HumaCount 60TS

| User Manual

CE

16420/601

Human

Diagnostics Worldwide

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SYSTEM VERSION

HumaCount 60^{TS} with software version 1.4 .

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1 SAFETY INSTRUCTIONS

1.1 Introduction

This manual is considered as a part of the instrument; it has to be at the operator's hand as well as at the maintenance operator's availability. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid instrument damage or personal injury, carefully read the "GENERAL SAFETY WARNINGS", describing the suitable operating procedures. In case of breakdowns or any troubles with the instrument, apply to the local Technical Service.

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 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, diskettes, 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.

HUMAN shall be relieved of any obligation under this warranty, unless a completed installation / warranty registration form is received by HUMAN within 15 days of installation of this product.

This warranty does not apply to damages incurred in shipment of goods. Any damage so incurred shall be reported to the freight carrier for settlement or claim.

1.3 Intended Use of the Instrument [IVD]

The instrument is intended for in vitro diagnostic application by professional users. It has to be used for the expected purposes and in perfect technical conditions, by qualified personnel, in working conditions and maintenance operations as described in this manual, according to the GENERAL SAFETY WARNINGS. This manual contains instructions for professional qualified operators.

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 stationary flat working surface, free from vibrations.

Do not operate in area with excessive dust.

Work at room temperature and humidity, according to the specifications listed in this manual.

Do not operate this instrument with covers and panels removed.

Only use 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, 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 potentially explosive environment or at risk of fire.

Prior to cleaning and/or maintaining the instrument, switch off the instrument and remove the power cord.

For cleaning use only materials specified in this manual, otherwise parts may become damaged. It is recommended always to wear protective apparel and eye protection while using this instrument. Respective warning symbols, if appearing in this manual, should be carefully considered.

1.5 Disposal Management Concept

The currently valid local regulations governing disposal must be observed. It is in the responsibility of the user to arrange proper disposal of the individual components.

All parts which may comprise potentially infectious materials have to be disinfected by suitable validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal have to be carefully observed.

The instruments and electronic accessories (without batteries, power packs etc.) must be disposed off according to the regulations for the disposal of electronic components.

Batteries, power packs and similar power source have to be dismounted from electric/electronic parts and disposed off in accordance with applicable local regulations.

1.6 Instrument Disinfection

Analytical instruments for in vitro diagnostic 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.

Before doing 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 should be performed by authorised well-trained personnel only, observing all necessary safety precautions. Instruments to be returned have to be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing centre, or from authority's interventions.

1.7 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.

For safety reasons, we have labeled instruments with the „BIOHAZARD“ warning label below.

FIGURE 1
Biological Hazard Symbol

Notes:

2 SYSTEM DESCRIPTION

The HumaCount 60TS is a fully automated cell counter designed for in vitro diagnostic use, developed for small clinics and point-of-care lab offices.

2.1 The Instrument

HumaCount 60TS is a fully automated, bench-top hematology cell counter.
It implements 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 LCD display module with touch screen, and has a separate START button.
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 1000 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 analyzer can process 60 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 18 hematology parameters, including 3-part WBC differential, from a 25 µl whole blood sample:

WBC	total white blood cell count
LYM	lymphocytes count
MON	monocytes count
NEU	neutrophil count
LYM%	lymphocytes percentage
MON%	monocyte percentage
NEU%	neutrophil percentage
HGB	hemoglobin
RBC	red blood cell count
HCT	hematocrit
MCV	mean corpuscular volume
MCH	mean corpuscular hemoglobin

MCHC mean corpuscular hemoglobin concentration
RDWcv red cell distribution width*
PLT platelet count
PCT platelet percentage
MPV mean platelet volume
PDWcv platelet distribution width*

*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: Isotonic saline solution, used to dilute whole blood samples and to rinse the fluidic system between measuring proce dures.

HC-LYSE: Creates hemolysate for 3-part WBC differential and for total WBC and HGB.

HC-CLEANER: For cleaning process of the fluidics.

2.1.3 TECHNICAL OPERATION

As the cell counter is a fully automated instrument, operating it 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 specific 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 description (5.3.).

2.1.4 CALIBRATION

HumaCount 60TS arrives to your laboratory factory-calibrated 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 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 (4.3).

2.2 Unpacking and Installation

This chapter provides instructions for the unpacking and installation of HumaCount 60TS hematology analyzer. 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.

! Always handle the instrument with care.

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.

! 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.

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 2.2.1 – Environmental factors)

! 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

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 60TS. 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

! 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.

Connect the power supply to the instrument. Attach power cord outlet to the external power supply of HumaCount 60TS 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 60TS, 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.b

! 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.

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.

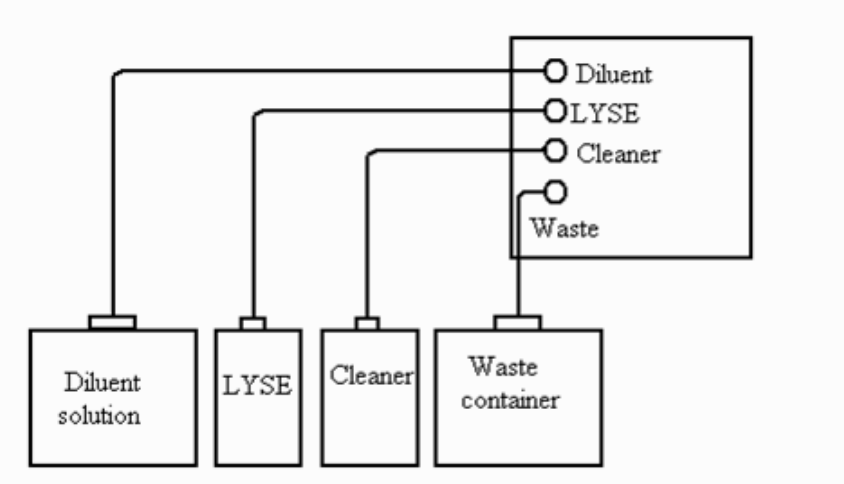


FIGURE 2

2.2.1 ENVIRONMENTAL FACTORS

Operate HumaCount 60TS 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 stand for an hour at the correct room temperature before use.

Reagents should be stored at a temperature range of 18...30°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 receiver, radars, centrifuge, X-ray devices, fans, etc.).

Operation at an altitude over 3000 meters (9000 ft) is not recommended, because the throughput will be degraded.
Instrument is safe for transient voltages to INSTALLATION CATEGORY II and POLLUTION DEGREE 2.
Environmental and electrical characteristics provide accuracy and precision of the instrument and maintain a high level of operational safety for lab personnel.

2.2.1.1 Electrical requirements

HumaCount 60^{TS} comes 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 bypasses important safety features and may result in electrical hazard.

2.2.1.2 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 0.5m (20in) space on both sides and above the instrument to access pneumatics and (optional) built in printer. Provide a minimum of 0.2m (8in) 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.

! 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.

2.2.1.3 Peripherals

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

external printer

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

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)

2.2.1.4 Reagents and waste handling

! 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.

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 5.2.2.

! 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.

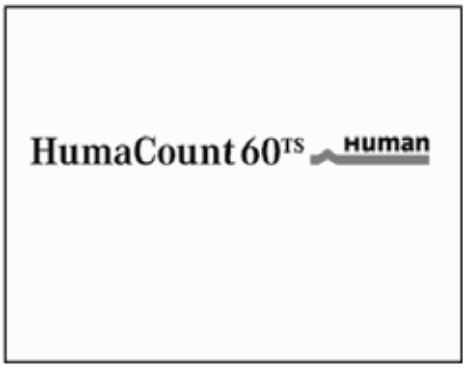
2.2.1.5 General points

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

2.2.2 TURNING THE INSTRUMENT ON, MAIN MENU

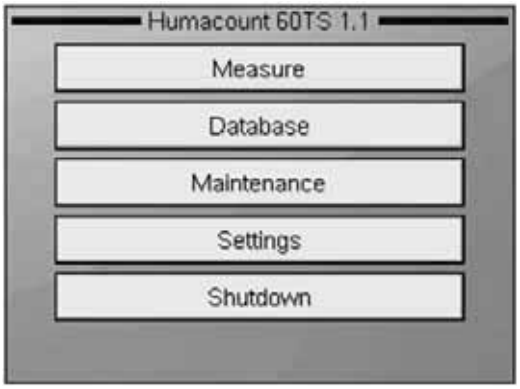
- In case you use an external printer (for information, read manual shipped with the printer) connect it and turn it on.
- Turn the analyzer on using the power switch on the rear panel. The 'ON' position is marked by the 'I' symbol.



After turning on power, there will not be LCD activity for a few seconds, but the status LED goes on.

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.



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.

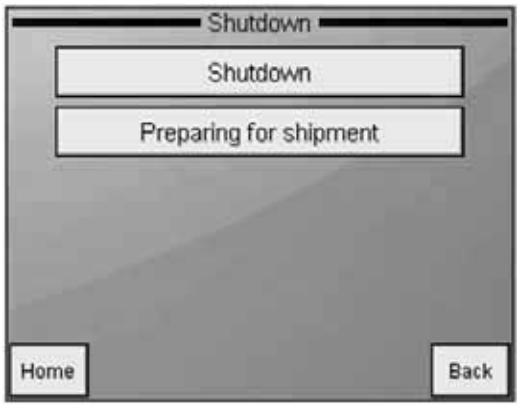
Run a priming cycle in case of:
- installation
- extended time out of use
- replacement of any component related to the Fluidic System
- replacement of reagents with instrument turned on

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

2.2.3 TURNING THE INSTRUMENT OFF

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. It can be so, because the instrument uses diluent. This liquid is an isotonic saline solution containing salt. Would it not be washed out of special units of the instrument or would chambers not be filled with this solution may lead to dust condensation or salt build up. Therefore always follow the instructions below when switching the instrument off.

In Main menu, select SHUTDOWN. The following screen appears:



SHUTDOWN

SHUT DOWN (1)

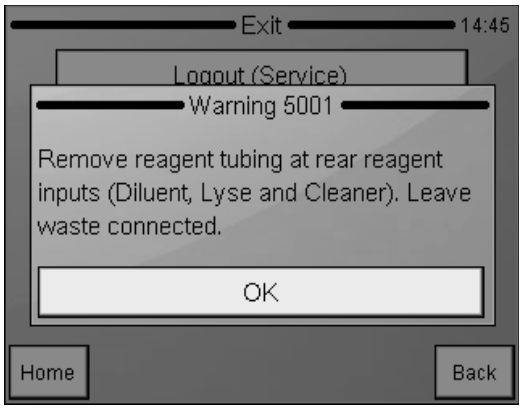
Select **Shutdown**.

The analyzer will perform the necessary steps to prevent failure to the pneumatic system, and then gives a tone indicating that it is safe to shut it off.

Turn off the instrument using the power switch on the rear panel. The 'OFF' position is marked by **'O'** symbol.

2.2.4 PREPARING FOR SHIPMENT

Use the second item in the Shutdown menu when the instrument is to be shipped or left unused for a longer time (more than 1 week). The instrument will ask you to use the cleaning tube kit and 100 ml of distilled water.
Follow the instructions appearing on the display.

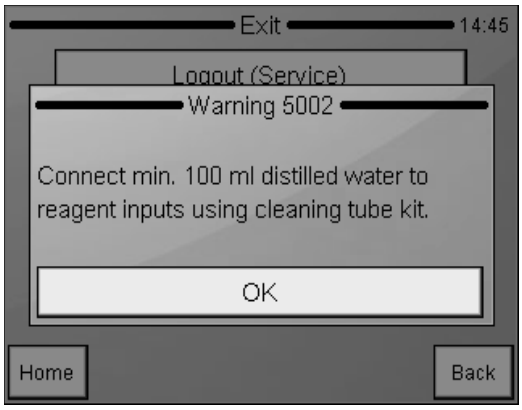


SHUTDOWN

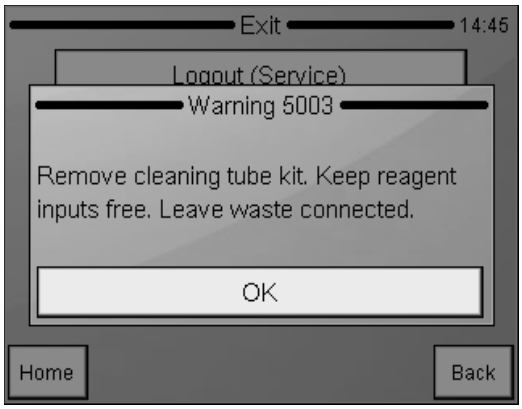
Preparing for shipment (2)

Remove tubing connectors, so the system can drain itself.

Leave the waste connector attached.



Next, you should connect the cleaning tube kit to the reagent inputs, submerging the free end in a bottle containing at least 100 ml of distilled water.
Cleaning tube kit connected
The analyzer will flush any remaining reagents from the system into the waste container.



As a next step, the analyzer asks you to remove the cleaning tube kit. Leave Waste connected.
When finished, the analyzer prompts you to power off the system. Remove the waste connector after shutting down.

2.2.5 HANDLING IN EMERGENCY

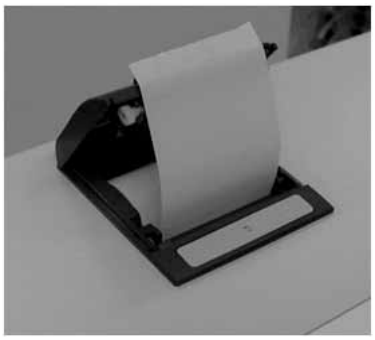
In case of emergency situation - like instrument catching on fire (short-circuit, etc.) - cut off power immediately by disconnecting mains power or DC input line, and use a fire-extinguisher if necessary.

2.2.6 REPLACING PAPER INTO THE PRINTER

To replace paper in the printer:

- 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

- gently drop the new roll into the holder of the printer, and hold the "starting edge" with your hand, and make sure it comes out on the front of the printer



- close the lid, making sure that the paper is captured between the lid and the front of the printer

! Use only the provided power supply with the instrument: "GlobeTek Electronics Corp." Model ID: GT-81081-6012-T3

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.

2.2.7 ACCESSORIES

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

TABLE 1
Accessories

HumaCount 60TS		
Hematology Analyzer	1	16420/60
User Manual	1	16420/601
Reagent Tubing kit (with coloured tubes):		16420/622
- Diluent Tube (green)	1	
- Lyse Tube (yellow)	1	
- Cleaner Tube (blue)	1	
- Waste Tube (red)	2	
- Cleaning Tube Kit	1	
- Caps for reagent containers (matching connector colors)	1	
Waste Container (20 l)	1	
External power supply and power cable	1	16420/168
Sample tube adapters	3	16420/180, -/181, -/323
Thermal roll-paper	2	16420/621

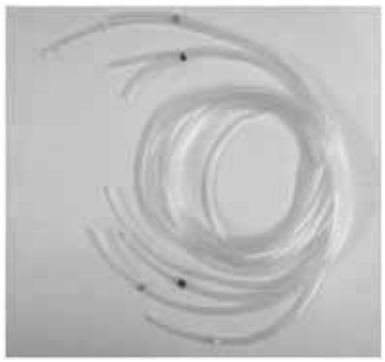


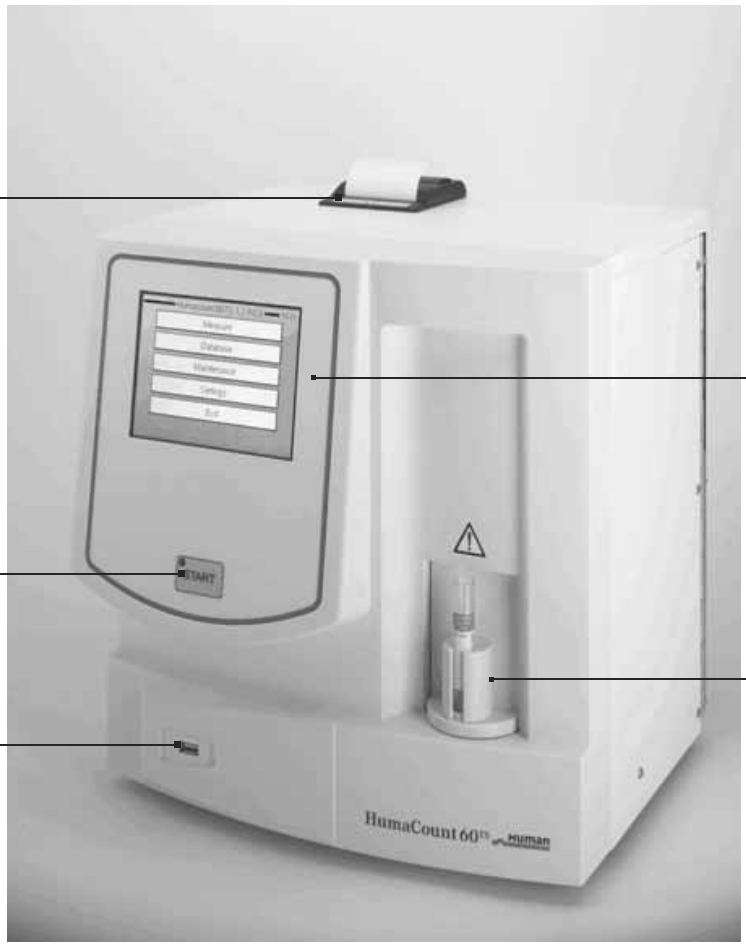
FIGURE 3
Reagent Tubing Kit

FIGURE 4
Cleaning Tubing Kit

2.3 Instrument features

Figures 5 and 6 show front and rear view of the analyzer, with controls and connectors.

FIGURE 5
Front View



1 **Built-in thermal printer**
2 **START button with status indicator**
3 **Front panel USB socket**
4 **Color LCD Touchscreen**
5 **Sample Holder with interchargeable adapters**

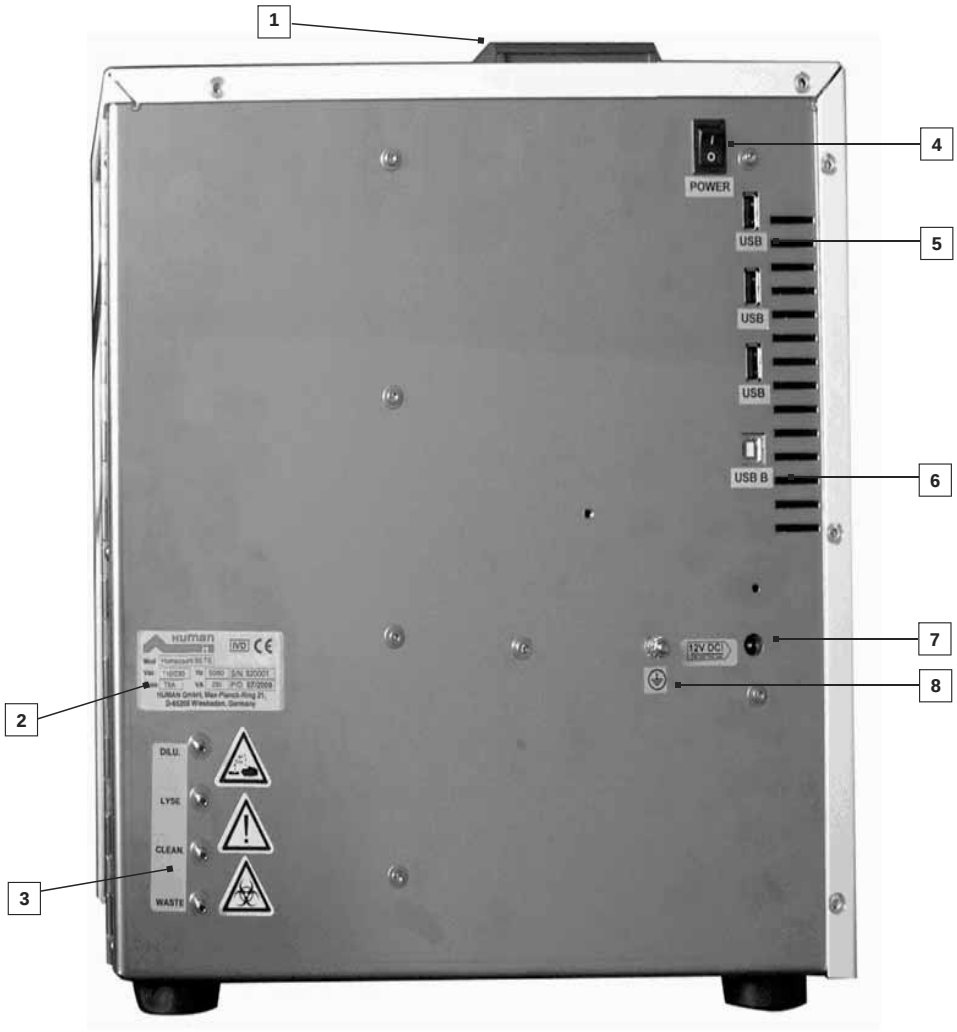


FIGURE 6
Rear View

1 **Built-in thermal printer**
2 **Instrument label (S/N, manuf.data)**
3 **Reagent Connector**
4 **Power Switch**
5 **USB A connectors**
6 **USB B connectors**
7 **Power source connector**
8 **External grounding connector**

2.4 Parts of the Analyzer

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.s.

2.5 Control Material

The analyzer allows continuous monitoring of measurement performance with **HC-CONTROL** 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.

2.6 Menu System

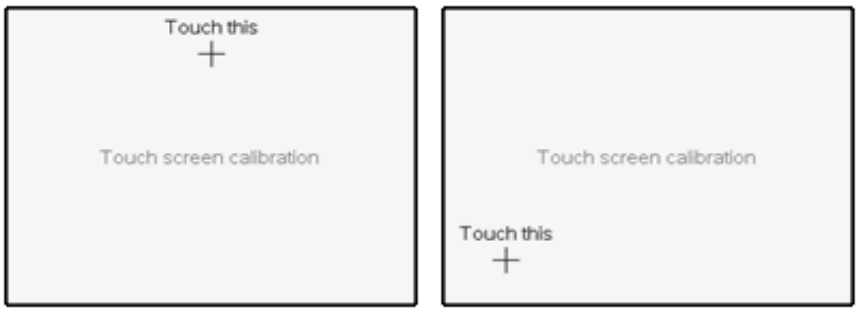
This chapter contains information about the structure and usage of the software implemented menu structure.

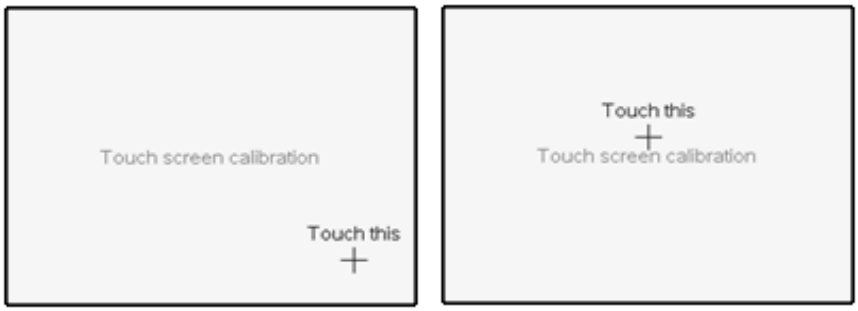
This integrated software controls instrument operations including calculation and evaluation of measured data, displaying results and information screens, storage and recalling of data.

2.6.1 TOUCH SCREEN CALIBRATION

In case you experience uncertainties during tapping the touch screen (you tap a specific location, still the required function key is not being activated) you will have to calibrate the touch panel.

Tap and gently hold any location on the touch screen. (Make sure not to press it hard, otherwise you can damage the screen.) After approx. 30 seconds, a calibrating screen appears. Tap the reference points one after another. If you made an error, you will hear beep, and the process restarts.





If the calibration was successful, you will return to the original screen.

2.6.2 NAVIGATING IN THE MENU SYSTEM

The instrument uses a menu system to initiate actions and to access settings. Navigate in the menu system by simply touching the LCD at the item you want to open/activate. From any submenu, the Home button will go back to Main menu, while Back moves one step back in the menu tree.
If you use an external keyboard, use the numbers indicated in front of the menu item as hotkeys.
Submenus are marked with a ▶symbol on the right of the menu line.

2.6.3 MENU STRUCTURE

Measure	New		
	Re-run		
	Blank		
	Print		
	Discard		

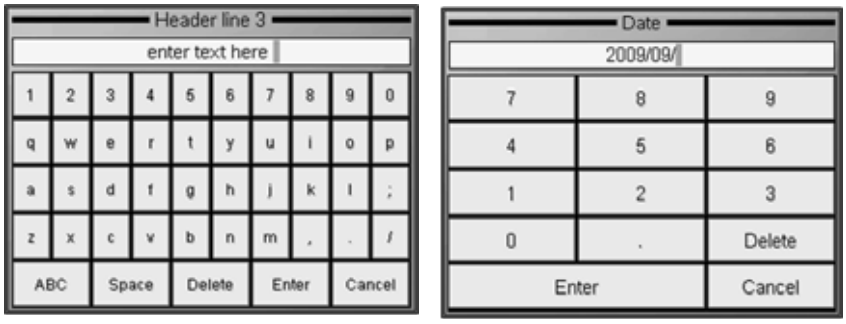
Database	Detail / Table view		
	Edit record		
	Print		
	Filter		
	Trends		
	Manage		

Maintenance	Cleaning	Cleaning	
		Hard cleaning	
		Drain chamber	
	Calibration	Factors	
		Measure	
		History	
	Quality control	QC1	References
		QC2	Measure
		QC3	Diagram
			Database
	Diagnostics	Device information	
		Self test	
	Reagent status	Volumes	

Settings	Printer	Device	
		Format	
		Header	
	General settings		
	Measurement	Units	
		Normal ranges	
		Settings	Result / Calibration
	Date and time	Set Date / Time	
		Date Format	

Exit	Logout	Add new user
	Shut down	Remove User
	Preparing for shipment	Auto login set
	User Management	Edit / View user

When you have to enter data, an on screen keyboard appears on the screen.
It can be a numerical or alphanumeric keyboard, depending on the function.



2.7 Method of Operation

2.7.1 IMPENDANCE METHOD

The impedance method (a.k.a. Coulter-method) counts and sizes cells by detecting and measuring changes in electrical impedance when a particle in a conductive liquid passes through a small aperture.

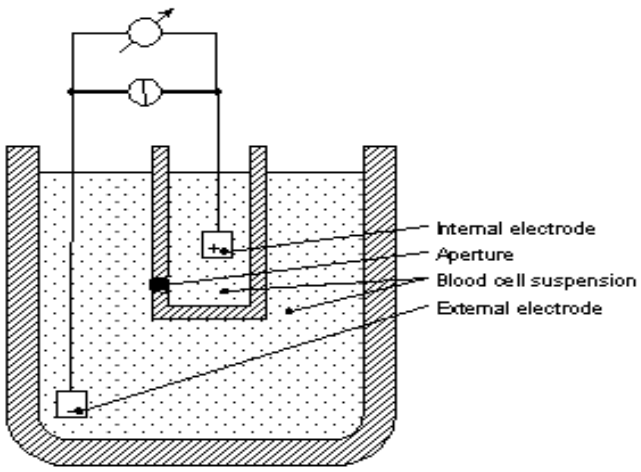


FIGURE 7
Impedance Method

Each cell passing through the aperture – there is a constant DC current flowing between the external and internal electrodes – causes some change in the impedance of the conductive blood cell suspension.
These changes are recorded as increases in the voltage between the electrodes.
The number of pulses is proportional to the number of particles.

The intensity of each pulse is proportional to the volume of that particle. The volume distribution of the cells are displayed on diagrams: WBC, RBC, and PLT histograms.distribution of the cells are displayed on diagrams: WBC, RBC, and PLT histograms.

2.7.2 PRINCIPLE OF HGB MEASUREMENT

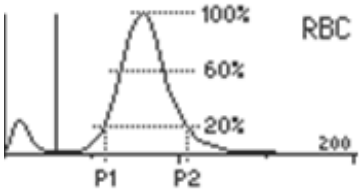
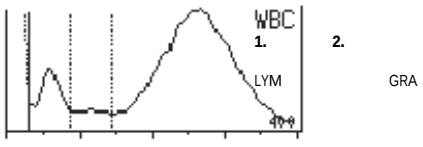
The lysed sample dilution can be measured by a photometric method. The reagent lyses the red blood cells, which release hemoglobin. The chemical process forms a stable form of methemoglobin. This is measured by a photometer on the chamber.

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.

2.7.3 PARAMETERS

HumaCount 60^{TS} measures and calculates 18 parameters, listed 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.

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_{ca}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)
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  $xDW\text{-}SD = RDW_{cal} \times (P2 - P1)$ (fl), $xDW\text{-}CV = RDW_{cal} \times 0.56 \times (P2 - P1) / (P2 + P1)$ 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, LY%** : lymphocytes **MON, MON%** : monocytes and some eosinophils **NEU, NEU%**: neutrophil granulocytes	Absolute values counted in the channels determined by the three WBC discriminators:  Percentages calculated from the absolute WBC value.

2.7.4 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 3.2.7 of this manual.

Linearity ranges of primary parameters in normal measuring mode:

TABLE 2
Linearity ranges of parameters

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

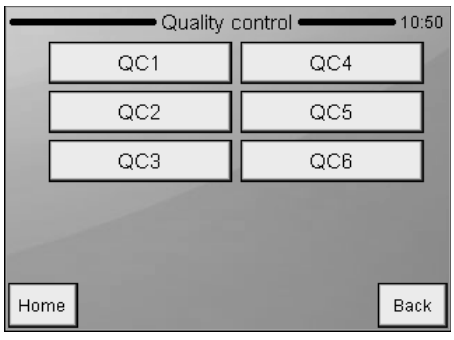
Linearity ranges for 1:5 pre-dilution mode:

TABLE 3
Linearity ranges of Pre-dilution mode

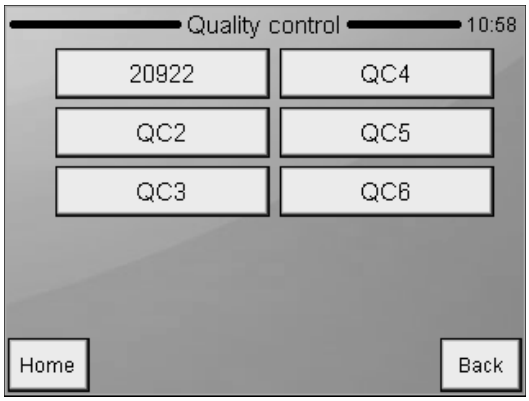
Parameter	Linearity Ranges	Maximum	Unit
WBC	2...200	300	10^9 cells/liter
RBC	1...30	40	10^{12} cells/liter
PLT	100...2000	3000	10^9 cells/liter

2.7.5 QUALITY CONTROL

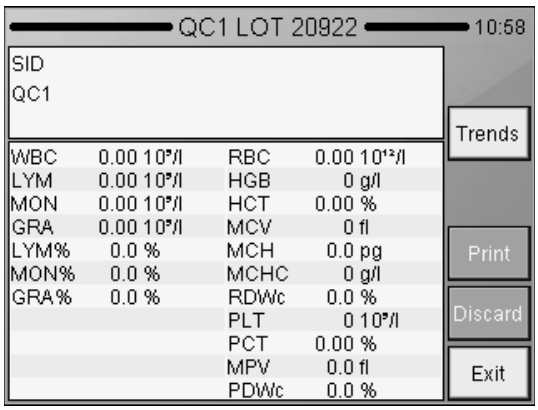
Quality control feature allows tracing the operation and reliability of the analyzer in time. The best practice is to run a control sample every morning. You can also use multiple control material lots.

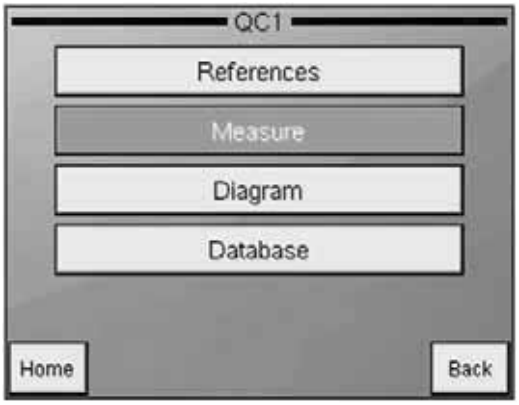


Maintenance
Quality control
Define QC level.
Select LOT to work on.
Press **HOME** to go to Main menu.
Press **BACK** to go back to previous menu.



QC results allow trend analysis for SD, CV% Mean.



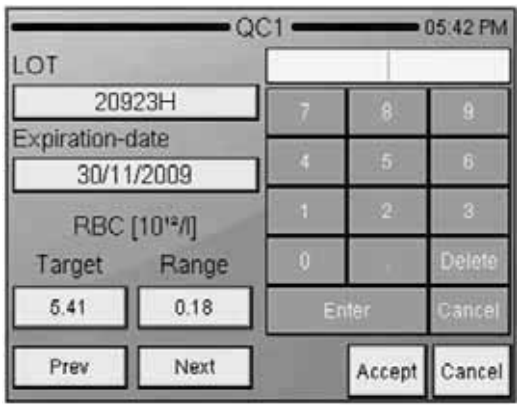


Maintenance
Diagnostics / QC1
Press HOME to go to Main menu.
Press BACK to go back to previous menu.

Control material is a defined and controlled quality prepared (almost artificial) blood product. It has conserved and treated blood cells inside which allows this material to be stable for a much longer time than normal blood would be.
The "Measure" option will become active only if there are reference values entered for the actual QC Lot.

2.7.5.1 References

To be able to run specific samples, and to see stability or variation of parameters, it is necessary to define a reference material for the software. This is going to be the basis for Quality Control. The idea is to enter these so-called expected or target values, and save everyday repeated runs of the same material in a separate database so that these values can be compared to the reference data. Reference values arrive with the control material. The manufacturer recommends using HC-CONTROL with the analyzer.
The assay value sheet contains all necessary parameters for the control material

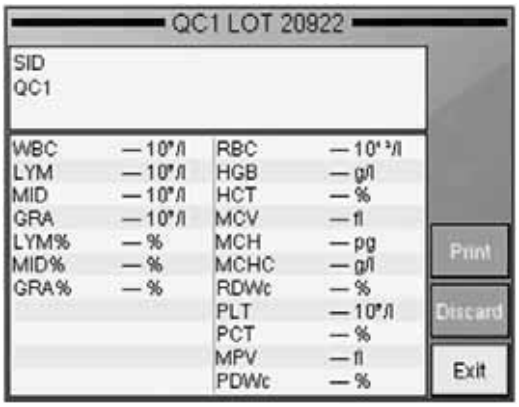


Maintenance
Quality control/Reference
Use Prev and Next to browse among parameters.
Press **Accept** to save data.
Press **Cancel** to discard changes and return to the previous menu.

Enter the values as defined on the assay value sheet of the control material.
In case you want to omit the trend analysis of a parameters, define 0 (zero) as target and range values.

2.7.5.2 Measure

This option puts you to the measurement screen and sets up the parameters for Control Blood measurement. Put the sample in the sample holder and press the START button. When analysis is complete, you will have to accept the results.



Maintenance

Quality control / Measure

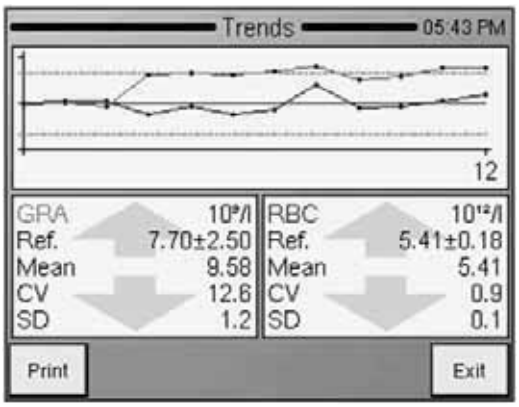
The software saves all results automatically to the selected QC lot database.

Press **Discard** to remove data from QC series.

Exit returns to the QC menu.

2.7.5.3 Diagram

QC Diagram displays the trends of parameters with respect to time. The screen will show two parameters at a time.



Maintenance

Quality control / Diagram

Use **Prev** and **Next** to browse among parameters.

Press **Accept** to save data.

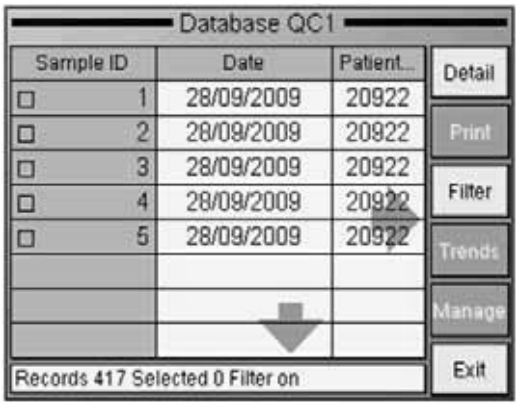
Press **Cancel** to discard changes and return to the previous menu.

Use the corresponding Prev and Next buttons to select parameters for display.

2.7.5.4 Database

This option displays the contents of the QC database. You can browse in this view just like in the regular database view. Functions (selection, browsing, details, printing) are the same as well.

! QC database is a filtered view of the normal database. The status bar shows the "Filter on" text.



Maintenance

Quality control / Database

Use **Prev** and **Next** to browse among parameters.

Exit returns to the QC menu.

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. Also, when taking blood, please make sure that requirements attached to sample tubes are met.

Important: 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.

There is another possibility that can help the user to help the analyzer get a reliable sample from the tube: using the needle setting function. This is available in Measurement Local menu, and controls sampling height of the needle inside the sample tube. If you have a sample tube with a higher/lower bottom, you can control the sampling height adjusting this option. This can also help if sample level is too low within a sampling tube.

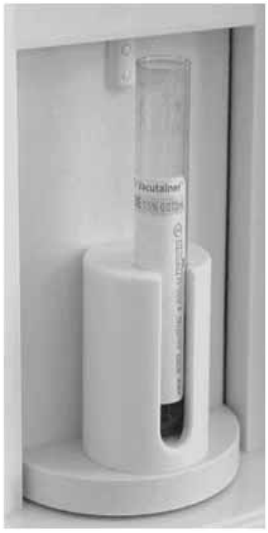
Needle offset is displayed in the lower left corner of the measurement screen.

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

To initiate analysis:

- 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!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 8
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 9
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 10
Tubes used in control adapter

1. Position the sample tube in the sample rotor.
2. Press START key.

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

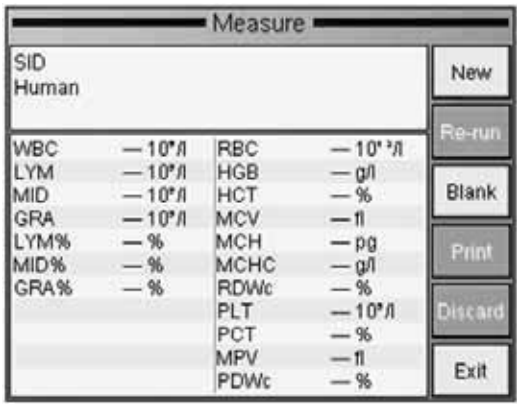
The sample rotor will turn the vial into the inside of the instrument and needle draws sample from the tube. The aspirating needle is retracted, while its outer surface is automatically rinsed with diluent by needle wash head. This insures the low carry-over between samples. After a few seconds, the rotor turns out. Now you can remove the sample tube from the adapter.

3.2 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.

3.2.2 RUNNING A (NEW) SAMPLE

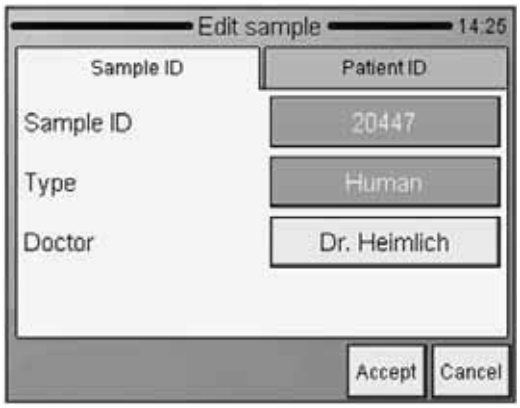


MEASURE
This is the screen where you can start measurements.
Exit will return to the Main menu

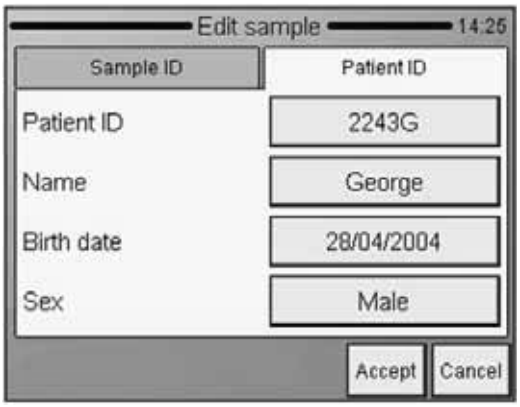
Press **New** to enter data for the sample.
Software allows the user to enter information for every sample. If an external PC keyboard (via USB) is used, it is suggested to be connected **before** turning the instrument on.

There are two options to enter sample information:
- immediately before analysis
- in Database menu

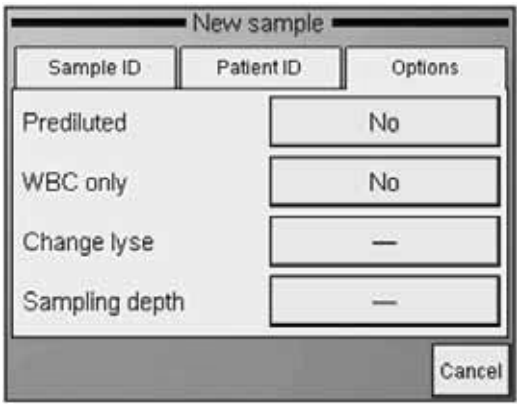
To enter sample information prior to sample analysis, touch sample info field in the MEASURE screen. The following screen appears:



MEASURE
New
Sample ID
A screen appears offering data entry for the upcoming sample.
Sample ID can be defined to identify the sample.
Type offers a list of profiles to select from.
Doctor will appear on the printout as well.
Cancel will return to the measurement screen (above).



MEASURE
New
Patient ID
A screen appears offering data entry for the patient.
Cancel will return to the measurement screen.



MEASURE
New
Options
A screen appears where offering data entry for the upcoming sample.
Settings remain as they are set for the following samples as well.
Cancel will return to the sample info screen.

Pre-diluted mode offers two options: Yes or No. If you set it to Yes, then the instruments expects a pre-diluted sample (with a ratio of 1:5 – 1 unit of sample and 5 units of isotonic saline solution – the total volume should be minimum 1ml)

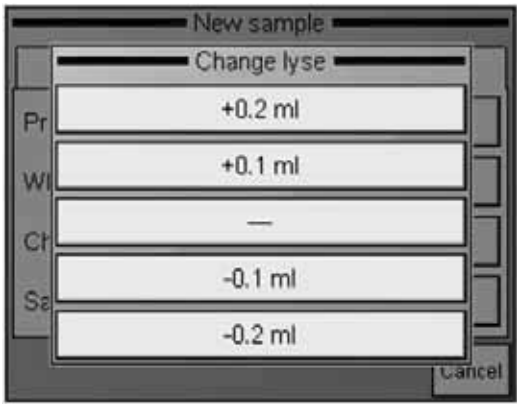
WBC only offers two options: Yes or No. If you set it to Yes, then the instrument will not measure and display RBC and PLT related parameters. You'll receive a total WBC count with 3part results and HGB reading (WBC, LYM, MID, GRA, LY%, MI%, GR%, HGB)

Change lyse

Volume of lyse reagent added to MIX dilution controls performance of WBC 3-part differential. Default lyse setting for each sample type (Human, control, Child, etc.) are specified by SW. Default lyse quantity can be adjusted in Patient limits menu (Settings / Measurement Limits)

Lyse volume

Select an increased (+0.1, +0.2ml) volume if the separation between lysed RBCs and WBC populations is poorly differentiated, resulting in increased WBC and LYM counts. Select a decreased (-0.1, -0.2ml) volume 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.

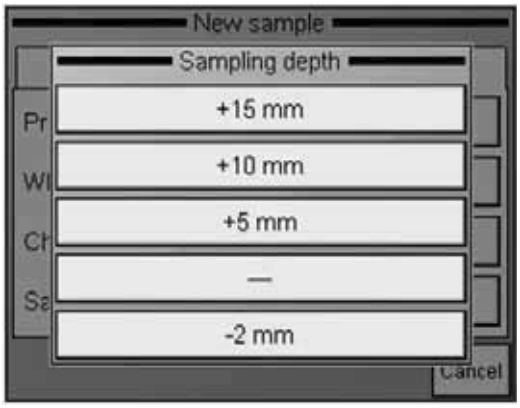


MEASURE
New Options / Lyse volume
Change lyse

These are the + or – options you can select from. See above description for information.

Sampling depth

The analyzer requires a minimum of 2 ml of whole blood in the sampling tube. HC60^{TS} can however be adjusted for low volume samples. This becomes necessary when there is extremely low volume of sample in the tube.
This option also allows using sampling tubes with an elevated bottom. In this case you have to set a higher sampling level to avoid the needle hitting the bottom of the tube.



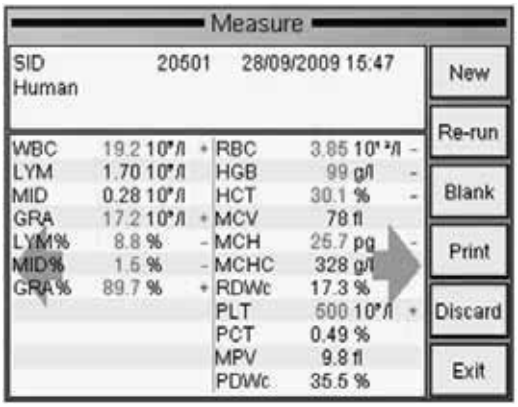
MEASURE
New
Options/Sampling depth

Select the necessary option so that the instrument can take sample from the right location.

When all parameters are set, press the START button to save your settings and start the measurement.

! Do not reach inside the instrument, as the needle can injure you!

3.2.3 RESULTS



When analysis is complete, the following screen is displayed, including all measured and calculated parameters as well as the WBC, RBC, and PLT histograms. Results, histograms and other terms will be stored automatically in the memory. To look at histograms in detail, tap the arrows to see further details.

3.2.4 WARNING FLAGS

Analyzer SW displays **warning flags** for each individual measurement to notify user about status of results. The following table summarizes **warning flags** and gives explanation of their possible cause and a few hints to overcome the problem.
Uppercase letters refer to WBC or HGB problems.

TABLE 4
Summary of warning flags related to WBC/HGB

Flag	Meaning	Recommended user action
E	No WBC 3-part differential	Possible lyse problem. May occur in pathological lymphocytosis.
H	HGB blank is high, or no HGB blank	Repeat the blank measurement. If HGB blank is not stable there are probably bubbles in the WBC chamber: Run a cleaning and try blank again. Close the side door if open during measurement.
B	WBC blank is high, or no WBC blank	Repeat the blank measurement, or run prime lyse and try blank again. Possible lyse contamination, or noise problem.

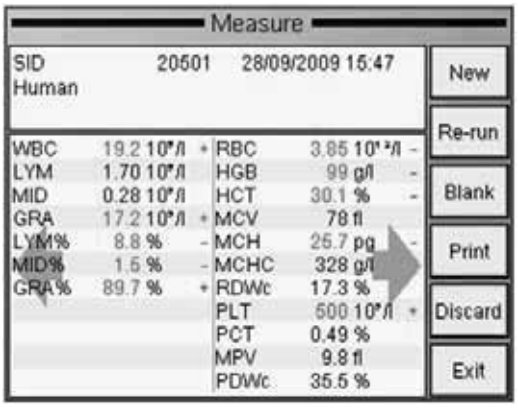
M	linearity range exceeded in WBC stage	The analyzer found that the cell count is higher than the linearity range of the analyzer. Make a pre-dilution, and run the same sample in prediluted mode
R	RBC cells found in sample during WBC stage	RBC cells were detected during the WBC measurement. Either the lyse reagent is not effective enough (volume should be increased) or the RBC's in the sample are somewhat lyse resistive
W	WBC 3-part warning	Probably large PLTs or clumped PLTs are present in the sample. Usually caused by the nature of the sample. cat and goat samples tend to clump. Intensive, but careful mixing of the sample (e.g. Vortex) can help remove the clumps. If the rerun sample gives the same results, consider that WBC and NEU values seem higher because of the clumps. Lyse modification can't solve the problem.
L	RBC-WBC limit warning	Typically insufficiently lysed RBC's interfere with the start of the WBC histogram. Repeating the measurement with an increased lyse volume should provide better separation. If the repeated run reports very similar results then the MON and NEU results are VALID but the WBC and LYM results may be higher because of interfering RBCs.
C	WBC clogging	Aperture clogging. Perform cleaning and repeat the measurement. If it is a general problem, please contact your Service Personnel. Low temperature reagents can cause it as well (mainly diluent), in this case you will have to wait until they reach room temperature

Warning flags in lowercase refer to RBC or PLT problems.

Flag	Meaning	Recommended user action
m	linearity range exceeded in PLT/RBC stage	The analyzer found that the cell count is higher than the linearity range of the analyzer. Make a predilution, and run the same sample in prediluted mode
k	RBC peak error	Multiple or incorrect RBC peak(s) detected. Try to run the sample again.
l	PLT / RBC limit not correct	PLT and RBC cells could not be separated, or the histogram remained high in the PLT/RBC valley range.
c	RBC/PLT clogging	The same action as in case of the C warning flag
p	PLT blank is high, or no PLT blank	Run cleaning and repeat the blank measurement. Diluent or system cleanliness problem. 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.

TABLE 5
Summary of warning flags related to RBC/PLT

Measurement conditions: when the flags are related to clogging **(c, C),** probably hemolysing problems **(E)**. Try to repeat the measurement.



The exclamation mark flag (!) near a parameter shows some doubt during the evaluation of that parameter.

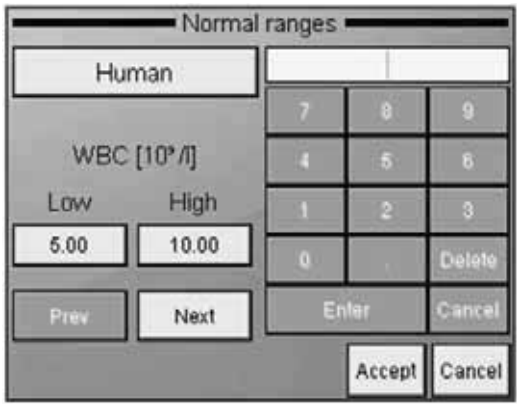
The reasons can be: a high PLT blank (PLT value will be marked), a case of indefinite discriminator setting (default location is used for some reasons, related parameters will be marked), etc.

Another flagging method is evaluation against the normal ranges. If some of the parameters is out of range it gets a (-) flag if under the range, or gets (+) if over the range. (And the given parameter will be highlighted as well.)

You can customize ranges for all kind of patients by setting the corresponding lower and upper ranges. If you set 0 for a range limit, it will be not verified.

3.2.5 PARAMTER LIMITS (NORMAL RANGES)

Limits define normal ranges.
Outside this range, parameters will be flagged: – or +.



Settings
Measurement
Normal ranges

The **"Human"** (profile) button brings up the profile selection menu.
Prev and **Next** allow browsing among parameters.
Parameter order: WBC RBC HGB HCT MCV MCH MCHC PLT PCT MPV PDWs PDWc RDWs RDWc LYM MID GRA LYM% MID% GRA%

You can modify normal range of parameters: left column is lower, right column is upper limit of normal range. Press Accept to accept changes, or Cancel to keep previous settings and return to the settings menu.

3.2.6 BLANK MEASUREMENT

The system uses blank measurements to check cleanliness of the system and reagents. Run a Blank measurement:

- Daily once, before sample analysis (automatic before the first analysis in MEASURE function).
- After any reagent change (activated manually from MEASURE/ BLANK menu).
- After the replacement of any hardware component that is closely related to the measuring process (aspiration, dilution, counting, rinsing).

In MEASURE mode press the **Blank** button. If Blank measurement was good, press **OK** to accept blank result. The analyzer is ready for sample analysis, and displays an empty sample measurement screen.
There are 3 regions for blank value handling:

1. Optimal – all results are within acceptable ranges.
2. Blank is high – ! flag displayed at relevant results.
3. Blank exceeds acceptability – no results displayed.

Parameter	1. No flag at parameter	2. ! flag at result	3. E (error) flag at result
HGB	0-10 g/l	10 - 25 g/l	> 25 g/l
WBC	0 - 0.5 x10^3 cells/µl	0.5 - 1.0 x10^3 cells/µl	> 1.0 x10^3 cells/µl
PLT	0 - 25 x10^3 cells/µl	25 - 50 x10^3 cells/µl	> 50 x10^3 cells/µl
RBC	0 - 0.05 x10^6 cells/µl	0.05 - 0.5 x10^6 cells/µl	> 0.5 x10^6 cells/µl

TABLE 6
Blank measurement ranges

Accepted blank values are essential for proper calibration.
Perform Calibration **only** if all blank values came in the first region (no flags or errors).
If analysis errors occur or blank measurement is too high, an E error flag appears along with the affected parameter and "---" is displayed instead of results. In this situation, perform a cleaning (see Section 5.1 and 4.3).

3.2.7 USING PRE-DILUTED MODE

Pre-diluted measurement mode allows to measure insufficient sample for normal mode, or if some parameter is out of the linearity range (WBC = 300 x 10^3 cells/µl).
Perform an external pre-dilution of the sample using clean isotonic saline solution, or diluent reagent. Dilute the sample to 1:5 ratio (1 part sample to 5 part diluent), using a clean sample vial. Mix it well.

To perform the analysis of a pre-diluted sample:
1. In Main menu select **Measure**
2. **New**
3. In **Options**, select Pre-diluted mode
4. Put pre-diluted sample into the sample adapter
5. Press **START** button. The analyzer will automatically calculate the results with the 1:5 pre-dilution factor.

3.3 The Measurement Process

For the Schematics of the fluidics system, see Section 6.3.

Sample aspiration and dilution:

	Stages of the blood testing process
a	25 µl of anti-coagulated (K3-EDTA) whole blood sample is aspirated into the sampling needle, and mixed with 4 ml of **diluent** and held in the chamber (MIX dilution).
b	25 µl of MIX dilution (aspirated by sampling needle) and 4 ml of diluent is injected into the RBC chamber.
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	WBC and RBC measurement starts.
e	HGB is read from the WBC chamber (photometric, light absorption).
f	Chambers are drained and cleaned, instrument prepares for the next sample.

Dilution rates used:		**Measurement times:**	
MIX dilution	1:160	WBC count	8 seconds
RBC dilution	1:32 000	HGB measurement	4 seconds
WBC dilution	1:196	RBC/PLT count	8 seconds
(depends on lyse amount)			

3.3.1 CONTROL PANELS

START button

Pressing and releasing the START button triggers an analysis cycle.

Status indicator

A two-color (red/green) LED (light emitting diode) is located above START button. Its actual color indicates the status of the analyzer.

LED color	**Analyzer status**
● Green	The analyzer is ready to measure sample. Analysis can be initiated by pressing START button.
✱ Red blinking	Blood sample can be removed when the LED blinks red 3 times and the instrument beeps 3 times.
● Red	The analyzer is currently performing an analysis. No new measurement can be started.
● Yellow	The analyzer is performing a maintenance process.
✱ Yellow blinking	The instrument is in stand-by and display light is off. Hit the screen to have SW wake up from stand-by.

3.3.2 DISPLAY

The display is 320 x 240 dots, high contrast backlit high-color graphic LCD module, with integrated touch screen.

3.3.3 TOUCH SCREEN

The LCD screen has a touch-sensitive foil on the front surface. If the operator touches the LCD active area gently, the analyzer can recognize it and identify the position where the screen was pressed. By touching (slightly pressing) one small spot on the touch screen, the SW will activate the function/menu/key that the corresponding area represents.

3.4 Printing

This chapter covers information on making reports on measured samples

3.4.1 PRINTOUTS

When required, the following items can be sent to an external printer or to the built-in printer by selecting Print option.

- Database result(s) (table format)
- Database (specified patient results with histograms)
- QC result (Levey-Jennings chart)
- QC result(s) (table format)
- Calibration results
- Last measured blank result
- Last measured patient result (with histograms)
- Last measured QC result
- Device information and statistics
- Self test result
- Set parameters

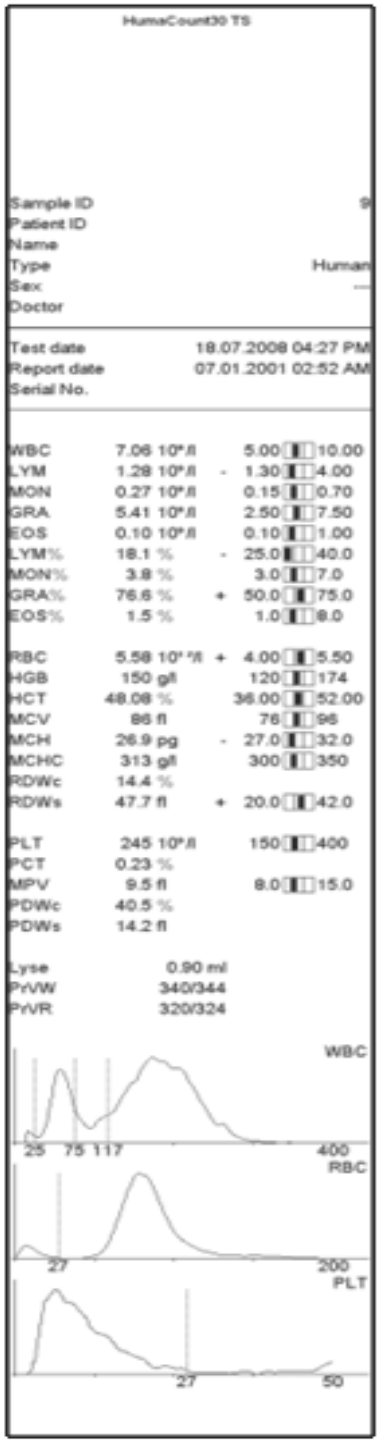


FIGURE 11

Thermal paper printout

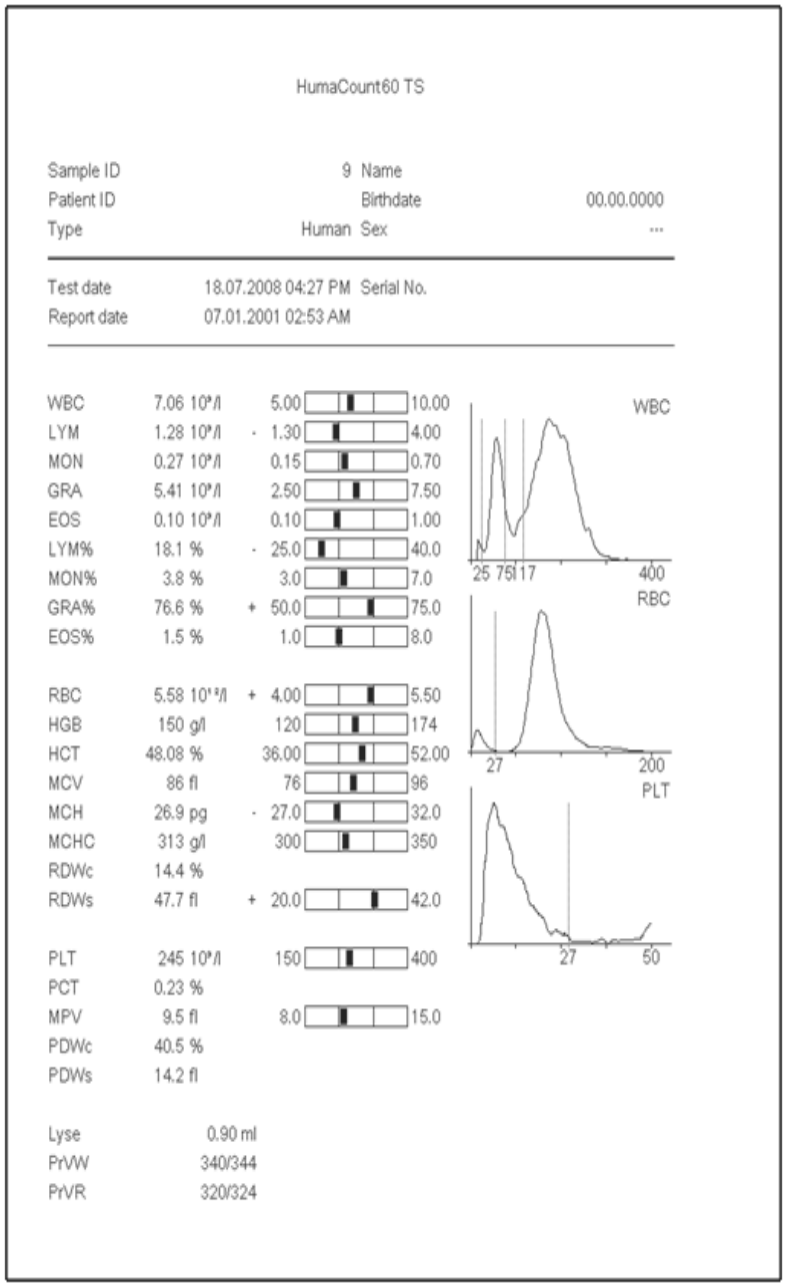


FIGURE 12

Printout on external printer

22/01/2010 14:29

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+	18.7	395	0.39	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	8.6-	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	38.9	
20474	18/01/2010 16:01	21.99+	0.67-	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	19/01/2010 16:03	9.79	4.73+	0.56	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 13
Database Table Printout

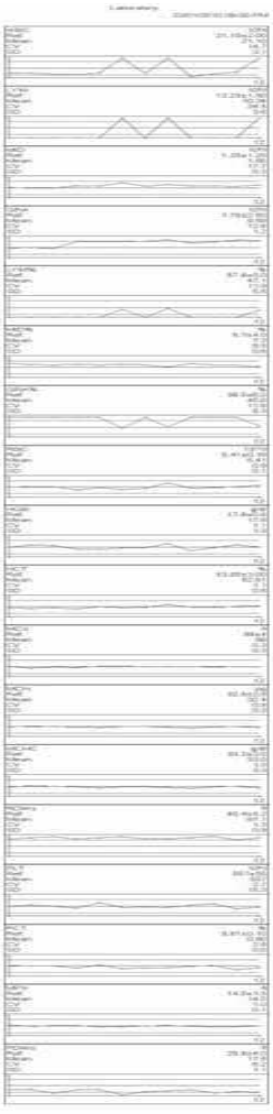


FIGURE 14
QC graphical printout on built-in printer

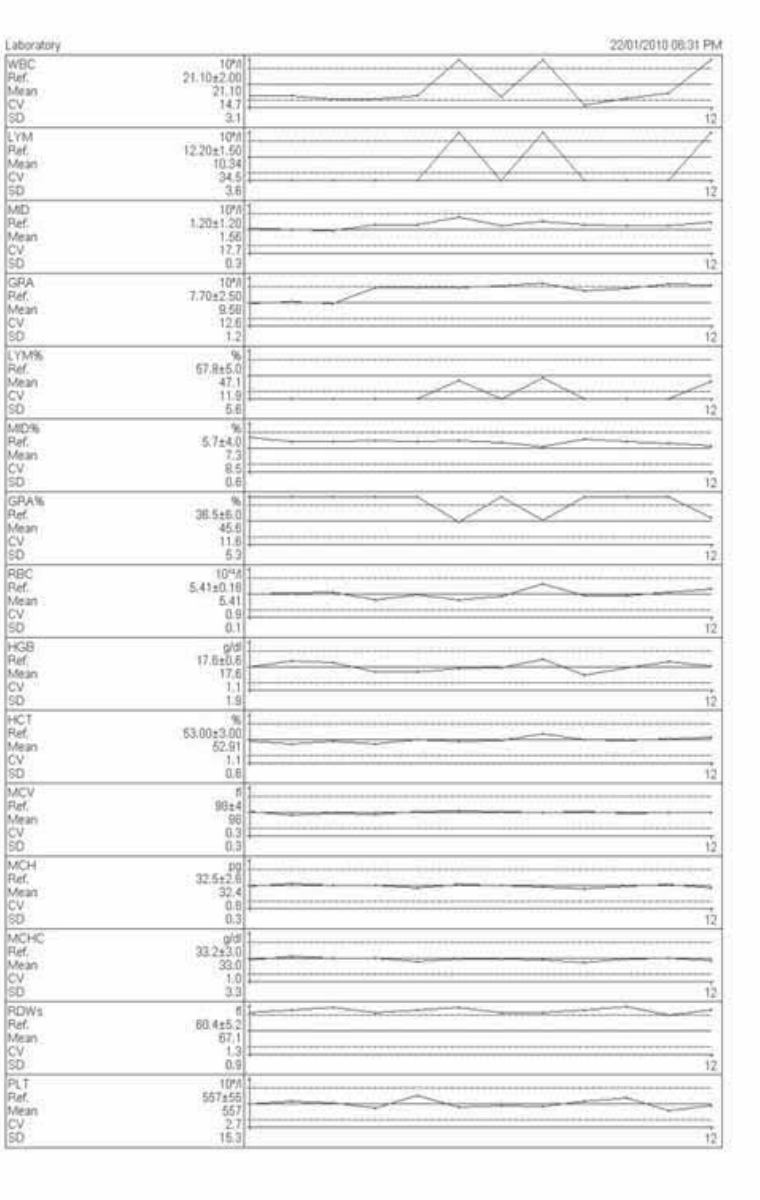
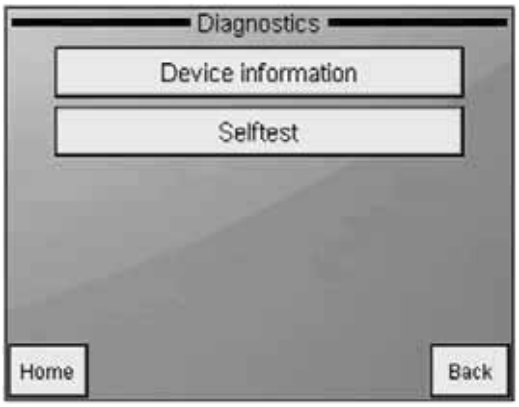


FIGURE 15
QC graphical printout on external printer

4 ADVANCED OPERATION

4.1 Diagnostics

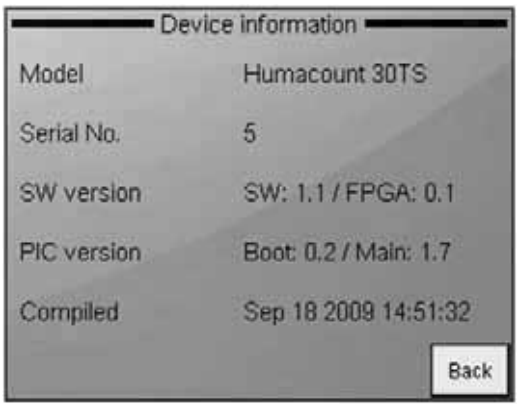
Diagnostics menu allows access to system information and hardware check-up



Maintenance
Diagnostics
Press **HOME** to go to Main menu.
Press **BACK** to go back to previous menu.

4.1.1 DEVICE INFOMATION

Device information shows system hardware and software setup.



Maintenance
Diagnostics/
Device Information
The various system parameters can be seen on the screen.
Press **EXIT** to go back to the previous menu.

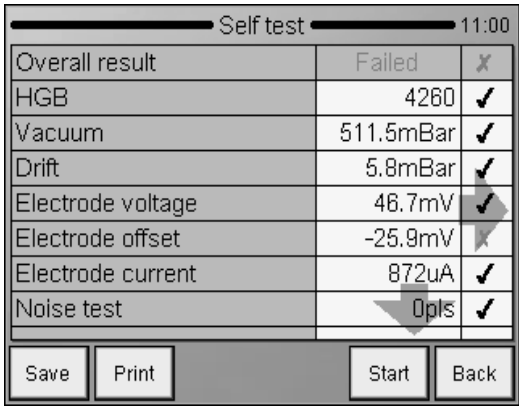
4.1.2 SELF TEST

Self test is a procedure to verify proper operation of essential components of the instrument. Self test should be performed:

- At installation.
- After replacing any component.
- After extended time out of use.

During self test, the analyzer checks system components, and displays the results.
On the right side of the results screen, the SW displays if the tested parameter falls into the desired range:

- If yes, a ✓ sign is displayed at the end of the line, or
- if it is out of range: a ✗ sign appears.



DIAGNOSTICS

SELF TEST (2)

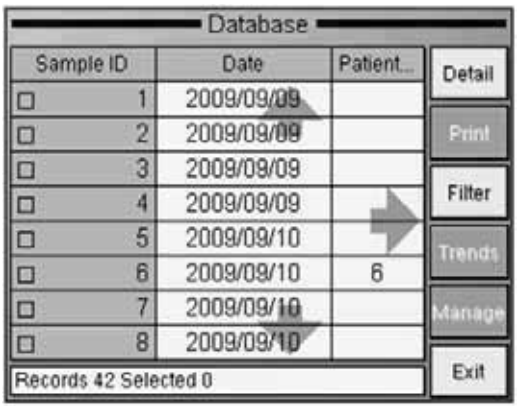
The analyzer lists and checks subsystems. When tests are finished, display shows a summary of the results. Various system parameters can be seen on the screen.

Press **BACK** to go back to previous menu.

4.2 Database

Patient results are stored in the memory in chronological order, and can be retrieved at any time. Data storing capacity is 1000 measurements, including the complete parameter list, histograms, flags, sample data, and date/time of measurements. If memory is full, newest (actual) record will overwrite oldest record.

Select Database to access records stored in the memory of the analyzer. The first screen that appears shows the most recent saved results.



DATABASE

Left and right arrows access remaining, non-visible parameter results, up and down arrows scroll among records individually.

Menu key opens up local menu for accessing further functions (see below).

Exit key returns to MAIN menu.

Each line starts with a checkbox and the Sample ID displayed. A filled checkbox indicates that a specific record is selected for further operations.

The bottom row of the screen shows the status line. This line provides information about the number of records stored in the database and the number of records selected.

As it can be seen on the screen, some buttons are not active (Print, Trends, Manage). They become active when at least one record is selected.

Detail will open up detailed data (parameters, histograms, flags) of the record at the top of the list.

Print will send the result to the selected printer (USB or internal)

Filter offers tools to select records from the database. You can select based on Sample ID, Patient ID, measurement time stamp, sample type.

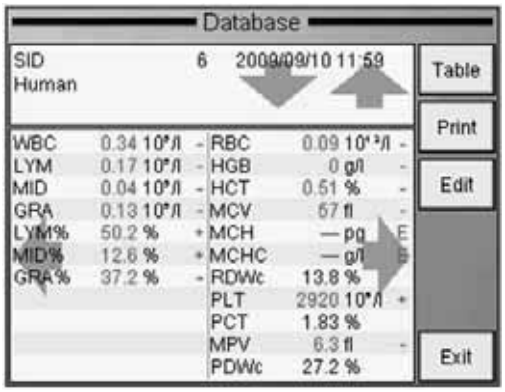
Trends offers a statistical tool to monitor variation of parameter values. It is an ideal tool to track variation of parameters of a specific patient with time.

Manage opens up a menu where data can be deleted, archived or transmitted to a computer.

Exit retruns to the main menu.

4.2.1 DATABASE SERVICE

Detail will open up the parameter and histogram view of a record.



DATABASE

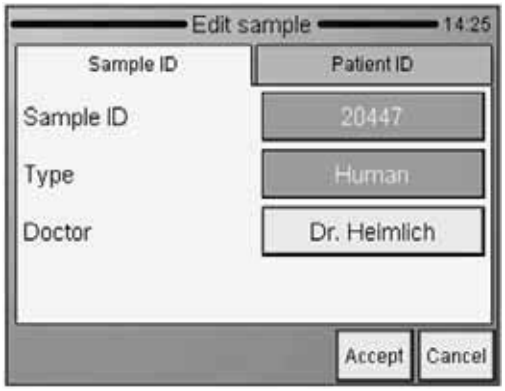
Detail

Table returns to the table view.

Print sends the record to the printer.

Edit opens up the dialog for data manipulation of the record.

Exit returns to the Main menu.

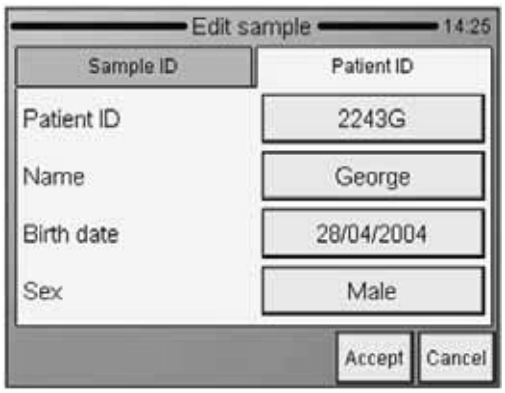


DATABASE

Detail

Edit

When looking at record from the database view, some fields are not editable (Sample ID, sample type). These can only be set before running the sample. Patient ID tab allows entering further data.



DATABASE

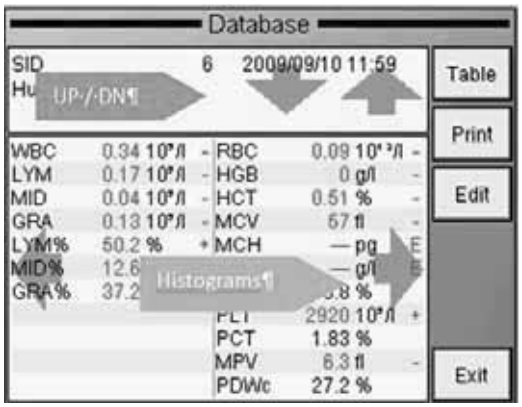
Detail

PID

This option allows editing patient information. When you push the ACCEPT button, your changes will be saved.

The Sample ID tab returns to the Sample ID screen (above)..

Patient ID can be 19 characters long and the name of the patient can hold 40 characters.



DATABASE

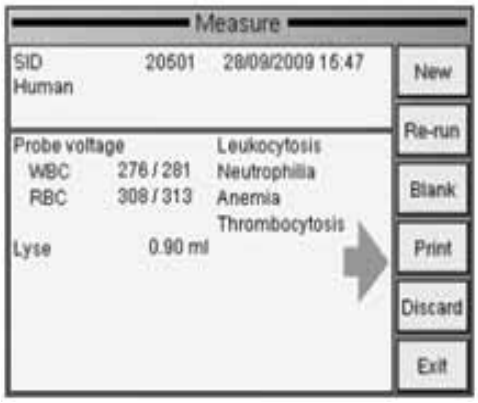
Detail

Arrows

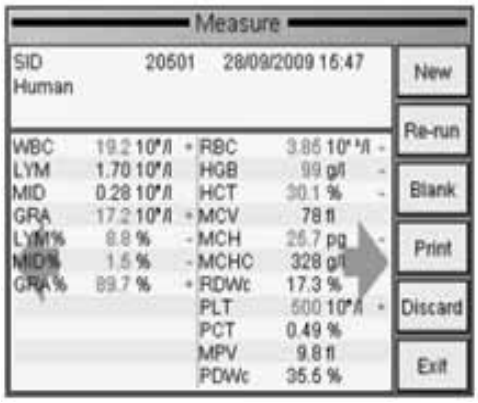
The database record view allows browsing in the database, and you can also look at histograms and various diagnostic parameters of the sample.

The arrows in the sample data field (indicated with BLUE marks) allow browsing in the database. Tapping them brings up the next or the previous record in the database.

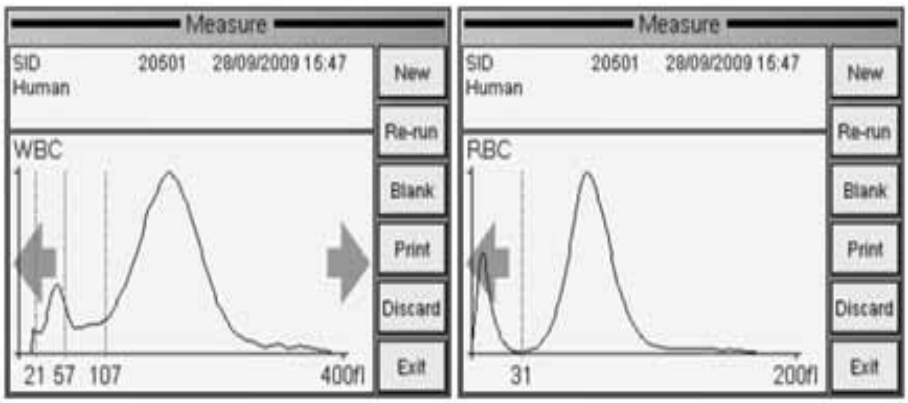
The arrows marked with GREEN color allow looking at various panels of the result.



Diagnostic flags

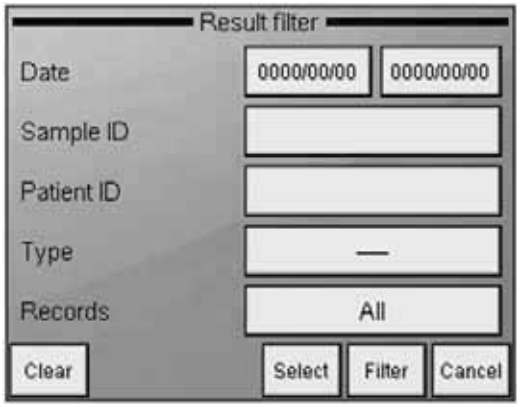


Parameter view



WBC histogram RBC histogram

4.2.2 THE FILTER / SELECT FUNCTION



DATABASE

Filter

Date allows defining the start and end dates for the search.

Sample ID and **Patient ID** can narrow the search. If you enter "5" for sample id, then all records, whose Sample ID contains the expression ("5" in our case) will be selected (5, 15, 451, etc.).

! There is an AND relation between the fields. If you fill in more than one field, then you can narrow the search: e.g. measured between 2009/08/10 and 2009/09/20 AND having a sample ID "1221".

Using **Type** you can further narrow the list of samples.

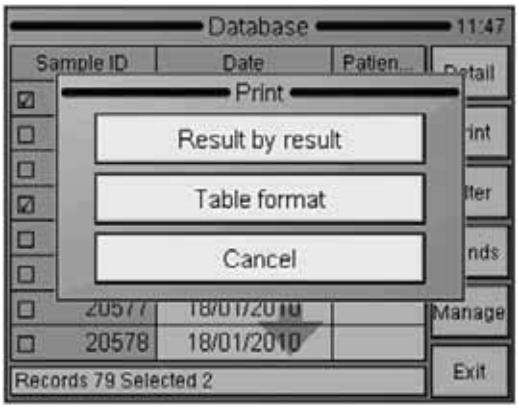
With **Records** you can define to use All or already selected results for the search.

Clear will reset all fields.

Select will return to the table view, and will fill the checkboxes of records matching the criteria.

Filter will also return to the table view, but only records matching the criteria will be shown. The status bar of the table view will show: "Filter on".

4.2.3 PRINTING RECORDS



DDATABASE

Print

If there is no record selected, then the software prints the actual (top / detail view) record. If there is more than 1 record selected, then you will be able to choose between individual printing **(Result by result)**, or **Table format**.

Cancel aborts the operation.

4.2.4 MANAGE RECORDS

The Manage button becomes active if there is more than 1 record selected in the database. Pressing Manage brings up the following screen:

DATABASE

Manage

Back aborts the operation and returns to the table view.

Deselect will clear the checkboxes of all selected records.

Send will transmit record(s) to a connected computer. A progress bar shows the status of the process.

Delete will permanently delete selected record(s) from the database. You have to confirm this operation.

Backup will save selected record(s) to an external USB memory device. A progress bar shows the status of the process.

! Do not remove the USB memory device as long as its status LED is blinking, because it can cause data loss on the memory device.

4.3 Calibration

The analyzer stability can be monitored with **HC-CONTROL** control blood. Performing QC determinations regularly verifies continued optimal performance. **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.
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.

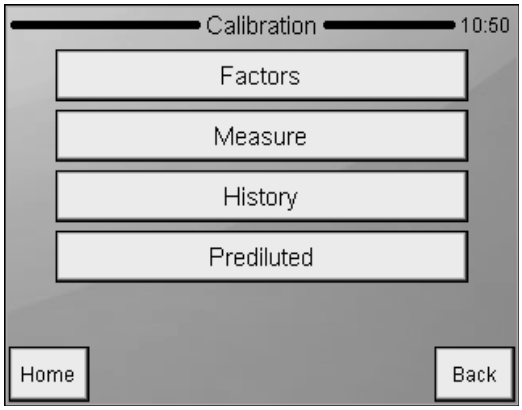
Calibration can be performed in two ways:

1. User can enter calibration factors – without any calibration measurements – using the numerical keypad.
2. 1, 2, 3 or more measurements of control blood or calibrator, with known parameters. In this case, the instrument automatically calculates new factors using the following formula:

$$\text{New factor} = \frac{\text{Assigned value} \times \text{Stored factor}}{\text{Measured value(s) (or average of those)}}$$

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

3. The instrument can be calibrated also for use of prediluted samples (1+5)



Maintenance

Calibration

You can select the following functions:

Factors: enter calibration coefficients manually

Measure: define target values and start calibration measurements

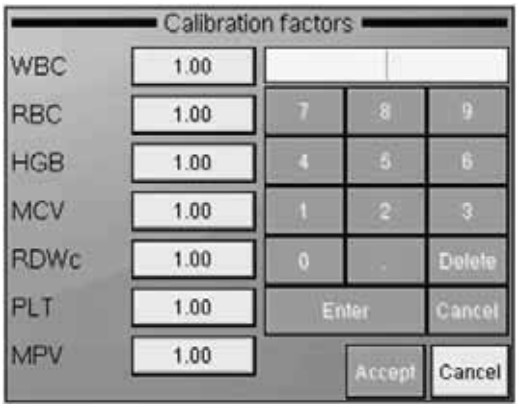
History: display past calibration factors.

Press **HOME** to go to Main menu.

Press **BACK** to go back to previous menu.

4.3.1 CALIBRATION WITH FACTORS

Factor based calibration allows adjustment of primary parameters with a factor



Maintenance

Calibration / Factors

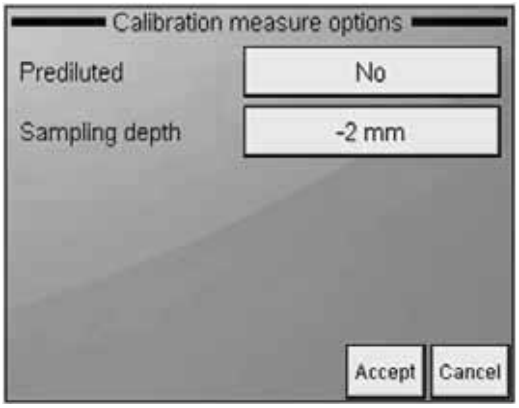
Press white data field to modify calibration factor. A numeric input screen will show up so that you can enter values.

All values must be in the 0.8...1.2 range.

Press **Accept** to proceed with new settings, or **Cancel** to keep values unchanged.

4.3.2 CALIBRATION BY MEASUREMENT

The analyzer can run calibrator, and perform calculation of factors automatically. User can decide the number of measurements to use for calibration.



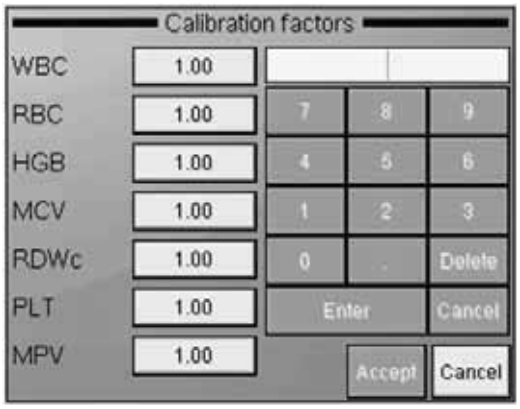
Maintenance

Calibration/Measurement

Prior to starting the calibration measurements, you have to define some basic parameters for the upcoming measurements.

.

As the next step, target values from the assay sheet of the calibrator or control must be entered before measurement



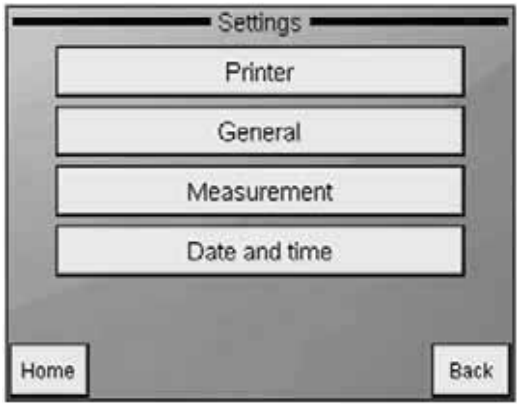
Maintenance

Calibration/Measurement

Prior to starting the calibration measurements, you have to define some basic parameters for the upcoming measurements.

4.4 Settings

Selecting Settings accesses various lists of options.

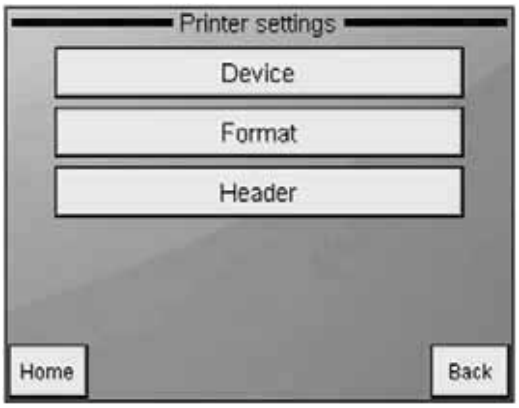


Settings

Press **BACK** to go back to MAIN menu.

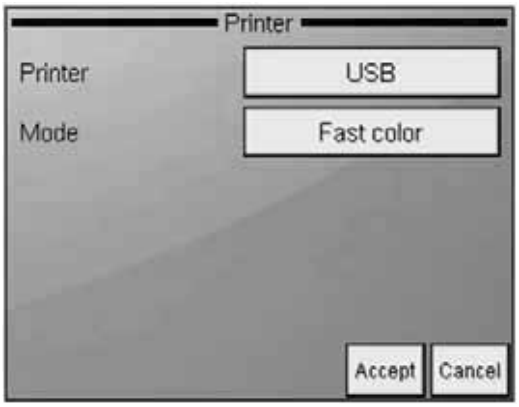
4.4.1 PRINTER SETTINGS

Printer settings menu allows setting up parameters of report printing.



Settings

Printer settings



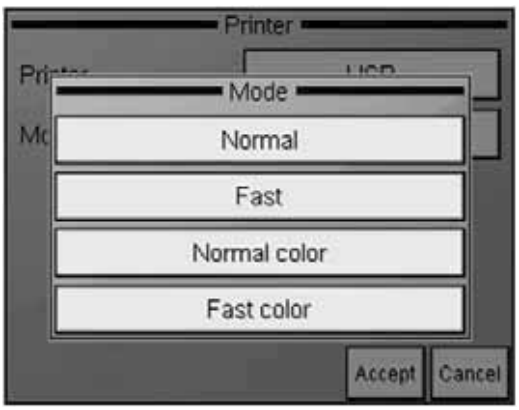
Settings

Printer settings / Device

Printer: Selection between built-in or USB printer. If the printer is recognized, the screen will show the printer's name.

Format: Selects printout quality. Press **Accept** to approve changes made.

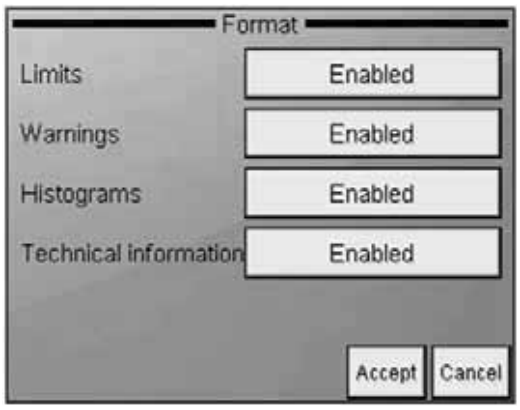
Press **Cancel** to go back to previous menu keeping the old settings.



Settings

Printer / Device / Mode

Fast modes save ink and provide faster printout. Only normal color and fast color printouts will give color printouts.



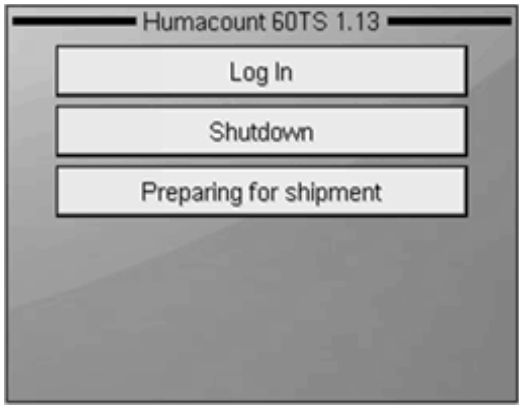
Settings

Printer settings / Format

Press **Accept** to approve changes made.

Press **Cancel** to go back to previous menu keeping the old settings.

Limits: Enable / Disable parameter limit (normal range) printing.
Warnings: If Enabled, warning flags appear on the report as well.
Histograms: Enable / Disable graph printing.
Technical information: If Enabled, probe voltages (WBC,RBC), lyse volume, (ml) and software/firmware version appear in the printout.



Settings

Printer settings / Header

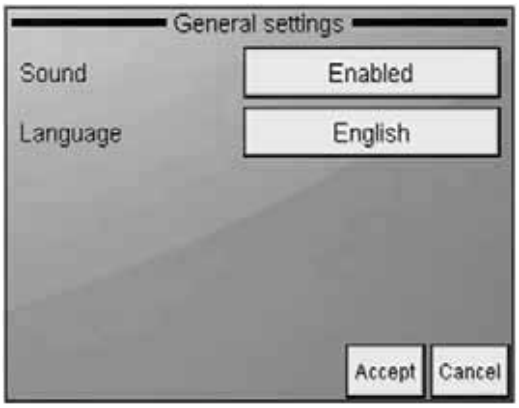
The data entered will be printed on the top of each printed report.

Press **Accept** to approve changes made.

Press **Cancel** to go back to previous menu keeping the old settings.

4.4.2 GENERAL SETTINGS

General settings control operation of the following functions.



Settings

General

Select any of the following options:

Press **Accept** to approve changes made.

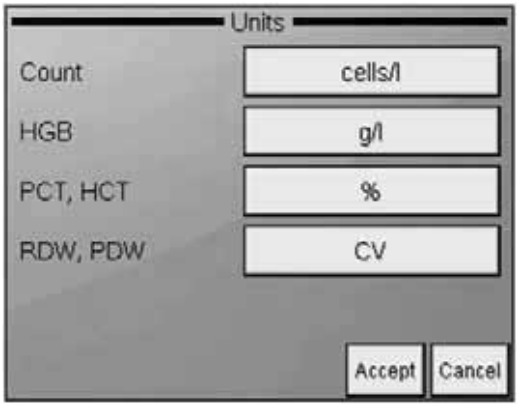
Press **Exit** to go back to previous menu.

4.4.3 MEASUREMENT

This section groups measurement related options and settings.

4.4.3.1 Unit settings

Unit settings menu allows to set up units of parameters displayed or printed.



Settings

Measurement/ Units

Press units to change them individually

Press **Accept** to approve changes made.

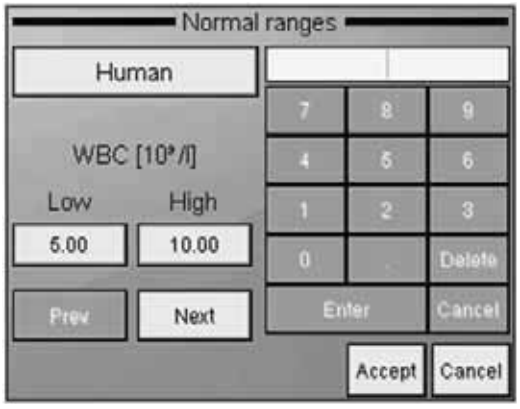
Press **Cancel** to go back to previous menu keeping the old units.

Possible units for the parameters:

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)

4.4.3.2 Normal ranges

Limits define normal ranges. Outside this range, parameters will be flagged: – or +.



Settings

Measurement

Normal ranges

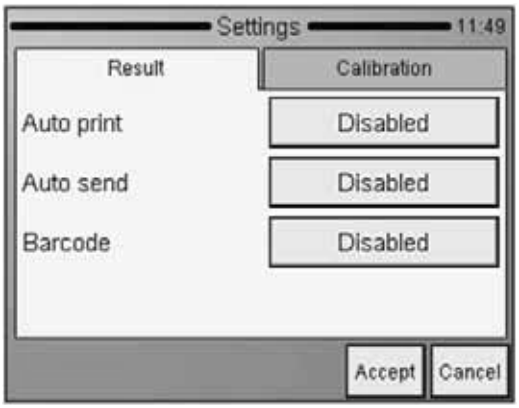
The **"Human"** (profile) button brings up the profile selection menu

Prev and **Next** allow browsing among parameters.

Parameter order: WBC RBC HGB HCT MCV MCH MCHC PLT PCT MPV PDWs PDWc RDWs RDWc LYM MID GRA LYM% MID% GRA%

You can modify normal range of parameters: left column is lower, right column is upper limit of normal range. Press Accept to accept changes, or Cancel to keep previous settings and return to the settings menu.

4.4.3.3 Settings



Settings

Measurement/Settings/
Result

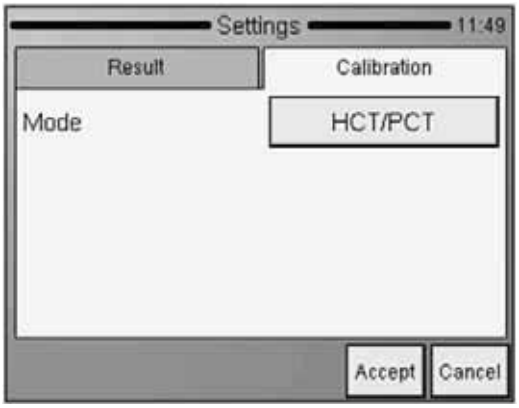
Auto print will print the report automatically when the results are displayed

Auto send will automatically transmit results if a PC is connected

Barcode allows setting scanned data to be entered as Sample ID or Patient ID

Accept saves changes made

Cancel returns to previous menu discarding changes made



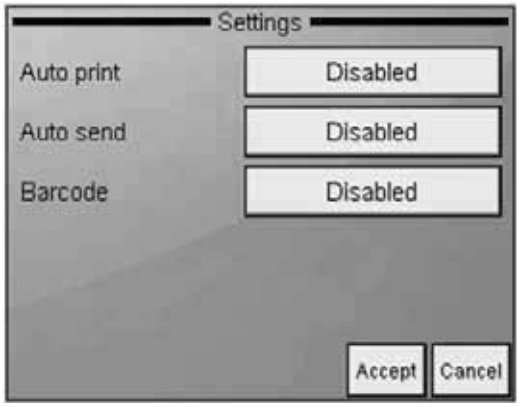
Settings

Measurement/Settings/
Calibration

Mode allows choosing between HCT/PCT or MCV/MPV based calibration

Accept saves changes made

Cancel returns to previous menu discarding changes made



Settings

Measurement / Settings

Auto print will print the report automatically when the results are displayed.

Auto send will automatically transmit results if a PC is connected.

Barcode allows setting scanned data to be entered as Sample ID or Patient ID.

Accept saves changes made.

Cancel returns to previous menu discarding changes made.

4.4.4 DATE AND TIME

Date and time of each analysis is stored with the results. This menu allows setting the built-in clock and the format of the date displayed.

Settings

Date and time

Type in the date and time.

Select formats for displaying the date.

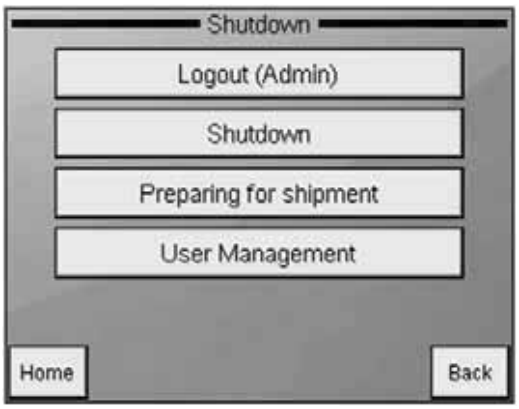
Press **Accept** to save settings.

Press **Cancel** to go back to previous menu keeping the old values.

The analyzer has a built-in battery responsible for running the built-in clock when the unit is powered off. If the analyzer asks for date and time setting after power on, then this battery is having problems. To resolve the problem, contact Service.

4.4.5 MULTI USER MODE

The analyzer allows operation in a multi-user environment, where users can have different rights and access levels.
This feature is accessed upon startup, and can of course be customized.
The analyzer by deafult operates in a multi-user environment – however the user should not notice this functionality.



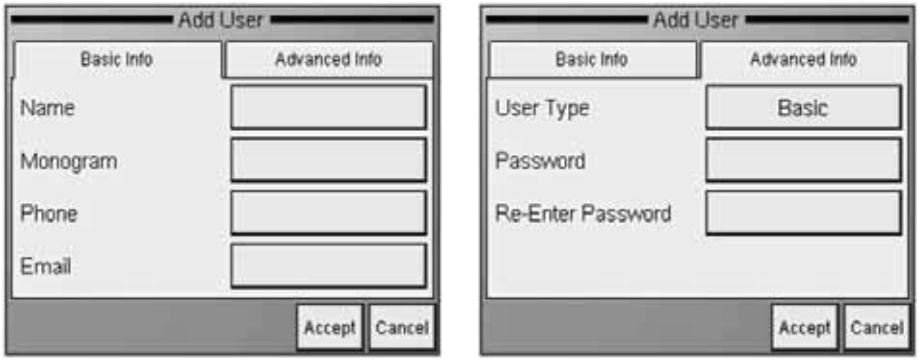
Exit
Logout will leave the unit on, and the login screen appears.
Multi user mode functionality can be enabled in the Exit menu by adding users in User Management..

! User Admin cannot be deleted. Admin password cannot be changed. Admin password: 0000

Exit
User Management
Auto Login Set will allow login-free starting of the analyzer.

Users can be added (Add New User) or edited (Edit / View User). Adding a user allows filling in the below parameters. Password must be defined on “Advanced Info” tab. Monogram will be displayed on the login screen.

User Admin cannot be deleted. Admin password cannot be changed. Admin password: 0000



Use Remove User option to disable its access.

User Type BASIC has limited access to the menu tree:

Measure	New	Options
	Re-run	
	Blank	
	Print	
	Discard	

Database	Detail / Table view
	Edit record
	Print
	Filter
	Trends
	Manage

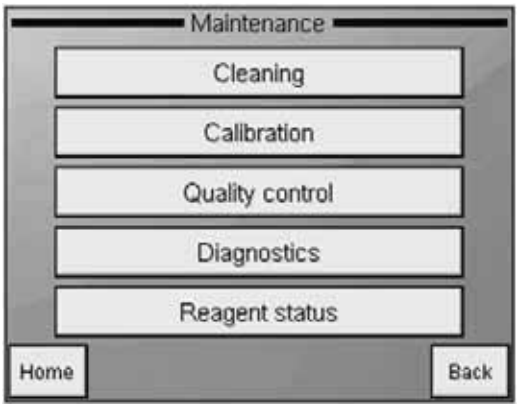
Maintenance	Cleaning	Cleaning
		Hard cleaning
		Drain chamber
	Calibration	Factors
		Measure
		History
	Quality control (forbidden)	
	Diagnostics	Device information
		Self test
		Service
	Reagent status	

(Settings forbidden)

Exit	Logout	Add new user
	Shut down	Remove User
	Preparing for shipment	Auto login set
	User Management	Edit / View user

5 MAINTENANCE

In the **Maintenance** menu you can initiate procedures, for cleaning, calibration or specific performance analysis.



Maintenance
Touch menu item of the desired function.
Home will return to the Main menu.
Back returns to the previous level.

! The power supply unit and internal electronic boards must NOT be opened or serviced by the user!

The user should check the following components weekly:

- bottom of washing head for salt build up – should be wiped off with a damp cloth or wiper
- tubing system – by opening the side door and look for any liquid leakage. If you experience leakage, contact authorized technician.

5.1 Cleaning

Cleaning functions allow cleaning of fluidics to reduce blank value by removing contamination from tubing, chamber and valves.

Maintenance
Cleaning
Press **HOME** to go to Main menu.
Press **BACK** to go back to previous menu.

Cleaning starts a washing cycle using the system cleaner reagent connected to the analyzer. This action is recommended if clogging problems are experienced (C or Q error flag), or the blank is high.

Hard cleaning initiates a process that uses a light solution of hypochlorite (NaHCL), and washes the sampling needle and related tubing with it. The instrument will ask for the cleaning solution in a sampling tube.

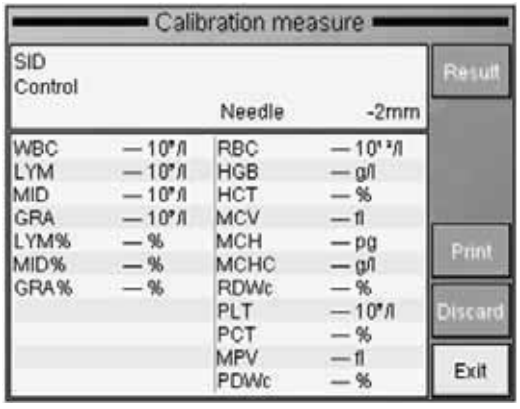
Drain chamber will empty the measurement chamber. You can use this option to manually add cleaning solution to the chamber when necessary (extreme contamination in the chamber). Clean the instrument and its power supply – in off state – on the outside only, using a damp cloth with a soft detergent. DO NOT let liquids get inside these units.

Target values for calibrated parameters can be set within the following ranges:

TABLE 7
Calibration target ranges

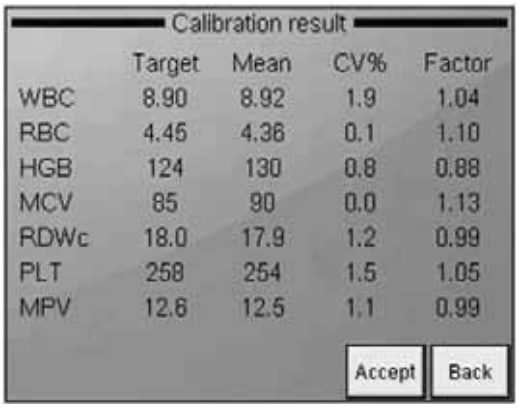
Parameter	Low limit	High limit
WBC	1.0	30.0
RBC	1.00	8.00
HGB g/l	30	300
MCV	50	120
RDW CV	10	50
PLT	30	800
MPV	5	15
PDW CV	5	50
HCT	0.1	0.6
PCT	0	2

When all parameters are set, press **Accept** key.
The display shows **Calibration measurement** at top.



Maintenance
Calibration / Measurement
Insert the sample tube to the sample door and press the START button.
Exit will abort the operation.

Calibration runs are saved automatically. If you find that a result should not be used, use the Discard button to delete the measurement so that it is not used for calibration.



Maintenance
Calibration/Measurement/
Result

Result will display the average of each parameter of accepted measurements compared to the target value and the calibration factor calculated.

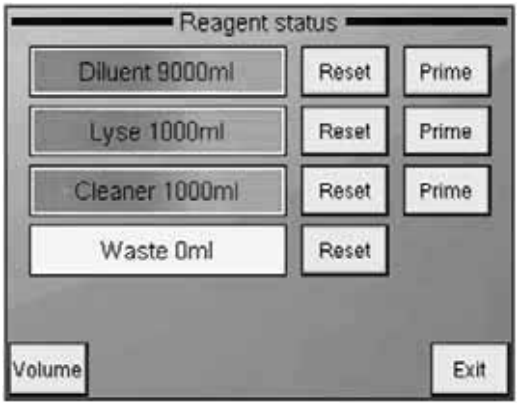
Accept saves new factors and aborts calibration.

Back will return to the calibration measurement screen so that you can measure more samples for calibration.

You can compare target and measured values, observe CV and see how the calibration factor would change.

5.2 Reagent Status

The screen shows reagent volumes in containers, as calculated by the instrument. With each measurement, the volumes are changing accordingly. When reagent volume in a container is running low, instrument will notify user, and ask for replacement.



MAINTENANCE
REAGENT STATUS

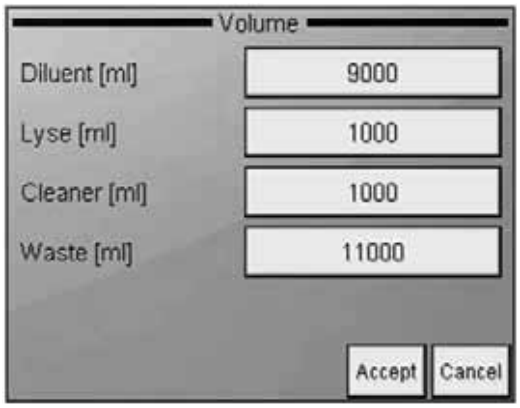
Bar graphs show reagent status.

Reset will reset reagent level to its full value.

If any of the reagents is replaced **(Reset)**, press **Prime** to aspirate liquid into the system

Volume opens up the container volume setup screen.

If Waste is high, it should be disposed of properly (see next section for instructions).



MAINTENANCE
REAGENT STATUS
Volume
Set the volume of the containers used. Values in ml. If volume of a reagent is set to 0 (zero), software will not keep track of consumption.

Accept saves your changes.
Cancel discards changes and returns to reagent status screen.

5.2.1 HOW TO EMPTY WASTE CONTAINER

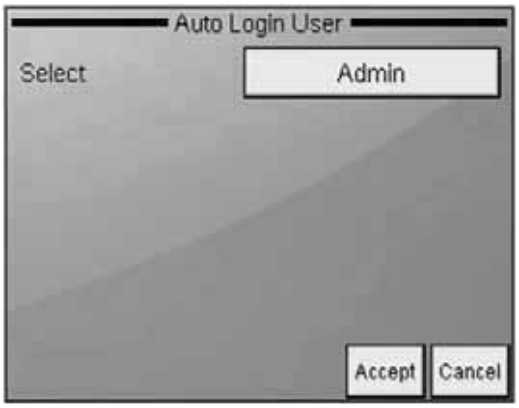
Software counts volume of waste, and gives warning message when the waste tank is close to its maximum capacity.
Empty the waste tank when this warning message appears. See next Section for neutralization steps.

5.2.2 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.



Exit

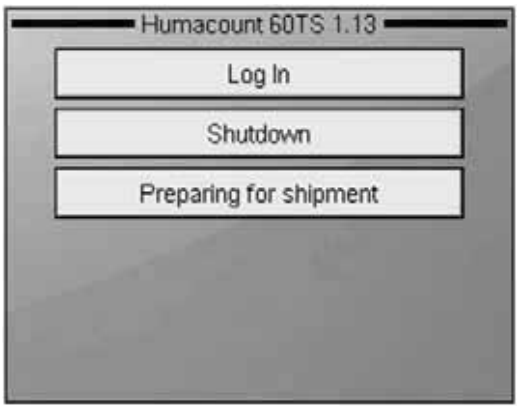
User Management

Auto Login Set

Auto Login Set will allow login-free starting of the analyzer.

Select the user to be logged in automatically.

With Auto Login Off selected, the instrument will prompt for a user and a password upon startup.



Login screen (with Auto Login Off)

Use Shutdown to stop the analyzer (power off).

Preparing for shipment will drain the unit so that it can be transported.

Log In brings up the login screen (below).

Login screen (with Auto Login Off)

Touch Login name. Select name from list.

Enter password.

Instrument will show database upon correct password entry.

5.3 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.

5.3.1 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:

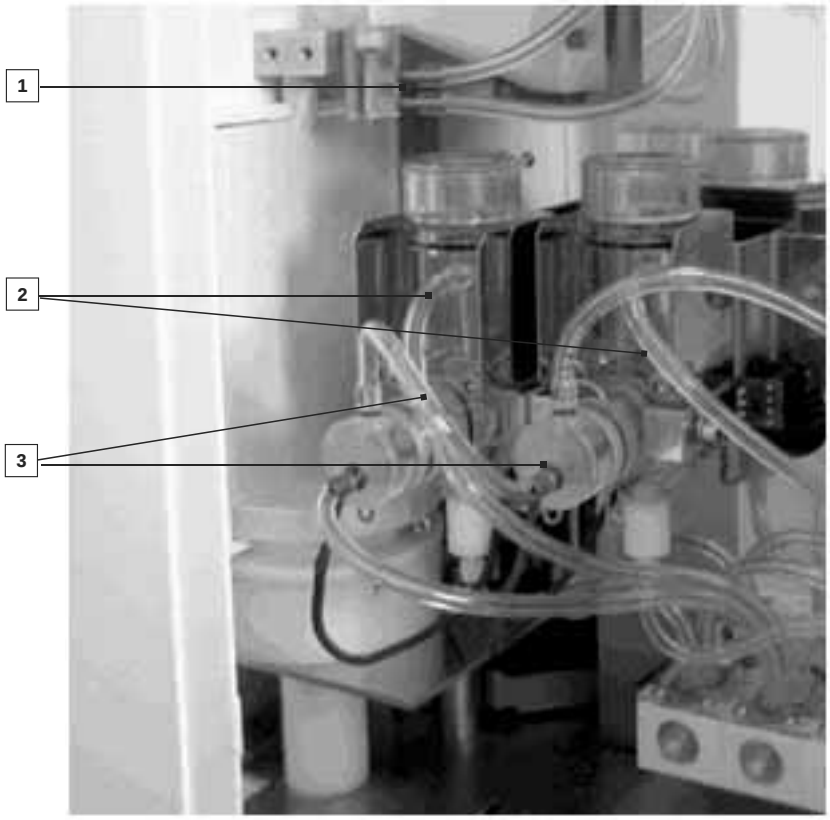


FIGURE 16
Parts of measuring block

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.

6 TROUBLESHOOTING

6.1 Regular Troubleshooting Procedures

From Troubleshooting submenu, user can initiate maintenance procedures such as blank measurement, cleaning, priming, or draining chamber.
For details on Blank measurement, see Section 3.2.6.

6.2 Specifications

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 Isotonic Diluent, Lyse, Cleaner
Aperture diameter 80 µm (RBC/PLT), 100µm (WBC)
Throughput 60 tests/hour

Characteristics Parameter	Accuracy	Reproducibility (CV)	Carry-over sample to sample	Test range	Unit
WBC	3%	3%	<1%	4.0...20.0	10^3/µl
RBC	3%	2%	<1%	4.0...15.0	10^6/µl
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/µl

Sampling method	Open tube system with automatic sample rotor.
Sample types	Human (general), male, female, baby, toddler and child.
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 (or HCT), RDW, and MPV. Independent calibration of pre-diluted mode.

User interface	Easy-to-use, menu driven user interface with touch-screen and separate START button, status LED.
Languages available	English, Spanish, Portuguese, French, Russian, Indonesian, German
Data capacity	1000 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 (PenDrive™)
Printer interface	USB with support for HP printers (DeskJet, LaserJet, PCL3, PS, LIDIL)
Built-in printer	Axiohm thermal printer module, 58 mm wide roll paper, full report with histograms
Display	320x240 -dots, high-contrast, backlit, color graphics LCD (liquid crystal display)
User interface	Full-LCD Touch-screen + separate START button, red/green state LED
External keyboard	USB keyboard via USB A port
Power requirement	12VDC, 5A, 60W max. operating power
Power supply unit	External, auto-ranging power unit for 100-120 or 200-240 VAC, 50–60Hz
Operating temperature	59–86 °F (15–30 °C). Optimal temperature is 77 °F (25°C)
Dimensions (W x D x H)	12.6 x 10.2 x 14.4 in (320 x 260 x 365 mm)
Net weight	12 kg

6.3 Fluidic Schematics

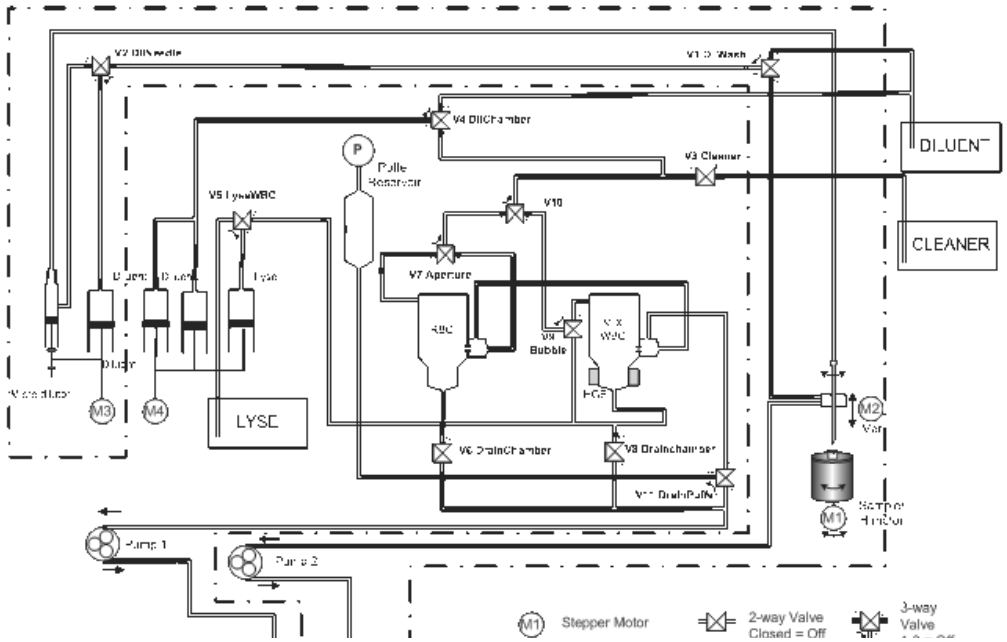


FIGURE 17

7 APPENDIX

7.1 Reagent Solutions 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. 1. [DIL]: An isotonic saline solution used to dilute whole blood specimens and to rinse the fluidic system between measuring procedures.
   HC-DILUENT [REF] 17400/10 (20 liters)

2. [LYSE]: Used to prepare blood hemolysate for WBC and HGB measure ment.
   HC –LYSE [REF] 17400/20 (1 liter)

3. [CLEAN]: Used to perform cleaning process of the fluidics.
   HC- CLEANER [REF] 17400/30 (1 liter)

Average reagent consumption HumaCount 60^{TS}

	Reagent consumption / function (ml)		
Function	**Lyse**	**Cleaner**	**Diluent**
Init	14	22	58
Start-up	2	12	46
Blank	0,7	0	36
Measurement	0,7	0,6	30
Standby	0	0	6
Wakeup	0	0	8
Cleaning	0	14	56
Prime All	2	8	56
Prime Diluent	0	0	56
Prime Lyse	2	0	4
Prime Cleaner	0	8	0
Shut-down	0	6	12

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