HumaCount 5

| User Manual

CE

Cat.-No. 16350/1

Revision List of the Manual		
No.	DATE / Rev.	REVISION DESCRIPTION
1	01/2007-02	First edition

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 or personal damages, 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.

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 re-ported to the freight carrier for settlement or claim.

3 INTENDED USE OF THE INSTRUMENT [IVD]

The instrument 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.

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.

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 of 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.

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/disinfected. Decontamination/disinfection should be performed by a authorised well-trained personnel, observing all necessary safety precautions. Instruments to be returned have to be accompanied by a disinfection certificate completed by the responsible laboratory manager. If a disinfection 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.

7 NOTICE

Every effort has been made to avoid errors in text and diagrams, however, HUMAN GmbH assumes no responsibility for any errors which may appear in this publication. It is the policy of HUMAN GmbH to improve products as new techniques and components become available. HUMAN GmbH therefore has to reserve the right to change specifications if necessary in the course of such improvements.

NOTICE

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.

BIOHAZARD

The „BIOHAZARD“ warning label must be affixed to instrument prior to first use with biological material !

Servicing Note:

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.

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Contents

1 INTRODUCTION

1.1 Intended Use

The HumaCount 5 hematology analyzer is a fully automated cell counter designed for in vitro diagnostic use.

The instrument was developed for use in hospitals and small- to medium-sized labs.

1.2 General Description

1.2.1 The Instrument

HUMAN's HumaCount 5 is a fully automated, bench-top hematology cell counter.
It implements the so-called Volumetric Impedance Method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells.

The analyzer features a graphical LCD display module and a foil keypad with 24 keys, including 6 software buttons (with icons) and 6 function keys (above LCD) in addition to a START button.

The instrument allows results to be sent to an external printer (parallel port or USB port), or to be printed on the optional built-in printer module.

Its internal memory is capable of storing up to 5000 records with full histograms and individual patient data. QC measurements can also be performed and stored. The operating system software is easy to upgrade using a standard 3.5" floppy diskette or a commercially available USB pen drive. The instrument can be connected to a host computer via the RS-232 serial port to upload records stored in the memory, and also enables the operator to archive and restore records to and from floppy diskette or USB pen drive.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. Misuse of the equipment or use for other than its intended purpose will invalidate the conditions of the warranty. The accuracy and precision may also be impaired.

1.2.2 Patient Testing

The analyzer can process 24 blood samples per hour. Samples can have individual sample data, and additional parameters. Full histograms of the blood cell types are also stored along with the above-mentioned data.

Results can be printed on the optional internal or external printer. The print-out format can be customised by the user.

The HumaCount 5 determines 22 hematology parameters including a five-part WBC differential. The instrument requires 90 µl of the whole blood sample either from open or from closed primary blood sampling tube:

WBC	total white blood cell count
LYM	lymphocytes count
MON	monocytes count
NEU	neutrophils count
EOS	eosinophils count
BAS	basophils count
LYM%	lymphocytes percentage
MON%	monocytes percentage
NEU%	neutrophils percentage
EOS%	eosinophils percentage
BAS%	basophils percentage
RBC	red blood cell count
HGB	hemoglobin
HCT	hematocrit
MCV	mean corpuscular volume
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
RDWc	red cell distribution width
PLT	platelet count
PCT	platelet percentage
MPV	mean platelet volume
PDWc	platelet distribution width

1.2.3 Reagents

Only genuine reagents from HUMAN GmbH should be used with the analyzer; otherwise accuracy cannot be guaranteed.

1. DIL: HC-Diluent Cat.- No.: 17400/10 (20 litres)
Diluent: isotonic saline solution used to dilute whole blood specimens and to rinse the fluidic system between measuring procedures.

- Sodium Chloride 2.5
- Inorganic Phosphate Buffer 5.6
- Sodium Solfate 10
- EDTA < 1
- Preservative < 0.5

2. LYSE: HC-Lyse CF Cat.- No.: 17400/20 (1 litre)
Cyanide-free lyse reagent

- Surfactants < 0.5
- Quaternary Ammonium Salts 35

3. BASOLYSE: HC5-BASOLYSE Cat.- No.: 16350/10 (1 litre)
Cyanide-free lyse reagent

- Sodium Chloride < 12
- Preservative < 1
- Quaternary Ammonium Salts < 3
- Surfactants < 3
- Citric Acid < 2.5
- Trisodium Citrate < 0.8

4. EOLYSE: HC5-EOLYSE Cat.- No.: 16350/20 (1 litre)
Cyanide-free lyse reagent

- Sodium Chloride < 1.5
- Borate Buffer < 2
- Sodium Sulphate < 3
- Nonionic based surfactants < 5.5

5. CLEAN: HC-Cleaner Cat.- No.: 17400/30 (1 litre)
Cleaning solution
Used to clean the fluidics system.

- Sodium Chloride 3
- Sodium Sulphate 8
- Sodium Phosphate 5
- Proteolytic Enzyme 8
- Preservative 1

(all concentrations in grams per litre)

1.2.4 Stability

The reagents are stable up to the expiry date on the label when stored at 15...35°C and protected from light (i.e. stored in a dark place).

Once opened and installed on the instrument the reagents are stable for 60 days at 15...35°C. Instability due to contamination is usually indicated by cloudiness or a colour change. In this case the reagent should be replaced at once.

DO NOT FREEZE! Replace reagents if frozen.

1.2.5 Precautions and Notes

- Allow the reagents to stand at room temperature for at least 24 hours before use.
- HUMAN reagents have been optimised for the HUMACOUNT system. The use of and/or mixing with third party reagents has not been tested and may cause erroneous results.
- LYSE contains quaternary ammonium salts which may cause irreversible damage to skin and eyes in case of contact. Wear appropriate protective clothing (gloves and lab coat). In case of contact rinse immediately with plenty of water. If swallowed, induce vomiting and seek medical attention.
- DIL and CLEAN contain no hazardous substances in dangerous quantities. In case of contact with skin or eyes rinse with water.
- Specimens, controls and material coming into contact with them should be handled as potentially infectious and must be disposed of in accordance with the applicable local regulations.

1.2.6 Technical Operation

As the HumaCount 5 is a fully automated instrument, operation requires minimal training or technical support. Operator interaction is reduced to the following:

- Perform a Blank Measurement if the instrument is left idle for a long time.
- Enter the sample and/ or patient data.
- Insert the sample into sample holder for analysis.
- Print results either one-by-one, or by selecting records from the database.
- Perform simple weekly maintenance, as described later in this manual.

1.2.7 Calibration and Quality Control

The HumaCount 5 is delivered to your laboratory factory-calibrated and ready to use. However, calibration needs updating whenever you find even a slight variation in results, or when a new or a different control material is used. With any control material to be used on the instrument you will find a control sheet listing the parameters the instrument should match. Perform the calibrations as explained in a later chapter.
Quality controls are used to check for proper calibration and performance of the analyzer. These samples should be run on a regular basis, as also explained in 7.2. Calibration

1.3 Instrument Features

Figures 1 and 2 show the front and rear view of the HUMACOUNT 5hematology analyzer.

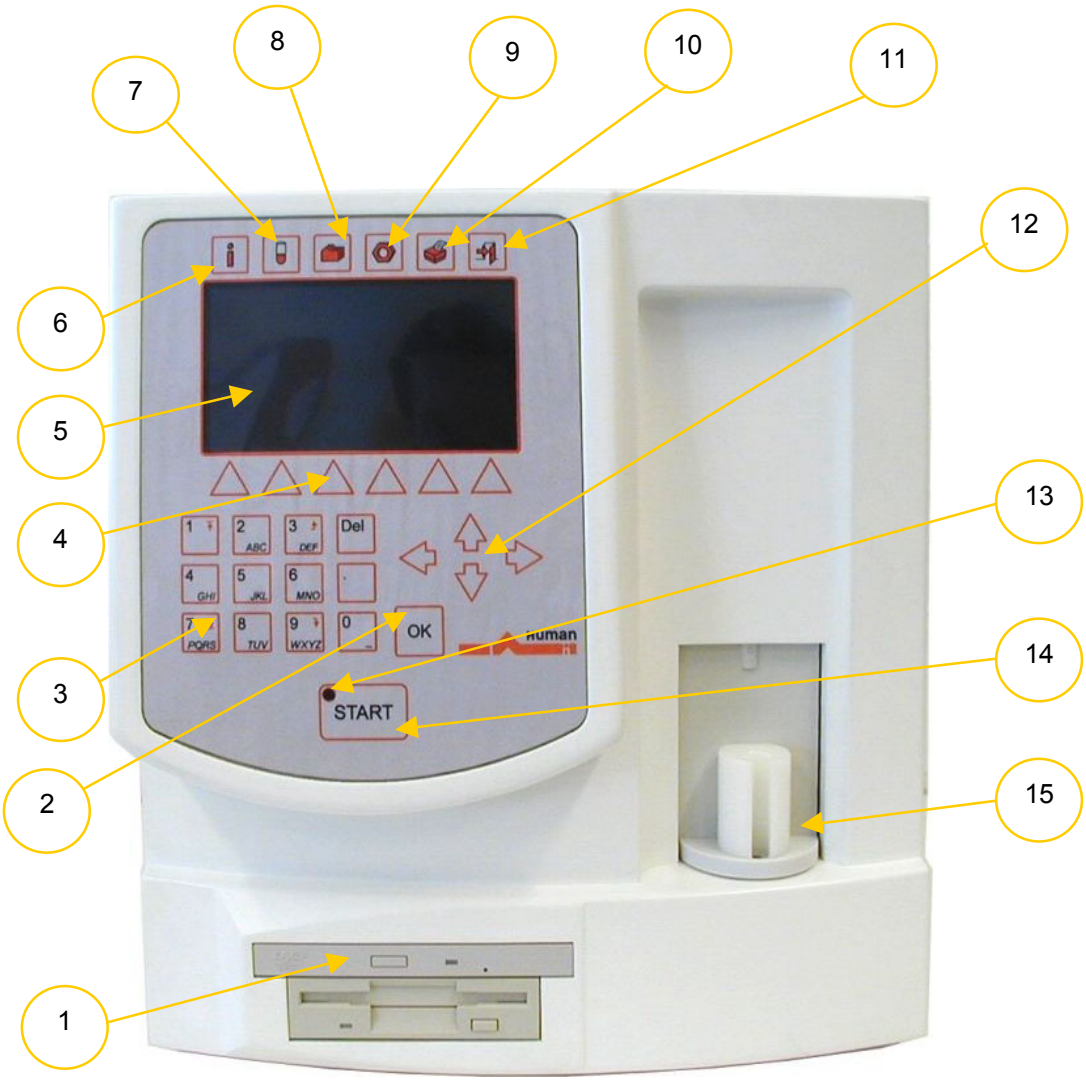


Figure 1. Front view

1. Floppy disk drive and optional CD ROM drive
2. OK key
3. Numerical keypad
4. Function keys
5. Graphic liquid crystal display
6. HELP key
7. Measure function key
8. Database function key
9. Utilities menu key
10. Printing function key
11. Exit menu key
12. Cursor control keys
13. Status indicator
14. START key
15. Sample rotor

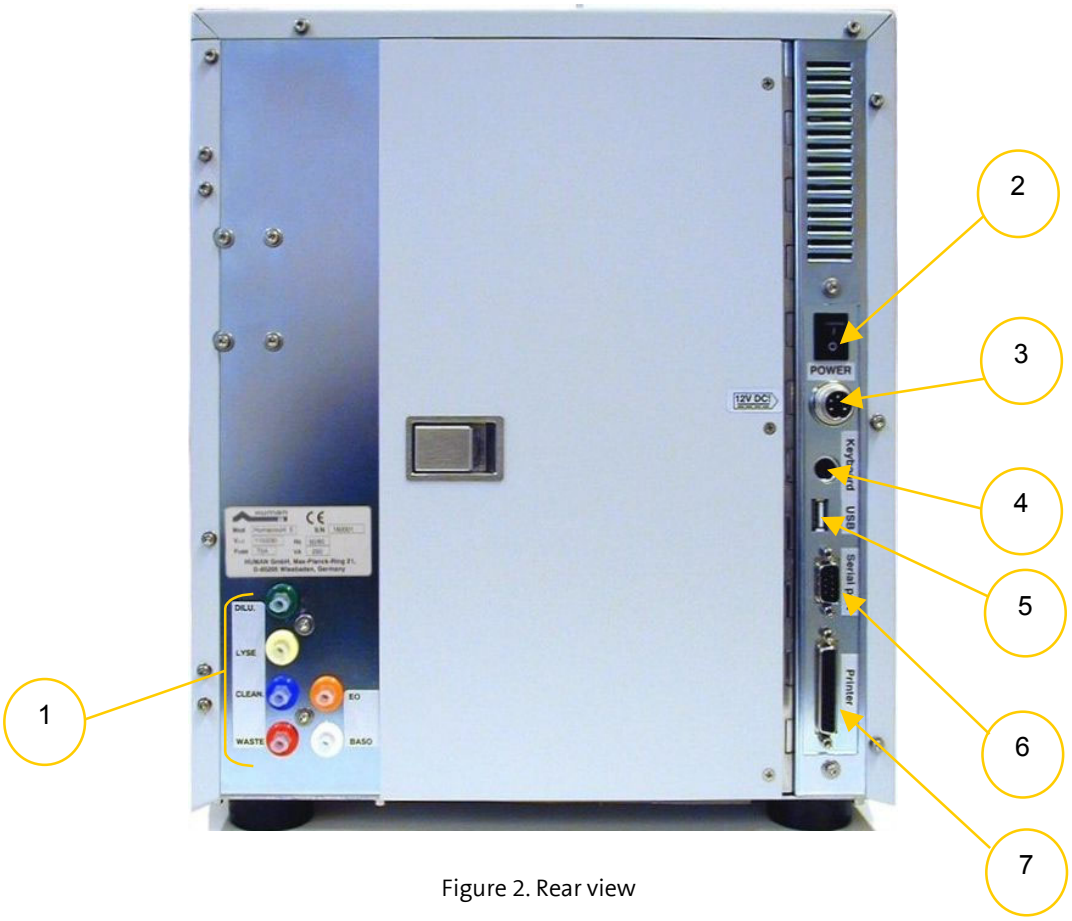


Figure 2. Rear view

1. Reagent tubing connections
2. On/Off switch
3. External power supply inlet 12VDC
4. PS2 external keyboard port
5. USB port
6. Serial (RS 232) port
7. Parallel printer port

Figure 3 shows the open built-in printer loaded with a roll of thermal paper inside.

To open the lid, press the button indicated in the picture. Drop in a roll of thermal printer paper and close the lid so that the end of the paper passes between the black paper guide and the printer mechanics.
The built-in printer can be selected for report generation in “Printer Settings” menu (see chapter 7.5.1).

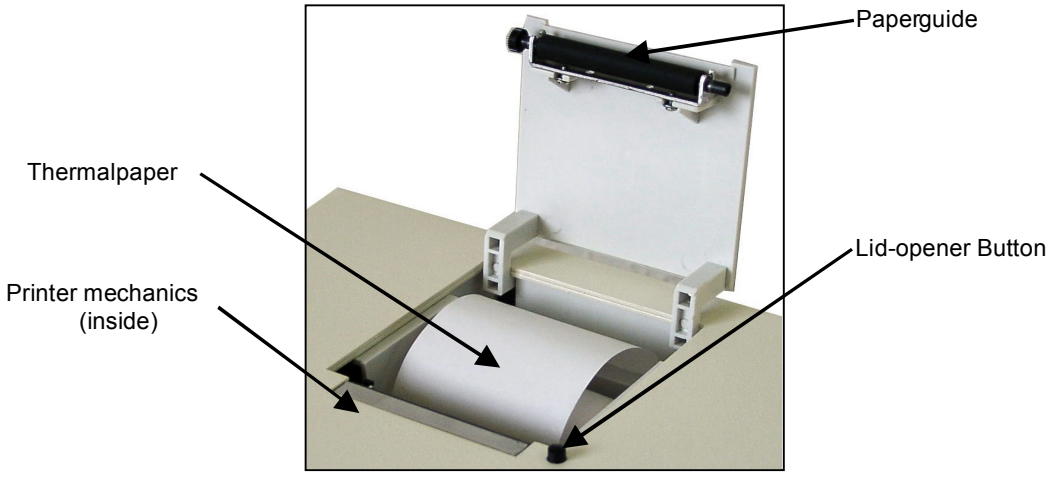


Figure 3. Built-in printer

The analyzer uses an external power supply. The figure on the left shows the power supply unit generating 12VDC.
The power supply module has an auto range input, allowing operation with 230V or 115V mains supply. It conforms to the CE and UL safety standards.
The input socket is a standard power cable connection, output is a special, lockable plug as shown in the picture.

Figure 4. External power supply unit

1.4 Parts of the Analyzer

The HumaCount 5 hematology analyzer is comprised of three main parts:
Fluidic System:
Performs sampling, diluting, mixing, and lysing functions. Generates regulated vacuum used for moving cells through the aperture during the counting process.
Data Processing System:
Counts, measures and calculates blood parameters, generates and stores numerical results and histograms.
User interface/peripherals:
Features an LCD display, a 29-button keypad, and parallel (external printer) and serial (computer) interfaces.

1.4.1 Function of the Fluidics

For the Schematics of the fluidics system, see Section 9.

Sample aspiration and dilution:

	Sample processing procedure
a.	Instrument takes sample by piercing the closed tube and aspirates 90µl of blood into the sampling needle.
b.	Partial blood samples are taken from this 90µl for each measurement to be performed later on during the process.
c.	The separated volumes are put into the EOS, BAS and MIX chambers with the necessary amount of the respective reagents to establish the required dilution and temperature.
d.	EOS and BAS measurements are done in the WBC chamber, after thorough cleaning.
e.	The MIX solution (in the MIX chamber) is the basis for the second dilution of RBC and for the WBC measurement.
f.	The MIX solution is drawn into the WBC chamber while LYSE is added to the blood. Lysing takes place and measurement is performed in the WBC chamber.
g.	RBC and PLT measurements are performed in RBC chamber.
h.	The system is cleaned and flushed with CLEANER and DIL solutions.

Table 1.

Dilution rates in HumaCount 5:		**Measurement time:**	
Primary dilution	1:160	WBC / EOS / BAS counts	5 seconds
RBC dilution	1:32000	HGB measurement	2 seconds
WBC dilution	1:200	RBC/PLT count	8 seconds
EOS, BAS dilution	1:160		

1.4.2 Control Panels

START button
Pressing and releasing the START button triggers an analysis cycle.

Status indicator
A three-colour LED is located near the START button.
Its current colour indicates the status of the analyzer.

LED colour	Analyzer status
Green	The analyzer is ready to work. Analysis can be initiated.
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 or is in stand-by state. The LED blinks in stand-by and the display light goes out.

1.4.3 Display

The display is a high contrast, CCFL backlit graphic LCD (Liquid Crystal Display) module with a resolution of 240 x 128 dpi.

1.4.4 Keyboard

The foil keypad consists of the following (shown in Figure 1):

- **Numeric keys** for entering numerical data and selecting menu items
- **Function keys** for specific functions. These functions are menu dependent and are indicated by icons appearing above the keys
- **Hardware function keys (short-cut keys)** for easier navigation among menus
- Cursor control keys ↑ and ↓ for moving among database items, ← and →, for moving among parameter columns or menu levels
- **START key** for initiating an analysis cycle
- **OK key** for confirming data
- **Del key** for deleting characters
- **Help key** for HELP function

Function keys

Below you will find all the possible icons and functions assigned to the so-called soft-keys (function keys)

Function key	Action triggered
	Exit from current menu or action
	Leave data-entry menu without saving any changes made to it (Cancel)
	Confirm the results or changes made (OK)
	Display histograms of the highlighted patient ID or QC Lot No.
	Redo action (e.g. Blank measurement)
	Enter/modify sample/patient data
	Print data (results, patient ID, QC)
 	Move among result pages
	PAGE-UP key in a multi-page menu
	PAGE-DOWN key in a multi-page menu
 	Change scaling of Levey-Jennings chart (16 or 64 days)
	Patient type selection
	Confirm error
	Go to local menu (database, measurement)
	Set Limits

	Stop the running process
	Show data in table format
	Set needle sampling position.

Below you will find all the possible icons and functions assigned to the so-called hardware function buttons

Function key	Action triggered
	Information
	Measuring process
	Database
	Utilities menu
	Printing function
	Exit menu

1.5 Control Material

The HumaCount 5 enables continuous monitoring of six different control levels (control blood). These should be matched to the types of samples usually run on the instrument. Specification (assay values and allowed tolerances along with expiry date) regarding these materials is always enclosed with the approved control.

1.6 Accessories

This list can also be referred as the " HUMACOUNT 5- pack"

- HumaCount 5 Hematology analyzer
- HumaCount 5 User's manual (this booklet)
- HumaCount 5 Reagent tubes (marked with coloured connector caps)
- Diluent tube (green)
- Lyse tube (yellow)
- Cleaner tube (blue)
- EOS tube (orange)
- BAS tube (white)
- Waste tube (red)
- HumaCount 5 Cleaning tube kit
- HumaCount 5 Caps for reagent containers (matches tube colours)
- HumaCount 5 Waste container (20 L)
- HumaCount 5 External power supply and power cable
- HumaCount 5 Spare part: pump tube
- HumaCount 5 Thermal paper (roll)

1.7 Specifications

Sample volume: 90 µl whole blood
Aperture diameter: 80 µm (RBC) 100 µm (WBC,EOS,BAS)
Measured Parameters: 22: WBC, LYM, MON, EOS, BAS, NEU, LYM%, MON%, EOS%, BAS%, NEU%, HGB, MCH, MCHC, HCT, RBC, MCV, PLT, MPV, PCT, RDWc, PDWc
Throughput: approximately 20 tests/hour

Characteristics:	**Accuracy max deviance from expected**	**Reproducibility (CV)**	**Carry over between samples**	**Test range**	
WBC	3%	< 3%	< 1%	4.00 – 20.0	10^9/l
RBC	3%	< 3%	< 1%	4.00 – 15.0	10^{12}/l
HCT	3%	< 3%	< 1%	25.0 – 50.0	%
MCV	2%	< 1%	N/A	50.0 – 90.0	fl
HGB	2%	< 2%	< 1%	9.00 – 16.0	g/dl
PLT	5%	< 5%	< 3%	200 – 900	10^9/l

Sampling method: Closed tube system, with automatic sample rotor and cap piercing
Sample types: Human (general), Male, Female, Baby, Toddler, Child
Fault statistics: RBC/WBC clogging < 1% of analyses (normal use)
Cleaning procedure: High-voltage aperture burst, high-pressure back-flush, chemical cleaning of aperture using Cleaner
Quality control: 6 levels, including: mean, ± range, SD and CV for all measured and calculated parameters, 16- and 64-day Levey-Jennings charts, separate QC database
Calibration: Automatic, based on 1 or 3 measurements, or manual calibration of WBC, EOS, BAS, HGB, RBC, PLT, MCV, RDW, MPV, monitoring of calibration factors by calibration events
Multi-user feature: 3-level multi-user operation with selective privilege levels, user identification with ID and password
User interface: Easy-to-use, menu-driven user interface with 6 software buttons (with icons), 6 hardware function buttons (above LCD), cursor and numeric keys
Languages available: English
Data storing capacity: 5000 results, including histograms
Host computer interface: Serial (RS-232) computer link
Data back-up Interface: 3.5" floppy disk or USB pen drive
Software upgrade: 3.5" floppy disk or USB pen drive
Printer interface: Centronics (parallel) or USB
Built-in printer: "Easy Paper Operation" built-in printer module
Display: high contrast, CCFL backlit graphic LCD with a resolution of 240 x 128 dpi.
Keypad: 29 foil keys + START button
External keyboard: Standard PS/2-compatible keyboard
Power supply: Auto-range, external 12VDC, 6A power module
Power supply (input): 100-120V/200-240V, 50-60Hz, 10W stand by, 80W max.
Operating temperature: 15-35°C
Dimension (WxDxH): 320 x 260 x 365 mm
Net weight: 15 kg

2 INSTALLATION

2.1 General Information

This chapter provides instructions for the installation of the HUMACOUNT 5hematology analyzer. The procedures described below must be followed closely to ensure proper operation and service. Please carefully read and follow all instructions in this User's Manual before attempting to operate the HUMACOUNT 5.

The HumaCount 5 hematology analyzer is a precision instrument, and must be handled accordingly. Dropping or other improper handling of the instrument will disturb calibrated mechanism and electronic components and/or cause other damage.
Always handle the instrument with care.

2.2 Environmental Factors

Locate the HumaCount 5 so that it will not be exposed to extreme temperature variations. The temperature should be held relatively constant to obtain maximum reliability. The ambient temperature range for the instrument is 15°C to 35°C.
Do not place the instrument close to any open windows, hot places (ovens, radiators), air conditioners, or in direct sunlight. Do not expose the instrument to vibrations from equipment such as centrifuges, shaker baths etc.

The HumaCount 5 external power supply must be plugged into a grounded AC outlet. Do not plug the instrument into electrical outlets on the same circuit as devices that operate intermittently and/or use large amounts of electrical current, such as air conditioners, refrigerators, compressors, etc. It is not advisable to use extension cords, especially multiple-outlet extensions. If you are located in an area that experiences excessive power fluctuations or are using a generator, connect the instrument to a surge protector (filtered surge protector preferred).

The HumaCount 5 should be installed on a flat, level surface with adequate room for the reagents, the optional keyboard and printer. The back of the instrument should be at least 15 cm from adjacent walls or other equipment to allow sufficient airflow and ventilation.

The HumaCount 5 uses external reagent containers. Care should be taken so that the table holding the instrument is not pushed against the wall, which could pinch the tubes between the instrument and reagent containers.

2.3 Unpacking and Installation

1. Carefully remove the HumaCount 5 hematology analyzer from the shipping carton. Inspect the instrument for any visible signs of damage incurred during shipping. If you find any damage, immediately file a claim with the carrier or your HUMAN distributor. Check the accessories received against the packing list. Contact your HUMAN distributor if anything is missing.

2. **CAUTION!** Prior to initial operation, allow the instrument to reach room temperature (approx. 2 hours). Rapid temperature changes in an operational unit can lead to water condensation, damaging electronic parts.

3. Place the instrument on a firm work surface in the designated work area, near an appropriate AC electrical outlet. **The connection MUST be grounded.**

NOTE

Before making connections: Be certain that all power is switched to "OFF" before connections (printer, external keyboard) are made. Carefully read all literature accompanying the instrument and its accessories. Pay particular attention to the operating instructions for the external printer.

4. Keyboard and external printer
   Attach the keyboard cable to the round "KEYBOARD" port on the back of the instrument. Attach both ends of the printer cable to the appropriate ports on the printer and the HumaCount 5. Attach the AC adapter to the printer (if required) and plug it into an AC outlet.

5. Host Computer
   The instrument has a built-in serial port that allows connection to a host computer. Results, including histograms, may be exported. Serial I/O settings can be found in Settings.

For installation instructions, please contact your HUMAN distributor.

6. Power supply
   Connect the power supply to the instrument. Attach the power cord connector to the external power supply of the HumaCount 5 and plug the other end into a properly grounded AC outlet.
   Please do not switch on the instrument before connecting the external power supply to the instrument and to the AC outlet, and before connecting an external printer or a keyboard to the instrument.

7. Reagent Containers
   Place the reagent containers near the instrument in an accessible location. Do not place the containers in a position higher than that of the HumaCount 5, because if a tube were to come loose from its connector the fluids would spill out. Use the supplied connecting tubes and special bottle caps. Be sure that the colour on each tube, cap and connector in the back of the instrument match. You can, for example, place the reagent containers below the table where the HumaCount 5 is installed, as the instrument has sufficient power to draw the liquids from a lower location.

All containers should be left open (do not block the small air vent hole on the special container caps) in order to provide free airflow.
(For connections, see Figure 5.)

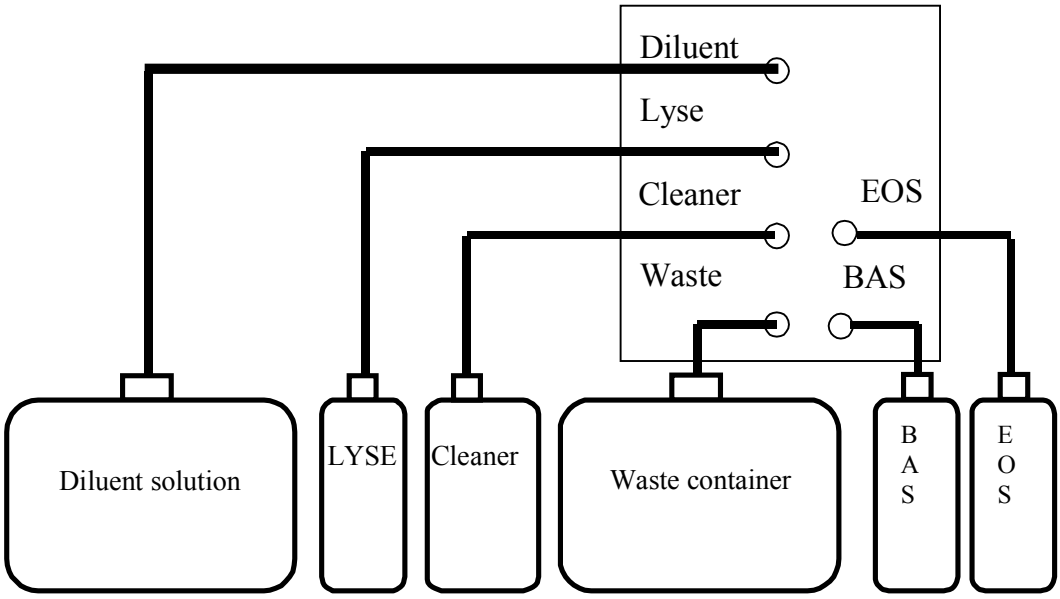


Figure 5. Reagent connections

8. Sample adapter

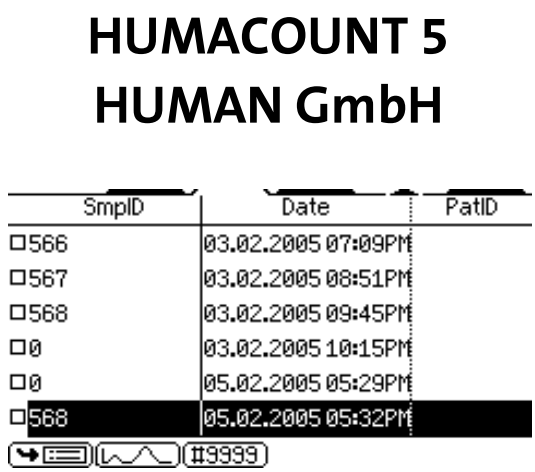
There is one adapter supplied in the HumaCount 5 basic pack.

Figure 6. Sample tube adapter– supporting BD Vacutainers and Sarsted Monovette (3.5ml)

2.3.1 Turning the Instrument ON

a. If you are using an external printer (for information, read the manual shipped with the printer) connect it and turn it on.

b. Turn the instrument on by flipping the power switch (above external power supply connector) to I position.



During start-up, the following screen is displayed. The software version number appears few seconds later, when the software starts.

An important feature of the instrument is that when software start-up is completed, the DATABASE will be displayed without any pneumatic initialisation (default setting). The pneumatics will only start when a measurement is started, or any pneumatics-related action is performed.
This default setting can be changed at the Service Menu level so that the instrument will start with pneumatic initialisation, providing the possibility to perform a measuring process immediately. Please contact HUMAN's service personnel if you want to change this setting.

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

In some cases, a priming cycle is necessary prior to sample introduction. The instrument will perform the cycle automatically if the fluid sensors are on (default setting) and additional liquid aspiration is required. A priming cycle should be run:

- after installation
- after an extended period of disuse
- after replacement of any component related to the Fluidic System

2.3.2 Turning the Instrument OFF

The instrument should never be switched off by simply pressing the power button on the rear panel. Doing so may result in erroneous results during later use. The instrument uses different kinds of solutions, one of which is the diluent. This liquid is an isotonic saline solution. If it is not washed out of the special chambers in the instrument, or if the chambers are not filled with it, this may lead to dust collection or salt buildup.
Therefore, always follow the instructions below when switching the instrument off.

Select the EXIT key  . The following screen is displayed.

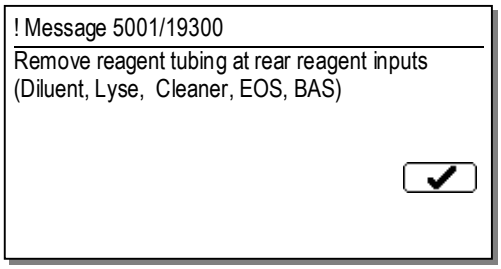
EXIT

SHUTDOWN (1)

The software will prompt you for confirmation. The analyzer will perform a priming cycle, filling the chamber to avoid dust collection and salt build-up. The screen will prompt the user again to power off accompanied by a continuous beep.

2.3.3 Preparing for Shipment

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

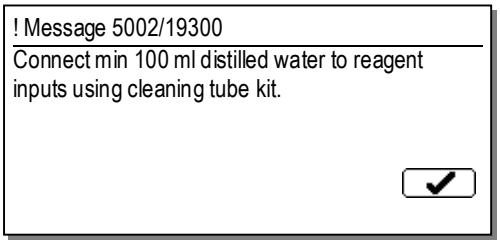


EXIT

PREPARING FOR SHIPMENT (2)

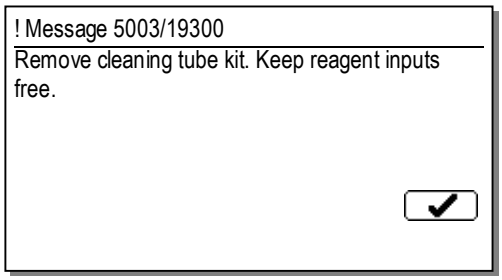
Here, the user is instructed to remove the tubing connectors so they can be drained.

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.

The analyzer will flush any remaining reagents from the system into the waste container.



Next, the analyzer asks you to remove the cleaning tube kit.

When finished, the analyzer prompts you to power off the system. Remove the waste connector after shutting down.

2.3.4 Emergency Handling

In case of an emergency situation- e.g. the presence of smoke or fire coming from the instrument (short circuit), cut off the power immediately and use a fire-extinguisher.

3 MENU SYSTEM

3.1 General Information

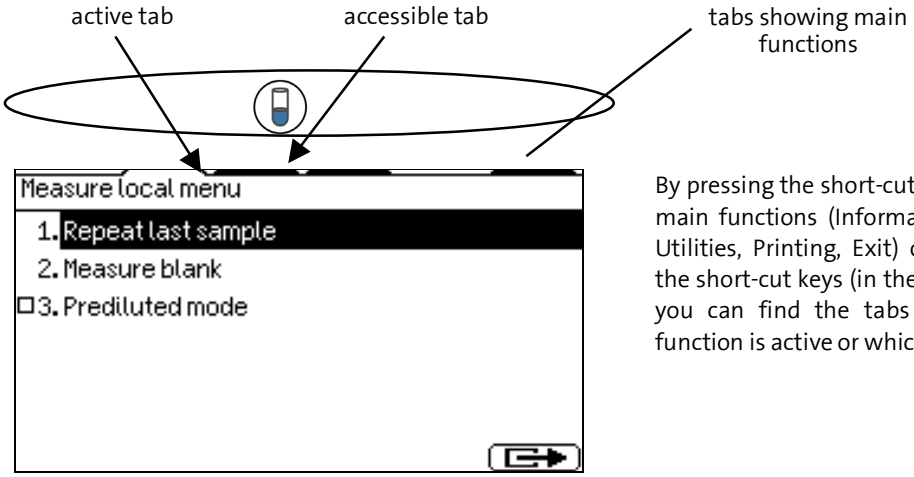
This chapter contains information about the functions and use of the software implemented menu structure.

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

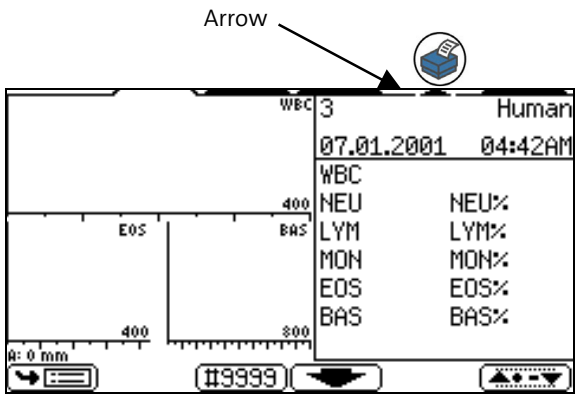
3.1.1 Navigating in the Menu System

The instrument uses a menu system to initiate actions and allow settings modifications. There are four possible ways to navigate among menus and menu items:

a. Most important are the 5 function keys above the LCD screen with which you can navigate among the main functions of the instrument (, , , ,).
These keys are short cut keys, so by pressing any of them you can select main functions, no matter which other submenu you are in.
If a keyboard is connected to the instrument you can use Function keys F7 to F12 on the keyboard as well (you will find the corresponding key under Menu Structure).



By pressing the short-cut keys you can activate the main functions (Information, Measure, Database, Utilities, Printing, Exit) of the instrument. Under the short-cut keys (in the upper part of the screen) you can find the tabs that show which main function is active or which are accessible directly.



The arrow under the Printing shortcut key indicates the Printing function is enabled.

b. You can select the desired item with the ↑ and ↓ keys and press the OK key to enter or activate the highlighted item.
Within a submenu, you can press the function key (if shown) to return to the previous menu level.
This method is suggested while learning instrument operation.

c. Pressing the numeric key corresponding to the desired menu item allows selection and confirmation of an item without the need to additionally press the OK key.
Pressing the 0 (zero) key has the same effect as the function key.

d. You can also move among the different menu levels using the ← and → keys. These have the same effect as OK and , respectively.

If selection of a menu item opens up a submenu, that item is indicated with a □ symbol at the end of the menu line.

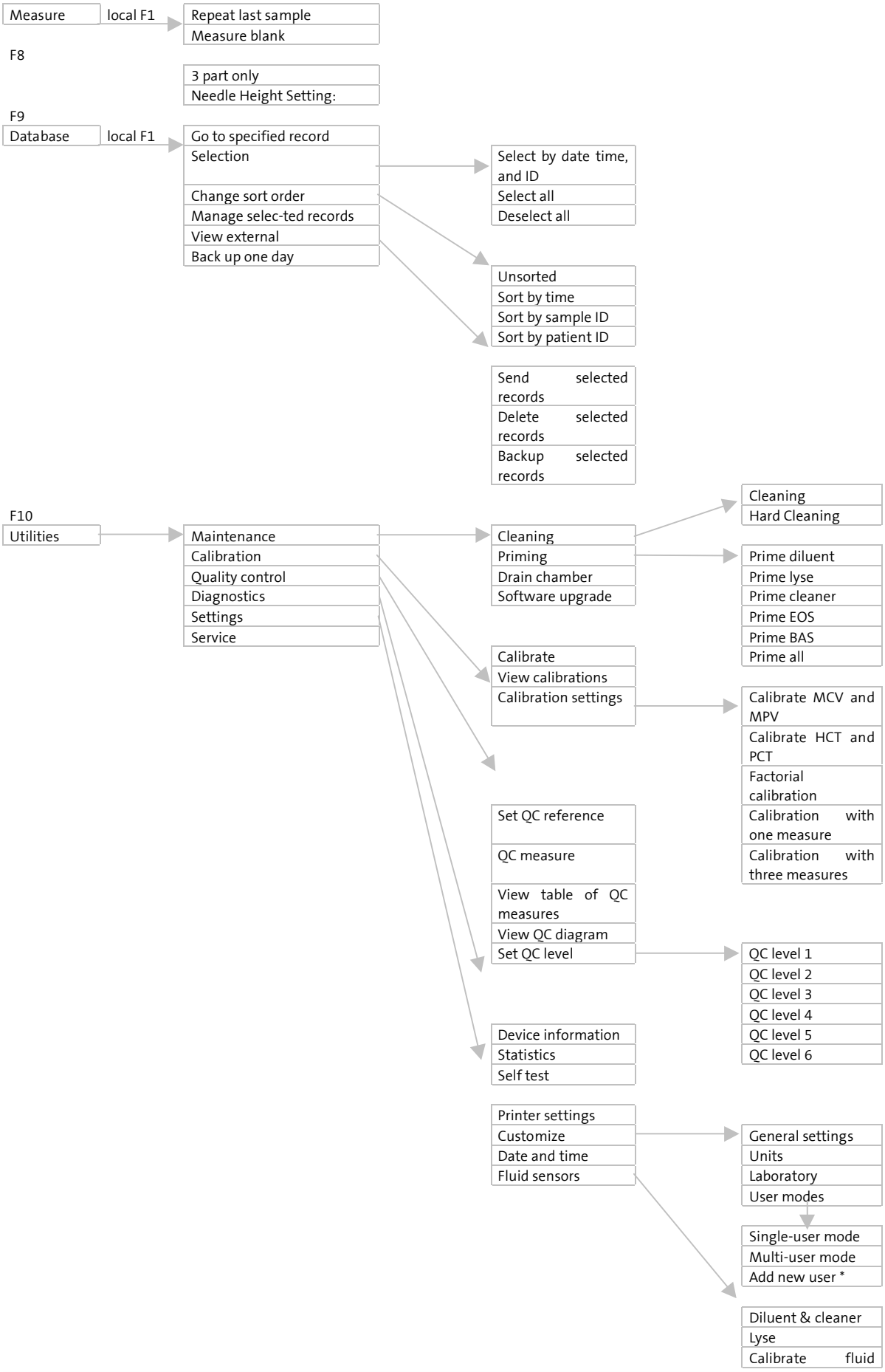
Some results can be displayed in table format. The following keys may be used for browsing the database:

3.= page up
9 ? page down
1 ↑ jump to top of list
7 ↓ jump to bottom of list

Several menus have items with boxes in front of the text. These indicate two-state options. The selected state is indicated by a filled box, the deselected state is indicated by an empty box. Selecting the item toggles its state.

Other items have circles in front of the text. These are called “radio buttons”.
They are divided into groups separated by horizontal lines.
Only one item from such a group can be selected at one time, indicated by a filled circle in front of the selected item. Selecting an item from the group will move the filled circle in front of this item, emptying the circle by the item selected previously.

3.1.2 Menu Structure



*if multi-user mode is enabled
**if serial communication is enabled

4 OPERATING PRINCIPLES

4.1 Impedance Method

The volumetric 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.

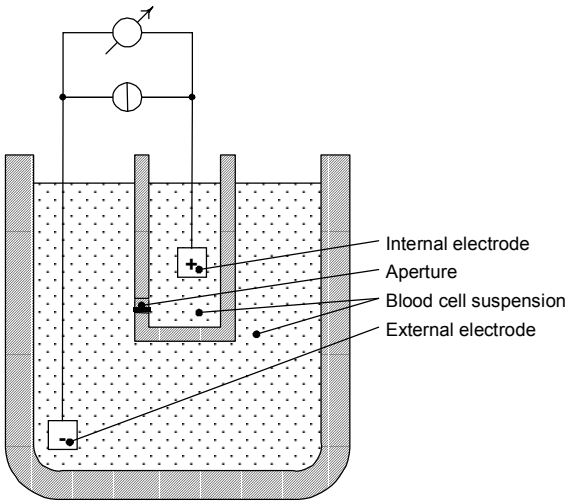


Figure 7. Impedance method

Each cell passing through the aperture – where a constant DC current flows 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 diagrams of the particles are WBC, RBC, and PLT histograms. EOS and BAS solutions (treated with the respective reagent) and their separate histograms are analyzed.
Pulses are counted only in channels (in terms of femtolitre, fl), which are between the lower and upper discriminators.

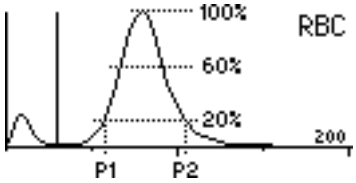
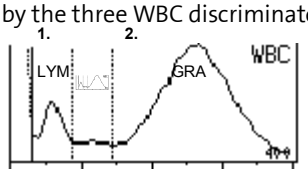
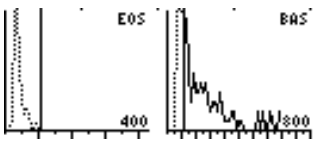
4.2 Principle of HGB Measurement

The lysed sample dilution can be measured by a cyanmethemoglobin method. The reagent lyses the red blood cells, which release hemoglobin.
Hemoglobin iron is converted from the ferrous (Fe^{2}+) to the ferric (Fe^{3}+) state to form methemoglobin, which combines with potassium cyanide (KCN) to produce the stable cyanmethemoglobin, or hemoglobincyanide. Subsequently, the HGB concentration is measured photometrically.

Note:
The above-mentioned measuring method is used to determine the HGB concentration. The HGB concentration can be measured using cyanide-free lysing reagents as well. In this case the effect is the same but the lyse used is an environmental-friendly reagent.

4.3 Parameters

The HumaCount 5 measures and calculates 22 different parameters, listed below. For each parameter, you can find name, abbreviation and measurement unit in the first column and also a short description for each parameter in the second column.

White Blood Cells–**WBC** (cells/l, cells/µl)	Number of leukocytes WBC = WBC_{cal} x (cells/l, cells/µl)
Red Blood Cells–**RBC** (cells/l, cells/µl)	Number of erythrocytes RBC = RBC_{cal} x (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 = HGBcal x ($HGB_{measured}$ – HGB_{blank})
Mean Corpuscular Volume - **MCV** (pg, fmol)	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-SD = RDW_{cal} x (P2 - P1) (fl), xDW-CV = RDW_{cal} x 0.56 x (P2 - P1) / (P2 + P1) by the factor of 0.56 CV is corrected to the 60% cut
Platelet – **PLT** (cells/l, cells/µl)	Number of thrombocytes (platelets) PLT = PLT_{cal} x (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 x MPV x 100 $PCT_{absolute}$ = PLT x MPV
White blood cell, 3 part differential: **- LYM (%)** : lymphocytes **- MON (%)** : monocytes and some eosinophils **- NEU (%)** : neutrophil granulocytes	Absolute values counted in the channels determined by the three WBC discriminators:  Percentages calculated from absolute WBC value.
EOS, BAS (%):eosinophil and basophil granulocytes	 Each distribution curve represents the given population.

4.4 Absolute and Linearity Ranges of Measured Parameters

Within the linearity range the instrument is guaranteed to provide the specified accuracy.

Beyond this linearity range, the instrument is able to display results, but the accuracy defined in the specifications is not guaranteed.

If the 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 the parameters of which exceed the maximum value indicated in the table below, pre-dilution is recommended. See section 5.3.1.2.1 of this manual.

The linearity ranges of primary parameters in normal measuring mode:

Parameter	Linearity Ranges	Maximum	Unit
WBC	0.5...75	100	109 cells/litre
RBC	0...15	20	1012 cells/litre
PLT	0...700	1000	109 cells/litre
HGB	0...250	400	g/l
HCT	0...100	-	%
MCV	30...150	-	fl
MPV	3...30	-	fl

Table 2. Linearity ranges of parameters

5 5 ROUTINE USE and MEASUREMENT

5.1 Measuring Process

5.1.1 Sample Handling

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

Care must be taken when using home-made containers pre-dosed with EDTA. If the container is not filled completely with blood, the ratio of EDTA to blood may reach a level that results in osmotic transfer from the RBCs, shrinking them. **The ratio of EDTA to blood should not exceed 3 mg/ml.** Generally, we suggest using manufactured sample tubes containing the necessary amount of EDTA and when you take blood. –please follow the instructions included with the tubes.

Important!
Sample tubes must be filled to at least the 7-8 mm mark with blood; otherwise correct sampling is not guaranteed! Most sampling tubes are marked with the minimum and maximum sampling volumes (blood level).

Biohazard! Protect yourself! Blood is a potentially infectious substance! Always use protective rubber gloves!

5.1.1.1 To initiate analysis:

1. Invert closed sample tube 11 times to achieve homogenous sample. Do not shake it, because micro-bubbles can form inside causing erroneous sampling!
2. Position the sample tube in the sample rotor, and push START key.

	
Closed vacutainer with sample blood	**Sample tube with 5 ml control blood** Please wipe the mouth of the tube. If bubbles have formed at the mouth, the instrument can be soiled with blood when they burst, causing measurement errors with subsequent samples.

Figure 8. Sample tubes used in tube adapter

The sample rotor turns, moving the sample inside the instrument and the needle draws 90 µl of sample from the tube. The aspirating needle is retracted, while its outer surface is automatically rinsed with diluent. This ensures low carry-over between samples. After a few seconds the rotor turns again, returning the sample tube, but the needle remains inside the instrument. The sample tube can now be removed from the adapter of the sample rotor.

5.2 Sample Analysis

5.2.1 Sample Preparation

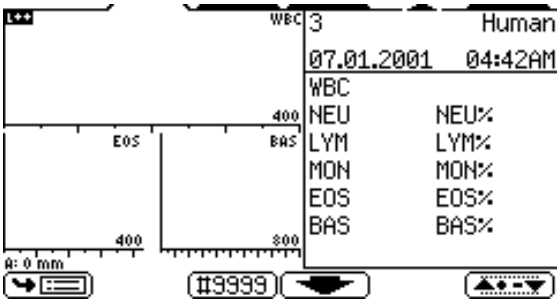
Use K3-EDTA anti-coagulated fresh whole blood as the sample. Prior to sampling, mix the sample gently by **inverting it 11 times. Do not shake** as this could damage the blood cells.

5.2.2 Modifying Lyse Quantity

The default lyse quantity can be adjusted by pressing [▲◆-▼] (LIMITS) if required in the measurement ready screen.

An additional option to modify the lyse quantity by **± 0.1 ml or ± 0.2 ml** is available during analysis (but this only functions for the current sample being run). Press ↑ to **increase** the lyse quantity **(+0.1/0.2 ml)** if the separation between lysed RBCs and WBC populations is poorly differentiated resulting in increased WBC and LYM counts. Press ↓ to **decrease** the lyse amount (-0.1/0.2 ml) if the WBC histogram seems to be skewed to the left, i.e. the different WBC populations are overlapped. This can inhibit proper separation of WBC populations.

If this function is selected, the **L+/L-**(for 0.1 ml) or **L++/L--**(for 0.2 ml) can be seen in the top-left corner during analysis (see the screen below).



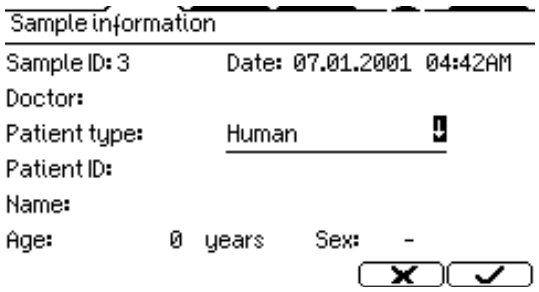
The two important parameters influencing lysing are reaction time and lyse quantity.
You cannot change the lysing reaction time, as it is adjusted to correspond to the lyse reagent.

5.2.3 Sample Information

The software allows the user to enter information for each sample that has been, or is to be measured. If an external PC keyboard is used, it must be connected to the instrument before turning the instrument on.
Two options exist for sample information entry:

- immediately before analysis
- after measurement in the Database menu

To enter sample information prior to sample analysis, press the [#9999] function key. The following screen appears:



Sample ID and patient data can be specified (name, sex, date of birth). Also, a doctor's name can be entered as sample data.
The patient name and data will appear on the printed result sheet.

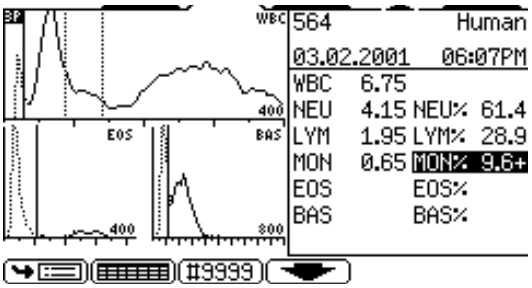
Type the name, using up to 32 alphanumeric characters, ("A-Z", "0-9", space, point and parentheses). Use arrow keys to move among characters and the backspace key for deletions. Press **Enter** to accept data, cancel with **Esc** or [✗], confirm with [✓]. The keypad can also be used to enter patient information just as on a mobile phone; keys are pressed until the desired letter (printed on the key) appears in the given field.

IMPORTANT:

IF A CONTROL IS MEASURED IN NORMAL SAMPLE MODE
ONE MUST SELECT PATIENT TYPE "CONTROL"

5.2.4 Results

At the end of an analysis, the following screen is displayed, including all measured and calculated parameters as well as the WBC, RBC and PLT histograms.



Results and histograms will be stored automatically in the memory without any operator confirmation.
If reference ranges are set (not 0.0), parameters will be verified and marked by:
+ if the value is over,
- if the value is under the range specified.

- If analysis errors occur or the blank measurement value is too high, the **E error flag** will appear next to the erroneous parameter and no results will be displayed for it; instead --- will appear.
- If there are warnings, a *** flag** will appear preceding the result.
  Any warning flags are displayed in the last line of the first result screen.

Note:
If the WBC count is below the low limit of 0.5 NO results for the different WBC groups will be displayed. Such sample must be checked by microscope.

In the following table the **warning flags** are summarised including an explanation of the possible causes and suggestions to solve the problem:

5.2.4.1 Uppercase letters refer to WBC or HGB problems:

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 the HGB blank is not stable there are probably bubbles in the WBC chamber: Run a cleaning cycle and try the blank again. Keep the side door closed during measurement.
B	WBC blank is high, or no WBC blank	Repeat the blank measurement, or run the prime lyse cycle and try the blank again. Possible lyse contamination or noise problem.
C,Q	WBC clogging	Aperture clogging. Perform cleaning cycle and repeat the measurement. If it is a persistent problem, please contact your HUMAN distributor. Low temperature reagents can cause clogging as well (diluent).In this case wait until the reagents warm to room temperature.
S	Slice error	The sample just run might have caused a clog, was not well mixed, or had too many cells. Try re-running the current sample or use pre-dilution.
D	Data error	The measurement-processing unit encountered problems it could not correct. If the problem persists, contact your HUMAN distributor for software or measurement unit revision.
M	More cells	There were too many cells in the WBC solution. Try running the sample in pre-diluted mode.
R	Too many RBC's in WBC sample.	Too many RBC were calculated in the sample. The reason can be an increased number of RBC's or decreased sensitivity for lyse reagent. A slight increase in the lyse amount can help solve this problem.
L	WBC-RBC differentiation warning	Too many RBC's were left in the WBC region. Try increasing the lyse volume.
W	3 part differentiation fault	The sample did not react to the lyse reagent as expected. The lyse volume should be changed to give better separation of cell populations.

Table 3. Summary of warning flags related to WBC/HGB

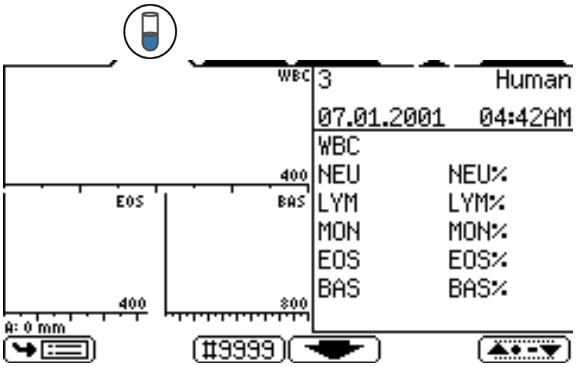
5.2.4.2 Warning flags in lowercase refer to RBC or PLT problems:

Flag	Meaning	Recommended user action
p	PLT blank is high, or no PLT blank	Run the cleaning cycle and repeat the blank measurement. Diluent or system cleanliness problem. If the reading remains high after numerous blanks, use a new container of diluent.
b	RBC blank is high, or no RBC blank	Same action as in the case of warning flag **p**.
c	RBC/PLT clogging	The same action as in case of the **C** warning flag (see above).
s	Slice error	The sample run previously might have caused a clog, was not well mixed, or had too many cells. Try re-running the current sample or use pre-dilution.
d	Data error	The measurement-processing unit encountered problems it could not correct. If the problem persists, contact your HUMAN distributor for software or measurement unit revision.
m	More cells	There were too many cells in the WBC solution. Try running the sample in pre-diluted mode.
k	RBC peak not good	The analytical algorithm found the RBC peak located at an unexpected position and could not define the exact RBC count. Make sure the sample was well mixed, and run it again.
l	RBC-PLT limit fault	The analytical software could not separate RBC's from PLT's as the populations overlapped. Run the sample in pre-diluted mode.

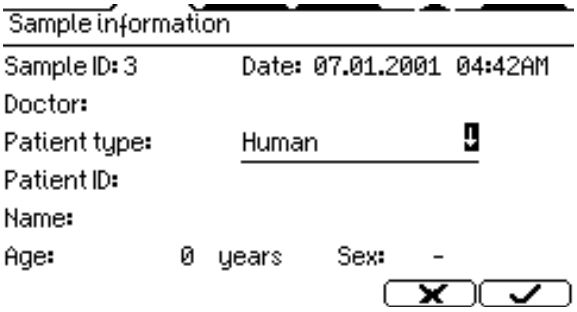
Table 4. Summary of warning flags related to RBC/PLT

Warning flags can be grouped according to measurement conditions and according to the problems relating to the blood sample.
Measurement conditions: when the flags are related to clogging **(c, C)**, or probable hemolysing problems **(E, b, B, p)** and pressure problems (Fatal pressure error), repeat the measurement.
The asterisk flag (*) next to a parameter indicates some uncertainty about 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 must be used, related parameters will be marked), etc.
Another flagging method is evaluation against the normal ranges. If a parameter is out of range, it receives a (-) flag if under the range or a **(+)** if over the range, and the parameter is inverted on the result screen. You can customise ranges for all types of patients by setting the corresponding lower and upper ranges. 0 (zero) value for range limit indicates no verification is needed.

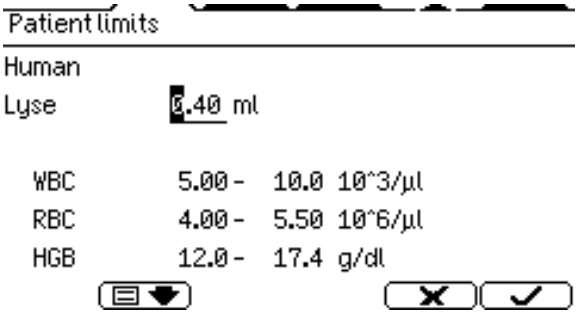
5.3 Measure



By pressing the MEASURE short-cut key, the measurement screen is displayed. The default measurement screen is set to Human normal ranges. The patient data entry screen is accessed by pressing the #9999 button.



The patient data entry screen allows sample specific data to be entered, and this is also where the measurement profile (patient type) is selected for the given sample.

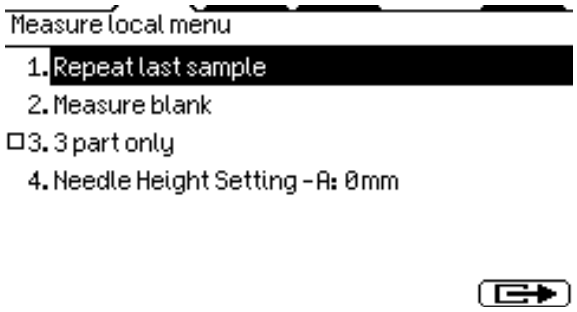


Once you set the required patient type, press the key to enter the Patient limits setting dialog.
This function allows the reference ranges used in your laboratory to be specified. Lower and upper limits for each parameter are displayed and can be modified using the numerical keypad.
Confirm data by pressing the OK key.
Pressing the and function keys accesses additional pages.
If 0.0 - 0.0 is specified for lower and upper limits, that parameter will not be verified.

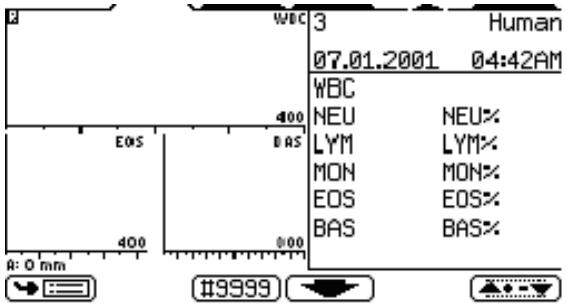
On the first limit settings screen , the software allows you to **change the amount of lyse added**. The instrument permits a range of 0.3 ml to 1.2 ml.
Optimal quantities are strongly influenced by the chemical composition and behaviour of the lysing reagent. The quantity of the lyse reagent can also be modified before each analysis by ▣ 0.1/0.2 ml without having to change the value in this sub-menu.

5.3.1 Measure Local Menu

From the Measure local menu you can access further sub-menus.


Measure local menu
1. Repeat last sample
2. Measure blank
3. 3 part only
4. Needle Height Setting - A: 0mm

5.3.1.1 Repeat Last Measurement

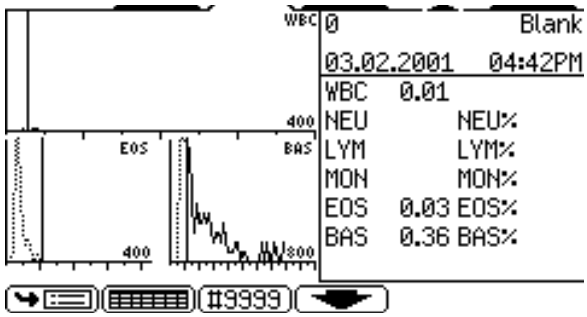


Choosing item 1 from the Measure local menu, the last measurement can be repeated and R will be displayed in the upper left corner of the screen.

5.3.1.2 Blank Measurement

Blank measurement is used for checking the cleanliness of the system and the purity of the reagents.
A blank measurement must be performed:

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



The user must accept blank values by pressing ✔.
To repeat the blank measurement, press ↻.
If any of the tested parameters has a high blank value, the message "Unsuccessful blank measure" appears at the top of the screen.

There are 3 regions for blank value handling:

1. Optimal- all results are within acceptable ranges.
2. Blank is high- * flag is displayed next to 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	0.00- 10.0 g/l	10.0- 25.0 g/l	> 25.0 g/l
WBC	0.00- 0.50 x 103 cells/µl	0.50- 1.00 x 103 cells/µl	> 1.00 x 103 cells/µl
PLT	0.00- 25.0 x 103 cells/µl	25.0- 50.0 x 103 cells/µl	> 50.0 x 103 cells/µl
RBC	0.00- 0.05 x 106 cells/µl	0.05- 0.50 x 106 cells/µl	> 0.50 x 106 cells/µl

Table 5. Blank measurement ranges

Accepted blank values are essential for proper calibration and quality control measurement. For this reason, no calibration or QC measurement can be performed without accepted blank values.

Quality control measurement and calibration can be performed only if all blank values are in the first region (receiving no flags or errors).

5.3.1.2.1 3 Part Only

Toggling this checkbox to the ON state will disable EOS and BAS measurement (and will not use those reagents) and speed up the measurement cycle for the given sample, producing a "regular" 3-part result with GRA (granulocytes) population having EOS, NEU and BAS calculated together. MID cells will be referred to as monocytes and some EOS cells as well. This option is valid for one sample run only, and is turned OFF for the next cycle. This

mode does not mean that EOS and BAS reagents can be disconnected, or that the instrument can be used without them for 3-part measurements. EOS and BAS are system reagents, thus they must be present in all cases.

5.3.1.3 Needle Height Setting

Selecting this option will modify sampling depth. Sampling depth is important for defining how deep the needle should go into the sampling tube. The less blood you have in the tube, the lower this value should be. Make sure that the value set matches sampling tube characteristics. Incorrect settings can damage the sample tube and sampling needle.

This value remains the same until it is changed again. It is always displayed in the bottom row of the measurement sampling-ready screen.

5.3.1.4 Prediluted mode

The software has a special Prediluted mode, useful in the following situations:

- Sample values exceed linearity (see section 4.4)
- Small sample volumes
- Capillary blood samples

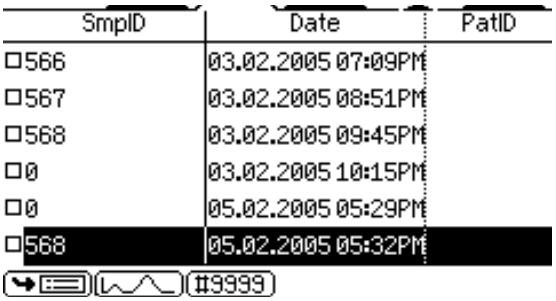
In Prediluted mode, operator must prepare an external 1:5 predilution:

Predilution: 1 UNIT OF SAMPLE + 5 UNITS OF DILUENT

Example: if 20µl capillary tubes are used for blood collection, add 100µl of pure diluent to create a proper predilution.

6 DATABASE

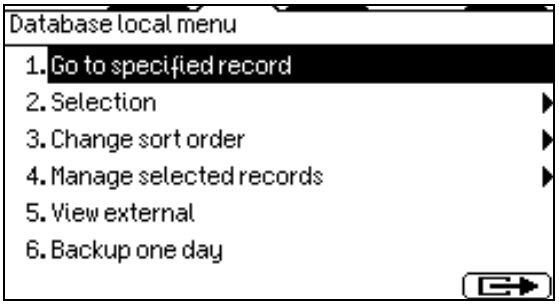
Patient results are stored in the memory in chronological order and can be retrieved at any time. Data storage capacity is 1,000 measurements, including the complete parameter list, histograms, flags, sample data, and date/time of measurements.



DATABASE

Pressing the ← or → key accesses the remaining, non-visible parameter columns. ↑ and ↓ keys scroll results one-by-one up and down. Keys 3 and 9 are equivalent to the PageUp and PageDown scrolling keys.
Toggle selection of records by pressing the OK key while record is highlighted. The box in front of the record will be filled.

From database table screen, WBC, RBC and PLT histograms can be displayed by pressing . By pressing the key, an additional panel with more parameters can be viewed. While in graph view, use ↑ and ↓ keys to jump to the previous or next record, respectively.



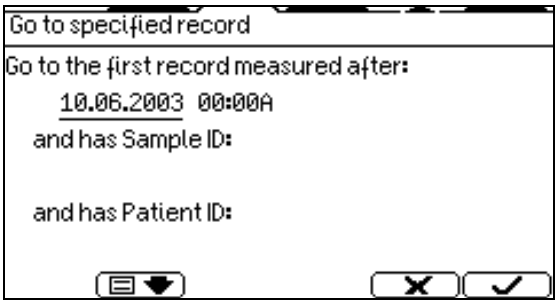
<DATABASE LOCAL MENU>

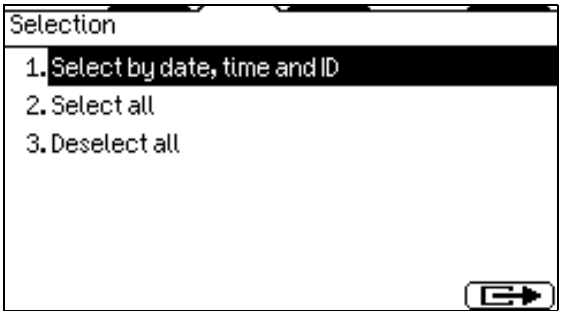
From the database table screen, enter Database local menu by pressing the key.

<DATABASE LOCAL MENU>

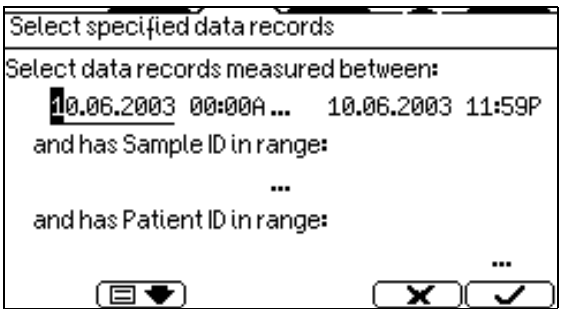
GO TO SPECIFIED RECORD (1)

Item 1 of the previous menu accesses a screen that asks for parameters defining any given sample (date, time ID) and jumps to it. If both ID's are left as 0, searching is performed only by date/time.

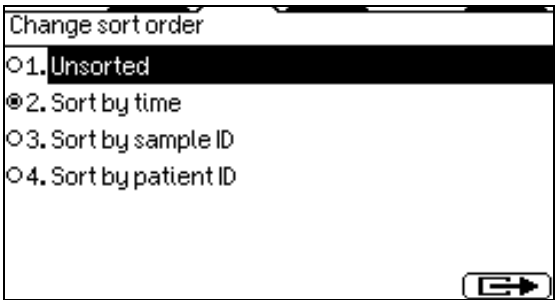




<DATABASE LOCAL MENU>
SELECTION (2)
Besides checking samples one-by-one, selection can also be done within the Database local menu.
SELECT ALL checks all boxes, DESELECT ALL clears all boxes.



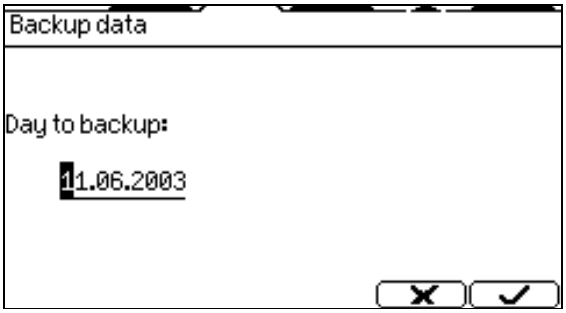
<DATABASE LOCAL MENU>
SELECTION (2)
SELECT BY DATE, TIME AND ID (1)
Select a range by date, time and/or ID number (see next screen)
Entering 0 as an ID results in a search by date only. Corresponding results will be marked with a filled box.



<DATABASE LOCAL MENU>
CHANGE SORT ORDER (3)
The order of the displayed results can be selected in this menu.

<DATABASE LOCAL MENU>
MANAGE SELECTED RECORDS (4)
From this sub-menu you can send the selected data-base to a PC, delete them or save them on a floppy and disk.

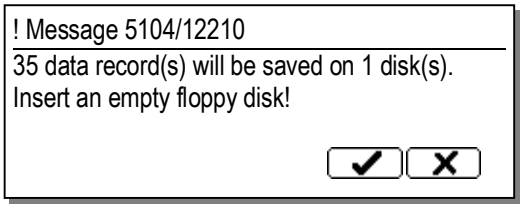
Data backup and monitoring can be performed in this submenu. Before menu selection, insert a 3.5” floppy disk into the drive located on the lower front panel of the analyzer. An empty floppy disk can store the results of 700 samples.



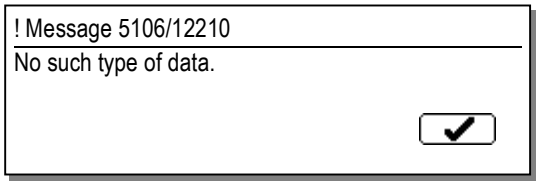
DATABASE

BACKUP ONE DAY (6)

Specify the day whose records you wish to back up to a floppy disk.

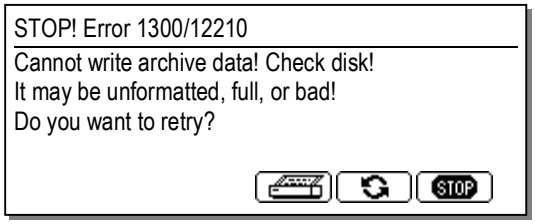


When you have selected the day or data to be saved, and confirmed it with the ✔ key, the instrument will prompt you for an empty disk.



Possible error messages include:

The instrument gives this warning if an attempt was made to save the data from a day when no data were available, or if no data are selected.



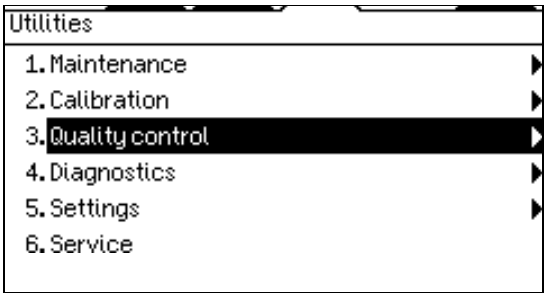
This warning appears if the inserted disk has errors on it or is write-protected.

Check the write protection of the disk or if necessary, insert a new, formatted disk.

7 UTILITIES

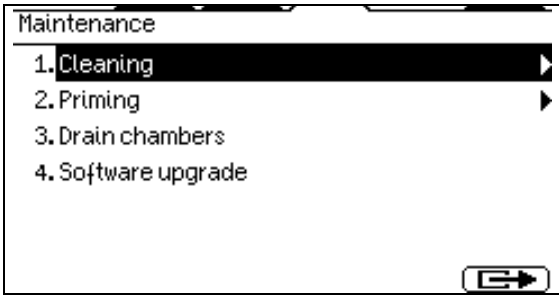
7.1 Maintenance

By selecting item (1) of the UTILITIES you can access the MAINTENANCE menu.

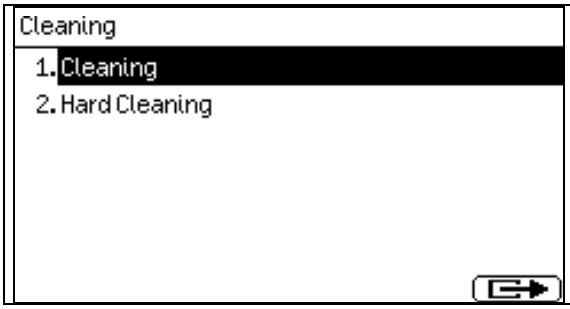


7.1.1 Regular Maintenance Jobs

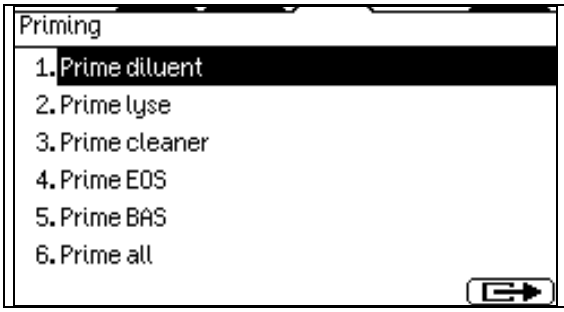
The Maintenance submenu offers tools including maintenance procedures such as cleaning, priming or draining.

	MAINTENANCE (1) Select the required submenu.

7.1.2 Cleaning

	Item 1 in the above-mentioned menu brings up the cleaning functions. Item 1 starts a washing cycle using the system cleaner reagent. This action is recommended if clogging problems are experienced (C or Q error flag). Item 2 initiates a process that uses a light solution of hypochlorite, and washes the entire system with it. The instrument will ask for the cleaning solution in a sampling tube.

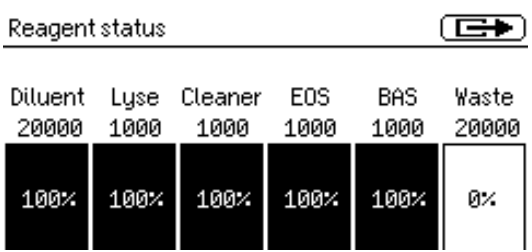
7.1.3 Priming

	During the priming cycle, the fluidic system is rinsed with a large amount of diluent. This differs from the process in a start-up procedure, as in the latter case a simple filling up of the fluidics is performed. If fluid sensors are on, the analyzer performs these procedures automatically; otherwise the user must initiate them by activating the appropriate item within this submenu.

7.1.4 Draining Chambers

Draining of chambers should be run before removal or replacement of parts related to the measuring chambers or apertures.

7.1.5 Reagent status



	The screen on the left shows reagent volumes in containers, as calculated by the instrument. As measurements are performed, the volumes are changing accordingly. When reagent volume in container is running low, instrument will notify user, and ask replacement.

7.1.6 Empty Waste Container

The software counts the waste container capacity and gives warning message when the tank is full. Empty the waste tank when the warning "waste is full" is displayed.
The waste container capacity can be modified on the Service level by your HUMAN service representative.

WASTE HANDLING – VERY IMPORTANT

Waste contains poisonous substances (because of possible cyanide content) and substances of human origin, a potential biohazard. These substances represent a potential danger to environment. For this reason, safe handling of the waste liquid is very important.

HUMAN reagents are cyanide free

Neutralisation of biohazard effect
Independent of whether the waste contains cyanide or not, you should follow this procedure.

- Put 2 ml/l hypochlorite solution into the waste receptacle. Close the cap, shake the container and wait 1 hour.
- Dispose of the waste by spilling it into the drain system.

7.1.7 Weekly Maintenance

Weekly maintenance should be performed before turning on the power switch.

- How to open the **side doors:**
  The left and rear panels of the instrument open to allow easy access to the fluidic system and mechanical parts (Figures 11 and 12).

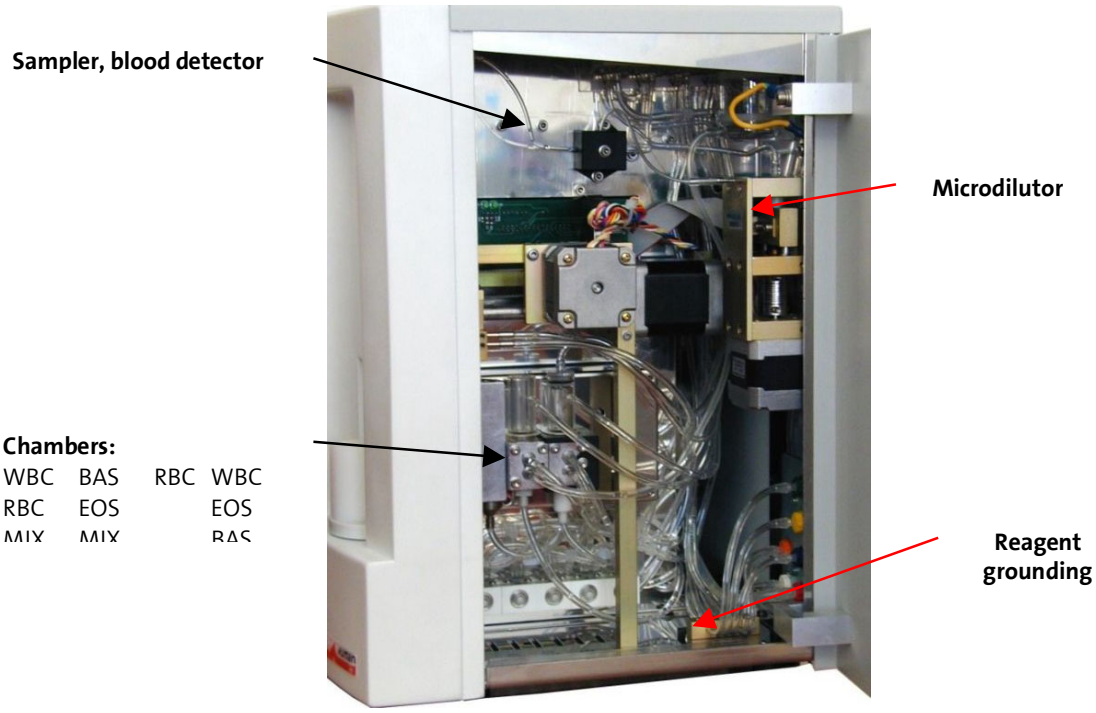


Figure 9. Side view

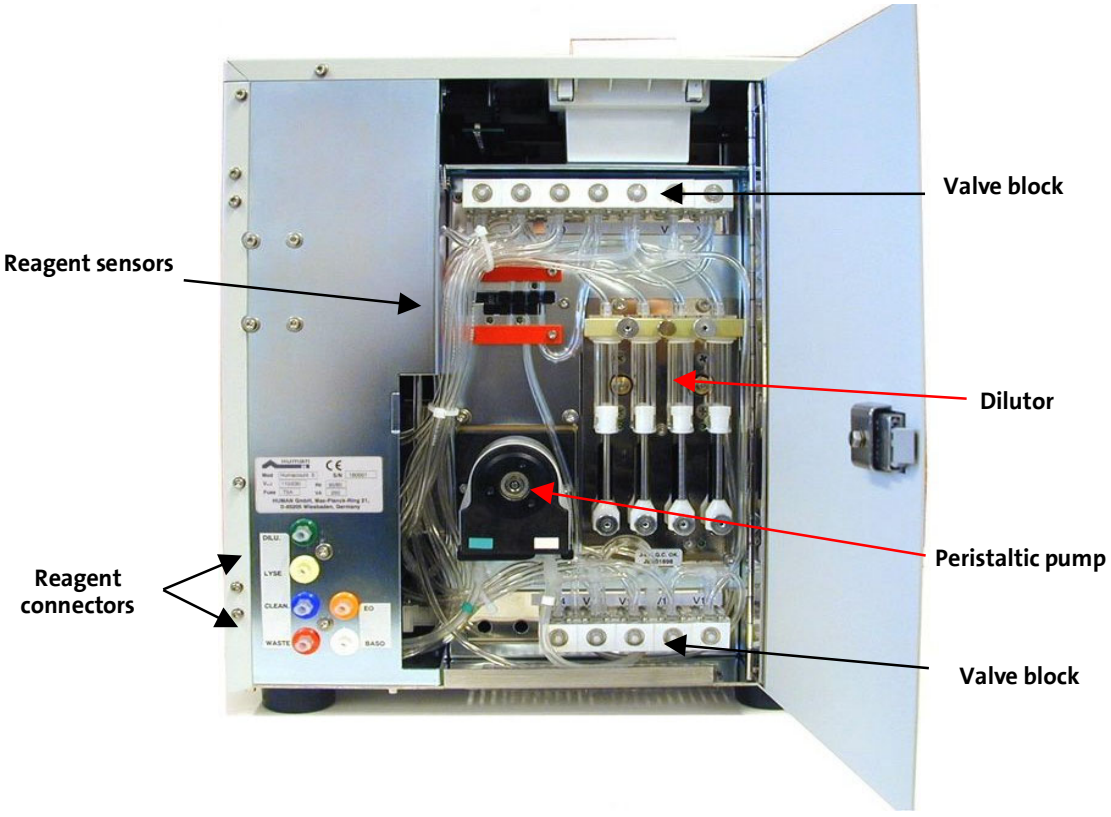


Figure 10. Rear view

7.1.7.1 Peristaltic Pump Maintenance

The pump installed in the instrument is maintenance free. However, should you experience leakage from the pump, or a vacuum error is displayed, the pump tube should be replaced.

1. Open the rear door.
2. Open the pump lock by turning the plastic holders to release the plastic pump housing (see figure 14.) Snap the pump tube out of the housing.

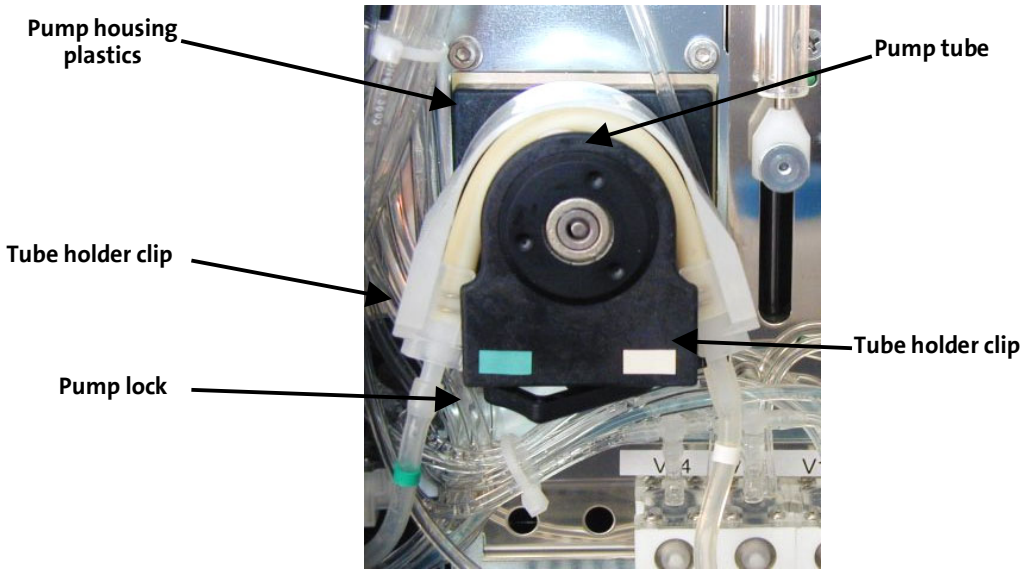


Figure 11. Peristaltic pump with open lock

3. Install the new tube into the plastic housing, then guide both ends into the lock.
4. Turn the lock back into the locked position to secure the tube in place. Match colours, and check connections for proper positioning. Close and lock the side door.

After replacing the tube, the pump should appear as in the figure below (original state).

Figure 12. Peristaltic pump after replacement of tube

7.2 Calibration

Calibration is the procedure used to standardise the instrument by applying the necessary correction factors.

It is recommended to perform a 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.

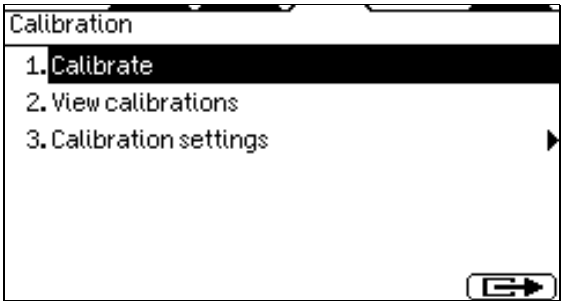
Calibration can be performed in two ways:

1. The user can enter calibration factors - without any calibration measurements – using the numerical keypad.
2. One-, or three-fold measurements of controls or special calibration material with known parameters. In this case, the instrument automatically calculates new factors using the following formula:

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

CAUTION!
A new calibration will invalidate previous factors. Old values cannot be retrieved, but can be viewed in VIEW CALIBRATIONS menu.

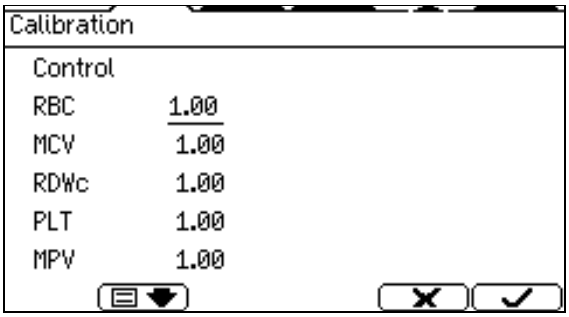
Calibration can be initiated by choosing Calibration in UTILITIES.



Item 1 opens CALIBRATE menu level, shown in the figure.
Item 2 displays the pervious calibration factors.
Item 3 allows selection of the calibration mode and basic parameters.

7.2.1 Factorial Calibration

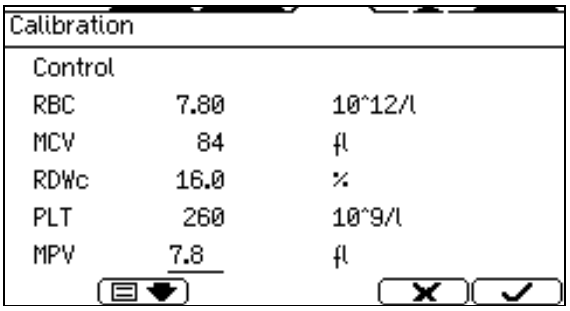
If the CALIBRATION MODE has been previously set to Factorial Calibration, the factors can be set manually in the 0.80 - 1.20 range.



UTILITIES
CALIBRATION (2)
CALIBRATE (1) (factorial)
Enter previously calculated factors using numerical keys; confirm with the OK key.

7.2.2 Automatic Calibration by Measurement

If the CALIBRATION MODE is set to one- or three-fold measurements, calibration measurements are performed with a hematology control blood.



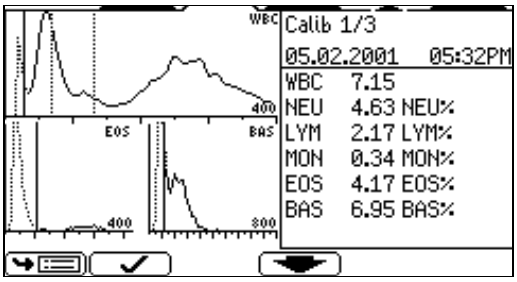
UTILITIES
CALIBRATION (2)
CALIBRATE (1) (automatic)

Set the target values of the control material using the numerical keys. Use the OK key to accept a value.
Specify 0 as target value for parameters that should be omitted from calibration.
After setting values, press ✔ to confirm and start calibration measurements.

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

Parameter	**Low limit**	**High limit**
RBC	1.00	8.00
HCT	0.10	0.60
MCV	50.0	120
RDW CV	10.0	50.0
PLT	30.0	800
PCT	0.00	2.00
MPV	5.00	15.0
PDW CV	5.00	50.0
HGB g/l	30.0	300
WBC	1.00	30.0

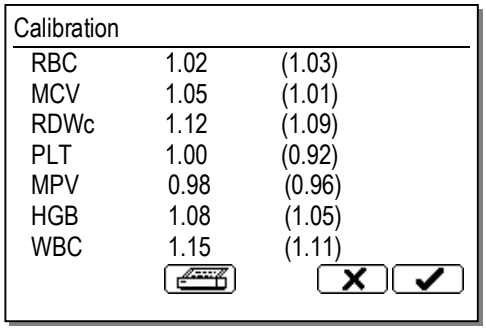
Table 6. Calibration ranges



After entering the required reference values, perform analyses on the control material.

Press ✔ to accept results.

The number of calibration analyses performed is shown in the first line.



Following calibration, the new factors are displayed. The previously used factors are shown in parentheses for reference. The calibration factors offered can be accepted by pressing ✔.
The factors will not be modified, but are flagged:
– if 0 was entered for low and high limits
– **B** if blank was not in the acceptable range
– **E** if the factor is out of the 0.80-1.20 range

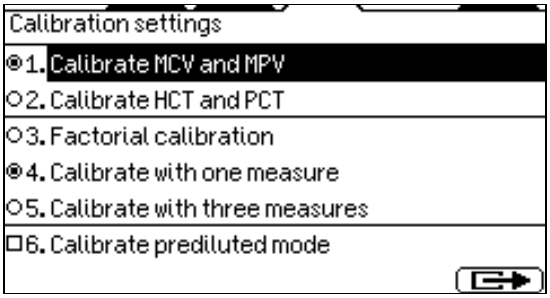
7.2.3 View Calibrations

From the Calibration menu you can view previous calibration factors. The instrument logs all calibration events and displays them in the following format.

Date	Time	OpID	RBC	MCV	RDWc	PLT
19.06.2003	16:50	0	0.80	0.80	0.80	0.80
18.06.2003	20:13	0	1.00	1.00	1.00	1.00
18.06.2003	20:05	0	1.00	1.00	1.00	1.00
16.06.2003	09:30	26	1.00	1.00	1.00	1.00
11.06.2003	14:53	0	1.00	1.00	1.00	1.00
11.06.2003	13:29	0	1.00	1.00	1.00	1.00
10.06.2003	11:31	0	1.00	1.00	1.00	1.00
16.05.2003	08:48	0	1.00	1.00	1.00	1.00

Calibration Settings

When CALIBRATION SETTINGS is selected, the following screen appears:



UTILITIES
CALIBRATION (2)
CALIBRATION SETTINGS (3)

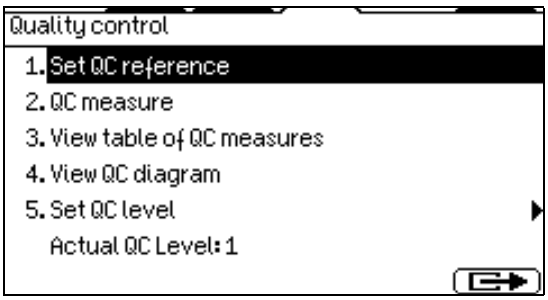
Items 1-2 select between parameters
Items 3-5 select among calibration modes.
Item 6: select calibration of prediluted mode.

To perform factorial calibration, enter reference parameters (MCV and MPV or HCT and PCT), and choose item 3, **Factorial Calibration**. In this case, the user must have performed the necessary number of measurements with the control material, based on which an average value can be calculated. This average value is used for fine-tuning the calibration parameters.

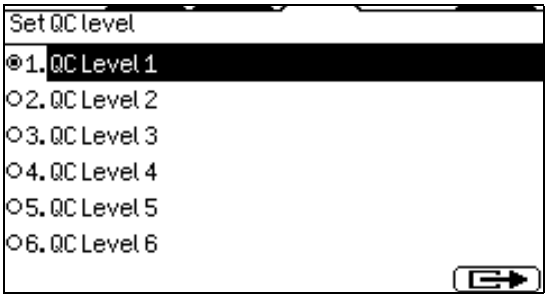
7.3 Quality Control

By analyzing control materials, day-to-day reproducibility can be monitored. Both target values and acceptable ranges for each parameter can be specified for different QC levels herein.
The **HumaCount 5** provides six different quality control levels. You can configure up to six individual reference sheets for each control material (e.g. low, normal and high control blood). QC measurement results will be saved to the selected level, as indicated at the top right corner.

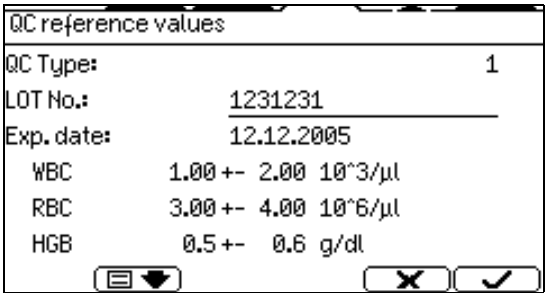
NOTE:
Target values of the control material should be set only once, at the beginning of the QC measurements. Resetting parameters deletes previous QC results at the current level.
CAUTION!
Any change in the QC material setting deletes previous QC results. It is strongly recommended to print results prior to changes.



From UTILITIES you can access Quality Control Menu
UTILITIES
QUALITY CONTROL (3)
This menu allows data related to the QC procedure to be entered and monitored.
Use commercially available control material. The preparation and analysis process is the same as with patient samples.

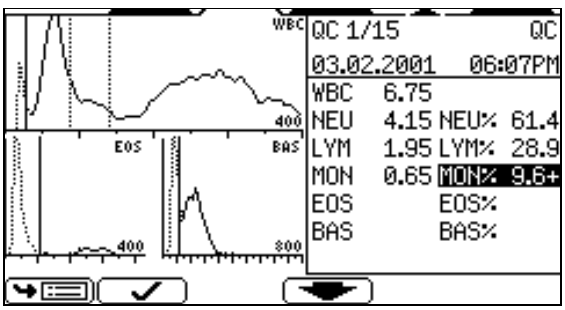


UTILITIES
QUALITY CONTROL (3)
SET QC LEVEL (5)
Select the level you wish to use.
The active level is displayed in the top right corner of QC-related screens.



UTILITIES
QUALITY CONTROL (3)
SET QC REFERENCE (1)
Both target values and acceptable ranges can be specified. Only parameters displayed on these screens are utilised. Modify displayed values using the numerical keyboard. The OK key accepts data. Use the page down function key to view additional parameters. Setting 0.0 disables QC for the parameter.

NOTE:
Quality control measurements can only be made after an optimal blank measurement result has been accepted (all parameters are in the 1st range).
When quality control measurements are made in 5-part mode no % results will be shown.



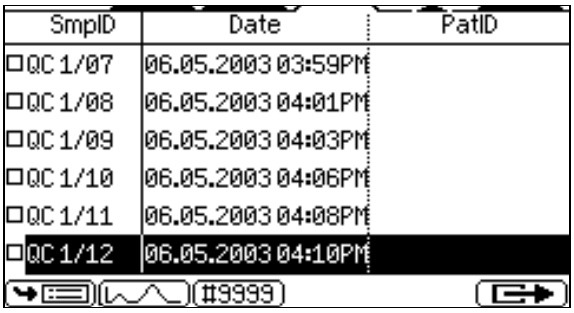
UTILITIES
QUALITY CONTROL (3)
QC MEASURE (2)
After selecting the target values (or targeted level), use the above menu to perform a QC analysis.
The result screen displays Quality Control as ID.

NOTE!

A result will only be accepted and saved if it is confirmed with the ✔ key.

7.3.1 QC Database

The database of measured and stored QC results can be displayed at any time in table or graphic (Levey-Jennings) formats. The QC measurement results will have sequential ID numbers.



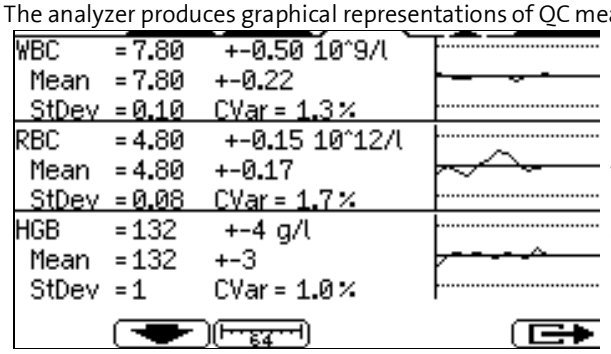
UTILITIES
QUALITY CONTROL (3)
VIEW TABLE OF QC
MEASURE (3)

Move the selection bar over entries with the ↑ and ↓ keys. Move among parameters with ← and → keys.

CAUTION!

Any change in the QC-material settings is followed by deletion of the QC database. It is strongly recommended to print the database before making modifications.

The analyzer produces graphical representations of QC measurements.



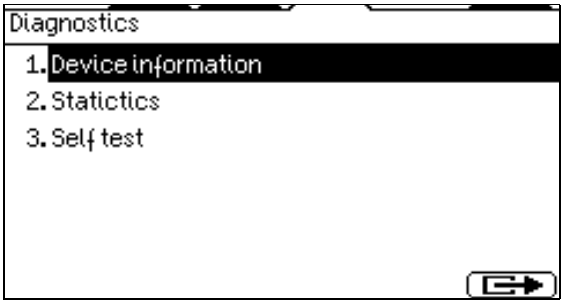
UTILITIES
QUALITY CONTROL (3)
VIEW QC DIAGRAM (4)

Means, standard deviations (StDev) and coefficients of variation (CVar) are calculated based on the QC analyses. The dotted lines delineate acceptable ranges on Levey-Jennings charts.

You can look at Quality Control information and results in table format as well. To access this format, select item 3, view table of QC measures.

7.4 Diagnostics

The DIAGNOSTICS submenu provides important information about the analyzer, statistics and built-in self-test.



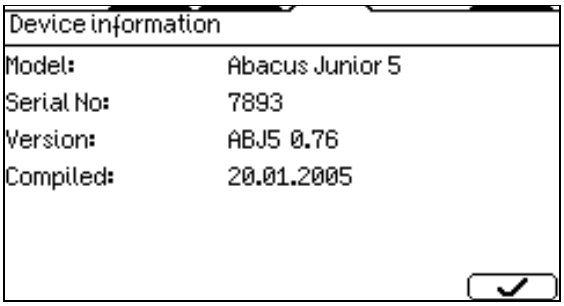
UTILITIES
DIAGNOSTICS (4)

This is the diagnostics menu.
Select the desired item.

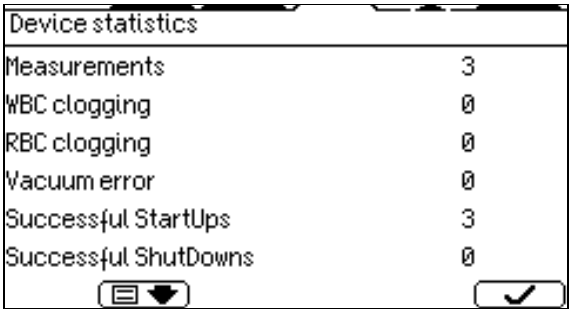
HUMACOUNT5
2518
HC5 1.08

UTILITIES
DIAGNOSTICS (4)
DEVICE INFORMATION (1)

Here, device-specific information can be retrieved. Model name, serial number, software version and the date of the compilation of the software are available.


Device information
Model: Abacus Junior 5
Serial No: 7893
Version: ABJ5 0.76
Compiled: 20.01.2005

7.4.1 Device Statistics



UTILITIES
DIAGNOSTICS (4)
STATISTICS (2)

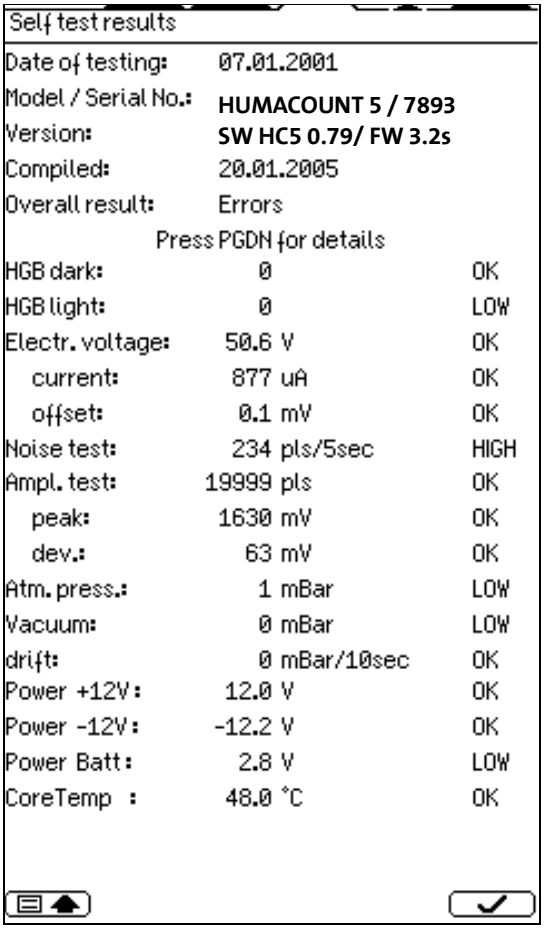
This menu includes important information about analyses previously performed, the total number of analyses and any clogging or errors that have occurred.

7.4.2 Self Test

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

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

The automatic Self test procedure can be initiated from the DIAGNOSTICS menu. During the test progress is displayed. The components that have passed the test are marked “OK”.

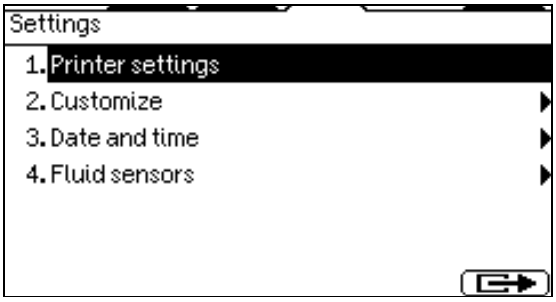


The first panel of the result screen includes the date of testing and device information, and on overall classification of test results.

The second and third panels of the result screen include every test result. At the end of the result line, OK, HIGH, LOW, or ERROR is displayed, which means that the current test result is within the normal range (OK), higher (HIGH) or lower (LOW) than the pre-determined limits, or the result is an error (ERROR).

7.5 Settings

You can access this menu by selecting item four (4) under UTILITIES.



The SETTINGS sub-menu allows the user to set the fluid detector operation, printing parameters, dates, user modes and various data.

7.5.1 Printer Settings

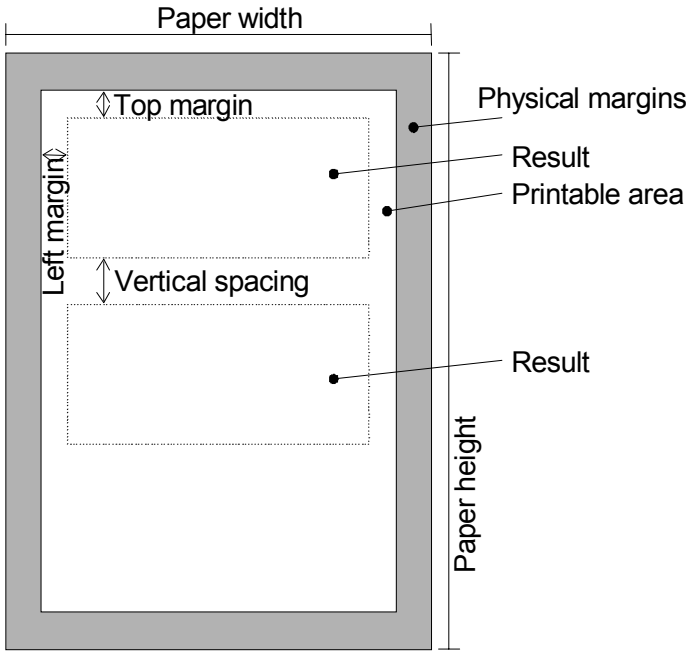
Make sure to select the appropriate printer mode for correct operation before printing.
The instrument supports the following printer modes and languages:

Selected mode	**Printer language**	**Supported printers**
"Built in Seiko"	Special language	Built-in thermal printer
"Canon BJC" "Canon BJC in 9-pin mode"	Canon BJC	Canon BJ and BJC series, e.g. BJC 100
"Epson 9-pin"	ESC/P	EPSON 9-pin dot matrix series, e.g. FX-980
"Epson 24-pin" "Epson 24-pin in 9-pin mode"	ESC/P2	EPSON 24-pin dot matrix series, e.g. LQ-580
"Epson Stylus Raster"	Epson ESC/P Raster	EPSON Stylus series, e.g. C20, C40SX, C60, C62, C80
"HP DeskJet"	PCL4	HP DeskJet series, e.g. DJ 920c, 940c, 960c
"HP LaserJet"	PCL4	HP LaserJet series and compatibles, e.g. LJ1100
"Seiko DPU414"	Special printer language	Seiko DPU414 printer
“Canon i70”	Canon BJC*	Canon i70 series
“EPSON C64”	EPSON Raster*	EPSON C64
“EPSON C84”	EPSON Raster**	EPSON C84

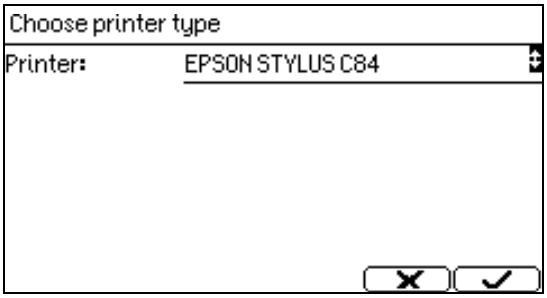
Table 7. List of selectable printers

Any printer compatible with the above listed modes (printer languages) can be connected to the instrument.
To set up the instrument for your printer, go to the **“Utilities/Printer/Printer Settings”** menu. Select from the options using the up and down arrow keys within the text fields, and fill in the numerical fields using the number keys.

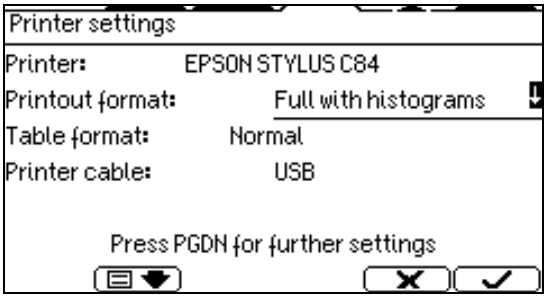
The general characteristics of the printable area of printer paper are below:
The paper is defined by its size:



It can be a standard size (A4, Letter) or any custom-sized paper (specify the actual size).
Printers cannot print on the whole surface of the paper. The blank area is described by the physical Margins, which may vary by printer model. The paper area inside the physical margins is called the printable area.
Top margin and Left margin settings are used for determining the location of printed results on the page.
If more than one result is to be printed per sheet, use the Vertical spacing to specify the distance between reports.



On the first page of the Printer Settings sub-menu, printer type can be selected. Here you can choose between the (optional) Seiko built-in printer, or any compatible external printer.
Initially, only the printer driver can be selected, and when accepted, driver and printout format details become available.



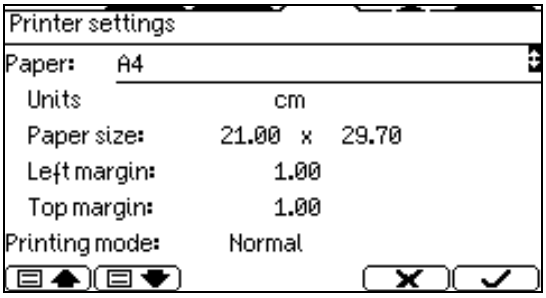
Select the Printer matching your printer hardware. Pressing the accept key ( ) will bring up printout details dialogs.

Printout format can be specified as one of the following (availability depends on the printer driver's allowable paper size):

- Full with histograms
- Narrow text only
- Wide text only
- Narrow full
- Full with histograms, ½ page

Table format defines what a table printout will look like. You can select normal or narrow view. A normal table is as wide as the paper, narrow format has grouped parameters. ???

Printer cable defines which communication mode is to be used between instrument and printer. Available options are USB and LPT. LPT refers to regular Centronics (parallel) printer cable. Not all drivers support USB communication.



Pressing PgDn brings up printout format definitions.

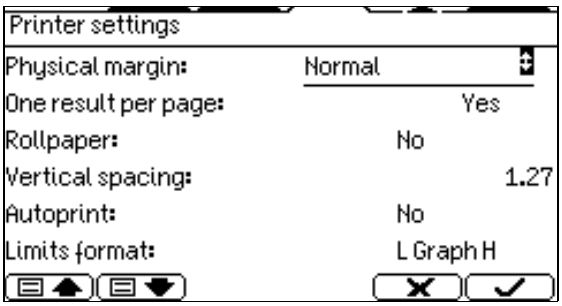
Paper size can be selected from the list below:

(name)	(size)		
A4	21	x	29.7 (cm)
Legal	8	x	14 (in)
Letter	8	x	11 (in)
Executive	18.42	x	26.67 (cm)
Rollpaper	..	x	NA
Custom	user	x	user

Paper sizes and margin positions can be defined freely (custom size).

Printing Mode changes printout sizes. Choose the one matching your needs. The available modes depend on the selected printer type. Possible options are:

Mini, Small, Normal, Enhanced and **Large** for vertical printout resolution
Wide and **Narrow** for horizontal resolution
Fast mode is optional, it usually indicates ink-saving printout.
Recommended mode is **Normal**.



The third page of printer settings contains further options to adjust printouts.

Physical margin defines how the margin should be handled.

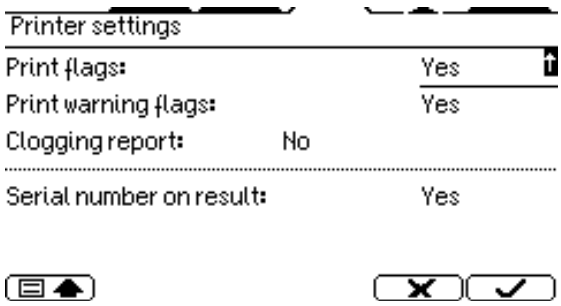
One result per page– if enabled– starts each printout on a separate sheet, if disabled then it will print as many records on a page as possible (small printout size combined with disabled "One result per page" may give e.g. 3 small reports on one sheet.)

Rollpaper ON will disable starting a new page at end of each record.

Vertical spacing will determine how much space should be left between two reports printed on the same sheet (One result per page must be OFF for this option to take effect)

Limits format defines what the ranges should look like on the printout.

You can have range (limit) printing disabled, displayed with numbers or as graphical symbols.



The third page of printer settings contains further options to adjust printouts.

If **Print flags** is set to Yes, any measured value out of the reference range or error that occurs during analysis will be shown on the printout.

If **Print warning flags** is enabled, any flags appearing on the result screen will be included on the printout.

Clogging report prints diagnostic numbers on how a measurement with a possible clog was handled. It should be enabled when instrument starts giving repeated clogging errors.

IMPORTANT! When changing printer types the following items should always be set:

1. For built-in printer:
   - Left-top margins both to 0.00
   - Rollpaper: Yes
   - Autoprint: No
   - Printout format: Narrow full (with histograms) or Narrow text only (without histograms)
   - Table format: Normal
   - One result per page: No

2. For other printer types:
   - Left-top margins both to 1.00
   - Rollpaper: No (especially for LaserJets)
   - Printout format: Full with histogram or Wide text only

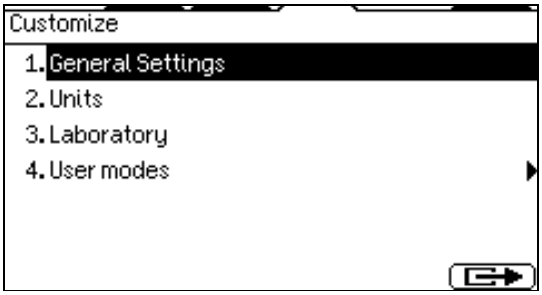
One result per page: Use “No” to save paper

7.5.1.1 Troubleshooting guide for printing problems

Problem	**Possible reasons/remedies**
Printer does not respond, no printout.	- Printer is off. Turn it on. - Printer is not connected to the analyzer. Connect it to the parallel or USB port of the analyzer. - Printer is not on line. Switch it to on-line mode. - Printer is out of paper. Load paper.
Strange symbols or letters appear on the printout.	- The selected printer type does not match your printer. Select a different driver in **Printer settings**. - Printer is not set up properly for HP or Epson (or compatible) mode. Modify the printer setup. Consult the printer’s manual.
Right side of the printed report is missing or appears on the next line.	- Decrease **Margin** settings in Printer Settings. - Try changing **Mode** to a smaller printout.
The printed report is too small with excess space on the paper.	- Try selecting Mode to a larger printout.
The end of the printout appears on the next page	- Enter the correct **Paper** size. - Try increasing **Margin**.
One more patient report could fit on the same page.	- Enter the correct **Paper** size. - Decrease **Margin, Top margin, Vertical spacing**.
The printed result is not centred	- Modify **Left margin**.

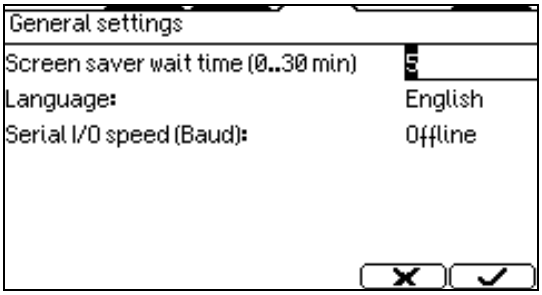
horizontally.	
The printed result is not centred vertically.	- Modify **Top margin**.
The distance between two results is too small or too big.	- Modify **Vertical spacing**.
After printing, the printer does not eject the paper.	Common in bubble-jet or laser printers. - Do not repeat printing. - When the page is full, or you leave the menu, the printer will eject the paper automatically.

7.5.2 Customise



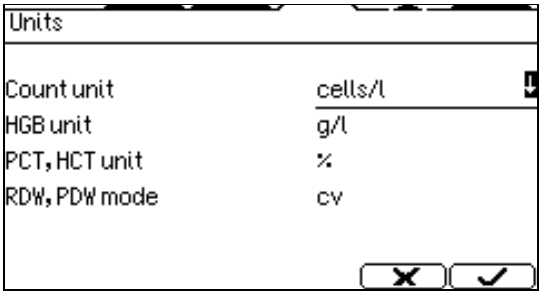
SETTINGS (5)
CUSTOMISE (2)
This is a collection of settings influencing instrument operation and customisation.

7.5.2.1 General settings



SETTINGS (5)
CUSTOMISE (2)
GENERAL SETTINGS (1)
This is a collection of settings influencing instrument operation and customisation.

7.5.2.2 Units



SETTINGS (5)
CUSTOMISE (2)
UNITS (2)
Units can be set in a sequential order. The arrow on the right indicates that there are more options for the entry. Select among options using the ↑ and ↓ keys. When done, press OK to open the next parameter. When the last entry is set, pressing ✔ confirms the data and returns the display to the Settings menu.

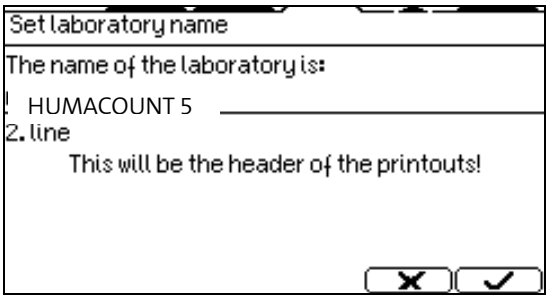
The possible units for above parameters are as follows:

Count unit	cells/litre (cells/l), cells/µl (cells/µl)
HGB unit	grams/litre (g/l), grams/decilitre (g/dl), millimol/litre (mmol/l)
PCT, HCT unit	percentage (%), absolute (abs)
RDW, PDW mode	standard deviation (sd), coefficient of variation (cv)

Table 8. Selectable units of parameters

7.5.2.3 Laboratory

This menu allows laboratory information to be entered.
This information will be printed in the header of reports printed by the instrument.



SETTINGS (4)
CUSTOMISE (2)
LABORATORY (5)

A maximum of 40 characters can be entered in each line. The user can enter this data by either using an external standard PC keyboard (US-layout) connected to the instrument, by scrolling to each letter using the ↑ and ↓ keys, or by using the keypad to enter text similar to the keypad of a mobile phone. Move among characters using the ← and → keys.

7.5.2.4 User Modes

This menu is accessed by selecting item six (6) of the Settings menu, where the Multiuser Mode of the HUMACOUNT 5can be enabled.

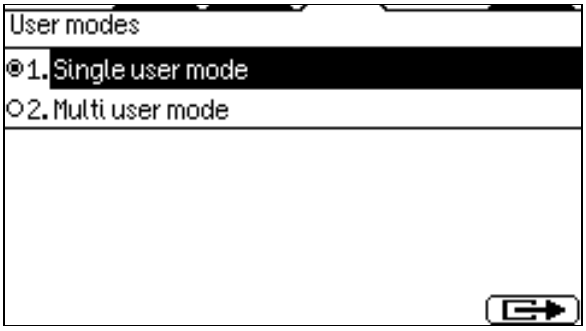
CAUTION:
Multi-user mode has both advantages and disadvantages. As it is a security option, maximum care should be taken when using it. It is based on operator ID's and passwords. If any operator should forget the password corresponding to the ID, a user with supervisor rights would be required for changing or re-enabling the user's password for the instrument.
There MUST always be a user with supervisor rights!
Should the user with supervisor rights forget the password for his/her ID, only an authorised HUMAN service technician can re-enable supervisor access and change the password.

The multi-user mode allows identification of operators through their personal settings, or profiles. It also restricts users to certain software functions.

With the **HUMACOUNT 5**, the term 'multi-user' means storing profiles for different users, but does not mean allowing more than one user to be logged in simultaneously.

- An operator at Basic level can perform analyses and enter patient data prior to the measurement process.
- Advanced users, in addition to Basic level functions, can modify instrument software settings, perform calibration and quality controls, and modify patient data when browsing the database.
- A Supervisor has the ability to do all of the above, and to modify user access or passwords.

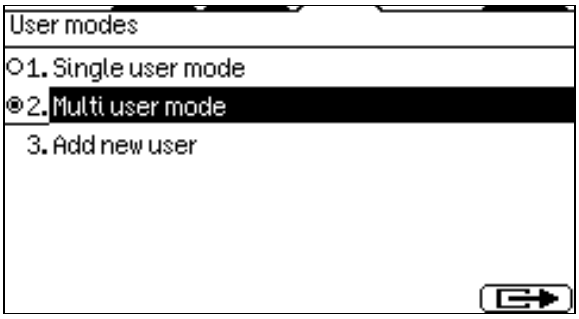
With multi-user mode enabled, users with different access levels will have different abilities within the menu system.
Some items will not be accessible for them.

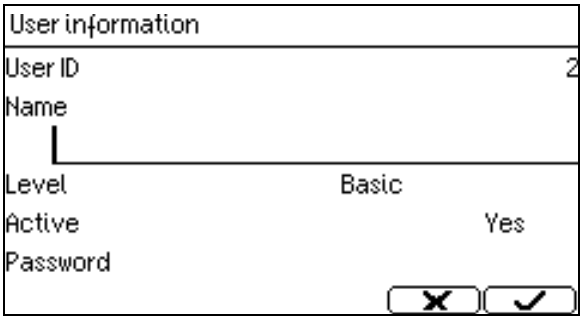


USER MODES (6)

This menu allows configuration of the instrument for single-user or multi-user mode.
Care must be taken when changing to multi-user mode to designate a supervisor on initial entry.

USER MODES (6)
MULTI USER MODE (2)
By selecting item 2, the instrument enters multi-user mode, and a new item appears on the screen:
Add new user.


User modes
1. Single user mode
2. Multi user mode
3. Add new user



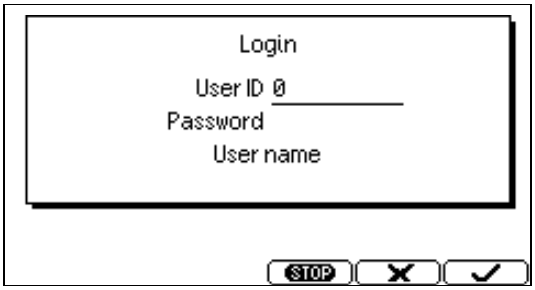
USERS MODES (6)

ADD NEW USER (3)

The software assigns an individual **ID** to each new user.

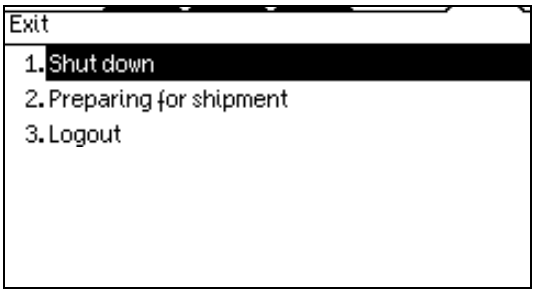
In the **name** field, a user name of 32 characters can be specified. You can use either the keypad, or the external PC-keyboard.
When the name is entered, the **level** should be defined as Supervisor, Advanced or Basic.
The default setting for **Active** is Yes. Change this option if you want to disable a user.
The last data to enter is the **password**, a maximum of 8 alphanumeric characters.

7.5.2.4.1 Multi-user mode



If the analyzer is in multi-user mode, a login screen will be displayed during start-up, asking for a user ID and a password.

After the User ID is entered and confirmed with the OK key, the user name corresponding to the ID appears in the bottom line. If the user name was correct, enter the password, and confirm with the function key. If the password was correct, the analyzer continues initialisation and is ready to work.

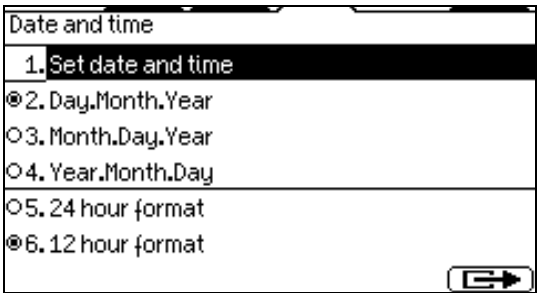


In multi-user mode the shut down menu is changed; the logout menu point appears.
SHUT DOWN (1)

A logged in user who has finished working with the instrument should select SHUT DOWN (1).
When logout is used instead of shutdown, the log-in screen will be displayed for the next user and the pneumatics will not be shut down.

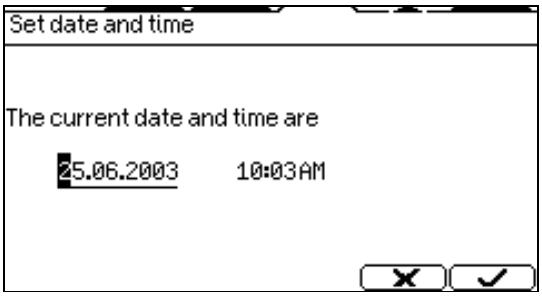
7.5.3 Date and Time

The 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 (5)
DATE AND TIME (2)

By selecting item 1, the date and time setting mode (next screen) is accessed. Items 2...4 and 5...6 are radio buttons; only one can be selected.

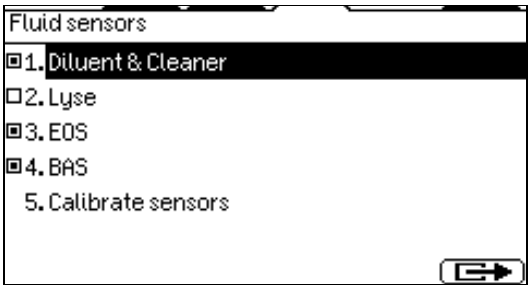


SETTINGS (5)
DATE AND TIME (2)
SET DATE AND TIME (1)

Enter the date and time using the numeric keys. Date format can be set in the previous menu. Confirm them by pressing the ✔ button.

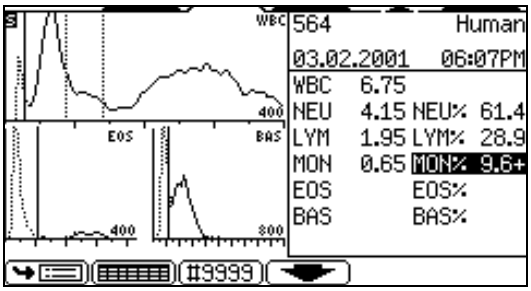
7.5.4 Fluid Sensors

Fluid sensors check for the presence of diluent, cleaner and lysing reagents.
In the event of a malfunctioning sensor, instrument operation can continue by disabling the defective component in this sub-menu.



SETTINGS (5)
FLUID SENSORS (4)

Using the OK key can toggle the state of each sensor. In the figure, the lyse sensor is disabled.
Item 3 sets the fluid sensors automatically.



When any of the fluid sensors is switched off, an S appears in the upper left corner of the display during analysis.

7.6 Software Update

Instrument software can be updated easily following the steps below:

1. Shut down the instrument and switch off the power.
2. Insert the upgrade floppy disk in the floppy drive.
3. Switch on the instrument and follow the on-screen instructions.
4. When instructed, remove the disk from the drive.

At the next start-up, the instrument will run the new software version.

8 PRINTING

This chapter covers information on making reports on measured samples.

8.1 Printouts

When required, the following items can be sent to an external printer or to the (optional) built-in printer by pressing the  function key button.

- 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

the format of a typical patient results printout is shown in Figure 16. (the appropriate printout format can be selected in UTILITIES/SETTINGS/PRINTER SETTINGS).

Full printout format with histograms:

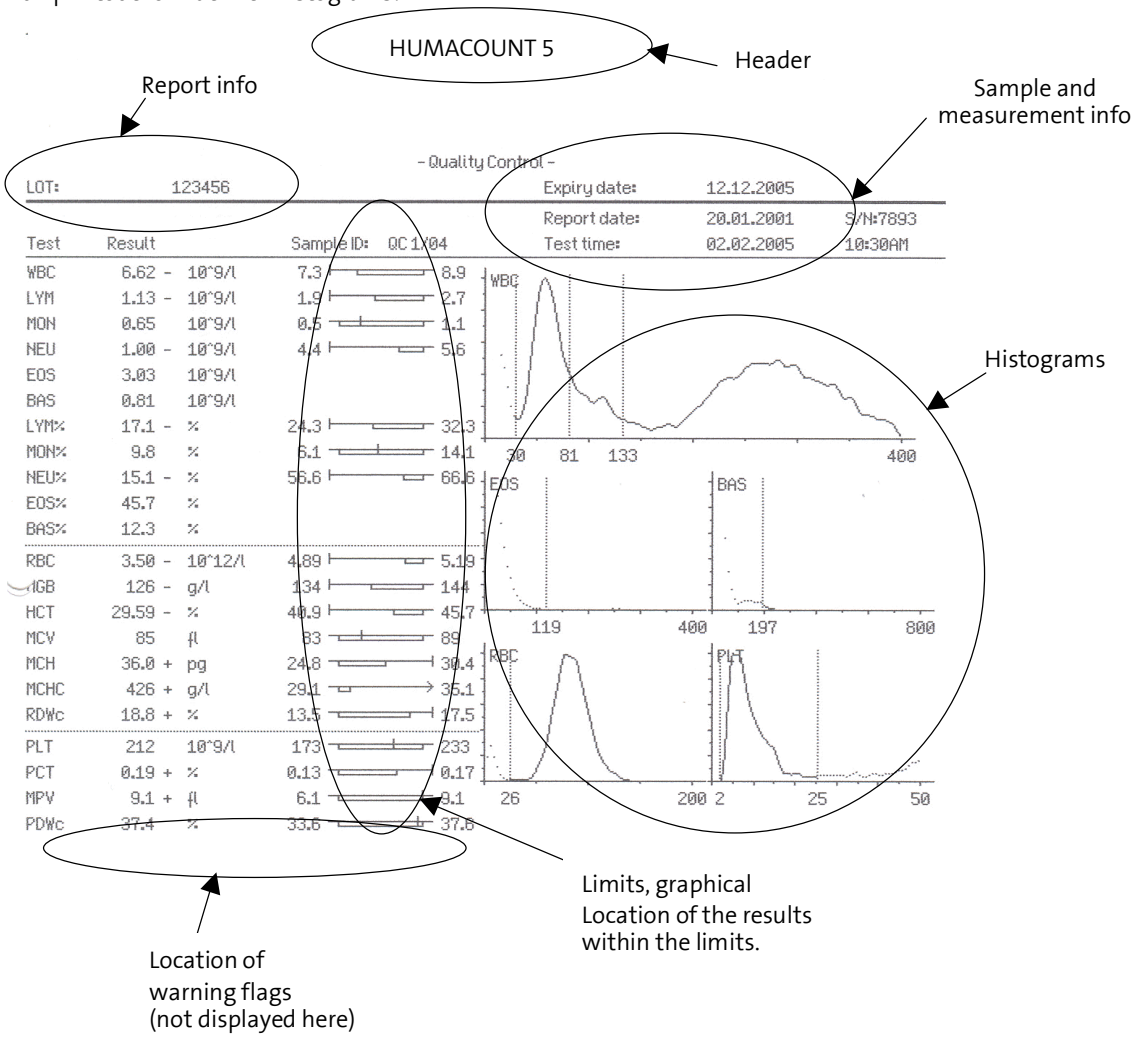


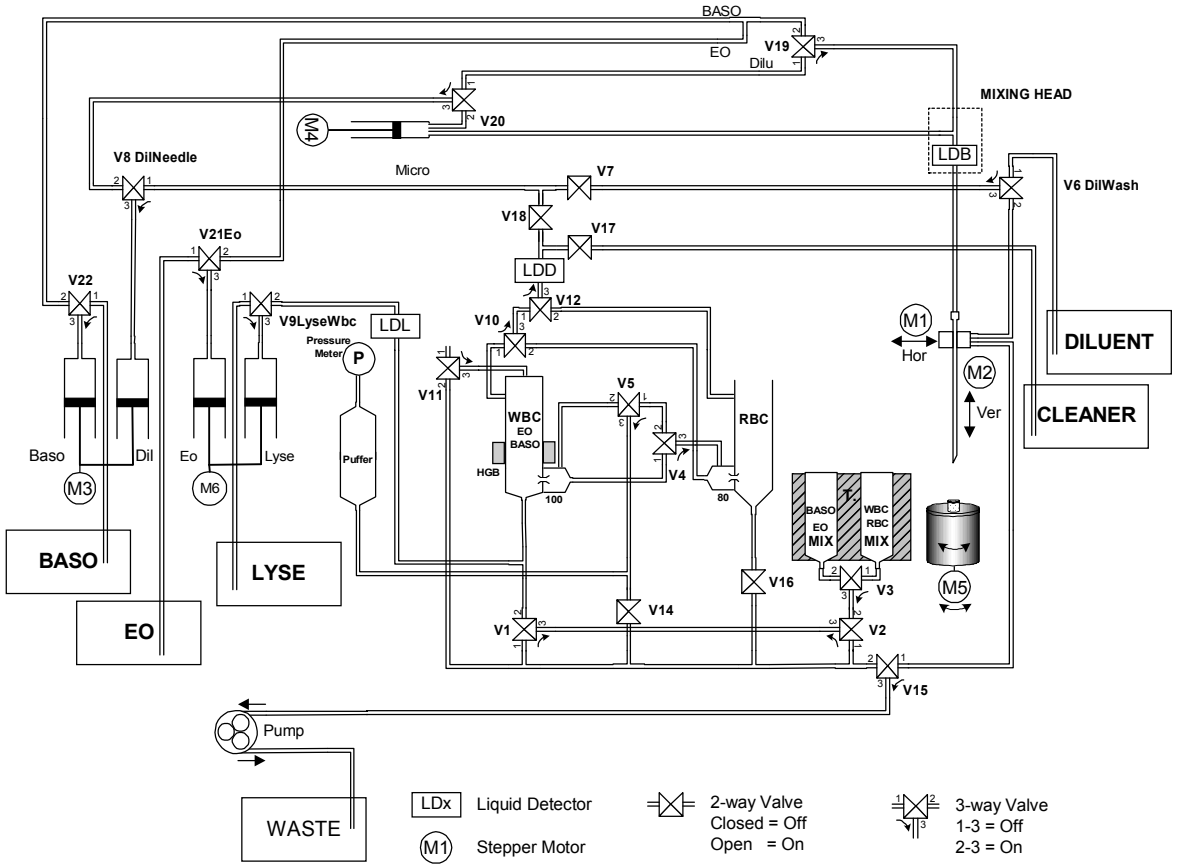
Figure 16. Built-in printer printout

On the left side of the printout the reference ranges (limits) are in normal mode (indicated by numbers) while on the right side of the printout the reference ranges (limits) are in graphical mode, flags and warning flags are not enabled. The printing modes of these parameters can be selected in the PRINTER SETTINGS submenu.
In graphical mode the normal range of each parameter is indicated with a rectangle. The left side of the rectangle shows the lower level and the right side shows the upper level. The value in the normal range is indicated with a marker.
If normal ranges are set, flags are enabled, and patient values are over or under the limits specified, the result out of the range is marked with an +/- mark near the value and the rectangle is compressed because of lack of space and the high/low value is indicated outside of the rectangle on the right/left side.

IMPORTANT!

- **The lifetime of the built-in printer printout (thermal rollpaper) is 1 year**
- **Do not expose the printout to heat**
- **Copy the printout to normal paper**

9 Fluidic Schematics



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