80^{TS} is capable of aspirating reagents from 3.3 ft. (1m) below the analyzer's base.
- Place the Diluent Lyse cleaner and Waste tanks below the analyzer.

FIGURE 3

Recommended placement of Reagents and Waste
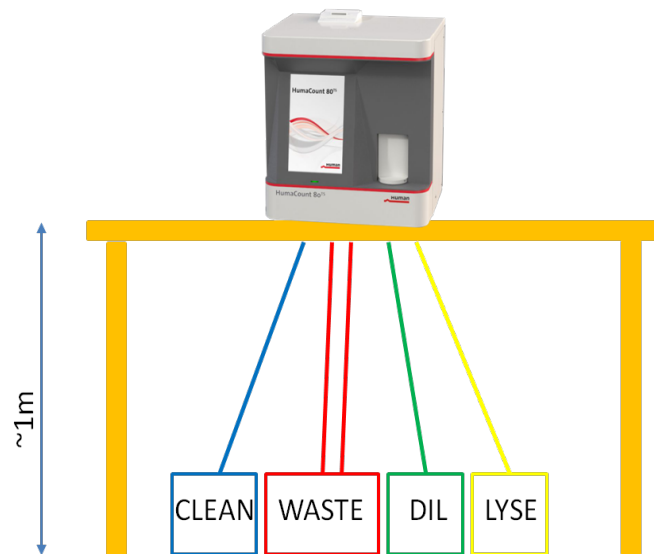
- Connect the reagent tubes to the analyzer, use the supplied connecting tubes and special bottle caps. Do not block the small air vent hole on the container caps to provide air flow.

FIGURE 4

Vent hole
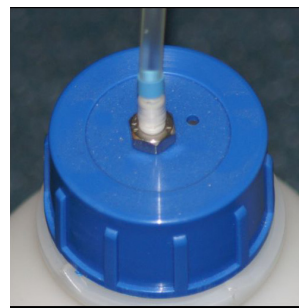
- Be sure that the color on each tube, cap and connector in the back of the instrument match;
- Before putting the drop-down tubes into the reagent containers, wipe the dust off from them using a lint-free wet paper wipe
- Use separate Waste lines for the waste tank connections as indicated below:
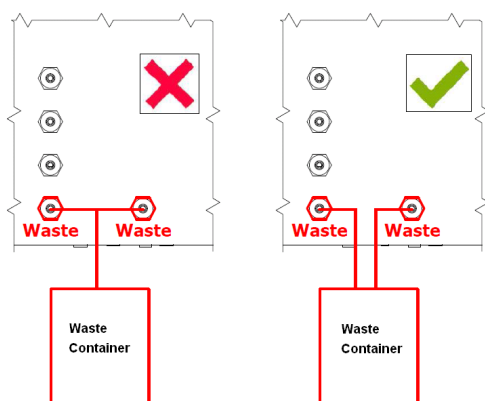
FIGURE 5
Establishing correct
waste connection

2.2.2 ENVIRONMENTAL FACTORS

Operate HumaCount 30[TS]/HumaCount 80[TS] within the ambient temperature range of 15...30°C and relative humidity of 45...85%. The optimum operating temperature is 25°C.

Avoid using the instrument in areas of extreme high or low temperatures or where it is exposed to direct sunlight. If kept at a temperature less than 10°C, the instrument should be allowed to sit for an hour at the correct room temperature before use.

Reagents should be stored at a temperature range of 15...35°C.

Place the instrument in a well-ventilated location. Do not place it near potentially interfering devices capable of emitting radio frequencies (e.g. radio or television rece iver, radars, centrifuge, X-ray devices, fans, etc.).

Operation at an altitude over 2000 meters (6540 ft) is not recommended, because the throughput will be degraded. A special software is requested.

Instrument is safe for transient voltages to INSTALLATION CATEGORY II andPOLLUTION DEGREE 2.

Environmental and electrical characteristics provide accuracy and precision of the instrument and maintain a high level of operational safety for lab personnel. HumaCount 30/HumaCount 80[TS] should be stored within the temperature range of 5-35°C (41-95°F)

2.2.2.1 Electrical requirements

The HumaCount 30[TS]/HumaCount 80[TS] come with an approved power cord, appropriate for your power system. Proper use of the appropriate power cord assures adequate grounding of the system.

! **Improper grounding of the analyzer by passes important safety features and may result in electrical hazard.**

The analyzer works with an external power supply. The power supply module has a so-called auto range input, allowing operation on 230V or 115V power system. The power supply unit complies CE and UL safety certifications.
The input socket is a standard power cable connection and the output is a DC jack.

* Optional the analyzer can be operated via a rechargeble battery system (HumaPower REF 18965/12) and a solar panel (Human SolarCharge REF 18965/14)

FIGURE 6
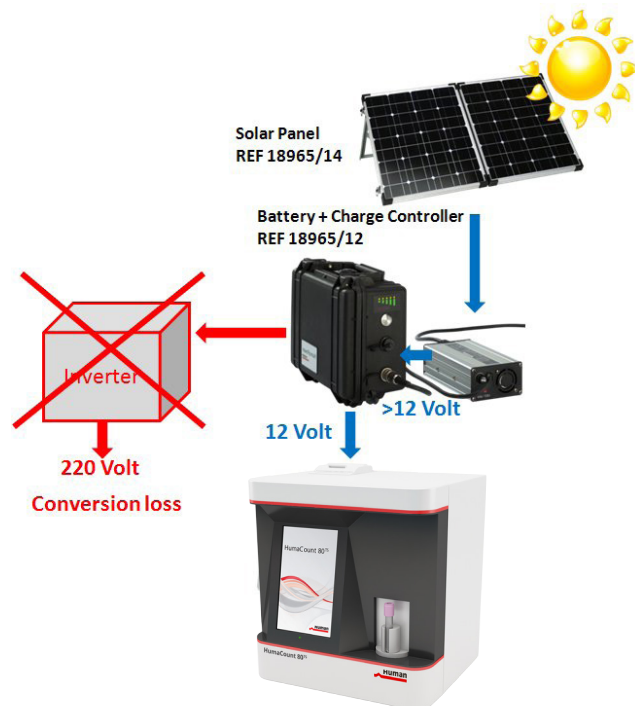
HumaPower and **Human SolarCharge**, a 12 Volt battery system charged by a solar panel to operate the HumaCount 30/HumaCount 80TS systems.

Solar panels generate DC power, being stored in Batteries (12 volt). Power supplies use 220 volt and convert this AC-voltage to 12 volt DC for the instrument.

Conventional systems with inverter lose energy in 2 ways - converting 12 volt to 220 volt and then converting 220 volt to 12 volt.

The HumaPower system uses just 12 volt directly applying it to the HumaCount 30TS/HumaCount 80TS.

HumaPower can be charged by **solar power, a generator or by ordinary mains.**
▷ HumaPower has a connector, being attached directly to the analyzer replacing the power supply. Insert connector to position 6 in Figure 24.

2.2.2.2 Space requirements

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance. Consider the following space requirements:

- Select a location near a power source and close to a suitable drain.
- Place the unit on a clean and level surface.
- Leave at least 0.5 m (20 inch) space on both sides and above the instrument to access pneumatics and (optional) external printer. Provide a minimum of 0.2m (8inch) between the rear panel and the wall to allow for heat dissipation and tube clearance.
- Install the reagents in a suitable place that will make your work easy. The best place is on the ground, below the supporting desk of the instrument. The pneumatic system is capable of aspirating reagents from containers being 1m (3ft) below the reagent inputs. Make sure the reagent tubes are not bent, broken, twisted or blocked in between the desk the instrument is on and the wall behind. Such circumstances can result in instrument operation failure.
- DO NOT PLACE the reagents above the instrument, as there can be a risk of falling and spilling.
- Leave space behind the equipment for easy disconnection in emergency state.

! **Install the unit on a table or workbench. If the unit was installed without a supporting desktop under the unit, there is a possibility that the analyzer could accidentally fall.**
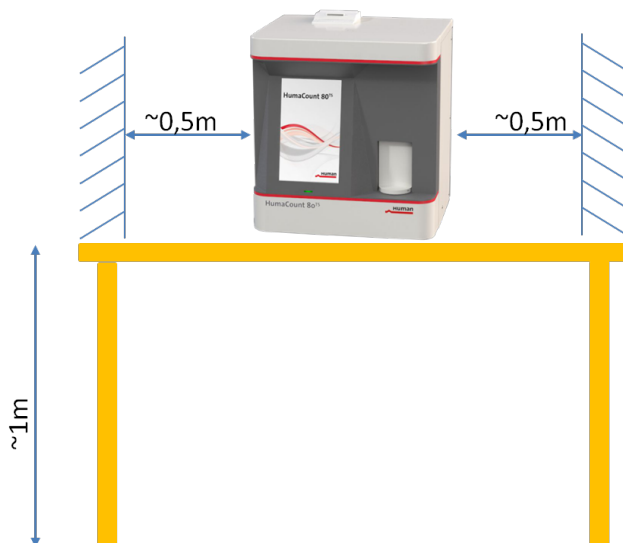
FIGURE 7
Space Requirements

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2.2.2.3 Peripherals

Connect external peripherals only when both the instrument and the peripheral device are off. Possible peripherals are:

2D Barcode reader

- optional 2D Barcode reader (REF 16430/11) allows you to scan-in all assay values at the control.

External printer

- the printer must be recommended by authorized technician
- the printer must be approved and listed
- the printer must have a CE mark

A so called printer box (REF 16430/13) allows you to connect almost every printer to the instrument.

External keyboard

- the external keyboard must be approved
- the external keyboard must have a USB port or suitable adapter

Link to host computer via USB port

- serial link cable must be approved by technician
- USB B port (linking to host computer) requires a USB A-B cable and USB driver software (contact service for availability)

Link to host computer via LIS

- contact your service engeneer

2.2.2.4 Reagents and waste handling

Handle reagents according to national or international regulations.
Waste generated by the unit is biohazard material. Handling and disposal must happen according to regulations regarding reagent systems. See section 4.10.6.

2.2.2.5 General points

The manufacturer guarantees work safety reliability and general characteristics under the following conditions only:

- services and repairs are performed by an authorized technician
- the electrical system of the laboratory follows national and/or international regulations
- the system is operated according to instructions contained herein

! **Reagents may cause corrosion and skin irritation. If any of the liquids leaked onto the cover of analyzer or the furniture, wipe it off immediately. In case of skin contact, rinse the liquid off with plenty of water.**

! **Waste contains poisonous substances (because of chemical content) and human origin substances meaning biohazard. These substances are representing potential danger to environment. For this reason, safe handling of the waste liquid is very important.**

2.2.3 TURNING THE INSTRUMENT ON

- In case you use an external printer (for information, read manual shipped with the printer) connect it and turn it on.
- Turn the analyzer on using the power switch on the rear panel. The 'ON' position is marked by the 'I' symbol.

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During start-up, the following screen is displayed:
The software version number appears few seconds later, when the software starts.
When SW is loaded, Main menu is displayed.

! Wait 5 minutes before initiating any measuring process to allow the instrument to reach the optimal working temperature.

FIGURE 8

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FIGURE 9
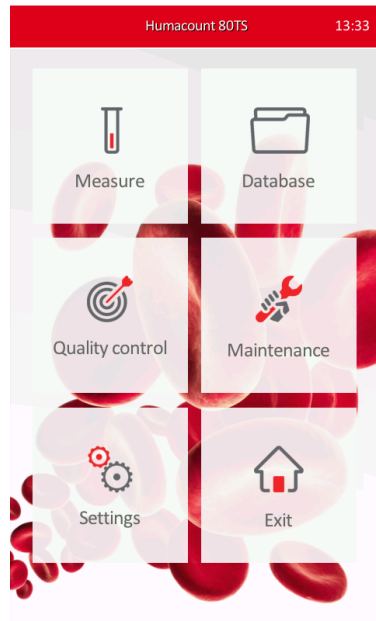
Tap a touch-screen item to activate the menu element.

In some cases, a priming cycle is necessary prior to sample introduction. The instrument will perform priming cycle automatically if additional liquid in the tubing system is required.

Run a priming cycle in case of:
- installation
- extended time out of use
- replacement of any component related to the Fluidic System
- replacement of reagents with instrument turned on

2.2.4 TURNING THE INSTRUMENT OFF

The built in Shut down procedure will set the analyzer electronics, fluidics and mechanics in a definite state:
- HumaCount 30^{TS} and HumaCount 80^{TS} save data, settings, closes the data-bases and other files. If the power is simply cut before all data items are securely saved, some data might be lost.
- The SW will perform cleaning to remove debris and fill chambers and apertures to avoid clogging and contamination. Without proper shut down, blood-sample can remain inside the instrument increasing the risk of contamination or if dried in, blood can permanently block the sample-paths.
- The analyzer will move the mechanical parts (sample needle, syringe pumps, valves) into their safe home positions to reduce risk of injury, and avoid more time and higher amount of reagents during the next start-up process.

Therefore always follow the instructions below when switching the instrument off.

To shut down HumaCount 30^{TS}/HumaCount 80^{TS}, press EXIT key in the Main menu. The following screen appears.

Press **Shutdown**.

HumaCount 30^{TS}/HumaCount 80^{TS} will display a message and give a tone indicating that it is safe to turn off power, after the shut down procedure is finished.

Turn off the instrument using the power switch on the rear panel. Off position is marked by '0' symbol.
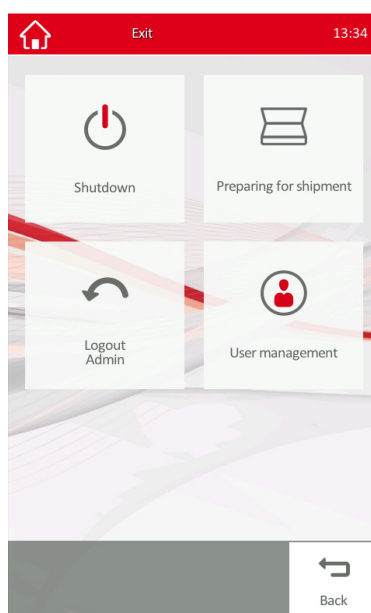
FIGURE 10

! **DO NEVER turn off the analyzer by simply flipping the power switch on the rear panel. Doing so may result in erroneous operation during later use.**

2.2.5 PREPARING FOR SHIPMENT

User should perform preparing for shipment procedure, before shipping the analyzer, or if it will not be used for more than a week.

The analyzer will perform three individual cycles:

1. Drain reagents into waste tank after disconnecting reagent lines
2. Prime Rinse reagent or DI water into reagent lines to dissolve and remove salt and reagent residuals
3. Drain all liquids into Waste tank.

For the above procedure, please, prepare the **cleaning tube kit** (refer to section 2.4) and 150ml clean DI (deionised) water.

To start the process, press **EXIT** key in the Main Menu.
Tap **Preparing for shipment** button.

Follow the on screen instructions:

1. Remove reagent tubing (diluent, lyse and cleaner), but leave waste lines connected. SW will prime on air, and empty reagent lines and syringe pumps.

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2. Connect the **cleaning tube kit** to the reagent inputs, submerging the free end in a bottle containing at least 150 ml of clean DI water. The SW will prime rinse to dissolve salt remains, and flush the fluidics.
3. Remove cleaning tube kit, leave waste connected. SW will drain the fluidics to remove all liquids.
4. Power off the analyzer and disconnect the waste tubes.
5. Disconnect electronic connection and power supply.
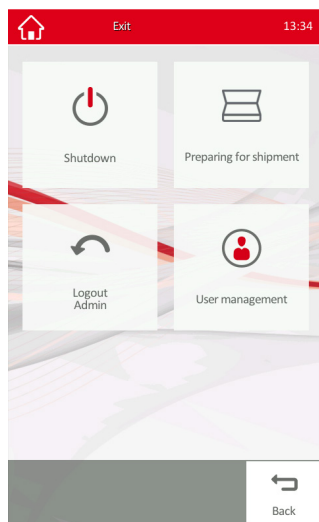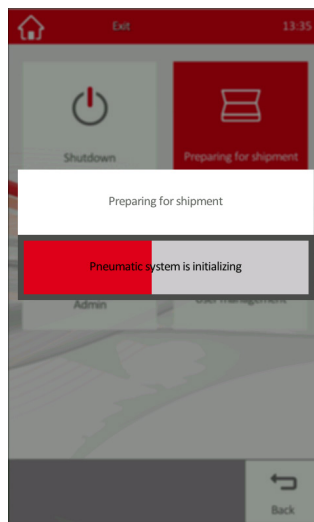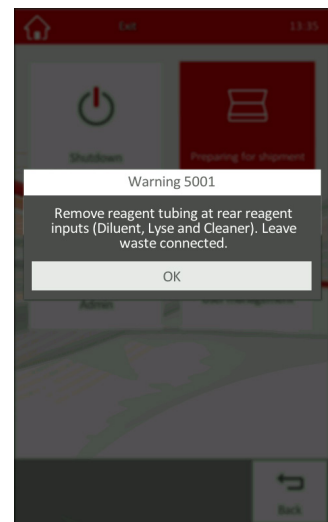
FIGURE 11   FIGURE 12   FIGURE 13

2.2.6 EMERGENCY SHUT-DOWN

In case of emergency situation - like instrument catching on fire (short-circuit, etc.) - cut off power immediately by disconnecting mains power or DC input line, and use a fire-extinguisher if necessary.

2.2.7 STANDBY

The analyzer automatically changes into the standby routine and perfoms a clean cycle.
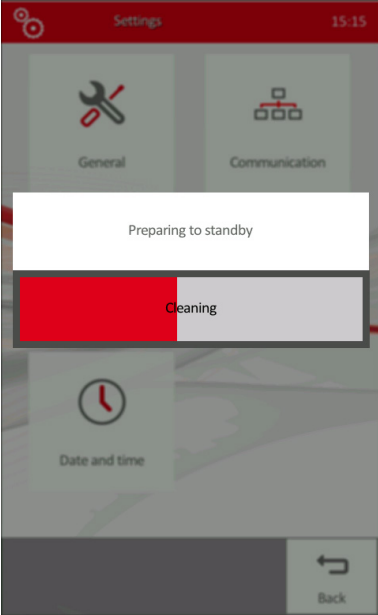
FIGURE 14

2.3 Built-in Printer

HumaCount 30^{TS}/HumaCount 80^{TS} is equipped with an optional built-in thermal printer. This printer is capable of printing on 58 mm wide thermal paper.

FIGURE 15
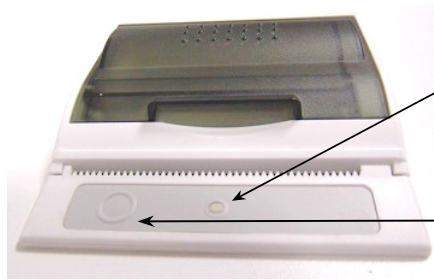
- If the status LED is lit, the printer is ready to use.

- If the status LED is blinking, then reload paper.

- Push the button on the right to advance paper.

Loading paper into the built-in printer

FIGURE 16
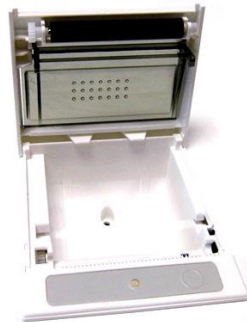
- Open the paper lid (pull the lid upwards by the handle)

- Remove central plastic roller of old paper roll

- Unwind new paper roll, so that the "starting edge" is coming from down under towards you.

FIGURE 17
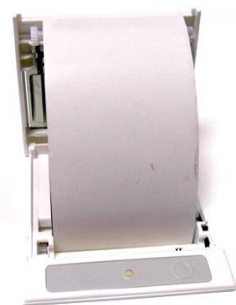
- Gently drop the new roll into the holder of the printer, hold "starting edge" with your hand, and make sure it comes out on the front of the printer as indicated in the picture.

FIGURE 18
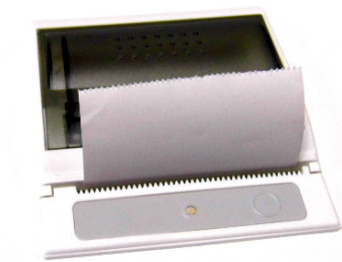
- Close the lid, making sure that the paper captured between it and the printer mechanics, and it is securely closed.

2.4 Accessories

In case of damage or missing item, please contact the supplier immediately.

2.4.1 SCOPE OF SUPPLY OF HUMACOUNT 30^{TS}

HumaCount 30^{TS} Hematology Analyzer	1	16420/30	**TABLE 3**
User Manual	1	16420/801	Accessories (Scope of supply) for HumaCount 30^{TS}
Reagent Tubing kit (with coloured tubes):			
- Diluent Tube (green)	1		
- Lyse Tube (yellow)	1		
- Cleaner Tube (blue)	1	16420/324	
- Waste Tube (red)	1		
- Cleaning Tube Kit.	1		
- Caps for reagent containers (matching connector colors)	1		
Waste Container (20 l)	1		
External power supply GlobTek GT-41132-6012-T3 (100-240 VAC, 50-60Hz) and power cable	1	16420/168	
Sample tube adapters	3	16420/180, - 181, -/323	
Thermal roll-paper	2		

2.4.2 SCOPE OF SUPPLY OF HUMACOUNT 80^{TS}

HumaCount 80^{TS} Hematology Analyzer	1	16420/80	**TABLE 4**
User Manual	1	16420/801	Accessories (Scope of supply) for HumaCount 80^{TS}
Reagent Tubing kit (with coloured tubes):			
- Diluent Tube (green)	1		
- Lyse Tube (yellow)	1		
- Cleaner Tube (blue)	1	16420/622	
- Waste Tube (red)	2		
- Cleaning Tube Kit	1		
- Caps for reagent containers (matching connector colors)	1		
Waste Container (20 l)	1		
External power supply Glob Tek GT-41132-6012-T3 (100-240 VAC, 50-60Hz) and power cable	1	16420/168	
Sample tube adapters	3	16420/180, -/181, -/323	
Thermal roll-paper	2		

Human

FIGURE 19

Reagent Tubing Kit
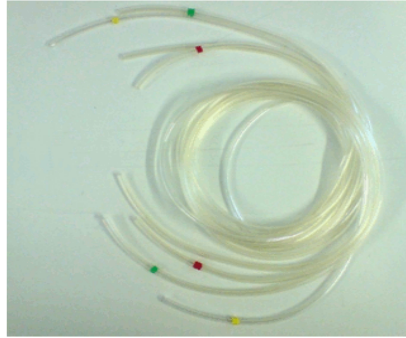
FIGURE 20

Cleaning Tubing Kit
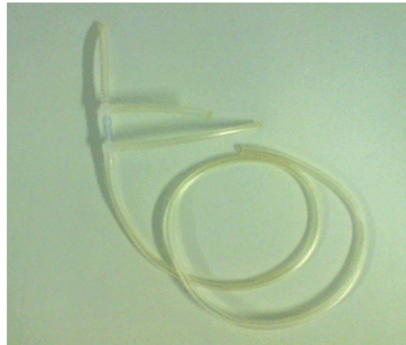
2.4.3 OPTIONAL ACCESSORIES

TABLE 5			
Replacement thermal roll-paper 5	5	18144/5
HumaPower (12 volt battery)	1	18965/12
Human SolarCharge (110 watt solar panel)	1	18965/14
2D barcode reader	1	16430/11
Bleach-Hard Clean	1	90150

FIGURE 21

Human SolarCharge
(110 watt Solar panel)

FIGURE 22
HumaPower (rechargable
12 volt battery system)

2.5 Parts of the Analyzer HumaCount 30^{TS}/80^{TS}

2.5.1 FRONT PANEL

FIGURE 23
Front View

1 **Built-in thermal printer**
2 **Sample Holder with**
   exchangeable adapters
3 **Status LED**
4 **Color LCD Touchscreen**

FIGURE 24
Rear View

1 **Power switch**
2 **USB A connector**
3 **USB B connector**
4 **Ethernet connector**
5 **Reagent key (HK) connector**
6 **Power source connector**
7 **External Grounding**
   Connector
8 **Reagent connectorsl**
9 **Instrument label**
   (Serial number)
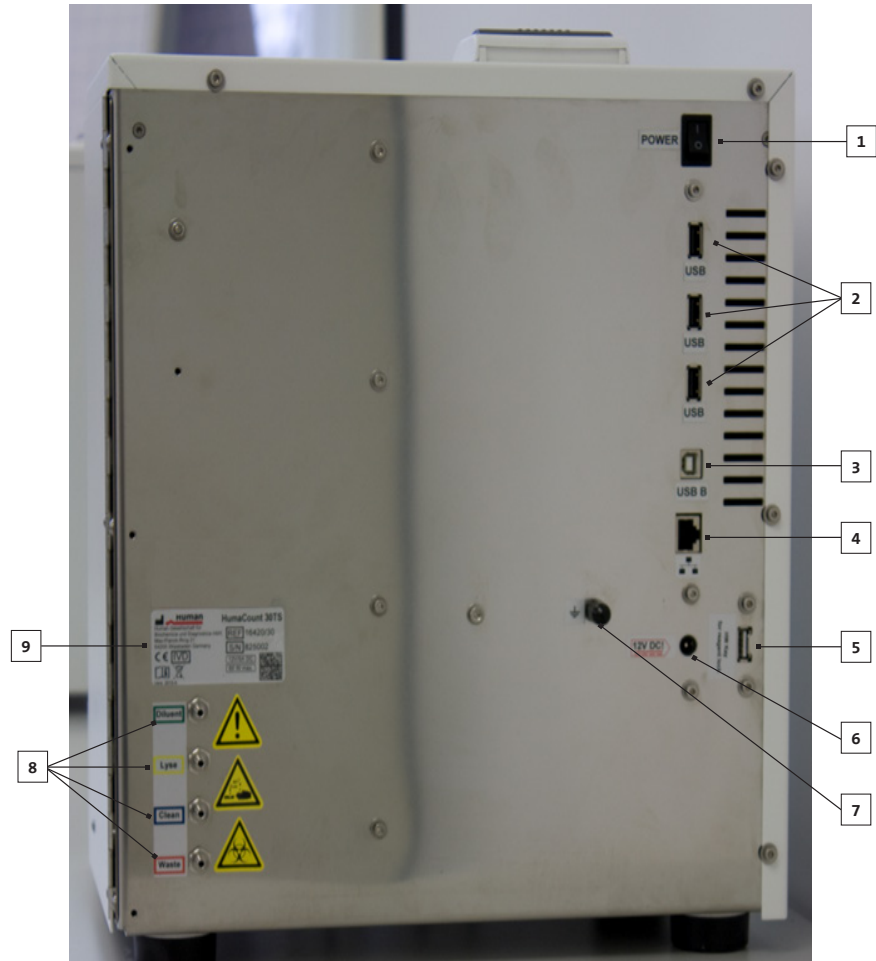
2.5.2 MAIN SUBUNITS

The hematology analyzer is composed of three main units:

Fluidic System:	Performs sampling, diluting, mixing, and lysing functions. Generates the regulated vacuum used for moving cells through the aperture during the counting process.
Data Processing System:	Counts, measures and calculates blood cell parameters, generates and stores numerical results and histograms.
Control Panel:	Features an LCD display, touch screen, START button, status LED, and USB port interfaces.

2.6 Control Material

The analyzer allows continuous monitoring of measurement performance with HC-CONTROL ($\boxed{\text{REF}}$ 17400/40) hematology control (control blood). This must match the types of samples usually run on the instrument. Specification for this material (assay values and allowed tolerances along with expiry date) is always packed with the approved control material (see chapter 2.9).
The assay value sheet contains a 2D barcode allowing to scan in all values into the analyzer with a 2D barcode reader (optional $\boxed{\text{REF}}$ 16430/11).

2.7 User Interface (Software)

This chapter contains information about the structure and usage of the software implemented menu structure. This integrated software controls instrument operations including calculation and evaluation of measured data, displaying results and information screens, storage and recalling of data.

2.7.1 USER INTERFACE

The user interface of the HumaCount 30^{TS}/HumaCount 80^{TS} analyzer is designed to be intuitive and easy to use, and provide access to all user level functions. You can interact with the HumaCount 30^{TS}/HumaCount 80^{TS} by using only the touch screen and the virtual on-screen keypad, or by using an external keyboard.

2.7.1.1 Using the Touch Screen

The touch screen is a capacitive sensor behind a glass. It must be operated by finger or a conductive stylus designed for capacitive touch screens, since it is not sensitive against pressure.
The touch screen allows selection of menu items and 'pressing' of buttons by gently tapping the surface over the selected item. The touch-screen device used in the HumaCount 30^{TS}/HumaCount 80^{TS} analyzer is selected for reliability, endurance and compatibility with the medical laboratory environment. Simple operations are supported, but multi-touch 'gestures' or multiple tapping are not supported. The surface glass material is resistant to liquids, however it should be dry when in use, otherwise it may not work reliably. Use a damp cloth to clean the glass surface when the analyzer is turned off.

2.7.1.2 Using an External Keyboard

An external keyboard provides the same data entry features as the on-screen virtual keypad presented by the touch screen, with faster typing.

Human

2.7.1.3 Sections of the Graphical User Interface

The graphical user interface (GUI) of HumaCount 30^TS/HumaCount 80^TS is menu driven, and changes its contents based on the function selected.

FIGURE 25

Graphical User
Interface Sections

1 Icon of menu

2 Title of the menu or function

3 Warning message indicator

4 Current time

5 Selectable menu buttons

6 Context sensitive function buttons

7 Background image
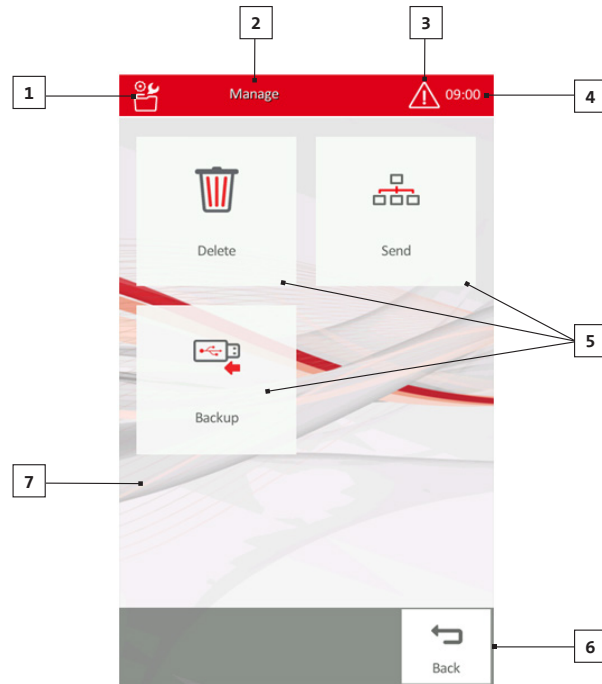
Tap on the warning message indicator ⚠ in the header for details.

2.7.1.4 Button color

Activated buttons are displayed in red color, while inactive or not selectable buttons remain faded.

2.7.1.5 Entering Information

HumaCount 30^TS/HumaCount 80^TS sometimes requires the operator to enter information such as sample ID or patient data. In order to enter information into a data field simply tap or click on its box. The data field will change color indicating that data entry is active for that field. Information can be entered using the virtual on-screen keypad or with an optional external keyboard.

Data is not saved until user presses **Enter** or **Save** or **Accept** to proceed.

2.7.2 MENU SYSTEM

HumaCount 30^TS/HumaCount 80^TS offers a menu tree to access all functions.

2.7.2.1 Main Menu

The Main menu will appear after start-up or when **Home** button is pressed in the menu tree.
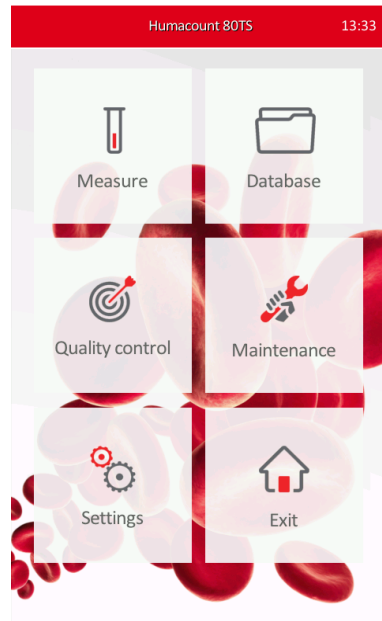
FIGURE 26

HumaCount 30^{TS}/HumaCount 80^{TS}

Main Menu

The different sub-menus are available by pressing their Name or icon.

2.7.3 MENU TREE

The following is a listing of the HumaCount 30^{TS}/ HumaCount 80^{TS} analyzer main menu tree.

FIGURE 27

2.7.3.1 Measure menu

- New Sample – with the following options:
    - o Run
    - o Blank
    - o Normal Range
    - o EMR (LIS) – Remote work list
- Re-run
- Print
- Discard
- Back to Main menu

Human

FIGURE 28

2.7.3.2 Database menu
- Details
- Print
- Statistics
- Filter
- Manage
- Back to Main menu

2.7.3.3 Quality Control menu
- New Lot
- Delete
- Print
- Export
- Monthly view
- Back to Main menu
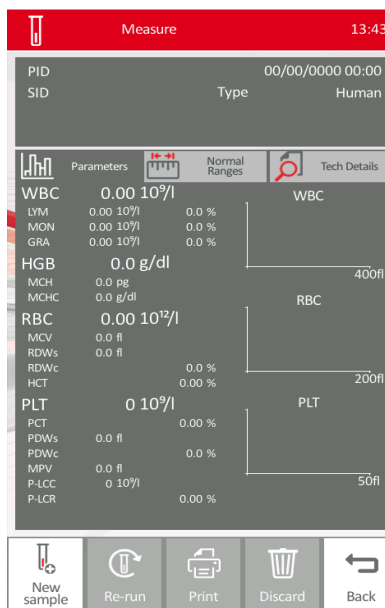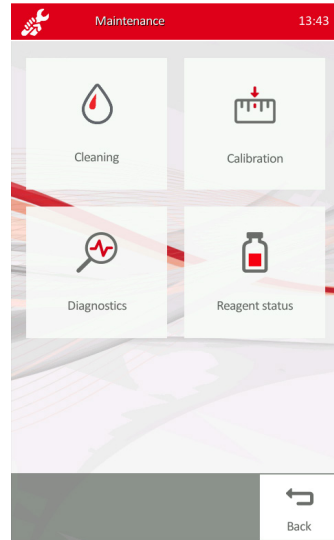
2.7.3.4 Maintenance menu
- Cleaning
- Calibration
- Diagnostics
- Reagent Status
- Back to Main menu

FIGURE 29
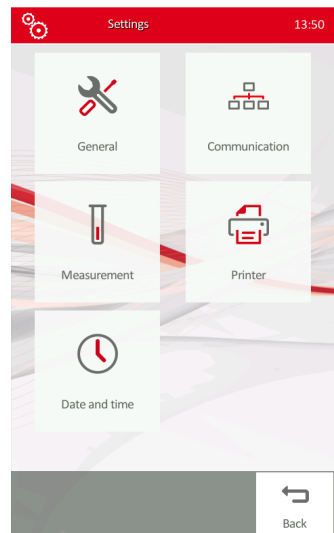
2.7.3.5 Settings menu
- General
  o Sound (enable or disable)
  o Language selection
  o Export format (advanced text, simple text, or extended text)
  o Barcode reader enable/disable
- Communication
  o Device communication (adjust settings)
  o Peer communication (adjust settings)
- Measurement
  o Units
  o Normal Ranges
- Printer (printer settings)
- Date and Time (adjust settings)
- Back to Main menu

2.7.3.6 Exit menu

- Shutdown
- Preparing for shipment
- Logout/Login
- User management (if Admin is logged in)
  - o Add new user
  - o Remove user
  - o Automatic login set
  - o Edit user
- Back to Main menu
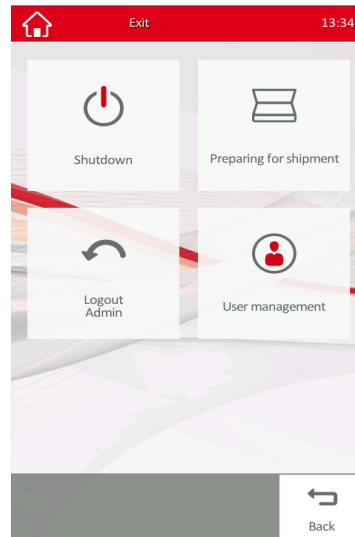
FIGURE 30

2.8 Method of Measurements

2.8.1 PHOTOMETRIC LIGHT ABSORBANCE METHOD

A lysed blood sample (WBC) dilution is analyzed for hemoglobin (HGB) concentration based on its stable chromogen content. The lyse reagent lyses the red blood cells causing them release cellular hemoglobin. The hemoglobin concentration is measured by taking a photometric reading across the HumaCount 30^{TS}/HumaCount 80^{TS} WBC chamber. HGB result is calculated as the difference between a blank and a sample measurement with and without illumination to reduce the effect of liquid refraction and incident light.

All HUMAN branded reagents are cyanide free, and thus are environment-friendly. However, some reagents from other manufacturers may contain cyanide. In that case, cyanide and any other chemical composition formed using cyanide is environmentally dangerous. Contact the reagent manufacturer for safety measures. The manufacturer (HUMAN GmbH) is not liable for any damage caused by using cyanide based reagents with any of its analyzers.
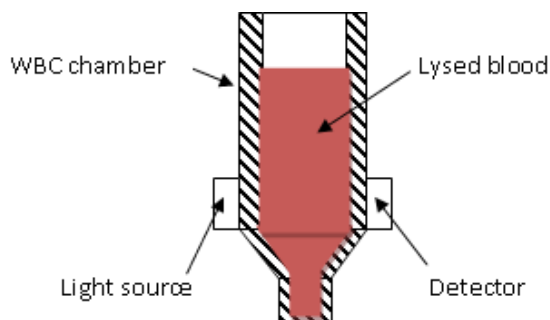
FIGURE 31

Photometric Light
Absorbance Method

Human

2.8.2 VOLUMETRIC IMPEDANCE METHOD

Volumetric impedance method determines cellular concentrations and volume distributions of cells by detecting and measuring changes in electrical impedance when particles suspended in a conductive liquid pass through a small aperture.

FIGURE 32

Volumetric Impedance Method
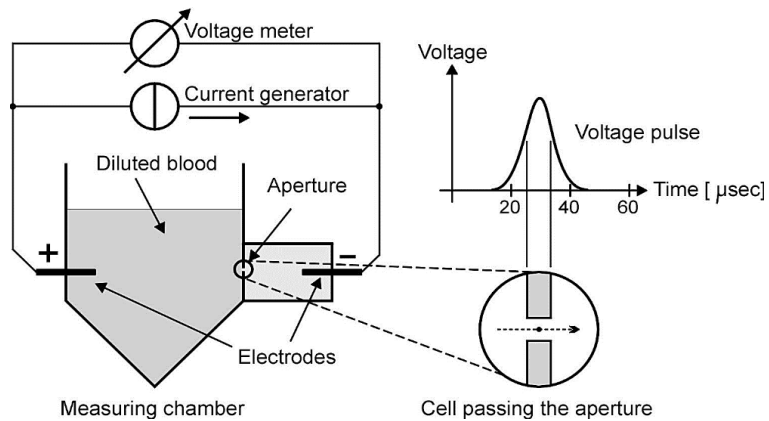
A constant direct current flows between the electrodes on both sides of the aperture. Each cell passing through the aperture causes a change in the electrical impedance of the conductive blood cell suspension (diluted blood). This impedance change is detected by the HumaCount 30^{TS}/HumaCount 80^{TS} electronics and converted to an electrical voltage pulse.

The number of pulses is proportional to the number of particles in the diluted sample.

Intensity (amplitude) of each voltage pulse is proportional to the volume of the particle. The volume distribution diagrams of the particles are displayed as the WBC, RBC, and PLT histograms measured in femtoliter (fl, μm^3) units.

Electronic discrimination by size allows separation of platelets (PLT) and erythrocytes (RBC), and WBC populations. Discriminators are indicated by dotted vertical lines on the histograms.
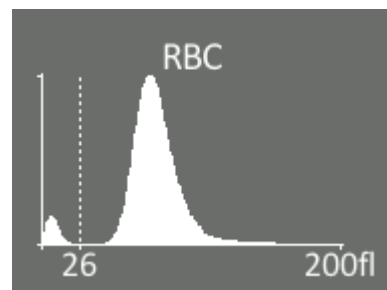
FIGURE 33

RBC histogram
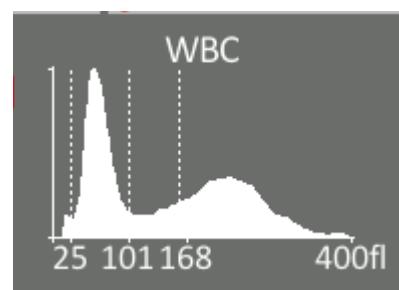
FIGURE 34

WBC histogram

2.8.3 3-PART DIFFERENTIAL ANALYSIS METHOD

HumaCount 30^{TS}/HumaCount 80^{TS} is a 3-part WBC differential hematology analyzer. It uses a WBC lytic process that allows the instrument to simultane- ously count and size-differentiate the white blood cells. There are three ele- ments controlling where the different cell types fall in the 3-population WBC histogram:

- **Chemical formulation and concentration of the lytic reagent:**
  It controls how different WBC types are differentially lysed. Concentration of the lytic reagent controls the rate of the lysing (shrinking) process.

- **Cell type and maturation of the cell types present for analysis:**
  Different WBC types and their grade of maturation have different sensitivi- ties to the lytic reagent. Different WBC types lyse at different rates: lympho- cytes are the most sensitive, while band neutrophils and segmented neutro- phils are the least sensitive. Eosinophils, basophils, immature granulocytes and blasts also have a cell wall membrane that is more sensitive to the lytic process thereby moving them into the Mid-size cell population following the lytic process and at the time, these cells are counted and sized.

- **Time window in the lytic process that the cells are counted and sized:**
  The lytic process is a dynamic reaction, not a static reaction. Therefore, the count and sizing time window used during the lytic process has been opti- mized for performance.

Data of particles are used to present a size distribution histogram of the WBC populations.

Since size distribution is the only data available for the WBC histogram, there is no enough resolution to accurately differentiate more than three distinct WBC populations.

Based on this fact, all possible normal and abnormal WBC cell types fall into those three histogram populations. This being the case, there is also not enough resolution to generate accurately specific morphological flags when abnormal WBC populations are present in the sample.

This is a known limitation of all 3-part differential WBC cell counter systems that are in the market today. Based on the above facts, HumaCount 30^{TS}/ HumaCount 80^{TS} does not have the ability to generate specific morphological flags.

2.8.4 PARAMETERS

HumaCount 30^{TS}/ HumaCount 80^{TS} measures and calculates 22 parameters, list- ed below. For each parameter we list the name, abbreviation and measurement unit in the first column. Short description for each parameter is in the second column.

Human
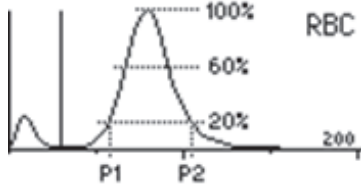
TABLE 6 Parameters	White Blood Cells – **WBC** (cells/l, cells/μl)	Number of leukocytes WBC = WBC$_{cal}$ x counted WBC (cells/l, cells/μl)
	Red Blood Cells – **RBC** (cells/l, cells/μl)	Number of erythrocytes RBC = RBC$_{cal}$ x counted RBC (cells/l, cells/μl)
	Hemoglobin concentration - **HGB** (g/dl, g/l, mmol/l)	Measured photometrically at 540 nm; in each cycle blank measurement is performed on diluent HGB = HGB$_{cal}$l x (HGB$_{measured}$ – HGB$_{blank}$)
	Mean Corpuscular Volume - **MCV**(fl)	Average volume of individual erythrocytes derived from the RBC histogram.
	Hematocrit – **HCT** (percentage, absolute)	Calculated from the RBC and MCV values. HCT$_{percentage}$ = RBC x MCV x 100 HCT$_{absolute}$ = RBC x MCV
	Mean Corpuscular Hemoglobin – **MCH** (pg, fmol)	Average hemoglobin content of erythrocytes, calculated from RBC and HGB values. MCH = HGB / RBC
	Mean Corpuscular Hemoglobin Concentration – **MCHC** (g/dl, g/l, mmol/l)	Calculated from the HGB and HCT values. MCHC = HGB / HCT$_{absolute}$ Unit of measurement is displayed according to the one chosen for HGB result (g/dl, g/l or mmol/l)
FIGURE 35	Red Cell Distribution Width – **RDW-SD** (fl) Platelet Distribution Width – **PDW-SD** (fl) Red cell Distribution Width – **RDW-CV** (absolute) Platelet Distribution Width – **PDW-CV** (absolute)	The distribution width of the erythrocyte or platelet population derived from the histogram at 20% of peak xDW-SD = RDW$_{cal}$ x (P2 - P1) (fl), xDW-CV = RDW$_{cal}$ x 0.56 x (P2 - P1) / (P2 + P1) by the factor of 0.56 CV is corrected to the 60% cut
	Platelet – **PLT** (cells/l, cells/μl)	Number of thrombocytes (platelets) PLT = PLT$_{cal}$ x counted PLT (cells/l, cells/μl)
	Mean Platelet Volume – **MPV** (fl)	Average volume of individual platelets derived from the PLT histogram

Thrombocrit – **PCT** (percentage, absolute)	Calculated from the PLT and MPV values $PCT_{percentage} = PLT \times MPV \times 100$ $PCT_{absolute} = PLT \times MPV$	
White blood cell 3-part differential: **LYM, LYM%** : count and % of lymphocytes **MID, MID%** : count and % of medium size cells **GRA, GRA%**: count and % of granulocytes	Absolute values counted in the channels determined by the three WBC discriminators: Percentages calculated from the absolute WBC value.	FIGURE 37
- **P-LCC** Platelet large cell concentration ▷ - **P-LCR** Platelet large cell ratio ▷ P-LCR and P-LCC are important parameters to investigate thrombocytopenia. Specification are described as below. P-LCC = platelet larger than 12 fl and smaller than 30 fl. P-LCR = P-LCC/PLT (PLT = total number of platelets, PL = femtoliter)	▷ research parameter only	FIGURE 36
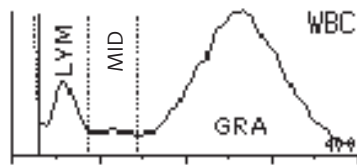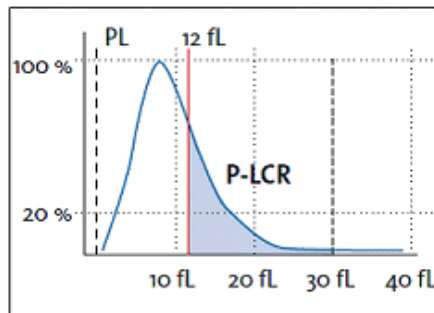
$$MPV\ (fL) \quad = \quad \frac{PCT\ (\%)}{PLT\ (\times 10^3/\mu L)} \times 10000$$

2.8.5 ABSOLUTE AND LINEARITY RANGES OF PARAMETERS

The analyzer provides specified accuracy within its linearity range. Beyond this linearity range, the instrument can display results but accuracy is impaired. If a value is over the maximum range of guaranteed linearity, the instrument cannot measure it and the result will be marked with an E (Error) flag.

To measure a sample, whose parameters exceed the maximum value indicated in the table below, pre-dilution is recommended.

See section 3.2.6 of this manual.

Linearity ranges of primary parameters in normal measuring mode:

Parameter	Linearity Ranges	Maximum	Unit
WBC	0...100	150	10^9 cells/liter
RBC	0...15	20	10^{12} cells/liter
PLT	0...700	1000	10^9 cells/liter
HGB	0...250	400	g/l
HCT	0...100	-	%
MCV	30...150	-	fl
MPV	3...30	-	fl

Linearity ranges for 1:5 pre-dilution mode:

Parameter	Linearity Ranges	Maximum	Unit
WBC	2...200	300	10^9 cells/liter
RBC	1...30	40	10^{12} cells/liter
PLT	100...2000	3000	10^9 cells/liter

2.9 Quality control

Quality control menu allows the operator to monitor day-to-day reproducibility, and accuracy of HumaCount 30[TS]/HumaCount 80[TS]. Before performing QC measurements the target values and tolerance ranges for each parameter must be entered for the QC material (control blood) you wish to use.

Target values and tolerance ranges are listed on the assay sheet of the QC material.

! Target values of the control material should be set only once, when you start using the given lot. Resetting parameters deletes previous QC results of that level. Any change in the QC material setting deletes previous QC results. It is strongly recommended to print QC results prior to changes.

In QC menu the operator can enter a new lot of controls (by scanning the barcode, loading from data file or by entering the assay data from the assay sheet manually), review data of previous control lots, and print Levy-Jennings graphs. For instructions on running QC samples, refer to chapter 3.2.7.

! Always follow the manufacturer's instructions for warming and mixing of the QC material before use. Instructions are listed in the package insert instruction sheet. Keep track of the expiration date and open-bottle stability of the QC material. Most QC materials (controls) are shipped with non-piercable hard caps. Please, remove the cap before running the control.

2.9.1 QC DATABASE

QC database contains the results of the QC measurements in both table and Levy-Jennings formats.

To access a QC Database, select the Quality Control in Main Menu. All QC files will be displayed (as shown on the left).

FIGURE 39
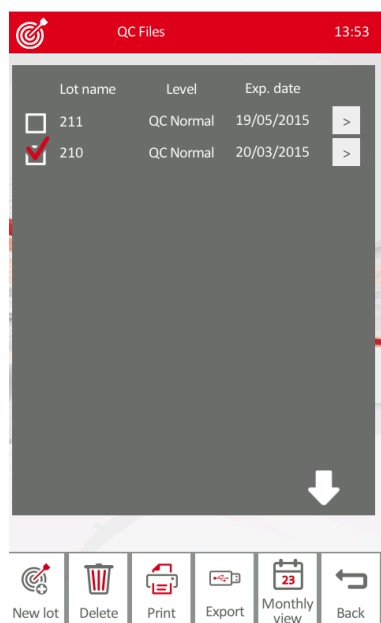
Use ↑ and ↓ to browse up/down in the list.

Select the lot number by tapping the **circle** in front of the lot number, and tap > to display Levy-Jennings chart.

Press **New lot** if you wish to enter a new control lot.

Monthly view brings up this screen for selecting month by tapping on ← and → in the header:
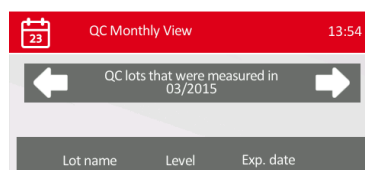
FIGURE 38

After selecting QC lots, **Delete** will delete all data related to the selected QC lots, **Print** will print, **Export** will save data onto a USB pen drive.

Press **Back** to return to Main menu.

2.9.2 ENTERING NEW LOT OF QC MATERIAL

In the Main menu/Quality control menu press **New lot.**

New lot input menu brings up.

Enter the lot number of the new lot of control material by pressing **LOT** box (e.g. B053) and press **Enter**.

If you have a 2D (Q-R) bar code reader connected to the analyzer, then target values and tolerance ranges can be read from the HumaCount 30^TS/ HumaCount 80^TS. assay sheet, by scanning the Q-R code (see example below):
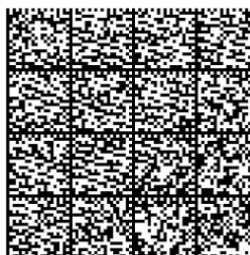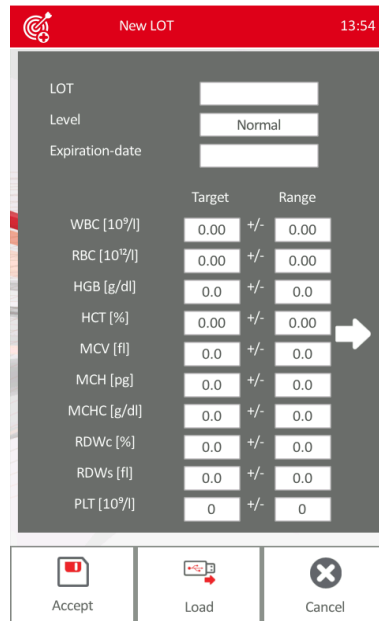
FIGURE 40

Human

FIGURE 41

Select **Level** as Low, Normal or High, and the correct **expiration date**. Type in target and range values manually.

When finished, press **Accept** to save QC lot data, or **Cancel** to return to previous menu without saving changes.

2.9.3 LEVY-JENNINGS QC CHART

FIGURE 42
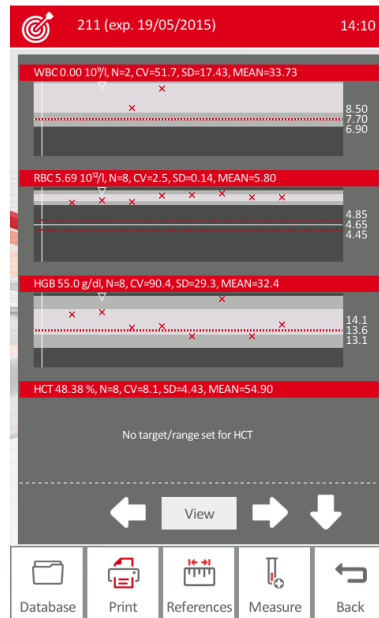
Levy-Jennings charts are displayed after selecting a control lot in Main menu/Quality control and pressing → arrow.

Measurement points are indicated as white 'o'. The mean and the specified range are displayed on the right for each parameter. If a result is out of range it is marked by a red 'x' on the chart.

Press **Print** to print table or Levy-Jennings charts.

Use ← and → to move between data points.

Press **View** to see the measurement results screen for the actual data point.

Use ↑ and ↓ to browse between parameters.

Tap **References** to show reference values.

Press Database to see the QC measurement results in database view. Refer to chapter 4.2 on database options.

Press **Measure** to start a new QC run of the selected lot, indicated in the header.

3 ROUTINE UTILIZATION AND MEASUREMENT

3.1 Sample Handling

Since some time will usually elapse between collection of samples and counting, it is necessary to preserve the sample with an anti-coagulant to prevent large groups of cells forming into clots or lumps of cell matter that will clog the cell counter. Choice of anti-coagulant is very important, as some anticoagulants will affect the shape and size of blood cells. In general **K3-EDTA** (liquid), preferably potassium based, is the only anti-coagulant recommended for use with electronic blood counters.

Care must be taken when using homemade containers pre-dosed with EDTA. If the container is not filled with enough blood, the ratio of EDTA to blood may reach a level, which results in osmotic transfer from the RBCs which shrinks them. **The ratio of EDTA to blood should not exceed 3 mg/ml.** Generally, we suggest using pre-manufactured sample tubes containing the necessary amount of EDTA. However, make sure not to get short draws. Also, when taking blood, please make sure that requirements attached to sample tubes are met.

We recommend HumaTube K3-EDTA (REF 73040/12).

To initiate analysis:
1. Invert the closed sample tube at least 8 times to achieve a homogenous sample. Do not shake the sample, because micro-bubbles can form inside which may cause erroneous sampling!

! **Make sure to fill sample tubes to at least 7-8 mm height with blood otherwise correct sampling cannot be guaranteed! Observe marking on sample tube.**

! **If you hurt yourself during analysis, biohazard substances can cause infection! Always take special care to sharp objects and always use rubber gloves!**

Human

3.2 Sample Analysis

3.2.1 SAMPLE PREPARATION

Use K-EDTA anti-coagulated fresh whole blood as sample. **Prior** to sampling, mix the sample gently by **inverting it at least 8 times. Do not shake** as this could damage blood cells.

We recommend HumaRoll ($\boxed{\text{REF}}$ 15460). You have the possibility to use 3 different interchangeable adapters for different tube types. Tube types are shown in the next pictures:

- Vacutainer tube adapter for 3-5 ml sample tubes
- Micro adapter for micro-tainers
- Control adapter for 2 ml blood control vial

FIGURE 43

Tubes used in Vacutainer adapter

Vacutainer with sample blood (cap removed)

Sample tube with 5 ml control blood

Below you can see 3 types of microtainer tubes used in micro adapter. These are only examples given by us, you can try to use other type of microtainers as well.
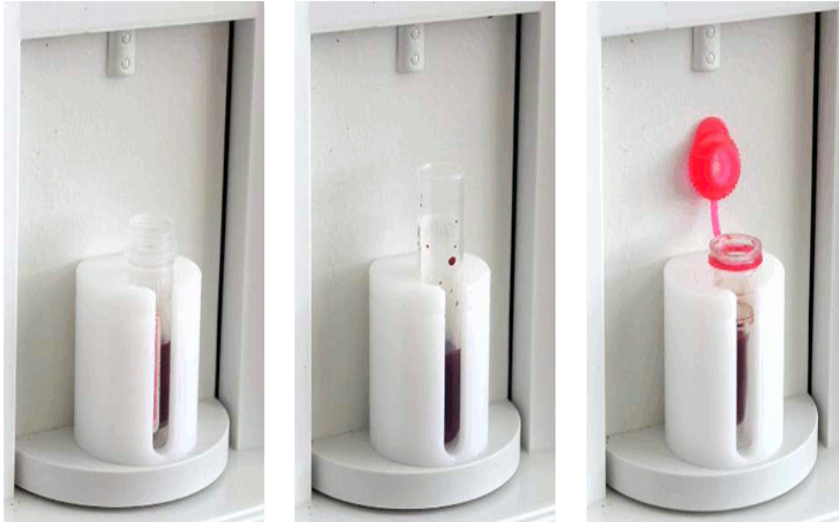
FIGURE 44
Tubes used in micro adapter

There must be at least 8 mm sample level for safe sampling

Be careful to place the tube with the cap always in the position shown above, otherwise the cap can get stuck when the sample holder turns.

FIGURE 45
Tubes used in control adapter

The sample rotor will turn the vial into the inside of the instrument and needle draws sample from the tube. The aspirating needle is retracted, while its outer surface is automatically rinsed with diluent by needle wash head. This insures

! **Remove the cap!! It is very important because the tip will not pierce the cap!**

Human

the low carry-over between samples. After a few seconds, the rotor turns out. Now you can remove the sample tube from the adapter.

3.2.2 RUNNING SAMPLES

After powering up HumaCount 30^{TS}/HumaCount 80^{TS} you need to perform the following steps in order to run samples.

FIGURE 46

Ensure that:

- All reagents and the waste are properly connected
- All environmental conditions are met
- Blank measurement has been run and accepted (see section 3.2.3 below).
- Quality Control material have been tested and produced acceptable results, so that calibration of the analyzer is valid (see chapter 2.9).
- Specimen is ready to use, mixed well and it is in the recommended time for measurement (see section 3.1).

3.2.3 RUNNING BLANK MEASUREMENT

There must be an accepted Blank measurement performed before running controls, calibrator or patient samples.

Blank measurement must be performed:

- Before sample analysis starts, and at the beginning of every shift
- If the analyzer was not used from more than 3 hours
- After any reagent replacement or service/maintenance operation

In Blank measurement mode, the analyzer will perform a measurement cycle without sample to check cleanliness of the analyzer. After this cycle the Blank values are displayed.

New sample   14:12

Sample ID	AUTO_00012
Type	Human
Patient ID	
Name	
Birthdate	
Sex	---
Doctor	
Prediluted	No
Sampling depth	---

Run | Blank | Normal ranges | EMR(LIS) | Cancel
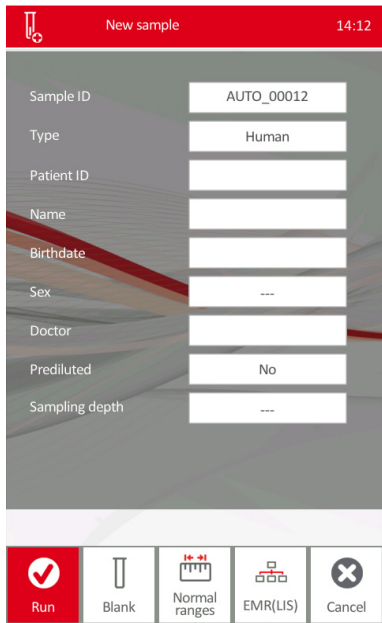
Follow the process below to run Blank:

- In the Main menu select **Measure**, then **New Sample**
- Press **Blank** to perform a blank cycle
- After 1 minute, the analyzer will display Blank values

Blank measure

Press OK to measure blank!

OK   Cancel
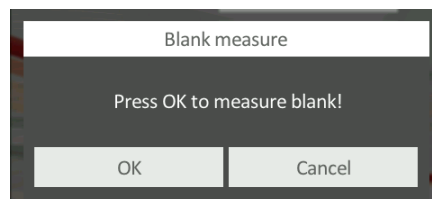
Blank results screen will appear.

FIGURE 47

Blank values ranges:

Parameter	Acceptable Blank range
HGB	0-1 g/dl
WBC	0-0.5 x10^3 cells/µl
PLT	0-25 x10^3 cells/µl
RBC	0-0.05 x10^6 cells/µl

If the blank values are within the above ranges, press **Accept** to store the blank values.
If one or more parameters are out of range, repeat Blank measurement 2-3 times, by pressing **Re-blank** key.
If the Blank is stable high for certain parameters, run Cleaning or Hard cleaning in Maintenance menu (refer to section 4.8.1).
Press **Print** to print blank results.
Press **Back** to return to measure menu.

Measure   14:19

PID   20/03/2015 14:19
SID   0   Type   Blank

Parameters | Normal Ranges | Tech Details

WBC	0.06 10^9/l	WBC
LYM	10^9/l	%
MON	10^9/l	%
GRA	10^9/l	%
HGB	0.0 g/dl	
MCH	pg	
MCHC	g/dl	
RBC	0.00 10^{12}/l	
MCV	fl	
RDWs	fl	
RDWc		%
HCT		%
PLT	2 10^9/l	PLT
PCT		%
PDWs	fl	
PDWc		%
MPV	12.3 fl	
P-LCC	10^9/l	
P-LCR		%

Accept | Re-blank | Print | Discard | Back

FIGURE 48

3.2.4 PATIENT SAMPLE RUN

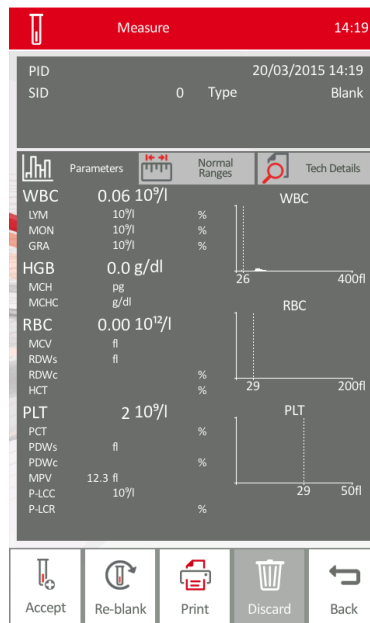There must be an accepted Blank measurement performed before running samples (see section 3.2.3)

FIGURE 49

Follow the process below to run patient samples:
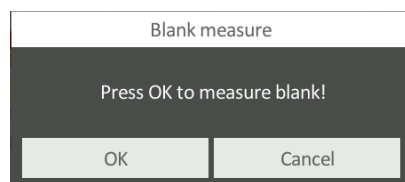
- Mix the sample gently but thoroughly by inverting the sample tube 8-10 times (refer to section 3.1).
- In the Main menu select **Measure**, then **New Sample.**
- Insert the applicable adapter into the sample rotor.
- Open the tube if necessary.
- Put the sample tube into the adapter
- Adjust sampling depth if needed (see section 0).

- Select sample profile (Human, Male, Female, Profile 1..7).
- Select Pre-diluted mode if needed.
- Select Small Sample mode if needed (open vial).
- Identify the sample (sample ID) either manually or by scanning the barcode. Refer to section 5.7.
- Push **Run** key on the display.

The sample rotor will turn in and the needle aspirates 100 µl of sample from the tube. Then the sampling needle is retracted, while its outer surface is automatically rinsed with diluent. After a few seconds, the sample rotor turns out.

- Remove the sample tube from the adapter.

FIGURE 50

If there was no Blank measurement performed before, then the SW will display the following message. Press **OK** to measure Blank.

You have the following options:

- You can **print** the results by pressing Print button.
- Return to measurement panel by tapping **Back** button.
- Run a new sample by pushing **New sample** button
- Re-run the previous sample with the same sample ID by pressing Re-run button
- Discard the measurement record if you made a mistake, or error is displayed. Press **Discard** button, and the actual measurement record will be deleted from the Database

Please, refer to chapter 3.3 for result interpretation, and understanding flagging.
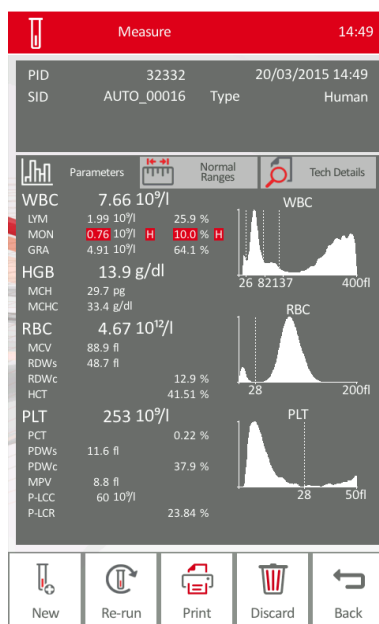
FIGURE 51

! **Do not reach inside the instrument during piercing because the needle can cause injury.**

3.2.5 REMOTE WORK LIST (EMR) MODE
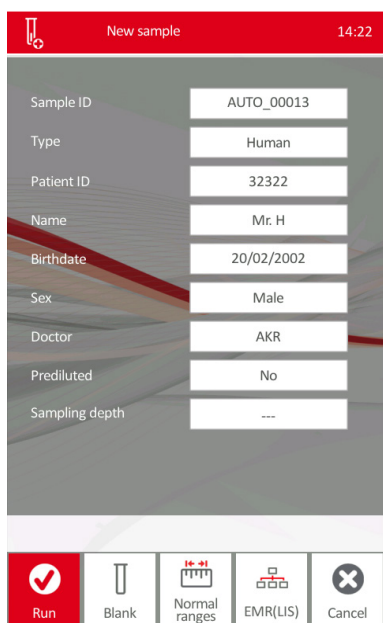
You have the following options:

If Remote work list was transferred to the HumaCount 30^{TS}/HumaCount 80^{TS} from LIS (laboratory information system), then this work list is available in Measure menu after pressing **New sample**.

Press **EMR(LIS)** to see the work list of samples to be measured:
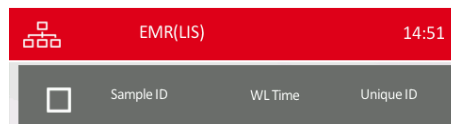
Select sample ID to measure that sample, or scan the bar code of a sample from the list to automatically set Sample ID and go to run mode.

Press **Run** to measure EMR (remote) sample.

FIGURE 52

Human

3.2.6 PRE-DILUTED SAMPLE RUN

This mode allows the operator to measure CBC results on samples having only small volumes, or when some parameters are out of the linearity range.

Sample must be diluted manually in an appropriate, clean sample tube with physiological saline at a ratio of **1 part blood sample to 5 parts clean saline.** It is important to ensure there is a sufficient final volume in the tube to enable the analyzer to aspirate the diluted sample satisfactorily.

The suggested minimum diluted sample volume is 300 µl for a Vacutainer sample tube.

When the pre-dilute mode is selected, all results are automatically corrected and calculated for the dilution factor of 1:6. Please, refer to Pre-diluted calibration in section 4.9.5 as well.

! Make sure to use physiological saline and not diluent to prepare diluted samples, otherwise some parameters may change due to the stabilizing effect of diluent.

FIGURE 53

Follow the steps below to run pre-diluted sample:

Prepare a diluted patient sample at a dilution ratio of 1:6 (1 part blood to 5 parts saline) using physiological saline. Please ensure that the sample is well mixed and measured on the analyzer immediately after preparation.

- Go to Measure menu, press **New Sample**
- Tap **Prediluted** box on the screen to change it to **YES**.
- Place the diluted sample into the appropriate sample adapter
- Initiate the measurement by pressing **Run** button.
- Analysis will take place. CBC results are corrected for the dilution factor, and displayed on the screen and can be printed.
- Remove sample when prompted.

3.2.7 CONTROL RUNS AND CONTROL BAR CODES

HumaCount 30^{TS}/HumaCount 80^{TS} offers Control measurement in Measure menu by selecting measurement type as Control.

With an optional data-matrix bar code reader, the operator can read the bar code of the Control vial and the system will recognize it, if the actual Control LOT has been already read in as quality control material. In this case the QC measure menu will pop-up and the operator only has to tap Run to initiate control measurement. Refer to section 2.9 for details on Quality control functions.
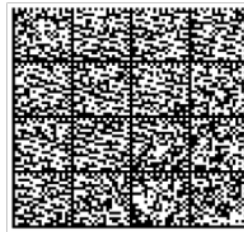
FIGURE 54

3.3 Interpretation of Results

This chapter provides description about interpreting and understanding results and flags.

3.3.1 RESULTS SCREEN

Result screen of HumaCount 30^{TS}/HumaCount 80^{TS} is displayed in 3 separate screens, where the header will be the same.

3.3.1.1 Parameter screen

In Parameters screen the Parameters tag is highlighted. There are three major sections.

In Parameters screen the Parameters tag is highlighted. There are three major sections.

Sample identification header with:
PID – patient ID, **date and time** of sample run,
SID – sample ID and sample **Type** (Human in this case)
WARNING – flags will be shown, **LYSE** setting, **Prediluted** and **Needle settings** will also appear here.
Parameters measured:
Parameter names, values, units, and evaluation if those are lower, inside or higher than the normal range.
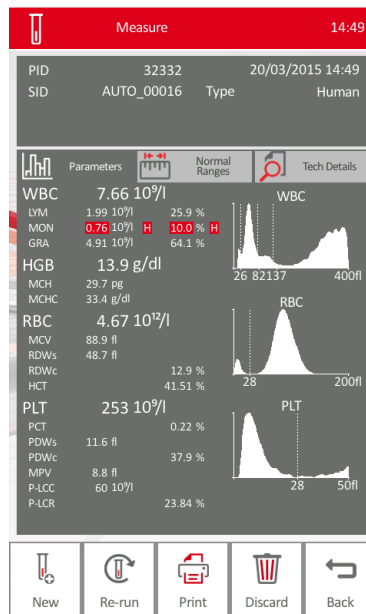
FIGURE 55

Values within the normal range are displayed in white, and outside the normal range are displayed in red, <u>and flagged:</u>

L – if lower than the normal range, or

H – if higher than the normal range specified by the measurement type.

Histograms: Graphical information about volume distribution of WBC, RBC and PLT. Histograms indicate discriminators by vertical lines that separate different cell populations.

3.3.1.2 Normal ranges screen

FIGURE 56
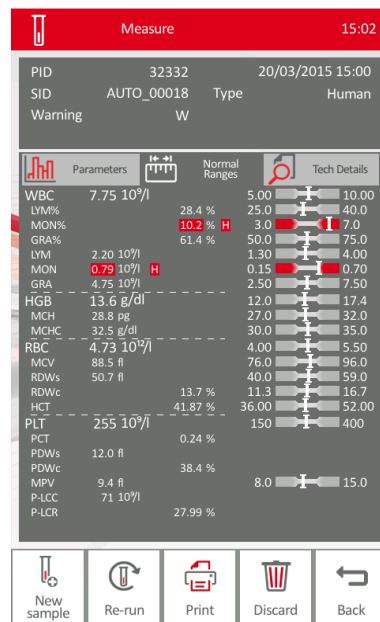
Pressing **Normal Ranges** tag brings up this screen.

<u>In normal range screen:</u> in place of the histograms on the right, normal ranges will be displayed in a graphic format.

Each value will be indicated by positioning a white arrow within the normal range graphics.

Low and high limits of the normal range are displayed on the two sides of the line. If the value is out of normal range, the line is red, otherwise it is shown in green.

If a parameter has no normal range defined then no normal range graphics will appear.

3.3.1.3 Technical details screen

Pressing **Tech Details** tag below the sample ID header, the following technical details screen appears.

Probe voltage:
This section shows electrode voltages for WBC and RBC counting, min. and max. values, for service purpose only.

WBC lyse volume: 0.9 ml.
It shows amount of lyse used for the measurement. Lyse setting can be modified by the user before measurement run. See section 6.2 for details on lyse volume setting.

Diagnostic flags: This area shows evaluations made by the analyzer SW based on the results. There may be numerous diagnostic flags and suspects appear here.

Warning flags are displayed for the measurement. See section 3.3.2 below for details on warning flags.
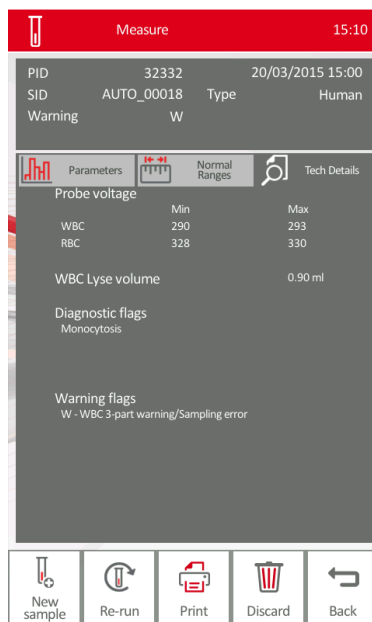
FIGURE 57

3.3.2 PARAMETER FLAGS

This section describes diagnostic and warning flags indicated by HumaCount 30^{TS}/HumaCount 80^{T}.

3.3.2.1 Out of normal range flags

The first flagging method is evaluation against the normal ranges.
If a parameter is out of range, it will generate:

-   **L** flag if under the normal range, or
-   **H** flag if over the normal range.

In addition, the flagged parameters are highlighted in red.

The operator can establish normal ranges for each Profile provided by the software (refer to section 4.7.5).
If 0 (zero) value is set for range limit of a parameter, it will not be verified, and no normal range graphics will appear behind it.

FIGURE 58

Human

3.3.2.2 Warning flags of Differential Parameters

If the following flags appear at differential parameters, see possible indication column for suspect.

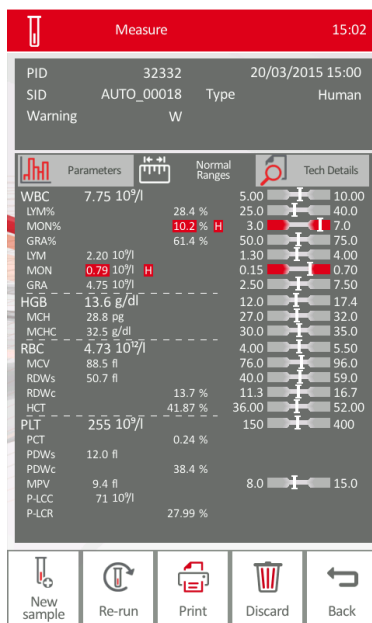|	Parameter	Flag	Flag type	Flag Description	Possible Indication
TABLE 9	LYM%	H	Distributional	LYM cell population >46%	Lymphocytosis; Variant lymphocytes; Chronic lymphoid leukemia;
	LYM%	L	Distributional	LYM cell population <11%	Lymphopenia; Chemotherapy; HIV
	MID%	H	Distributional	MID cell population >17%	Abnormal WBC cell types; immature granulocytes; blasts; basophilia, monocytosis, esosinophilia; Chronic inflammation; Leukoerythroblastic pattern if combined with a "d" or "D" region interference flag.
	GRA%	H	Distributional	GRA cell population > 81%	Granulocytosis; left shifted myeloid maturation (Bands); Bacterial Infection
	N/A	D	Region Interference	Interference between PLT and WBC population	WBC fragments; RBC agglutination
	N/A	d	Region Interference	Interference between PLT and RBC population	Nucleated RBC's; Giant platelets; Platelet clumps

3.3.3 MEASUREMENT CONDITION FLAGS

If the instrument cannot interpret measurements appropriately, measurement condition flags will be attached to the result. These flags are displayed in the header of the results screen, after 'Warning', and appear in Tech. details screen in the lower section, with a short explanation.

3.3.3.1 Flagging on WBC and HGB channels

Uppercase letters refer to WBC or HGB flags.

	Flag	Meaning	Explanation, recommended user action
TABLE 10	E	No WBC 3-part differential	Possibly lyse problem, or sample was inadequate. May also occur in pathological lymphocytosis. Rerun sample, making sure it is enough.
	W	3-part differential warning	Possibly lyse problem, or the sample is more than 7 hours old. Run prime lyse, and rerun sample.

G	HGB blank is high, or no HGB blank	Repeat blank measurement. If HGB blank is still not stable, there are probably bubbles in the WBC chamber. Run prime lyse, run cleaning and try blank again. Close the side door if open during measurement.
B	WBC blank is high, or no WBC blank	Possibly lyse contamination, or noise problem. Repeat blank measurement, or run prime lyse and try blank measurement again.
C	WBC clogging	Aperture clogging. Perform cleaning or hard cleaning and rerun sample. If this flag persists, please, contact your Service Personnel. Low temperature reagent can cause it as well (mainly diluent), in this case, you will have to wait until they reach room temperature.
M	WBC coincidence is too high. Linearity error.	Rerun sample in pre-diluted mode. See section 3.2.6 for details.
D	WBC/RBC threshold Interference	The RBC-WBC discriminator is over 45 fl on the histogram. Rerun sample with higher lyse volume setting.

! Tip: Flagged results should be repeated.

3.3.3.2 Flagging on RBC/PLT channel

Lowercase letters refer to RBC/PLT flags.

Flag	Meaning	Explanation, recommended user action
p	PLT blank is high, or no PLT blank	Run cleaning or Hard cleaning and repeat blank measurement. Diluent or system cleanliness problem. Check for bubbles at reagent inlets, and prime diluent. If it is stable high, replace the diluent by opening a new tank.
b	RBC blank is high, or no RBC blank	Same action as in case of warning flag p.
c	RBC/PLT clogging	See remedial action above described in case of warning flag C.
m	RBC/PLT coincidence is too high. Linearity error.	Rerun sample in pre-diluted mode. Refer to section 3.2.6 for details.
d	RBC/PLT threshold Interference	The analytical software could not separate RBC's from PLT's because of a population overlap. Possibly clumped PLTs.

TABLE 11

! Tip: Flagged results should be repeated.

3.3.4 BLANK MEASUREMENT FLAGGING

Parameters will be flagged if the operator accepted high Blank value. In some cases the associated parameter is flagged, but in other case it is dashed out. See details below.

TABLE 12

Parameter	Value is displayed but flagged by '* '	Value is dashed out '——' and flagged by 'E' (error) flag
HGB	1 – 2.5 g/dl	> 2.5 g/dl
WBC	0.6 - 1.0 x10^3 cells/µL	> 1.0 x10^3 cells/µL
PLT	26 - 50 x10^3 cells/µL	> 50 x10^3 cells/µL
RBC	0.06 - 0.5 x10^6 cells/µL	> 0.5 x10^6 cells/µL

Tip: Perform cleaning, and run Blank measurement again to correct blank measurement flags.

3.3.5 DIAGNOSTIC FLAGS

In order to assist the operator, the analyzer provides dignostic flags. The flags are generated, if the results are not in the defined reference ranges. The preset reference ranges of the parameters and diagnostic flags are shown below in Table 13 for adults. Reference ranges may vary for different populations, regions age and many other factors.

TABLE 13

Diagnostic flags and reference range of parameters

Possible Disease	Flag (low)	Normal	Flag (high)	Possible Disease
Leukopenia	WBC-	WBC	WBC+	Leukocytosis
Neutropenia	GRA-	GRA	GRA+	Neutrophilia
Lymphopenia	LYM-	LYM	LYM+	Lymphocytosis
		MON	MON+	Monocytosis
		RBC	RBC+	Erythrocytosis
Anemia	HGB-	HGB		
Microcytosis	MCV-	MCV	MCV+	Macrocytosis
		RDW	RDW+	Anisocytosis
Hypochromia	MCHC-	MCHC		
Thrombocytopenia	PLT-	PLT	PLT+	Thrombocytosis
		PDW	PDW+	Macro PLT

The diagnostic flags are only a hint supporting the interpretation of results, but need always to be verified by a clinician.

In order to modify the normal ranges refer to chapter 4.7.5.

3.4 Known Limitations in WBC Differentials

- Each laboratory is responsible for establishing its own protocols for addressing flags. HumaCount 30^TS/HumaCount 80^TS classifies cells based on size differentiation only and does not have the capability of flagging specimens with morphologic abnormalities of any of the particular cell types.
- Due to the limited performance characteristics of HumaCount 30^TS/HumaCount 80^TS, some abnormal cell types that are present at low frequencies (e.g. ≥1% leukemic blast or plasma cell, >5% atypical lymphocytes, >2% metamyelocytes, ≥1% myelocyte or 1% promyelocyte or a few blast abnormalities in the absence of a leukocytosis or lymphocytosis) are not likely to be identified.
- HumaCount 30^TS/HumaCount 80^TS does not have the resolution to flag atypical lymphocytes or abnormal lymphocytes from normal lymphocytes, based strictly on size differentiation.
- Nucleated RBCs are not classified or flagged by the HumaCount 30^TS/HumaCount 80^TS analyzer.

3.5 Sample Tube Support

3.5.1 SUPPORTED SAMPLE TUBE TYPES
HumaCount 30^TS/HumaCount 80^TS supports the following K2- or K3-EDTA, 13x75mm sample-tubes:
- Becton Dickinson (BD) Vacutainer®
- Terumo Venosafe®
- Sarstedt Monovette® (in open mode only)

Use only sample tubes with K2- or K3-EDTA anticoagulant.

You can use sample tubes from other vendors if the below conditions are met:
- It should be mechanically compatible (13x75 mm family) with the sample rotor and adapter
- It can be pierced or should be used in open vial mode
- If the bottom of the tube is lifted, adjustment of the sampling depth is necessary (see section 3.5.2 below).

It is recommended to contact your service representative before using another type of sample tube.

! Although these sample tube types are designed for multiple piercing, it is recommended to remove the cap after 3-4 piercing cycles. Small rubber bits can crumble into the blood and adversely affect the performance of theHumaCount 30^TS/HumaCount 80^TS analyzer, or it can cause aperture clogging.

Human

3.5.2 SAMPLING DEPTH

HumaCount 30^{TS}/HumaCount 80^{TS} is equipped with a piercing needle capable of aspirating samples from closed sample tubes. Since piercing is performed from the top, the needle goes to the bottom of the sample vial to take sample if few blood is available in the tube.

In case of using a sample tube with a lifted bottom (such as Sarstedt Monovette®), the sampling depth should be adjusted before pressing Run button in Measure menu.

Sampling depth can be adjusted in the following steps: -2mm, ——, +5mm, +10mm, +15mm.

Default sampling depth is: 0 mm, indicated by '——' in the selection list, and it means approximately 3 mm clearance between the bottom of sample tube and the tip of the piercing needle.

Example to set up sampling depth correctly: if the bottom of the tube is lifted by 12 mm, select +15 mm setting to make sure the needle will not intend to pierce the bottom of the sample tube.

! **If sampling depth is not adjusted to the tube correctly, the piercing mechanics will try to pierce the bottom of the tube, which may result in damage to the sampling needle, or pneumatic error of Vertical motor.**

4 ADVANCED OPERATION

4.1 Diagnostic menu

Diagnostics menu can be reached via **"Maintenance"** in the Main menu.

Then press **"Diagnostics"**.

Diagnostics menu contains **Device Information, Statistics,** and **Self test** sub-menus.

Select the desired submenu.

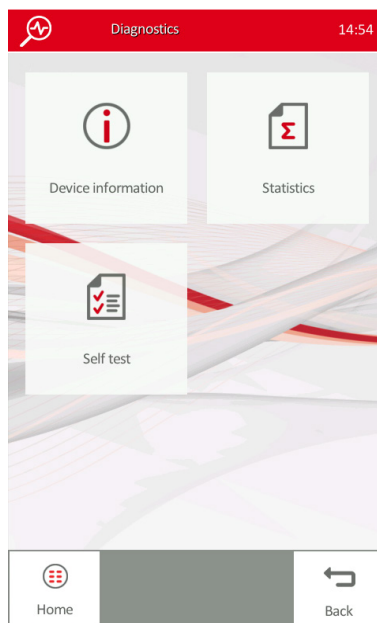Tap **Home** to go to Main menu to exit to Maintenance menu.

FIGURE 59

4.1.1 DEVICE INFORMATION

Device information includes the Model, Serial Number, SW version, PIC version, and SW Compilation date, as shown below:
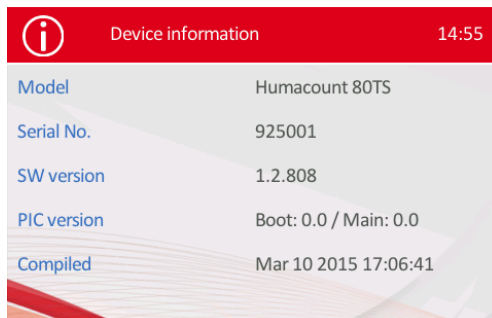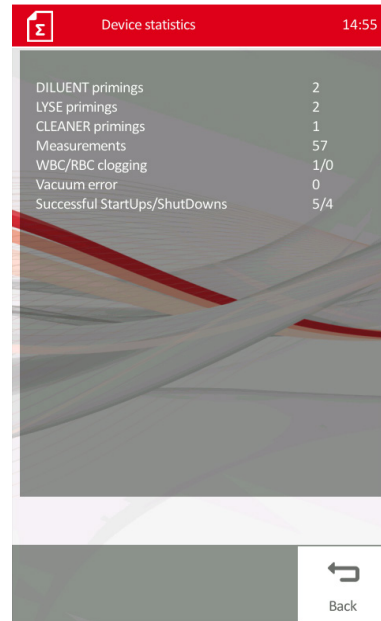

FIGURE 60

4.1.2 DEVICE STATISTICS

Device statistics show statistics of measurement cycles, errors, and other technical information.
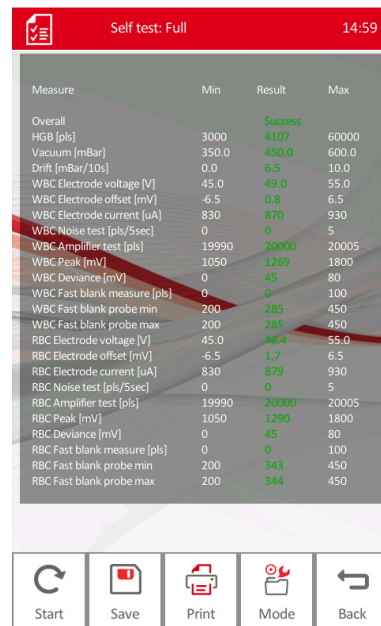
Device statistics	14:55
DILUENT primings	2
LYSE primings	2
CLEANER primings	1
Measurements	57
WBC/RBC clogging	1/0
Vacuum error	0
Successful StartUps/ShutDowns	5/4

Back

Press **Back** to return to previous menu.

4.1.3 SELF-TEST

Run self-test to verify operation of essential components of the analyzer.

Self test: Full			14:59
Measure	Min	Result	Max
Overall		Success	
HGB [pls]	3000	4107	60000
Vacuum [mBar]	350.0	450.0	600.0
Drift [mBar/10s]	0.0	6.5	10.0
WBC Electrode voltage [V]	45.0	49.0	55.0
WBC Electrode offset [mV]	-6.5	0.8	6.5
WBC Electrode current [uA]	830	870	930
WBC Noise test [pls/5sec]	0	0	5
WBC Amplifier test [pls]	19990	20000	20005
WBC Peak [mV]	1050	1269	1800
WBC Deviance [mV]	0	45	80
WBC Fast blank measure [pls]	0	0	100
WBC Fast blank probe min	200	285	450
WBC Fast blank probe max	200	285	450
RBC Electrode voltage [V]	45.0	49.4	55.0
RBC Electrode offset [mV]	-6.5	1.7	6.5
RBC Electrode current [uA]	830	879	930
RBC Noise test [pls/5sec]	0	0	5
RBC Amplifier test [pls]	19990	20000	20005
RBC Peak [mV]	1050	1290	1800
RBC Deviance [mV]	0	45	80
RBC Fast blank measure [pls]	0	0	100
RBC Fast blank probe min	200	343	450
RBC Fast blank probe max	200	344	450

Start   Save   Print   Mode   Back

! **If any of the self-test parameters fail, contact your local service representative.**

Self-test should be performed:
- After installation.
- After replacing any component.
- After extended time not in use.
- If you have any doubt that the analyzer is not reliable.

When self-test is finished, HumaCount 30^{TS}/HumaCount 80^{TS} displays a summary of the results: Success or Error.
The results should fall within the ranges specified by the Min. and Max. values.
Tap **Save** if you wish to save the results onto a USB pen drive.
Press **Print** to print self-test results.
Press **Start** to start self-test again.
Press **Back** to return to Diagnostics menu.

4.2 Database

Patient results are stored in the analyzer's memory in chronological order, and can be viewed in the database at any time.

Memory capacity is 10.000 patient records, including all parameters, histograms, flags, sample ID and date/time of measurement.

! If storage space is full, the latest (actual) record will overwrite the oldest record in the Database.

4.2.1 MAIN DATABASE MENU

To access Database table, press the Database icon in the Main Menu. This will display a main database screen, which allows selecting stored results for further operation.

All records can be selected/deselected by pressing **Select all** button on top of the screen.

Selected state is indicated by red check at box in front of each record. Press this box to select/deselect that record.

The top indicator is active if at least one record is selected.

Use the ↑ and ↓ keys to browse within records, and tap ← and → to browse between parameters columns.

FIGURE 63

Details button allows the user to view results with histograms, the same results screen like after measurement.

Total number of records, and the number of selected records are displayed below the list.

If more than one records are selected, the **Statistics** button will be activated, and the SW will be capable of calculating statistics of the parameters (mean, SD, CV, Levy-Jennings chart).

Print will start printing selected records on the actually selected printer.

Filter button allows searching/selecting records by specific criteria.

Manage button allows the user Delete, Send, or Backup selected records.

Back button will return to Main menu.

Human

4.3 Database detail view

Pressing **Details** button in Database menu will show the actual or the first selected record.

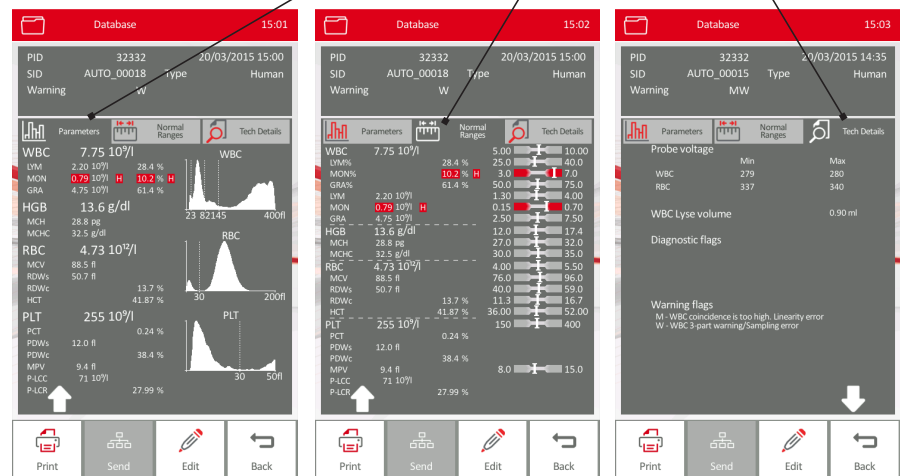The user can switch between **Parameters**, **Normal ranges** and **Tech details** views by pressing the tag.

FIGURE 64

Parameters

FIGURE 65

Parameters Normal Ranges

FIGURE 66

Tech Details

4.3.1 EDITING STORED RECORDS

In database detail view certain data fields of the database records can be edited/updated.

FIGURE 67

Sample ID, Type of measurement, Prediluted mode, Lyse settings, and Sampling depth cannot be modified. Those are indicated by shaded box.

Patient ID, Name of patient, Birthdate, Sex and name of Doctor can be modified. Pressing the white box of the data field, an on-screen keyboard will pop up (see screen below).

After making all modifications, press **Accept** to save changes and return to Details view.

Press **Cancel** if you wish to exit by discarding all changes made.

This screen shows an example of on-screen keyboard when entering the Name of the patient.

The field identifier (Name) appears in the header of the keyboard pop-up menu item.

Type in the desired data, and press **Enter** to save changes.

Use **Shift** to toggle between uppercase/lowercase characters.

Use **Del** key to delete the last character.

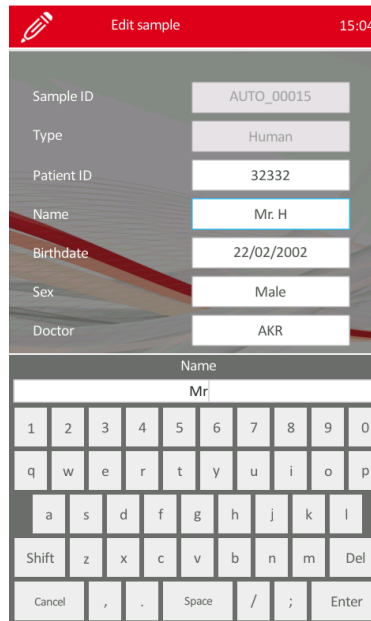Press **Cancel** to discard changes and return to previous screen.

FIGURE 68

4.3.2 FILTERING AND SELECTING RECORDS IN DATABASE

Data records can be selected either individually by pressing the selection button in front of the record, or by using Select in Filter function. Result filter helps filtering the database for further operations.

Press **Filter** button in Database menu to access Result filter function.

Stored records can be filtered/selected by the following criteria (see screen for further details):

- Measured between specified dates (date from/to)
- Patient ID
- Sample ID
- Type of measurement (Human, Blank, etc.)
- Records: All/Selected settings only

The default setting for the date is the actual date. Pressing **Clear** will delete dates and restore default settings.

Press **Cancel** to return to main database menu without changes.

FIGURE 69

Human
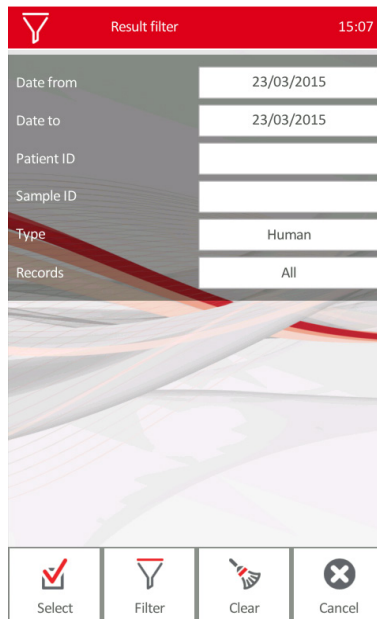
A numerical input pop-up screen will appear after pressing e.g. Date to field.

FIGURE 70

Type the desired date and press **Enter.** '/' character will appear automatically. Use Delete to delete the last character.

Press **Cancel** to discard changes.
Data input is similar for Patient ID and Sample ID fields as well.

Selection on filtering can be applied on the whole database (All) or on the already Selected records only. Push the Records field to toggle between these two states.

Press **Type** field if you wish to filter/select based on type of measurement. The following selection screen will appear. Push the desired type of measurement, or push **All**.

FIGURE 71

Database main menu after filtering records:
After filtering or selecting records, the number of filtered and selected records will appear in the database main menu.
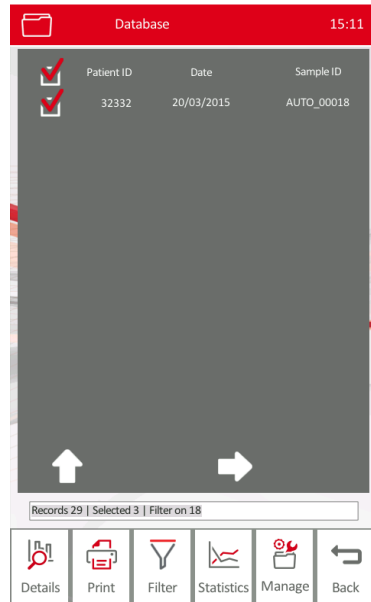In this case, filtered records will be shown in the list only.

FIGURE 72

4.4 Managing selected records in database

After selecting records in database main menu, press **Manage** to select from the operations below.

By pressing **Delete**, selected records can be deleted.

FIGURE 73

Send button can be used to transmit selected records to external computer or laboratory information system (LIS).

Backup button will open back-up options menu. Selected records can be saved in different file formats onto USB mass storage device connected to the analyzer, such as a USB pen drive.

Press **Back** to return to Database menu.
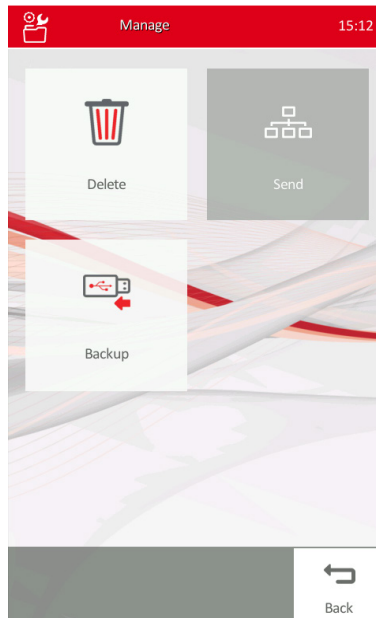
4.4.1 DELETING SELECTED RECORDS

FIGURE 74
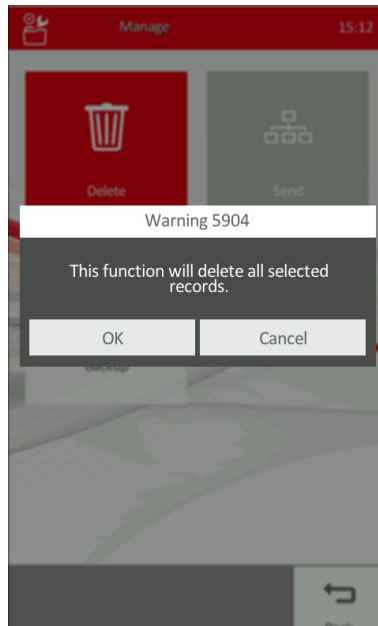
Pressing **Delete** button in Manage database menu will delete records selected previously.

Since deleted records cannot be restored, the SW will ask for confirmation with this screen.

Press **OK** to proceed, or **Cancel** to return without deleting records selected.

4.4.2 SENDING SELECTED RECORDS TO COMPUTER OR LIS

It is possible to send selected records to a connected computer or laboratory information system (LIS). There must be a hardware connection already established between the analyzer and the external PC or network. For details on setting up communication link, please, refer to section 4.7.8.

After selecting records in database main menu, press **Manage** and tap **Send** button to transmit selected records to external computer or laboratory information system (LIS).

Send menu will appear, to select from connections enabled.

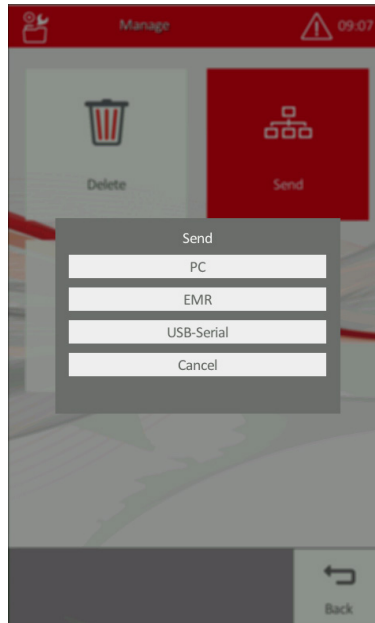Select the connection to send the selected records to, or press **Cancel** to cancel the operation.

FIGURE 75

On the Send screen select:
- **PC** to transmit selected records to a PC via Ethernet channel
- **EMR** to upload the selected record to a PC or LIS connected via Ethernet port, as remote work list was previously downloaded from LIS to HumaCount 30^{TS}/HumaCount 80^{TS}.
- **USB-Serial** to use PC link via USB-B port connection, and serial communication protocol.

Human
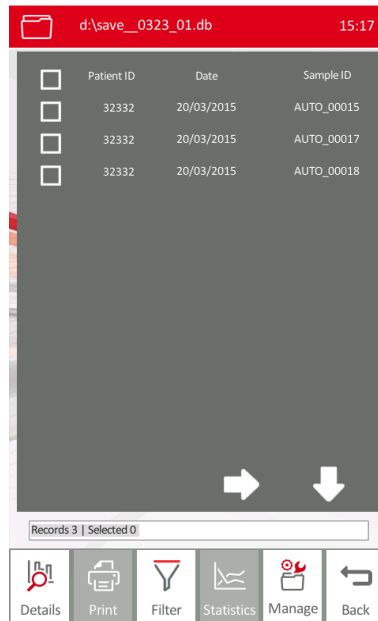
After selecting the communication port, a progress bar will appear, showing the link as the selected data are being sent.

Press **Abort** to stop sending the data record, and return to Manage menu or wait until transmission is over.

4.4.3 BACKUP OF SELECTED RECORDS

Tapping **Backup** button in Manage database menu will open backup options menu. **Before proceeding with backup function, insert a pen drive into one of the USB ports.**

Select one of the **Backup** options below:
Save: to save selected records in **.db** format. Data saved in this format can be viewed later using Backup view function.

- Export: to export selected records as **.txt** file. In this ASCII format, data can be easily imported into Excel and other programs.
(Refer to section 4.7 to set up format of text exported to file.)

- Backup view: function will open .db format data files previously saved onto a pen drive. See section 4.4.4 for details.

- Backup one day: function will allow you to backup data record of a specific day in **.db** format. See section 4.4.5.

Press **Home** to go to Main menu.

Press **Back** to return to Manage menu.

If **Save** or **Export** functions are selected, the following progress bar will appear during file saving, indicating the name of the file being saved.

FIGURE 78

Wait until the save operation is completed (progress bar is over), check the pen drive if there is further activity (LED flashing).

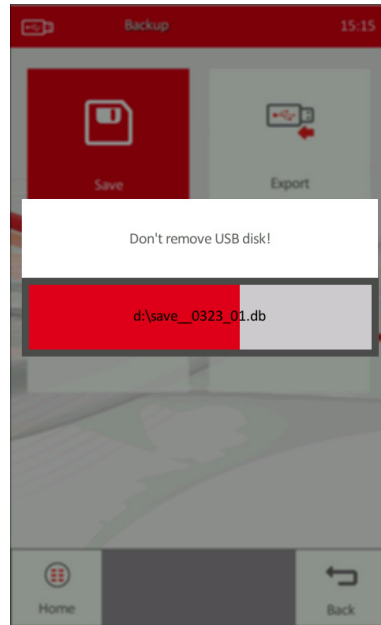Remove pen drive from USB port if no activity detected to avoid data loss.

4.4.4 BACKUP VIEW FUNCTION

This function allows the operator to retrieve saved records database and view the data records on the display. Data opened in backup view mode can be, selected, printed or transmitted.

FIGURE 79

- **Insert the pen drive** containing saved data record database in **.db** file format.
- Tap **Backup** view in Backup menu.
- The analyzer will list saved database files found.
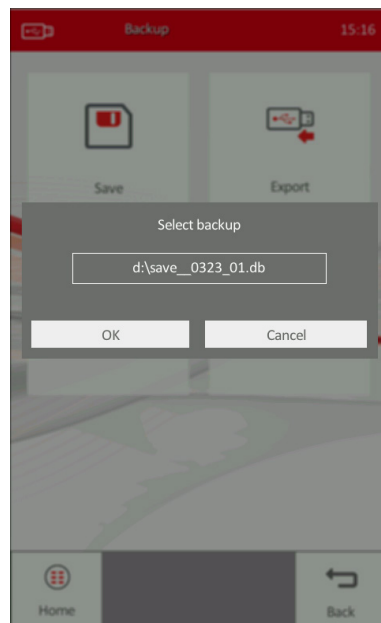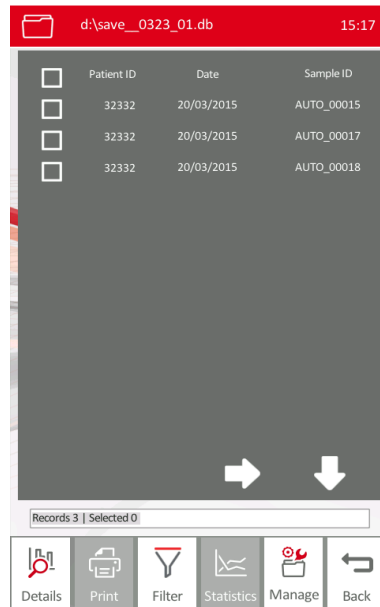
Select the one to open and press OK.

After opening the record database from pen drive, the following menu appears.
The header will show the file name.

FIGURE 80

Individual records can be viewed by **Details** button.

Records loaded from the USB storage device can be viewed, printed, filtered, managed, and statistics calculated just like for normal database records.
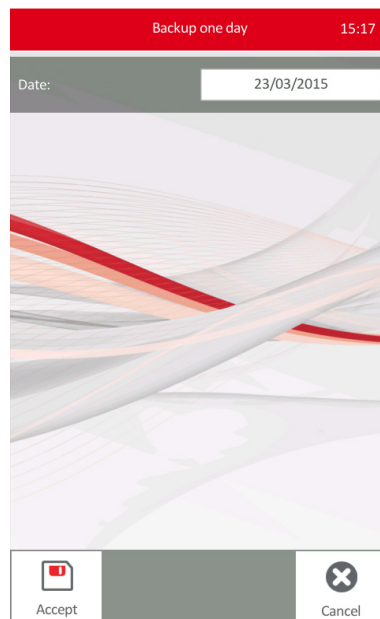
See chapter 4.2 for details on database functions.

Tap Back to return to **Backup** menu.

4.4.5 BACKUP ONE DAY

Use this function if you wish to save records of one particular day from the database.

FIGURE 81

Tap Backup one day button in Backup menu, and follow the steps below:

- Connect a pen drive into a USB port.
- Tap the white **Date** field and enter the date you wish to save.
- Press **Enter**, then tap **Accept**. The SW will save data records in **.db** (database) format.

Press **Cancel** to return to Backup menu without saving data onto the pen drive.
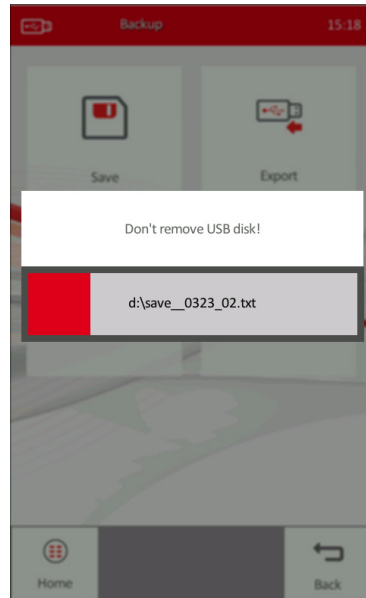
4.4.6 EXPORT

4.5 Statistics of selected records (Levy-Jennings)

HumaCount 30^TS/HumaCount 80^TS can calculate and display statistics on selected sample records. In main database menu select the records to calculate statistics on. Refer to sections 4.2 and 4.4

Tap **Statistics** button in Database menu. A Levy-Jennings chart will be displayed.

Data of each measurement record will be displayed in graphics. The SW will calculate N (number of data points), CV (coefficient of variance), SD (standard deviation), and MEAN of data points.

Use ← and → keys in the bottom of the screen to move between previous/later data points indicated by the white pointer.

Press **View** button to view details of the actual data point indicated by the arrow white pointer.

Use ↑ and ↓ in the bottom of the screen to browse between parameters.

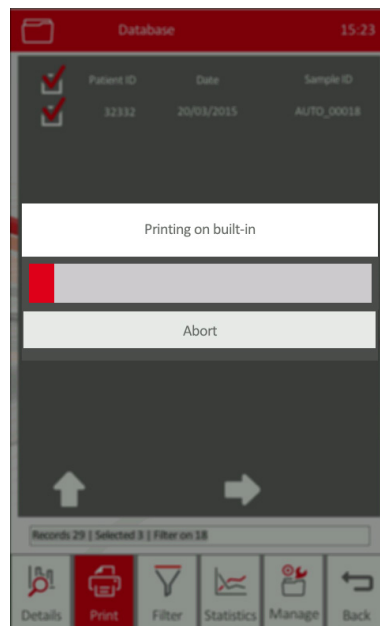**Press** Print to print tabular or Levy-Jennings charts.

Press **Back** to return to main database menu.

Human

4.6 Printing selected records

Pressing **Print** key after selecting samples, the following option screen pops up.
Press **Result by result** to print normal report format.
Press **Table format** to print a summary of records without histograms.
Press **Cancel** to cancel printing.

There will be a progress bar displayed during printing.
The operator can abort printing by pressing **Abort** key.
Refer to chapter 4.6.2 for available printing formats.

4.6.1 HANDLING PRINT JOBS

If printing is started but not finished due to an error situation (no connection to the printer or printer is out of paper), the analyzer will show an error icon in the header.

Push this icon to open the Print jobs menu.

Print jobs screen (indicated on the left) will show the actual printer status and list of printer jobs pending.

The operator can **Abort current job** to cancel current printing, and **Abort all** to delete all printing jobs from the printer queue.
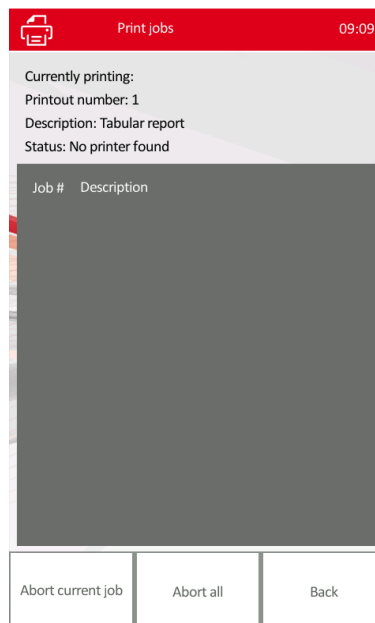
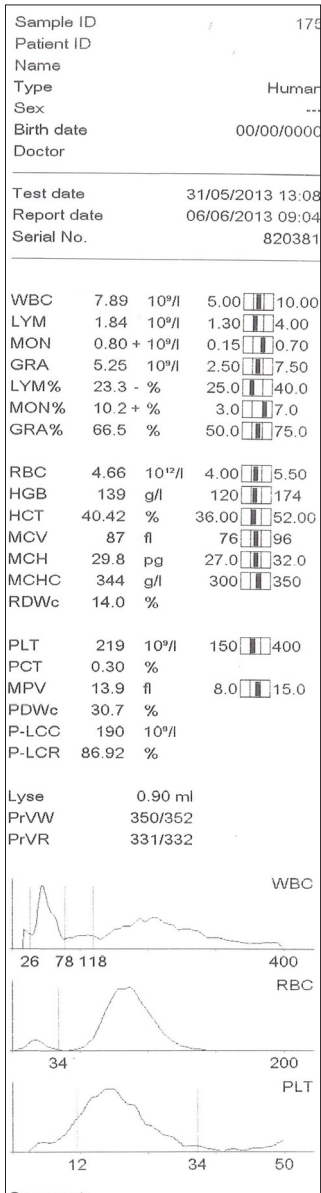Press **Back** to exit this menu.

FIGURE 85

Print jobs   09:09

Currently printing:
Printout number: 1
Description: Tabular report
Status: No printer found

Job #   Description

| Abort current job | Abort all | Back |

4.6.2 AVAILABLE PRINTING FORMATS


```
Sample ID                        175
Patient ID
Name
Type                        Human
Sex                            --
Birth date              00/00/0000
Doctor
_____
Test date              31/05/2013 13:08
Report date            06/06/2013 09:04
Serial No.                     820381


WBC      7.89    10⁹/l     5.00‖10.00
LYM      1.84    10⁹/l     1.30‖4.00
MON      0.80 +  10⁹/l     0.15‖0.70
GRA      5.25    10⁹/l     2.50‖7.50
LYM%     23.3 -  %        25.0‖40.0
MON%     10.2 +  %         3.0‖7.0
GRA%     66.5    %        50.0‖75.0

RBC      4.66    10¹²/l    4.00‖5.50
HGB      139     g/l       120‖174
HCT      40.42   %        36.00‖52.00
MCV      87      fl         76‖96
MCH      29.8    pg       27.0‖32.0
MCHC     344     g/l       300‖350
RDWc     14.0    %

PLT      219     10⁹/l      150‖400
PCT      0.30    %
MPV      13.9    fl         8.0‖15.0
PDWc     30.7    %
P-LCC    190     10⁹/l
P-LCR    86.92   %

Lyse            0.90 ml
PrVW            350/352
PrVR            331/332
```


FIGURE 86

Thermal paper printout


```
                         HumaCount 30TS

Sample ID                    1  Name
Patient ID                      Birthdate          00/00/0000
Type                   Human    Sex                      —

Test date              29/03/2011 09:52  Serial No.        64005
Report date            05/05/2011 10:45


WBC        2.61 - 10⁹/l    5.00 [   ]  10.00              WBC
LYM        1.40   10⁹/l    1.30 [   ]  4.00
MON        0.20   10⁹/l    0.15 [   ]  0.70
GRA        1.01 - 10⁹/l    2.50 [   ]  7.50
LYM%       53.8 + %       25.0 [   ]  40.0
MON%       7.6 + %         3.0 [   ]  7.0         26  85  143      400
GRA%       38.6 - %       50.0 [   ]  75.0                        RBC

RBC        3.27 - 10¹²/l   4.00 [   ]  5.50
HGB        82 - g/l        120 [   ]  174
HCT        26.97 - %      36.00 [   ]  52.00
MCV        83    fl         76 [   ]  96
MCH        25.0 - pg      27.0 [   ]  32.0         25           200
MCHC       303   g/l       300 [   ]  350                       PLT
RDWc       15.8  %

PLT        79 - 10⁹/l      150 [   ]  400
PCT        0.06  %
MPV        7.8 - fl        8.0 [   ]  15.0
PDWc       34.5  %                                 25           50

Diagnostic flags: Leukopenia, Neutropenia, Anemia, Thrombocytopenia

Warning                     W

Lyse            0.70 ml
PrVW            258/264
PrVR            283/286
```

FIGURE 87

Printout on external printer

FIGURE 88

Database Table Printout

Sample ID	Date	WBC	LYM	MID	GRA	LYM%	MID%	GRA%	RBC	HGB	HCT	MCV	MCH	MCHC	RDWc	PLT	PCT	MPV	PDWc	Warning
8	18/01/2010 13:26	9.21	3.94	0.97+	4.29	42.8+	10.6+	46.6-	4.17	143	33.20-	80	34.4+	432+	17.5	235	0.30	12.9	39.2	
9	18/01/2010 13:27	9.38	3.98	0.84+	4.57	42.4+	8.9+	48.7-	4.28	143	33.79-	79	33.4+	423+	18.0	238	0.31	13.0	40.1	
12	18/01/2010 15:00	9.34	4.02+	0.42	4.90	43.0+	4.5	52.5	4.29	147	33.29-	78	34.3+	441+	18.4	308	0.38	12.2	40.6	
13	18/01/2010 15:02	9.51	4.21+	0.76+	4.54	44.2+	8.0+	47.7-	4.31	144	33.56-	78	33.5+	430+	18.0	289	0.35	12.0	42.2	
20474	18/01/2010 15:35	22.45+	0.77-	0.17	21.51+	3.4-	0.8-	95.8+	4.49	160	34.91-	78	35.6+	458+	16.7	385	0.38	9.9	39.2	W
20447	18/01/2010 15:47	—E							4.48	518+	36.11	81	—E	—E	16.5	714+	0.67	9.3	39.0	MLW
20448	18/01/2010 15:54	0.17-	—E	—E	—E	—E	—E	—E	0.00-	1-		—E	—E		11-	0.01	6.6-	27.9	IE
20447	18/01/2010 15:56	9.69	4.52+	0.41	4.76	46.6+	4.2	49.1-	4.44	162	35.95-	81	36.4+	450+	16.5	688+	0.63	9.2	38.8	
20474	18/01/2010 16:01	21.99+	0.87-	0.95+	20.18+	3.9-	4.3	91.7+	4.56	158	35.50-	78	34.7+	446+	16.7	402+	0.39	9.8	38.6	
20447	18/01/2010 16:03	9.79	4.73+	0.58	4.48	48.3+	5.9	45.8-	4.91	174+	40.04	82	35.5+	436+	16.7	680+	0.63	9.2	39.0	

FIGURE 89

QC graphical printout on built-in printer
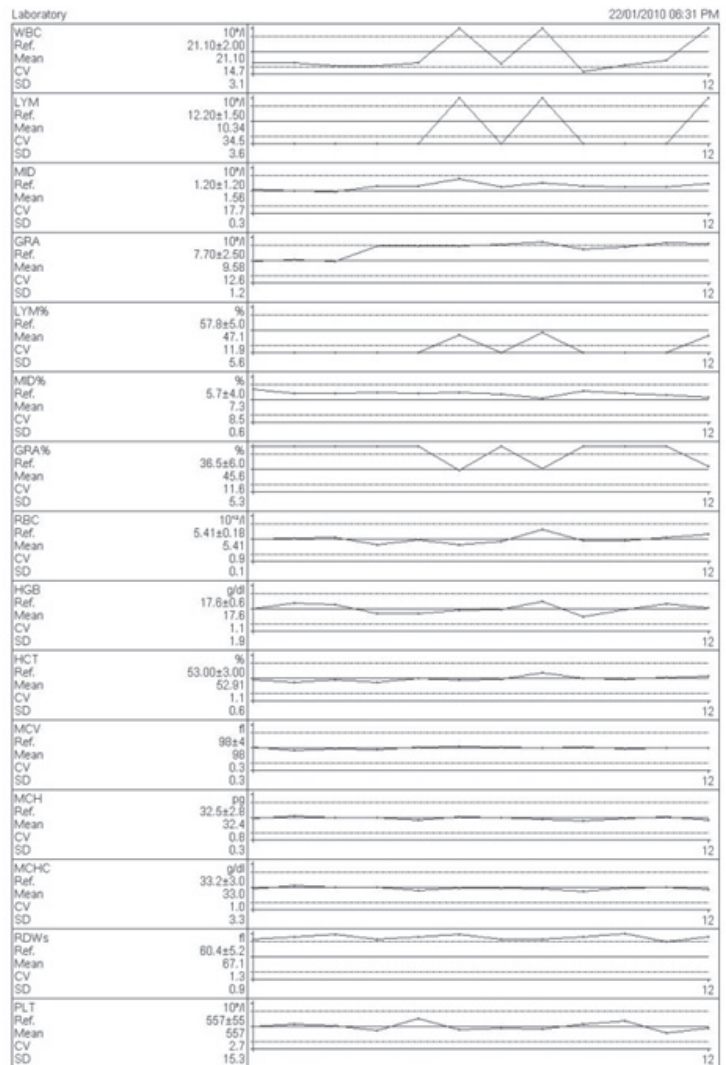
FIGURE 90

QC graphical printout on external printer

4.7 Settings menu

From the Settings menu, there are five settings submenus that can be accessed.

FIGURE 91

! **If any of the self-test parameters fail, contact your local service representative.**
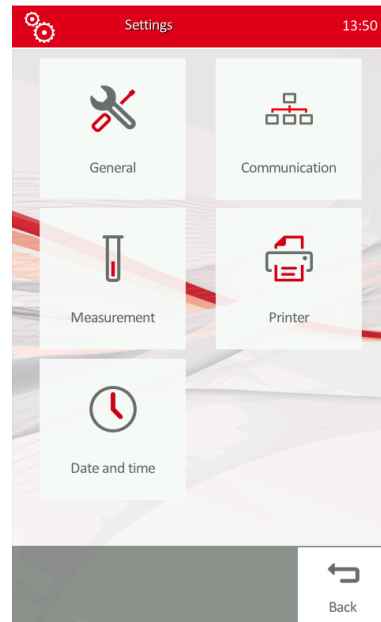
- **General** settings
- **Communication** settings to set up and enable communication links
- **Measurement** settings
- **Printer** settings, and
- **Date and time**
- Tap the submenu icon or text to proceed.
- Pressing **Back** button will return to Main menu.

4.7.1 PRINTER SETTINGS

Enter this menu to select printer used for printing and other settings related to printing.

FIGURE 92
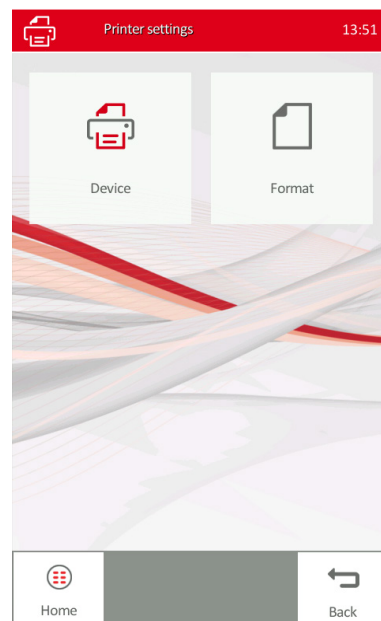
- Tap **Device** to select printer and related settings, or
- Push **Format** to adjust individual fields printed
- **Home** button takes you to Main menu
- **Back** button will step back to Settings menu

In **Printer settings** menu tap the white field to modify settings:

Printer: USB or Built-in

Mode: printing mode can be Black&White or Color.

Paper: sets up paper size for printing: A4 or Letter

Top margin: displacement from edge of paper, expressed in Margin unit setting option (cm or inch).

Automatic printing: if enabled, the analyzer will print all measurement results automatically after each measurement.
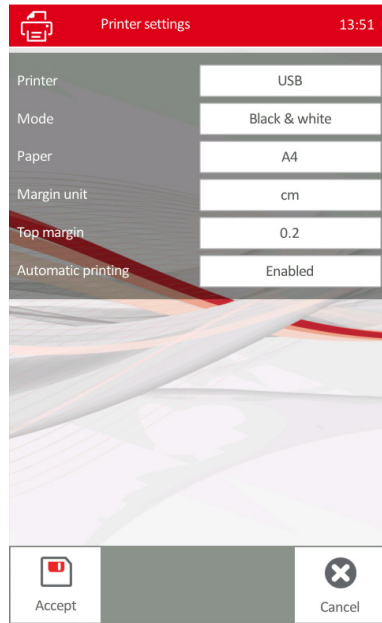
In **printer format** menu, tap the white field to Enable/Disable:

Limits: if Enabled, normal ranges will be printed on the report

Warnings: if Enabled Warning flags will appear on printout

Technical information: controls printing of lyse volume and probe voltages

Diagnostic flags: if Enabled diagnostic flags will be printed

Logo: if enabled, HumaCount 30^{TS}/Huma-Count 80^{TS} logo will be printed in header

Operator can set up text printed into the Laboratory headers.

Header lines 1..4: can contain customized text, name of lab, address, telephone number, contact person, etc.

Tap the appropriate white field to enter or modify text.

Press **Accept** to save settings and exit, or press **Cancel** to exit without saving changes.

Human
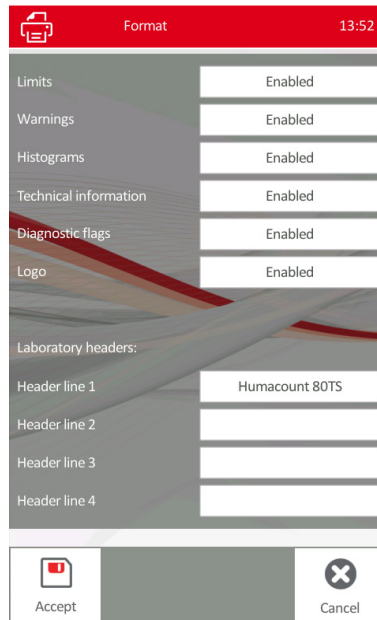
4.7.2 GENERAL SETTINGS

In General settings screen the following settings can be set up or modified:
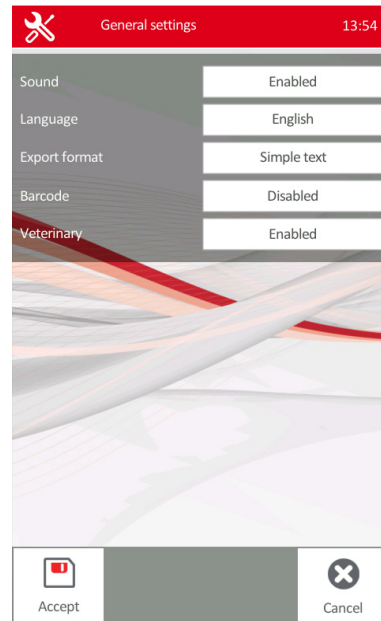
- Sound Enabled or Disabled.
- Language of the user interface:
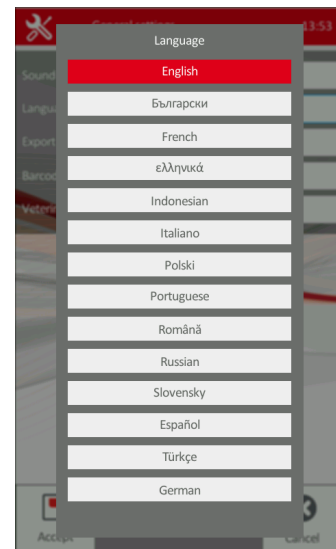
- Export format of data transmission can be set up, as
  - o **Advanced text:** Results are saved only
  - o **Simple text:** Results are saved with ranges
  - o **Extended text**: Results are saved with histograms and ranges

- Screensaver time setting:
  - o specifies the time elapses without touch screen activity before the screen goes off to conserve power. Default setting: 15 min.

- Barcode reader can be Enabled or Disabled.
  After changes made, press **Accept** to save changes and exit. Press **Cancel** to discard changes, and return to Settings menu.

4.7.3 MEASUREMENT SETTINGS

In this menu measurement related set-
tings can be modified.
Press **Measurement** in Settings menu to
enter this menu.

There are three options:
-   going to **Units** submenu, or
-   selecting **Normal ranges** menu
-   selecting **Profile** men

Press **Home** to return to Main menu.
Press **Back** to return to Settings menu.
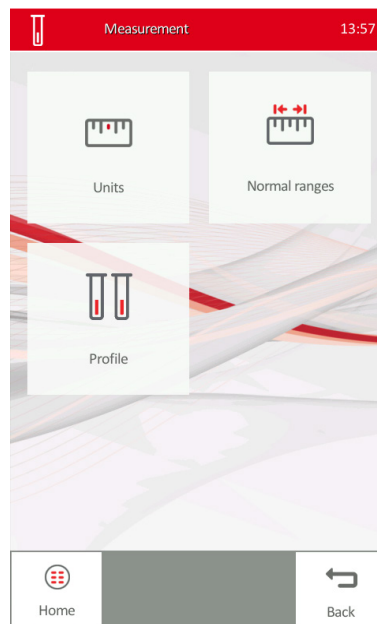
FIGURE 96

4.7.4 MEASUREMENT UNITS SETTINGS

This setting menu can be used to set up units of measured parameters.

FIGURE 97
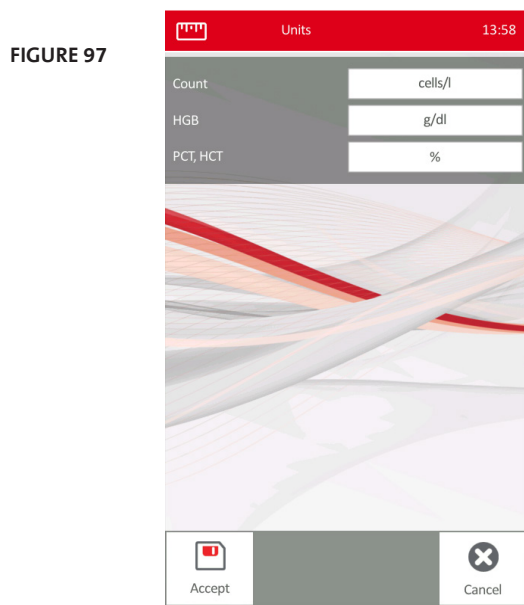
Tap the white fields to change and **Accept** to save changes made.

Possible units for the parameters:

TABLE 14

Parameter	Available units
Count unit	cells/liter(cells/l)
	cells/µl(cells/µl)
HGB unit	grams/liter (g/l)
	grams/deciliter (g/dl)
	millimols/liter (mmol/l)
PCT, HCT unit	Percentage (%),
	absolute(ABS)
RDW, PDW mode	standard deviation (SD),
	coefficient of variation(CV)

4.7.5 NORMAL RANGES SETTINGS (PROFILES)

In this menu Normal ranges can be set up for Human, Male, Female and all other Profiles.

The sub-menu can be reached
 a) via **settings menu**
    Measurement settings
 b) via Main menu
    Measure
    New sample
Tap the Type field to select profile to edit or review.

Profile 1..7 can be renamed by pressing **Rename** button.

Press ← and → keys to move between normal ranges screens of parameters.

Push any of the parameters field to edit the value, and press **Enter**.

Press **Accept** to save changes made, or **Cancel** to discard changes.
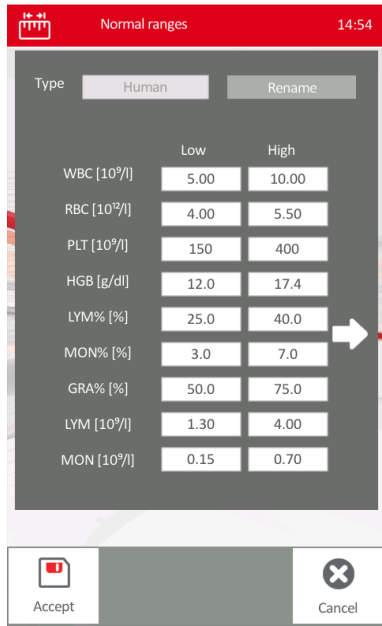
FIGURE 98
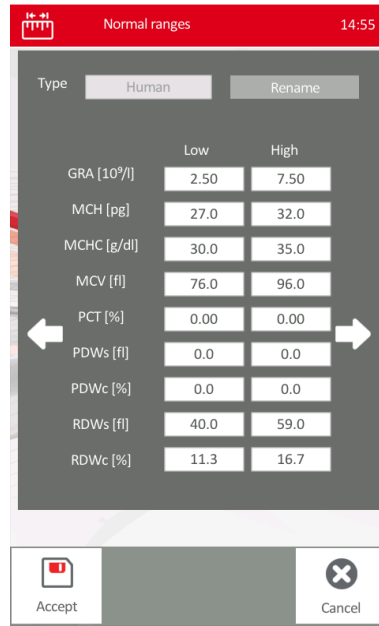
FIGURE 99

		Human		Male		Female		Baby/Toddler/Child	
		low	*high*	*low*	*high*	*low*	*high*	*low*	*high*
WBC	10^9/l	5.0	10.0	5.0	10.0	5.0	10.0	5.0	19.0
RBC	10^12/l	4.0	5.5	4.5	5.5	4.0	5.0	3.9	5.3
HGB	g/l	120	174	140	174	120	160	95	141
HCT	%	36	52	45	52	36	48	30	40
MCV	fl	76	96	84	96	76	96	70	84
MCH	pg	27	32	27	32	27	32	23	29
MCHC	g/l	300	500	300	500	300	500	310	350
PLT	10^9/l	150	400	150	400	150	400	150	450
MPV	fl	8	15	8	15	8	15	8	15
RDWs	fl	20	42	20	42	20	42	20	42
LYM	10^9/l	1.3	4.0	1.3	4.0	1.3	4.0	2.3	14.4
MON	10^9/l	0.15	0.70	0.15	0.70	0.15	0.70	0.0	0.95
GRA	10^9/l	2.5	7.5	2.5	7.5	2.5	7.5	1.0	8.5
LYM	%	25	40	25	40	25	40	46	76
MON	%	3.0	7.0	3.0	7.0	3.0	7.0	0.0	5.0
GRA	%	50	75	50	75	50	75	20	45

TABLE 15

Pre-defined settings

for normals ranges

Human

		Dog		Cat		Horse		Cattle	
TABLE 16		*low*	*high*	*low*	*high*	*low*	*high*	*low*	*high*
Pre-defined settings	**WBC** 10^9/l	6.0	17.0	5.5	19.5	5.4	14.3	4	12
for normal ranges in	**RBC** 10^12/l	5.5	8.5	5	10	6.8	12.9	5	10
veterinary mode	**HGB** g/l	120	180	80	150	110	190	80	150
	HCT %	37	55	24	45	32	53	24	46
	MCV fl	60	77	39	55	37	59	40	60
	MCH pg	19.5	24.5	12.5	17.9	12.3	19.7	11	17
	MCHC g/l	310	340	300	360	310	390	300	360
	PLT 10^9/l	200	500	300	800	100	400	100	800
	MPV fl	3.9	11.4	12	17	-	-	-	-
	LYM 10^9/l	1.0	4.8	1.5	7.0	1.5	7.7	2.5	7.5
	MON 10^9/l	0.2	1.5	0.0	1.5	0.0	1.5	0.0	0.84
	GRA 10^9/l	3	12	2.5	14.0	2.3	9.5	0.6	6.7
	LYM %	12	30	20	55	17	68	45	75
	MON %	2.0	4.0	1.0	3.0	0.0	14	2	7
	GRA %	62	87	35	80	22	80	15	65

4.7.6 PROFILE - LYSE RATE

! **Attention, any change will cause different CBC counts.**

FIGURE 100

This menu allows the change of the Lyse rate for each sample
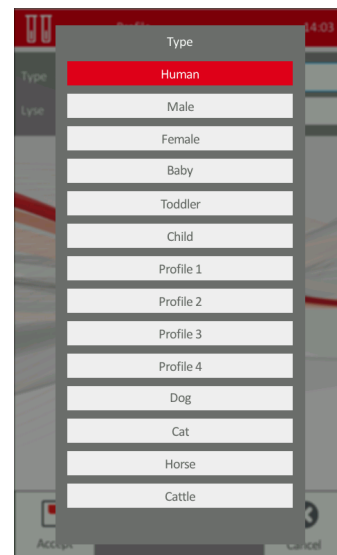
FIGURE 101

4.7.7 DATE AND TIME SETTINGS

In this menu format and actual value of system date and time can be set up.

To enter this menu select **Date and time** in Settings menu

Tap the white field to modify settings:

Date: enter current date in the format selected below under Date format.

Time: enter current time, and press **Enter**.

Date format: select date format one of **Day/Month/Year** or **Month/Day/Year** or **Year/Month/Day** formats.

Time format: can be 12h mode or 24h mode.

Press **Accept** to save date and time settings and exit or **Cancel** to exit without saving changes.
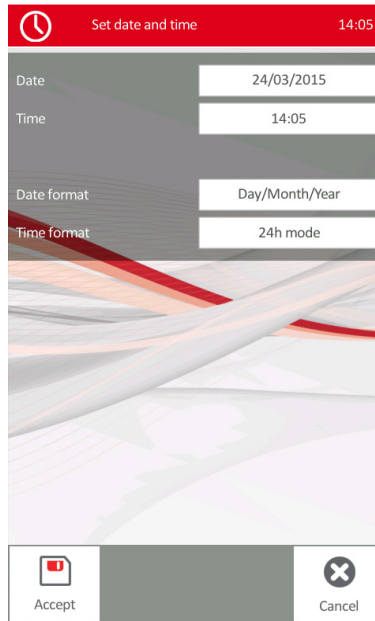
FIGURE 102

4.7.8 COMMUNICATION SETTINGS

Communication settings menu is used to set up communication ports.

Tap **Communication** in Settings menu to enter Communication settings menu.

There are two submenus available:

- **Device communication** – this menu allows the operator to set up network address or enable DHCP and other network settings.
- **Peer communication** – this menu helps enabling and disabling different communication ports.

See details in the sections below.

FIGURE 103

Human
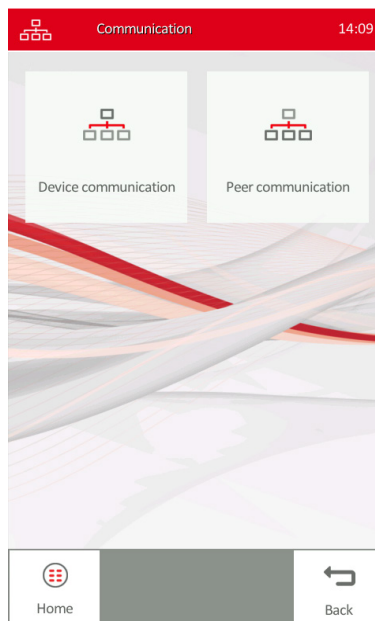
4.7.8.1 Device communication
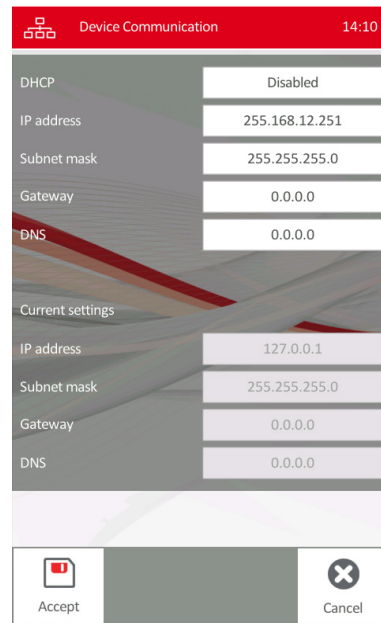
Tap **Device communication** in Communication settings menu to enter this menu. The following settings can be modified:

DHCP: Disabled or Enabled. If DHCP is enabled, the master device on the local network will assign device address for HumaCount 30^{TS}/HumaCount 80^{TS}.

IP address: If DHCP is disabled, enter a valid IP address in order to use HumaCount 30^{TS}/HumaCount 80^{TS} in the network. Contact the network administrator for details on IP address in your laboratory network.

Gateway: typically set to 0.0.0.0
DNS: typically set to 0.0.0.0

Current settings are shown for reference below in shaded area.
Press **Accept** to save settings and return to previous menu.
Press **Cancel** to exit without saving changes.

4.7.8.2 Peer communication

Tap **Peer communication** in Communication settings menu to enter this menu. The following settings can be modified:

PC: PC communication can be Active or Inactive.

PC remote IP address: A valid network address should be set up here if PC setting is Active, otherwise the analyzer cannot transmit data to the LIS.

EMR: EMR (remote work list mode) can be Active or Inactive.

EMR remote IP address/EMR local port: A valid network address should be set up here if EMR setting is Active, otherwise the analyzer cannot transmit/receive work list to/from LIS.
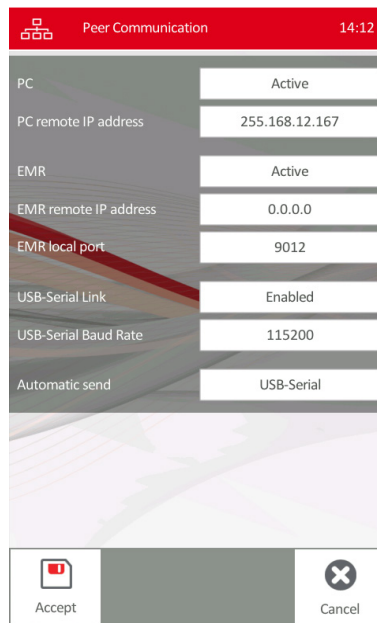
FIGURE 105

USB-Serial link: Can be Enabled or Disabled. If a PC is connected via the USB-B port, this setting should be Enabled.

USB-Serial Baud Rate: To connect PC via USB B emulated serial link, set up baud rate here identically to the setting of the connected PC serial link baud rate.

Automatic send: This setting can be one or combination of links enabled. After a measurement is completed, data record will be sent automatically to the ports selected here.

Press **Accept** to save settings and exit or **Cancel** to exit without saving changes.
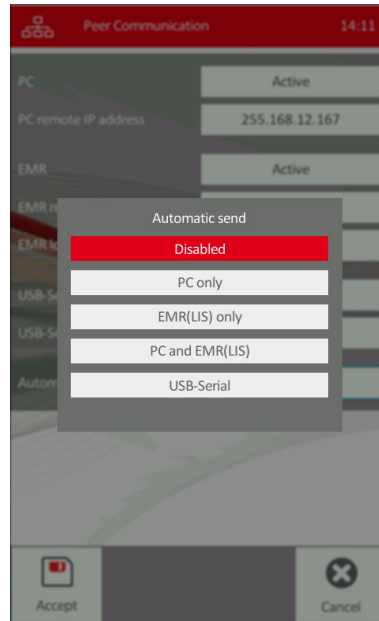
By tapping automatic send button, the active/enabled ports can be configured for automatic data transmission after every measurement.

Select one of the options on the screen for automatic sending of data records after measurement:

- Disabled: no records will be transmitted automatically
- PC only: records will be sent to PC connected via LAN port
- EMR (LIS) only: records will be sent to LIS address via LAN
- PC and EMR(LIS): records will be sent to both addresses via LAN (Ethernet) port
- USB-Serial: records will be sent on USB B port to PC.

Contact service personnel or LIS administrator for more information on network settings.

4.7.9 MULTI-USER MODE
Multi-user mode provides the clinical laboratory manager the means to control access to the HumaCount 30^{TS}/HumaCount 80^{TS} analyzer by ensuring that only authorized users can operate the analyzer. With the multi-user mode, the laboratory manager can assign some users the authority to perform critical system functions such as maintenance and calibration, and restrict other users to routine activities such as running samples.

4.7.9.1 Types of Users
Multi-user mode provides three types of users:

- Admin (administrator) users have access to all system functions.
- Advanced user can access all functions, except for setting up users.
- Basic users can run samples, but cannot perform calibration and system settings.

4.7.9.2 Logging in

The operator has to log in using its pass-word in order to use the analyzer. Users can be set up by the person having Admin access to the analyzer.

In Exit menu, press **Log in** to start log in.

In order to manage users, Admin level of user has to log in.
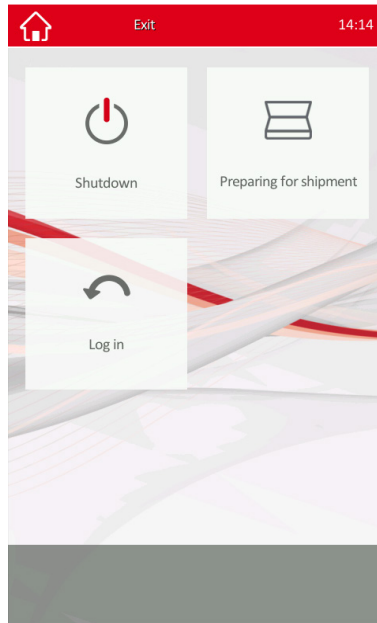
! The default Admin password is '0' (one zero character). If Multi-user mode is used, it is strongly recommended to change the Admin password, so that no one can manage the user privileg-es without knowing the new password.

Log in screen will appear.
Tap the box over Login name to select from available users, enter the password, then press Enter.

FIGURE 108

If you are logged in as Admin, then in the Exit menu **User management** menu will be available, otherwise Logout only.
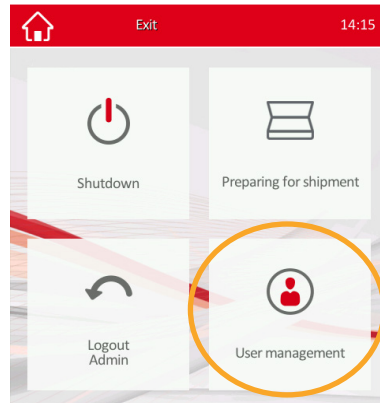
FIGURE 109

4.7.9.3 User Management
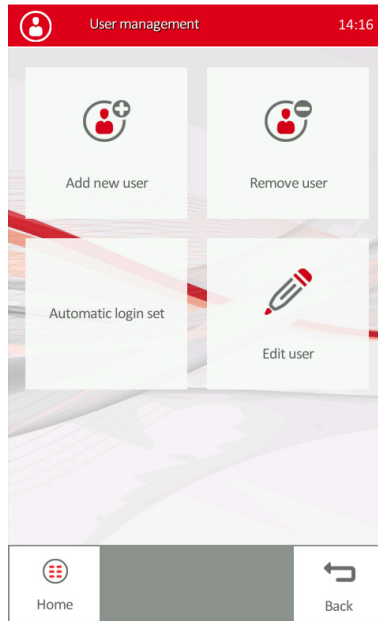
After logging in as Admin user, the User management menu is available to set up and modify users.

Tap **Add new** user to set up a new user account.

Press **Remove user** to delete an existing user account.

Tap **Automatic login set,** to set up automatic login option.

Tap **Edit user** to modify an existing user account.

4.7.9.4 Add new user

Use this menu to set up new user accounts and privilege levels for multi-user mode. Tap each box to modify its contents.

Login name will appear in the Log in box to select from.

Password should be entered and **re-entered** for security reasons. This password must be entered by the user selected for the log in name.

User type should be selected: Admin, Advanced or Basic.

Refer to section 4.7.9.1 for details on user types.

Additional data fields, such as name, phone, email can be entered for each user as well.

Press **Accept** to save the new user account.
Press **Cancel** to exit without saving.

4.7.9.5 Deleting or Editing Users
Edit user and delete user menu will bring up selection menu and allows deletion or editing of user data, such as User type, name, Log in name and password.

4.7.9.6 Automatic login set
If automatic log in feature is set for any of the existing users, the analyzer will log in into that user.

Log in as Admin and press Automatic login set. The following menu appears.

Select the user account for automatic log in.

By tapping **Automatic login off** the operator can turn off this feature, then the analyzer will start with the **Exit menu** to start with **Log in**.
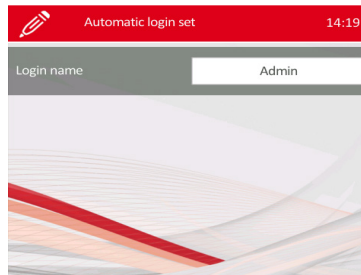
FIGURE 112

! **Be careful to set Admin as automatic log in user, because then all multi-user modes will be available, including editing Admin password.**

4.7.9.7 Installation of 2D Barcode reader
The 2D Barcode reader is a very helpful optional accessory (see chapter 2.4 and 3.2.7), because with a 2D Barcode reader, in a few seconds, all target values from the control-assay-value-sheet can be uploaded to the instrument.

The following configuration steps are necessary, before the 2D-barcode reader will work on the instrument.

Installation:
Connect the 2D Barcode reader via the USB cable to an USB port of the analyzer (or alternatively a PC).

The configuration of the 2D Barcode reader can be done by scanning of the following 4 barcodes in the order as shown below.

Human

Step 1:

Set Factory Defaults

Step 2:

<PREFIX> <DATA> <SUFFIX 1>
(05h)

Step 3:

Scan Prefix
(07h)

Step 4:

5

Step 5:

0

Step 6:
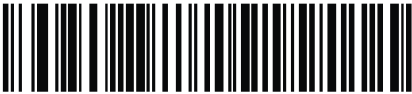
2

Step 7:

3

Step 8:

Scan Suffix 1
(06h)

Step 9:

5

Step 10:

0

Step 11:

2

Step 12:

4

Step 13:

1 msec

Now the 2D Barcode reader is ready for use on the analyzer.

Before up-load the target values of the controls, make sure you have the correct assay value sheet and Data-Matrix-Code for the instrument. Data-Matrix-Codes from another instrument types cannot be uploaded.

Human

4.8 Maintenance menu

FIGURE 113
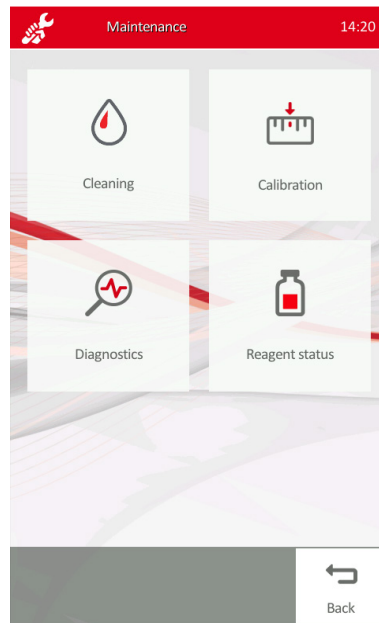
Maintenance icon allows access to **Cleaning, Calibration, Diagnostics,** and **Reagent Status** menus.

4.8.1 CLEANING

FIGURE 114
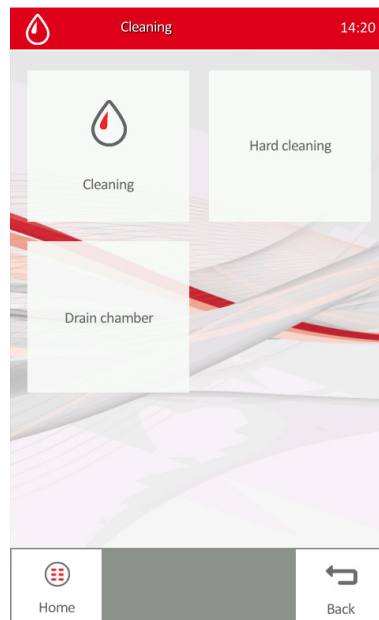
Cleaning: Starts a wash cycle using the cleaning reagent connected to cleaner input. A cleaning cycle is automatically performed during a start-up and a shutdown procedure.

Hard Cleaning: It must be performed weekly as part of routine maintenance. Clogging errors or high PLT blank indicates the need for additional hard cleaning.
The SW will prompt to insert the **Hypochlorid solution** ($\boxed{\text{REF}}$ 90150) into the sample rotor using a sample vial.

Drain Chamber: Used during troubleshooting or component replacement only. Drain of the chamber should be run before removal or replacement of parts related to the measuring chambers or apertures (Service personnel task).

4.8.2 WEEKLY USER MAINTENANCE

Perform weekly maintenance before turning on the power switch. The right side has a side door giving access to the fluidic system and the mechanical parts easily.

4.8.3 CLEANING NEEDLE WASHING HEAD

Needle washing head cleans the outer surface of the aspirating needle with diluent.

Any salt build-up on the lower surface may cause malfunction during operation. Use a soft cloth or wiper dampened with water to clean this area. You can see the washing head indicated in the following figure:

FIGURE 115
Parts of measuring block

1   Washing head

1. Exit Measure menu. Open the side door after the needle has stopped moving.
2. Gently rub the lower surface of the washing head with a damp cloth or wiper to remove the salt build-up.
3. Close the side door.

4.9 Calibration

The analyzer stability can be monitored with **HC-CONTROL** control blood (REF 17400/40). Performing QC determinations regularly verifies continued optimal performance.

The analyzer can be calibrated by HC-calibrator (REF 17400/50).

It is recommended to do calibration in the following cases:

1. At analyzer installation, before beginning the analyses.
2. After replacing any component, related to the process of dilution or measurement.

Human

3. When quality control measurements show any systematic error (bias) or they are outside predefined limits.
4. At regular time intervals (determined by the lab itself).
5. If you want to use the instrument in Pre-diluted mode.

! New calibration will invalidate the previous factors. Old values cannot be retrieved.

Calibration can be performed in two ways:
1. User can enter calibration **factors** – without any calibration measurements – using the numerical keypad.
2. Calibration by **measurements** of HC-calibrator, with known parameters (REF 17400/50). In this case, the instrument automatically calculates new factors.

4.9.1 CALIBRATION MENU
From Maintenance menu the calibration menu can be reached.
In the Calibration menu, the operator can initiate calibration of HumaCount 30^{TS}/ HumaCount 80^{TS} or can review calibration history.
Prior to Calibration, a Self-Test and a Blank Measurement must be performed with acceptable results.
Calibration is required at installation, or when the control values are out of range.

FIGURE 116
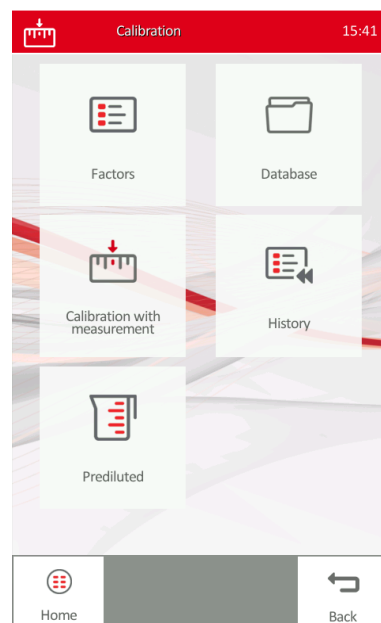
Press **Factors** to check or modify Calibration factors manually.

Tap **Database** to see calibration database.

Push **Calibration with measurement** to run calibrator.

Tap **History** to see history of calibration events by factors.

Pressing **Prediluted** enters to Prediluted calibration menu. Prediluted calibration factors are used to calulate results measured in Pre-diluted mode. Refer to section 3.2.6 for details on pre-diluted sample mode.

4.9.2 CALIBRATION FACTORS MENU
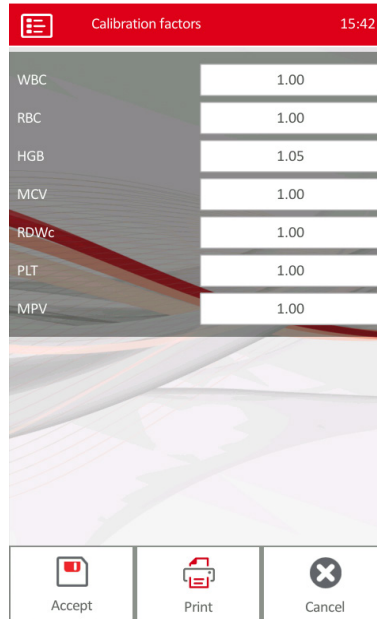
This menu allows the operator view or modify the actual calibration factors.

Tap the white box of a factor to enter a new value.

Press **Accept** after all modifications are made to save the new factors. This will generate a new event in the calibration history log, with the current date and time, by storing the new factors.
See calibration history in section 4.9.4.

Press **Print** to print the factors.

Press **Cancel** to discard changes and return to Calibration menu.

FIGURE 117

4.9.3 CALIBRATION WITH MEASUREMENT

In Calibration menu, select 'Calibration with Measurement' menu.

If you have a 2D bar code reader connected, simply scan the 2D (Q-R) barcode on the assay sheet of the control to upload l**ot number, expiration date, and target values** for the calibration material.

In the absence of a bar-code reader, enter these values manually, one after another by tapping on the value boxes.

Human

FIGURE 118

Select the **number of calibration** runs desired (3 or 7).

If you wish to calibrate pre-diluted mode, then prepare pre-diluted calibrator, and set **Prediluted** mode to YES.

Select **sampling depth** based on the vial used, or leave it in default '――' (= 0 mm) setting. See section 3.5.2 for details.

Tap **Accept** to proceed to run calibrator, or **Cancel** to exit without calibration.

If **Accept** is pressed, the analyzer will save the target values and proceed to calibration measure screen.

Mix the calibrator thoroughly, insert it into the sample adapter and press **Run**.

After calibrator measurement is complete, the results will be displayed.

FIGURE 119

If the results look good, and there are no warning flags displayed, **Run** calibrator again until the preset number of runs (3 or 7) is reached.

If warning flag was received ('C' or 'c' meaning clogging, etc.), press **Discard** to delete that particular calibration run and Run calibrator again.

After performing the last run, the **Calibration results** screen will appear, as indicated below.

A statistical evaluation of calibration results will appear.

Target values, means of runs, CV% and the new calculated factors will appear (see screenshot to the left).

If CV% (coefficient of variance) values and the new factors are satisfactory, press **Accept** to save the new calibration factors.

Each calibration factor must be within 1.00 ± 0.20 limits.

If a calibration factors is outside this range, it will be highlighted by red.

Press **Cancel** if you do not wish to modify calibration factors.

- If results are not acceptable, repeat the calibration process using a new vial of calibrator material.
- If it is still not acceptable, call Technical Support.

FIGURE 120

Calibration result				13:38
Param	Target	Mean	CV%	Factor
WBC	8.28	8.23	0.8	1.01
RBC	5.70	5.82	0.6	0.98
HGB	15.1	14.7	0.1	1.02
MCV	85.0	79.3	1.1	1.07
RDWc	13.2	10.2	1.1	1.30
PLT	302	301	4.7	1.00
MPV	7.9	8.7	1.7	0.91

Accept   Cancel

4.9.4 CALIBRATION HISTORY AND CALIBRATION DATABASE

In Calibration menu both the Database and History menus contain historical calibration information.

- Database contains the details of each calibration run.
- History menu contains the calibration factors generated with each calibration.

Calibration history					15:54
Date	WBC	RBC	HGB	MCV	RD...
16/03/2015 15:08	1.00	1.00	1.00	1.00	1.00
16/03/2015 15:07	0.91	0.80	0.85	1.06	0.82

Print   Back

FIGURE 121

	Calibration database		16:04
✓	Sample ID	Date	LOT
☐	CAL1/1	13/03/2015	b024
☐	CAL1/2	13/03/2015	b024
✓	CAL2/1	13/03/2015	b024
☐	CAL2/2	13/03/2015	b024
✓	CAL2/3	13/03/2015	b024
☐	CAL3/1	16/03/2015	211
☐	CAL3/2	16/03/2015	211
☐	CAL3/3	16/03/2015	211

Records 8 | Selected 2

Details   Print   Filter   Statistics   Manage   Back

FIGURE 122

Human

4.9.5 PRE-DILUTED MODE CALIBRATION MENU
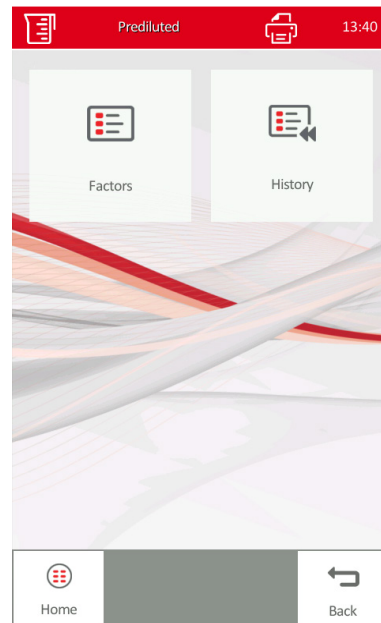
In Calibration/Prediluted menu there are two options.

In **Factors** menu, the operator can check and set up the calibration factors used for pre-diluted sample runs.

In **History** menu the history of the pre-diluted calibration factors can be reviewed, just like for normal calibration factors.

Tap **Home** to return to Main menu.

Press **Back** to return to Calibration menu.

Prediluted calibration factors and history menus. See sections 4.9.2 and 4.9.4 for details on use.
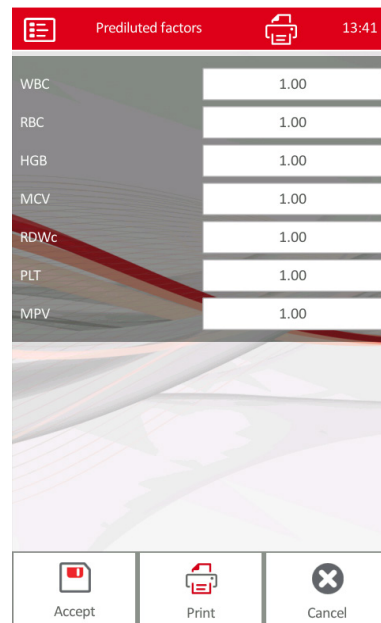
FIGURE 124
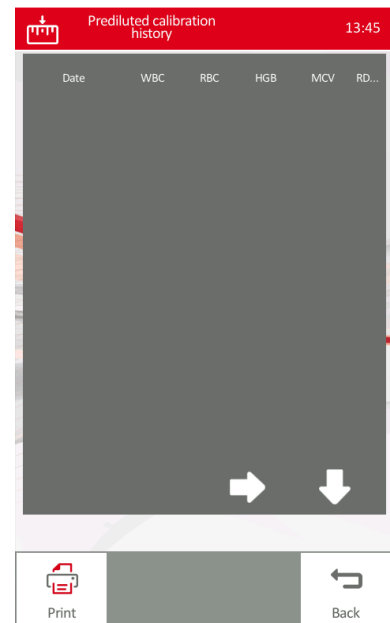
FIGURE 125

4.10 Reagent Status

This menu is reached via Maintenance menu and helps monitoring reagents, set up and check lot numbers, expiration date, and actual level.

There are individual sensors for the three reagents, which can be turned On/Off by switching the sensor icon by pulling left/right.

For priming press **Prime** at the selected reagent, or **Prime all** to prime all reagents. Reagent sensors will control priming.

Go to **Replace** menu, if you wish to replace one or more reagents. Waste and reagent level % calculation is based on the setting of the tank capacity. Use **Volume** key to set up capacity of tanks.

Tapping **View log** will show reagent replacement history.

FIGURE 126

Tap **Measurement credits** to check measurement credit counter (see section 4.10.3).

Pressing **Empty Waste** will restore Waste counter to 0%. Make sure to dispose of the contents of waste container.

Human

4.10.1 REPLACING REAGENTS

Follow the steps below to replace reagents. The SW will record reagent replacement events.

FIGURE 127

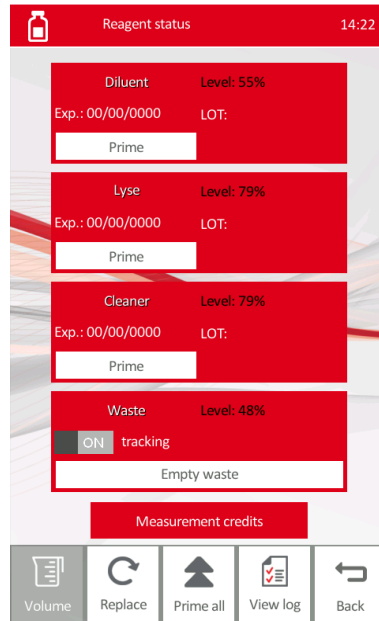- From the Main Menu select Maintenance/Reagent Status, then press the **Replace** button at the bottom of the screen.
- Touch the white box of **Reagent type** and select the reagent to be replaced from the drop down menu that opens.
- Type in the Lot number and the expiration date.
- If you replace **HC-Lyse CF,** then insert the reagent HK into the 'HW key for reagent' slot on the back. See section 4.10.2.
- Press **Accept** to complete the replacement or **Cancel** to exit.

Repeat the above process for the all reagents to be replaced.

When you push **Accept** in case of **HC-Lyse CF** reagent, the instrument will look for a reagent key (HK). This key must be inserted into "HW Key for Reagent" slot at the back of the analyzer.

Below the stepwise instruction for the replacement of the first and second bottle. It must be done in tow different steps, to get the correct open bottle stabilty for each of the two lyse bottles.

Replacement of **first** lyse bottle
1. Connect hardware key to the instrument
2. Go to the Reagent status menu
3. Press the **Replace** button
4. Select the **Human Lyse Diff**
5. Press the **Load** button to read the information from the Hardware Key
6. The LOT No, Expiration date will be filled out.
7. Press **Accept**.

Replacement of **second** lyse bottle
8. Go to the Reagent status menu
9. Press the **Replace** button

10. Select the **Human Lyse Diff**
11. Fill out the LOT manually
12. The **Accept** button will be active.
13. Press the **Accept** button
14. Now the new open bottle stability will be displayed for the second lyse bottle.

4.10.2 REAGENT LOCK SYSTEM (REAGENT HARDWARE KEY)

HumaCount 30^TS/HumaCount 80^TS is equipped with a Reagent Lock System to prevent use of inappropriate or bad quality reagents, and in order to provide the best results possible.

Reagent Lock System is based on number of measurement credits, which is factory set to 2x1050. By running each measurement, the number of credits is decreased by one. If the number of credits reaches 0 (zero), the analyzer will not perform more measurements, but displays an error message.

To restore measurement credits, reagent hardware key (HK) must be introduced.

Packaging of each **HC-Lyse CF** reagent comes with a hardware key (HK) containing 2x1050 measurement credits.

FIGURE 128

FIGURE 129

For each lyse bottle you have 1050 measurement credits. 1050 tests is a maximum, which you will only achieve if you run 400 tests per day on one instrument.

Follow the steps below to load the measurement credits from the HK module

to the analyzer:

FIGURE 130

1. Remove HK from the zip bag of a new HC-Lyse CF reagent box.
2. Plug the Hardware Key into the HW key connector on the back of the Huma-Count 30^{TS}/HumaCount 80^{TS} in the way indicated by the picture to the left.
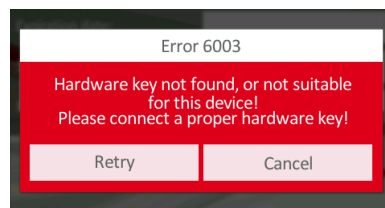
FIGURE 131

The golden connectors of HK should face outwards (towards the white part of the connector socket).

3. In Maintenance/Reagent Status menu perform a replace function after selecting **HC-Lyse CF** and press Accept.
4. All measurement credits will be moved to the analyzer, while the credits will be deleted from HK.
5. Remove the HK from the Reagent Lock connector. This reagent HK cannot be used again.

! Do not connect the reagent Hardware Key into USB ports, because the analyzer cannot read the credits via USB. Use the 'HW Key for reagent lock' connector on the back only.

FIGURE 132

Error 6003

Hardware key not found, or not suitable for this device!
Please connect a proper hardware key!

Retry   Cancel

Failure to insert the key, or if a used key is inserted, or a key that is not compatible with your analyzer, the following error message will be displayed. If this happens, insert a good key and press **Retry**.

> ! Every measurement cycle will decrease the number of measurement credits, except for initialization, standby and wake up cycles.

> ! Counting of measurement credits is connected to lyse reagent usage. It is possible that lyse still remains in the reagent container when the counter gets to 0. This is caused by the extra amount of lyse in the lyse container to make sure that lyse will be enough for extra maintenance and/or service procedures.

4.10.3 MEASUREMENT CREDITS MENU

This menu is available from the Reagent status menu, by tapping on **Measurement credits.**

With this function the available number of measurement on the reagent HK and on the instrument can be displayed. The software will read the number of available credits from the instrument and from the HK module connected to the analyzer.

FIGURE 133
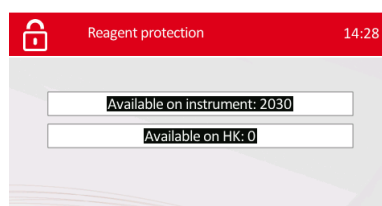
Example: if there are 100 remaining measurements on the analyzer, and the operator connects and uploads the content of a new HK (2100 credits), then there will be 2150 measurement credits on the analyzer and all other credits will be deleted from HK.

4.10.4 REAGENT LOG MENU

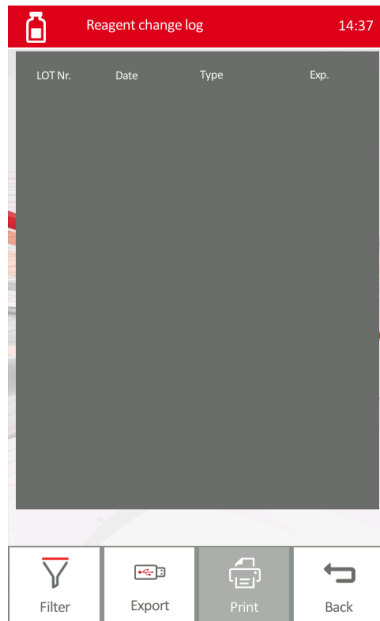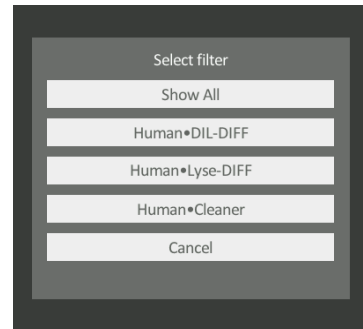From the Main Menu select Maintenance/Reagent Status, then press the View log button at the bottom of the screen.

By pressing **Filter** button the operator can select which reagents to show in the log:

Press **Export** to save Reagent change log on an USB pen drive as file "reagent_tracking.csv" in ASCII format. It can be opened in Excel.

Press **Print** to print reagent log.
Tap **Back** to return to previous menu.

4.10.5 HOW TO EMPTY WASTE CONTAINER
Software counts volume of waste, and gives warning message when the waste tank is close to its maximum capacity. Tap Empty waste to set the waste counter to zero see Figure 126.
Empty the waste tank when this warning message appears. See next section for neutralization steps.

4.10.6 NEUTRALIZATION OF WASTE
Waste contains human origin substances representing biohazard.
These substances are representing potential danger to environment. For this reason, safe handling of the waste liquid is very important.

Neutralization of biohazard waste:
- Put 2 ml per liter of **hypochlorite** solution into the waste. Close the cap and shake the container.
- After 1 hour you can dispose of the Waste liquid into the drain.

5 TROUBLESHOOTING

HumaCount 30^{TS}/HumaCount 80^{TS} provides all the necessary software mainte-
nance functions required to keep the analyzer operating in optimum working
order. Despite excellent maintenance, the analyzer can still encounter problems
where operator intervention is required. HumaCount 30^{TS}/HumaCount 80^{TS}
analyzer software informs the operator of situations when further help is re-
quired. These are called error messages.

5.1 Error messages

HumaCount 30^{TS}/HumaCount 80^{TS} analyzer provides additional information in
the form of numerical codes that help the operator to identify the root cause of
the error. These error codes are important for service personnel. They can inter-
pret the messages and take necessary actions.

If you receive error messages with codes,
please write them down. If possible, de-
scribe what you were doing before the er-
ror appeared. This important information
helps your service engineer to help you
when necessary.
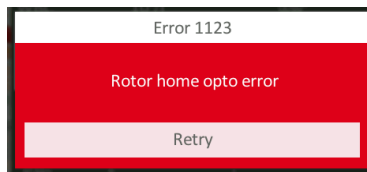
FIGURE 136

The software will store and re-display every
error message, but it cannot describe the
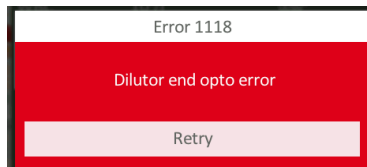operation you were performing when the
error happened.

FIGURE 137

When an error comes up, the software usu-
ally attempt to offer a solution, or will try
to resolve the problem and retry the cur-
rent operation. If this recovery process fails,
or the problem continues to occur, please
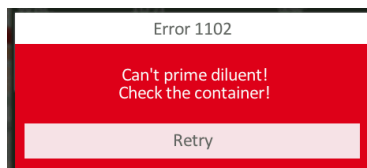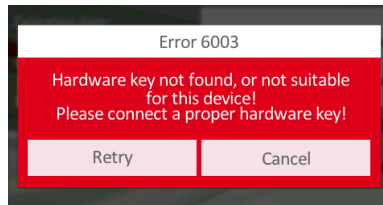contact your service engineer.

FIGURE 138

Human

5.2 Pneumatic/mechanical error messages

FIGURE 139

Error 6003

Hardware key not found, or not suitable
for this device!
Please connect a proper hardware key!

| Retry | Cancel |

The analyzer software is designed to be error tolerant and recover from minor problems.

However, if some physical obstructions or extreme operating conditions cause some mechanical parts to behave un-expectedly, the system will give you an error message such as this.

Clicking **Retry** retries the current operation.

5.3 Known Limitations

Blood samples should be analyzed within 7 hours of venipuncture, otherwise precision is not guaranteed, especially on 3-part differential WBC parameters see also chapter 3.4.

Any result provided by the analyzer should be verified by a professional and only the full clinical picture of the patient can lead do a diagnosis.

5.4 Specifications

5.4.1 SPECIFICATIONS HUMACOUNT 30^{TS}

TABLE 17

! **Differential results for WBC counts below 1.00 are not displayed, due to low cell count.**

Sample volume	25 µl of whole blood in normal 3-part mode
	50 µl of whole blood in pre-diluted mode
Chambers	1 counting chambers
Reagent system	HC-Diluent, HC-Lyse CF, HC-Cleaner
Aperture diameter	70 µm (RBC/PLT/WBC)
Throughput	30 tests/hour

5.4.2 SPECIFICATIONS HUMACOUNT 80^{TS}

TABLE 18

Sample volume	25 µl of whole blood in normal 3-part mode
	50 µl of whole blood in pre-diluted mode
Chambers	2 counting chambers
Reagent system	HC-Diluent, HC-Lyse CF, HC-Cleaner
Aperture diameter	80 µm for RBC/PLT
	100 µm for WBC
Throughput	80 tests/hour

5.4.3 HUMACOUNT 30^{TS} AND HUMACOUNT 80^{TS}

Characteristics Parameter	Accuracy	Reproducibility (CV)	Carry-over sample to sample	Test range	Unit	
WBC	3%	3%	<1%	4.0...20.0	$10^3/\mu l$	**TABLE 19**
RBC	3%	2%	<1%	4.0...15.0	$10^6/\mu l$	
HCT	3%	3%	<1%	25.0...50.0	%	
MCV	2%	1%	N/A	60...100	fl	
HGB	2%	2%	<1%	9...16	g/dl	
PLT	5%	5%	<3% or <20	200...900	$10^3/\mu l$	

Sampling method	Open tube system with automatic sample rotor.	**TABLE 20**
Sample types	Human (general), male, female, baby, toddler and child and veterian samples as defined by the software.	
Clog prevention	High-voltage pulse on aperture in each analysis cycle, chemical cleaning and high pressure back-flush of the aperture using Cleaner reagent.	
Cleaning procedure	High-voltage burst of the aperture, high-pressure back-flush, chemical cleaning of the aperture using cleaner reagent.	
Calibration	1-,2-, or 3-measurement automatic and manual (factors) calibration of WBC, HGB, RBC, PLT, MCV, RDWcv and MPV. Independent calibration of pre-diluted mode.	
User interface	Easy-to-use, menu driven user interface with touchscreen and status LED.	
Languages available	English, Spanish, Portuguese, French, Russian, Indonesian, German, Polish, Czech	
Data capacity	10.000 results, with RBC, PLT, and WBC 3-part histogram	
Host computer interface	USB B port	
Data back-up method	USB mass storage device (PenDriveTM)	
Software upgrade method	via USB A port using USB mass storage device (PenDriveTM)	
Printer interface	USB with support for HP printers (DeskJet, LaserJet, PCL3, PS, LIDIL), EPSON Dot-matrix printers	
Built-in printer	Thermal printer module, 58 mm wide roll paper, full report with histograms	
Display	800x480 -dots, high-contrast, capacity color touch screen	

Human

User interface	Color Touch-screen + separate red/green state LED
External keyboard	USB keyboard via USB A port
Power requirement	12VDC, 5A, 60VA max. operating power
Power supply unit	External power supply GlobTek GT-41132-6012-T3 (100-240 VAC, 50-60Hz) and power cable
Operating temperature	59–86 °F (15–30 °C). Optimal temperature is 77 °F (25°C)
Dimensions (WxDxH):	Instrument without any components: 32 x 26 x 36.5 cm
	Space required for routine use 52 x 46 x 50 cm
	Packaging 50 x 41 x 59 cm
Weight:	Gross: 12.5 kg, Net: 12 kg
Storage and Transportation storage temperature	5-35°C (54 95°F)

5.5 The Measurement Process

For the schematics of the fluidics system, see section 5.6.

Sample aspiration and dilution:

Stages of the blood testing process for HumaCount 30^{TS}

a	25 µl of anti-coagulated (K3-EDTA) whole blood sample is aspirated into the sampling needle, and mixed with 4 ml of diluent (**HC-DILUENT**) and stored in the chamber (MIX dilution).
b	25 µl of the MIX dilution is aspirated into and stored in the needle during WBC measurement and hemoglobin analysis
c	**Lysing reagent (HC-LYSE)** is added to the mix dilution held in the chamber for WBC differential analysis. This amount of **lysing** reagent is patient type dependent and the operator can change it.
d	After WBC counting, HGB reading and washing process, 4 ml of diluent is added to the second dilution (using the 25 µl of mix dilution stored in the needle).
e	This portion is analyzed for RBC count, PLT count and their parameters.
f	Another washing process prepares the unit for the next analysis.

Dilution rates used:		Measurement times:	
MIX dilution	1:160	WBC count	8 seconds
RBC dilution	1:32 000	HGB measurement	3 seconds
WBC dilution	1:196	RBC/PLT count	8 seconds
(depends on lyse amount)			

Sample aspiration and dilution:

	Stages of the blood testing process HumaCount 80TS	
a	25 µl of anti-coagulated (K3-EDTA) whole blood sample is aspirated into the sampling needle, and mixed with 4 ml of **HC-Diluent** and held in the chamber (MIX dilution).	**TABLE 22**
b	25 µl of the MIX dilution is aspirated into and stored in the needle during WBC measurement and hemoglobin analysis.	
c	**Lysing reagent (HC-LYSE CF)** is added to the mix dilution held in the chamber for WBC differential analysis. This amount of **lysing reagent** is patient type dependent and the operator can change it.	
d	After WBC counting, HGB reading and washing process, 4 ml of diluent is added to the second dilution (using the 25µl of mix dilution stored in the needle).	
e	This portion is analyzed for RBC count, PLT count and their parameters.	
f	Another washing process prepares the unit for the next analysis.	

Dilution rates used:

		Measurement times:	
MIX dilution	1:160	WBC count	8 seconds
RBC dilution	1:32 000	HGB measurement	3 seconds
WBC dilution	1:196	RBC/PLT count	8 seconds
(depends on lyse amount)			

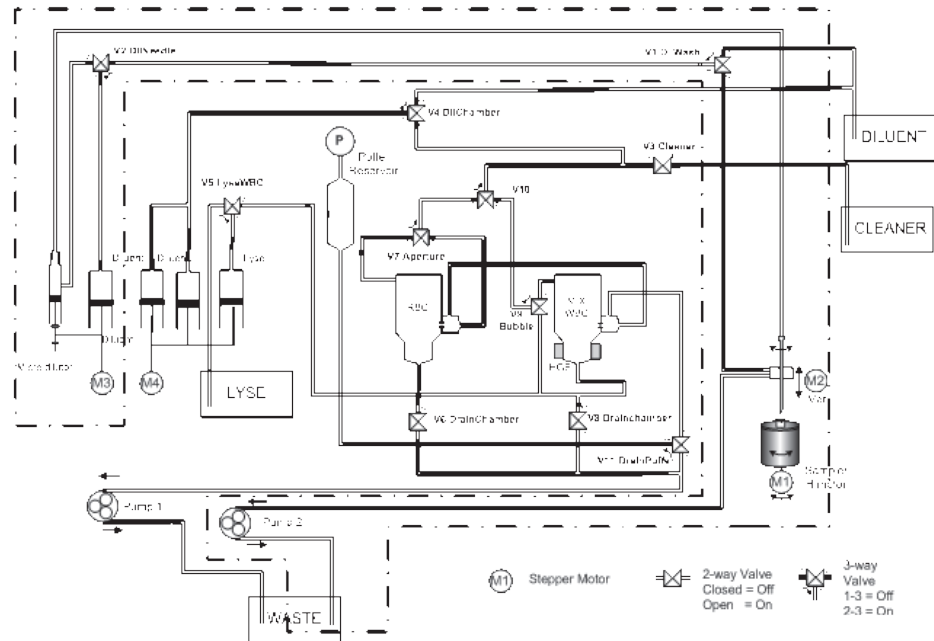## 5.6 Fluidic Schematics

5.6.1 FLUIDIC SCHEMATICS OF HUMACOUNT 30^{TS}

FIGURE 140
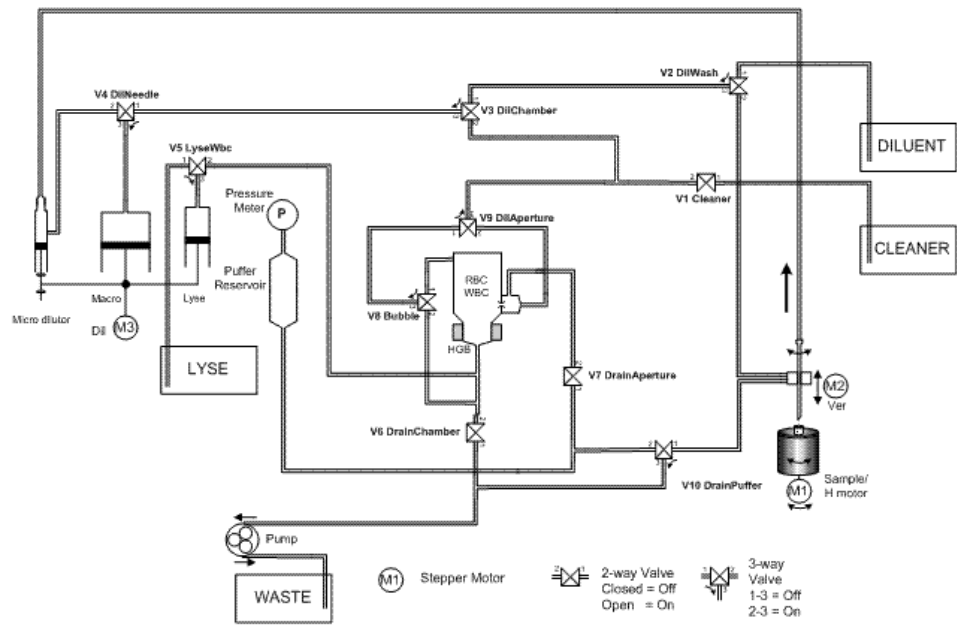
5.6.2 FLUIDIC SCHEMATICS OF HUMACOUNT 80^{TS}

FIGURE 141

5.7 Sample Identification

The following sample information items are used to uniquely identify samples:

- Sample Mode (Blank, Control, Human, pre-diluted, etc.)
- Time of measurement: assigned automatically by the HumaCount 30^{TS}/ HumaCount 80^{TS} analyzer SW.
- Sample ID: assigned by the operator – or automatically assigned by HumaCount 30^{TS}/HumaCount 80^{TS}.
  - o HumaCount 30^{TS}/HumaCount 80^{TS} doesn't require the sample ID to be unique.
  - o Sample ID can submitted by:
    - • Manual typing
    - • Bar code reading (with a manual bar code reader)
    - • Automatically assigned by HumaCount 30^{TS}/HumaCount 80^{TS}
  - o Sample ID is not applicable on blank measurements
- Patient ID: assigned by the operator by manually typing in
  - o Not applicable for blank and QC measurements
  - o Can be changed in the database later on

! **Use caution and ensure accurate data entry when manually entering sample ID or patient ID information into the user interface of the HumaCount 30^{TS}/ HumaCount 80^{TS} analyzer to avoid possible misidentification of sample results.**

Human

6 APPENDIX

6.1 Reagent Solution and Consumption

Reagents supplied by Human are the only ones recommended for use with the analyzer.

Reagents supplied by **Human GmbH** are the only ones recommended for use with the analyzer.

1. DIL :   An isotonic saline solution used to dilute whole blood specimens and to rinse the fluidic
system between measuring procedures.
HC-DILUENT REF 17400/11 (20 liters)

2. LYSE :   Used to prepare blood hemolysate for WBC and HGB measurement.
HC –LYSE CF REF 17400/22 (2x1 liter)

3. CLEAN :   Used to perform cleaning process of the fluidics.
HC- CLEANER REF 17400/31 (1 liter)

6.1.1 AVERAGE REAGENT CONSUMPTION HUMACOUNT 30^{TS}

	Reagent consumption / function (ml)			
Function	**Diluent**	**Lyse**	**Cleaner**	TABLE 23
StartUP (Init + wake up)	50	2.5	2.5	
Shut down	10	0	0	
Measure Blank	32	0.7	1.3	
Measure Human	32	0.9	1.3	
Measure Calibration	32	0.8	1.3	
Measure QC	32	0.8	1.3	
Prime Diluent	15	0	0	
Prime Lyse	12	3.5	0	
Prime Cleaner	13	0	5.5	
Standby	7.5	0	0	
Wake up	7	0	0	
Clean	22	0	1.2	
Hard clean	26	0	0	
Selftest	15	0	0	

Preparing for shipment: Rinse 105 ml
Hard Clean: Cleaning solution 0.1 ml

6.1.2 AVERAGE REAGENT CONSUMPTION HUMACOUNT 80^{TS}

TABLE 24

Function	Reagent consumption / function (ml)		
	Diluent	Lyse	Cleaner
StartUP (Init + wake up)	150	5	7
Shut down	40	0	5.5
Measure Blank	31	0.5	0
Measure Human	31	0.9	0
Measure Calibration	31	0.7	0
Measure QC	31	0.7	0
Prime Diluent	31	0	0
Prime Lyse	26	2.4	0
Prime Cleaner	31	0	1.5
Standby	10.5	0	0
Wake up	8	0	0
Clean	42	0	5.5
Hard clean	52	0	0
Selftest	16	0	0

Preparing for shipment: Rinse 80 ml
Hard Clean: Cleaning solution 0.2 ml

6.2 APPENDIX "A": FINDING THE CORRECT ⎡LYSE⎤ VOLUME FOR VETERINARY APPLICATIONS

The software running on the instrument uses some default ⎡LYSE⎤ volumes, pre-set at software installation. However, the required ⎡LYSE⎤ volume depends on several parameters. ⎡LYSE⎤ volume can be adjusted in the SETTINGS/LIMITS menu for each species. An additional option to modify ⎡LYSE⎤ quantity by ± **0.2 ml** is available during analysis.

The manufacturer cannot guarantee that pre-set volumes will always give the best results. It is therefore strongly recommended that the user oneself shall find the necessary volumes for the veterinary application. This requires some experiments, but the result validated a user doing vet practice will be worth it.

The two most important parameters influencing lysing are lysing time and ⎡LYSE⎤ quantity. You cannot change the lysing time, as it is fine-tuned for the ⎡LYSE⎤ supplied by HUMAN GmbH.

Above you could read that ⎡LYSE⎤ quantity can be adjusted either at patient limits, or right before measurement. In the following figures, you can see examples of over- or under-lysed samples.

Increase the LYSE quantity **(+0.1 ml)** if the separation between lysed RBCs and WBC populations is poorly differentiated, resulting in increased WBC and LYM counts.

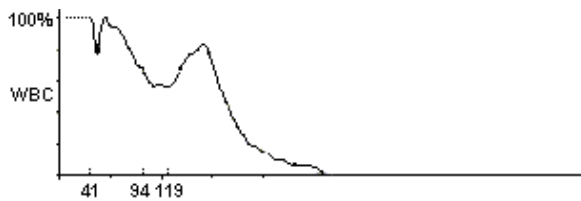
FIGURE 142

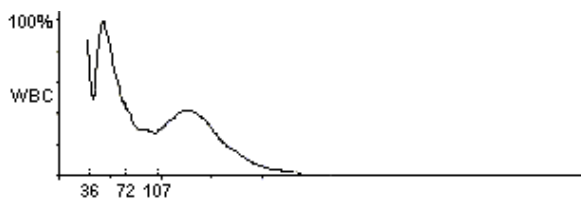Under-lysed sample, some RBCs counted as WBCs
WBC = 16.9, LYM% high

FIGURE 143

The same sample with LYSE boost (+0.1 ml)
WBC =13.7, good 3-part differential
You can see that a lower amount of LYSE will result in a less differentiated curve.
If you increase the LYSE quantity it will be more differentiated, and well evaluated.

Decrease the LYSE amount **(-0.1 ml)** if the WBC histogram seems to be shrunk to the left, i.e. the different WBC populations are overlapped. This can inhibit proper separation of WBC populations.
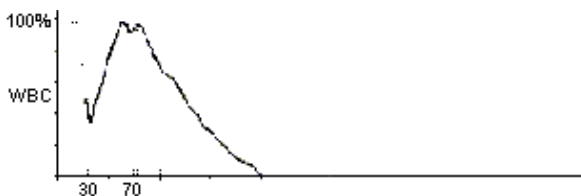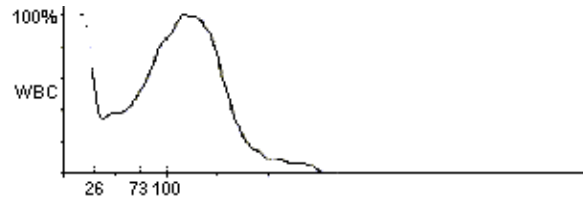

FIGURE 144

Over-lysed sample, LYM and GRA overlapped
WBC = 20.6, poor 3-part differential

FIGURE 145

The same sample with LYSE decreased (− 0.1 ml)

WBC = 21.0, good 3-part differential

An over lysed sample will have all its cells shifted down towards the smaller cells. It is because of too much lysing reagent is shrinking all cells to the size of their nuclei.

With LYSE quantity decreased, the cells will not shrink that much, and can be differentiated easily.

Human