

A38-1 Abacus 380

Hematology Analyzer

User's Manual

Rev 1.20



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This user manual is intended to give detailed information for end users of the Diatron 'Abacus 380' hematology analyzer.

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1. INTRODUCTION

1.1. Intended Use

This hematology analyzer is a fully automated cell counter designed for *in vitro* diagnostic use, developed for small clinics, and point-of-care lab offices.

1.2. The Instrument

Abacus 380 is a fully automated, bench-top hematology cell counter.

This device implements the so-called Coulter-method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells.

The analyzer features a color graphical LCD display module with touch screen, and has a separate START button.

The software allows sending results to an external printer (via USB port), or can have an optional, 58 mm built-in thermal printer module.

The internal memory is capable to store 10 000 records with histograms, and individual patient data. QC measurements are stored in a separate database. The software which is operating the instrument is easy to upgrade using a USB pen-drive. The instrument allows connecting to a host computer for uploading records stored in the memory through a USB B (slave) port. Archiving and restoring of records to and from USB pen-drive is also possible.

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

1.2.1. Patient Testing

The analyzer can perform 80 samples per hour in 3-part WBC differential mode. Samples can have individual sample data, and additional parameters.

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

The analyzer determines the following 20 hematology parameters, including 3-part WBC differential, from a 25 µl whole blood sample:

WBC	total white blood cell count
LYM	lymphocytes count
MID*	medium size cells count
GRA	granulocytes count
LYM%	lymphocytes percentage
MID%*	medium size cells percentage
GRA%	granulocytes percentage
HGB	hemoglobin
RBC	red blood cell count
HCT	hematocrit
MCV	mean corpuscular volume
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
RDWcv**	red cell distribution width
PLT	platelet count
P_LCC***	macro platelet count
P_LCR***	macro platelet percentage
PCT	platelet percentage
MPV	mean platelet volume
PDWcv**	platelet distribution width

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

**Medium size cell population includes monocytes and a part of eosinophil's.

***P-LCC and P-LCR are research parameters.

1.2.2.Reagents

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

Diatro•Dil-DIFF	Isotonic saline solution, used to dilute whole blood samples and to rinse the fluidic system between measuring procedures.
Diatro•Lyse-DIFF	Creates hemolysate for 3-part WBC differential and for total WBC and HGB.
Diatro•Cleaner	For cleaning process of the fluidics.

1.2.3.Technical Operation

As the cell counter is a fully automated instrument, operating it requires minimal training or technical support. Operator interaction reduced to the following:

- Perform a *Blank Measurement* in case the instrument is not used for a specific time
- Enter sample and/or patient data
- Insert the sample to be analyzed into the sample holder
- Print results either one-by-one, or in groups by selecting records from the database
- Perform simple weekly maintenance, as described later in this manual (7.1.2.).

1.2.4.Calibration

Abacus 380 arrives to your laboratory factory-calibrated and ready to use. However, calibration needs updating whenever you find that the results have slightly changed, or a different or new control material is used. With each control material you receive for the instrument, you will find a control sheet listing the parameters the instrument should match. Perform these calibrations as explained in a later chapter (7.2).

1.3. Instrument features

Figures 1 and 2 show front and rear view of the analyzer, with controls and connectors.

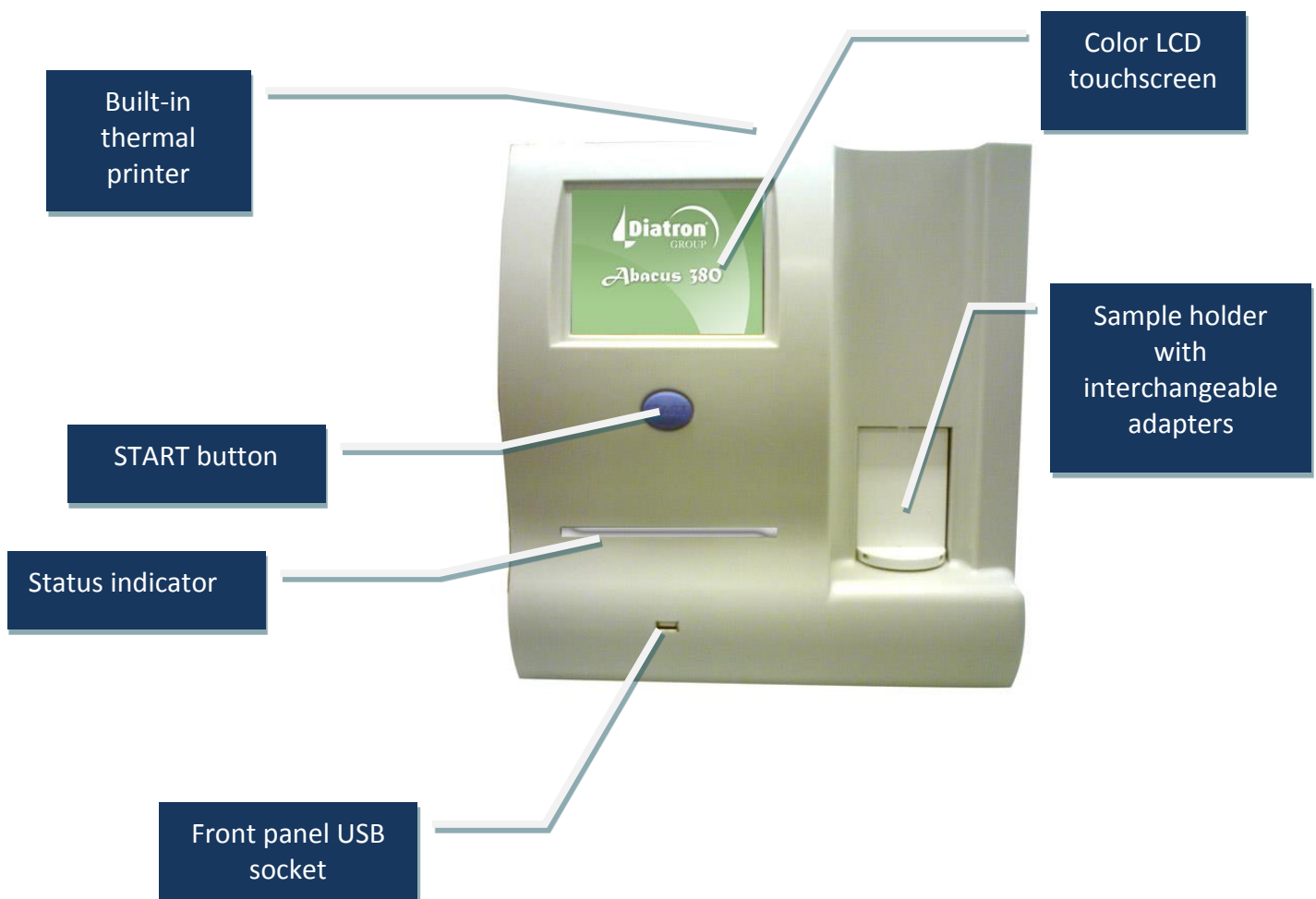


Figure 1. Front view

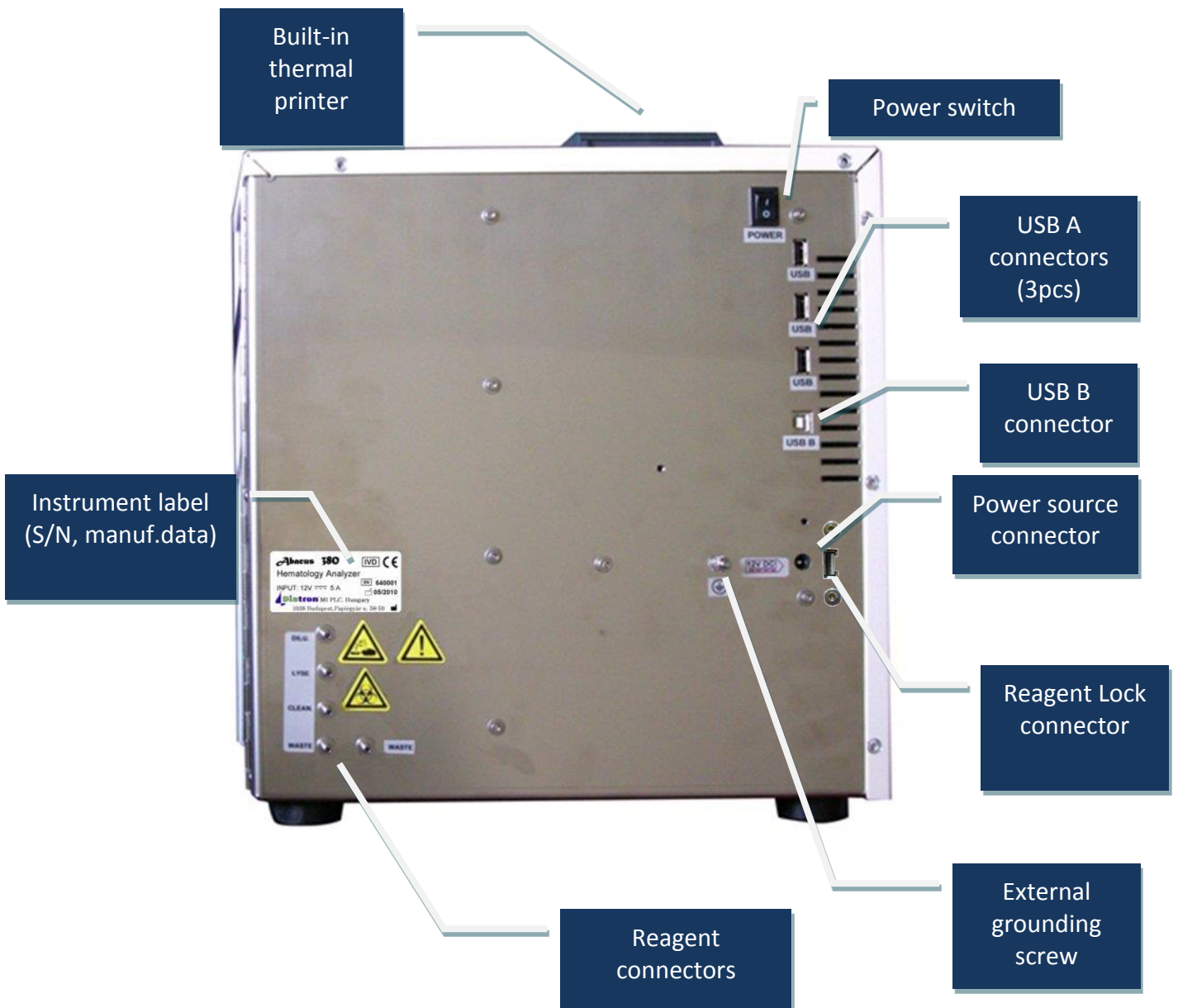


Figure 2. Rear view

To replace paper in the printer:

- open the paper lid (pull the lid upwards by the handle)
- remove central plastic roller of old paper roll
- unwind new paper roll, so that the “starting edge” is coming from down under towards you



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



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



The analyzer works with an external power supply. The power supply module has a so-called auto range input, allowing operation on 230V or 115V power system. The power supply unit complies **CE** and **UL** safety certifications.

The input socket is a standard power cable connection and the output is a DC jack.

CAUTION!**Use only the provided power supply with the instrument:**

Model type: “GlobeTek Electronics Corp.” Model ID: GT-81081-6012-T3

1.4. Parts of the Analyzer

The hematology analyzer is composed of three main units:

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

1.5. The measurement process

For the Schematics of the fluidics system, see Section 12.

Sample aspiration and dilution:

Stages of the blood testing process	
a.	25 µl of anti-coagulated (K3-EDTA) whole blood sample is aspirated into the sampling needle and mixed with 4 ml of diluent (Diatro•Dill-Diff) and stored in the WBC chamber (MIX dilution).
b.	25 µl of the MIX dilution is aspirated into the needle
c.	Lysing reagent (Diatro•Lyse-DIFF) is added to the mix dilution held in the chamber for WBC differential analysis. This amount of lysing reagent is patient type dependent and the operator can change it.
d.	Till, 4 ml of diluent is added to the second dilution in the RBC chamber (using the 25 µl of mix dilution stored in the needle).
e.	This portion analyzed for RBC count, PLT count and their parameters. Parallel the lysed dilution and HGB concentration in the WBC chamber is measured.
f.	Another washing process prepares the unit for the next analysis.

Table 1.

Dilution rates used:

MIX dilution	1:160
RBC dilution	1:32 000
WBC dilution	1:196
(depends on lyse amount default: 0,9ml)	

Measurement times:

WBC count	8 seconds
HGB measurement	3 seconds
RBC/PLT count	8 seconds

1.5.1. Control Panels**START button**

Pressing the START button triggers an analysis cycle.

Status indicator

A two-color (red/green) bar is located under the display. Its actual color indicates the status of the analyzer.

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

1.5.2. Touch screen display

The 320 x 240 dots, high contrast backlit high-color graphic LCD screen has a touch-sensitive foil on the front surface. If the operator touches the LCD active area gently, the analyzer can recognize it and identify the position where the screen was pressed. By touching (slightly pressing) one small spot on the touch screen, the SW will activate the function/menu/key that the corresponding area represents.

1.6. Control Material

The analyzer allows continuous monitoring of measurement performance with **Diacon 3** hematology control material (control blood). This must match the types of samples usually run on the instrument. Specification for this material (assay values and allowed tolerances along with expiry date) always packed with the approved control material.

1.7. Accessories

Below is a list of accessories shipped with your analyzer.
This list can also be referred as the “**Abacus 380 - pack**”

Abacus 380 Hematology Analyzer

User's Manual (this booklet)

Reagent Tubing kit (with colored tubes)

Diluent tube (green)

Lyse tube (yellow)

Cleaner tube (blue)

Waste tube (red)

Cleaning Tube Kit.

Caps for reagent containers (matching connector colors).

Waste Container (20 L).

External power supply and power cable.

Sample tube adapters.

Optional: spare thermal roll-paper.

Reagent Tubing Kit:



Cleaning Tube Kit:



1.8. Specifications

Measured parameters	20 (WBC, LYM, MID, GRA, LYM%, MID%, GRA%, RBC, HGB, MCH, MCV, HCT, RDW _{cv} , MCV, PLT, PDW _{cv} , MPV, PCT, PLC-R, PLC-C)
Sample volume	25 µl of whole blood in normal 3-part mode 50 µl of whole blood in pre-diluted mode
Chambers	2 counting chambers for diluting whole blood and counting
Reagent system	Isotonic Diluent, Lyse, Cleaner, barcode reagent ID system
Aperture diameter	70 µm (RBC/PLT), 100 µm (WBC/MIX)
Measurement method	WBC, RBC, PLT (blood cell count): impedance measurement HGB: photometry HCT: calculated (RBC x MCV) 3diff (LYM%, MID%, GRA%): impedance (population analysis) other parameters: computation from stored data
Dilution ratio	WBC, HGB: 1:160 / RBC, PLT: 1:32000
Throughput	80 tests/hour
Sampling method	open tube system with automatic sample rotor.
Specimen types supported	human
Recommended sample collection method	K3 EDTA primary blood sample tubes
Sample identification method	Individual sample ID entered by user. Barcode with external manual barcode reader (optional accessory)
Sample types	Human (general), male, female, baby, toddler and child.
Clog prevention	High-voltage pulse on aperture in each analysis cycle, chemical cleaning and high pressure back-flush of the aperture using Cleaner reagent.
Cleaning procedure	High-voltage burst of the aperture, high-pressure back-flush, chemical cleaning of the aperture using Cleaner reagent.
Calibration	1 or more measurement automatic and manual (factors) calibration of WBC, HGB, RBC, PLT, MCV (or HCT), RDW, and MPV.
User interface	Easy-to-use, menu driven user interface with touch-screen and separate START button, status bar.
Languages available	Korean, Chinese, Spanish, Vietnamese, Polish, German, French, Portuguese, Russian, Italian, Czech, Greek and English
Data storage capacity	10 000 results, including 3-part WBC, RBC and PLT histograms, including QC database (shared storage)
Computer interface	USB B port, Ethernet
Data back-up method	USB mass storage device
Software upgrade method	via USB A port using USB mass storage device (flash drive)
Printer interface	USB with support for most HP printers (DeskJet, LaserJet, PCL3, PS, LIDIL), EPSON Dot-matrix printers
Built-in printer	Axiom thermal printer module, 58 mm wide roll paper, full report with histograms
Display	320 x 240 – dots, high-contrast, backlit, color graphics LCD (liquid crystal display)
User interface	Full-LCD Touch-screen + separate START button, red/green state bar
External keyboard	USB keyboard via USB A port
Power requirement	12V _{DC} , 5A, 60W max. operating power
Power supply unit	External, auto-ranging power unit for 100-120 or 200-240 VAC, 50–60Hz
Operating temperature	59–86 °F (15–30 °C). Optimal temperature is 77 °F (25 °C)
Storage temperature	41-90 °F (5–35 °C)
Transport temperature	41-104 °F (5-40 °C)
Dimensions (W x D x H)	320 x 300 x 350 mm
Net weight	15 kg

Accuracy - The parameters listed below are directly measured or derived from directly measured parameters. Parameters not listed below are calculated from these parameters and therefore do not have independent criteria of their own.

Parameter	Criteria		Evaluation Levels					Units
	Absolute	Percent	CDP1	CDP2	CDP3	Range Low	Range High	
WBC	0.30	6.00%	2.00	4.20	10.50	0.00	75.00	10 ³ /μl
GRA%	3	10.00%	10	40	86	0	100	%
LYM%	3	10.00%	20	45	80	0	100	%
MID%	3	10.00%	2	17		0	40	%
RBC	0.15	6.00%	3.84	5.85		0.00	8.00	10 ⁶ /μl
HGB	0.3	6.00%	6.0	11.7	17.2	1.0	25.0	g/dl
MCV	1.0	6.00%	79.1	98.6		50.0	120.0	fL
RDWcv	1.0	6.00%	11.8	15.1		8.0	20.0	%
PLT	15	8.00%	50	134	429	0	1000	10 ³ /μl
MPV	1.0	10.00%	7.1	10.8		5.0	30.0	fL

Precision - Repeatability performance is defined as repeatability CV or SD, whichever is greater. Within-device precision is defined by CLSI EP5-A2 for long-term evaluation of device precision rather than short-term evaluation of repeatability.

Parameter	Repeatability		Reproducibility/Precision		Units
	SD	CV%	SD	CV%	
WBC	< 0.18	< 2.7 %	< 0.20	< 3.4%	10 ³ /μl
GRA%	< 3.50		< 3.50		%
LYM%	< 3.10		< 3.10		%
MID%	< 2.00		< 2.00		%
RBC	< 0.11	< 1.7 %	< 0.13	< 2.0%	10 ⁶ /μl
HGB	< 0.20	< 2.0 %	< 0.22	< 2.4%	g/dl
MCV	< 1.0	< 1.7 %	< 1.20	< 2.0%	fL
RDWcv	< 0.4	< 2.5%	< 0.45	< 3.0%	%
RDWsd	< 0.8	< 2.5%	< 0.90.	< 3.0%	fL
PLT	< 23	< 6.0 %	< 27	< 7.0%	10 ³ /μl
MPV	< 0.45	< 8.7 %	< 0.50	< 10.0%	fL
PDWcv	< 1.5	< 3.0%	< 2.0	< 4.0%	%
PDWsd	< 1.0	< 8.0%	< 1.25	< 10.0%	fL

Linearity – Linearity is characterized by linear regression against a known dilution sequence. Linear regression is also compared against 2nd and 3rd order regression.

Parameter	Determination (R2)	Nonlinearity absolute error	Nonlinearity relative error	Linearity Range Low	Linearity Range High	Units
WBC	> 0.95	< 0.80	< 3.0 %	0.0	75.0	10 ³ /μl
RBC	> 0.95	< 0.20	< 3.0 %	0.00	8.00	10 ⁶ /μl
HGB	> 0.95	< 0.27	< 3.0 %	0.0	25.0	g/dl
PLT	> 0.95	< 35	< 3.0 %	0	1000	10 ³ /μl

Carryover - Carryover is defined as high-to-low carryover.

Parameter	Carry over
WBC	< 1.00%
RBC	< 1.00%
HGB	< 1.00%
PLT	< 1.00%

2. INSTALLATION

2.1. General information

This chapter provides instructions for the installation of Abacus 380 hematology analyzer. The procedures described below must be followed correctly to ensure proper operation and service. Please carefully read and follow all instructions in this *User's Manual* before operating the analyzer.

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

CAUTION: Always handle the instrument with care.

2.2. Environmental factors

Operate Abacus 380 within the ambient temperature range of 15-30°C and relative humidity of 45% .. 85%. The optimum operating temperature is 25°C.

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

Reagents should be stored at a temperature range of 18-30°C.

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

Operation at an altitude over 3000 meters (9000 ft) is not recommended, because the throughput will be degraded.

Instrument is safe for transient voltages to *INSTALLATION CATEGORY II* and *POLLUTION DEGREE 2*.

Environmental and electrical characteristics provide accuracy and precision of the instrument and maintain a high level of operational safety for lab personnel.

2.2.1. Electrical requirements

Abacus 380 comes with an approved power cord, appropriate for your power system. Proper use of the appropriate power cord assures adequate grounding of the system.

WARNING: Improper grounding of the analyzer bypasses important safety features and may result in electrical hazard.

2.2.2.Space requirements

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

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

WARNING: Install the unit on a table or workbench. If the unit was installed without a supporting desktop under the unit, there is a possibility that the analyzer could accidentally fall.

2.2.3.Peripherals

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

- external printer
 - the printer must be recommended by authorized technician
 - the printer must have a CE mark
- external keyboard
 - the external keyboard must be approved
 - the external keyboard must have a USB port or suitable adapter
- link to host computer via USB port
 - serial link cable must be approved by technician
 - USB B port (linking to host computer) requires a USB A-B cable and USB driver software (contact service for availability)
- Optional: USB datamatrix barcode reader and PrinterBOX
 - Barcode reader for reading datamatrix barcodes, which are containing the control/calibrator ranges.

- PrinterBOX can be connected to instrument to help using any kind of printers of the market. For more information please contact sales@diatron.com

2.2.4.Reagents and waste handling

Handle reagents according to national or international regulations.



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

Waste generated by the unit is biohazard material. Handling and disposal must happen according to regulations regarding reagent systems. See Section 7.5.2



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

2.2.5.Maintenance

The user should check the following components weekly:

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

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

2.2.6.Cleaning

Clean the instrument and its power supply – in off state – on the outside only, using a damp cloth with a soft detergent. DO NOT force the needle holder mechanics and do not let liquids get inside other units.

2.2.7.General points

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

- services and repairs are performed by an authorized technician

- the electrical system of the laboratory follows national and/or international regulations
- the system is operated according to instructions contained herein

2.3. Unpacking and installation

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

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

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

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

3. Keyboard and external printer

Attach the keyboard cable to one of the USB A ports on the back of the instrument. Attach both ends of the printer cable to the appropriate ports on the printer and Abacus 380. Attach the AC adapter to the printer (if required) and plug it into an AC outlet.

4. Host Computer

The instrument has a built-in USB B port that allows connection to a host computer. You can export results, including histograms. USB B I/O settings are located in Settings menu.

For installation instructions for communication, please, contact Service.

5. Power supply

Connect the power supply to the instrument. Attach power cord outlet to the external power supply of Abacus 380 and plug the other end into a properly grounded AC outlet.

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

6. Reagent Containers

Place the reagent containers near the instrument, to an accessible location. Do not place the containers to a higher position than that of Abacus 380, because a tube might come off its connector, the fluids spill out. Even there would be an extra pressure, which might cause unreliable measurement result. Use the supplied connecting tubes and special bottle caps. Be sure that the color on each tube and cap match. The best, for example, is to place the reagent containers below the desk the analyzer 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.

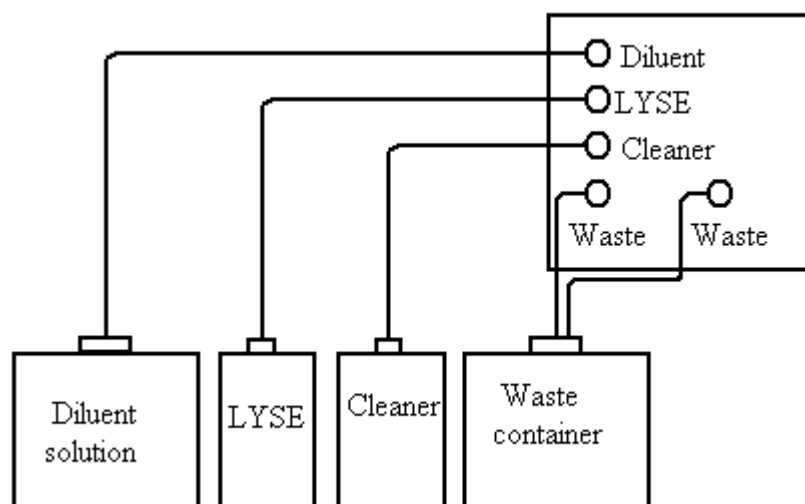


Figure 5. Reagent connections

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



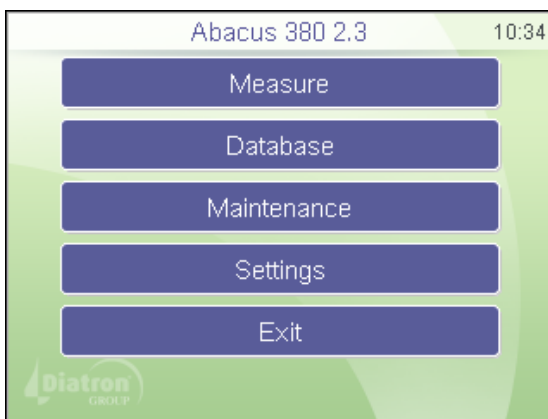
2.3.1. Turning the Instrument ON, Main Menu

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



After turning on power, there will not be LCD activity for a few seconds, but the status bar will start to lit RED.

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



When SW is loaded, Main menu is displayed.

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

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 priming cycle automatically if additional liquid in the tubing system is required.

Run a priming cycle in case of:

- installation
- extended time out of use
- replacement of any component related to the Fluidic System
- replacement of reagents with instrument turned on

2.3.2. Turning the Instrument OFF

DO NEVER turn off the analyzer by simply flipping the power switch on the rear panel. Doing so may result in erroneous operation during later use. It can be so, because the instrument uses diluent. This liquid is an isotonic saline solution containing salt. Would it not be washed out of special units of the instrument or would chambers not be filled with this solution may lead to dust condensation or salt build up.

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

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



EXIT
SHUTDOWN

Select **Shutdown**.

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

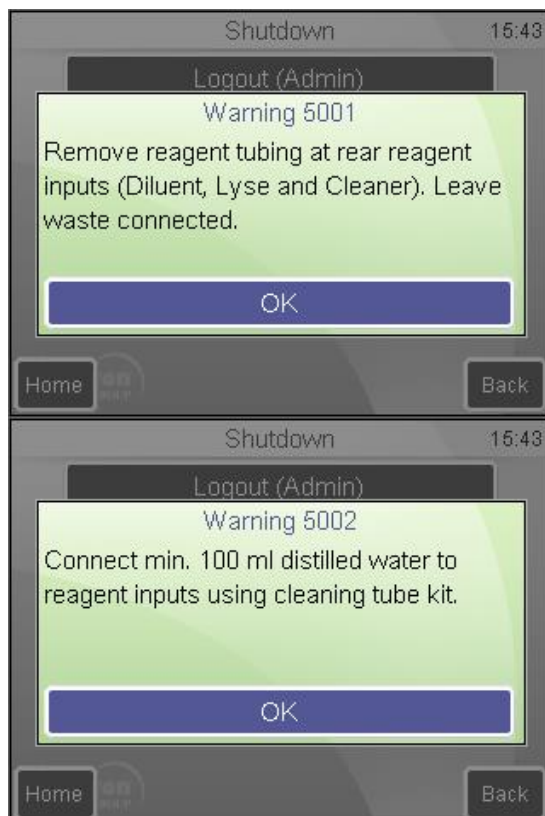
Turn off power using the rear power switch.

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

2.3.3.Preparing for shipment

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

Follow the instructions appearing on the display.



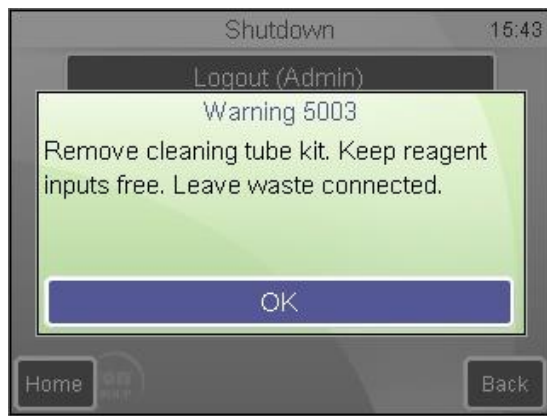
SHUTDOWN
Preparing for shipment (2)

Remove tubing connectors, so the system can drain itself.

Leave the waste connector attached.

Next, you should connect the cleaning tube kit to the reagent inputs, submerging the free end in a bottle containing at least 100 ml of distilled water.

Cleaning tube kit connected
The analyzer will flush any remaining reagents from the system into the waste container.









As a next step, the analyzer asks you to remove the cleaning tube kit. Leave Waste connected.

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

2.3.4. Handling in Emergency

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

2.3.5. Special symbols on the analyzer

Label	Meaning	Explanation
	Biohazard	Sample and waste are potentially infectious material
	Corrosive	Reagents may cause corrosion or skin irritation.
	Warning	General warning of injury.
	Sharp needle warning	Sampling needle may cause injury.
	IVD label	In Vitro Diagnostics – only for laboratory use
	Conformité Européenne	The marked product conforms with the product related standards and regulations.

3. MENU SYSTEM

3.1. General Information

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

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

3.1.1. Navigating in the Menu System

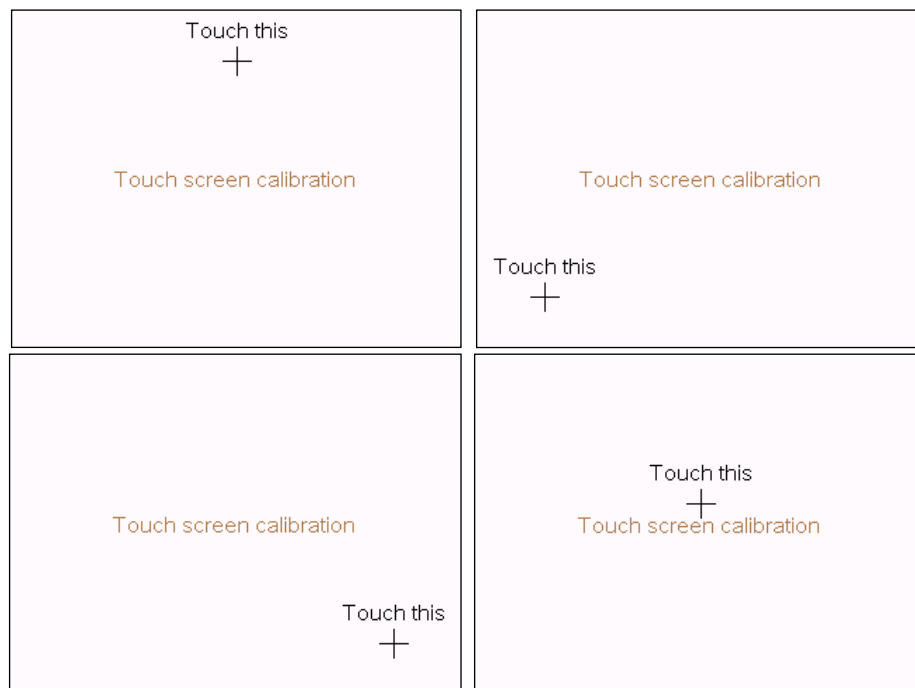
The instrument uses a menu system to initiate actions and to access settings.

Navigate in the menu system by simply touching the LCD at the item you want to open/activate. From any submenu, the Home button will go back to Main menu, while Back moves one step back in the menu tree.

3.1.2. Touch screen calibration

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

Tap and gently hold any location on the touch screen. (Make sure not to press it hard, otherwise you can damage the screen.) After cca 10 seconds, a calibrating screen appears. Tap the reference points one after another. If you made an error, you will hear an error beep, and the process restarts.

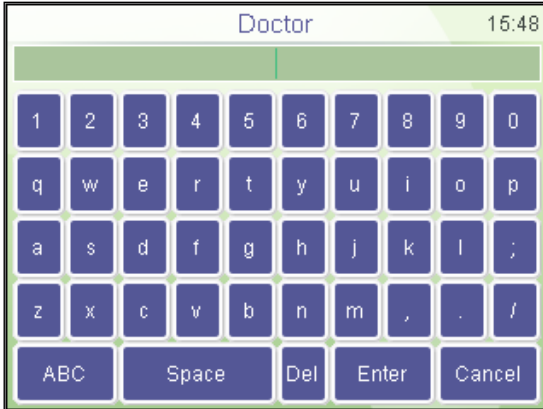


If the calibration was successful, you will return to the original screen.

3.1.3.Menu structure

Measure	New		
	Re-run		
	Blank		
	Print		
	Discard		
Database	Detail / Table view		
	Edit record		
	Print		
	Filter		
	Trends		
	Manage		
Maintenance	Cleaning	Cleaning	
		Hard cleaning	
		Drain chamber	
	Calibration	Factors	
		Measure	
		History	
		Pre-diluted	Factors
			History
	Quality control	QC1	References
		QC2	Measure
		QC3	Diagram
		QC4	Database
		QC5	
		QC6	
		Load datamatrix	
Diagnostics	Device information		
	Self-test		
Reagent status	Volumes		
Settings	Printer	Device	
		Format	
		Header	
	General settings		
	Measurement	Units	
		Normal ranges	
		Profile	
		Settings	Result / Calibration
	Date and time	Set Date / Time	
		Date Format	
	Exit	Logout	
Shut down			
Preparing for shipment		Add new user	
User Management		Remove User	
	Auto login set		
	Edit / View user		

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



4. OPERATING PRINCIPLES

4.1. Impedance Method

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

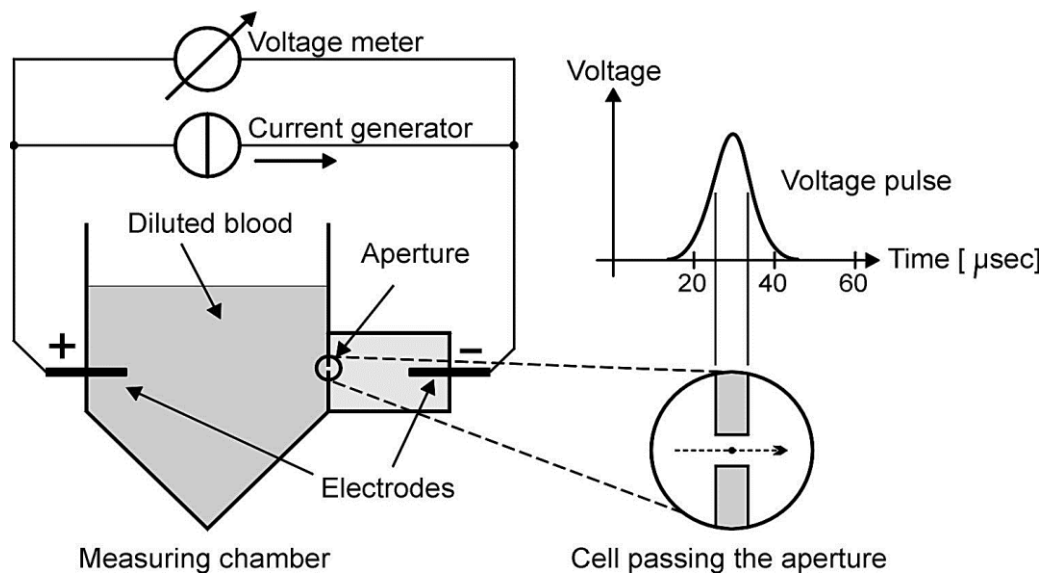


Figure 7. Impedance method

Each cell passing through the aperture – there is a constant DC current flowing between the external and internal electrodes – causes some change in the impedance of the conductive blood cell suspension.

These changes are recorded as increases in the voltage between the electrodes.

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

4.2. Principle of HGB Measurement

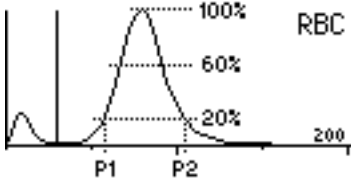
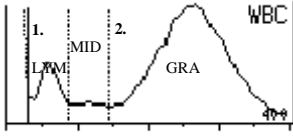
The lysed sample dilution can be measured by a photometric method. The reagent lyses the red blood cells, which release hemoglobin. The chemical process forms a stable form of methemoglobin. This measured by a photometer on the WBC chamber.

All **Diatron** branded reagents are cyanide free, and thus are environment-friendly. However, some reagents from other manufacturers may contain cyanide. In that case, cyanide and any other chemical composition formed using cyanide is environmentally dangerous. Contact the reagent manufacturer for safety measures.

The manufacturer is not liable for any damage caused by using cyanide based reagents with any of its analyzers.

4.3. Parameters

Abacus 380 measures and calculates 20 parameters. For each parameter, we list the name, abbreviation and measurement unit in the first column. Short description for each parameter is in the second column.

White Blood Cells – WBC (cells/l, cells/μl)	Number of leukocytes $WBC = WBC_{cal} \times \text{counted WBC (cells/l, cells/μl)}$
Red Blood Cells – RBC (cells/l, cells/μl)	Number of erythrocytes $RBC = RBC_{cal} \times \text{counted RBC (cells/l, cells/μl)}$
Hemoglobin concentration - HGB (g/dl, g/l, mmol/l)	Measured photometrically at 540 nm; in each cycle blank measurement is performed on diluent $HGB = HGB_{cal} \times (HGB_{measured} - HGB_{blank})$
Mean Corpuscular Volume - MCV (fl)	Average volume of individual erythrocytes derived from the RBC histogram.
Hematocrit – HCT (percentage, absolute)	Calculated from the RBC and MCV values. $HCT_{percentage} = RBC \times MCV \times 100$ $HCT_{absolute} = RBC \times MCV$
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  $xDW-SD = RDW_{cal} \times (P2 - P1) \text{ (fl)}$ $xDW-CV = RDW_{cal} \times 0.56 \times (P2 - P1) / (P2 + P1)$ by the factor of 0.56 CV is corrected to the 60% cut
Platelet – PLT (cells/l, cells/μl)	Number of thrombocytes (platelets) $PLT = PLT_{cal} \times \text{counted PLT (cells/l, cells/μl)}$
Macro platelet count – P-LCC	Number of platelets size larger than 12fl (cells/l, cells/ μl)
Macro platelets percentage – P-LCR	Percentage of platelets size larger than 12fl (%)
Mean Platelet Volume – MPV (fl)	Average volume of individual platelets derived from the PLT histogram
Thrombocrit – PCT (percentage, absolute)	Calculated from the PLT and MPV values $PCT_{percentage} = PLT \times MPV \times 100$ $PCT_{absolute} = PLT \times MPV$
White blood cell 3-part differential: LYM, LYM% : lymphocytes MID, MID% : medium size cells GRA, GRA% : granulocytes	Absolute values counted in the channels determined by the three WBC discriminators:  Percentages calculated from the absolute WBC value.

4.4. Absolute and Linearity Ranges of Parameters

The analyzer provides specified accuracy within its linearity range. Beyond this linearity range, the instrument can display results but accuracy is impaired.

If a value is over the maximum range of guaranteed linearity, the instrument cannot measure it and the result will be marked with an E (Error) flag.

To measure a sample, whose parameters exceed the maximum value indicated in the table below, pre-dilution is recommended. See section 5.2.7 of this manual.

Linearity ranges of primary parameters in normal measuring mode:

Parameter	Determination (R2)	Nonlinearity absolute error	Nonlinearity relative error	Linearity Range Low	Linearity Range High	Units
WBC	> 0.95	< 0.80	< 3.0 %	0.0	75.0	10 ³ /μl
RBC	> 0.95	< 0.20	< 3.0 %	0.00	8.00	10 ⁶ /μl
HGB	> 0.95	< 0.27	< 3.0 %	0.0	25.0	g/dl
PLT	> 0.95	< 35	< 3.0 %	0	1000	10 ³ /μl

Table 2. Linearity ranges of parameters

Linearity ranges for 1:5 pre-dilution mode:

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

Table 3. Linearity ranges of Pre-dilution mode

5. ROUTINE UTILIZATION and MEASUREMENT

5.1. Sample handling

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

Use of 'home made' containers pre-dosed with EDTA is not suggested, because if the container is not filled with enough blood, the ratio of EDTA to blood may reach a level, which results in osmotic transfer from the RBCs which shrinks them. **The ratio of EDTA to blood should not exceed 3 mg/ml.** Generally, we suggest using pre-manufactured sample tubes containing the necessary amount of EDTA. Also, when taking blood, please make sure that requirements attached to sample tubes are met.

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

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

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

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

To initiate analysis:

You have the possibility to use three different interchangeable adapters for different tube types. Tube types shown on the next pictures:

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

ROUTINE UTILIZATION & MEASUREMENT

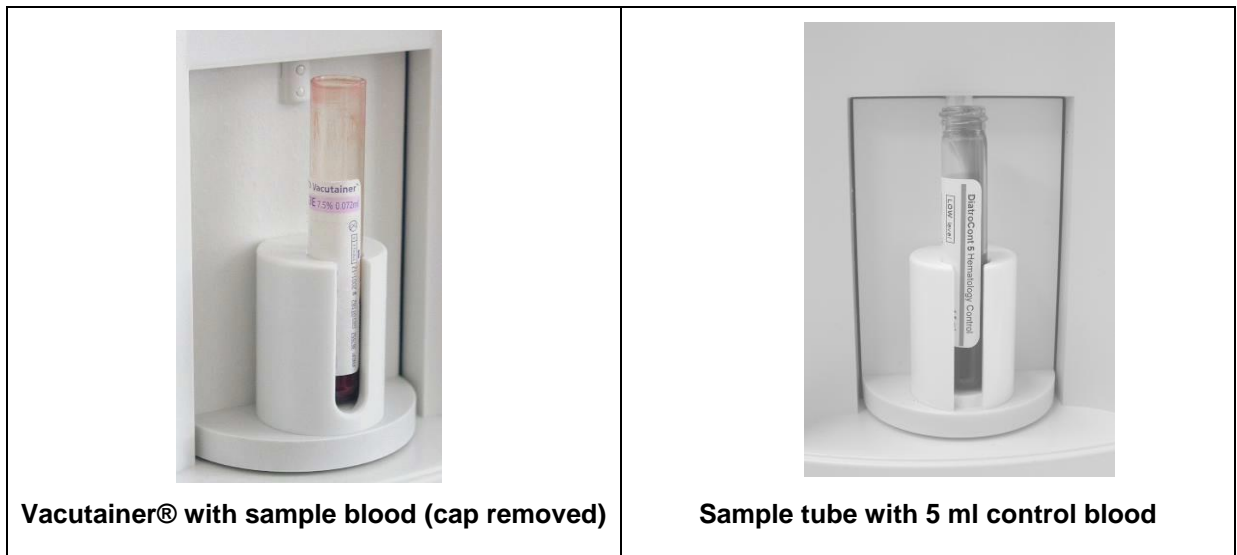


Figure 8. Tubes used in Vacutainer® adapter

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

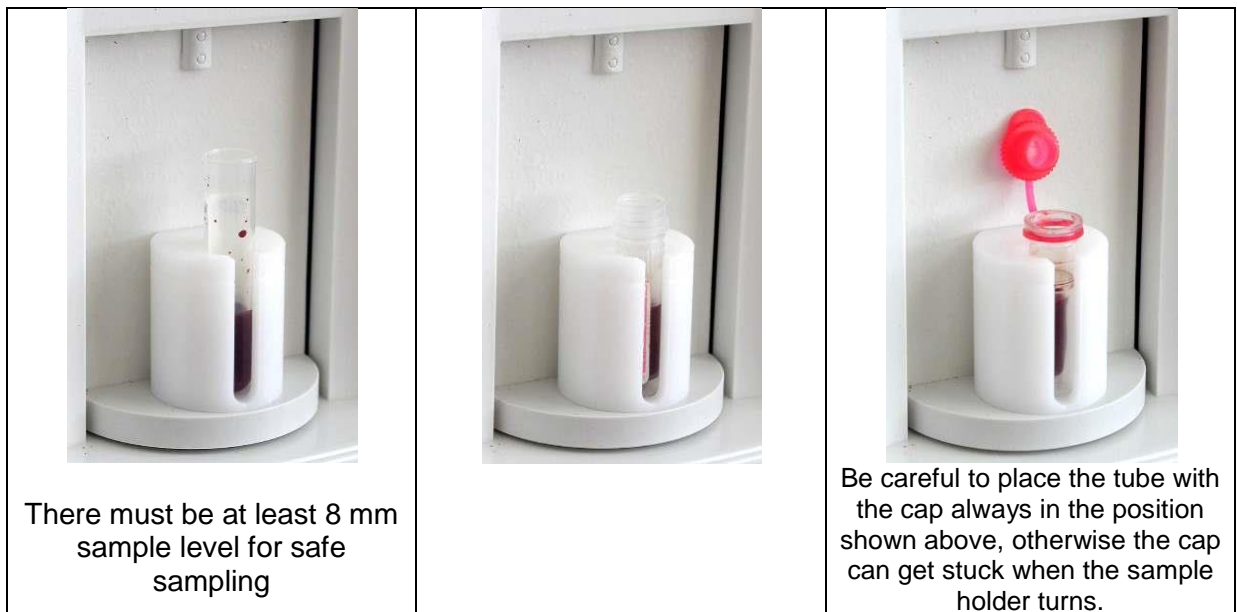


Figure 9. Tubes used in micro adapter

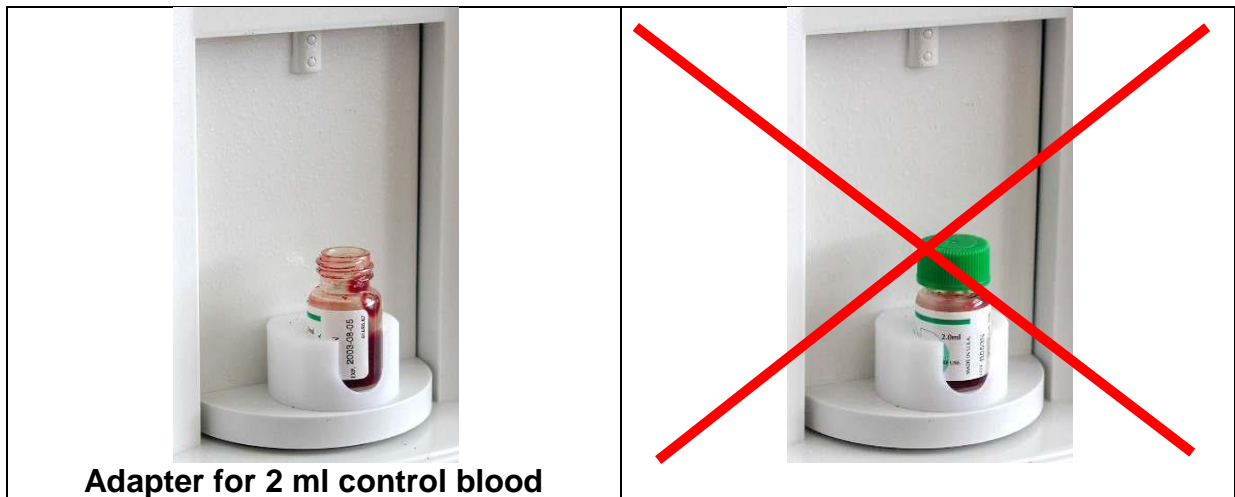


Figure 10. Vial used in control adapter

1. Remove the cap!! It is very important because the probe tip cannot pierce the cap!!!

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

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

5.2. Sample analysis

5.2.1. Sample preparation

Use K3-EDTA anti-coagulated fresh whole blood as sample. **Prior** to sampling, mix the sample gently by **inverting it at least 8 times**. **Do not shake** as this could damage blood cells and create micro-bubbles that cause sampling error.

5.2.2. Running a (new) sample

Measure				10:49
SID				New
Human				Re-run
WBC	0.00 10 ⁹ /l	RBC	0.00 10 ¹² /l	Blank
LYM	0.00 10 ⁹ /l	HGB	0 g/l	Print
MID	0.00 10 ⁹ /l	HCT	0.00 %	Discard
GRA	0.00 10 ⁹ /l	MCV	0 fl	Exit
LYM%	0.0 %	MCH	0.0 pg	
MID%	0.0 %	MCHC	0 g/l	
GRA%	0.0 %	RDWc	0.0 %	
		PLT	0 10 ⁹ /l	
		PCT	0.00 %	
P-LCC	0 10 ⁹ /l	MPV	0.0 fl	
P-LCR	0.00 %	PDWc	0.0 %	

MEASURE

This is the screen where you can start measurements.

Exit will return to the Main menu

Press **New** to enter data for the sample.

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

There are two options to enter sample information:

- immediately before analysis
- in Database menu

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

New sample		06:18
Sample ID	Patient ID	Options
Sample ID	1	
Type	Human	
Doctor		
Comment		
Diatron GROUP		Cancel

MEASURE

New

Sample ID

A screen appears offering data entry for the upcoming sample.

Sample ID can be defined to identify the sample

Type offers a list of profiles to select from
Doctor will appear on the printout as well
Comment it is possible to add comments to the ID.

Cancel will return to the measurement screen (above).

New sample 15:51

Sample ID Patient ID Options

Patient ID

Name

Birth date

Sex

Diatron GROUP

Cancel

MEASURE

New

Patient ID

A screen appears offering data entry for the patient.

Cancel will return to the measurement screen.

New sample 15:51

Sample ID Patient ID Options

Prediluted

WBC only

Change lyse

Sampling depth

Diatron GROUP

Cancel

MEASURE

New

Options

A screen appears where offering data entry for the upcoming sample.

Settings remain as they are set for the following samples as well.

Cancel will return to the sample info screen.

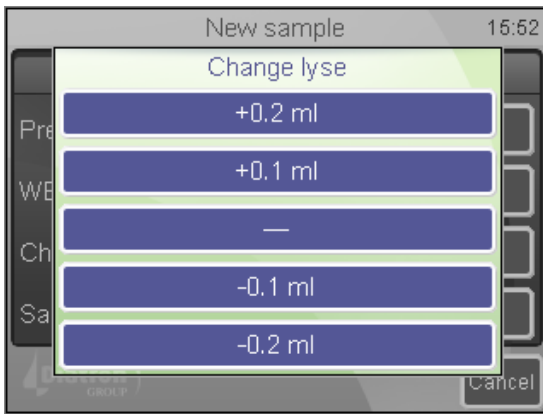
Pre-diluted mode offers two options: Yes or No. If you set it to Yes, then the instrument expects a pre-diluted sample (with a ratio of **1:5** – 1 unit of sample and 5 units of isotonic saline solution the total volume should be minimum 1ml)

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

Change lyse

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

Select an increased (+0.1, +0.2ml) volume if the separation between lysed RBCs and WBC populations is poorly differentiated, resulting in increased WBC and LYM counts. Select a decreased (-0.1, -0.2ml) volume if the WBC histogram seems to be shrunk to the left, i.e. the different WBC populations are overlapped. This can inhibit proper separation of WBC populations.



MEASURE

New

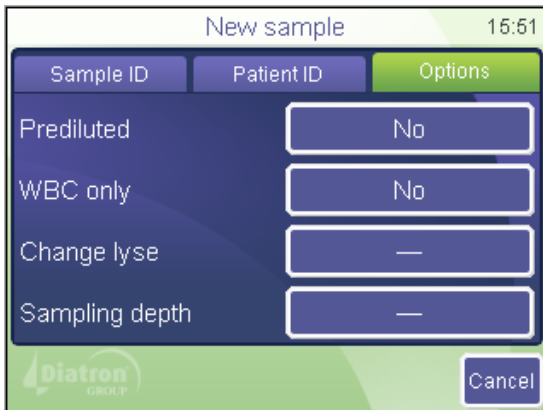
Options / Lyse volume
Change lyse

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

Sampling depth

The analyzer requires a minimum of 2ml of whole blood in the sampling tube. Abacus 380 can however be adjusted for low volume samples. This becomes necessary when there is extremely low volume of sample in the tube.

This option also allows using sampling tubes with an elevated bottom. In this case you have to set a higher sampling level to avoid the needle hitting the bottom of the tube.



MEASURE

New

Options / Sampling depth

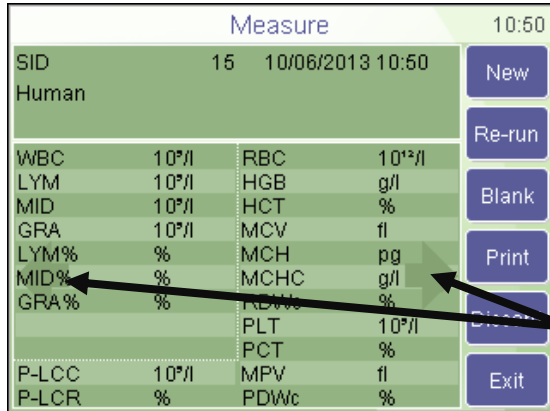
Select the necessary option so that the instrument can take sample from the right location.

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



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

5.2.3.Results



When analysis is complete, the following screen displayed, including all measured and calculated parameters as well as the WBC, RBC, and PLT histograms.

Results, histograms and other data will be stored automatically in the memory.

To look at histograms in detail, tap the arrows (left/right) to see further details.

5.2.4.Warning flags

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

Flag	Meaning	Recommended user action
E	No WBC 3-part differential	Possible lyse problem. May occur in pathological lymphocytosis.
H	HGB blank is high, or no HGB blank	Repeat the blank measurement. If HGB blank is not stable there are probably bubbles or dirt in the WBC chamber: Run a cleaning and try blank again. Close the side door if open during measurement.
B	WBC blank is high, or no WBC blank	Repeat the blank measurement, or run prime lyse and try blank again. Possible lyse contamination, or noise problem.
M	linearity range exceeded in WBC stage	The analyzer found that the cell count is higher than the linearity range of the analyzer. Make a pre-dilution, and run the same sample in pre-diluted mode
R	RBC cells found in sample during WBC stage	RBC cells were detected during the WBC measurement. Either the lyse reagent is not effective enough (volume should be increased) or the RBC's in the sample are somewhat lyse resistive
W	WBC 3-part warning	Probably large PLTs or clumped PLTs are present in the sample. Usually caused by the nature of the sample. cat and goat samples tend to clump. Intensive, but careful mixing of the sample (e.g. Vortex) can help remove the clumps. If the rerun sample gives the same results, consider that WBC and GRA values seem higher because of the clumps. Lyse modification can't solve the problem.
L	RBC-WBC limit warning	Typically insufficiently lysed RBC's interfere with the start of the WBC histogram. Repeating the measurement with an increased lyse volume should provide better separation. If the repeated run reports very similar results then the MID and GRA results are VALID but the WBC and LYM results may be higher because of interfering RBCs.
C	WBC clogging	Aperture clogging. Perform cleaning and repeat the measurement. If it is a general problem, please contact your Service Personnel. Low temperature reagents can cause it as well (mainly diluent), in this case you will have to wait until they reach room temperature.

Table 4. Summary of warning flags related to WBC/HGB

Warning flags in lowercase refer to RBC or PLT problems.

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

Table 5. Summary of warning flags related to RBC/PLT

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

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

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

Another flagging method is evaluation against the normal ranges. If some of the parameters is out of range it gets a (-) flag if under the range, or gets (+) if over the range. (And the given parameter will be highlighted as well.) You can customize ranges for all kind of patients by setting the corresponding lower and upper ranges. If you set 0 for a range limit, it will not be verified.

PLT related parameters can receive * (asterisk) flags if the previous blank measurement had high PLT value, and this value has been accepted.

5.2.5. Parameter Limits (Normal ranges)

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



Settings

Measurement

Normal ranges

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

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

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

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

Note: P-LCC and P-LCR are only research parameters, ranges added by the Lab responsible.

5.2.6. Blank Measurement

The system uses blank measurements to check cleanliness of the system and reagents. Blank measurement should be performed:

- Once daily, before sample analysis
- 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).

In MEASURE mode press the **BLANK** button. If Blank measurement was not acceptable, press **DISCARD** to discard blank result or repeat the Blank measurement pressing **BLANK** button. The analyzer is ready for sample analysis, and displays an empty sample measurement screen.

There are 3 regions for blank value handling:

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

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

Table 6. Blank measurement ranges

Accepted blank values are essential for proper calibration.

Calibration can **only** be performed if all blank values are in the first region (no flags or errors).

If analysis errors occur or blank measurement is too high, an E error flag appears along with the affected parameter and “---“ is displayed instead of results. In this situation, perform SW related cleaning (see Section 7.1).

5.2.7.Using Pre-diluted Mode

Pre-diluted measurement mode allows to measure insufficient sample for normal mode, or if some parameter is out of the linearity range (WBC = 300×10^3 cells/ μ l).

Perform an external pre-dilution of the sample using clean isotonic saline solution, or diluent reagent. Dilute the sample to **1:5** ratio (1 part sample to 5 part physiological saline), using a clean sample vial. Mix it well.

To perform the analysis on pre-diluted sample:

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

6. DATABASE

Patient results are stored in the memory in chronological order, and can be retrieved at any time. Data storing capacity is 10 000 measurements, including the complete parameter list, histograms, flags, sample data, and date/time of measurements. If memory is full, newest (actual) record will overwrite oldest record.

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

Database			15:59
Sample ID	Date	Patient I..	
<input type="checkbox"/>	1	22/03/2010	20942
<input type="checkbox"/>	2	22/03/2010	20942
<input type="checkbox"/>	3	22/03/2010	20942
<input type="checkbox"/>	4	22/03/2010	20942
<input type="checkbox"/>	5	22/03/2010	20942
<input type="checkbox"/>	6	22/03/2010	20942
<input type="checkbox"/>	7	22/03/2010	20942
<input type="checkbox"/>	8	22/03/2010	20942
Records 62 Selected 0			

DATABASE

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

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

Exit key returns to MAIN menu.

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

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

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

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

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

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

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

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

Exit returns to the main menu.

6.1. Database services

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

Database		10:47	
SID	8	05/06/2013	14:38
Human			
WBC	2.66	10 ⁹ /l	-
LYM	1.28	10 ⁹ /l	-
MID	0.29	10 ⁹ /l	-
GRA	1.09	10 ⁹ /l	-
LYM%	48.1	%	+
MID%	10.8	%	+
GRA%	41.0	%	-
P-LCC	77	10 ⁹ /l	
P-LCR	30.05	%	
RBC	3.39	10 ¹² /l	-
HGB	121	g/l	
HCT	34.43	%	-
MCV	102	fl	+
MCH	35.7	pg	+
MCHC	352	g/l	+
RDWc	14.2	%	
PLT	255	10 ⁹ /l	
PCT	0.26	%	
MPV	10.1	fl	
PDWc	39.2	%	

DATABASE

Detail

Table returns to the table view.

Print sends the record to the printer.

Edit opens up the dialog for data manipulation of the record

Exit returns to the Main menu

Edit sample		11:41	
Sample ID	Patient ID		
Sample ID		3	
Type		Human	
Doctor		Dr. Thomas	
Comment		comment 123	
		Accept	Cancel

DATABASE

Detail

Edit

When looking at record from the database view, some fields are not editable (Sample ID, sample type). These can only be set before running the sample. Patient ID tab allows entering further data. There is an option for giving comments for the measurement also.

The system will recognize the doctor's name from the first letters. This autocomplete function is working only with the last given doctor's name.

Edit sample		16:02	
Sample ID	Patient ID		
Patient ID		2243G	
Name		George	
Birth date		05/04/2000	
Sex		Male	
		Accept	Cancel

DATABASE

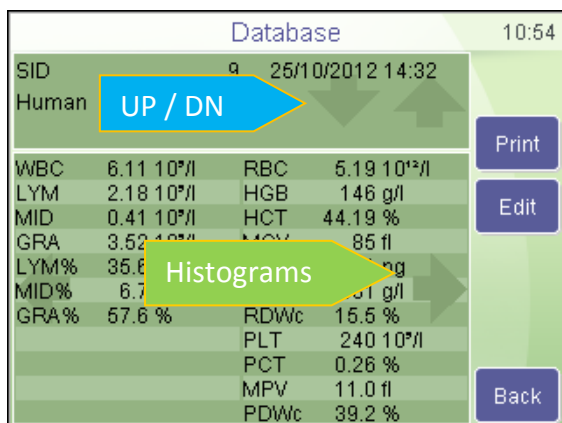
Detail

PID

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

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

Patient ID can be 32 characters long, the name of the patient can hold 40 characters.



DATABASE

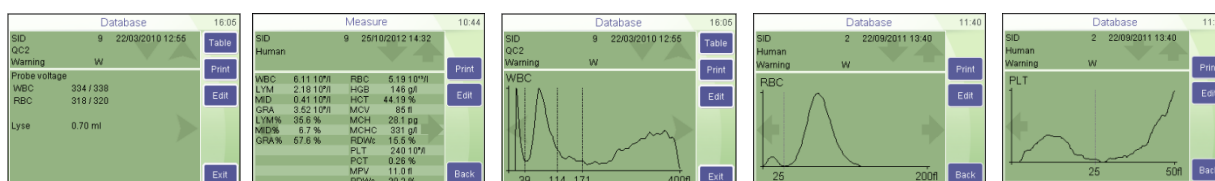
Detail

Arrows

The database record view allows browsing in the database, and it is possible to look at histograms and various diagnostic parameters of the sample.

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

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



Diagnostic flags

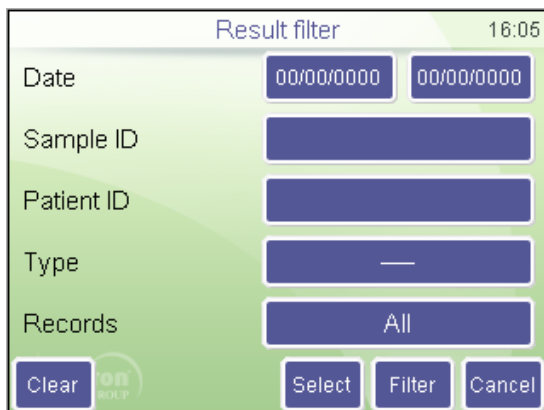
Parameter view

WBC histogram

RBC histogram

PLT histogram

6.2. The Filter / Select function



DATABASE

Filter

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

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

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

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

Clear will reset all fields.

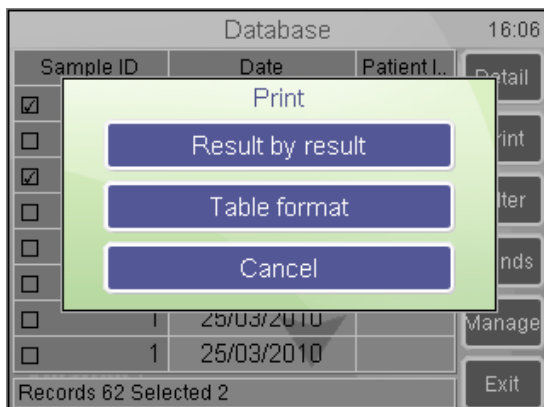
Select will return to the table view, and will fill the checkboxes of records matching the criteria.

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

NOTE

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

6.3. Printing records



DATABASE

Print

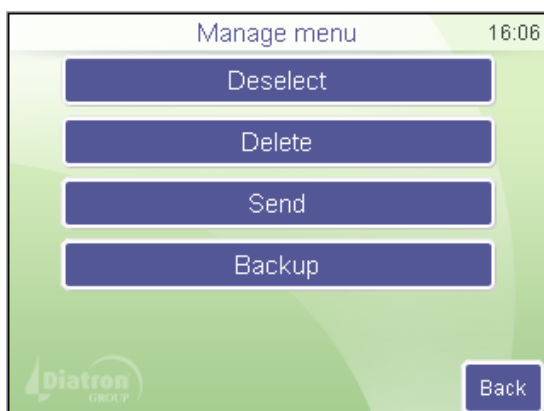
If there is no record selected, then the software prints the actual (top / detail view) record.

If there is more than 1 record selected, then you will be able to choose between individual printing (**Result by result**), or **Table format (only using USB printer)**.

Cancel aborts the operation.

6.4. Manage records

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



DATABASE

Manage

Back aborts the operation and returns to the table view.

Deselect will clear the checkboxes of all selected records.

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

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

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

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

7. MAINTENANCE

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



Maintenance

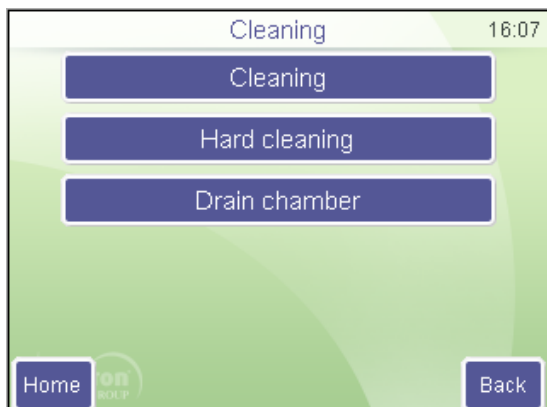
Touch menu item of the desired function.

Home will return to the Main menu

Back returns to the previous level.

7.1. Cleaning

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



Maintenance

Cleaning

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

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

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

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

Drain chamber will empty the measurement chamber. You can use this option to manually add cleaning solution to the chamber when necessary (extreme contamination in the chamber).

7.2. Calibration

The analyzer stability can be monitored with **Diacon3** control blood. Performing QC determinations regularly verifies continued optimal performance.

It is recommended to do calibration in the following cases:

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

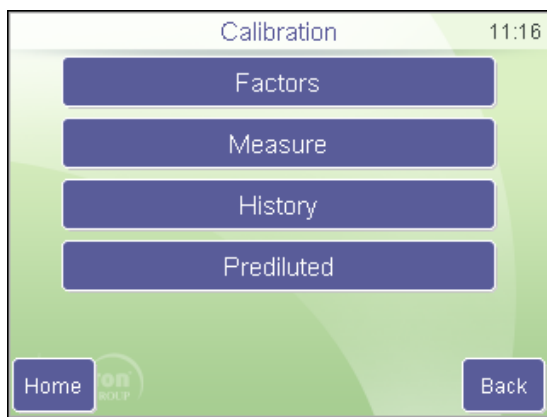
3. When quality control measurements show any systematic error (bias) or they are outside predefined limits.
4. At regular time intervals (determined by the lab itself).
5. If you want to use the instrument in Pre-diluted mode (separate prediluted calibration factors are available).

Calibration can be performed in two ways:

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

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

CAUTION! New calibration will invalidate the previous factors.
Old values can be checked at Calibration History.



Maintenance
Calibration

You can select the following functions:

Factors: enter calibration coefficients manually

Measure: define target values and start calibration measurements

History: display past calibration factors.

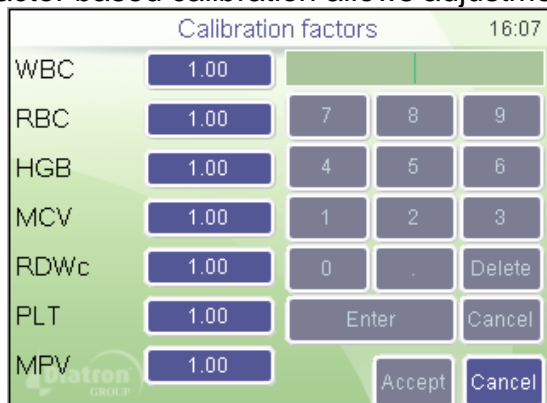
Pre-diluted: calibration factors and History for pre-diluted measurements.

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

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

7.2.1. Calibration with factors

Factor based calibration allows adjustment of primary parameters with a factor.



Maintenance

Calibration / Factors

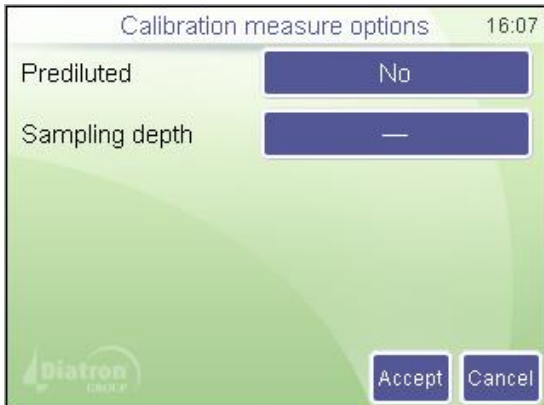
Press white data field to modify calibration factor. A numeric input screen will show up so that you can enter values.

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

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

7.2.2. Calibration by measurement

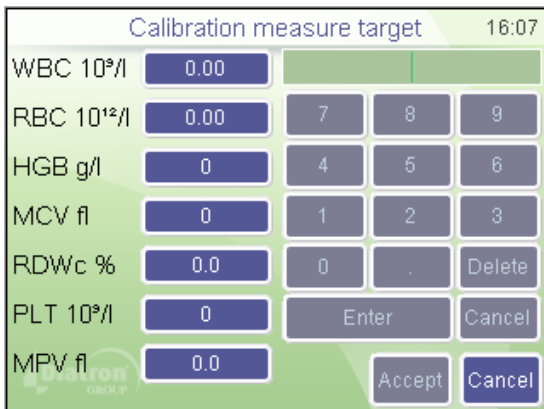
The analyzer can run calibrator, and perform calculation of factors automatically. User can decide the number of measurements to use for calibration.



Maintenance
Calibration / Measurement

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

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



Maintenance
Calibration / Measurement

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

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

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

Table 7. Calibration target ranges

When all parameters are set, press **Accept** key.

The display shows **Calibration measurement** at top.

Calibration measure				11:49
SID Control				Result
WBC	0.00 10 ⁹ /l	RBC	0.00 10 ¹² /l	Print Discard Exit
LYM	0.00 10 ⁹ /l	HGB	0 g/l	
MID	0.00 10 ⁹ /l	HCT	0.00 %	
GRA	0.00 10 ⁹ /l	MCV	0 fl	
LYM%	0.0 %	MCH	0.0 pg	
MID%	0.0 %	MCHC	0 g/l	
GRA%	0.0 %	RDWc	0.0 %	
		PLT	0 10 ⁹ /l	
		PCT	0.00 %	
P-LCC	0 10 ⁹ /l	MPV	0.0 fl	
P-LCR	0.00 %	PDWc	0.0 %	

Maintenance
Calibration / Measurement

Insert the sample tube to the sample door and press the START button.
Exit will abort the operation.

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

Calibration result					16:21
	Target	Mean	CV%	Factor	
WBC 10 ⁹ /l	7.30	7.31	2.6	1.00	Accept Back
RBC 10 ¹² /l	4.13	4.22	0.4	0.98	
HGB g/l	121	122	0.2	0.99	
MCV fl	90	90	0.0	1.00	
RDWc %	15.3	15.7	0.6	0.98	
PLT 10 ⁹ /l	216	215	2.1	1.01	
MPV fl	12.1	11.6	0.1	1.04	

Maintenance
Calibration / Measurement / Result

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

Accept saves new factors and aborts calibration
Back will return to the calibration measurement screen so that you can measure more samples for calibration.

Calibration history					16:44
Date	WBC	RBC	HGB		

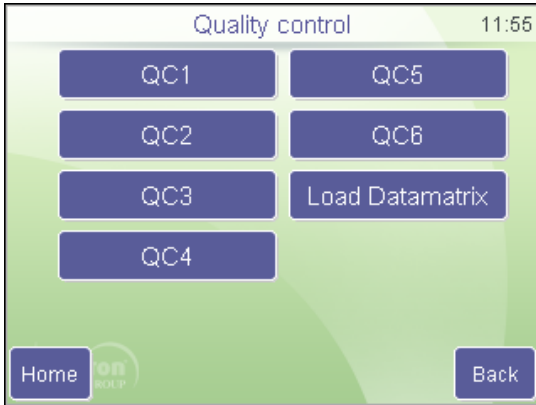
You can compare target and measured values, observe CV and see how the calibration factor would change.

Maintenance
Calibration / History

You can check the date and values of previous calibrations.

7.3. Quality control

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



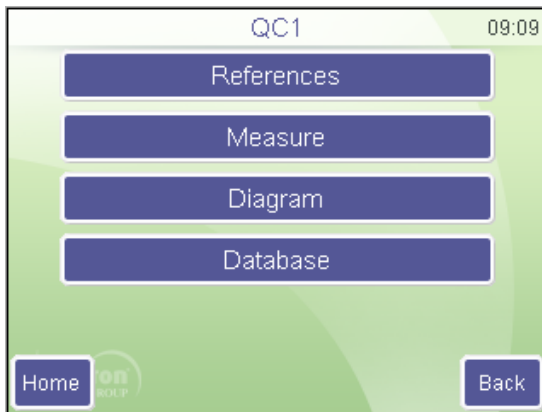
Maintenance

Quality control

Select LOT to work on.

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

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



Maintenance

Diagnostics / QC1

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

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

Control material is a defined and controlled quality prepared (almost artificial) blood product. It has conserved and treated blood cells inside which allows this material to be stable for a much longer time than normal blood would be.

The “Measure” option will become active only if there are reference values entered for the actual QC Lot.

7.3.1. References

To be able to run specific samples, and to see stability or variation of parameters, it is necessary to define a reference material for the software. This is going to be the basis for Quality Control. The idea is to enter these so-called expected or target values, and save everyday repeated runs of the same material in a separate database so that these values can be compared to the reference data.

Reference values arrive with the control material. The manufacturer recommends using **Diacon3** with the analyzer.

The assay value sheet contains all necessary parameters for the control material.

It is possible to add the ranges in three ways. Type it in by hand, copying the data from provided assay sheet.

Use Diatron provided QC_xxxx.ini file.

The screenshot shows a control screen titled "QC1" with a time of 11:42. It features a numeric keypad for entering data. Fields include "LOT" (with a green bar), "Expiration-date" (00/00/0000), and "WBC [10⁹/l]" with "Target" and "Range" both set to 0.00. Navigation buttons at the bottom include "Prev", "Next", "Load", "Accept", and "Cancel".

To use this file write the xxxx (LOT number) into the control LOT numbers place. It will automatically search for the plugged in USB drive with the QC_xxxx.ini file on the root.

The system will read the file and fill the ranges with the actual LOT's ranges.

The third way is to use Data matrix barcode reader.

The screenshot shows a "Quality control" menu with a time of 11:41. It contains buttons for "QC1", "QC2", "QC3", "QC4", "QC5", and "QC6". A "Load Datamatrix" button is also present. At the bottom, there are "Home" and "Back" buttons.

On the assay sheet there is a Data matrix barcode, which is possible to read in with a datamatrix barcode reader.

The instrument supports only one type of a matrix barcode reader yet. (For information, contact Technical Support)

In this case, choose "Load Datamatrix" option and as the next screen with the range table comes up, read the barcode in, and wait a few seconds until the system generates the ranges.

It will read the Low, Normal and High control ranges as well.

The screenshot shows a "DataMatrix" screen with a time of 11:42. It displays a table with the following data:

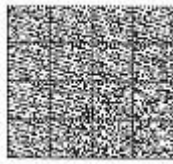
Parameter	Low	Normal	High
WBC	0.00+-0.00	0.00+-0.00	0.0..
RBC	0.00+-0.00	0.00+-0.00	0.0..
HGB	0.00+-0.00	0.00+-0.00	0.0..
HCT	0.00+-0.00	0.00+-0.00	0.0..
MCV	0.00+-0.00	0.00+-0.00	0.0..
MCH	0.00+-0.00	0.00+-0.00	0.0..
MCHC	0.00+-0.00	0.00+-0.00	0.0..

At the bottom, there is a message "Please use DataMatrix reader!" and "Accept" and "Cancel" buttons.

After the read process the system will ask the user to choose which QC# the LOT will be saved under.

(QC1, QC2, QC3 or QC4, QC5, QC6)

The assay sheet with Matrix barcode:



This barcode can be read by the Datamatrix barcode reader.

40200000 Rev. 09/12/11

Diatron Diacon 3 Hematology Control
HEMATOLOGY CONTROLS
CONTROL

ASSAY VALUES AND EXPECTED RANGES
SOP DATA MONTH: MAY, JUNE, JULY

Parameter	Unit	Low		High	
		Target	Range	Target	Range
WBC $\times 10^9/L$		2.0 \pm 0.4	1.7 \pm 0.8	20.0 \pm 2.0	
RBC $\times 10^{12}/L$		3.40 \pm 0.10	3.77 \pm 0.10	6.50 \pm 0.50	
HGB $\mu g/L$		81 \pm 0.4	107 \pm 0.5	184 \pm 0.8	
HCT %		184 \pm 1.4	403 \pm 2.4	555 \pm 3.9	
MCV %		70 \pm 4.4	89 \pm 4.4	85 \pm 4	
RDW %		28.2 \pm 2.4	38.7 \pm 2.8	51.8 \pm 2.8	
MPV μm^3		102 \pm 2.8	105 \pm 2.0	102 \pm 0.8	
PDW μm^3		18.3 \pm 2.8	17.8 \pm 2.0	16.0 \pm 2.8	
RDW-CV %		10.6 \pm 0.9	14.2 \pm 0.9	12.4 \pm 2.8	
PLT $\times 10^9/L$		44 \pm 1.0	116 \pm 2.0	402 \pm 0.5	
MPV %		8.7 \pm 2.8	10.1 \pm 1.6	10.1 \pm 1.6	
PCT %		0.94 \pm 0.02	1.22 \pm 0.02	0.40 \pm 0.08	
PDW-CV %		27.8 \pm 2.8	38.2 \pm 3.0	50.2 \pm 2.8	
RDW-SD %		12.0 \pm 2.8	13.9 \pm 2.0	13.6 \pm 2.8	
CVW %		100.1 \pm 0.5	104.4 \pm 0.5	116.4 \pm 4.8	
MCH %		5.5 \pm 0.8	8.1 \pm 0.8	8.8 \pm 4.0	
MCHC %		16.0 \pm 0.8	16.3 \pm 0.8	10.7 \pm 5.0	
LYM $\times 10^9/L$		1.2 \pm 0.2	3.2 \pm 0.4	2.4 \pm 0.8	
NEU $\times 10^9/L$		0.7 \pm 0.1	0.7 \pm 0.3	1.8 \pm 0.8	
PLT $\times 10^9/L$		87 \pm 0.2	4.8 \pm 0.4	12.2 \pm 1.2	

Diatron BE PLC
Hematology, Tashkent, Uzbekistan

QC1 16:46

LOT |

20923H 7 8 9

Expiration-date

30/11/2010 4 5 6

WBC [$10^9/L$]

Target Range 1 2 3

5.41 0.18 0 . Delete

Enter Cancel

Prev Next Accept Cancel

Maintenance

Quality control / Reference

Use Prev and Next to browse among parameters.

Press **Accept** to save data.

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

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

7.3.2.Measure

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

QC1 LOT y66778				12:03
SID				Trends
QC1				
WBC	0.00 10 ⁹ /l	RBC	0.00 10 ¹² /l	Print
LYM	0.00 10 ⁹ /l	HGB	0 g/l	
MID	0.00 10 ⁹ /l	HCT	0.00 %	
GRA	0.00 10 ⁹ /l	MCV	0 fl	
LYM%	0.0 %	MCH	0.0 pg	
MID%	0.0 %	MCHC	0 g/l	
GRA%	0.0 %	RDWc	0.0 %	
		PLT	0 10 ⁹ /l	
		PCT	0.00 %	
P-LCC	0 10 ⁹ /l	MPV	0.0 fl	
P-LCR	0.00 %	PDWc	0.0 %	

Maintenance

Quality control / Measure

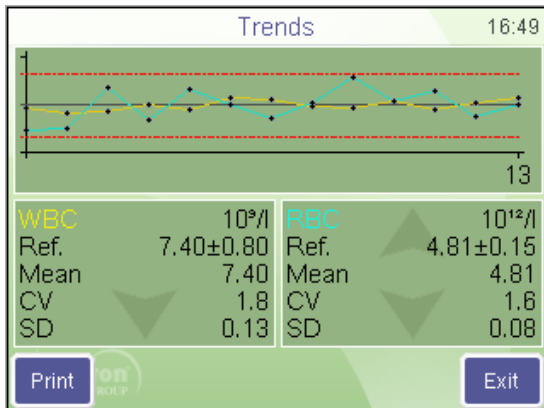
The software saves all results automatically to the selected QC lot database.

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

Exit returns to the QC menu

7.3.3. Diagram

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



Maintenance

Quality control / Diagram

Use **Up** and **Down** shaded arrows to browse among parameters on both sides.

Press **Exit** to return to the previous menu.

This mode allows comparing tendencies, trends of any two parameters.

7.3.4. Database

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

Database QC1				16:49
Sample ID	Date	Patient I..		Detail
<input type="checkbox"/> 6	18/03/2010	191N		Print Filter Trends Manage Exit
<input type="checkbox"/> 7	18/03/2010	191N		
<input type="checkbox"/> 8	18/03/2010	191N		
<input type="checkbox"/> 9	18/03/2010	191N		
<input type="checkbox"/> 10	18/03/2010	191N		
<input type="checkbox"/> 11	18/03/2010	191N		
<input type="checkbox"/> 12	18/03/2010	191N		
<input type="checkbox"/> 13	18/03/2010	191N		
Records 66 Selected 5 Filter on				

Maintenance

Quality control / Database

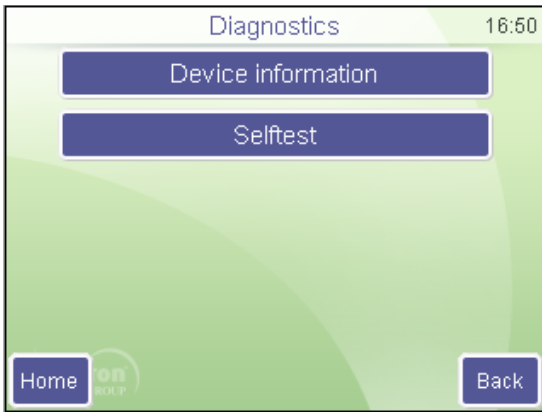
Use **Prev** and **Next** to browse among parameters.

Exit returns to the QC menu.

Note: QC database is a filtered view of the normal database. The status bar shows the “Filter on” text.

7.4. Diagnostics

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



Maintenance
Diagnostics

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

7.4.1. Device Information

Device information shows system hardware and software setup.



Maintenance
Diagnostics / Device Information
The various system parameters can be seen on the screen.

Press **EXIT** to go back to the previous menu.

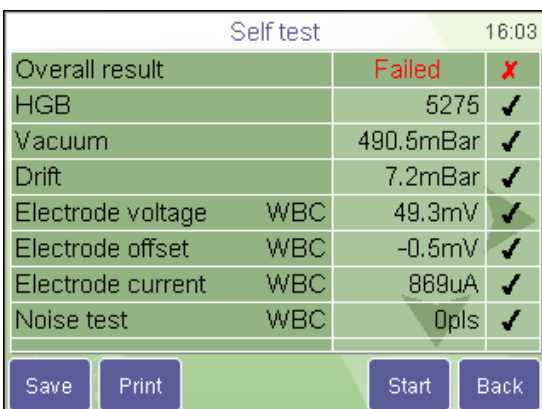
7.4.2. Self-Test

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

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

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

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



DIAGNOSTICS
SELF-TEST (2)
The analyzer lists and checks subsystems. When tests are finished, display shows a summary of the results. Various system parameters can be seen on the screen.
Press **RETRY** to run Self-test again.
Press **BACK** to go back to previous menu.

To reduce time required for self-test, and to allow testing parts of the system that do not require reagents, you can chose to run the Self-test in “fast” mode.

7.5. Reagent status

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



MAINTENANCE

REAGENT STATUS

Bar graphs show reagent status.

Reset will reset reagent level to its full value.

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

Volume opens up the container volume setup screen.

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



MAINTENANCE

REAGENT STATUS

Volume

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

Accept saves your changes.

Cancel discards changes and returns to reagent status screen

7.5.1.How to empty waste container

Software counts volume of waste, and gives warning message when the waste tank is close to its maximum capacity.

Empty the waste tank when this warning message appears. See next Section for neutralization steps.

7.5.2.Neutralization of Waste

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

Neutralization of biohazard waste:

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

8. SETTINGS

Selecting Settings accesses various lists of options

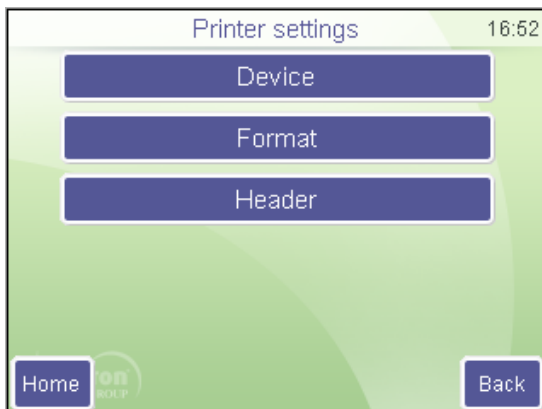


Settings

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

8.1. Printer settings

Printer settings menu allows setting up parameters of report printing.



Settings

Printer settings



Settings

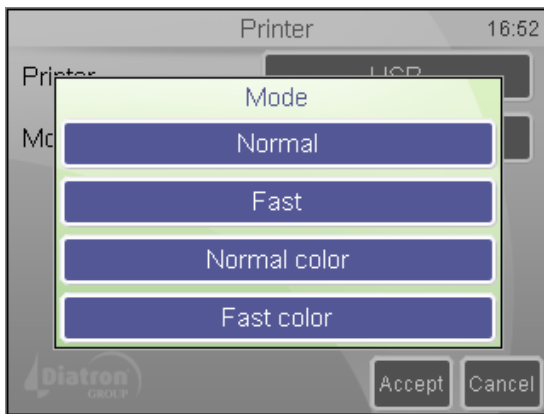
Printer settings / Device

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

Format: Selects printout quality.

Press **Accept** to approve changes made.

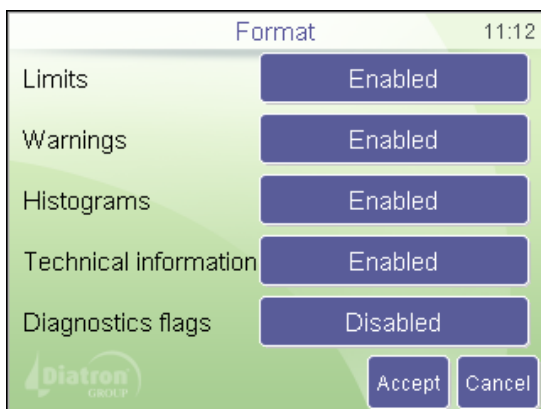
Press **Cancel** to go back to previous menu keeping the old settings.



Settings

Printer / Device / Mode

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



Settings

Printer settings / Format

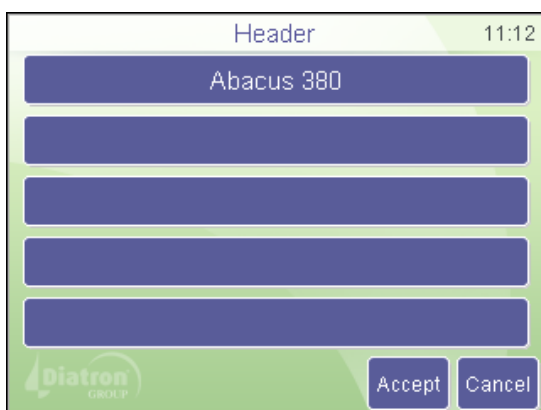
Press **Accept** to approve changes made.
Press **Cancel** to go back to previous menu keeping the old settings.

Limits: Enable / Disable parameter limit (normal range) printing.

Warnings: If Enabled, warning flags appear on the report as well.

Histograms: Enable / Disable graph printing.

Technical information: If Enabled, probe voltages (WBC,RBC), lyse volume, (ml) and software/firmware version appear in the printout.



Settings

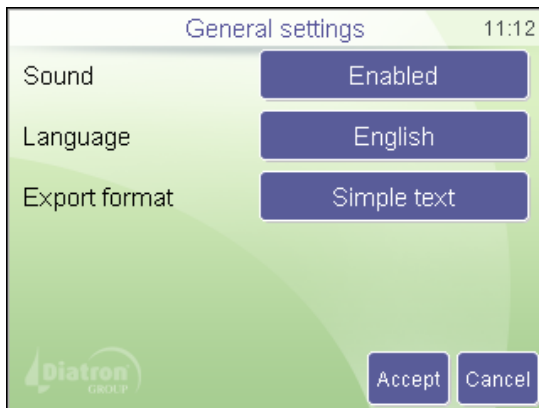
Printer settings / Header

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

Press **Accept** to approve changes made.
Press **Cancel** to go back to previous menu keeping the old settings.

8.2. General settings

General settings control operation of the following functions.



Settings

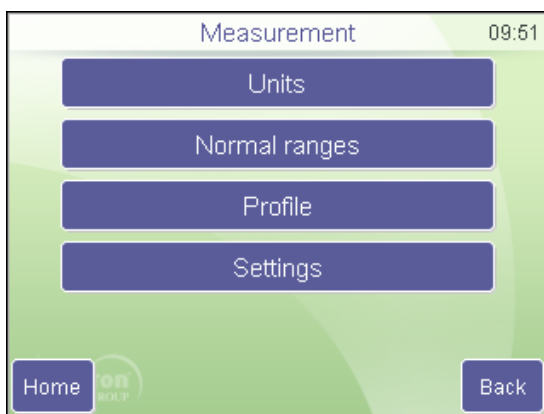
General

Select any of the following options:

Press **Accept** to approve changes made.
Press **Exit** to go back to previous menu.

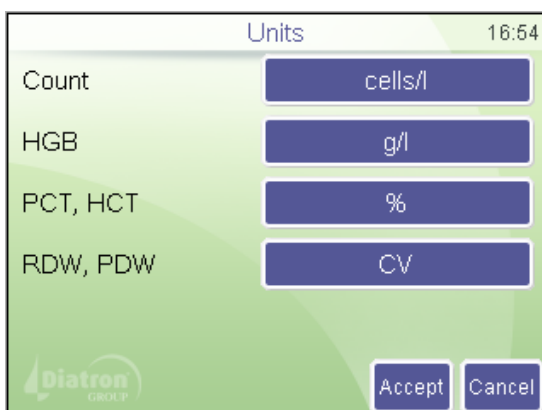
8.3. Measurement settings

This section groups measurement related options and settings.



8.3.1. Unit settings

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



Settings

Measurement / Units

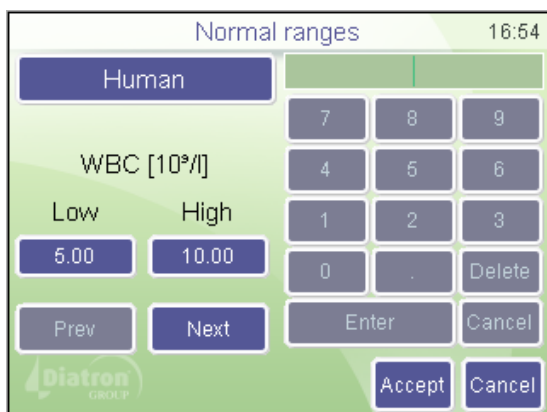
Press units to change them individually
Press **Accept** to approve changes made.
Press **Cancel** to go back to previous menu
keeping the old units.

Possible units for the parameters:

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

8.3.2.Normal ranges

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



Settings

Measurement

Normal ranges

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

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

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

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

8.3.3.Profile



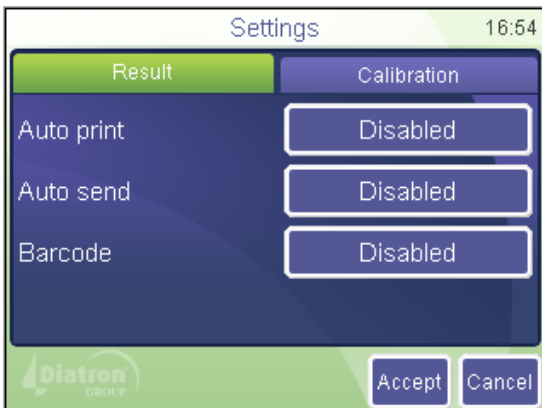
Settings

Measurement

Profile

The default lyse volume can be set for each profile.

8.3.4. Settings



Settings

Measurement / Settings/Result

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

Auto send will automatically transmit results if a PC is connected

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

Accept saves changes made

Cancel returns to previous menu discarding changes made



Settings

Measurement / Settings/Calibration

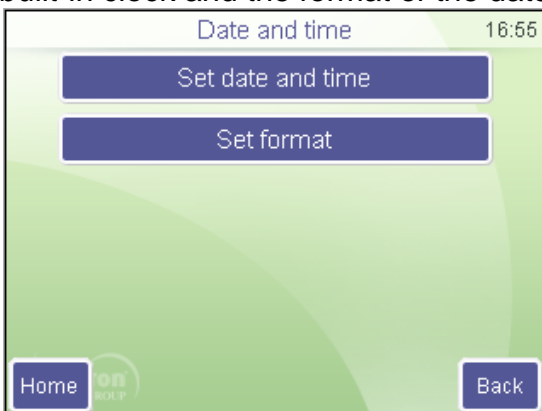
Mode allows choosing between HCT/PCT or MCV/MPV based calibration

Accept saves changes made

Cancel returns to previous menu discarding changes made

8.4. Date and Time

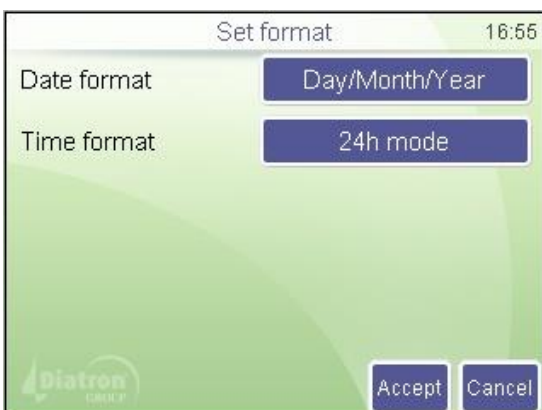
Date and time of each analysis is stored with the results. This menu allows setting the built-in clock and the format of the date displayed.



Settings

Date and time

You can set date and time and choose the format of time display.



Settings

Date and time

Choose the desired time and date format.



Settings

Date and time/ Set date and time
Type in the date and time.

Select formats for displaying the date.
Press **Accept** to save settings.
Press **Cancel** to go back to previous menu keeping the old values.

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

8.5. Multi user mode

The analyzer allows operation in a multi-user environment, where users can have different rights and access levels.

This feature is accessed upon startup, and can of course be customized.

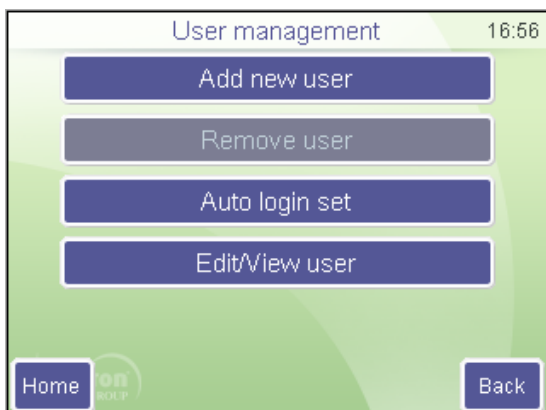
The analyzer by default operates in a multi-user environment – however the user should not notice this functionality.



Exit

Logout will leave the unit on, and the login screen appears.

Multi user mode functionality can be enabled in the Exit menu by adding users in User Management.

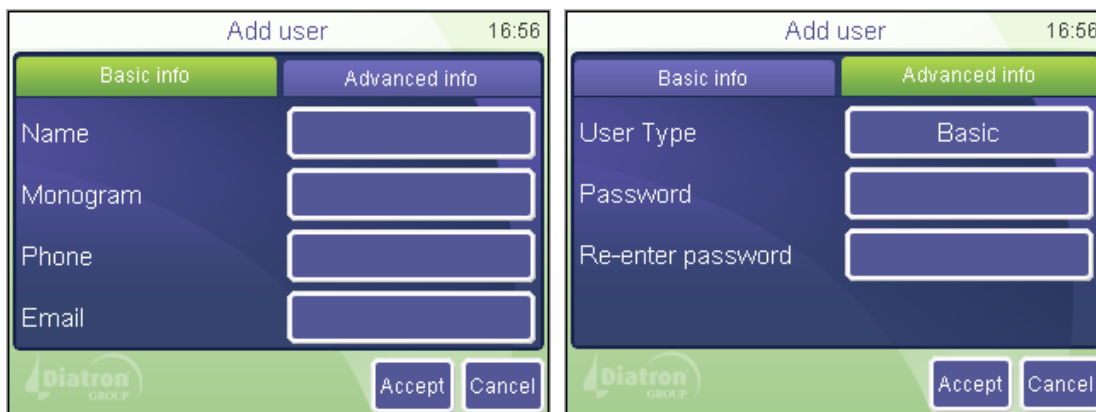


Exit

User Management

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

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



Use Remove User option to disable its access.

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

User Type BASIC has limited access to the menu tree:

Measure	New	Options		
	Re-run			
	Blank			
	Print			
	Discard			
Database	Detail / Table view			
	Edit record			
	Print			
	Filter			
	Trends			
	Manage			
Maintenance	Cleaning	Cleaning		
		Hard cleaning		
		Drain chamber		
	Calibration	Factors		
		Measure		
		History		
		Prediluted		Factors
				History
	Quality control (forbidden)			
	Diagnostics	Device information		
		Self test		
		Service		
	Reagent status			
(Settings forbidden)				
Exit	Logout			
	Shut down			
	Preparing for shipment			
	User Management	Add new user		
		Remove User		
		Auto login set		
		Edit / View user		



Exit

User Management
Auto Login Set

Auto Login Set will allow login-free starting of the analyzer.
Select the user to be logged in automatically. With Auto Login Off selected, the instrument will prompt for a user and a password upon startup.



Login screen (with Auto Login Off)

Use Shutdown to stop the analyzer (power off)
Preparing for shipment will drain the unit so that it can be transported.

Log In brings up the login screen (below)



Login screen (with Auto Login Off)

Touch Login name. Select name from list.
Enter password.

Instrument will show database upon correct password entry.

9. PRINTING

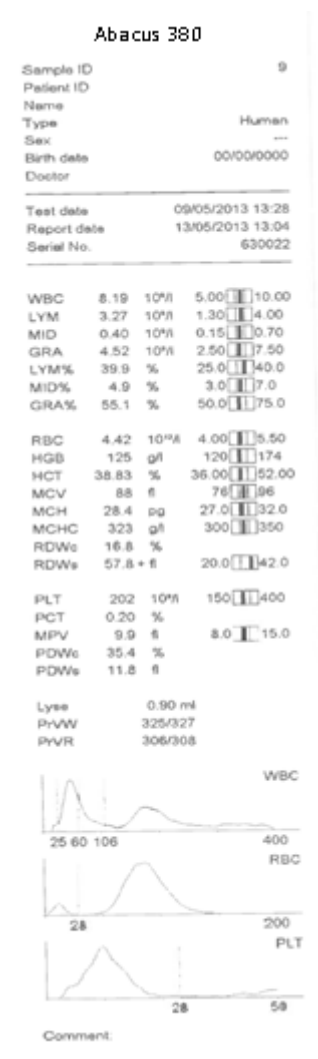
This chapter covers information on making printed reports on measured samples.

9.1. Printouts

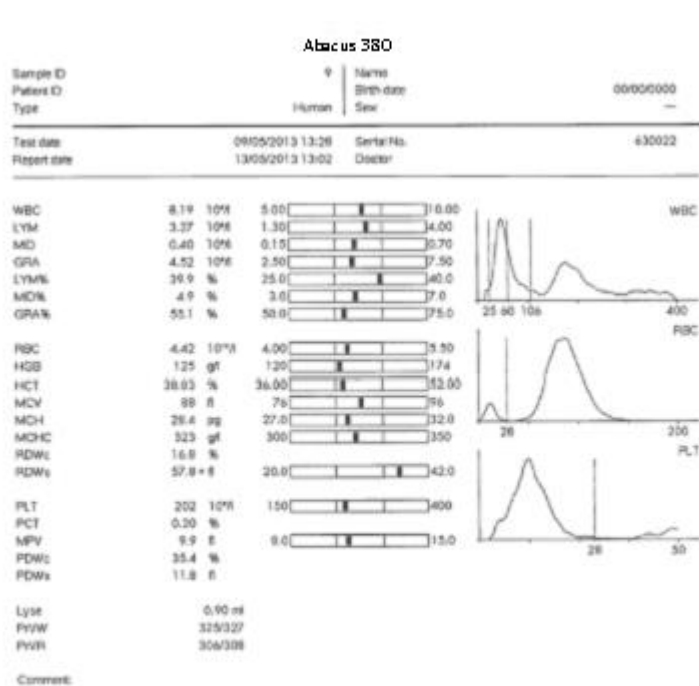
When required, the following items can be sent to an external printer or to the built-in printer by selecting Print option.

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

Thermal paper printout



Printout on external printer



Database Table Printout

Abacus Junior 30
Records 1 to 4 of 4

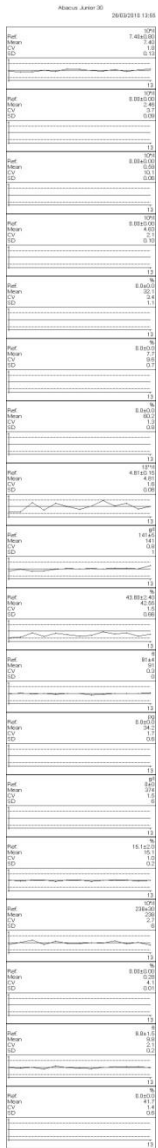
21/05/2013 11:47

Sample ID	Date	WBC 10 ⁹ /l	RBC 10 ¹² /l	HGB g/dl	HCT %	MCV fl	MCH pg	MCHC g/dl	PLT 10 ⁹ /l	PCT %	MPV fl	PDWc %	RDWc %	LYM 10 ⁹ /l	MID 10 ⁹ /l	GRA 10 ⁹ /l	LYM% %	MID% %
CAL019	17/05/2013 13:19	7.77	5.05	14.4	40.63	80	28.5	35.5	247	0.24	9.7	39.8	17.9	2.10	0.83	4.84	27.0	10.7
1	17/05/2013 14:44	7.96	4.89	13.6	42.20	86	27.8	32.1	233	0.23	9.9	40.4	16.3	2.32	0.65	4.98	29.2	8.2
2	17/05/2013 14:49	7.86	4.79	13.8	41.46	87	28.7	33.2	230	0.22	9.7	39.6	16.3	2.15	0.79	4.92	27.3	10.1
3	17/05/2013 14:54	8.03	4.88	13.6	42.19	86	27.8	32.2	236	0.23	9.9	39.2	16.6	2.23	0.86	4.94	27.8	10.7

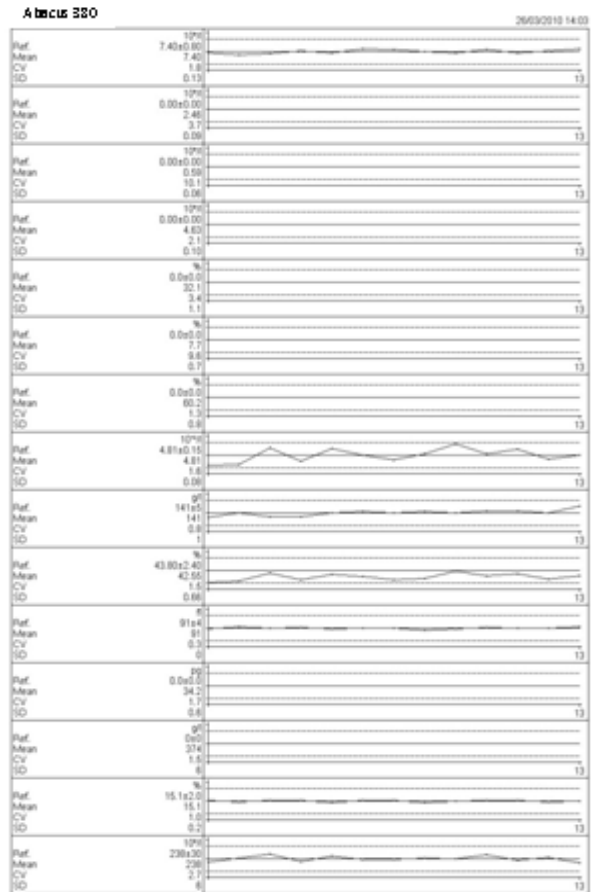
Abacus Junior 30
Records 1 to 4 of 4

Sample ID	GRA% %	P-LCC 10 ⁹ /l	P-LCR %	Warning
CAL019	62.3	64	25.71	
1	62.6	75 +	32.37	
2	62.6	71 +	30.75	
3	61.5	74 +	31.46	

QC graphical printout on built-in printer



QC graphical printout on external printer



10. REAGENT LOCK SYSTEM

The Abacus 380 hematology analyzer is equipped with a Reagent Lock System to prevent use of inappropriate, bad quality reagents in order to provide the possible best quality of results.

The Reagent Protection Module stores the available number of tests.

The packaging of each **Diatro•Lyse-DIFF** contains a Reagent Lock Hardware Key (HK).



Reagent Lock Hardware Key

The connected Lyse bottle has to be replaced by the following procedure in case there is low measurement left on the system.

1. Open a new bottle of **Diatro•Lyse-DIFF**. The HK is located on the top of the cap of bottle.
2. Connect the new lyse bottle to the Lyse reagent input.

Be careful! Improper replacement can contaminate the reagent and the system

Do not put the absorption tube on the ground it should be cleaned with distilled water at every reagent replacement.

3. Plug the Hardware Key into the Reagent Lock connector at the back of the Abacus 380.

Plug key in the reagent key slot in the position: connection side to the right.

4. At the Maintenance → Reagent Status screen: press the RESET button.
5. All the measurement credits are going to be transferred to the analyzers Reagent Protection Module. All of measurements from HK will disappear.
6. Remove the HK from the Reagent Lock connector. The HK is not able to be used again.

WARNING! If the HK was not connected during the previous procedure, after a certain number of tests no more measurement cycle can be initiated. In order to start new measurements, connect an unused HK to the Reagent Lock connector and repeat steps 3-6!



Reagent Status Menu

Here the level of reagents and the remaining number of measurement is visible for the user.

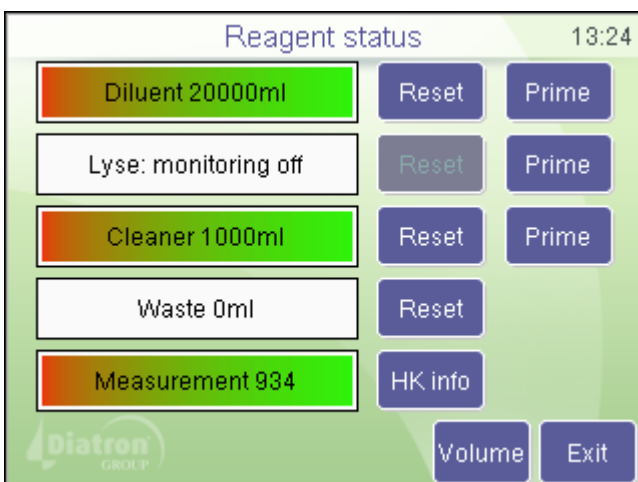
Here you can RESET, PRIME reagents and it's counters and UPLOAD measurements from Hardware Key.

With RESET ALL, you can reset the counters for all reagents and Waste.



Entering the VOLUME menu the user can define the size, volume of the reagent and waste containers.

If the lab uses 10L of Diluent for example than Diluent (ml) should be set to 10000.

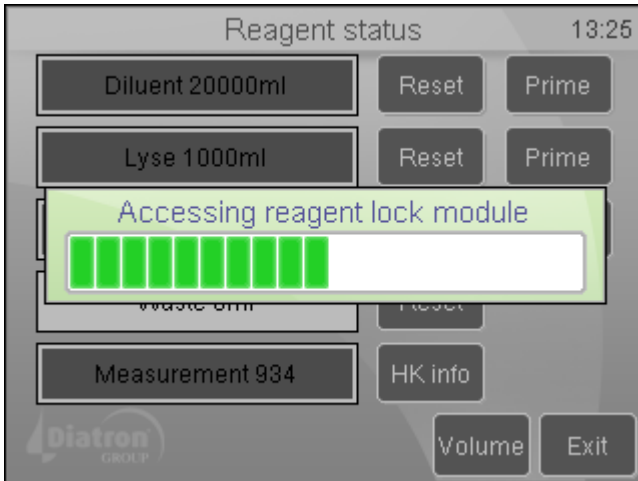


If the user enters, "0" into - for example the Lyse volume column – than the system will not monitor the reagent level of lyse.

This counter is independent from the Measurement counter.

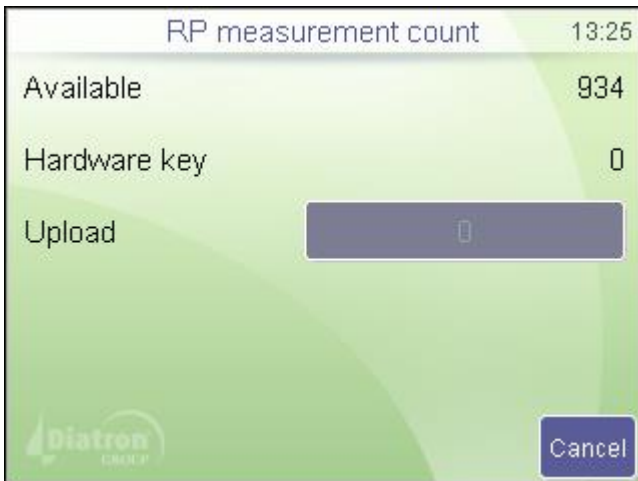


Human, Control, QC and Blank measurements are decreasing the measurement counts, but Initialization, Wake up and Prime is not!
The Measurement countdown is connected together with lyse! It is possible that you still find remaining lyse reagent in the container when the counter gets empty because we give extra amount of lyse just to be sure it will be enough for extra maintenance and/or service procedures.



When you are entering Hardware Key Information menu the system will start to read the attached HK and the module.

If there is any problem occurs during the reading, the system will warn the user with the proper error message.



In Hardware Key Information menu, the user can see the available measurements on the system, and the same on the HK if attached.

Upload column will be available only in service mode.

Summary:

1 key = 900 measurements. It consumes around 1L of Lyse reagent. It is possible that the user will find remaining lyse reagent in the bottle, but it has be replaced by the new one.

For more information, please contact to your local support.

11. TROUBLESHOOTING

11.1. Regular Troubleshooting Procedures

From Maintenance submenu, user can initiate maintenance procedures such, cleaning, priming, or draining chamber.

11.2. Weekly User Maintenance

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

11.2.1. Cleaning needle washing head

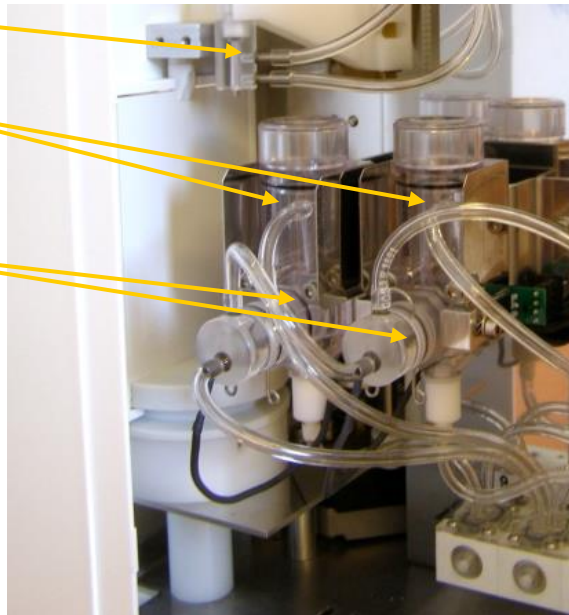
Needle washing head cleans the outer surface of the aspirating needle with diluent.

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

Washing head

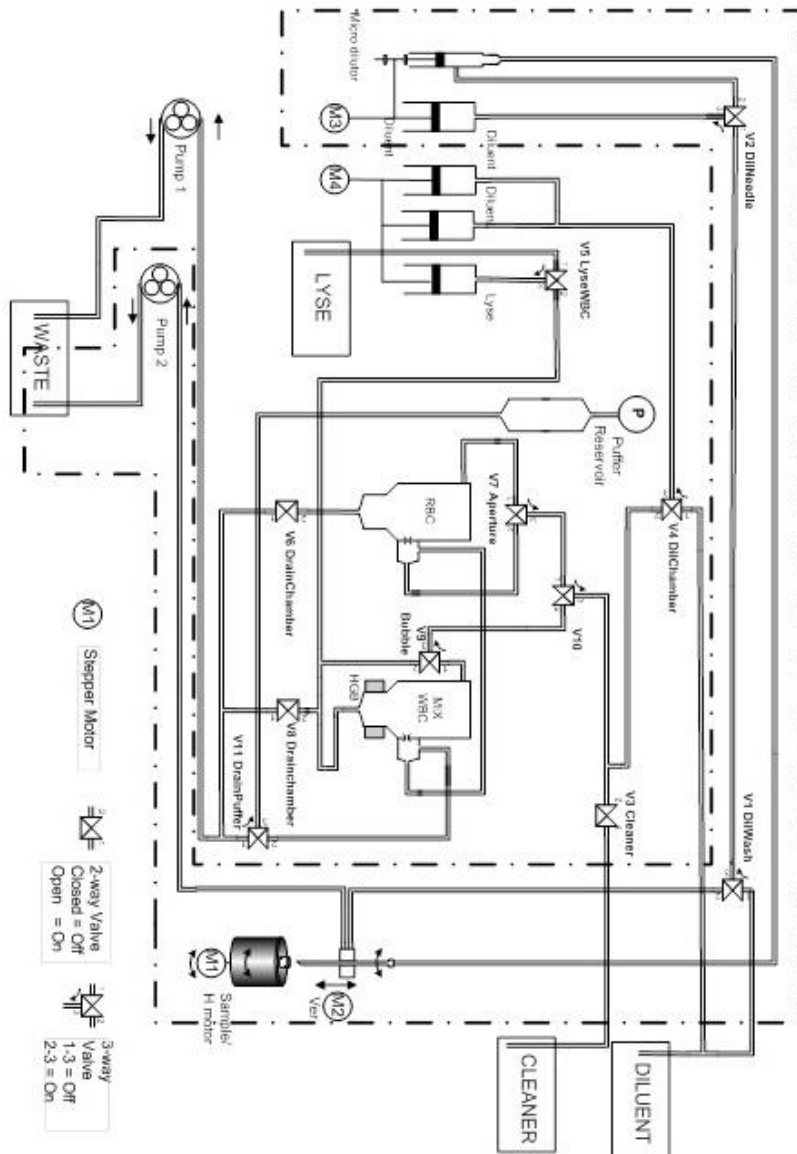
Measuring chambers

Measuring apertures



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

12. FLUIDIC SCHEMATICS



13. CALIBRATION OF BARCODE READER

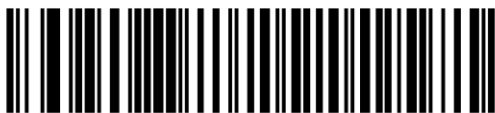
Calibration sheet for Barcode reader DS 4208 for ACS instruments.



Set Factory Defaults



<DATA> <SUFFIX 1>
(01h)



Medium Delay (20 msec)



1 msec

The calibration of the Barcode reader is the following:

- Connect to one of the USB slot on the back of the instrument
- Turn on the analyzer
- Read the barcodes above, one after another from the top to the bottom.
- The barcode reader is ready to use.

REVISION HISTORY

Rev.	Date	Edited by	Sections affected
1.18	2015.10.08	Tóth Eszter	Main page – part number added
1.19	2016.02.18	Tóth Eszter	Added page1 – warranty and contact information, extension of 2.3.5 with CE and IVD mark
1.20	2016.07.18	Tóth Eszter	Added Diatron Logo and revision history, added transport temperature to section 1.8, correction of storage temperature in section 1.8