ELite 5

Hematology Analyzer



USER MANUAL

CE IVD

REF **INS00068**

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Introduction

This user manual is intended to give detailed information for end users of the ‘ELite 5’ optical hematology analyzer.

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This manual was written with the intention to give the most precise and up-to-date, detailed description of operation and use of the analyzer for laboratory purposes.

Despite careful revision and multiple grammar and content control, mistakes can still be present in this manual. Erba Lachema may from time to time issue errata, or a new revision of the manual. Would you find things unclear, please contact your service engineer for assistance.

Descriptions contained herein are relevant to ‘ELite 5’, software versions (latest available at the publication of the manual):

High Level SW version:	1.5.2105.0
Low Level SW version:	1.5.2105.0
Low Level boot version	2.0
Firmware:	2.78 (1208)
PIC SW:	2.1
Laser SW:	3.5
TCU SW:	3.42

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1 For Your Safety

1.1 Who Should Use This Manual

This User Manual is intended for clinical laboratory professionals using the 'ELite 5' automated hematology analyzer. The Manual includes information about the operation and user interface of the 'ELite 5' analyzer.

It also contains basic steps necessary to perform the setup procedures to adapt the operation of the analyzer to the requirements of your laboratory.

This manual also describes daily routine maintenance requirements to keep your analyzer functioning properly.

1.2 Special symbols used in this Manual

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

1.3 General Precautions

	The analyzer weighs 35kg (~77lbs).Please do not attempt to move it alone. The analyzer should always be moved by two persons holding the analyzers by its sides in an upright position.
	Always use safe lifting procedures when lifting the analyzer.
	Make sure to retain the original packaging material for safe transportation and storage in the future.
	To prepare the analyzer for shipping, storage or extended periods of inactivity, please drain the reagents and repackage the 'ELite 5' in its original packaging. Do not expose the 'ELite 5' to direct sunlight, extreme temperature or humidity (>80%).
	The analyzer operates with chemically and biologically active reagents. Physical contact with these reagents should be avoided. Please read reagent descriptions carefully for possible emergency actions.

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	To ensure reliable operation and reliable results: • Only human blood samples should be analyzed • Only original Erba Lachema reagents should be used • Required maintenance (user and service level) should be performed as recommended in this Manual • Only Erba Lachema certified service personnel should perform service actions • Only original Erba Lachema service materials and spare parts should be used
	Original reagents and service materials and spare parts are available from Erba Lachema.
	Only Erba Lachema certified service personnel that have successfully completed the 'Erba Lachema ELite 5 Service Training program are qualified to service the 'ELite 5' analyzer.
	Before operating the 'ELite 5' analyzer, all operators should complete the 'Erba Lachema ELite 5 Operator Training' program. This program is offered by Erba Lachema or by Erba Lachema certified service personnel.
	Replacement materials or spare parts (tubes, valves, etc.) which might have been in contact with human blood or reagents should be handled as a potentially biologically hazardous and chemically dangerous material. All applicable laws and regulations must be observed in the handling and disposal of these materials.
	The 'ELite 5' is designed for laboratory operation. Mobile operation is not supported. Operate 'ELite 5' within the ambient temperature range described in section 1.4.
	The IVD equipment complies with the emission and immunity requirements described in relevant part of the IEC 61326 series.
	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to reduce the interference.
	Electromagnetic environment should be evaluated prior to operation of the device.
	This analyzer contains electronic components. Please handle electronic waste adhering to local or federal regulations.

1.4 Environmental Factors

Operate the 'ELite 5' analyzer at the ambient temperature within the range of 15-30°C (59-86 °F) and a relative humidity range of 10% - 80%. The optimum operating temperature is 25°C (~77°F).

Avoid exposing the 'ELite 5' analyzer to direct sunlight or to extreme high or low temperatures. If the 'ELite 5' analyzer was subjected to extreme temperatures during shipment or storage, the analyzer must be placed for at least one hour in a room whose temperature is within the operational range before installation or use.

Reagents should be stored within the temperature range of 15-30°C (59-86 °F).

The analyzer should be placed in a well-ventilated location.

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Operation at an altitude above 3000 meters (9800 ft) is not recommended.

1.5 Electrical Requirements

The analyzer should only be operated from a wall outlet meeting these power input requirements:

- 100-127VAC/200-240VAC; 47Hz to 63Hz
- Power Consumption: maximum 400 VA

Please ensure that the wall outlet is also capable of supplying the power consumption of any additional devices (such as a printer).

Only the power cord supplied with the instrument should be used. Avoid using extension cords. The 'ELite 5' analyzer comes with a power cord appropriate for your power system. Proper use of the appropriate power cord assures adequate grounding of the system. If the power network is not reliable, contact your representative for options such as the installation of an external UPS module.



Failure to properly ground the 'ELite 5' bypasses important safety features and may result in electrical hazard.

The instrument should not be placed near potentially interfering devices capable of emitting radio frequencies (e.g. radio or television transmitters/receivers, radars, centrifuges, X-ray devices, fans, etc.).

This analyzer is designed to be safe for transient voltages to INSTALLATION CATEGORY II and POLLUTION DEGREE 2.

1.6 Space Requirements

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance.

Select a well-ventilated location near a power source and close to a suitable drain.

Place the unit on a clean, level surface. Leave at least 0.5 m (18 inches) space on both sides and above the instrument to access pneumatics. A minimum of 0.2 m (8 inches) must be maintained between the rear panel and the wall to allow for heat dissipation and tube clearance.

Ensure there is enough clearance in front of the 'ELite 5' analyzer to open the front panel. Allow enough space if you want to use optional external keyboard, mouse or bar code reader.

Your selected location should allow placement of the reagents in an unobtrusive location below the laboratory bench that the instrument is placed on, or on the same surface. Placement below the laboratory bench also allows for storage of a spare set of reagents. Never place the reagents above the 'ELite 5' analyzer.

See **Chyba! Nenalezen zdroj odkazů.** and **Chyba! Nenalezen zdroj odkazů.** for more information about proper analyzer location and clearance.

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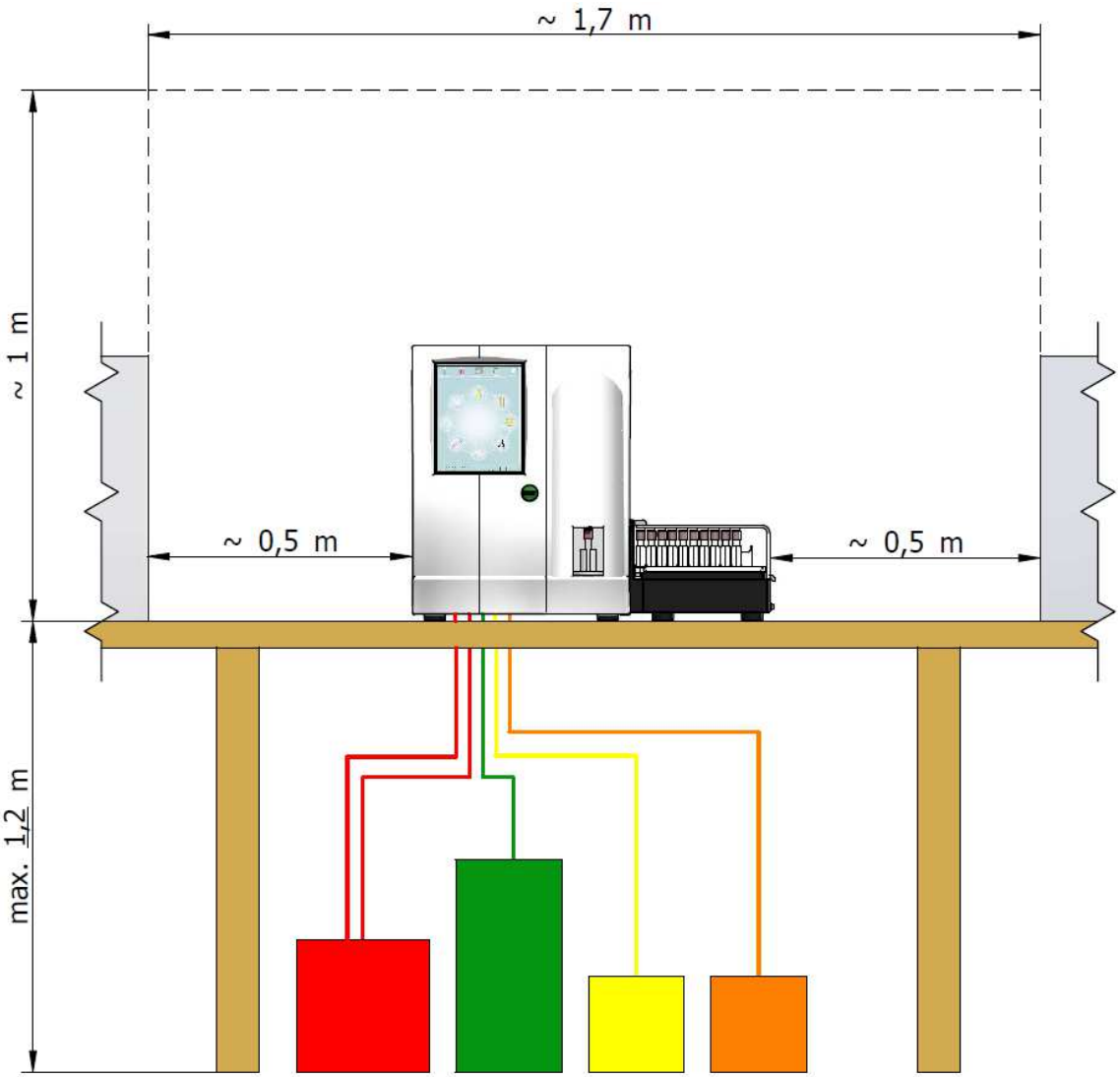

Figure 1. ELite 5 with Autosampler Space Requirements

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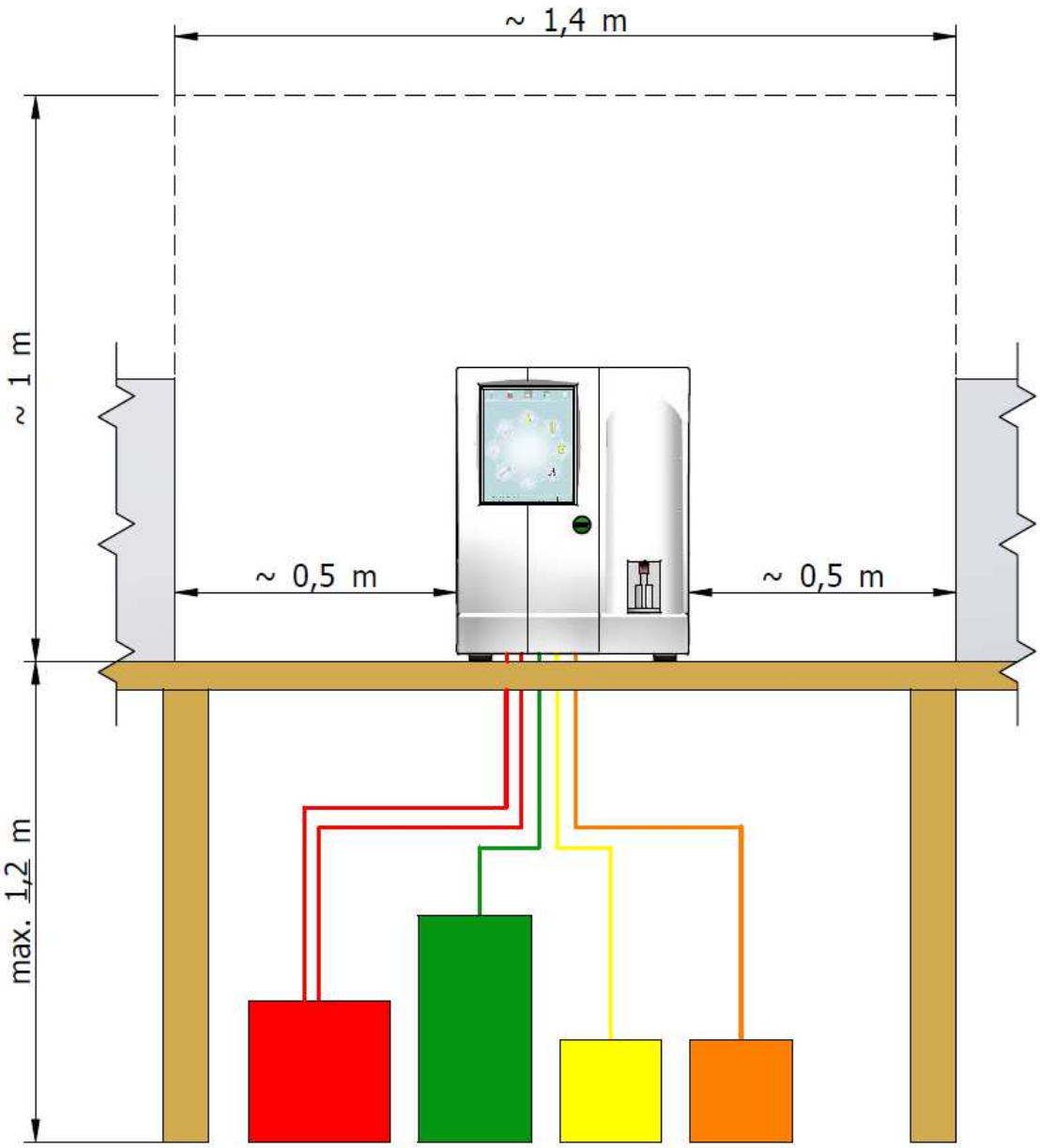

Figure 2. ELite 5 Without Autosampler Space Requirements

1.7 Weight Requirements

The 'ELite 5' analyzer weighs 35 Kg (77 lb) without the Autosampler. The 'ELite 5' with optional Autosampler weighs 47Kg (104 lb). Adding an external keyboard, printer etc. can bring the total weight up to 60 Kg (132 lb). If you decide to store the reagents on the same surface, then the combined weight can reach 100 Kg (220 lb).

Please select a table, laboratory shelf, or other location which can support the weight of the 'ELite 5' with accessories and is free from vibration.

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	**To allow reliable operation and to provide a safe working environment, make sure that the table supporting the unit is stable enough to carry the weight of the instrument and accessories.**

1.8 Waste Disposal

'ELite 5' analyzer waste contains human blood and reagents that are chemically and biologically active, and should be considered to be a potential infection and biohazard threat. Safe laboratory practices must be followed including the use of personal protective when operating the 'ELite 5' and handling blood, reagents, and waste.

1.9 Known Limitations

The 'ELite 5' is not intended for analysis of animal blood samples. Anti-coagulated and homogenized human blood samples must be free from contamination.

Blood samples must be analyzed within 12 hours of venipuncture.

1.10 Emergency Situations

Always follow all applicable laws and regulations with regard to emergency situations.

If the 'ELite 5' needs to be powered off due to an emergency situation (like fire, thunderstorm etc.), follow the procedures in chapter 6.3.4.

	**In case of fire, do not use water to extinguish the fire unless the 'ELite 5' is disconnected from the electrical network!**

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2 Product Support

Your sales representative is trained and qualified to answer questions about applications and the operation of the ‘ELite 5’ analyzer. If you have additional questions regarding the ‘ELite 5’, please ask for manufacturer support through your sales representative.

Erba Lachema makes every effort to provide excellent support and up to date information and services regarding the ‘ELite 5’ analyzer. Software updates and application documents are available on the Erba Lachema web site at http://www.erbamannheim.com.

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3 Installation

Your Erba Lachema certified service engineer will perform the initial installation of the 'ELite 5' analyzer and train you and selected laboratory personnel on the proper use and maintenance of the analyzer. The analyzer should only be operated by properly trained personnel. You'll also be explained about necessary maintenance actions.

3.1 Package contents

3.1.1 The 'ELite 5' Analyzer Package

After opening the 'ELite 5' analyzer packaging, you will find an accessory box. The analyzer is in a plastic bag in between cushioning protective material. After opening the bag, remove the desiccant packs. The package should contain the following items:

- 'ELite 5' analyzer
- Accessories box on top of the analyzer, containing:
- Power cord
- User Manual (this document)
- Sample tube adapter for the individual sample unit (1 pc)
- Reagent tube kit (in a plastic bag, with special caps)
- Plastic waste container
- Cardboard box for the waste container
- "Preparing for shipment" tube kit
- 'ELite 5' analyzer Final Check Report

Please inform your Sales Representative if any item is missing or damaged. Retain the original 'ELite 5' analyzer packaging for future transportation and storage.

3.1.2 The Autosampler Package

The Autosampler is an optional unit that attaches to the ELite 5. If the optional Autosampler unit was ordered, package should contain the following items:

- Autosampler unit
- Sample tray
- Sample racks -10 pieces
- Autosampler Final Check Report

Please inform your sales representative if any item is missing or damaged. Retain the original Autosampler packaging for future transportation and storage.

3.1.3 Small Sample Package (optional)

- SSM Micro dilutor front-left frame rail assembly
- Ribbon cable #1 with connectors for the SSM micro dilutor
- SSM valve assembly with connected Tygon tubing
- "T" fitting with attached 3 cm Tygon tube
- 4-way ribbon cable #2 with connectors for the SSM valve assembly
- Pre-dilution chamber plus pre-dilution chamber holder assembly with rubber chamber protector
- SSM sample rotor plate
- 2 pcs of 3x10 hex screws with washers (used for mounting SSM pre-dilution chamber holder)
- Adhesive cable holder, plastic adhesive tube holder and 2 pcs of plastic tube holders

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- Silicon edge protectors and cable guide tool

3.2 Connecting the reagents

The 'ELite 5' is capable to aspirate reagents from 1.2m (~4'). (Measured from the bottom of the reagent container to the table level where the 'ELite 5' is installed.)

You will use 3 input reagents and the 2 waste-output. Select a location close to a suitable drain. The waste container should be periodically emptied.

You can place the reagent below or on the same level where the 'ELite 5' is installed. Do not place the reagents to a higher location than the bottom of the 'ELite 5', because in case of any tubing problem, valve error etc. the reagent can spill out.

3.3 Power connection



The analyzer should only be operated from a wall outlet meeting general specifications of power input requirements: 100-127VAC/200-240VAC; 47Hz to 63Hz
Power Consumption: maximum 400 VA
If the power network is not reliable, contact your representative for options (e.g. installation of an external UPS module).
Only the power cord supplied with the instrument should be used. Avoid using extension cords.

Please check the power consumption of the additional devices (printer) as well.

3.4 Connections to the peripherals

If you plan to connect any external devices (printer, host-computer etc.) to 'ELite 5' then prior the installation please check the possible cable paths. If it is necessary then make all the preparations (cable-channels, cable-binders, drilling trough tables, walls etc.) before the installation starts.

Although the Windows® XP® Embedded operating system can recognize several peripheral devices please prepare the installation material provided by the vendor of the device.

3.5 Environmental conditions



The 'ELite 5' is designed for laboratory operation. Mobile operation is not supported. Operate 'ELite 5' at the ambient temperature within the range of 15-30°C (59-98 °F) and maximum relative humidity of 80%. The optimum operating temperature is 25°C. Reagents should be stored at a temperature range of 15-30°C. The 'ELite 5' operates properly up to 3000 meters above sea-level.
Do not place the reagent containers to a higher position than 'ELite 5'. This is to avoid unintentional spilling of reagents. The vertical distance between the reagent container and 'ELite 5' must not be more than 120 centimeter.

The instrument should be placed in a well-ventilated location. The instrument should not be placed near potentially interfering devices capable of emitting radio frequencies (e.g. radio or television transmitters/receivers, radars, centrifuge, X-ray devices, fans, etc.).

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Operation at an altitude over 3000 meters (9000 ft) is not recommended.

3.6 Visual inspection

To ensure correct operation, and to check that the instrument has been delivered to you without any damage, please check the following before starting the unit for the first time:

'ELite 5':

- The front panel should have no cracks;
- The screen should have no cracks;
- No visible dents or bumps on instrument housing (front, side rear, top cover);
- Open the front panel of the unit:
    - The front panel is easy to open and close (see section 15.1);
    - Inspect that the syringes are not cracked;
    - Check if the shear valve has the safety card installed;
    - Check if there are no fluid inside the tubing;
    - Check if there are no salt build-ups inside the tubing.

Autosampler:

- No visible dents or bumps on the housing of the Autosampler;
- The transparent cover opens and closes smoothly;
- The sample-tray and the racks have no visible damage.

3.7 Moving to the selected location

Check the presence of all necessary connections.

Move the 'ELite 5' to the selected location.

If it is hard to access the back of the 'ELite 5' after it is in the final location then connect the reagent tubes to the 'ELite 5' but not to the reagent containers. (For details see chapter 3.2)

Be sure that the main switch (right next to the power connector) is in off position.

3.8 Removing the safety card from the shear valve

In order to prevent the damage of the shear valve during transportation a protective plastic card is placed between the ceramic disks of the shear valve. Before using the 'ELite 5' instrument, this card must be removed.

Please perform the following steps:

- Open the cover of the equipment
- Locate the white plastic card in shear valve
- Pull out the card
- Check and tighten the locking screw of the shear valve if necessary

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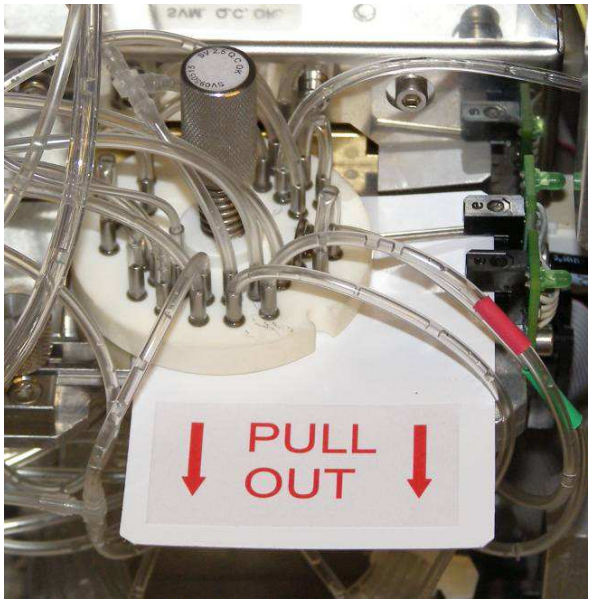

Figure 3. Shear Valve with plastics card

3.9 Connecting the Autosampler

If the optional Autosampler unit also purchased then:

- Remove the secondary cover-plate from the right-side cover-plate of the ‘ELite 5’;
- Check that the connection surface is clean and there are no blocking objects (like hanging, swinging cables);
- Push the Autosampler into the ‘ELite 5’ until the clamps are locked.

3.10 Connecting the reagents

If it was not done beforehand than:

- Connect the reagent tubes to the ‘ELite 5’:
  - Use the supplied connecting tubes and special bottle caps;
  - Be sure that the color on each tube, cap and connector in the back of the instrument match.
- Connect the reagent containers to the reagent tubes.

The analyzer operates with chemically and biologically active reagents. Direct (skin) contact with these reagents should be avoided. Please read reagent descriptions carefully for possible emergency actions. Only original reagents are usable with ‘ELite 5’, available from Erba Lachema.

Place the reagent containers near the instrument, to an accessible location. Do not place the containers to a higher position than ‘ELite 5’. This is to avoid unintentional spilling of reagents.

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4 General Overview and Principles of Operation

4.1 General Overview

The 'ELite 5' is a fully automated high quality hematology analyzer for *in vitro* diagnostic use in clinical laboratories. It provides precise and accurate 5-part differential measurement using a laser based optical measurement technology.

The 'ELite 5' analyzer uses the impedance method for measurement of leukocytes (WBC), erythrocytes (RBC) and platelet (PLT) concentrations. Measurement of the hemoglobin (HGB) content of red blood cells is accomplished by photometric measurement technology. 5-part leukocyte differentiation (LYM%, MON%, NEU%, EOS%, BAS%) is accomplished using optical laser-based flow cytometric technology.

A vivid color touch screen display is featured with an intuitive, informative, and attractive user interface. A START button allows one-touch operation for ease of use.

The 'ELite 5' analyzer's unique software system supports the use of many commonly used external printers with its USB connections. The 'ELite 5' internal database is capable of storing 100,000 patient, QC, and calibration result records including flags and graphical scatter diagrams and histograms. The system software is field-upgradeable to ensure up-to-date operation.

An automatic optional Autosampler is available (sold separately) for automated processing up to 100 sample tubes for increased laboratory efficiency. The system software supports a variety of flexible LIS download techniques for efficient integration into laboratory workflow.

The 'ELite 5' features advanced Ethernet LIS connectivity using the HL7 protocol in addition to standard serial interfaces, providing the clinical laboratory with flexible connectivity options.

Small Sample Module (optional) enables to test patient samples having only a small venous blood volume.

4.1.1 Measured Parameters

'ELite 5' determines 26 hematology parameters including 5-part WBC differential. The instrument requires 110 µl of whole blood-sample in closed- and open-vial mode. Cycle time is 60 seconds.

With SSM (small sample module - optional) 25 µl of venous blood is aspirated in open-vial mode.

Parameter	Symbol	Measurement method
White Blood Cell count	WBC	Impedance measurement
Lymphocyte count	LYM	Calculated
Monocyte count	MON	Calculated
Neutrophil count	NEU	Calculated
Eosinophil count	EOS	Calculated
Basophil count	BAS	Calculated
Lymphocyte percentage	LYM%	Optical measurement
Monocyte percentage	MON%	Optical measurement
Neutrophil percentage	NEU%	Optical measurement
Eosinophil percentage	EOS%	Optical measurement
Basophil percentage	BAS%	Optical measurement

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Parameter	Symbol	Measurement method
Red Blood Cell count	RBC	Impedance measurement
Hemoglobin	HGB	Photometric measurement
Hematocrit	HCT	Calculated
Mean Corpuscular Volume	MCV	Derived
Mean Corpuscular Hemoglobin	MCH	Calculated
Mean Corpuscular Hemoglobin Concentration	MCHC	Calculated
Red Blood cells Distribution Width	RDWcv	Derived
Red Blood cells Distribution Width	RDWsd	Derived
Platelet count	PLT	Impedance measurement
Mean Platelet Volume	MPV	Derived
Platelet Distribution Width** *(for Research Use Only)*	PDWcv	Derived
Platelet Distribution Width** *(for Research Use Only)*	PDWsd	Derived
Thrombocrit** *(for Research Use Only)*	PCT	Calculated
Large platelet count	PLCC	PLT count above 12 fl in size
Large platelet percentage	PLCR	Calculated
**The PDWcv, PDWsd, and PCT parameters are considered to be for Research Use Only (RUO), and will be marked on the screen, printout, database, and LIS transmission.		

Table 1. ‘ELite 5’ Analyzer Parameters

4.1.2 Approved Reagents and Control Materials

Always use reagents, control and calibration materials that are recommended and approved by the manufacturer. The ‘ELite 5’ analyzer, controls, calibrator and reagents are part of a system and are carefully designed and selected for optimal performance. Using unapproved reagents or controls may cause false flagging or incorrect, inaccurate results.

Only original Erba Lachema reagents may be used in the ‘ELite 5’ analyzer. For additional details about these materials, please contact the manufacturer directly.

4.1.3 Original Erba Lachema Reagents

Use only the original Erba Lachema reagents listed below to ensure proper performance of the ‘ELite 5’ analyzer. Reagents are manufactured and provided by Erba Lachema s.r.o., and are for *in vitro* diagnostic use only. For using leave the reagent at room temperature for at least 12 hours. Do not use reagent once frozen.

Kat. číslo	Název	Objem
HEM00006	Erba Lyse-5P	5 l
HEM00002	Erba Diff-5P	1 l
HEM00005	Erba Hypoclean CC	100 ml

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HEM00003	Erb Dil-5P	20 l

Additional cleaning solutions – use as needed

HEM00017	Erba Clenz	1 l
HEM00016	Erba Hypoclean	1 l

For package insert for reagents and cleaning solutions please see Appendix

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4.2 Principles of Operation

The 'ELite 5' analyzer uses a combination of methods to provide measurement results:

- Volumetric impedance (the Impedance method) is used to determine the cellular concentrations and volume distributions of leukocytes (WBC), erythrocytes (RBC), and platelets (PLT).
- Photometric measurement of light absorbance is used to determine hemoglobin (HGB) concentration.
- Optical measurement of light scattering and diffraction is used to determine 5-part leukocyte (LYM%, MON%, NEU%, EOS%, BAS%) differential parameters.

4.2.1 Volumetric Impedance Method

The volumetric impedance method determines cellular concentrations and volume distributions of cells by detecting and measuring changes in electrical impedance when particles suspended in a conductive liquid pass through a small aperture. The method is "volumetric" because a small known volume of blood is precisely diluted with a conductive diluent and forced through the aperture at a fixed rate.

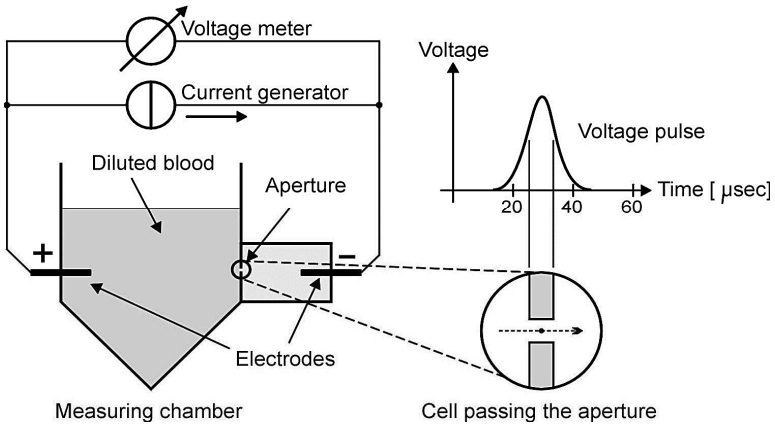

Figure 4. Volumetric Impedance Method

A constant direct current flows between the electrodes on either side of the aperture. Each cell passing through the aperture causes a change in the electrical impedance of the conductive blood cell suspension. This change is sensed by the 'ELite 5' electronics and converted to an electrical pulse. The quantity of pulses is proportional to the number of particles. The intensity of each pulse is proportional to the volume of the particle. The volume distribution diagrams of the particles result in the WBC, RBC, and PLT histograms that measured in femtoliter volume units.

Electronic discrimination allows separation of erythrocytes (RBC) and platelets (PLT). A lytic reaction lyses erythrocytes to clearly measure leukocytes (WBC).

4.2.2 Photometric Light Absorbance Method

A lysed blood sample dilution can be analyzed for hemoglobin (HGB) concentration based on its stable chromogen content. The reagent lyses the red blood cells causing the release of cellular hemoglobin. The hemoglobin concentration is measured by taking a photometric reading across the 'ELite 5' WBC chamber. The HGB measurement is calculated as the

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difference between blank and sample measurement with and without illumination to reduce the effect of liquid refraction and incident light.

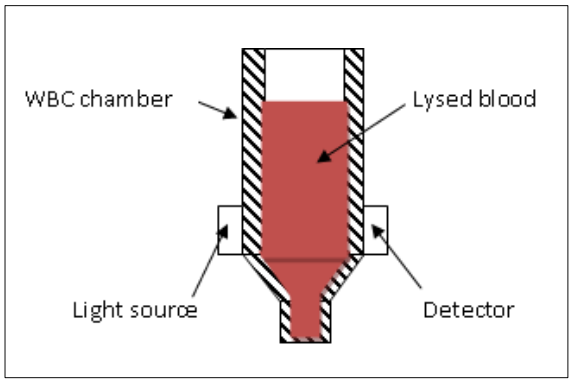

Figure 5. Photometric Light Absorbance Method

4.2.3 Optical Light Scatter and Diffraction Method

Optical measurement of light scattering and diffraction is used to determine 5-part leukocyte (LYM%, MON%, NEU%, EOS%, BAS%) differential parameters. An optical measuring head contains a focused laser source that is used to illuminate a stream of leukocytes (WBC) suspended in an optically clear diluent moving through a flow cell.

The cells scatter light as they flow through the path of the laser beam. An optical detector senses changes in the intensity of the scattered laser light which are proportional to the cell volume and granularity of the cell's internal structure. The 'ELite 5' electronics convert these changes to electrical pulses which are gathered and stored for analysis. Five part population discrimination is based on analysis of the two dimensional volume and granularity distribution scatter diagram.

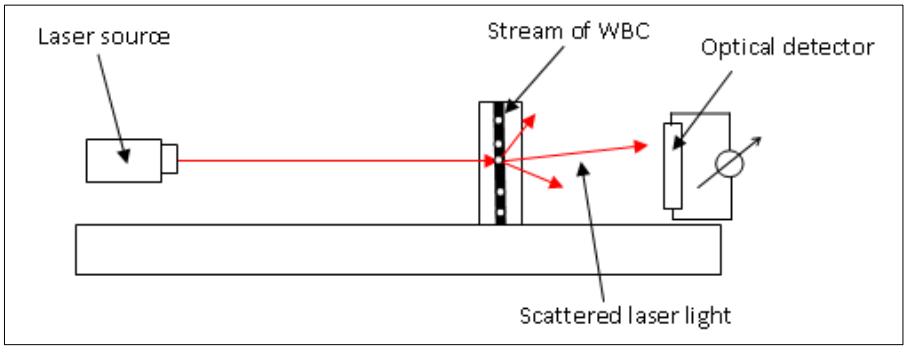

Figure 6. 'ELite 5' Optical Head Block DIagram

Cells with greater volume or size or more granularity will tend to scatter greater amounts of light. The intensity of scattered light is detected by an optical signal processing system.

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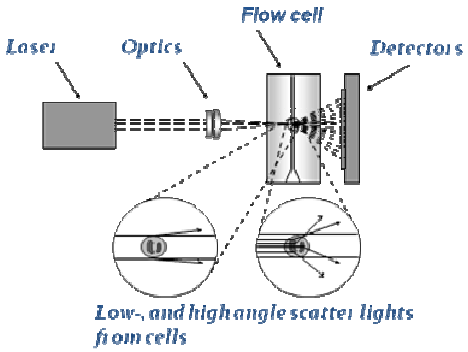

Figure 7. Optical Signal Processing System

External structure (and the size of the cell) causes lower angles of scatter, and internal granularity or complexity causes higher angles of diffraction. Both low and high angles of light scatter are captured by optical sensors, providing the 'ELite 5' analyzer with two independent measurements for each cell crossing the path of the laser beam.

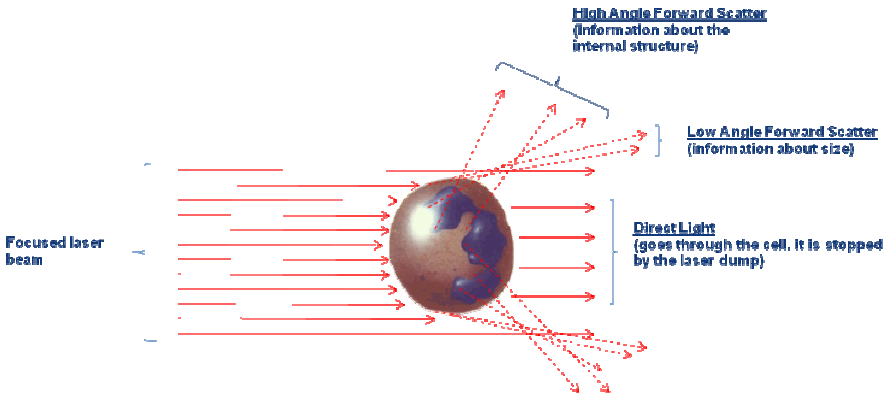

Figure 8. Cellular Light Scatter

The light scatter data are gathered and plotted as a two dimensional scatter diagram. Similar cells have similar scatter characteristics and tend to group together. This allows the analytical software to differentiate and identify the leukocyte populations and generate the 4DIFF and BASO scatter diagrams.

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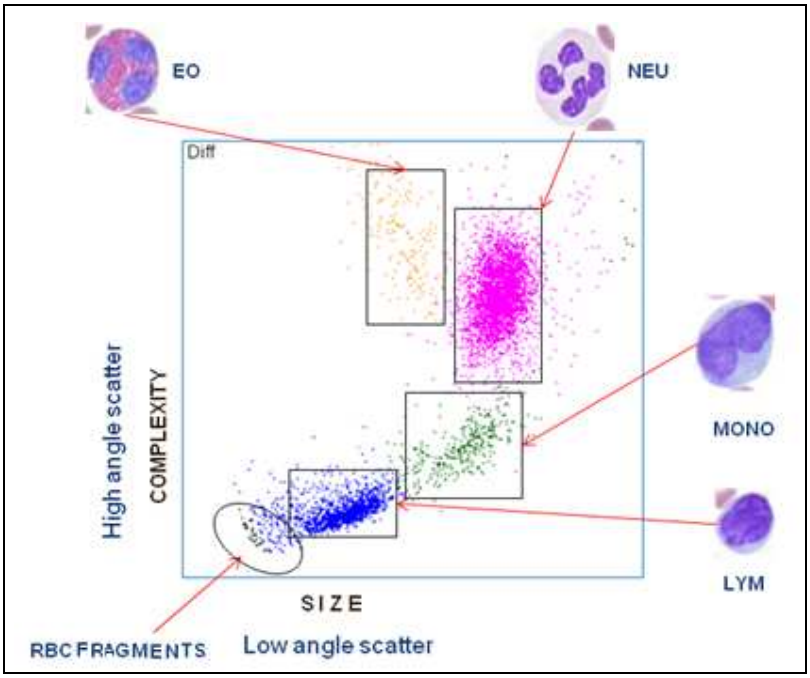

Figure 9. 4DIFF Scatter Diagram

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Inside the 'ELite 5' Analyzer

4.2.4 Front Panel

The touch screen display is the primary user interface of 'ELite 5' analyzer for user interactions and data entry. The LCD screen can be cleaned with a damp sponge and gentle detergent.

The front panel is a hinged cover that provides easy access to the shear valve, sampling needle and syringes for cleaning and maintenance. The front panel, START button, and the sample rotor can be cleaned with a damp sponge and ethanol or isopropanol.

Sample tube is placed into a tube adapter inserted on the sample rotor for closed vial or open vial single-tube manual sample processing. The sample tube is rotated from the front of the unit into the inside of the 'ELite 5' for aspiration. This safety feature protects the operator from inadvertent contact with the aspiration needle during specimen processing.

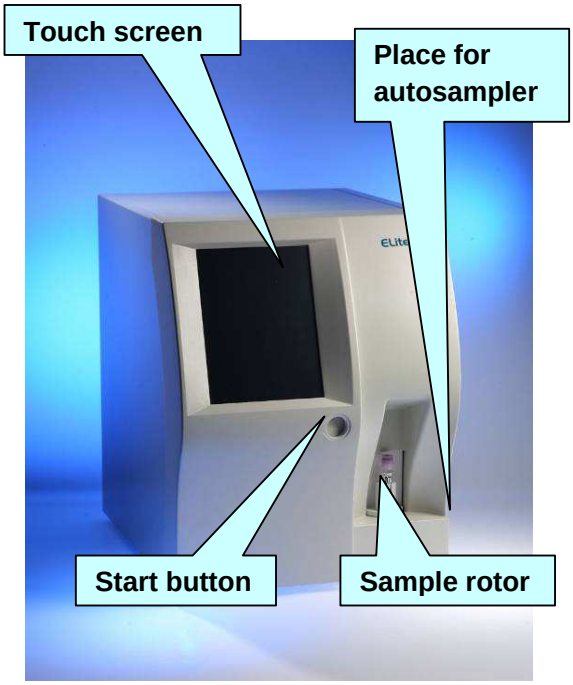

Figure 10. Elite 5 Front Panel

Automatic sample processing with the optional Autosampler can be interrupted in order to run one or more stat samples with the sample rotor. Automatic processing can be resumed after stat sample processing is complete.

The START button allows easy one-hand operation of the 'ELite 5' analyzer. The color of the START button indicates the status of the 'ELite 5' analyzer:
Green - ready to process samples
Red – busy
Orange - standby mode.

4.2.5 Back Panel

①Power connector: the 'ELite 5' power connector should be connected to a grounded power outlet that meets the requirements listed in section 1.5.

②Main power switch: this is a small switch located next to the power connector. This switch turns off all electrical power to the 'ELite 5' analyzer. Leaving this switch on allows the 'ELite 5' to remain in the standby mode. The switch is on when it is in the 'up' position labeled '1' and is off when it is in the down position labeled '0'.

③Standby switch: flipping this switch to the 'up' position takes the 'ELite 5' main computer out of the standby state and powers up internal analyzer components. Please note that this switch springs back to the down position when released and does not stay in the 'up' position.

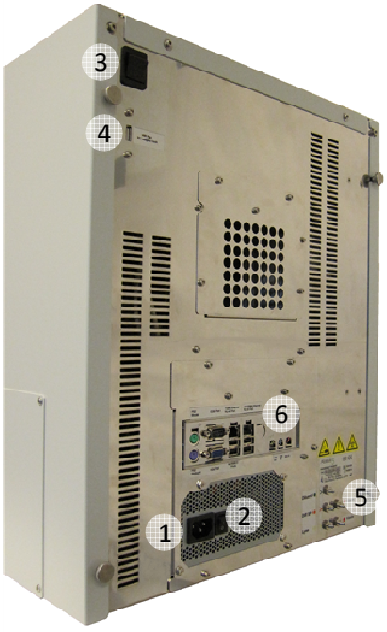

Figure 11. ELite 5 Back Panel

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④Hardware key connector: this connection is used to plug in the hardware key supplied with every new package of original Erba Lachema Erba•Lyse-5P reagent. A new reagent key provides the analyzer with the ability to run 800 measurements. When the measurement count has been exhausted, the 'ELite 5' analyzer stops processing samples.

⑤Reagent connectors: five color-coded tubing connectors provide connection to the reagents. There are three reagent connectors and two waste connectors.

●	Green	1 connector	Erba•Dil-5P diluent
●	Orange	1 connector	Erba•Diff-5P
●	Yellow	1 connector	Erba•Lyse-5P
●	Red	2 connectors	Waste

Table 2. Reagent Connector Color Codes

⑥Main board back panel I/O Ports: these are the back panel computers of the 'ELite 5' analyzer main computer board. They provide standard connection to peripherals such as external keyboard and mouse, printers, bar code readers.

Avoid getting liquids on the electrical connectors. The rear panel of the analyzer should be cleaned with a cloth or sponge with 70% ethanol

1	PS2 Mouse port for optional mouse
1	PS2 Keyboard for optional PS2 keyboard
1	COM port for LIS
2	RJ45 Ethernet port for LIS
1	VGA port (unused)
4	USB 2.0 ports for peripherals
3	Audio jacks (unused)

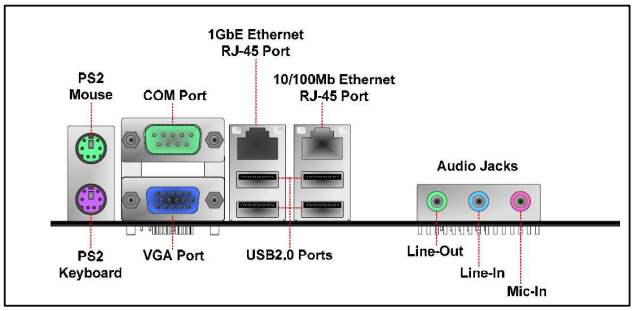

Figure 12. Main Board Back Panel I/O Ports

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4.2.6 Left Side Assembly

To access the left or right side assemblies, the side panels must be removed. Please refer to section 15.1.2 for information about removing the side panels.

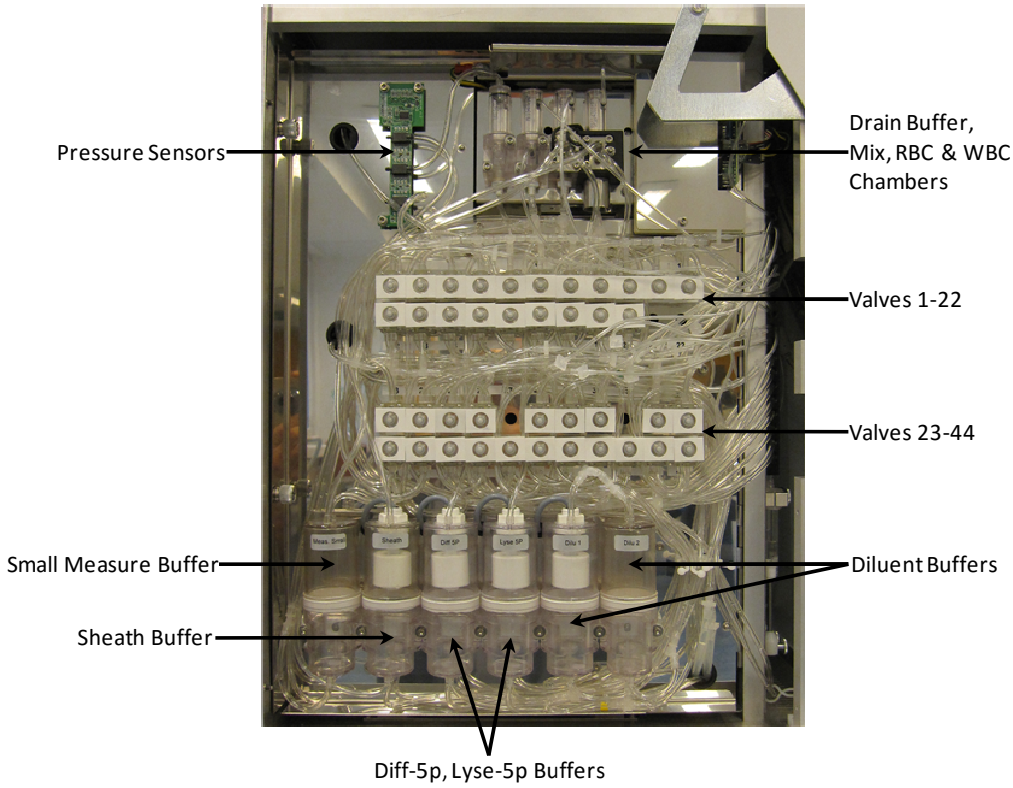

Figure 13. Left Side Assembly

- Pressure sensors measure the differential pressures of vacuum buffer for impedance base and optical measurement and empty chamber process.
- Small Measure buffer is a vacuum buffer used for impedance measurement.
- Sheath buffer is a reservoir for Erba•Dil-5P diluent for optical measurements.
- Diff-5P buffer is a reservoir for Erba•Diff-5P reagent.
- Lyse-5P puffer is a reservoir for Erba•Lyse-5P reagent.
- Diluent buffers are reservoirs for Erba•Dil-5P diluent.
- Valves 1-44 connect pneumatic components to carry out dilution, reaction, measurement, and waste disposal processes.
- Drain buffer controls chamber draining procedures.
- Mix chamber performs the first step of RBC dilution.
- RBC chamber performs the second step of RBC dilution and contains the RBC aperture.
- WBC chamber performs the WBC dilution and holds the WBC aperture and HGB photometric measurement system.

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4.2.7 Right Side Assembly

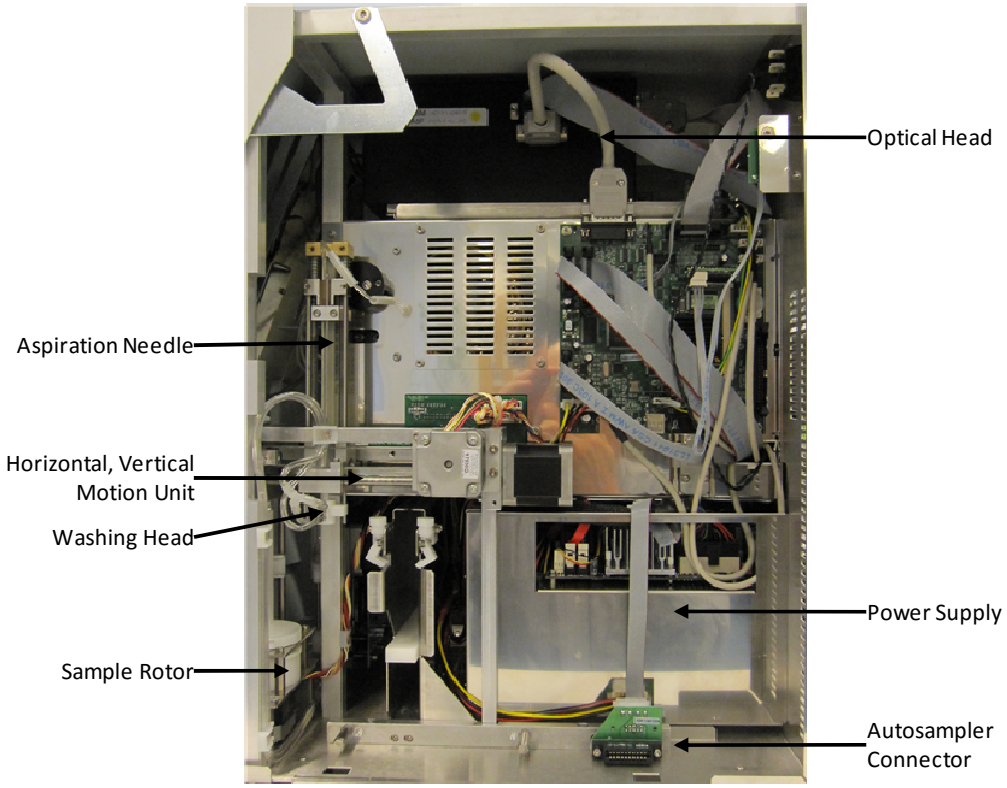

Figure 14 Right Side Assembly

- Aspirating needle aspirates a blood sample from the sample tube.
- Horizontal, vertical motion unit positions the aspiration needle.
- Washing head cleans the aspiration needle to prepare for the next sample.
- Sample rotor holds the sample tube for single tube manual presentation.
- Autosampler connector is the power and control connector of the optional Autosampler.
- Optical head contains the laser source, optical detectors and auto alignment mechanism for the optical measurement.

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4.2.8 Front Assembly

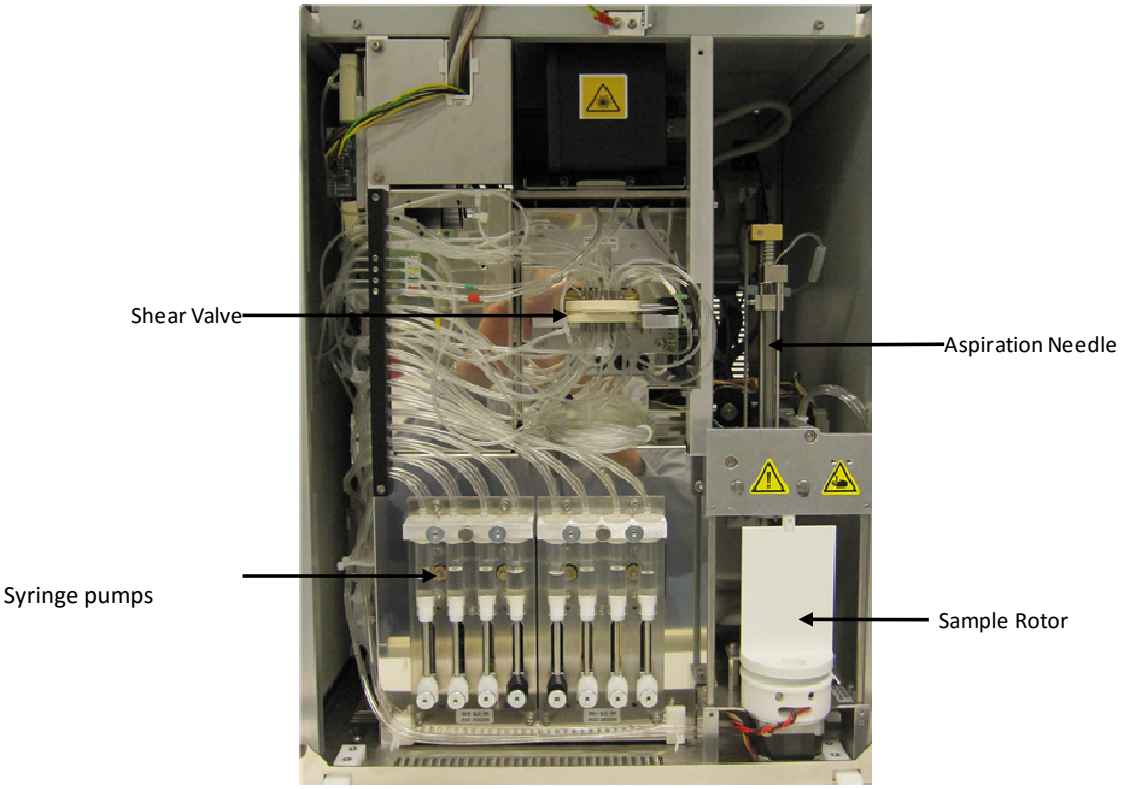

Figure 15. Front Assembly Behind the Front Panel

- Syringe pumps control the volume and flow rate of reagents through the pneumatic components.
- Shear valve is an integrated multi functional valve for segmenting precise volumes of blood.

4.3 Small Sample Mode (SSM) – optional

Instruments which have the small sample module (SSM) installed can be used for taking sample from a small amount of whole blood sample, which is not enough for normal sampling.

- **SSM measurements are only open vial measurements**.
- At least 250 µl of sample is necessary for reliable sampling.
- The analyzer will aspirate 25 µl of whole blood and put it in to the pre-dilution chamber to dilute it to 1:6.
- After pre-dilution, the needle will take 100 µl of diluted sample into the shear valve and ´ELite 5´ is going to proceed with the normal measuring process.

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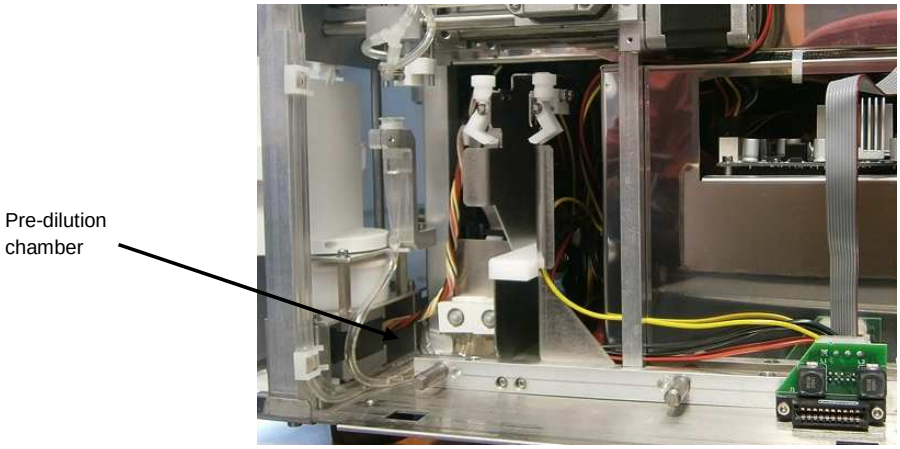

Figure 16. SSM installed instrument Sampling side with Pre-dilution chamber

In small sample mode there is no possibility using the Auto Sampler. It is working only in manual feeding mode through the sample rotor.

⚠	Small Sample Mode is NOT a cap piercer mode. Please remove the cap from the vial before measurement.

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5 User Interface

The user interface of the 'ELite 5' analyzer is designed to be intuitive and easy to use, and provide access to all user level functions. You can interact with the 'ELite 5' by using the touch screen and the virtual on-screen keypad, or by using an external keyboard and mouse (PS2 or USB). The Start button is considered an important part of the user interface, allowing one-hand, one touch processing of sample tubes.

5.1 Using the Touch Screen

The touch screen is a pressure sensitive overlay on the screen of the 'ELite 5'. It allows selection of menu items and pressing of buttons by gently pressing or tapping the surface over the selected item. This method is called 'tapping'. The touch-screen device used in the 'ELite 5' analyzer is selected for reliability, endurance and compatibility with the medical laboratory environment. Simple operations are supported, but multi-touch "gestures" or multiple tapping are not supported

The touchable items on the 'ELite 5' user interface are designed to be large enough to tap with finger. The use of a tapping tool may be useful if the operator has larger or thicker fingers, or when wearing oversize gloves. A tapping tool can be pencil eraser or a specially designed stylus available at computer or consumer electronics stores.

Do not use sharp or heavy objects to operate the touch screen. The surface material is moderately resistant to liquids. Avoid touching the screen with wet fingers, or allow liquids to come in contact with the screen or the surrounding area.

If you find that the 'ELite 5' touch screen responds in a different area than the one you are tapping, then please perform a touch screen calibration procedure before calling for service or support. See chapter 15.2 for more details on touch screen calibration and other maintenance procedures.

5.2 Using the 'Start' Button

The 'Start' button is a physical button on the front cover of the 'ELite 5'. It has the following functions:

- Start a single tube, closed or open vial measurement using the sample rotor by pressing the Start button.
- Provide color-coded feedback about the status of the measurement system.
- Green means that the 'ELite 5' is ready to start a new measurement.
- Red means that the system is busy running a measurement or a procedure.
- Orange color means that the analyzer is in standby mode.

5.3 Using an External Mouse

An external mouse can be used to perform the same functions as the touch screen. Navigate the mouse pointer over the desired item and click the left mouse button instead of tapping the touch-screen to activate the function. This procedure is referenced as clicking (click) an item. Touch screen operation continues to be available even if an external mouse is connected to the 'ELite 5' analyzer.

It is possible to move the mouse pointer to a place on the screen where it is not viewable. Move the mouse pointer up or to the left to make it visible again.

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5.4 Using an External Keyboard

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

The “Settings/Customize/On screen keyboard active” check-box allows you to choose whether the on-screen virtual keypad is presented or not when data entry is required (name, sample ID, target value etc.). If the check box is left unchecked, then the on-screen virtual keypads are not presented and an external keyboard is required for data entry. If the check box remains checked, the external keyboard can still be used by pressing the ‘ESC’ key on the external keyboard to dismiss the on-screen virtual keyboard and complete the data entry using the external keyboard.

5.5 Using the On-Screen Virtual Keypads

There are three types of virtual on-screen keypads:

- Alpha-numeric with shift and symbol options
- Numeric only
- Date

The particular virtual on-screen keypad presented is tailored to the data entry required. If only numeric values are accepted than a numeric-only keypad is presented. For selection of dates, a date keypad is presented.

The touch-pad of the ‘ELite 5’ handles single taps only. The Shift and Symbol keys are ‘sticky’ on the virtual on-screen keypads like the ‘caps-lock’ on a PC key-board. Click/tap on the appropriate buttons to type in the required value. Complete the operation by clicking/tapping the ‘Done’ button. The ‘Symbols’ button presents special characters such as the question mark or ampersand (&).

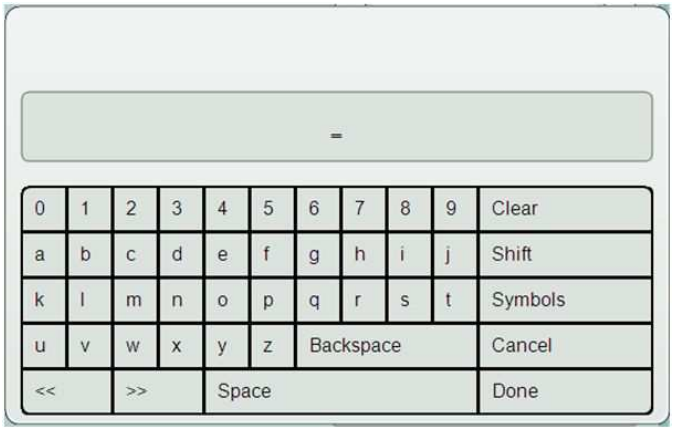

Figure 17. Alphanumeric Virtual On-Screen Keypad

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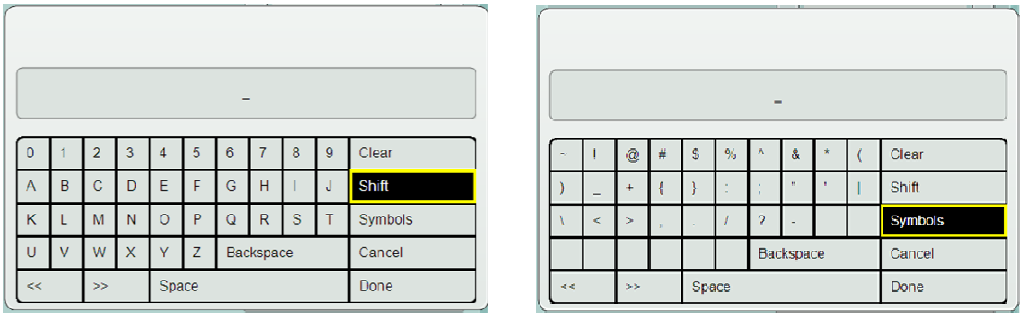

Figure 18. Sticky' Shift and Symbol Buttons

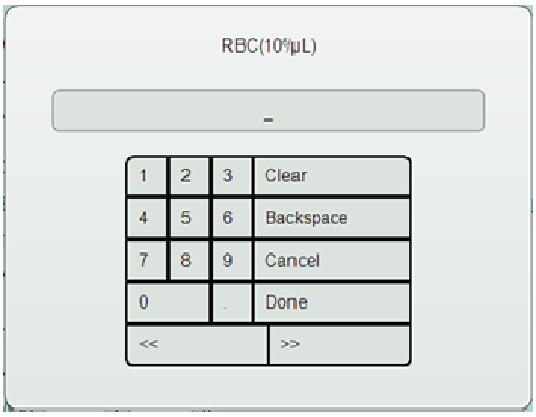

Figure 19. Numeric Virtual On-screen Keypad

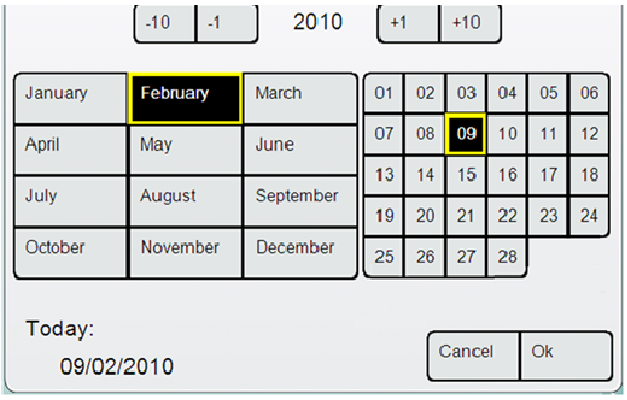

Figure 20. Date Virtual On-Screen Keypad

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5.6 Using the Graphical User Interface

The graphical user interface (GUI) of the 'ELite 5' is divided into three main sections. Refer to **Chyba! Nenalezen zdroj odkazů.** to see these sections:

1. Quick links to main functions (top section)
2. Interactive display area (middle section)
3. Status display (bottom section)

The main menu shown below is displayed in the interactive display area when the 'ELite 5' analyzer is initially powered up.



Figure 21. Graphical User Interface Sections

5.6.1 Quick Links

The upper part of the GUI is always visible during all operations and presents several quick link buttons. Selecting one of the quick link buttons determines what is displayed in the interactive display area. The selected button is framed on three sides for clear visual feedback. The quick link for Auto-sampler functions is enabled only if the optional Auto-sampler is connected and turned on.

5.6.2 Interactive Display Area

The middle section is used to display the main menu, functions, information, results, and all the panels that contain information about the active mode.

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5.6.3 Status Display

The bottom section is called the Status display, and shows information of the following:

- Status of the Autosampler unit
- The state of the reagent and waste containers
- Error/ warning icons
- Status of the pneumatic system (standby, manual measure, rinse, clean)
- Progress of the active operation
- Time
- Printer status

Clicking or tapping on an error or warning icon navigates directly to the relevant menu where the problem can be addressed, or provides the user with information on how to resolve the problem.



Figure 22. The Status Display

5.6.4 Entering Information

The 'ELite 5' sometimes requires the operator to enter information such as sample ID or patient data. In order to enter information into a data field simply tap or click on it. The data field will change color to yellow indicating that data entry is active for that field. Information can be entered using the virtual on-screen keypad or with an optional external keyboard.

5.7 The Menu System

The graphical user interface of the 'ELite 5' analyzer has primary functions that are accessible directly by means of icons or controls that are always available to the operator. The 'ELite 5' analyzer also has secondary functions that are available via two or more taps or clicks through the menu structure, or menu tree.

5.7.1 Primary Menu Items

The following menu items or functions are directly accessible:

- Start a manual single tube measurement
- Start an automated measurement
- Access the database
- Initiate printing
- Access the main menu
- Access the control panel of the Autosampler (opens with double click or tap)
- Access the time adjustment panel (opens with double click/tap)
- Access the warnings panel (only visible if an error or warning was reported)

5.7.2 Starting a Manual Single Tube Measurement

Tapping or clicking on the 'Measure' icon with the single sample tube graphic allows access to the following functions:

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- Initiate a primary blank measurement
- Make adjustments and settings about the manual measurement:
  - Enter the Sample ID (unique or auto-increment)
  - Select the associated patient
  - Select the sample type or patient mode
- Start a manual measurement
- View the measurements results in detail:
  - View the measured parameters
  - View the calculated parameters
  - View parameters that are out of the normal range
  - View error, warning, or clinical flags

See section 7.4.1 for more information about manual measurements.

5.7.3 Start Automated Measurements

Tapping or clicking the 'AS' icon with the multiple sample tube graphic allows access to the following functions:

- Initiate automated measurements in one of three run modes:
  - Full scan mode
  - Free list mode
  - Selected samples mode
  - Remote worklist mode
- Define sample parameters (the parameter list depends which one of the three sample modes is selected)
- Monitor the progress of the automated measurements
- View the details of completed measurements

See section 7.4.3 for more details about the automated measurements.

5.7.4 Access the Database

Tapping or clicking the 'Database' icon with the file cabinet graphic allows access to the following functions:

- Select completed and measurement stored as database records
- Export database records for storage or import results for viewing
- Delete database records
- Send database records to the LIS
- Review the details of selected measurements

See section 9 for more details about accessing and using the 'ELite 5' database.

5.7.5 Initiate Printing

Tapping or clicking the 'Print' icon with the printer graphic will print the active panel or measurement result according to the printer settings.

See section 13.6 for more details about printing on the 'ELite 5' analyzer.

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5.7.6 Main Menu

Tapping or clicking the 'Menu' icon with the main menu graphic displays and allows access to the main menu. The main menu is automatically displayed when the 'ELite 5' analyzer is started up. The main menu icons are arranged in an intuitive and attractive circular design.



Figure 23. 'ELite 5' Main Menu

5.7.7 Autosampler (AS) Control Panel

If you have an optional Autosampler installed, the Autosampler control panel can be opened by double clicking/tapping the Autosampler status on the left side of the status display on the bottom of the screen. The Autosampler control panel allows you to see whether the Autosampler is operational and perform an Autosampler initialization.

See section 7.4.3.6 for more details about the Autosampler control panel.

5.7.8 Adjust the Time and Date

Double click/tap the time display on the right side of the status display on the bottom of the screen to bring up a panel for adjusting the stored time and date of the 'ELite 5' analyzer. See section 13.9 for more information about time and date adjustment.

5.7.9 Open the Warning Panel

If an error or warning is currently active, an exclamation point icon appears on the status display. Click the icon to review the active error or warning and jump to the appropriate menu where the error or warning can be addressed (such as reagent replacement).

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5.7.10 Menu tree

The following is a listing of the 'ELite 5' analyzer main menu tree:

Patient
New: Add a new patient
Edit: Modify an individual patient's information
Details: View an individual patient's information
See section 12 for more details about patient data
Exit
Cancel: Cancels shutdown of the 'ELite 5' analyzer
Prepare for shipment: Performs an extensive drain procedure of the 'ELite 5' pneumatic system in preparation for shipment or an extended period of inactivity
Log off: Logs off the current user session
Shutdown: Prepares the 'ELite 5' for a complete shutdown
See section 6.3 to learn how to power down the 'ELite 5' analyzer correctly
Settings
Customize
Language: Change the active language
Limit Style: View parameter normal range status in numerical or graphical format
Sound Volume: Change the volume of the 'ELite 5' built-in speaker
On screen keyboard active: Turn off on-screen virtual keypads for use with an optional external keyboard
Patient's displayed data: Patient identifier visible in the database display
Laboratory: Seven lines of text of lab information be displayed on each printed page
Skins: Change the display skin
Demo mode: The analyzer will not perform any pneumatic action
External devices
Sending port baud rate: Select transmission rate for serial LIS
Automatic LIS: Select whether to automatically transmit results each time a sample is processed
LIS: Select Ethernet LIS connection
IP: IP address of Ethernet-based LIS host computer listening port
Port: Port number of Ethernet-based LIS host computer listening port
Bidirectional LIS: Selects whether Autosampler information downloads are allowed
System
Database column order: Change visibility and position of the database columns
Waste container volume: Selects a 10L, 20L, or no waste container (direct to drain)
Database display limit: Selects all or only last month of database record display
Use only Sarstedt-Monovette tubes from sample rotor: Change sampling adjustments to accommodate Sarstedt Monovette tubes. Please refer to Section 7.1.1 for further description of the same.
Standby time: Time period of inactivity before the 'ELite 5' automatically enters standby
Offline rinsing frequency: Time period of inactivity before the 'ELite 5' performs an offline rinse to keep the pneumatic system in peak operating condition
Screen saver – Time period of inactivity before screen saver takes effect
Special flags(G, L): Select whether G, L flags are displayed or printed
Blank Request Time: Time interval between system requests to process a blank specimen (0 h = no blank request reminders)
Units
HGB unit: Selects the units for HGB and HGB-derived or calculated parameters
Count unit: Selects the units for WBC, RBC, and PLT and derived or calculated parameters
PCT/HCT unit: Selects the units for PCT/HCT parameters
MCV unit: Selects the units for MCV parameters
Printer

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Printer: Selects which printer to print to
Printer status: Display the currently selected printer status
Color printing: Selects whether to print in color
Double sided printing: Selects whether to print multi-page printouts on both sides of a page
Items in queue: Number of items in the printer queue
Cancel all jobs: Cancels all items in the selected printer's queue
Pre-printed paper´s header length (px): Reserves space (pixels) at top of page for pre-printed letterhead
Automatic print: Selects whether to print for every new sample processed
Logo visible: Selects whether to print or omit graphical logo to printout
Warning flags are visible: Selects whether to print or omit warning flags to printout
Diagnostic flags are visible: Selects whether to print or omit diagnostic flags to printout
Refresh printers list: Refreshes the list of displayed printers
Profile limits: Enter normal ranges for various profile limits
X-B: Change X-B limits and targets
User: Add and manage users of the 'ELite 5' analyzer (only available to administrator users)
Delete user: Initiates deletion of a user account
Administrator: Selects or unselects administrator privileges for the currently selected user
See section 13 for more details about 'ELite 5' analyzer settings
Maintenance
Cleaning: Perform extended cleaning of various pneumatic components
Draining: Drain various internal system reservoirs
Empty chamber: Empty RBC, WBC, and mix chambers
Prime: Prime one or all reagent reservoirs
Fill: Fills the fluidic components of the system with reagents
Show MS On-Screen Keyboard: Brings up a vertical keyboard
Touch screen: Calibrate the touch screen location for taps and button presses
Reset Auto Sampler: Sets Auto Sampler to home position
See section 15 for more details about 'ELite 5' maintenance procedures
Calibration
Calibrate
Calibration mode: Select type of calibration procedure to run
Calibration type: Select human blood or calibration material
Target values: Enter the target values for each calibrated parameter
Cancel: Cancel a calibration procedure
Next: Initiates processing of calibration run
View Calibrations: View and delete previous calibrations
See section 10 for more details about 'ELite 5' calibration
QC
QC Measure: Initiate processing of a control sample
QC Reference select: Select which stored QC reference this measurement belongs to
Set QC Reference: Create a new stored QC reference
Load QC reference: load QC reference values from removable media such as a flash drive
Save reference: Save entered QC reference values
View QC references: Browse stored QC references
Delete: Delete a stored QC reference
Details: View detailed results for a stored QC reference
View QC data: Browse individual QC sample measurements
Delete: Delete currently selected QC run
View QC diagrams: View QC diagrams for currently selected control
Details: View detailed result screen of a QC run
View QC diagrams: View Levy-Jennings diagrams of QC data for the currently selected QC reference
View QC data: Browse individual QC sample measurements
Next diagrams: Browse the next set of QC diagrams

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View X-B data: Browse individual X-B sample measurements
Reject: Reject a run from being included in X-B calculations
View rejected: View previously rejected X-B runs
Undo reject: Restore a previously rejected X-B run and use in X-B calculations
View X-B diagrams: Navigate directly to X-B diagrams
See section 11 for more details about quality control on the 'ELite 5' analyzer
Diagnostics
Self test: perform electronic and/or pneumatic system self test
Load last self test: Loads the results of the last self test
Start electronic: Starts the electronic tests
Start both: Starts both electronic and pneumatic tests
Log: Review and obtain additional details about events in the system log
Details: Display details about the selected event in the system log
Self test: Navigates directly to self test screen
Reagent status: Reset levels for individual reagents and waste (or all) for reagent replacement
Statistics: Provides operating statistics such as cycle counts, errors, etc.
Information: Provides version information for all software items in the 'ELite 5' analyzer
Collect: Creates a collect file with information about the analyzer for troubleshooting

Table 3. 'ELite 5' Analyzer Menu Tree

5.7.11 Safety Access Codes

Some functions require password protected confirmation. For example, deleting a record from the database requires entry of a password.

The security password for deleting database entries is: **555**.

5.7.12 SSM Menu Add-ons

- With SSM mode turned on there will be new options available. In Maintenance menu there is a new option called Empty Pre-dilution Chamber:



Figure 24. Empty Pre-dilution Chamber

- Under Calibration menu, now you can calibrate for the Small Sampling measurement. Also you can view these calibartion factors.

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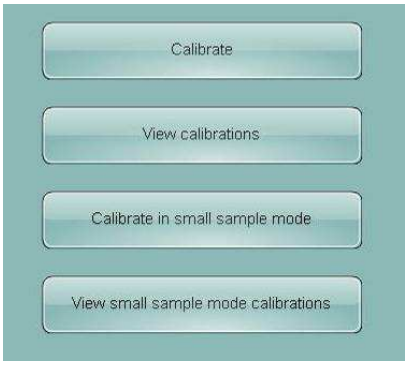

Figure 25. Calibration in small sample module

- In QC menu there is a new feature for Small Sample Mode.
- Under Diagnostics, Information menu there is a new line which is indicating the state (on/off) of the Small Sample Mode.
- In Self-test the presence of Microdilutor is also indicated.
- In measurement a new option will appear. There is a square you have to mark if you would like to use the sample Small Sample Measurement Mode.
- Also you can choose the Tube type you will use at the measurement.

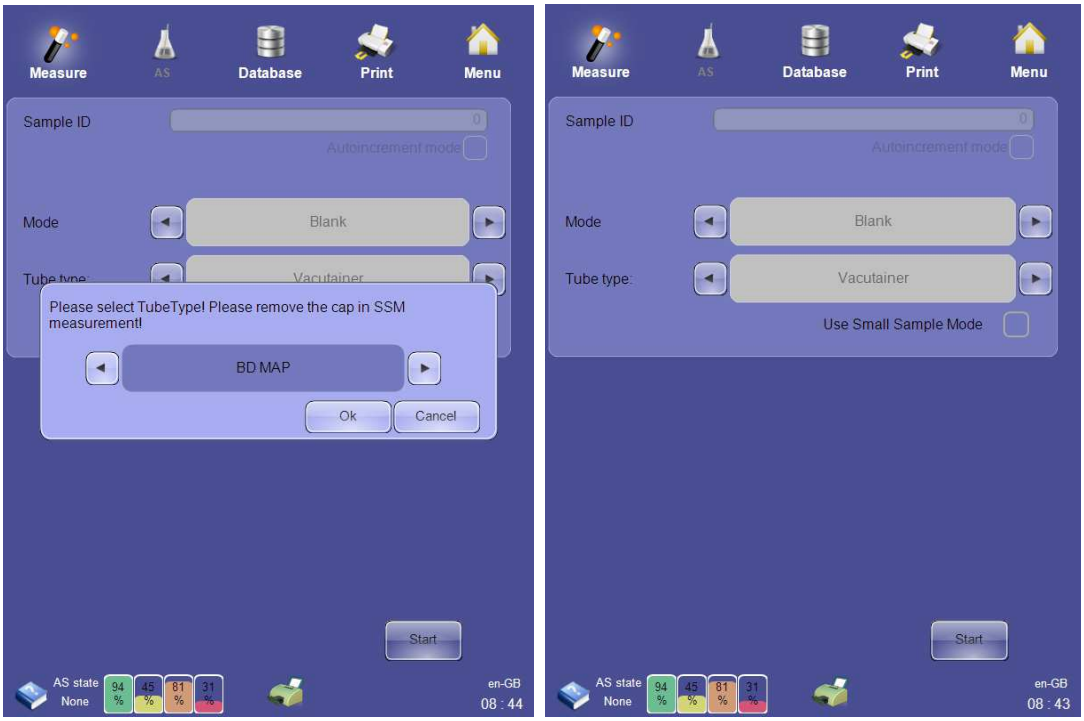

Figure 26. Measurement menu in Small Sample Mode

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6 Start Up and Shut Down of 'ELite 5'

6.1 Start Up and Shut Down Overview

The 'ELite 5' is an advanced instrument with computer and pneumatic subsystems that need to be properly started up and shut down for continuing reliable performance. Not following proper startup and shutdown procedures may lead to increased maintenance and unnecessary service calls.

The 'ELite 5' analyzer start up sequence requires four steps:

- Power up the electrical system.
- Start up the internal user interface computer and log in if the multi-user mode is activated.
- Start up the pneumatic system components.
- Perform and accept an initial 'blank' measurement.

A normal shut down of the 'ELite 5' analyzer has the reverse steps:

- Clean and empty the pneumatic system components.
- Log off (multi-user mode is activated) and properly shut down the internal user interface computer.
- Power down the electrical subsystem.

The 'ELite 5' analyzer also has a 'prepare for shipment' shut down option that performs an extended cleaning and emptying of the pneumatic components. This option can be used to prepare the 'ELite 5' analyzer for an extended period of inactivity or for shipping to a new location.

There are also emergency shutdown procedures in case of emergency.

6.2 Starting Up the 'ELite 5' Analyzer

6.2.1 Visual Inspection

Perform a visual inspection of the 'ELite 5' analyzer before starting up. This is particularly important if the 'ELite 5' is operated by multiple operators.

- Check the reagent tubes by gently pulling on them to make sure that connections are not loose.
- Open the front cover and ensure that there is no leakage around the shear valve or the syringe pumps.
- Check for salt stains around the reagent tubing and the reagent containers.
- Check that the power cord is plugged in both into the back panel of the 'ELite 5' analyzer and to the wall outlet.
- Empty the waste container. After start up reset the waste level in the "Main menu/ Diagnostics/Reagent status panel".

6.2.2 Power Up the 'ELite 5' Analyzer

To power up the 'ELite 5' analyzer, perform the following steps:

- Turn on the main power switch (small switch) on the rear panel of the 'ELite 5' analyzer located near the power connection to the 'up' position labeled '1' to power on the electrical system of the 'ELite 5' analyzer.

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- If the optional Autosampler is installed, turn the power switch on the right side of the Autosampler to the ‘on’ position labeled ‘1’ to power on the electrical system of the Autosampler.
- Turn on printers or any peripherals that have their own power switches.

The electrical system of the ‘ELite 5’ analyzer can remain powered up indefinitely. Please follow local regulations or laboratory procedures when deciding whether to fully power down the ‘ELite 5’ analyzer after work hours.

6.2.3 Start Up the User Interface

To start up the internal user interface computer of the ‘ELite 5’ analyzer, flip the standby switch near the top of the rear panel of the ‘ELite 5’ analyzer to the ‘up’ position. The standby switch springs back to the ‘down’ position after activation.



Figure 27. Start Up Logo Screen

The following sequence of events takes place after enabling the standby switch:

- The internal computer starts displaying the ‘EPIA’ logo in a rotated way.
- The embedded Windows® XP® operating system starts up. As the display initializes the screen changes color.
- The ‘ELite 5’ application software starts up displaying the ‘ELite 5’ logo screen. Individual component start up status is displayed in the bottom right corner of the logo.
- If the multi-user option is enabled then a user ID and password is required.
- The ‘ELite 5’ main menu is displayed.

At this point, the ‘ELite 5’ analyzer user interface is ready to use, but the analyzer is not yet ready to measure samples. This requires initialization of the ‘ELite 5’ pneumatic system. The following functions are available at this time:

- Use the patient database to add and modify entries.
- Review, archive, send to LIS and print existing measurement records.
- Review calibration and QC results and history.
- Change settings.

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6.2.4 User Login

If the multi-user feature is activated, a user must be logged in before the user interface of the ‘ELite 5’ can be accessed. You can log in on two different ways:

- Enter the user ID and password assigned to your account.
- Create a new user account.

The multi-user feature of the ‘ELite 5’ analyzer tracks which user is logged on when important activities are performed such as sample or QC measurements or calibration. The multi-user feature allows full access to administrator users while restricting regular users from actions that change the way the ’ELite 5’ analyzer operates, such as changing calibration settings.

See section 13.8 for more details about the user management.



Figure 28. Log In

6.2.5 Pneumatic System Start and Blank Measurement

Before measuring any blood or control samples, the pneumatic system components of the ‘ELite 5’ analyzer need to be initialized and a blank measurement run and accepted. To start the pneumatic system and run a blank measurement, click or tap the ‘Measure’ icon with the single test tube graphic on the top left corner of the screen. The following sequence takes place:

- The color of the ‘Start’ button changes to red.
- The reagents are primed.
- The measuring system is flushed.
- The sample-door, syringe, needle x/y movement, and shear valve motors are activated and tested.
- The vacuum system is activated, and pump sensors and vacuum leakage is tested.
- A blank measurement is initiated automatically.
- An empty result screen is displayed.
- The blank measurement is performed.
- The results of the blank measurement are displayed.

The results of a blank measurement must be accepted before blood or control samples can be processed. If the results from the first blank measurement are not acceptable, it does not necessarily mean that something is wrong about your ‘ELite 5’ analyzer. Please consider the following:

- Blood proteins or other particles can accumulate in the pneumatic tubing or components.

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- Contaminated reagent may cause high background. Perform cleaning/hard cleaning, replace the diluent and try Blank measurement again.
- An extended period of inactivity without performing a 'prepare for shipment' procedure may result in salt crystal development in the pneumatic components, which will increase background count. Perform cleaning.

Running additional blank measurements will usually bring the blank measurements down to an acceptable level. Blank measurements will be flagged if they exceed the following thresholds:

- WBC ≥ 0.2 * 10^3 cells/µL
- RBC ≥ 0.05 * 10^6 cells/µL
- PLT ≥ 15 * 10^3 cells/µL
- HGB ≥ 100 g/dL

If the 'ELite 5' was not in use for an extended period of time, the start up of the pneumatic system components can take significantly longer time and require more blank measurements. To prevent these problems, use the 'prepare for shipment' process when the 'ELite 5' analyzer will be inactive for an extended time.

6.3 Exiting the 'ELite 5' Analyzer

After you have completed lab operations and you are ready to exit the 'ELite 5' analyzer, you can:

- Log off
- Shut down the 'ELite 5'
- Power off the 'ELite 5'
- Prepare the ELite 5' for shipment

Click or tap the Exit icon on the main menu to access various exit options. Click or tap the 'Cancel' button to return to normal operation.



Figure 29. 'ELite 5' Exit Options

6.3.1 Log Off

Clicking or tapping the Exit icon on the main menu brings up the 'Shutting down Analyzer' panel. Select 'Log off' to end the active user session.

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Figure 30. Log Off

After the current user is logged off the login panel is displayed.

6.3.2 Shut Down

The shutdown procedure has to be used to maintain the reliable operation of the instrument. To properly shut down the 'ELite 5' analyzer, click or tap the Exit icon on the main menu and select 'Shutdown.'



Figure 31. 30 Shut Down

The shutdown procedure performs two key functions:

- If the pneumatic system components of the 'ELite 5' analyzer were initialized, a shut down procedure is performed that rinses the pneumatic components. This prepares the 'ELite 5' analyzer for shorter periods of inactivity such as overnight or over a weekend.
- The 'ELite 5' operating software and the Windows® XP® Embedded operating system are shut down. The analyzer saves all settings, closes the file system and database, and automatically shuts down the internal user interface computer.

The 'ELite 5' analyzer may ask to perform a cleaning cycle based on the analyzer's usage patterns and the state of the pneumatic components. If this occurs, the 'ELite 5' analyzer will request that a tube with cleaning solution (Erba•Hypoclean CC) to be introduced at the sample rotor. The cleaning procedure may take a few minutes. Do not turn off the analyzer until it indicates that it is safe to do so.

6.3.3 Prepare for Shipment

If the 'ELite 5' analyzer is not used for a significant period of time or is being transported to a new location then the 'prepare for shipment' procedure should be performed instead the regular shutdown procedure. Click or tap the 'Exit' icon on the main menu, then select the 'Prepare for shipment' button.

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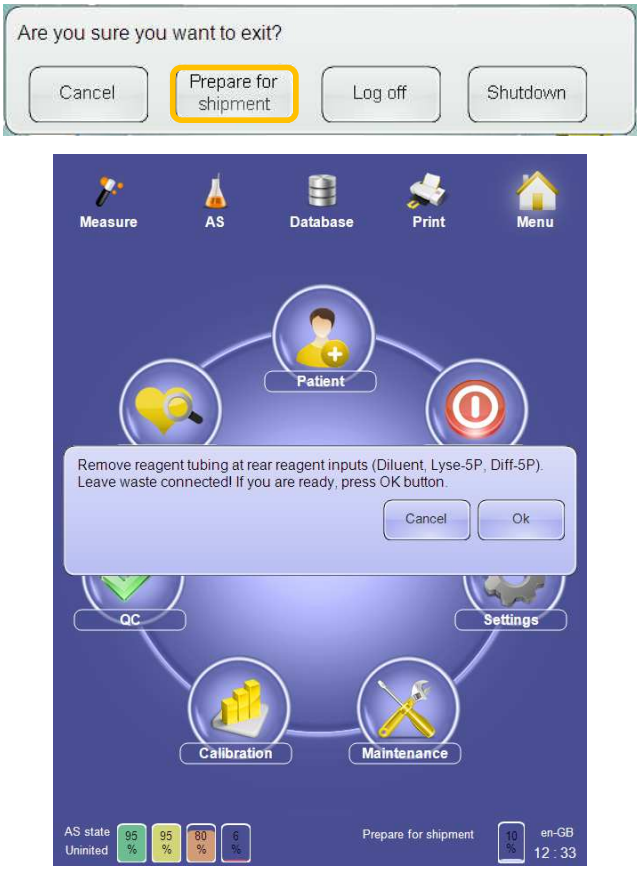

Figure 312. Prepare for shipment

⚠	**If the 'ELite 5' analyzer is powered off without a proper shutdown or prepare for shipment procedure, the following may occur:** • **The pneumatic components may lock in an undefined state. The next startup and pneumatic initialization may take longer with increased reagent consumption.** • **The 'ELite 5' application software and/or the Windows® XP® Embedded operating system can suffer damage or data loss.** • **The 'ELite 5' analyzer may have to be restarted by a service engineer after an improper shut down or power off sequence.**

The 'Prepare for Shipment' procedure should be used for following reasons:

- The reagents may spill out if the 'ELite 5' is tilted, potentially causing electrical short circuit or corrosion.
- Reagents can flow out of the 'ELite 5' if the reagent intakes are disconnected.
- Evaporation may cause reagents left in the pneumatic components in the 'ELite 5' analyzer to become concentrated and form crystals that increase blank results, damage pneumatic components, and may require a service engineer to restore proper operation.

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- Microbial growth may occur if reagents are left in an inactive analyzer for extended time periods, causing high blank results and may require a service engineer to restore proper operation.
- Accidental storage at very low temperatures may cause freezing that damages the pneumatic components.

It is strongly recommended that the 'Prepare for shipment' procedure is used if the analyzer will be inactive for more than five days. Higher temperature or lower humidity decreases the period of time the 'ELite 5' can be idle without performing the 'Prepare for shipment' procedure.

The analyzer will guide you through the preparing for shipment process. This process takes about 30 minutes and requires the following items:

- "Prepare for shipment" tube set included in your 'ELite 5' analyzer accessories kit
- Distilled water

After initiating the 'Prepare for shipment' procedure the system will prepare itself for the draining process. Do not power off the analyzer during these steps unless the system indicates that is safe to do so.

Step 1: The analyzer will ask you to disconnect the reagents from the reagent connectors on the back panel except for the waste connection. Leave the waste container tubing connected to the analyzer. The system will drain all inner reagent buffers throughout the pneumatic system. This step takes approximately 9 minutes. Do not turn the analyzer off during this step.

Step 2: The instrument will ask you to connect distilled water to the reagent inputs.

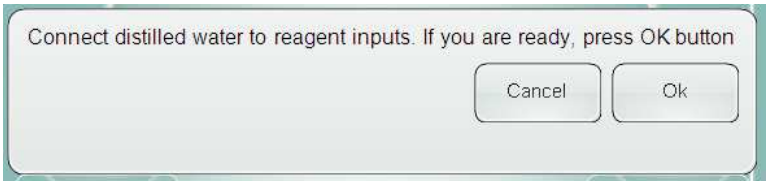

Figure 323. Prepare for shipment - Distilled Water connection

Use the 'Prepare for shipment' tube set included in your 'ELite 5' analyzer accessories to perform this step. The system will prime and fully rinse the tubing and pneumatic system with distilled water. This step takes approximately 7 minutes. Do not turn the analyzer off during this step.

Step 3: The analyzer will ask you to disconnect the 'Prepare for shipment' tube set from the reagent connectors on the back panel except for the waste connection. Leave the waste container tubing connected to the analyzer.

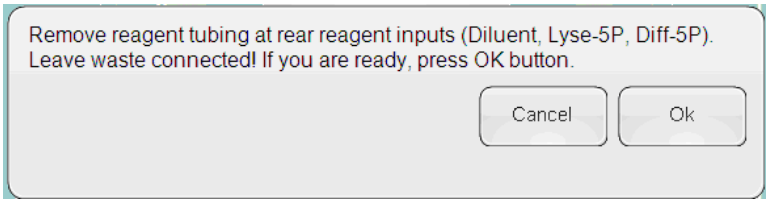

Figure 34. Remove Reagent Tubing Panel

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The analyzer will drain all liquids from the instrument. This step takes approximately 10 minutes. Do not turn the analyzer off during this step. When the process is over, the system will notify you about switching off the instrument. Click or tap the 'OK' button on the notification panel and wait until the Windows® XP® Embedded exits and power off the user interface computer.

⚠	**Do not turn off power of the 'ELite 5' at this stage. First click or tap the 'OK' button, then wait until the Windows® XP® Embedded operating system exits and shuts down the internal 'ELite 5' user interface computer.** **After the shut down process is completed, you can turn off the main power switch (small switch) on the rear panel of the 'ELite 5' analyzer near the power connection to the 'down' position labeled '0'.**



Figure 33. Shut Down Ready Panel

Step 4: Disconnect the waste container tubing from the waste reagent connector on the back panel of the 'ELite 5' analyzer.

Small droplets of distilled water may remain in the tubing after the 'Prepare for shipment' process is completed. These droplets will not cause any malfunction during transportation or the next start up procedure.

The preparing for shipment procedure cleans the Small Sample Mode related lines too, if the function is enabled.

6.3.4 Emergency Shut Down

⚠ **The procedures described in this section can damage the 'ELite 5' analyzer or cause data loss or damage to critical system computer files. Use these procedures in case of emergency only!**

6.3.4.1 Immediate Shut-Down

The immediate shut-down can be initiated by pressing the standby button near the top of the back panel of the 'ELite 5' analyzer. This is the same button which is used to start up the 'ELite 5' user interface computer. This shuts down the user interface computer without properly shutting down the pneumatic system components.

Possible side-effects:

- The pneumatic components may be left in an undefined state. The next startup and pneumatic initialization may take longer with increased reagent consumption.
- The last settings changes and measurement results are not saved.

Immediate shut down should be avoided as a routine procedure. It should only be used if loss of electrical power is imminent such as thunderstorms or if loss of uninterruptible power supply (UPS) backup power is imminent.

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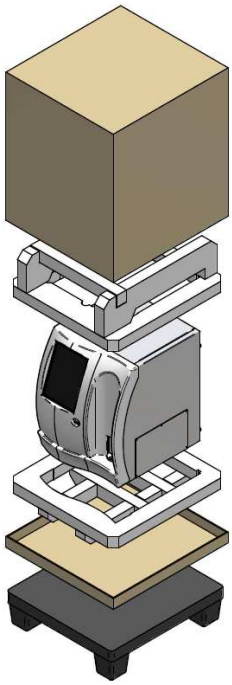
6.3.4.2 Immediate Switch Off

In case of immediate danger (fire or electric shock caused by the analyzer) you can power off the ‘ELite 5’ analyzer by turning off:

- main laboratory power supply
- unplugging the power cord from wall outlet
- main power switch (small switch) on the rear panel of ‘ELite 5’ analyzer located near the power connection to the ‘down’ position labeled ‘O’.

6.3.5 Repackaging the ‘ELite 5’ Analyzer



Before repackaging your ‘ELite 5’ analyzer for transportation or storage, always do the following:

- Perform a ‘Prepare for shipment’ procedure.
- Fully power down the analyzer.
- Disconnect all reagent tubes, power cords and peripheral connections.
- Clean the shear valve and put “pull out” card between the two ceramics plates.
- Always use the original packaging materials to repackage the ‘ELite 5’ analyzer.

Prepare the following packaging materials which were included in your original shipment:

- Mini-pallet
- Upper and lower packaging foams
- Upper and lower carton box
- Accessory box for power cord, reagent tubing, sample adapter, etc.
- Plastic bag with desiccant bag

Follow the steps below for packing up the analyzer.

- Collect all accessories into the accessory box.
- Place the pallet on the ground.
- Place the lower part of the carton box on the pallet, and place the lower packaging foam on the carton bottom.
- Put the ‘ELite 5’ into the plastic bag, and place it into the bottom foam part.
- Put a desiccant bag into the plastic bag and close it.
- Place the top packaging foam on the analyzer.
- Place the accessory box on top of the top foam spacer.
- Put on the top carton cover box over the package.
- Align the lower carton box flaps so that they fit beneath the upper box edges.
- **Use shipping straps to fix and hold the package on the pallet**.

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Make sure to use shipping straps or band to hold the package fixed on the pallet, otherwise the analyzer can be seriously damaged during shipping.

Do not apply excess force to the straps because that may break the carton box and damage the analyzer.

Never put the analyzer upside down on the pallet.

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7 Sample Measurement

7.1 Sample Types Supported by the 'ELite 5'

In this chapter you will find information about the samples usable with the 'ELite 5' analyzer.

7.1.1 Supported Sample Tube Types

The 'ELite 5' supports the following K_3-EDTA, 13x75 mm sample-tubes:

- Sarstedt Monovette®
- Becton Dickinson (BD) Vacutainer®
- Terumo Venosafe®
- BD MAP® tube (only in SSM mode)

	**Please note that the Sarstedt Monovette® sample tubes have a false bottom that is not the same as the bottom of the sample tube. The sampling depth on the 'ELite 5' analyzer must be changed for a Sarstedt Monovette® sample tube. To change the sampling depth for manually presented Sarstedt Monovette® tubes at the sample rotor, check the 'Use only Sarstedt Monovette tube from sample rotor' check box in the Main menu/Settings/System panel.** **The Autosampler automatically recognizes Sarstedt Monovette® tubes and automatically changes the sampling depth.**

You may use sample tubes from other vendors if certain conditions are fulfilled. For manually presented sample tubes at the sample rotor measurement check if the new tube type:

- Is mechanically compatible (13x75 mm family)
- Can be pierced or used in open vial mode
- Can be handled by the tube centralizing mechanisms on the 'ELite 5' analyzer

It is suggested to contact your sales representative before using the new sample tube type.

For automated sample handling with the optional Autosampler, contact your sales representative before using a new sample tube type. The Autosampler may not reliably recognize sample tube types other than the officially supported sample tubes.

Although these sample tube types are designed for multiple piercing, it is recommended to replace the cap after 3-4 piercing cycles. Small rubber bits parts can crumble into the blood and adversely affect the performance of the 'ELite 5' analyzer.

7.1.2 Sampling Depth

The 'ELite 5' is equipped with a piercing needle capable of aspirating samples from closed sample tubes. To prevent needle blockage from rubber sample tube cap material and blood particulates, the piercing needle hole is located on the side of the needle rather than at the bottom. Also, the sampling needle is given a safety clearance of two millimeters from the bottom of the tube to prevent accidental breakage of sample tubes. This means that the sampling needle cannot aspirate the last 8 millimeters (0.31 inches) of sample at the bottom of a tube. This results in sample volume that cannot be aspirated of 0.5 ml for a Beckton Dickinson Vacutainer® tube and 0.3 ml for a Sarstedt Monovette® tube.

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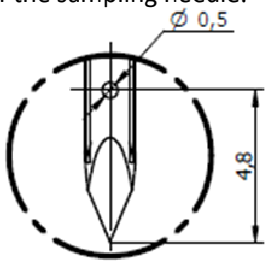
The sampling hole is 4,8 mm (~0.19”) from the tip of the sampling needle.



On the cross-section of the piercing needle you can see the 3 grooves designed to equalize the pressure in the closed sample-tubes.

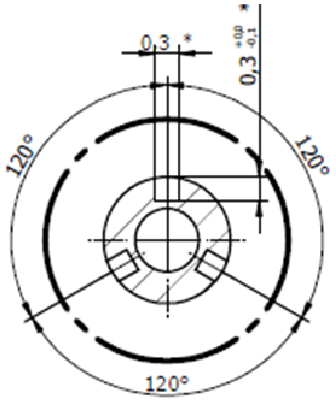


Figure 36. Sampling Needle

7.1.3 Open or Closed Sample Tubes

The ‘ELite 5’ can process both open and closed sample tubes in manual mode using the sample rotor. Manually presented sample tubes must be mixed properly before being presented to the ‘ELite 5’ analyzer.

Only closed sample tubes will be automatically processed by the optional Autosampler. Open sample tubes placed in the Autosampler will be skipped and not processed.

In Small Sample Mode ‘ELite 5’ can only take sample from vial with the cap REMOVED!

7.1.4 Sample Collection and Handling

Please consider the following when collecting and handling blood samples:

- The ‘ELite 5’ analyzer aspirates 110 µL of sample in both closed and open vial modes. Under the following conditions, the ‘ELite 5’ may aspirate less than 110 µL of sample, but will detect and flag any inadequate sample aspirations:
  - The sample tube does not vent properly and contains residual vacuum
  - The viscosity of the blood is very high
- The ‘ELite 5’ is unable to aspirate the last 8 mm (0.31 inches) or 0.3 to 0.5 ml of sample volume.
- Make sure that the sample tube is filled to the sample level line indicated by the tube manufacturer. The anticoagulant not only prevents the coagulation of blood, but also dilutes it. If the volume of blood is too low, than this dilution can adversely affect measurement results.
- Ensure that the blood and anticoagulant are properly mixed by inverting it at least 8 times. Do not shake the sample as this could damage blood cells.
- A minimum of 30 minutes should elapse between taking the blood sample and running it on the ‘ELite 5’ for analysis to ensure that the interaction of blood and anticoagulant has fully stabilized. Check the data sheet of the sample tube for the exact period of time.
- Use only K_3-EDTA anticoagulated fresh whole blood as sample.
- Analyze blood samples within 7 hours of collection.
- Samples should be analyzed at room temperature.
- Do not deliver or store the samples at temperatures above normal body temperature.

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	**All samples should be handled as potentially infectious material and treated as a biohazard.**

7.2 Sample Types and Modes

The 'ELite 5' analyzer is designed to process the following sample types:

- Whole human blood to determine the hematology parameters of the blood,
- Quality control (QC) materials for quality control purposes,
- Calibration material for calibration of the hematology parameters.

QC samples are artificially modified human or human and animal blood samples with known parameter values. QC samples can be stored for a period of time as indicated by the manufacturer.

The 'ELite 5' analyzer works in the following modes. The sample mode must be selected before a measurement starts:

- Blank mode: no sample need be presented to run a blank. Blank mode checks that the measuring system is operating correctly and that blank measurement results are acceptable.
- Human blood mode: choose one of five human blood modes (Human, Male, Female, Alternate 1 or Alternate 2). Each mode has a unique set of normal ranges associated with it. NOTE: Alternate 1 and Alternate 2 are sample modes that are different than Human, Male and Female and have user-definable normal ranges.
- Control (QC) mode: the hematological parameters of QC materials are known prior to analysis. Controls are used to check the long term stability of the 'ELite 5' analyzer.

Calibration with a calibration material is not one of the 'ELite 5' sample modes, but a specific procedure that can be accessed from the Calibration icon on the main menu.

7.3 Sample Identification

	Use caution and ensure accurate data entry when manually entering sample ID or patient ID information into the user interface of 'ELite 5' analyzer to avoid possible misidentification of sample results.

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

- Sample Mode
- Measurement time: assigned automatically by the 'ELite 5' analyzer
- Result ID: unique database identifier automatically assigned by the 'ELite 5' analyzer
- Sample ID: assigned by the operator
    - The 'ELite 5' doesn't require the sample ID to be unique
    - The sample ID can be submitted by:
        - Manual typing
        - Bar code reading (manual or Autosampler)
        - Auto-increment
    - The sample ID is not applicable on blank measurements
- Patient:
    - A record from the patient database connected to a measurement

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- Not applicable for blank and QC measurements
- Can be changed by setting the name or the database identifier of the patient displayed with the measurement results
- The ‘default’ patient (ID =1) patient is used if no patient is selected

7.4 Running Samples

The ‘ELite 5’ supports both manual and automatic sample presentation modes. Automatic sample presentation requires the optional Autosampler. The ‘ELite 5’ analyzer software automatically detects and initializes the Autosampler.

Before performing any measurement the ‘ELite 5’ should be:

- Powered up and started
- The pneumatic system initialized and a blank measurement performed and accepted

7.4.1 Manual Mode

To use Sarstedt Monovette® manually presented tubes at the sample rotor, check the ‘Use only Sarstedt Monovette tube from sample rotor’ check box in the Main menu/Settings/System panel.



Figure 37. Sarsted Monovette tube

	**Always ensure the ‘Use only Sarstedt Monovette tube from sample rotor’ check box in the Main menu/Settings/System panel is checked if you are manually presenting Sarstedt Monovette® tubes in the sample rotor. Needle damage, tube damage and spilled blood may result if Sarstedt Monovette® tubes are presented and this option is not checked.**

Select the ‘Measure’ quick link at the top left of the screen to initiate a manual measurement. The new measurement panel opens, giving you the following options:

- Review the results of the previous measurement by using the ‘Last Measure’ function. This feature can be useful if you were interrupted during the measurement batch, and you want to double-check which sample is the last processed sample.
- Define the sample ID of the sample to be processed by clicking or tapping on the “Sample ID” field:
  - You can type it in the Sample ID using the virtual on-screen keypad or an external keyboard.
  - You can use an external (USB) bar-code reader.
  - You can use the auto-generated sample ID.
- Activate or deactivate the automatic generation of sample IDs. If the ‘Autoincrement mode’ check box is checked, then the ‘ELite 5’ will add 1 to the last sample ID if it was fully numeric or offer ‘0’ if the last sample ID had any non-numeric characters.
- Connect a patient to the sample by clicking/ tapping on the Patient field:

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- The name of this field can be ‘Name’ or ‘ID’ depending on the ‘Main Menu Settings/ Customize/Patient’s displayed data’ setting.
- If you don’t select a patient then the default patient will be used.
- As you select the patient field, the patient menu is displayed. You can select an existing patient or define a new one. See section 12 or more detail about Patients on the ‘ELite 5’ analyzer.

- Select the sample mode:
  - Blank: a blank measurement will be processed. This is the only option available if the pneumatic system is not initialized, or the ‘ELite 5’ was inactive for an extended period of time. After performing and accepting a blank measurement the other modes will be available.
  - Control: QC sample is expected. QC measurements initiated from this menu will not be saved into the QC database, and are not part of the QC procedure. This mode is intended only as a quick system checks. See section 11 for more information about the QC process.
  - Human blood modes: Human, Male, Female, Alternate 1 and Alternate 2. Select the mode which has the appropriate normal ranges. NOTE: Alternate 1 and Alternate 2 are sample modes that are different than Human, Male and Female and have user-definable normal ranges.
- Start the measurement by clicking or tapping the ‘Start’ button on the screen or by pressing the physical ‘Start’ button located on the front panel of the ‘ELite 5’.

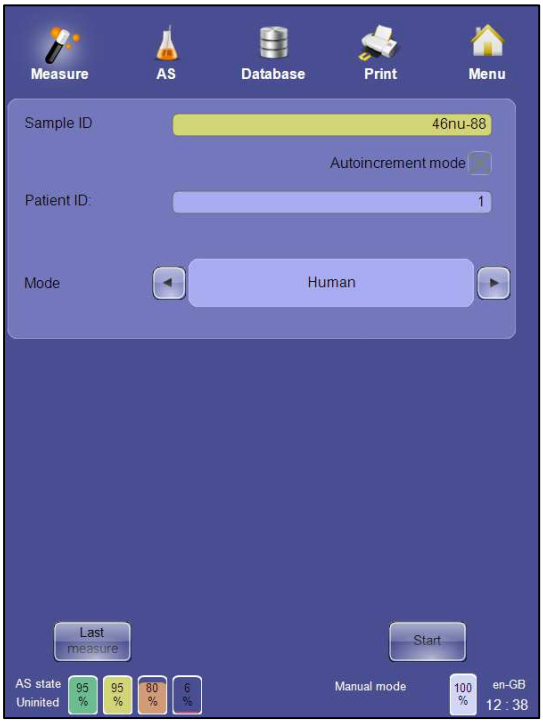

Figure 38. Sample Measurement Panel

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After starting the measurement the sample door rotates and takes the sample tube inside the ‘ELite 5’ analyzer. This is a key safety feature of the ‘ELite 5’ and protects the operator from the sample needle during routine operation. The Start button changes color to red to indicate that the system is busy processing the sample. The sample is aspirated inside the analyzer and returned to the operator when the sampling process is complete. As soon as the measurement results are available the result screen is displayed. See section 8 for more information about the results screen.

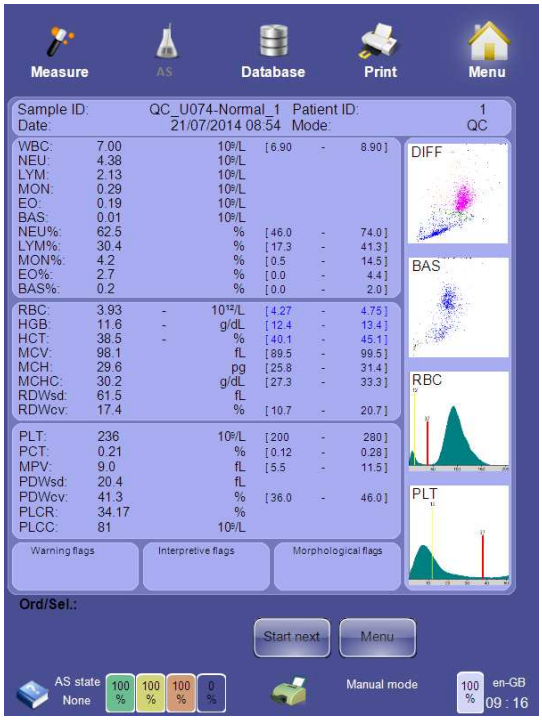

Figure 39. Result Screen

The ‘ELite 5’ analyzer will be ready to take the next sample after it has finished cleaning and preparing for the next sample. The Start button will change to green indicating it is ready to start the next sample measurement.

On the result screen you have the following options:

- You can print the results by clicking/ tapping on the ‘Print’ quick link at the top of the screen. Please note that the printing is a feature that is always available. See section 5.6 for more details about printing.
- Return to the measurement panel by clicking or tapping the using the ‘Back’ button.
- Run the next sample in routine mode by:
  - Editing the ‘Next sample ID’ just below the actual results
  - Accepting the auto-generated sample ID
  - Starting the next measurement by clicking/ tapping the ‘Start’ button on the screen or by pressing the physical ‘Start’ button on the front panel of the ‘ELite 5’.
  - Please note that in this mode the patient and sample mode will be carried over from the previous sample unless they are changed.

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7.4.2 Prediluted mode

The sample pre-dilute method test protocol has been specifically developed to allow Elite 5 users to measure CBC results on samples having only small volumes or when one of the counted parameter result is higher than its linearity range. The sample must be diluted off-line in an appropriate tube with physiological saline at a ratio of 1 part blood sample to 5 parts saline. It is important to ensure there is a sufficient final volume in the tube to enable the analyzer to aspirate the diluted sample satisfactorily. The suggested minimum diluted sample volume is 300ul from Vacutainer.

When the pre-dilute mode is selected on the analyzer all results are automatically corrected and calculated for the dilution factor.

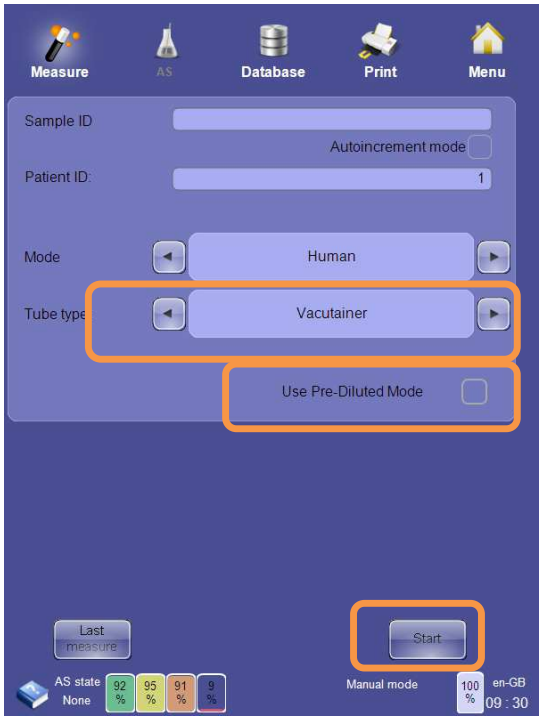

Figure 40. Autosampler Panel

How to use the pre-diluted sample mode

- Step 1. Prepare a diluted patient sample at a dilution ratio of 1:6 (1 part blood to 5 parts saline) in physiological saline. Please ensure that the sample is well mixed and placed on the analyzer immediately after preparation.
- Step 2. Select the pre-dilute mode on the analyzer
- Step 3. Place the diluted sample onto the analyzer using the
- appropriate tube holder
- Step 4. Initiate the measurement by pressing start button.
- Step 5. Analysis will take place. Please note that due to the lower cell numbers it is necessary for analyzer to count for a longer period than in the normal sample mode. (Approximate read time is 16 seconds as opposed to 8 seconds)
- Step 6. CBC results are corrected for the dilution factor, displayed on screen and can also be printed. Please note it is indicated on the screen and on the print-outs that the measurement was conducted in the pre-diluted sample mode.
- Step 7. Remove diluted sample and to move next measurement ensuring correct sample type is selected.

Important notes

- It is also important to use physiological saline and not analyzer diluent to prepare diluted samples.
- The pre-diluted sample option can only be used manually and not with the autoloader.

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7.4.3 Automatic Mode

Only human samples in closed sample tubes can be processed in automatic mode from the Autosampler. QC samples and open tubes must be processed in manual mode.

After starting up the 'ELite 5', select the 'Measure' quick link. A new blank must be processed if this is the first time a new measurement panel is opened since starting up, or if an earlier blank has expired due to inactivity. An accepted blank measurement is required before starting automatic sample processing.

Open the AS panel by using the "AS" quick link at the top of the screen.

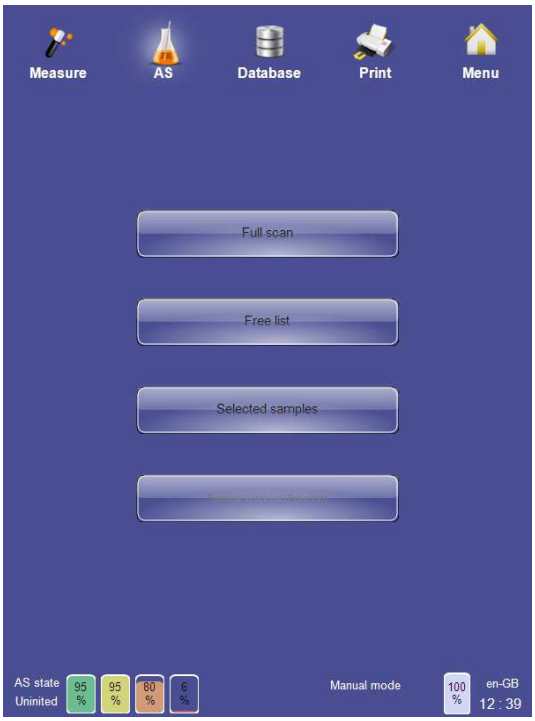

Figure 41. Autosampler Panel

From the AS panel, you can initiate automated sample measurement in 3 modes:

- Full Scan mode:
  - The Autosampler will scan the whole sample tray
  - The same sample mode will be used for all the samples
  - The sample ID is generated from the sample tube barcode (if available)
  - It is not possible to assign a patient to automatically processed samples. The default patient will be used for all samples.
- Free List mode:
  - The samples are defined in a list.
  - The following parameters can be individually defined per sample:
    - Sample ID
    - Patient
    - Sample mode
  - The samples should be placed in the same order in the sample tray as the samples defined in the list.

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  - Empty sample positions will be skipped on the sample tray.
- Selected Samples mode:
  - A sample can be defined for each position on the sample tray.
  - Only defined samples positions on the sample tray will be processed. Additional samples will be skipped and missing samples will be marked for later review.
  - The following parameters can be defined per sample:
    - Sample ID
    - Patient
    - Sample mode
- Remote Work list (Free list)
  - The samples are defined in a list received from the LIS.
  - There is no need to put the samples in the same order into the sample tray as the samples defined in the list.
  - Empty sample positions will be skipped on the sample tray.

Samples are automatically scanned and processed in the following order:

- Rack order starting with rack ‘A’ to rack ‘J’
  - Rack ‘A’ is the rack nearest to the front panel of the ‘ELite 5’
  - Rack ‘J’ is the rack nearest to the back panel of the ‘ELite 5’
- Sample order for each rack starting with sample ‘1’ to sample ‘10’
  - Sample ‘1’ is the sample closest to the ‘ELite 5’
  - Sample ‘10’ is the sample closest to rounded edge of the Autosampler cover
- Sample A1 is the first sample processed and sample J10 is the last.

7.4.3.1 Supported Barcode

Some of the ‘ELite 5’ analyzer automatic processing modes use the barcode on the sample tube to determine the sample ID of the sample tube. The following bar code symbols are supported by Auto sampler bar code reader:

Bar Code	**Checksum Status**
Code 128	Uses check digits
Code 39	No check digits used. If check digit are present they are considered part of the sample ID
Interleave 2 of 5	No check digits used. If check digit are present they are considered part of the sample ID
Codabar	Uses check digits
Code 93	Uses check digits
Code 11	Uses check digits

The use of bar code symbologies with check digits will identify incorrect bar code reads in the unlikely event that the Auto sampler bar code reader incorrectly reads the sample tube bar code. Erba Lachema recommends the use of bar code symbologies that uses check digits to help prevent sample misidentification.

Symbols of sample types in tray view:



Sample (in position 6) has bar code and cap. Auto sampler finished the mixing.



Sample (in position 5) has bar code and cap. Sample is currently measured.

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Sample (in position 4) has bar code and cap. Sample measurement is finished.



Sample (in position 1) has no barcode but has cap. Sample measurement is finished.



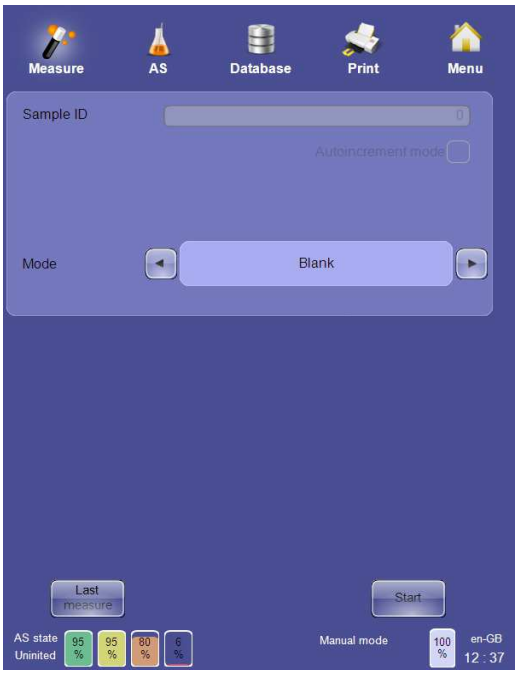
Sample (in position 2) has no cap. Sample is ignored.

7.4.3.2 Full Scan Mode

Full Scan mode is suitable for laboratories where:

- There are batches of samples with the same sample mode,
- Barcode labels are in use, and
- An LIS system rather than the 'ELite 5' is used to associate patients with sample results.

In Full Scan mode it is possible to add more samples to the batch after starting the automated measurement. As usual, an accepted blank is necessary before starting automatic sample processing.



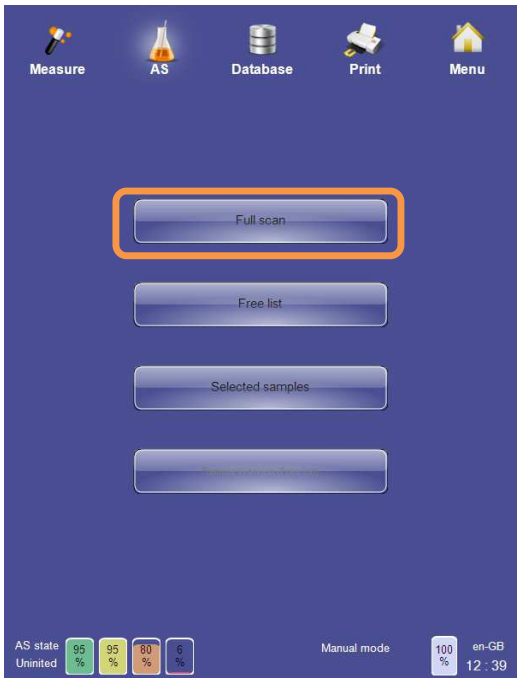


Figure42. Full Scan Automatic Processing Mode

On the Full Scan mode panel you can:

- Return to the AS panel to select a different type of automated measurement by using the 'Back' function.
- Select a common measure mode for all samples in the tray.
- Swap between the tray and list views by using the 'View list' and 'View tray' functions.
- Start the automated measurement by clicking or tapping on the 'Start' button on the GUI.

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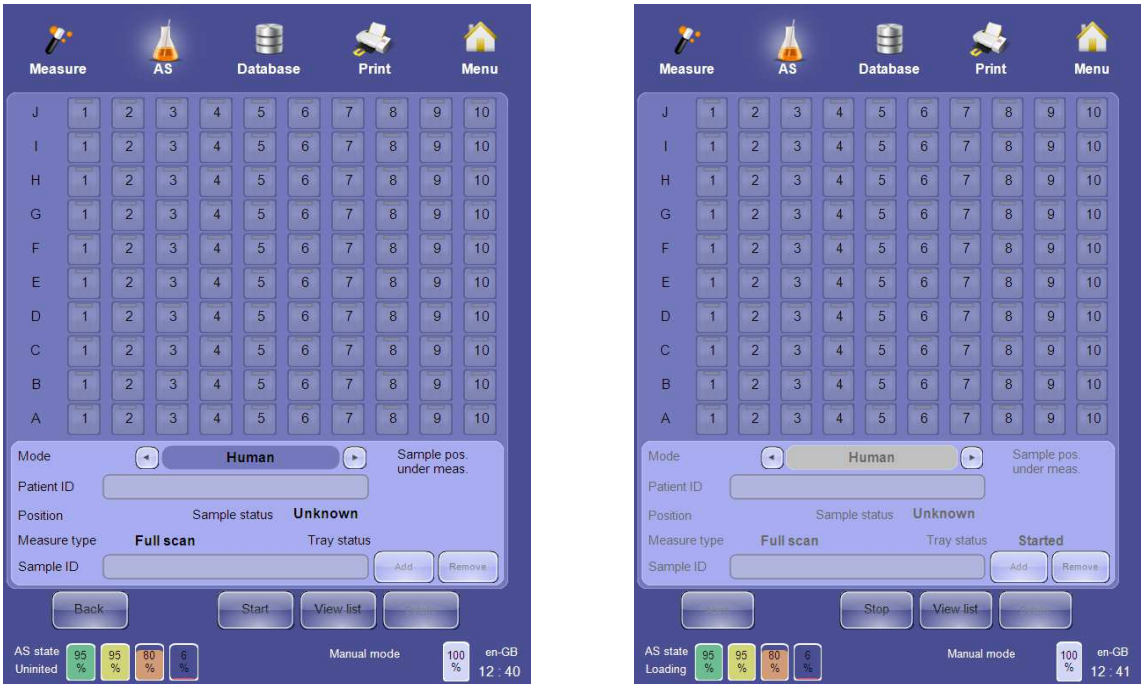

Figure 43. Full Scan Mode Tray View Progress

After starting the automated measurement in Full Scan mode, the Autosampler will scan all the sample positions on the tray. Any rows with missing racks will be skipped. The Autosampler can detect the tube type and whether the tube has a cap. Sample tubes will be skipped if it has no cap or the Autosampler cannot determine the tube type.

The Autosampler then mixes the sample tube and reads the barcode label if one is used. The sample tube is then moved to the aspiration position where the sample is aspirated and measurement is performed. The aspiration and measurement process is the same in automatic mode as in manual mode.

The sample tray progress can be followed in the tray view or the list view. The results for completed samples can be reviewed by clicking or tapping on a completed sample.

The patient ID is not editable in the Full Scan mode as it is automatically set to the default patient. The sample ID is not editable as it is read from the barcode label. If the barcode label is missing or not readable, the ‘ELite 5’ analyzer assigns a default value and allows manual entry of the sample ID.

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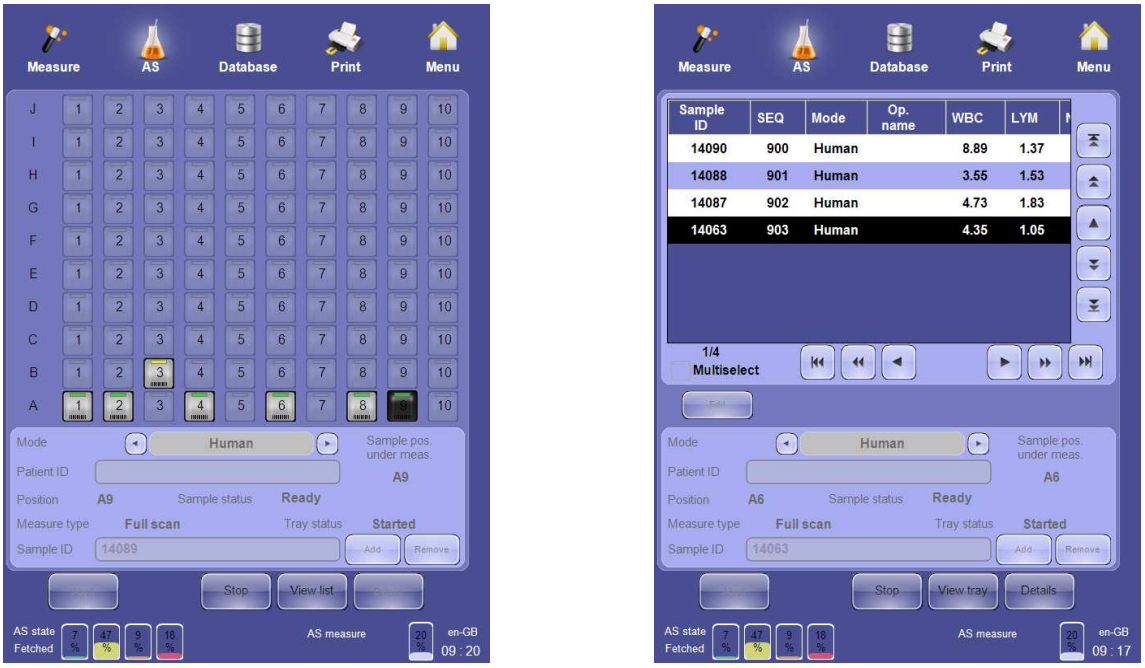

Figure 44. Full Scan Mode Tray and List Views

The Autosampler allows the addition of sample tubes to a Full Scan process already in progress. To add more sample tubes, perform the following steps:

- Click or tap the ‘Stop’ button. The ‘ELite 5’ will prompt you to wait until the current sample is completed.
- Acknowledge the message by clicking or tapping the ‘OK’ button.
- Insert the new samples into a rack.
- Open the cover of the Autosampler.
- Place the new samples behind the last measured sample.
- Close the Autosampler cover.
- Start the automated measurement by clicking or tapping on the ‘Start’ button on the GUI or by pressing the physical Start button.

The ‘ELite 5’ analyzer keeps track of the last analyzed sample on the sample tray of the Autosampler. After restarting the full scan process the ‘ELite 5’ moves the Autosampler to the last processed position and continues scanning from there.

7.4.3.3 Free List Mode

Free List mode is suitable for laboratories where:

- The barcode labels are not used, or the bar codes are not the primary identifiers. (This is the only mode where the sample ID is defined before the measurements.)
- Samples are arriving from multiple sources in small batches.
- In a given batch there are samples which should be measured using different modes for different normal ranges.

To start sample measurement in Free List mode, first perform and accept the blank measurement if one is needed. Click or tap the ‘AS’ quick link at the top of the screen and select ‘Free list mode’. The Free List mode only requires that samples are placed in the same sequence as in the free list. It does not require that samples be matched to exact rack

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and sample positions. It is not possible to add additional samples to the batch in free list mode after automated measurement has started.

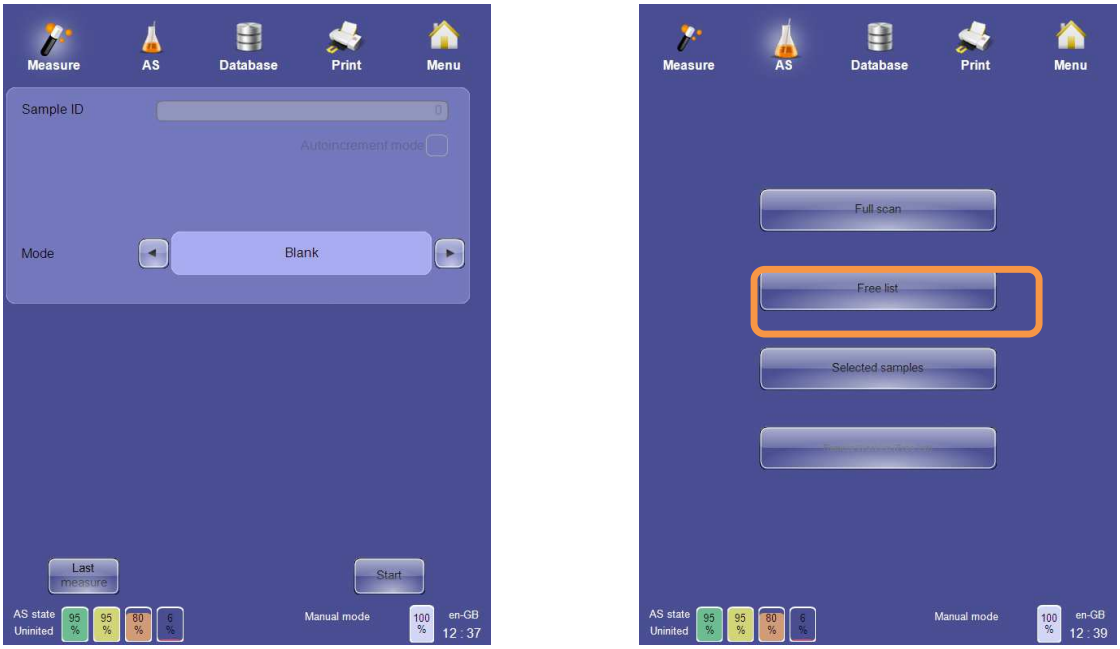

Figure 45. Free List Mode Selection

On the Free List mode panel you can:

- Return to the AS panel to select a different type of automated measurement by using the ‘Back’ function
- Add or remove list items
- Define the following parameters for the new list items:
  - Measure mode
  - Sample ID
  - Patient ID
- Swap between the tray and list views by using the ‘View list’ and ‘View tray’ functions
- Start the automated measurement by clicking or tapping on the ‘Start’ button on the GUI or by pressing the physical Start button

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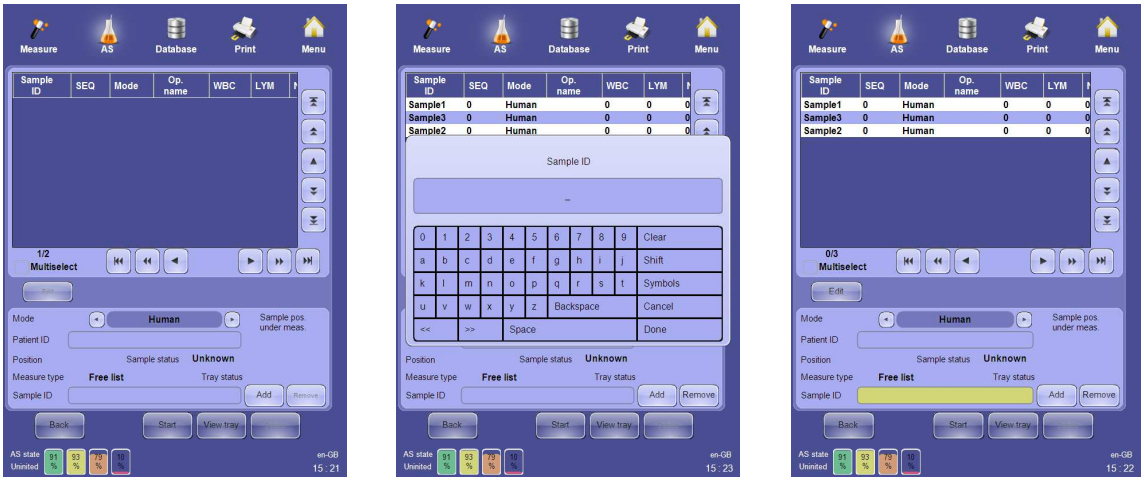

Figure 46. Preparing a Free List

As with the Full Scan mode, the Autosampler will scan all the sample positions on the tray and rows with missing racks will be skipped. The Autosampler will only process tube types it recognizes with caps attached. The automated mixing, aspiration, and analysis process is the same as the Full Scan Mode, and the progress can be followed in tray or list view.

The main difference between the Free List mode and the Full Scan mode is that the Free List mode identifies samples by matching them sequentially to the list, and comparing their measurement results to the normal range associated with the sample mode selected for that sample.

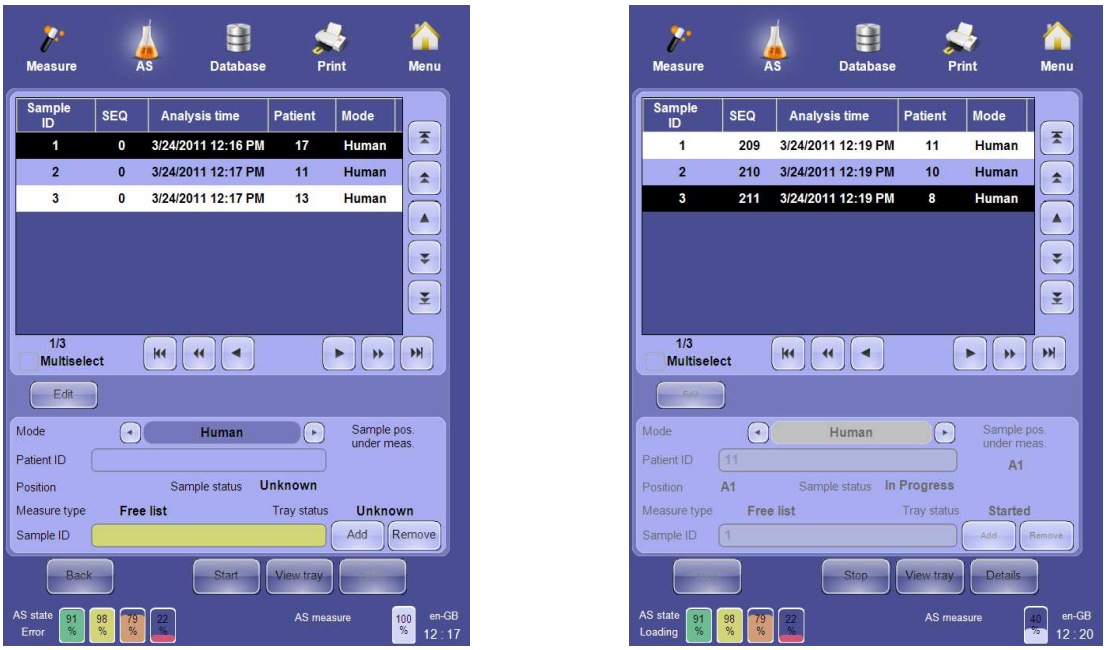

Figure 47. Free List Mode Progress: List View

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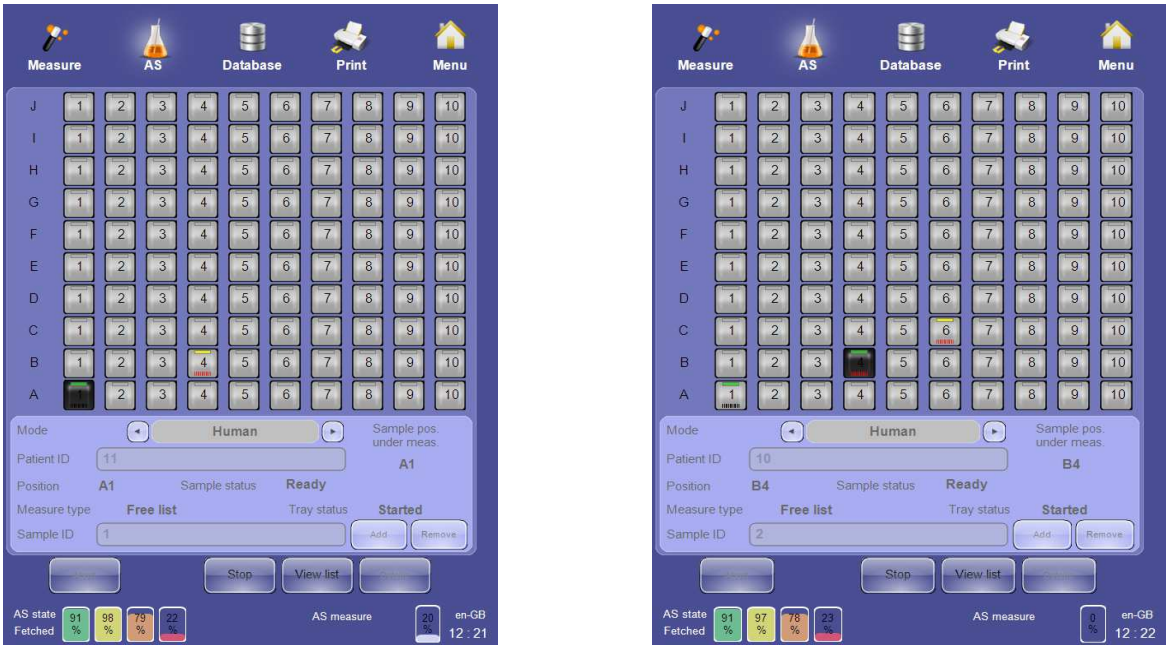

Figure 48. Free List Mode Progress: Tray View

Sample barcode labels are read and compared with the sample ID that was previously entered into the free list before starting automatic processing. If the two do not match, the barcode part of the tray view sample icon changes to red.

If the automated interrupted for any reason, it can be restarted it by clicking or tapping on the 'Start' button on the screen or by pressing the physical Start button.

7.4.3.4 Selected Samples Mode

Selected Samples mode is suitable for laboratories where:

- Barcode labels are used.
- In a given batch there are samples which should be measured using different modes for different normal ranges.
- Data security is a concern.

Selected Samples mode can also be used to rerun only certain samples in a sample tray already processed in one of the other two modes. Samples cannot be added to the sample tray once automatic processing is started in Selected Samples mode. An accepted blank measurement is required as with all sample processing.

In Selected Samples mode, the 'ELite 5' analyzer will only look for samples in the sample positions selected for analysis. All other samples in sample positions that are not selected will be ignored. If a sample position is selected for processing but contains no sample tube, the sample position will be marked for review.

On the Selected Sample mode panel you can:

- Return to the AS panel to select a different type of automated measurement by using the 'Back' function.
- Define the samples to be measured:

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- Click or tap the sample tray position icon where the selected sample is located.
- Select the appropriate measure mode.
- Define the sample ID.
- Define the patient ID.
- Save the changes by clicking or tapping the ‘Add’ button.

- Remove selected samples by clicking or tapping the “Remove” button.
- Swap between the tray and list views by using the ‘View list’ and View tray’ functions.
- Start the automated measurement by clicking or tapping on the ‘Start’ button on the GUI or by pressing the physical Start button

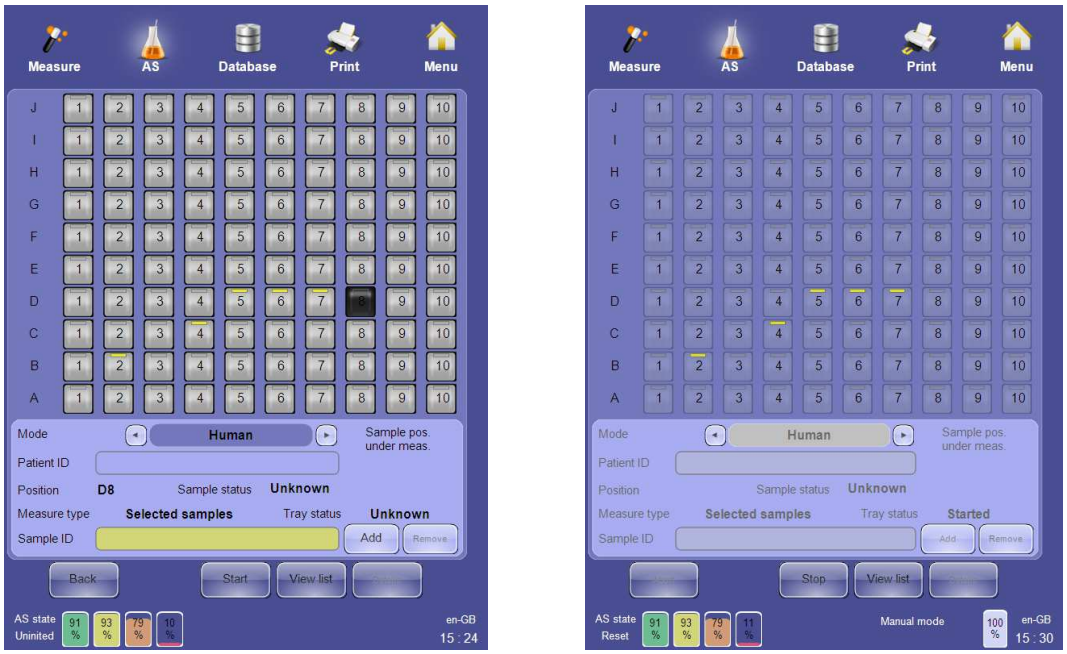

Figure 49. Selected Sample Mode Panel

7.4.3.5 Interrupting Automatic Processing for Stat Samples

If one or more stat samples need to be processed, you can interrupt automatic processing to analyze the stat sample(s) without having to wait until the entire sample tray has been processed. To interrupt automatic processing for stat specimens, perform the following steps:

- Click or tap the ‘Stop’ button. The ‘ELite 5’ will prompt you to wait until the current sample is completed.
- Acknowledge the message by clicking or tapping the ‘OK’ button.
- Place the stat sample into the sample rotor.
- As soon as the current measurement completes change to the manual measurement panel by clicking or tapping the ‘Measure’ quick-link at the upper left corner of the screen.
- Process the stat sample(s) in manual mode.
- Return to the automated measurement panel by clicking or tapping the ‘AS’ quick link;
- Restart the measurement by clicking or tapping the ‘Start’ button or by pressing the physical Start button.
- The ‘ELite 5’ will continue automated measurement from where it was interrupted.

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7.4.3.6 Controlling the Autosampler

Detailed information about the Autosampler is available from the Autosampler info panel. You can also reset the Autosampler from this panel. Double click or tap the Autosampler status in the bottom left corner of the screen to view the Autosampler info panel. With this panel, you can command the Autosampler to repeat the last command, or reset the Autosampler. You can also view Autosampler messages with detailed information about the last action or sample tube processed.

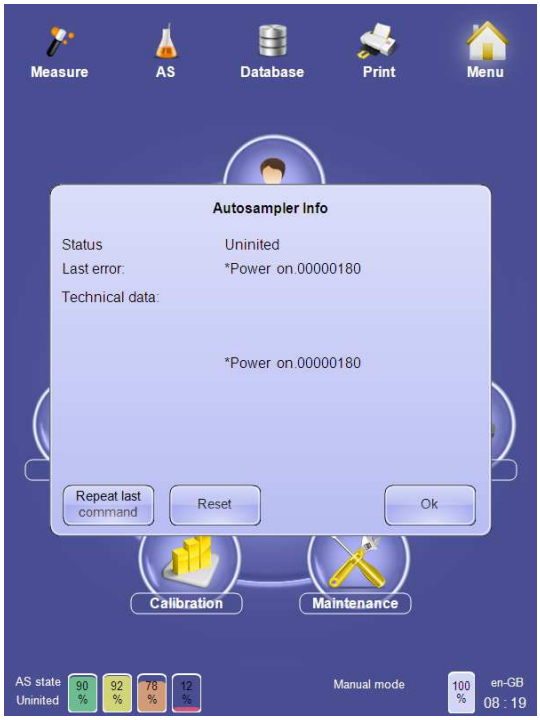

Figure 50. Autosampler Info Panel

The following is a list of messages from the Autosampler:

- Home message:
  - Response after a successful reset
  - +HOME_XX.YY (The XX.YY is the software revision number)
- VT zzzzzzz XY:
  - Vacutainer® style tube detected
  - Barcode content: “zzzzzzzzzzz”
  - Tray position XY
- MV zzzzzzz XY:
  - Monovette® style tube detected
  - Barcode content: “zzzzzzzzzzz”
  - Tray position XY
- +F : confirmation that the tube was moved from the mixing to the sampling position
- The power-on message contains the serial number of the Autosampler unit.

During the reset cycle are the Autosampler components moving to their ‘home position’. The mixing stations moves to an upright position, the active rack moves back on to the sample tray, and the entire tray moves to its home position. Small Sample Mode is not supported by the Autosampler.

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7.5 Result Display

After the analysis is completed, the result screen displays all measured parameters, flags, histograms and scatter plots. This information is automatically stored in the database, and stored result data can be retrieved at any time from the database.

Histograms and scatter plots can be zoomed for closer inspection. Click or tap the histogram or scatter plot to magnify it. Click or tap the 'Close' button on the upper right corner of the image to close it and return to the result display.

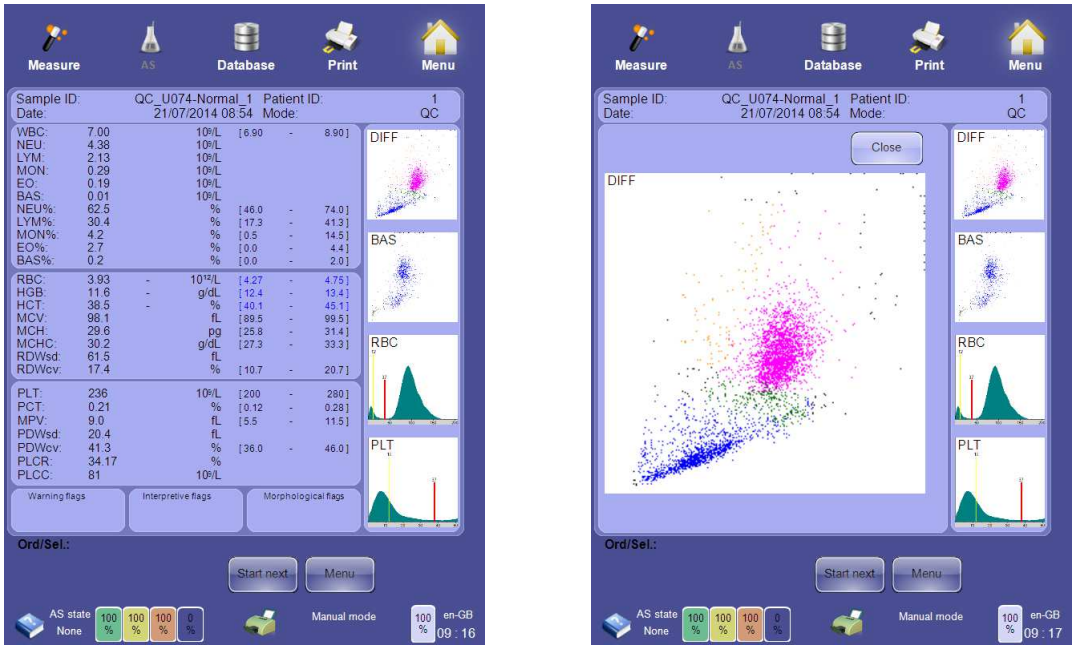

Figure 51. Results Display and Magnified Scatter Plot

Comparison of parameters to the normal range can be displayed numerically or graphically. See section 13.7 for more information on display of normal range status. Other kinds of flags are also displayed in the result screen.

See section 8 for detailed information about the 'ELite 5' result screen.

7.6 Printing Reports

Click or tap the Print icon at the top of the screen to send a report (or any displayed screen) to the external printer.

7.7 The Measurement Process

The 'ELite 5' analyzer measures 24 parameters of whole human blood samples. Internal dilutions are made to allow measurement of particles in the sample. Manual or automatic mode samples are processed in the same way.

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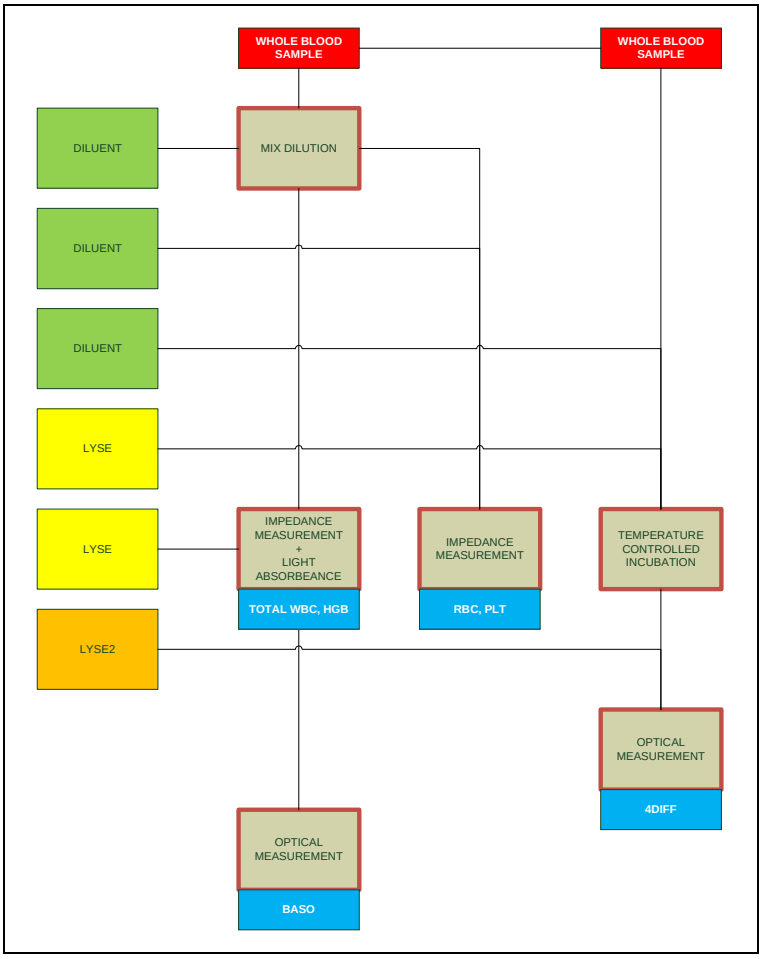

Figure 52. 'ELite 5' Measurement Process

When you present the sample tube and press the Start button, the 'ELite 5' rotates the sample rotor and takes the sample tube inside the analyzer. The piercing needle pierces the sample tube cap (if present) and aspirates approximately 110 µL of primary blood sample. Blood sensors ensure that the primary blood sample is continuous and free of major bubbles as it is moved to the shear valve. The shear valve separates the primary sample into further samples of exact volumes of blood that are distributed to provide dilutions for the RBC, WBC, HGB and 5 Diff population measurements. Lysing reagents are used to eliminate RBCs for dilutions that measure WBCs.

RBC/PLT and WBC are measured with impedance technology through 70 and 80 µm apertures respectively. Two portions of the sample are used for determining a five subpopulation differential of WBC in two independent 4DIFF and BASO measurements.

Sample results are displayed on the screen as the process is nearing completion. Results are stored in the internal database and transmitted to an external LIS if configured to do so. The 'ELite 5' performs a cleaning rinse of the internal pneumatic components and prepares to measure the next sample.

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8 Result Interpretation

This chapter provides description about interpreting and understanding reports provided by the ‘ELite 5’ analyzer.

8.1 The Result Screen

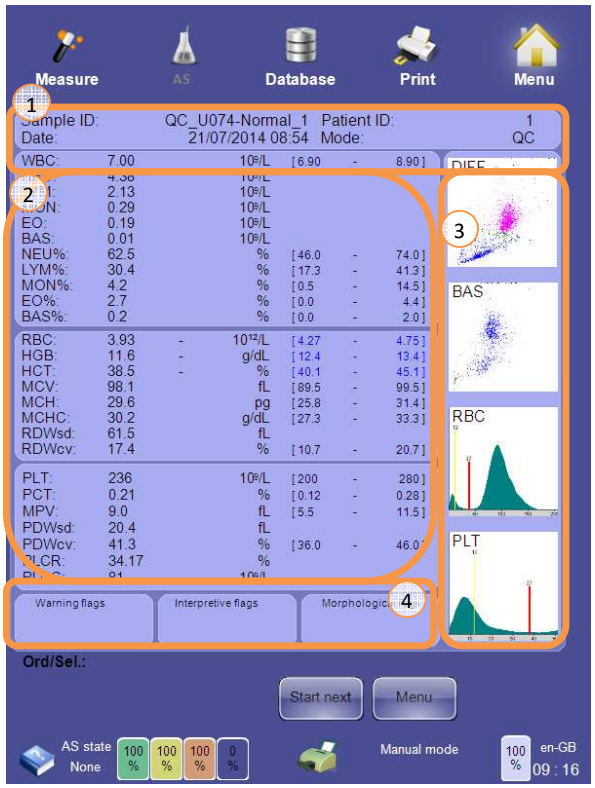

Figure 53. ‘ELite 5’ Result Screen

The ‘ELite 5’ analyzer result screen is divided into 4 major areas:

1. Sample identification information: contains identifying information used to uniquely identify this sample’s information.
2. Parameter information: contains parameter names, values, units, and normal range. Normal range, linearity, and high blank flags are also displayed in this area.
3. Histograms and scatter diagrams: visual elements that provide information about the measured population dispersion. These are active elements that can be individually magnified by clicking or tapping.
4. Warning flags area: this area displays warning, interpretive, and morphological flags associated with this sample. If flag display overflows its assigned space, an ellipsis will be displayed and the user can click on the information icon to see a detailed display of flags.

8.2 Sample Identification Information

This part of the results screen contains information that uniquely identifies a particular sample run.

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Sample ID	The Sample ID is the ID entered by the operator from a keyboard or hand-held barcode reader for a manually processed specimen. For automatically processed specimens, the sample ID can be read from a sample tube barcode or entered into a list for one of the automatic processing list modes. Sample IDs can be reused in the 'ELite 5' analyzer, but other identifying information together with the sample ID uniquely identify the sample run.
Patient ID	This is the patient associated with this sample run. If none was entered or selected, the default patient ID is set to 1.
Run Date/Time	This is the time and date that this sample was run.
Sample Mode	This is the sample mode selected for this specimen. Each sample mode applies a different set of normal ranges to this sample run.

Table 4. Sample Identification Information

8.3 Parameter Information

The parameter information area of the 'ELite 5' analyzer result screen lists information on 26 parameters.

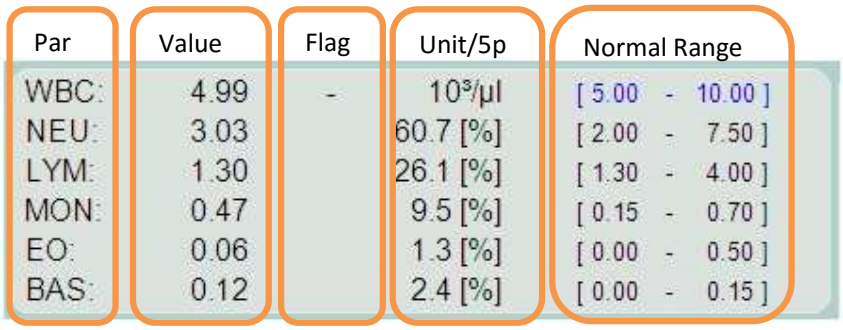

Figure 54. Parameter Information Display

Each row shows the parameter name, value, flags (normal range, linearity range, and high blank), units, and normal range. The unit area displays the differential percentage for the five leukocyte subpopulations (NEU, LYM, MON, EO, BAS).

Parameter names are listed with their standard abbreviation. Parameter values are always displayed according to their selected unit. In case of error during sample evaluation, the software will display 'E' or" ---" signs to indicate the problems. Parameter values falling within the normal range are un-flagged and displayed with black text. Parameter values falling above the normal range are marked with a '+' and displayed with red text, and values falling below the normal range are marked with a '-', and displayed in blue text.

Normal range information can also be conveyed graphically as well as numerically. This setting can be changed in the Main menu/Settings/Customize panel.

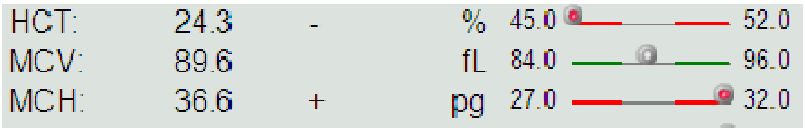

Figure 34. Graphical Normal Range Display

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The flags displayed in the parameter information area are as follows:

Normal range flags	Normal range flags are raised when a particular parameter is above or below the normal range, which is defined for the patient profile currently in effect.		
Flag	Meaning	Hierarchy	Color Code
-	Parameter is under normal range	Lowest	Blue
--	Parameter is under the half of the low limit of normal range	Low	Blue
+	Parameter is over normal range	Lowest	Red
++	Parameter is over the double of the high limit of normal range	Low	Red

Table 5. Normal Range Flags

Linearity range flag	Linearity range flags are raised when a particular parameter is above or below the linearity range of the device.		
Flag	Meaning	Hierarchy	Color Code
*****	The related parameter is out of the linearity range	High	N/A
******	The related parameter is out of the display range.	High	N/A

Table 6. Linearity Range Flag

High blank flag	A high blank flag is raised when the blank measurement result of the particular parameter was higher than the blank limit.		
Flag	Meaning	Hierarchy	Color Code
!	The blank value of the related primary parameter is high	Middle	N/A

Table 7. High Blank Flag

8.3.1 Scatter Diagrams and Histograms

The ‘ELite 5’ analyzer displays the results of the optical measurements in scatter diagram representation. Scatter diagrams represent two-dimensional data. There are two scatter diagrams in the patient report: the 4-DIFF and BASO scatter diagrams.

The 4-DIFF scatter diagram displays cells identified after the first lysing and optical measurement process. Due to the measurement technology, cells are classified based on their optically detected properties: low and high angle scattered light intensity. The optical detector can measure the intensity of the light scattered or diffracted by each cell. One portion of this scattered light is proportional to size of the cell the other is proportional to the complexity of the internal structures in the cell.

Cells in a leukocyte sub-population have similar light scattering properties, allowing them to be grouped together and identified separately from other cell types. Different colors are used to identify various populations of blood cells.

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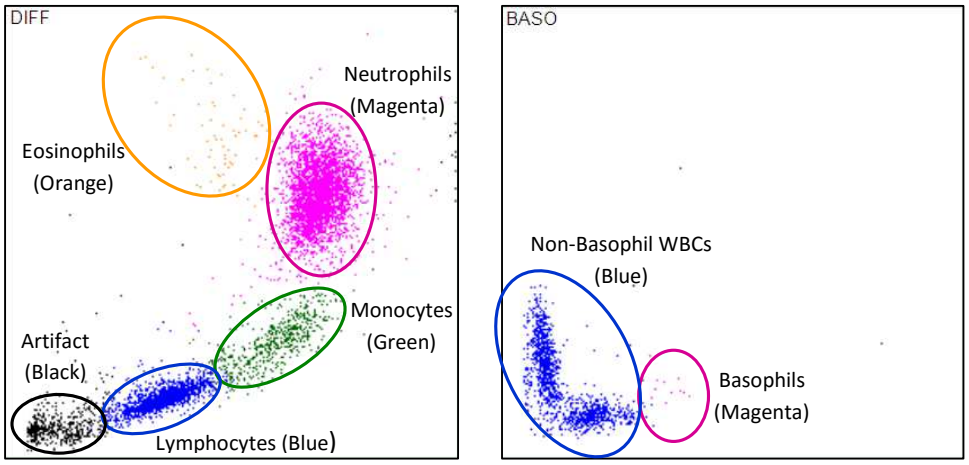

Figure 56. Result Screen Scatter Diagrams

RBC and PLT impedance-based measurements are represented by histograms. These diagrams show the number of cells on the Y axis and the cell size on the X axis. Smaller cells are displayed on the left side of the histogram, and larger cells are displayed on the right side. The height of the histogram at a given size represents the number of cells with that size. Greater histogram height indicates more cells.

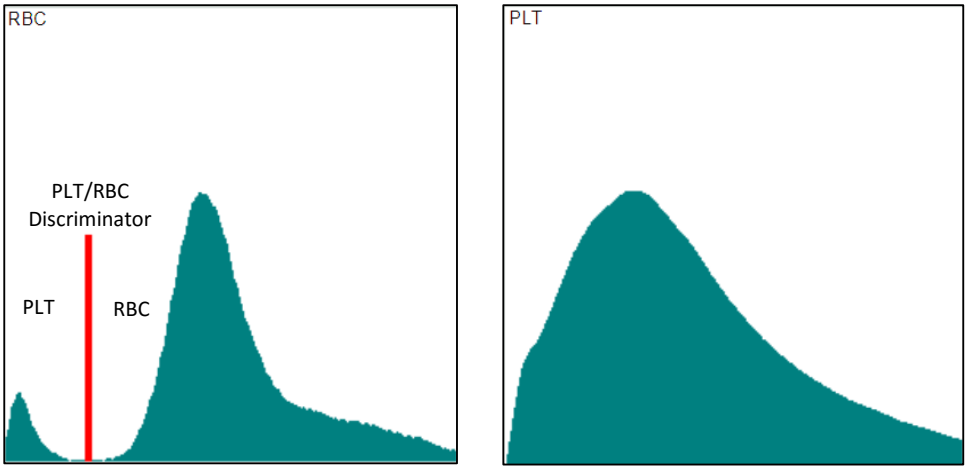

Figure 57. Result Screen Histograms

Both the RBC and PLT histograms can be zoomed. Discriminators (thresholds) are displayed with red color. Platelets are located on the leftmost part of the RBC histogram to the left of the red discriminator. The PLT histogram is a magnified version of this region.

8.3.2 Warnings

The warnings area of the result screen shows flags and messages related to the evaluation of the sample. Clicking or tapping the question mark icon on the left side of the warnings section of the results screen displays a detailed warnings panel. Click or tap OK to close the detailed warnings panel.

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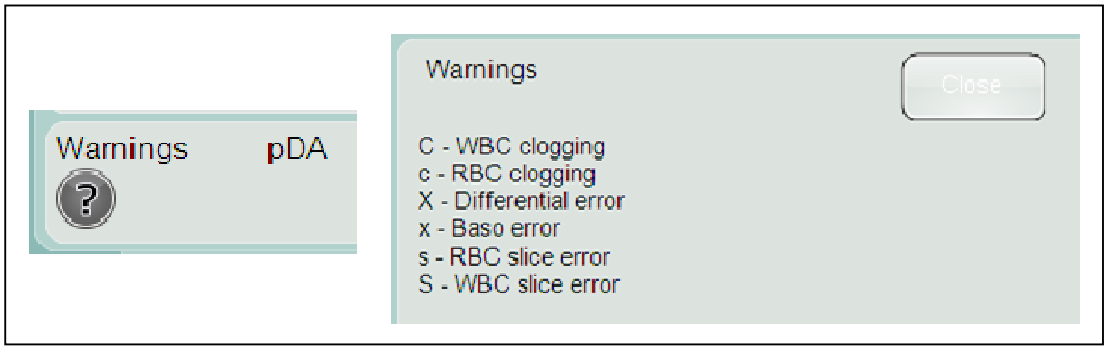

Figure 58. Warnings Section of Results Screen

The ‘ELite 5’ analyzer provides Warning flags, Morphological flags, and Interpretive messages in the Warnings panel. The following tables describe these flags and messages in detail. It also provides guidance on actions the operator can take to correct the problem described by the flag.

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Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	**Meaning**	**Cause**	**Action**
A	4 Diff Alarm	The 4DIFF populations are not clearly distinguishable on the scatter diagram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If 4DIFF results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.
B	WBC blank is high	WBC > WBC blank high limit	Check cleanliness of the reagents and the 'ELite 5'. Perform cleaning of the 'ELite 5'. Repeat blank measurement. See chapter: 6.2.5:Pneumatics start and blank measurement Treat WBC result as 'reduced reliability'.
b	RBC blank is high	RBC > RBC blank high limit	Check cleanliness of the reagents and the 'ELite 5'. Perform cleaning of the 'ELite 5'. Repeat blank measurement See chapter: 6.2.5 :Pneumatics start and blank measurement Treat RBC result as 'reduced reliability'.
C	WBC clogging	Drift in the probe voltage of the WBC capillary. The two main reasons for this drift are the misconnected reagent and the clogging of the capillary.	Check the reagent connections. Perform a cleaning procedure! See chapter: Maintenance. Please repeat the measurement.
c	RBC/PLT clogging	Drift in the probe voltage of the RBC capillary. The two main reasons for this drift are the misconnected reagent and the clogging of the capillary.	Check the reagent connections. Perform a cleaning procedure! See chapter: Maintenance. Please repeat the measurement.

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Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	**Meaning**	**Cause**	**Action**
D	MON - NEU alert	The MON and NEU populations are not clearly distinguishable on the scatter-gram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If MON, MON%, NEU, NEU% results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.
E	EO - NEU alert	The EO and NEU populations are not clearly distinguishable on the scatter-gram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If EO, EO%, NEU, NEU% results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.
F	Differential blank high	More than 100 cells detected during the '4Diff-blank' procedure.	Check cleanliness of the reagents and the 'ELite 5'. Perform flow cell cleaning of the 'ELite 5'. Repeat blank measurement. See chapter: 6.1.5 :Pneumatics start and blank measurement Treat 4 Diff results as 'reduced reliability'.
f	BASO blank high	More than 100 cells detected during the 'Baso-blank' procedure.	Check cleanliness of the reagents and the 'ELite 5'. Perform flow cell cleaning of the 'ELite 5'. Repeat blank measurement. See chapter: 6.1.5 :Pneumatics start and blank measurement Treat BASO result as 'reduced reliability'.
H	HGB blank high	Last accepted blank result: HGB ≥ 10 g/l	Check cleanliness of the reagents and the 'ELite 5'. Perform cleaning of the 'ELite 5'. Repeat blank measurement. See chapter: 6.2.5:Pneumatics start and blank measurement Treat HGB result as 'reduced reliability'.

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Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	**Meaning**	**Cause**	**Action**
l	PLT URI	The PLT-RBC gap is not clearly detectable on the PLT-RBC histogram: small MCV, fractured RBC-s, aggregated PLT-s (cold blood), side-effect of blood-transfusion.	Check the sample quality. Repeat the sample. If the problem persists then perform a manual count on a stained smear.
M	Out of RBC linearity range	The RBC coincidence is over the limit: too high RBC count.	Check the sample homogeneity. Repeat the sample with manual pre-dilution.
m	Close to RBC linearity range	The RBC coincidence is close to the limit: too high RBC count.	Treat RBC result as 'reduced reliability'. Check the sample homogeneity. Repeat the sample with manual pre-dilution.
N	High angle noise	The flow in the optical head is not clean or contains bubbles	Perform a blank measurement. If noise still appears, make a flow cell backwash.
n	Low angle noise	The flow in the optical head is not clean or contains bubbles	Perform a blank measurement. If noise still appears, make a flow cell backwash.
O	High linearity range limit exceeded	If any of RBC,PLT or WBC results are higher than high linearity range limits.	Perform manual pre-dilution of sample and re-measure it.
o	Low linearity range limit exceeded	If any of RBC,PLT or WBC results are lower than Low linearity range limits.	None
p	PLT blank high	Last accepted blank result: PLT ≥ 15 * 103 cells/µl	Check cleanliness of the reagents and the 'ELite 5'. Perform cleaning of the 'ELite 5'. Repeat blank measurement. See chapter: 6.2.5:Pneumatics start and blank measurement Treat PLT result as 'reduced reliability'.
Q	MON - LYM alert	The MON and LYM populations are not clearly distinguishable on the scatter-gram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If MON, MON%, LYM, LYM% results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.

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Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	**Meaning**	**Cause**	**Action**
S	WBC measurement statistics warning	The distribution of the RBC detection changes in time. It points to clogging, non-homogeneous sample, cold sample, partial coagulation of the sample.	Perform cleaning of the 'ELite 5'. Check the homogeneity, the temperature and the coagulation of the sample. Repeat the sample.
s	RBC measurement statistics warning	The distribution of the RBC detection changes in time. It points to clogging, non-homogeneous sample, cold sample, partial coagulation of the sample.	Perform cleaning of the 'ELite 5'. Check the homogeneity, the temperature and the coagulation of the sample. Repeat the sample.
T	Blood detector error	Blood Detector malfunction (received signals are all zeros or not received signals)	Check BD and its connection to the LSDACQ card. Check sampling tube connection to BD.
u	BASO high	The number of the BASO population is high or there are lyse-resistant cells in the sample.	Repeat the measurement or perform a manual count on a stained smear.
V	WBC vacuum warning	There is a (partial) clogging or leakage in the RBC part of measurement system. A faulty/ worn-out pump can create vacuum errors as well.	Perform cleaning of the 'ELite 5'. Perform a self-test. If vacuum problems persist then call for service.
v	RBC vacuum warning	There is a (partial) clogging or leakage in the RBC part of measurement system. A faulty/ worn-out pump can create vacuum errors as well.	Perform cleaning of the 'ELite 5'. Perform a self-test. If vacuum problems persist then call for service.
W	Sampling warning	Blood Detector detected a sample volume that was too small.	Check sample volume in sample vial. Check sampling process. Re-run sample.
X	Differential error	Not enough cells detected during the 4DIFF WBC differentiating.	Perform a flow cell cleaning procedure! Repeat the measurement. If the problem persists then ask for service.
x	BASO error	Not enough cells detected during the BASO WBC differentiating.	If the total-WBC count is below 2 * 103 cells/µl then perform a manual count on a stained smear. Perform a flow cell cleaning procedure! Repeat the measurement. If the problem persists then ask for service.
Y	Differential percentage error	Algorithm error while distinguishing the WBC-s in the 4DIFF procedure.	Repeat the measurement. If the problem persists on a given sample then perform a manual count on a stained smear.

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Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	**Meaning**	**Cause**	**Action**
y	Baso percentage error	Algorithm error while distinguishing the WBC-s in the BASO procedure.	Repeat the measurement. If the problem persists on a given sample then perform a manual count on a stained smear.
Z	WBC noise high	During WBC count there is too much (more than 10% of the total) detected pulse on the first 10 channel of the 255 channel full range. This may be caused by lyse resistant RBC, electronic noise, contaminated WBC chamber or contaminated reagents.	Perform Clean process. Perform Hard Clean process.

Table 8. Warning Flags

Morphological flag		Morphological flags are raised when the presence of morphologically abnormal cell types such as immature granulocytes are suspected.	
Flag	**Meaning**	**Cause**	**Action**
G	Immature granulocytes	The count in the region of (low - high angle scatter of ELite 5) where the Immature granulocyte typically located is > 3% of the total WBC count.	Perform a manual count on a stained smear.
L	Atypical lymphocytes	The count in the region of (low - high angle scatter of ELite 5) where the atypical lymphocytes typically located is > 1% of the total WBC count.	Perform a manual count on a stained smear

Table 9. Morphological Flags

Interpretive flag	Interpretive flags infer the presence of distributional abnormalities such as leukocytosis.
Flag	**Meaning**
Leukopenia	WBC --
Leukocytosis	WBC + or WBC ++
Neutropenia	NEU --
Neutrocytosis	NEU ++
Lymphopenia	LYM --

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Interpretive flag	**Interpretive flags infer the presence of distributional abnormalities such as leukocytosis.**
Flag	**Meaning**
Lymphocytosis	LYM ++
Monocytosis	MON ++
Eosinophilia	EOS ++
Basophilia	BASO ++
Anemia	RBC - or RBC --
Polycythemia	RBC + or RBC ++
Microcytic RBC	MCV - or MCV --
Macrocytic RBC	MCV + or MCV ++
Hypochromic	MCHC - or MCHC --
Hyperchromic	MCHC + or MCHC ++
Anisocytosis	RDW + or RDW ++
Thrombocytopenia	PLT --
Thrombocytosis	PLT + or PLT ++
Microcytic PLT	MPV - or MPV --
Macrocytic PLT	MPV + or MPV ++

Table 10. Interpretive Flags

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9 Database Functions

The ‘ELite 5’ database stores all measured data including sample results, QC, and patient data. Each sample result stored includes the complete parameter list, histograms, flags, and identifying data. The ‘ELite 5’ has a data capacity of up to 100,000 total records.

To activate Database panel, clicking or tapping the Database quick link on the top of the screen will take you to the database view from any screen.



Figure 59. Accessing the Database

The database can be accessed at any time, even when processing samples in the background. You can return to the measurement panel anytime to view ongoing sample measurements.

9.1 Database Overview

The ‘ELite 5’ analyzer database provides a powerful, easy-to-use method of storing, accessing, and managing patient and sample result information. The database of the ‘ELite 5’ analyzer is capable of storing up to 100,000 measurement, control and patient records.

The database presents information in a table view of rows and columns. Each row in the database panel represents one sample measurement. Rows are also called ‘records.’ Each column in the database consists of sample identification information and measurement parameter results.

The database information can be scrolled using navigation buttons along the right and the bottom of the database view, or by a moving a vertical scroll bar. Database records can be selected individually or in groups. Detailed result views are available for selected database records. Selected records can be printed, sent to LIS and exported into a tab file. Various sort options are provided for quickly finding results.

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Database records can be exported for storage and backup. Exported database information can be later imported for review. Imported records do not become part of your ‘ELite 5’ analyzer’s database. They are only imported for viewing, but can be sorted, selected, and managed in the same way as with the regular data stored inside the ‘ELite 5’ analyzer database.

The ‘ELite 5’ database displays two numerical counters separated by a slash under the left side of the database table. The left number is the number of selected rows, and the right number is the total number of rows in the database.

9.2 Scrolling the Database View

The limited size of the interactive database display acts like a viewport into the large amount of information inside your database. You can scroll the database view to bring desired information into view. The ‘ELite 5’ analyzer provides several powerful and easy-to-use scrolling methods. The numbered items below match the items in Figure below.

1. The scrollbar: tapping, holding and moving the scrollbar labeled ‘1’ with the tip of your finger on the touch screen display will quickly scroll information in the vertical direction. Clicking and dragging with an optional external mouse will achieve the same effect.
2. Tapping or clicking the buttons labeled ‘2’ will advance the display by one line or one column.
3. Tapping or clicking the buttons labeled ‘3’ will advance the display by one page of information at one time.
4. Tapping or clicking the buttons labeled ‘4’ will advance the display to the first or last item in the list.

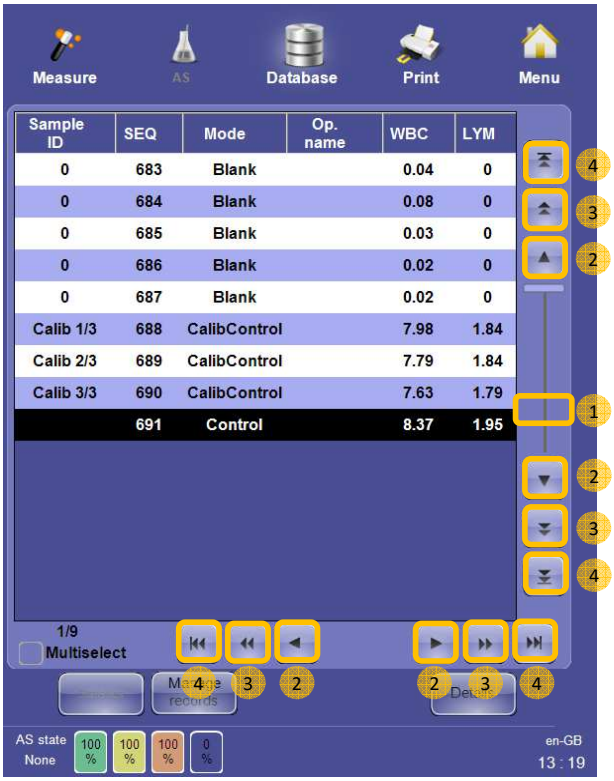

Figure 60. Scrolling and Selecting

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9.3 Sorting Database Information

The database is sorted by Result ID by default. Clicking or tapping the following database column headings changes the sort order of the database records:

Sample ID	Sample ID entered by the operator or read from a sample tube barcode label
Patient	Identifier that associates a result record with a patient records
Analysis Time	Time and date this sample tube was analyzed
Result ID	Unique sequential identifier assigned by the 'ELite 5' to each records

Table 11. Database Sort Criteria

Clicking or tapping the same column heading again changes the ascending or descending order of values in the column.

9.4 Manual Selection of Database Records

Clicking or tapping on a row in the database display single-selects a row. Clicking or tapping it again de-selects the row. Selecting another row will de-select previously selected rows in single selection. Selected rows are highlighted with white text on a black background.

Checking the 'Multiselect' check box below the left side of the database table allows the selection of multiple rows. Tapping or clicking once selects a row, but previous selections remain selected unless you click or tap it again to de-select it. Un-checking the Multiselect check box will de-select all selected records.

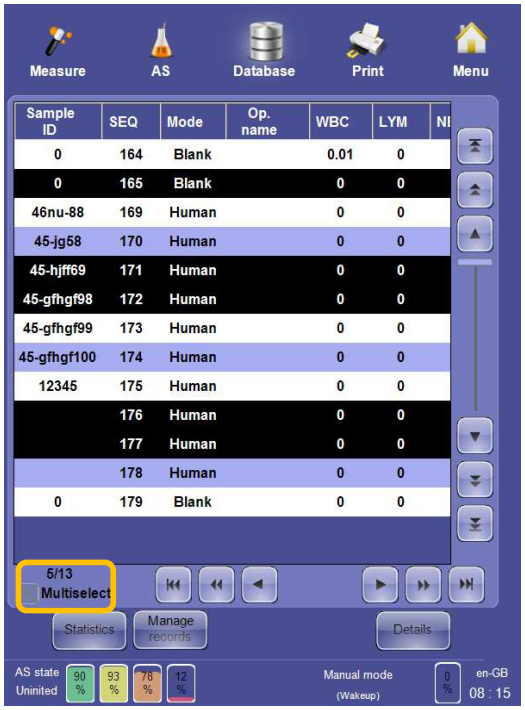

Figure 61. Multiselect and Multiple Selection

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Multiple selections are useful for viewing, managing and quickly viewing statistics of only a few selected records.

9.5 Automatic Selection of Database Records

When the total number of records in a database becomes very large, manual selection of records can become difficult. The ‘Select by’ function in the Manage records panel provides the means to select a group of records automatically according to their identifying information. See section 9.8.1 for more information on the Select by database function.

9.6 Viewing Detailed Results

Multiple selections are also useful for viewing the detailed results of a few records rather than navigating through the database. After selecting several records, clicking or tapping the ‘Details’ button on the database panel will display the detailed results for the first record in the selection. Clicking or tapping the ‘Up’ or ‘Down’ buttons on the details screen displays the details of the next record in the selection.

9.7 Statistics

After selecting a group of records, click or tap the ‘Statistics’ button on the database panel to view the coefficients of variation (CV) associated with each of the 26 parameters. This function is useful to quickly measure the imprecision of multiple runs of the same sample.

9.8 Managing Database Records

‘ELite 5’ analyzer database management functions are accessed by clicking or tapping the ‘Manage records’ button to bring up the Manage records panel.



Figure 62. Manage Records Panel

All data manipulation actions that change the data stored in the ‘ELite 5’ database are logged in the ‘ELite 5’ log. If the multi-user mode is enabled, the name of the operator logged on at the time the data manipulation occurs will also be stored in the log.

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9.8.1 Select By

Click or tap the ‘Select by’ button on the Manage Records panel to display the Select by panel. The Select by panel allows you to select a group of records with dates and Result IDs that match criteria entered into the panel.

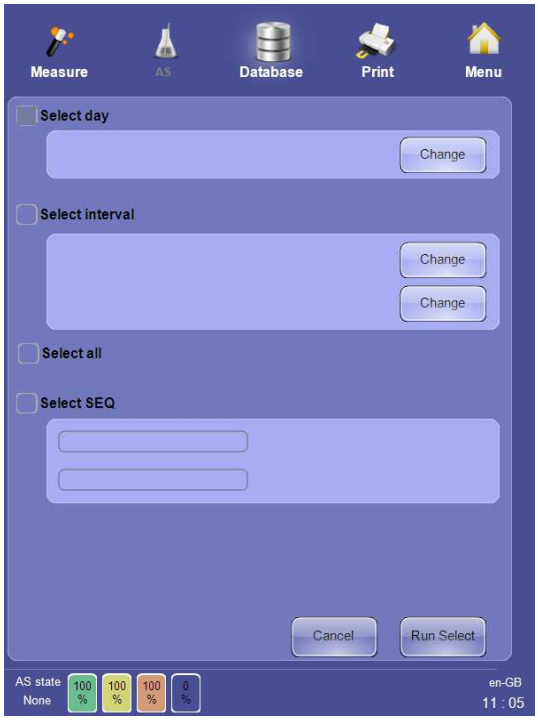

Figure 63. Select By Panel

The Select by panel provides various ways to select records. Only one of the four selection methods can be chosen.

Select day	Clicking or tapping the ‘Change’ button displays a virtual on-screen date keyboard. All records analyzed on the date entered will be selected.
Select interval	The two ‘Change’ buttons allow entry of a start and end date. All records on the start date, the end date, and all dates in between will be selected.
Select all	All records in the database will be selected.
Select Result ID	Entering one Result ID will select a record with the same Result ID. Entering two Result IDs will select a range of records including the start and end Result IDs.

Clicking or tapping the ‘Run select’ will create a multiple selection of all database records that match the criteria (if any). The ‘Cancel’ button returns to the database view and the current selection is not changed.

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9.8.2 Importing

Clicking or tapping the ‘Import’ button displays a blank, modified version of the database panel.

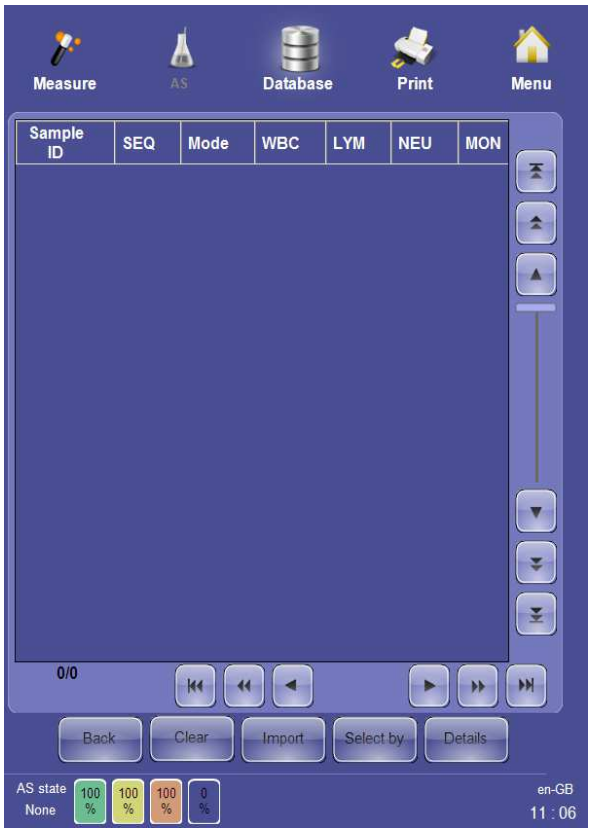

Figure 64. Database Importing Panel

The database importing panel provides the following options:

- The ‘Import’ button brings up a panel to select previously exported database record files to load and view.
- ‘Select by’ performs the select by database function to select a group of imported records according to criteria entered by the operator.
- ‘Details’ views the detailed result information for all or a selection of imported records.
- ‘Clear’ removes selected records from the imported records table, but does not permanently remove the cleared records from the stored database file.
- ‘Back’ ends viewing of imported database information and returns to the ‘ELite 5’ stored database.

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9.8.3 Export

The database export panel allows you to select a directory location to store records in a selection for backup or reference purposes. To back up all records in the database, first use the Select by function to select all records in the database and export them using the export function.

Clicking or tapping the 'Export' button displays the database export panel.



Figure 65. Directory Panel for Data Storage

Introduce a USB storage device (USB hard drive, memory stick, etc.) into an available USB port on the back panel of the 'ELite 5' analyzer. Select the directory to store the exported data and press the 'Ok' button to start the export.

The file format of exported data is an internal format, and can only be read and interpreted by the 'ELite 5' analyzer using the Import function. Each database record is stored as an individual file with a '.rp' extension.

9.8.4 Send to LIS

The 'Send to LIS' button immediately transmits selected database records to the external LIS according to your LIS settings.

9.8.5 Save Tab File

The Save tab file function is used to archive database data to a tab separated text file. The 'Save tab file' button displays a directory panel like Figure , except that the file saved in the

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selected location is a tab separated text file rather than a database backup file. Tab separated text files can be loaded and viewed by a text editor or imported into spreadsheet software.

The filename created by the Save tab file function is generated automatically in the following format: TAB_YYYYMMDDHHMMSS.txt with the year, month, day, hour, minute, and second of the time when the operation started.

To archive database data using this function, insert a USB data storage device to one of the USB inputs on the back panel of the 'ELite 5' analyzer. Select the file location of your USB data storage device and click or tap the 'OK' button to begin the export.

9.8.6 Save Raw Data

The Save raw data function saves the raw data information associated with a selection of database records. Raw data files are only suitable for internal use by Erba Lachema staff. Your service engineer may ask you to save raw data files to help diagnose a service issue.

A confirmation password is required to save raw data. The default factory-set confirmation password is **555**. This password can be changed only by Erba Lachema certified service engineer.

Insert a USB data storage device to one of the USB inputs on the back panel of the 'ELite 5' analyzer. Click or tap the 'Save raw data' button on the Manage records panel, then enter the correct confirmation password. Click or tap the 'Ok' button to display a directory panel like Figure . Select the file location of your USB data storage device and click or tap the 'OK' button to save raw data.

9.8.7 Delete

The Delete function is used to delete permanently the records from a selection from the 'ELite 5' analyzer database. To permanently delete records, select a group of records and click or tap the 'Delete' button on the Manage records panel.

To prevent accidental deletion of data, the 'ELite 5' requests the same confirmation password used in the save raw data function. After entering the correct password and clicking or tapping the 'Ok' button, the records will be permanently deleted.

The password to allow deleting records is: **555.**

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10 Calibration

The ‘ELite 5’ analyzer must be calibrated in order to provide correct, reliable results. Calibration should be done at the following times:

- At initial installation,
- After replacing any component critical to the dilution or measurement process,
- Any time quality control shows a systematic error or is outside predefined limits,
- At periodic time intervals determined by laboratory regulations.

The ‘ELite 5’ analyzer calibration process consists of running a commercial calibration material or a human whole blood sample with known parameter values multiple times. The known parameter values and the average values of multiple runs are used to calculate calibration factors. The new calibration factors take effect once they are accepted by the operator.

If you are using a human whole blood as a calibrator, the calibration target values must be measured on a reference analyzer according to applicable regulations, standards, or laboratory procedures.

An automated calibration procedure is provided that guides the operator through the calibration process and performs the calibration factor calculation. Calibration factors can also be modified directly without running a calibration procedure. Only the parameters that are traceable to reference methods are calibrated: WBC, RBC, PLT, HGB, MCV and MPV.

To view the calibration functions of the ‘ELite 5’ analyzer, select the ‘Calibration’ icon on the main menu to display the calibration panel. The Calibration panel displays an option to calibrate the ‘ELite 5’ analyzer or to view prior calibrations.

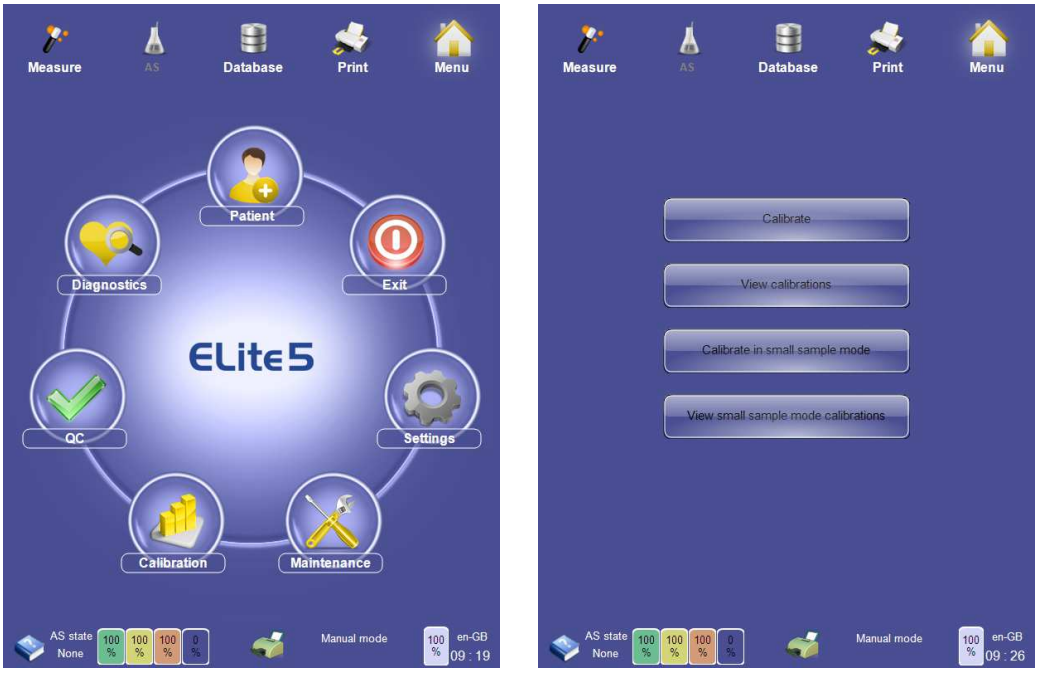

Figure 66. Calibration Options

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10.1 Calibrating the 'ELite 5'

.

Selecting the 'Calibrate' option on the calibration options panel displays the calibration panel.

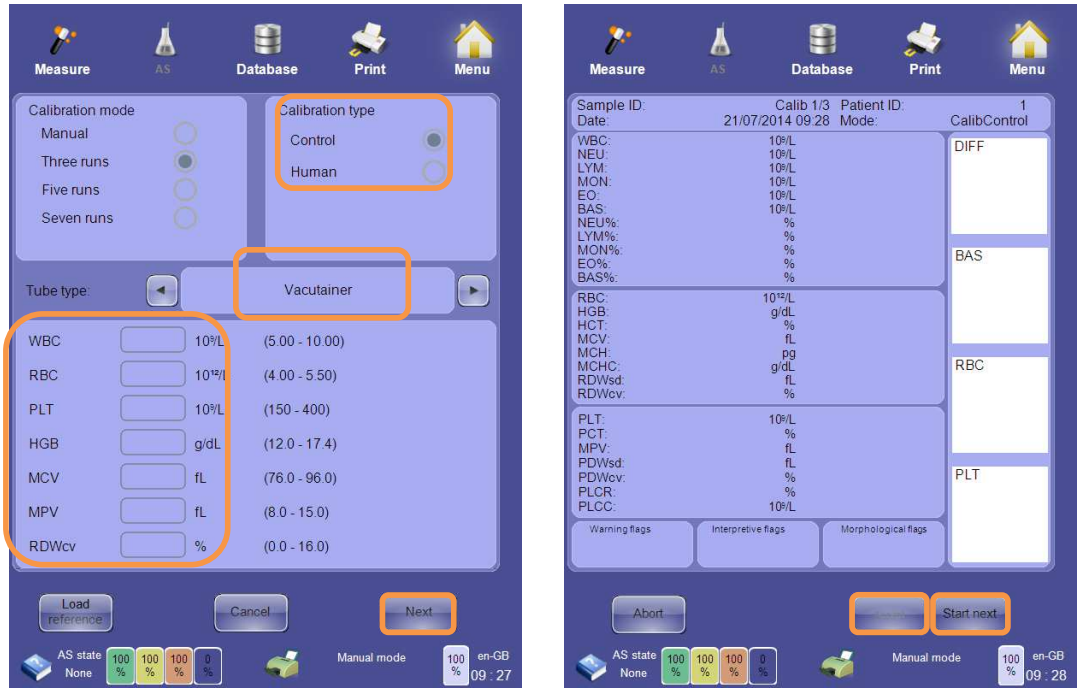

Figure 67. Calibration Panel and Calibration Run Result Panel

The limits of the calibration target values are linked to the normal range of the 'Human' sample mode.

	**Commercial calibration material and sample tube should be handled as a potentially biohazardous material. All applicable laws, regulations, and laboratory practices should be followed in the handling and disposal of calibration materials.**

To perform the automated calibration procedure, ensure that the 'ELite 5' pneumatic system is started up and that a valid blank measurement has been accepted. Perform the following steps:

- Prepare a sample tube with commercial calibration material or human whole blood. Ensure that there is sufficient sample volume for three or seven consecutive runs.
- Place the sample tube with calibration material in the sample rotor.
- Select 'Three measures' or 'Seven measures' according to your laboratory's standard practices.
- Select 'Control' for a commercial calibration material (control or calibrator) or 'Human' for whole human blood calibration.
- Enter the calibration target values provided with your commercial calibration material or the previously determined parameter values for human blood calibration.
- Click or tap the 'Next' button to begin the calibration process.

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- The analyzer displays a blank result screen and begins sample measurement of the calibration material. Wait for the screen to be populated with results when sample measurement is complete.
- Click or tap the ‘Accept’ button if the measurement run is acceptable.
- Click or tap the ‘Start next’ button to begin the next calibration run. Selecting ‘Start next’ without accepting a calibration run discards the run. Selecting ‘Abort’ will abort the entire calibration procedure and discards all calibration results.
- The calibration procedure ends when three or seven accepted calibration runs are completed. The calibration factors are calculated and presented in the calibrator factor. The previous calibration factors and the coefficient of variation (CV) of the sample runs for each parameter are also displayed.
- Select ‘Accept’ to replace the current calibration factors with the accepted factors. Selecting ‘Discard’ eliminates the entire calibration process.

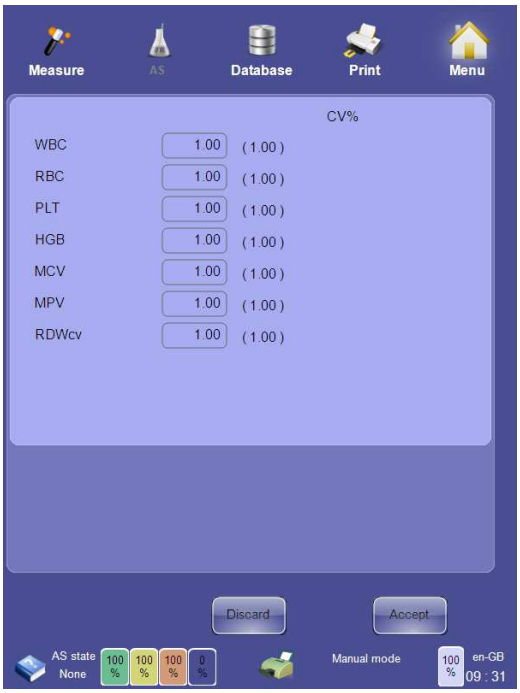

Figure 68. Calibration Factor Panel

The automatic calibration process can be skipped by selecting the ‘Manual’ calibration mode on the calibration panel and clicking or tapping the ‘Next’ button proceeds directly to the calibration factor panel for manual entry of factor values. Manually entered factor values can be accepted in the same way as calculated factors from calibration sample runs, and are treated by the ‘ELite 5’ in the same way.

10.1.1 View Calibrations

The view calibration features is helpful for reviewing the calibration history for the analyzer. Increasing or decreasing calibration value trends over time may indicate a problem that requires service intervention.

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To view the calibration history click or tap the ‘View calibration’ function on the calibration panel. The calibration history is presented in a table view that can be navigated in the same way as the database panel.

Any calibration can be deleted. Deleting the last calibration causes the ‘ELite 5’ analyzer to revert to the last accepted calibration.



Figure 69. View Calibration Panel

To delete a calibration, click or tap the ‘Delete’ button. The system will ask you for a confirmation password to avoid accidental deletion of calibration data. The confirmation password is set at the factory to **555**, and can be changed by your Erba Lachema certified service engineer.

10.2 SSM Calibration

The Small Sample Calibration procedure is the same as the Calibration in normal mode.

Be aware of choosing the right vial which you are using for calibration. For the best precision we recommend to choose the calibration for the most measurements in SSM mode.

Calibration factors are going to be generated like:

Measurement result = raw result x calibration factors x SSM calibration factors

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11 Quality Control

Regular use of quality control (QC) ensures that the ‘ELite 5’ analyzer is operating optimally. Stable recovery of standard QC material parameters assures the operator that the ‘ELite 5’ is operating consistently on a day-to-day basis and is functioning correctly.

By analyzing control materials on a regular basis, day-to-day reproducibility and general condition of the analyzer can be monitored. Target values and acceptable (tolerance) ranges for each parameter can be specified for an unlimited number of QC materials.

⚠	**Control materials must be used before their expiry date. Always observe the control manufacturer’s instructions for storage and use. Control materials must be well mixed before use.**

The ‘ELite 5’ analyzer does not limit the number of QC material lots or the number of QC measurement runs that are stored in the control database. Each QC measurement run is saved to the selected QC material lot.

QC lots can be commercial control materials or a whole human blood sample whose parameter values and ranges are determined by other means. The advantage of a commercial control material is that its shelf life is much longer than human blood, allowing control of the analyzer for a longer period of time.

Controls in the ‘ELite 5’ are processed in manual mode only. To access the QC panel, select the ‘QC’ icon on the main menu.



Figure 70. QC Panel

11.1 Set QC Reference

Before taking any QC measurements, target values and acceptable ranges must be specified for a lot of control material. Click or tap the ‘Set QC reference’ button to display the Set QC panel.

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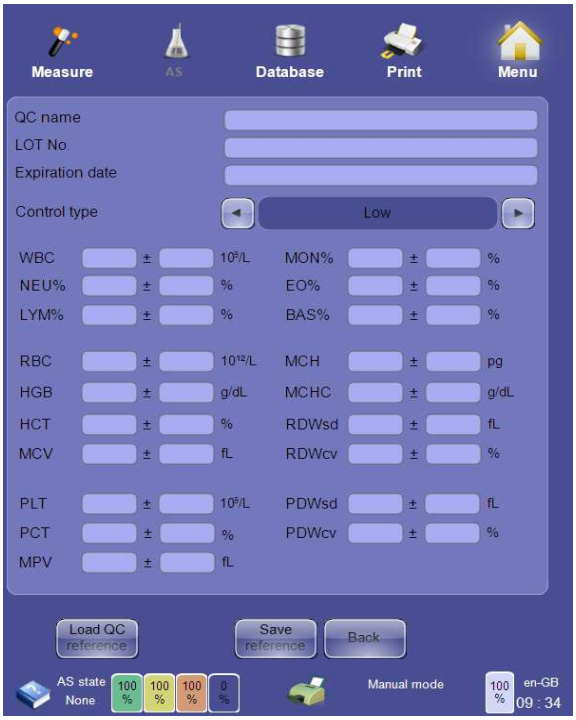

Figure 71. Set QC Reference Panel

The ‘QC name’ is the name that will be displayed for selecting the control to associate with a QC measurement. Enter the identifying information, and the target values and tolerance ranges for any parameters that are to be controlled with the ‘ELite 5’ QC system. To exclude a parameter from the QC procedure, leave its target value and tolerance range field empty. Press the ‘Save reference’ button after data entry is completed.

Tapping the “Load QC reference” button will allow filling QC material data electronically – using a file provided by the manufacturer of the analyzer. A dialog will open. Browse to the correct folder, and select the file by tapping the check box in front of the filename.

The file contains information for all three levels of the control material (Low, Normal and High). All three levels will be loaded into the system and will become selectable in the QC menu.

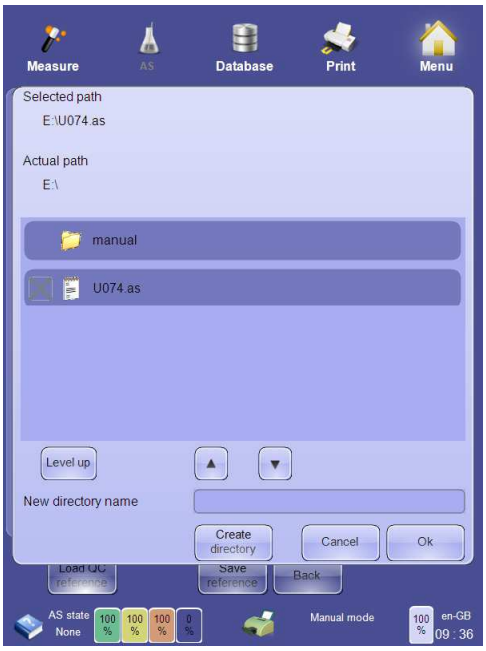

Figure 72.35 Load QC Reference Panel

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11.2 QC Measure

To run a QC measurement, please ensure that a valid blank measurement has been run and accepted. Associate the QC measurement to the correct control material lot by select the matching QC name in the selector below the ‘QC measure’ button on the QC panel. Place sample tube with the control material in the sample rotor and click or tap ‘QC measure’.

The QC measurement results will be added to the QC database and associated with matching QC material lot.

11.3 View QC References

Click or tap the ‘View QC References’ button to see a list of QC lot references stored in the ‘ELite 5’ analyzer control database. Target values and ranges can be viewed for any stored QC references.

11.4 View QC Data

Selecting ‘View QC data’ displays QC runs stored in the QC database in a table format that operates the same way as the ‘ELite 5’ analyzer database. QC measurement results will have sequential ID numbers. Option buttons are provided to switch back and forth between viewing QC data and viewing QC diagrams.

11.5 View QC Diagrams

Click or tap ‘View QC diagrams’ to see the QC diagrams for control measurements.

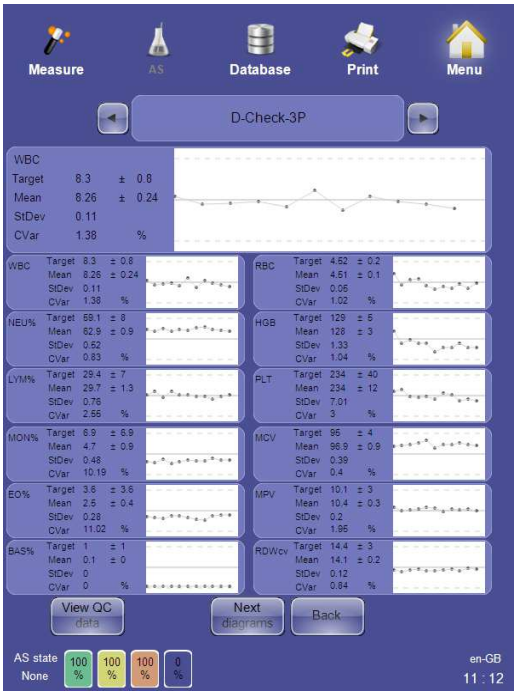

Figure 73. View QC Diagrams Panel

Means, standard deviations (SD) and coefficients of variation (CV) are calculated based on the QC analyses. The dotted lines delineate acceptable ranges on QC diagrams. Use the

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selector control at the top of the panel to view graphical control information for other lots of control materials.

In Small Sample Mode there is a new AS file with modified ranges for Small Sample Mode. The QC will only work with choosing the vial type “Vacutainer”, because the control and calibrator blood is provided in that type of vial.

The Small Sample QC measurement procedure is the same as it is on normal mode.

⚠	Take attention to choose the proper values and ranges for QC.

11.6 View X-B Data

‘ELite 5’ offers X-B to facilitate trend analysis of samples run.

The X-B moving average is an algorithm which is capable of tracking changes of the accuracy- alternating of the measurements. The algorithm observes the alteration of the derived values which are generally stable.

For example the MCV, MCH and MCHC values show the proportion between the blood components. These values fall within narrow limits in human blood therefore these values are able to show the drifting of the device.

The X-B algorithm works with batches. There are 20 samples in the batches. The average deviation of the corresponding batch is calculated as follows:

The X-B algorithm is illustrated below:

$$X_{(B,i)} = X_{(B,i-1)} + SGN \left\{ \sum_{j=1}^{N} SGN\,[X_{(j,i)} - X_{(B,i-1)}] * \sqrt{[X(j,i) - X_{(B,\,i-1)}]} \right\} * \frac{\left\{ \sum_{j=1}^{N} SGN\,[X_{(j,i)} - X_{(B,\,i-1)}] * \sqrt{[X_{(j,i)} - X_{(B,\,i-1)}]^2} \right\}}{N}$$

Where:	i	=	present batch
	j	=	present specimen
	$X_{(B,i)}$	=	ith X-B value (current batch)
	$X_{(B,\,i-1)}$	=	(i-1)th value (previous batch)
	SGN	=	the arithmetric sign or number in parenthesis
	N	=	the number of samples in the batch
	*	=	symbol used to represent multiplication

Divide the average deviation of the corresponding batch by the number of the items in the batch (N=20). Add the square of the resulting deviation to the mean. Then the result represents a point on the diagram. The value of the mean will be changed with all counted average deviation from the corresponding batch.

The average of the first batch (X) equals the target value. All the average deviations belonging to the corresponding batch are added to the mean with correct signs.

The samples are used in calculation chronologically therefore the copulated deviation points show the deviation from the mean line.

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11.7 View X-B diagrams

View X-B diagrams displays X-B charts for MCV, MC and MCHC.

View X-B data function displays X-B information in a table format similar to view QC data.

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12 Patients

The ‘ELite 5’ analyzer allows the operator to define and store patients in the patient database during manual measurement. Patients can also be predefined while creating a list for one of the automatic processing modes.

Select the Patients icon on the main menu to display the Patients panel.



Figure 74. Patients Panel

The Patients panel displays patient information in the familiar table format of the ’ELite 5’ analyzer database, and operates the same way as the database panel. Use the ’New’ function to define new patient, and ’Edit’ to change existing patient information. ’Details’ displays patient data in a read-only mode.

The Patient panel can also be accessed by clicking or tapping the Name or Patient ID field in the Measurement panel. Two additional function buttons are available if the Patient panel is accessed from the Measurement panel.

The ‘Select ID’ function associates the currently selected patient to the sample measurement and returns to the Measurement panel. The ‘Cancel’ function returns to the measurement panel without selecting any patient to associate to the sample measurement.

You can select either Name or Patient ID to be displayed as the patient identifier in the Measurement panel by changing the settings in the ‘Patient’s displayed data’ in the Main Menu/Settings/Customize panel.

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Figure 75. Edit Patient Panel

The ‘Save’ function saves any changes made. To discard any changes made, simply click or tap the ‘Back’ button.

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13 Settings

The ‘ELite 5’ analyzer can be tailored to your laboratory’s needs by changing the settings. Click or tap the ‘Settings’ icon on the main menu to access the Settings panel.



Figure 76. Settings Panel

The options available on the Settings panel are:

- Customize
- Laboratory
- External Devices
- System
- Units
- Printer
- Profile Limits
- X-B
- User (only if Multi user option is enabled)

Clicking or tapping one of the buttons in the Settings panel displays the selected panel where settings changes can be made. Each panel has a ‘Back’ and ‘Save’ button. The ‘Save’ button saves any changes made and returns to the Settings panel, and the ‘Back’ button discards any changes and returns to the Settings panel.

13.1 Customize Settings

The Customize panel allows you to customize the ‘ELite 5’ analyzer user interface language and other preferences about the analyzer operation. Click or tap the ‘Customize’ button on the Settings panel to access the Customize panel.

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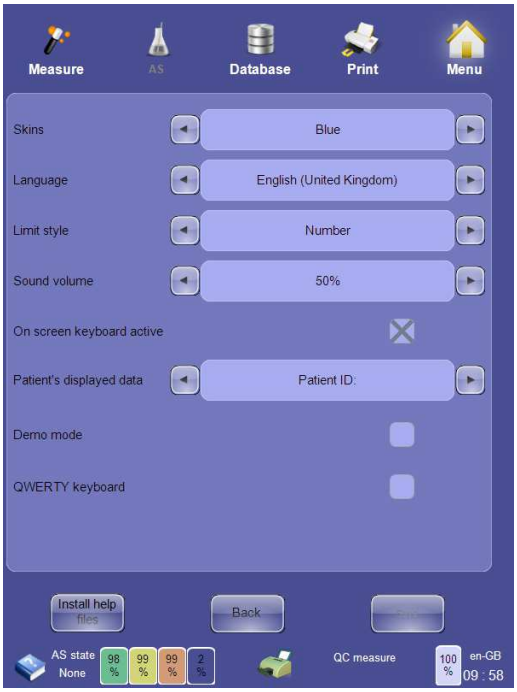

Figure 77. Customize Settings Panel

On the Customize panel, you can change the following settings:

- Skins – by changing the 'skin' the appearance of the menus, GUI elements will change. The 'skins' has no effect on the behavior of the 'ELite 5'.
- Language – select the language that the 'ELite 5' analyzer user interface uses to communicate with the operator. Available languages are English, Spanish, French, Croatian, Hungarian, Italian, Polish, Russian, Turkish, Chinese, German & Greek.
- Limit style – select Number, Graphical1, and Graphical2 display modes to change the display method for parameters outside the normal ranges on the result screens and printed reports.
- Sound volume – modify the sound volume up or down.
- On screen keyboard active – select whether to use the on-screen virtual keyboards for displaying information, or an external keyboard.
- Patient's displayed data – choose Name or Patient ID as the patient identifier displayed in the Measurement panel.
- Demo mode.
- QWERTY keyboard

13.2 Laboratory Settings

The Laboratory settings panel allows entry of seven lines of text up to 50 characters of descriptive information about the laboratory such as laboratory name, address, etc. All non-empty lines are displayed at the top of every result printout.

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13.3 External Devices

The External Devices panel allows entry of external LIS settings. The ‘ELite 5’ analyzer support external LIS communications over a serial communications link using the Erba Lachema version 3.1 protocol. It also supports an Ethernet communications link over the HL7 version 2.5 protocol.

The External Devices panel lets you change the following settings:

- Sending port baud rate – select 9600 or 115200 baud for serial LIS connection.
- Automatic LIS – The ‘ELite 5’ will transmit every measurement result as soon as it is available if this check box is checked.
- LIS – the ‘ELite 5’ analyzer will use an Ethernet connection rather than a serial connection of this check box is checked.
- IP – the IP address of the external LIS computer should be entered here if an Ethernet LIS connection is used. IP addresses consist of four numbers from 0 to 255 separated by periods. See your IT administrator for more information about the IP address of your host LIS computer.
- Port – the port number of the external LIS computer should be entered here with nor commas if an Ethernet LIS connection is used. Ports are a single number between 0 and 65535. See your IT administrator for more information about the port number of your host LIS computer.
- Bidirectional LIS – check this check box if the LIS computer will download lists for one of the list modes for automatic sample processing.

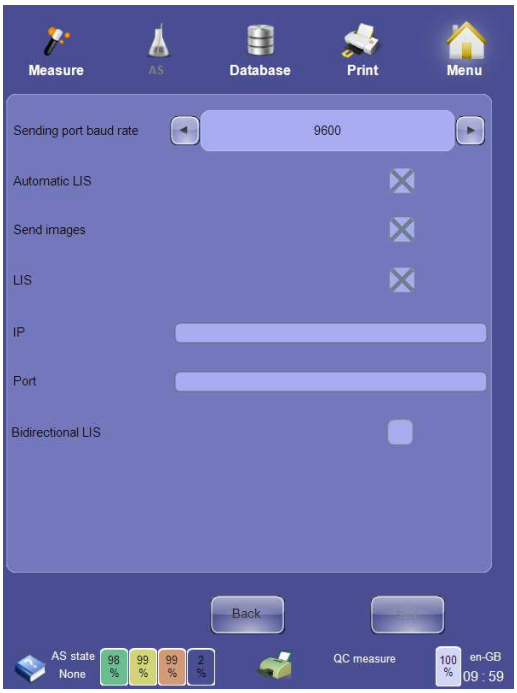

Figure 78. External Devices Settings Panel

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NOTE: when using bidirectional LIS settings, the ‘ELite 5’ analyzer “listens” for an external device (or LIS computer) to send it instruction. Consult your information technology staff regarding the configuration of the host computer and the ‘ELite 5’ analyzer for proper LIS operation. Your information technology staff person may need to consult your Erba Lachema certified service engineer to ensure the Internet Protocol (IP) settings of the ‘ELite 5’ analyzer are set properly.

The ‘ELite 5’ analyzer “listens” on port 6600 for incoming LIS instructions.

13.4 System Settings

System settings change various options about the operation and behavior of the ‘ELite 5’ analyzer.

The System settings panel lets you change the following settings:

- Database columns order – which column (parameter) of the measurement database is displayed / hidden.
- Waste container volume – select 10L, 20L, or None. Selecting 10L or 20L changes the waste container tracking display behavior in the reagent status area at the bottom of the screen. Selecting None assumes waste is being drained directly into the laboratory drain and the level of waste in container is not monitored.
- Database display limit – select All or Last month to change the number of database records displayed in the database panel. Last month only displays the last 30 days of measurement results, and displays all measurement results stored in the ‘ELite 5’ database.
- Use only Sarstedt Monovette tube from sample rotor – check this check box to change the sampling depth for manually presented tubes at the sample rotor to accommodate Sarstedt Monovette tubes. Uncheck this check box to manually process standard sample tubes. This setting does not affect automatic sample processing with the optional Autosampler, which is able to recognize tube types and change sampling depth automatically.
- Standby time – This defines the time period of inactivity before the analyzer automatically leaves the ready state and drains the pneumatic components to prepare for overnight standby. If this time is set to zero, the analyzer will never enter the standby state automatically.
- Offline rinsing frequency – this defines the time period between automatic fluidic operations to ensure that fresh reagents are available in critical pneumatic components so that the analyzer can quickly return to the ready state from standby. If this time is set to zero, the analyzer will never perform automatic fluidic operations while in the standby state, but may increase the amount of time needed to return to the ready state from standby.
- Screen saver – this defines the time period of inactivity before the analyzer automatically starts the screen saver. Entering a time of zero prevents the analyzer from every starting the screen saver.
- Special flags (G, L) – checking the check box disables the generation, storage, LIS transmission and display of the G and L flags on the screen, printout.

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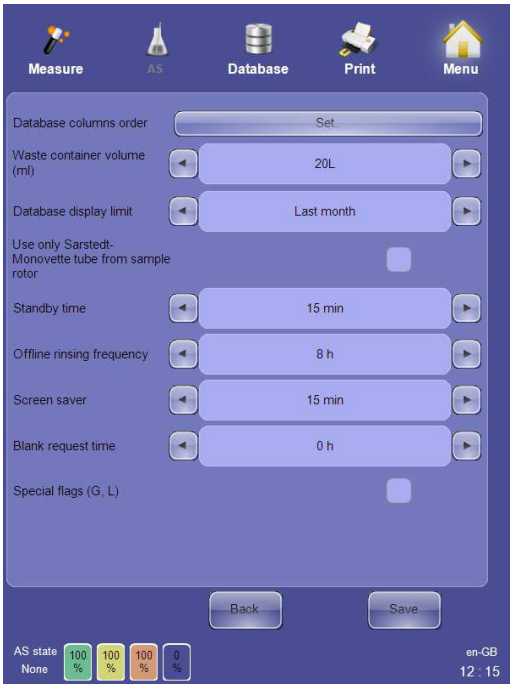

Figure 79. System Settings Panel

13.5 Units

The Units panel allows the user to choose which units are displayed for certain parameters.

The following options are available on the Units panel:

- HGB unit – choose g/dL or g/L to change the displayed units for the HGB and MCHC parameters.
- Count unit – Choose cells/µL or cells/L to change the displayed units for the parameters in the table below.

Parameter	Cells/µL	Cells/L
WBC	10^3/µL	10^9/L
LYM	10^3/µL	10^9/L
NEU	10^3/µL	10^9/L
MON	10^3/µL	10^9/L
EO	10^3/µL	10^9/L
BAS	10^3/µL	10^9/L
PLT	10^3/µL	10^9/L
RBC	10^6/µL	10^{12}/L

Table 12. Count Unit Parameters

PCT / HCT unit – choose Abs / Percentage to change the displayed units for PCT / HCT.

MCV unit – choose fL/μm^3 to change the displayed units for MCV.

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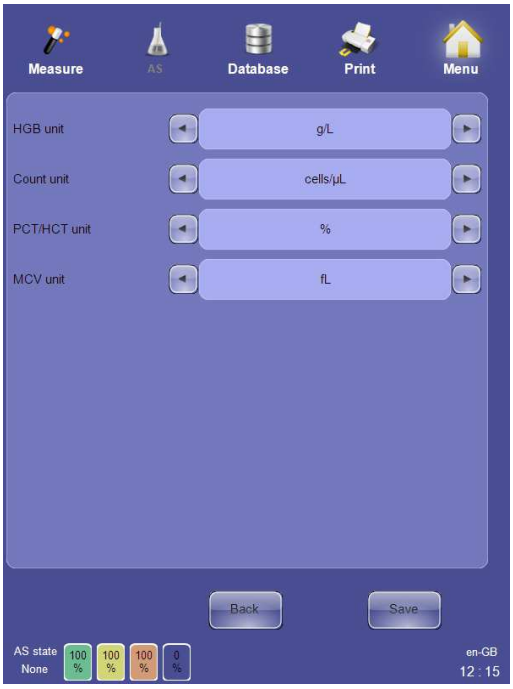

Figure 80. Units Settings Panel

13.6 Printer Settings

The Printer Settings panel lets you choose which installed printer to use, view the status of the printer, and change the print behavior of the analyzer during operation.

The following options are available on the Printer Settings panel:

- Printer – select an installed printer to use.
- Printer status – indicates the status of the currently selected printer.
- Color printing – check this check box to print in color, or uncheck to print in black and white.
- Double sided printing – check this check box to print on both sides of the paper, or uncheck to print on one side only. This option is only available if your installed printer supports double-sided printing.
- Items in queue – indicates how many printouts are currently waiting in the printer queue.
- Cancel all jobs – Click or tap this button to cancel printing and clear all items waiting in the printer queue.
- Printout format – select Default, Wide names, or User printout formats
- Automatic print – check this check box to print every sample or control as it is run.
- Logo visible – check this box to print the Erba Lachema logo on every printed report.
- Warning flags are visible – check this box to print warning flags on every printed report.
- Diagnostic flags are visible – check this box to print diagnostic flags on every printed report.
- Pre-printed paper header height – select from 0 to 80 pixels.

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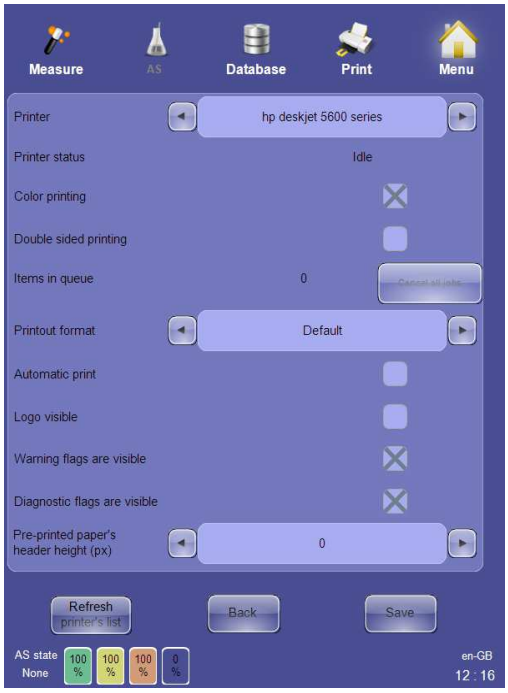

Figure 81. Printer Settings Panel

13.7 Profile Limits Settings

The Profile Limits settings are used to view and modify the normal ranges associated with the ‘ELite 5’ analyzer’s five sample modes: Human, Male, Female, Alternate 1 and Alternate 2. NOTE: Alternate 1 and Alternate 2 are sample modes that are different than Human, Male and Female and have user-definable normal ranges.

The control at the top of the panel selects one of the five sample modes. The panel is then populated with the lower and upper limit values for each of the 24 parameters. Modify the values as needed, then click or tap ‘Save’ to save the new values and return to the Settings panel, or select Back to discard any changes and return to the Settings panel.

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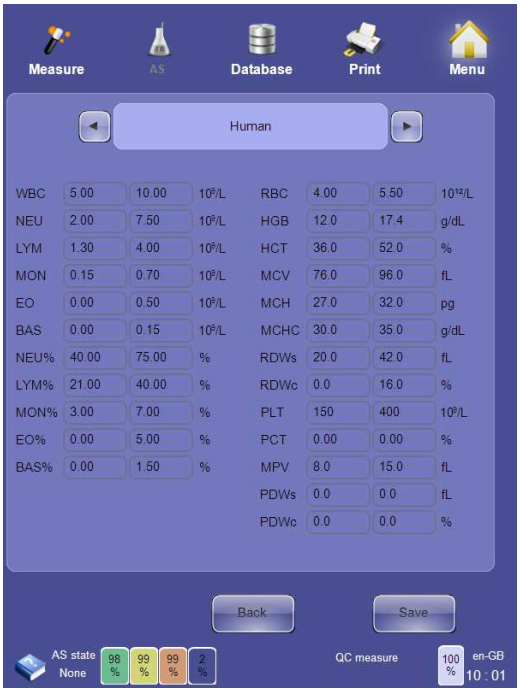

Figure 82. Profile Limits Settings Panel

In SSM mode we are using the same profile limits as we are using in normal mode.

13.8 X-B Settings

The X-B panel displays the currently selected X-B constants. Change the values as needed, then click or tap Save to save the new values and return to the Settings panel, or select Back to discard any changes and return to the Settings panel.

The following X-B settings are available:

- Lower and upper limit – A parameter is usable in X-B statistics if its value is between these criteria
- Target – the start value of the first batch in the X-B algorithm
- Action limit (%) - maximum percent deviation of the running average values from the target value. The user needs to check the X-B diagrams regularly as no action is performed by the software if the action limit is reached

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13.9 User Settings

The User Settings panel allows administrators to delete users, or assign administrator rights.

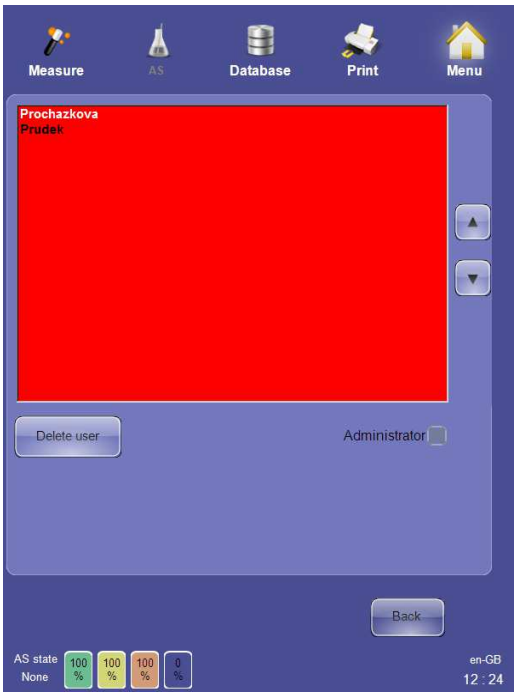

Figure 83. User Settings Panel

Users with Administrator privileges can have access all over the system. Only an administrator user can grant or revoke administrator rights.

Regular users have limited access to the system. A regular user is:

- allowed to modify Settings / Customize only (language, skin, sound volume),
- allowed to run and monitor QC measurements, but cannot define QC target values,
- not allowed to perform Calibration.

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13.10 Date and Time Adjustment

Double-click or tap the time display on the bottom right side of the screen to display a time/date settings panel. Change the time and date as needed and select ‘OK’ to save the new settings. Click or tap ‘Cancel’ to exit the Time/Date settings without saving.

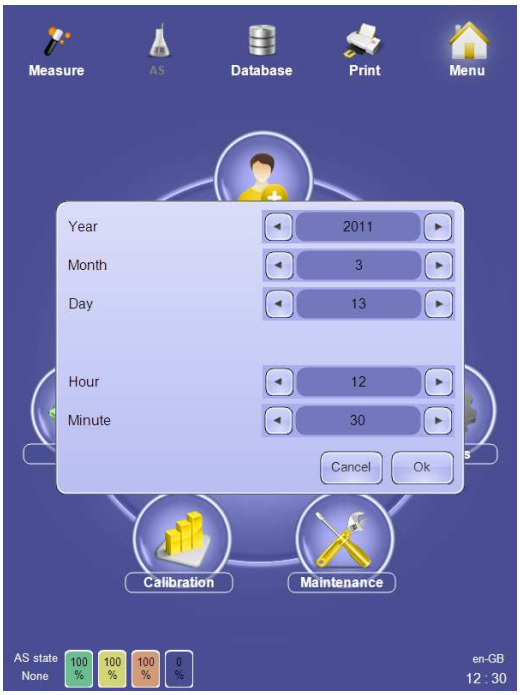

Figure 84. Time/Date Settings

The ‘ELite 5’ analyzer does not support automatic time zone or daylight savings time changes. Please change the time and date manually when necessary.

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14 Instrument Diagnostics

This section allows the operator to perform diagnostic procedures, check the operational history of the instrument, set or check the status of the reagents and view stored information about the system. Click or tap the ´Diagnostics´ button on the main menu to view the available options in the Diagnostics panel.



Figure 85. Diagnostics Settings

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14.1 Self Test of the Analyzer

Initiating a self test will test the key functions and components of the analyzer. The process takes approximately one minute and gives evaluation of each parameter. The acceptable ranges of each tested parameter or function can be found in the following table.

Clicking or tapping any tested parameter's small box gives detailed information of the parameter, limits and comments.

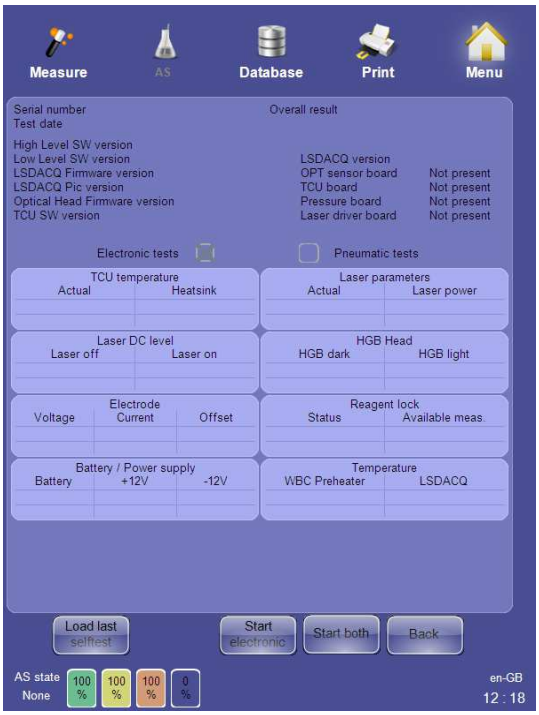

Figure 86. Diagnostics

By using the "Load last self-test" function you can check the results of the previous self-test sequence.

Self-test checks parameters for the ranges defined below:

Big puffer time Generate 3000 - 13000sec Release 3000 - 5500sec	**Small puffer time** Generate1 800 - 4000sec Generate2 800 - 4000sec Release 500 - 2000sec
Big puffer drift Maximum 540 - 560mBar Minimum 530 - 560mBar Drift -5 - 15mBar	**Small puffer drift** Maximum 225 - 235mBar Minimum 215 - 235mBar Drift -5 - 15mBar
Max vacuum P1 Maximum: 550 - 1000 mBar Time: 0 – 6000 ms	**Max vacuum P2** Maximum: 550 - 1000 mBar: Time: 0 – 6000 ms
Pump status Pump1 1 - 1 Pump2 1 - 1	**Null pressures** Sheath -20 - 20mBar Capillary -20 - 20mBar

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	Chamber -20 - 20mBar
Noise/Pulse	**HGB head**
pls/5sec 0 - 2000 pulses	HGB Dark 0 - 3000 pulses
20000pls 19990 - 20050 pulses	HGB light 3000 - 60000 pulses
TCU temperature	**Laser parameters**
Actual Reference +- 0.2 °C	Reference +-10%
Sink 0 - 55°C	Laser power 32.0 – 128.0
Laser DC level	**HGB head**
Laser off 0 - 0.05mV	HGB Dark 0 - 3000 pulses
Laser on 0.10 - 0.45mV	HGB light 3000 - 60000 pulses
Electrode	**Reagent lock**
Voltage 45 - 55V	Status: UNLOCKED / LOCKED / NA
Current 620 – 680µA	Available measurements: none
Offset -3.0 - 1mV	
Battery /Power supply	**Temperature**
Battery voltage 2.7 - 3.3V	WBC pre-heater:
+12V 11.4 - 12.6V	none (LSDACQ v3.0),
-12V -12.6 - -11.4V	34.0 -38.0 (LSDACQ v3.1)
	LSDACQ: none

If any of the values falls outside the above limits, the SW is going to list the errors on the self test report screen.

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14.2 Daily Log

The system log provides information for service or troubleshooting purposes. It lists events and possible problems related to operation or measurements. It also lists routine events such as logon.

The selector at the top of the panel filters the log entries according to following categories:

All – all log entries are displayed, no filter;
Error – only the error log entries are displayed;
Pneumatic – only pneumatic errors are displayed;
Software - only software system errors
User – displays only user-related log entries
System – displays only system action log entries

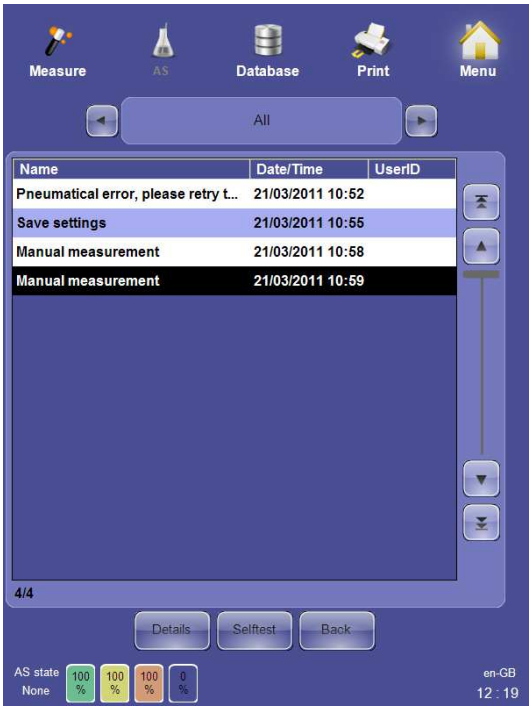

Figure 87. LOG file

14.3 Reagent Status

The reagent status panel displays the level of each of the on-line reagents and waste containers. It provides the means to reset the levels of each of the reagents in the event of a reagent container change.

The analyzer has built-in reagent consumption calculators. The calculated level of each reagent is indicated on the screen. The height of the bar shows the level in the container. These levels are also indicated on the screen in the status area. ELite 5 send special message if any of the reagents are running low. Check and change the reagent container and reset the reagent status bar on the screen.

If the reagent-locking feature is activated then the resetting of the 'Lyse' reagent activates the uploading of the measurement count from the hardware key. If the reagent-lock is in use then please connect the hardware key when resetting the 'Lyse' reagent-level.

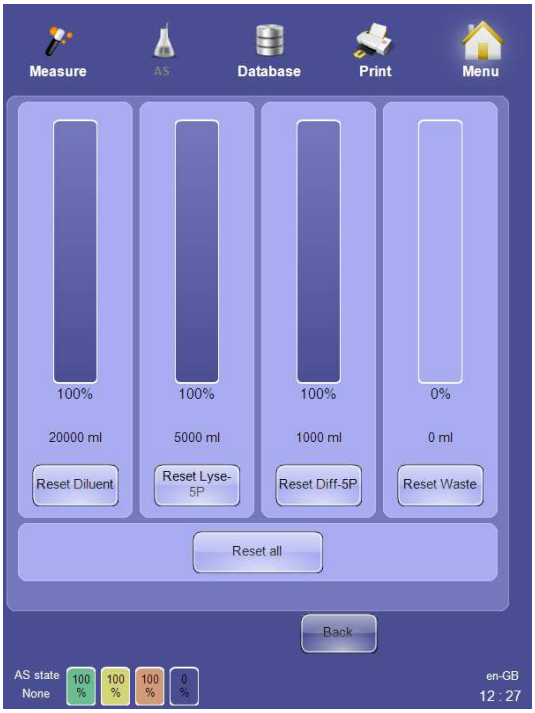

Figure 88. Reagent status

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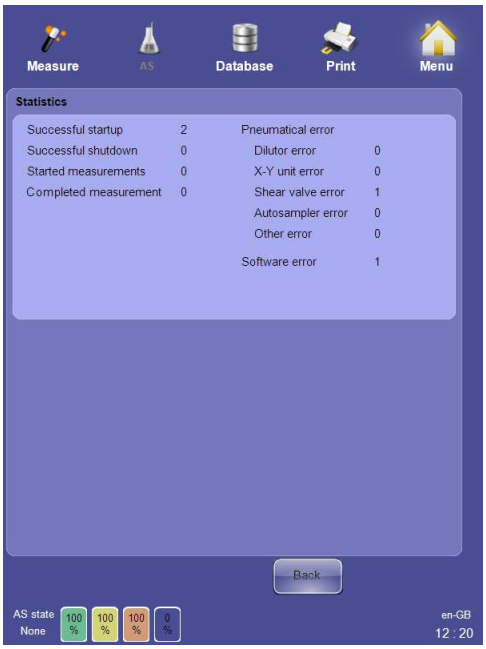
14.4 Statistics

This menu item will display cumulative number of measurements and number of possible failure events experienced during operation. Statistical data can be reset by a certified service engineer only.



F

Figure 89. Statistics display

14.5 Information

This menu item displays instrument specific data (serial numbers, SW versions of various system components). These data are important for maintenance purposes. Your service engineer will ask for these before a service visit.



Figure 90. Information display

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The information panel also contains a Collect button. By pressing this, there is a chance to save a .gz file to the selected path. This file can be sent to the local service engineer. The file contains valuable information about the instrument including self test, stress measurement and the calibration factors.

If the instrument has a problem, the collect file will help the engineer to analyze the problem, check the measurements and read the log file.

With this function the service engineer has a chance to study the instrument from a distance and give valuable information to the end user.

Before pushing the collect button, the user has to plug in a pen drive to make the system able to find this external storage after collect button is pressed. After the pen drive is found, the user can browse it to save the .gz file.

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15 Maintenance

To ensure reliable operation, regular maintenance, or occasional corrective actions are required. This chapter describes necessary procedures and steps required to keep your analyzer in a good operating condition.

ELite 5 is a completely automated hematology analyzer. Special 'Erba Lachema ELite 5 Service Training' is required to resolve major problems occurring during operation. Electrical and moving parts should always be serviced by trained person.

There are, however some maintenance actions the operator should perform to keep the analyzer in a reliable and clean state.

Any elements inside the analyzer like tubes, valves, chambers, containers should be handled as a potentially biologically and chemical dangerous material. Observe the related law and regulations regarding handling. Follow the hospital handling instruction during disposal.

15.1 Opening the Front Panel

Several components that require regular cleaning and maintenance are behind the front panel. To access the pneumatic system, and to be able to perform some maintenance actions, you have to open the front panel of the instrument.

Make sure that nothing is placed on the top, or in front of the analyzer. Grab the lower sides of the front panel, gently pushing the sides. Pull the lower part towards you, and lift up the front panel.

Upon opening, a lever becomes visible. Make sure to tilt the front panel upwards so that you can push the lever into the secure position.

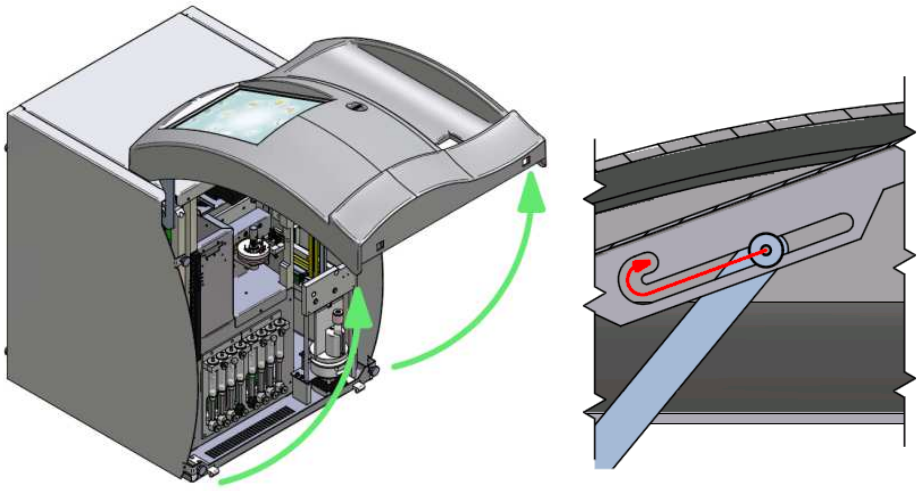

Figure 91. Front cover

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15.1.1 Closing the Front Panel

Do not push on the front panel while the security level is in the "lock" position.

Gently lift the front panel so that the security support lever can be moved to the free position.

Gently lower the front panel. When it reaches its lowest position, gently push on the front side to click the lock-levers in place.

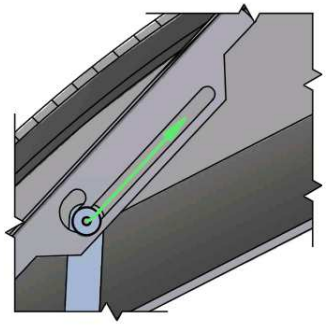

Figure 9236. Closing the front panel

15.1.2 Removing the Side Panels

With the front panel open and secured, thumb screws become visible. Both side panels are fixed to the instrument with these screws: 2 in the front, and 2 in the back. The screws are designed to stay on the analyzer to avoid losing them.

The system valves and measuring chambers are behind the left side panel. Open the left side panel if chamber cleaning is requested by the analyzer.

Right side covers sampling unit, wash head and sampling needle. You need to open the right side cover if the wash head needs to be cleaned or replaced.

After removing the cover, potentially hazardous parts become accessible, electronic boards, motors, moving parts, sampling needle, chambers, tubes and valves.

These components may cause injury, or can get damaged if handled incorrectly. Only certified personnel should open the covers. Running measurements with opened cover is not recommended due to the risk of possible injury. Always wear safety gloves while performing maintenance actions.

Always make sure to re-tighten the thumb screws when reinstalling side panels.

15.1.3 User Maintainable Parts of the Analyzer

There are three user maintenance points in ´ELite 5´ analyzer.

Shear valve: this is a key component and is responsible for correct sampling and diluting procedures.
Wash head: key component in keeping the sampling needle clean and ensuring reliable piercing and sampling procedures.

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Measuring chambers: contamination induced problems such as noise, high blank values can usually be resolved by cleaning the plastic measuring chambers.

General precautions: Always wear protective gloves when working on internal parts of the analyzer.

15.2 Maintenance Programs of the Analyzer

Maintenance functions can be accessed from the menu system by clicking or tapping the Maintenance main menu. This opens the maintenance function panel.

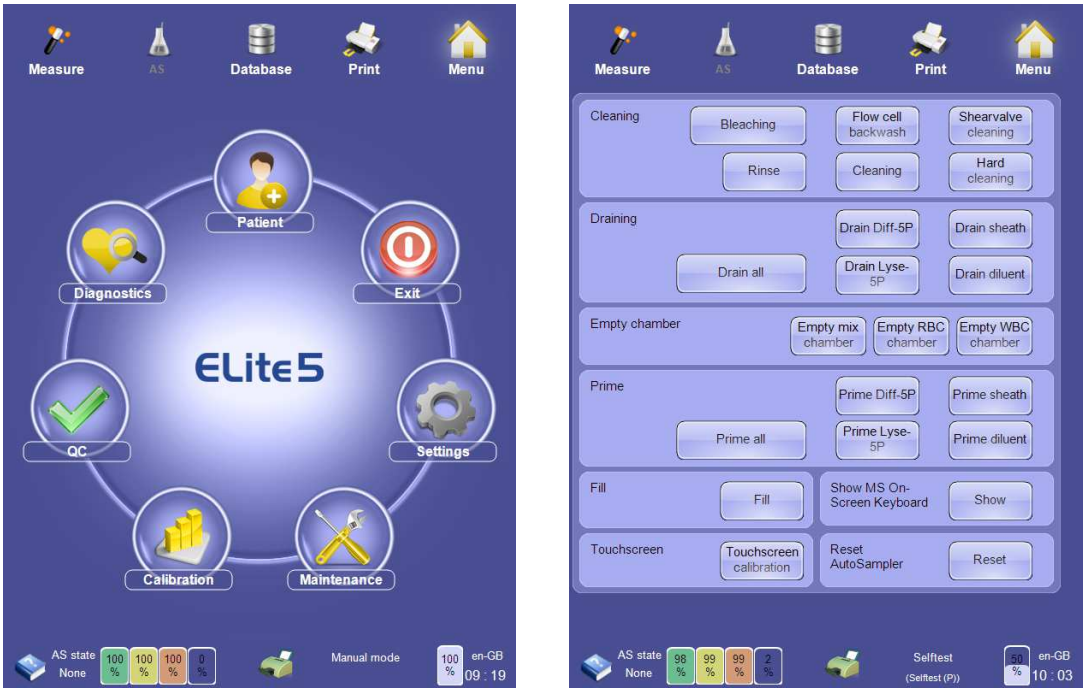

Figure 93. Maintenance menu

Clicking or tapping any of the function buttons initiates the corresponding maintenance function. The maintenance functions are grouped into the following categories.

Cleaning

Bleaching: cleans the diluent buffer and the connecting tubes with external cleaner reagent introduced through the sample rotor. This type of cleaning does not affect the optical head´s flow cell and its tubing.
Flow cell backwash: cleans the optical head and the flow cell by draining the sheath buffer through the optical head with a frequently used back flush through the flow cell, then refills and rinses the system.
Shear valve cleaning: drains the shear valve so the user can open it to clean the ceramic valve, then refills and rinses the system.
Rinse: washes the tubing system with diluent.
Cleaning: cleans the system with external cleaning reagent introduced through the sample rotor.
Hard cleaning: extended cleaning of the system with external cleaner through the sample rotor. The cleaning of measurement chambers and connected tubing is performed. The

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software is going to prompt the user to add external cleaning reagent (Erba Hypoclean CC) in the sample position (manual measurement).

Draining

Drain Diff-5P: drains the Diff-5P reagent
Drain sheath: drains the sheath buffer
Drain Lyse-5P: drains the Lyse-5P reagent
Drain diluent: drains the diluent
Drain all: drains all the above mentioned reagents

Empty chamber

Empty Pre dilution chamber: empties the Small Sampling Mode pre-dilution chamber (behind the sample rotor).
Empty Mix chamber: empties the Mix chamber (intermediate step for RBC dilution).
Empty RBC chamber: empties the RBC counting chamber.
Empty WBC chamber: empties the WBC counting chamber.

Prime

The analyzer primes reagents individually or all reagents together.

Fill

Fill: initial filling of the system with reagents. This must be performed PRIOR to first use of the instrument after installation or after the system has been drained for transportation or storage.

Show MS On-Screen Keyboard

Show: activates on-screen (qwerty keyboard) on the bottom of the display.

Touch-screen

Touch screen calibration: the software will instruct the user to tap specific areas of the display. This is going to help calibrate the touch sensitive surface.

Reset Autosampler
Reset: initializes the sampler to home position.

15.2.1 Cleaning the Shear Valve

Any salt build-up on the inner surface of the shear-valve may cause malfunction during operation. **To avoid this problem, it is recommended to clean the shear valve after every 1200 samples.**

You need the following materials to complete the shear-valve cleaning:

- A clean, soft, damp cloth
- A clean, soft, dry cloth
- A lint-free, soft, dry-cloth (like a non-woven sheet)
- Gloves
- Tweezers
- A few tooth-picks
- Water

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The shear-valve is in contact with the sample blood. Wear gloves while cleaning the shear-valve. Handle the materials use to clean the shear-valve as potentially infectious material.

The parts which should be disassembled / re-assembled are fixed with so called thumb-screws. No screwdriver or other similar tools are required to tighten these screws.

Go to the Maintenance menu, and select Shear Valve Clean function to initiate the procedure.

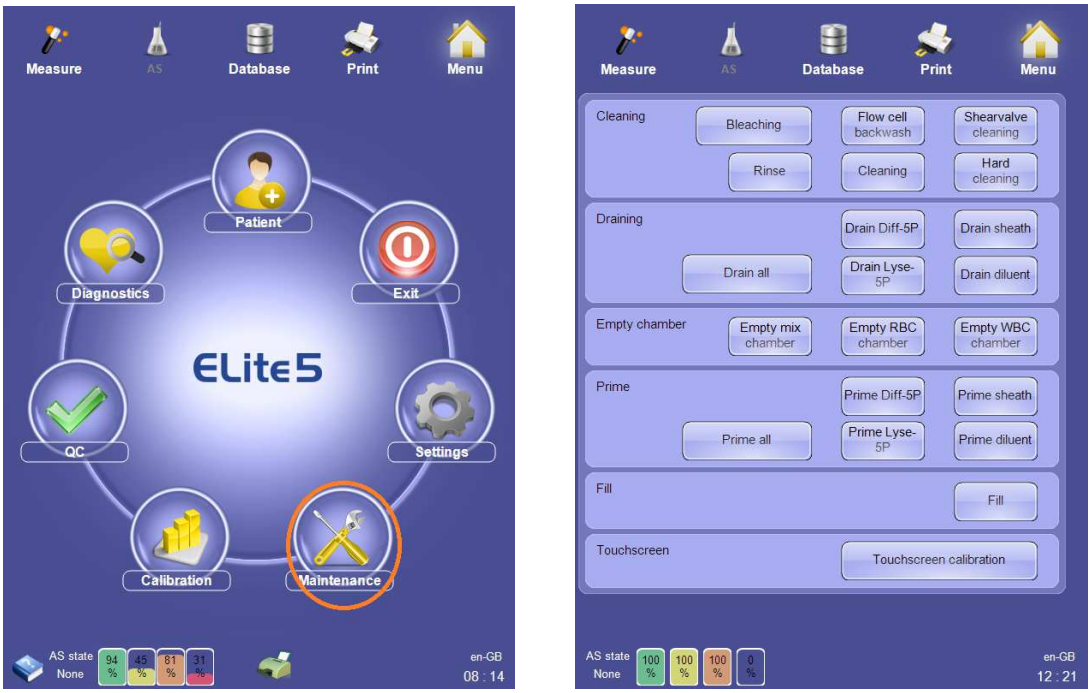

Figure 94. Maintenance menu-shear valve

The ‘ELite 5’ asks for confirmation to start the procedure. After clicking or tapping the ’OK’ button the ‘ELite 5’ empties the shear-valve and the connecting tubes. A small amount of liquid may remain inside the tubing and inside the shear-valve.

When the procedure completes, the ‘ELite 5’ prompts the user to proceed the shear valve cleaning with the following message:

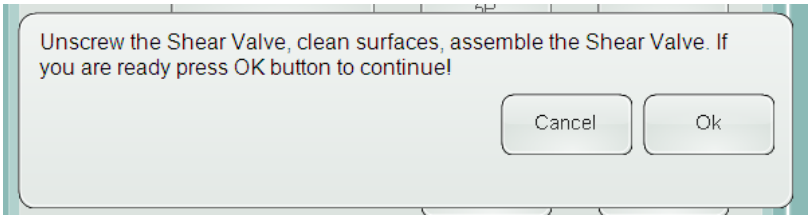

Figure 95. Shear valve cleaning info

Don’t press the ‘OK’ until the shear valve has been cleaned and re-assembled again!
Perform the shear valve cleaning according to the instructions below.

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Any salt build-up on the inner surface of the shear-valve may cause malfunction during operation. To avoid this problem, it is recommended to clean the shear valve after every 1200 samples.

1: Open the front cover and secure it with the latch. Locate the shear valve in the center of the analyzer.

2: Unscrew and remove the “Axis thumb screw” that secures the shear valve. Clean the “Axis screw” by using water and wipe it dry.

3: Slide off the upper disk of the shear valve. Due to the extremely smooth surface of the ceramic discs they may stick together. If the shear valve was not in use for a few days, then apply a few drops of water to the contact of the upper and lower disks. The salts will dissolve in a short time and release the upper disk.

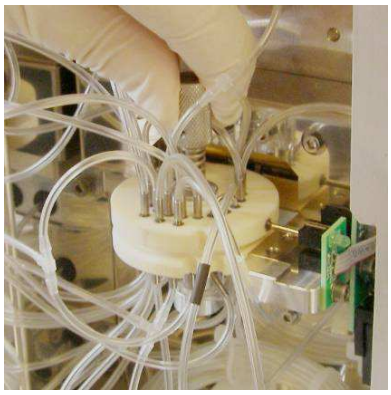

Figure 96. Removing the shear valve axis thumbscrew

WARNING!!
Some of the tubes connected to the shear valve have critical length and position. Do not pull or move the upper disk of the shear valve, because some attached tubes can get pulled. Make sure that the thin tube connecting the shear valve and optical head is not pulled it can cause serious damage to the laser injector.
After the upper disk is cleaned, the best place to put it is the shear valve mechanics metal plate cover. This way the tubes won´t be pulled accidently.
After assembling the shear valve, make sure that the tube between the shear valve and the needle is horizontal and not bended!

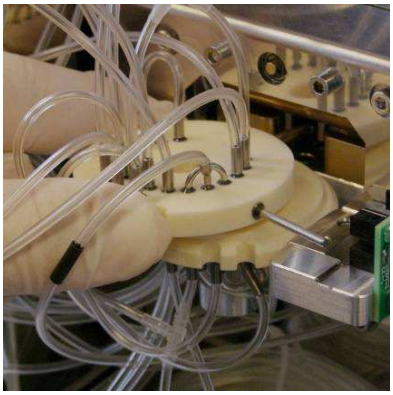

Figure 97. Disassembling the shear valve

4: Gently clean the mating surfaces of the disks of the shear valve, the housing of the valve and the tube connections.

5: Remove any salt build-up. Use tweezers to push in the dampened and the dry cloths. Apply a few drops of water to soften any hardened deposits.

6: Use a tooth pick to remove any salt crystals from narrow places. Do not use any sharp metal or hard objects which can scratch the smooth surfaces of the shear valve.

7: Clean the outside of the shear valve and the housing and mounting parts of the shear valve. Pay attention to clean the aligning surface.

.

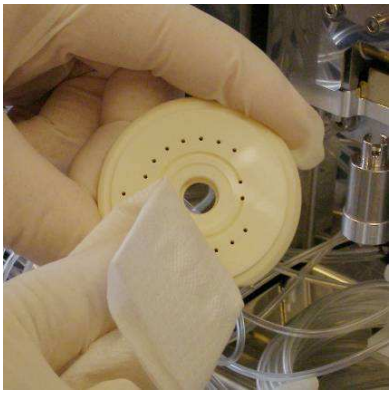

Figure 98. Shear valve cleaning procedure

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8: Ensure that no lint or fibers remain on the smooth mating surfaces of the ceramic disks.

9: After cleaning the shear valve, housing and surrounding area, gently put the disks together.

10: Put the “axis thumb screw’ back into the center of the upper disk. The spring on the axis of thumbscrew guarantees the necessary closing force for the two disks. Gently press down and rotate the axis thumbscrew clockwise until it clicks into the lower part.

11: Twist the axis thumbscrew until it stops. The mechanical design of the thumbscrew prevents over-tightening.

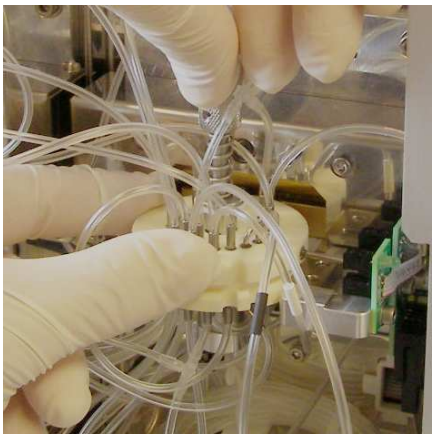

Figure 99. Reassembling the shear valve

12: Clean the area surrounding the shear valve again. You can let salt crystals and other small debris fall down. Sweep any particles laying on bottom of the ‘ELite 5’ though the ventilation holes. Remove the gloves. Close the front door and remove gloves.

13: Click or tap the ‘OK’ button to inform the ‘ELite 5’ that you completed the cleaning of the shear valve. The ‘ELite 5’ will check the movement and end-positions of the shear valve.

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15.2.2 Cleaning the Washing Head

The washing head cleans the outer surface of the aspirating tip with diluent. Any salt build-up on the lower surface may cause malfunction during operation. The wash head must be removed from the needle assembly for correct cleaning.

Open the front panel, and secure it with the support bar. The right side panel of the analyzer must be removed to access the wash head. Loosen the 2+2 screws on the front and rear of the side panel. The panel can be pulled off the analyzer.

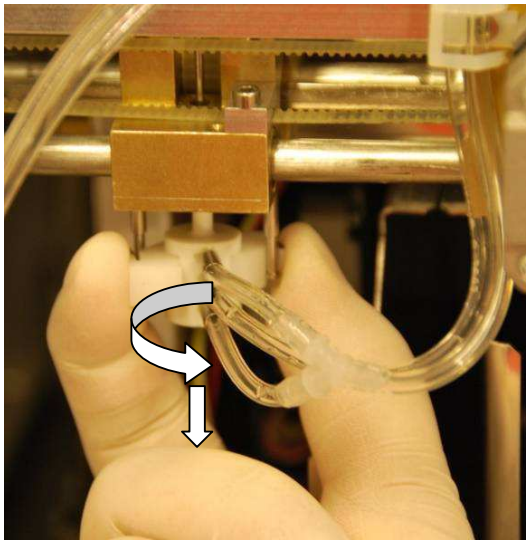

Figure 100. Wash head



Locate the sampling needle. Be careful! The sampling needle is sharp, and can cause injury!

The wash head should be “twisted off” from the needle, and pulled off downwards. Use a soft cloth dampened with water to clean the bottom of the wash head.

To put the wash head back:

Push the wash head onto the needle. Push it up as much as you can (taking care of the sharp needle) and lock it back by twisting it into the grooves of the holding rods.

Replace the side cover and close the front panel.

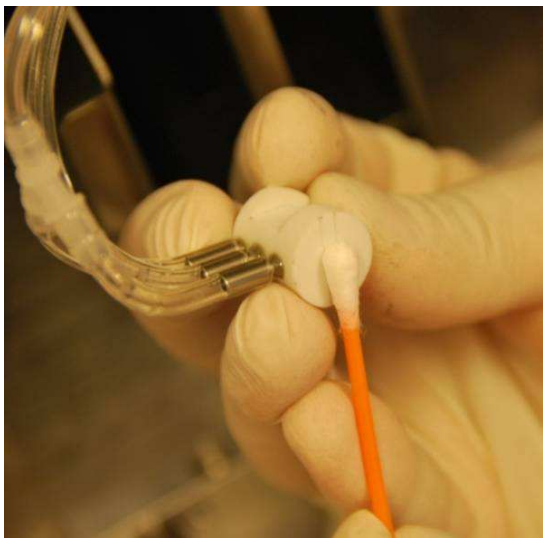

Figure 101. Wash head cleaning procedure

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15.2.3 Cleaning the Measuring Chambers (Hard Cleaning)

If the system keeps reporting high blank values, direct cleaning of measuring chambers must be carried out.

The analyzer software will ask for a sample vial filled with Erba•Hypoclean CC as a sample.

The analyzer used for hard cleaning about 1.5 ml Erba•Hypoclean CC.

15.2.4 Daily Cleaning

At the end of the daily routine (during shutdown), the analyzer software will ask for a sample tube filled with Erba•Hypoclean CC as a sample. This will clean the whole measurement related tube path.

EVEN THOUGH ELITE 5 CAN PIERCE THE CAP OF A SAMPLING TUBE, THE RUBBER CAPS ARE NOT DESIGNED FOR MULTIPLE PUNCTURES. THEREFORE IT IS RECOMMENDED TO REMOVE THE CAP OF THE VIAL WITH THE CLEANING SOLUTION, OTHERWISE THE RUBBER WILL HARDEN UP, AND SMALL PARTICLES WILL FALL INTO THE SOLUTION WHICH CAN CAUSE CLOGGING IF ASPIRATED BY THE SAMPLING NEEDLE.

After this operation, you can leave ELite 5 on for the rest of the day. It will go into a low power state after a specified time.

Note: It is recommended to perform this cleaning every day!

15.2.5 Special Cleaning Procedure

Despite regular cleaning, Emergency cleaning procedure is advisable, if the blank measurement result is too high or unacceptable result appear during the measurement or calibration.

Use the built-in cleaning process in the maintenance/prime and clean/clean menu and check the proper result with a blank measure.

If the blank is still too high use the built-in hard clean process and check the proper result with some blank measures.

If the blank is still too high use the built-in internal diluents reservoir cleaning process and check the proper result with some blank measures.

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15.2.6 Replacing Reagents

'ELite' 5 analyzer is designed to be able to run continuously without the need to stop if a reagent container needs to be replaced. To support this feature, internal buffers keep regents sufficient for one measurement cycle.

The analyzer will warn the user when a reagent is about to run out. An exclamation mark within a yellow triangle will be displayed by the reagent level indicator.

To facilitate replacement, “double tapping” on the exclamation mark takes you to an explanation screen. Pressing the “Go to” button will take you further to the reagent status screen.

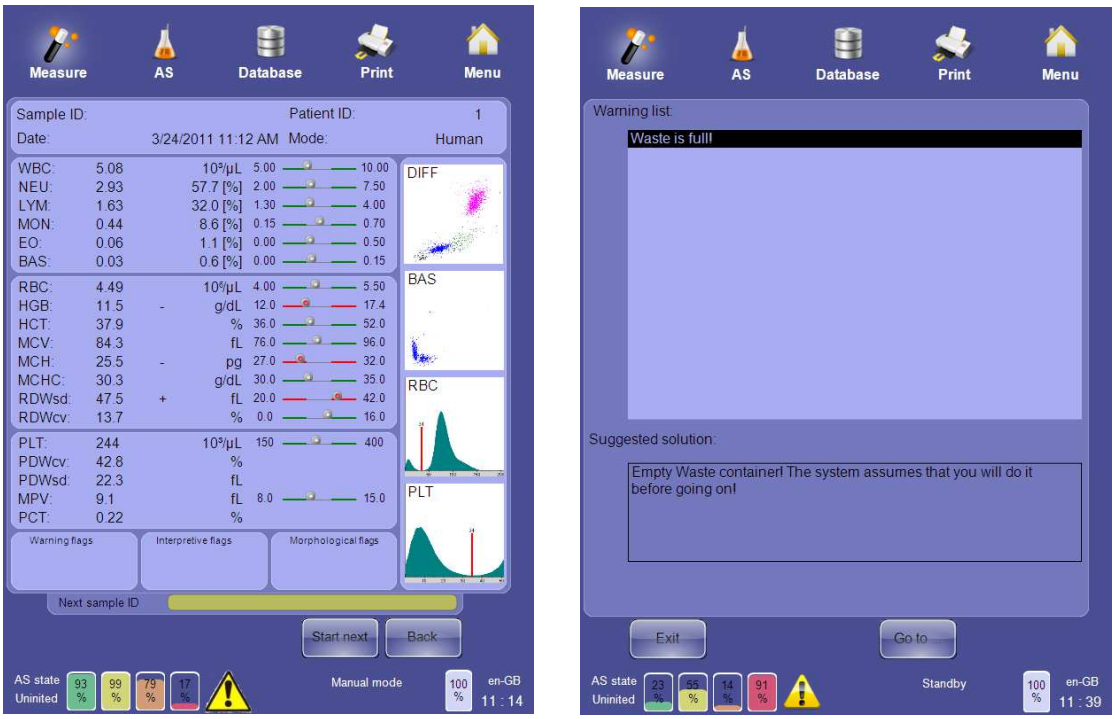

Figure 102. Reagent warning

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To replace reagent containers:

- Prepare the new container, and place it near the place of operation.
- Open the bottle (remove cardboard flaps if necessary (5L and 20L containers).
- Unscrew the cap from the used container and place it into the new container.
- Replace the old containers with the new ones.
- Dispose of used containers according to local regulations.

When a reagent is replaced, it is not enough to replace the external container only the reagent level counter must also be reset.

Push the button below the corresponding reagent bar to reset its level back to 100%.

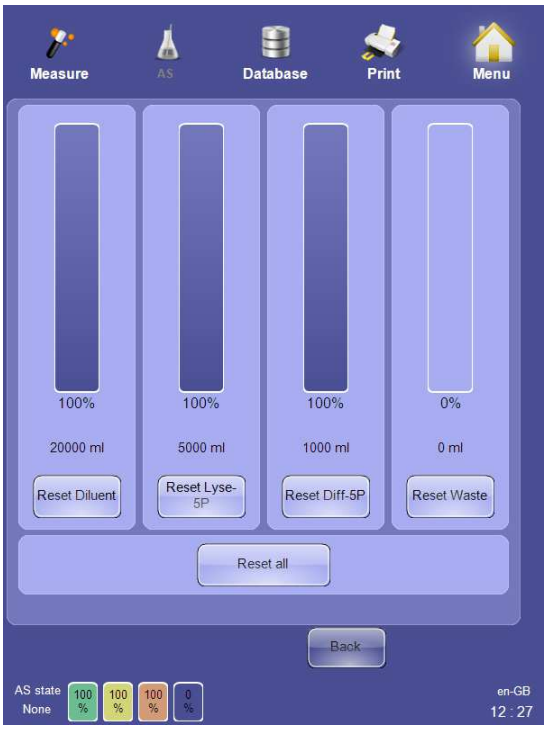

Figure103. Reset of reagent status

15.2.7 Disposal of Reagent Containers



Always follow local regulations of hazardous waste disposal!

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16 Reagent Locking

Reagent locking is a commercial feature of the 'ELite 5' ensuring that only manufacturer recommended and approved reagents are used with the analyzer. This way analyzer performance cannot be impaired by incompatible reagents. All necessary hardware and software elements are installed and configured on each 'ELite 5' unit individually.

Each Erba•Lyse 5P reagent bottle comes with a reagent key. The key is in a plastic bag glued to the tear-open flap of the cardboard box container. Each key contains license for 800 measurements.



Figure 104. Reagent key inside the Lyse cardboard

With active 'reagent lock' there is an administrative limit of measurements run on the 'ELite 5'. The 'ELite 5' keeps track of the number of measurements performed. If the limit is reached, then the 'ELite 5' will first warn the user about the fact, then it will refuse to perform further measurements.

The analyzer decreases the number of available measurements with each sample run, even Blank, Calibration and QC measurements. When the counter decreases below 50, and any sample run is started, the user will receive a warning message about this counter decreasing. When the number available reaches zero, the analyzer will not run more samples.



Figure105. Reagent Lock socket

To increase the number of 'remaining' measurements, you have to upload measurement licenses from the hardware-key to the 'ELite 5'. The uploading can be initiated during 'Lyse' reagent level reset. See chapter 14.3.

The hardware-key is similar to a USB memory device but it is not a real USB memory device. Do not insert it into a USB connector. (The hardware key will not harm USB ports however it can't be predicted how the USB drivers react if a hardware-key is connected as USB device).

To transfer measurement licenses to the 'ELite 5':

- Remove the hardware key from its protective packaging.
- Insert the hardware-key into the HK-connector on the right side of instrument (see chapter 4.2.5);
- Initiate 'Reset' of 'Lyse' reagent and follow instructions on the screen;
- All (800) measurement licenses will be transferred from the key to the analyzer.
- Remove the hardware-key from the 'ELite 5'.

Any already used (empty) hardware key cannot be used again.

- Collect and return them to your dealer/ service personnel/ sales representative for re-cycling or dispose them as electronic waste adhering local regulations.

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17 The Daily-Routine

In this chapter a typical daily routine is described. Of course your daily routine can differ from the one described here. This chapter also contains some trick and tips.

The below assumes that the laboratory works during ‘office hours’ only.

The daily routine:

- Power up and start-up the ‘Elite 5’ analyzer. See Chapter 6.2.2. for details
- Perform the pneumatics initialization and blank measurement (tap the sampling tube icon)
- Check reagent levels, start your internal procedure to get new reagents from the storage if necessary
- Collect the samples
- Check if the correct (K_3-EDTA) tubes are used
- Check if the samples are within the 6 hours of processing limit
- Check if the samples are at room-temperature (refrigerated samples)
- Power on the Autosampler (if installed)
- Perform the QC procedure as scheduled
- Start the measurements in manual or automated mode; see chapter 7 for details
- Check and release the results according to your internal regulations
- Perform the necessary maintenance actions; see chapter 17 for details
- Shut down the instrument; see chapter 6.3 for details
- Clean the instrument; see chapter 15.2.4. for details

Notes:

Blank measurements:

If you want to check whether the reagent-path was contaminated during the reagent replacement then perform 4-5 blanks measurements before accepting the blank result. The reagents from the internal reservoirs should be used before the new reagent reaches the measurement system;

If you receive the samples in batches and more than 2 hours elapsed between the last sample of the previous batch and the first sample of the next batch, then it is a good practice to repeat the blank measurement;

Quality Control:

Perform QC measurements according to your local regulations;

Please monitor the expiration date and stability after first use of the QC material;

If there are more hematological instruments in your laboratory then it is also a good practice to measure the same human sample on all the instruments to compare the instruments. Use multiple parallel runs to reduce the effect of random error (CV %);

We suggest performing at least one blank measurement before starting QC measurements;

Calibration:

Calibrate the ‘ELite 5’ according to laboratory regulations;

Calibration is due with every new control material lot. Also, if QC results or comparison of results to other instruments’ results shows permanent error in measurements;

If you perform a measurement based calibration then it is recommended to run a blank measurement before the calibration procedure; see chapter 10;

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Cleaning:

Perform cleaning / hard cleaning if:
High blank results experienced;
Clogging related flags are added systematically to measurement results;
After service actions, service level maintenance;
Measurement results, QC results are drifting (perform hard cleaning);
Clog formation in the tubing (first remove the plugging, contamination);
Reagent connected to wrong place, wrong reagents were used.

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18 Troubleshooting

Your 'ELite 5' software is equipped with all the functions to keep the analyzer in good working conditions. Despite careful planning and SW features, the analyzer can still encounter problems where user interaction is required or the user needs to be informed of situations when further help is required.

These are called error messages. Error messages can be further classified. Your analyzer will provide all details to identify the error – however most of the times these errors will be composed of numerical codes. These are important for the service personnel – they can interpret the messages and take necessary actions.

Would you receive error messages with codes, please write them down. If possible, describe with a few words what you were doing before the error came up. This is important so that your service engineer can help you when necessary. The software memorizes every error, but it cannot describe the operation you performed.

When an error comes up, the software will most of the times try to offer solutions, or will try to resolve the problem and retry the current operation. If this recovery process fails, or the problem keeps coming back, please contact your service engineer.

18.1 Software error messages



If Windows® XP® Embedded operation system errors come up, please accept the error message and repeat the operation. If there is any other error please restart the 'ELite 5'. At the next service visit, please let the service engineer know about the problem.

Low level error messages provide status information about data acquisition system and pneumatic system. Each Error message includes the affected part and the area of the equipment. Check this area and part to find any irregularities like clogging, mechanical problems, blocked elements. Try to repeat the operation. The system will try to recover from the failure. Would it not go away, please contact your service personnel.

18.2 Pneumatic error messages

The analyzer software is designed to be error tolerant, and as such it is able to deal with minor problems. However, if some physical obstructions or extreme operating conditions cause some mechanical parts to behave unexpectedly, the system will give you an error message:



Figure 106. Pneumatic error

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With the 'Ok' button, you can return to the current operation and retry the actual process.

You can also tap on the Details button and then you will be able to get further informaion about the error. It will describe additional conditions of the failure. The numbers in the second row are important for the service personnel.

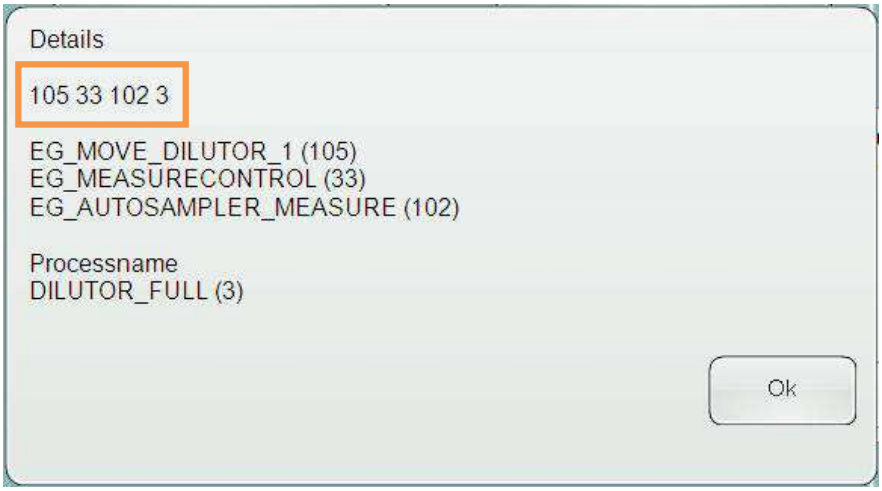

Figure107. Pneumatic error detail

18.3 Mechanical Problems

Most mechanical problems arise because of some physical blockage of the moving parts. Problems caused by severe blocks are most often accompanied by a grinding noise. The noise is a result of a motor not being able to move – however most of the time this will not cause mechanical damage to moving parts.

Typical situations can be traced back to salt build-ups around the wash head or the shear valve. Incorrect operation of cleaning of the system – especially after long inactive periods of time can cause valves or tubes to get filled with somewhat dried salt. These problems can be the sources of dilutor motor noise.

In extreme tube or valve clogging situations the pressure built inside the dilutors can cause some tubes to be released from their connections. This symptom is not normal, but will not cause damage to the system. However, it is recommended to contact Service Personnel to sort out the cause and resolve these problems.

18.4 Sample Rotor (SR) Failures

18.4.1 SR Gives Grinding Noise And / Or SW Displays SR Error Messages

- The front panel is not closed properly
  - The opening does not match with the sample rotor door
- There is liquid in the SR, if you can see traces of salt around the SR, contact service
- Check the washing head for contamination (blood and salt) as excessive salt build up can prevent the wash head to lift up effectively and the sample rotor door can get stuck

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18.4.2 SR Error Appears During Initialization Process:

- Check the washing head for contamination (blood and salt)
- Contact service

18.4.3 The SR Does Not Turn Into the Analyzer Even With Open Front Panel

- Check the washing head for contamination (blood and salt)

18.5 Needle Mechanics, Vertical Motor (Mvert) Problems

18.5.1 The Needle Carriage Keeps Dropping Back (Down) At Initialization

- Is the wash head and its surrounding free of any salt build-ups?
- Salt build up or thick salt layer at the bottom or on the inside can block the movement of the needle in the wash head (or the movement of the wash head around the needle if you like).
- The through hole of the needle in the vertical carriage should be free of salt.
- Salt around the needle can even damage the needle and can influence the sampling process, or sampling quality or amount of sample.
- The wash head position relative to the needle and to the SR is not correct.
- The wash head comes down too much, and even if lifted, leaves no room for the SR door to turn.
- The vertical rod holding the wash head (if removed or modified) is not inserted correctly. The rod was not pushed up to the maximum, and the wash head is sitting in a position too low.

18.6 Shear Valve (SV) Related Errors

18.6.1 SV Error at the First Startup

- The SV cannot turn:
  - Make sure that the pull tab has been removed
  - Check free movement by hand (rotate the shear valve)
- The SV is stuck:
  - Try to open the Shear Valve

18.6.2 Grinding Noise after SV Cleaning, (after SV Reinstallation)

- The rotating part cannot reach opto position
- The lower disc is not aligned correctly – see section SV cleaning
  - Contact service for guidance

18.6.3 SV Leakage

- The upper disc is not sitting well on the lower disc
- Open, and reseat the upper disc
- There must not be any opening left between the closing screw and the upper disc

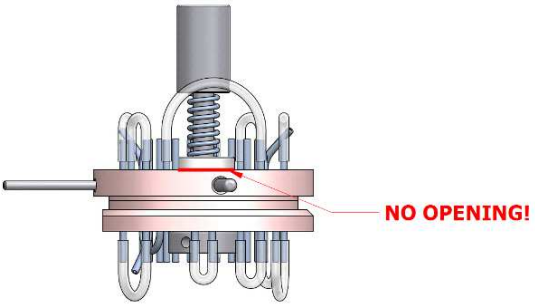

Figure 108. Screw position of shear valve

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18.7 Dilutor Errors

- Pinched, clogged tube around dilutor or at the rear reagent tubes
- Physical obstruction (foreign material)

18.8 Priming Problems

18.8.1 The Analyzer Would Not Prime Liquids

- The respective reagent is out
- Aspirating tube (in container)
  - has fallen off,
  - has a leakage,
  - is broken,
- A reagent puffer is leaking… look for liquid below the analyzer
- Damaged tube in the system… look for leakage, or traces of liquid, contact service

18.9 Electronics Related Problems

18.9.1 No Image on Display, No Backlight

- Contact Service

18.9.2 Touch Sensitive Surface Not Working

- Connect an external USB mouse
  - this will allow clicking on the screen elements
  - contact service for resolution of the problem

18.9.3 Touch (Click) Is Inaccurate

- The touch screen needs calibration
- Connect an external USB mouse
  - perform the calibration under Main Menu / Maintenance / Touch screen calibration

18.9.4 The Cursor Seems To Be Moving With Good Ratios, But In a Smaller Area

- Try to calibrate the touch screen (use a mouse to access the functions)
- If the problem persists, contact service

18.10 The Analyzer Does Not Power On

- Check proper power connections, and the state of the (small) switch at the power supply
- If the above fails, contact service

18.11 I2c Errors Displayed At Startup

- Contact Service

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18.12 Measurement results related problems

18.12.1 Fluctuating PLT background values

When the ELite 5 is used under increased workload, running even 300 samples a day (meaning 5 hours of continuous operation) is possible.

Despite built-in maintenance programs, the system may require intensive cleaning from time to time. If you find that Blank PLT values are increasing and decreasing unprecedentedly, please run a “Hard Cleaning” function.

Go to Main Menu, Maintenance. Tap the Hard Cleaning button to initiate the procedure. You will need a syringe (10ml) to dose cleaning liquid into the analyzer’s measuring chambers. The process is described below.

18.12.2 Long, smeared population

This image shows that neither the TCU nor the reagents or the mixing cannot do their jobs.

Possible reason:

- Both lyse reagents are interchanged.
- check tube connections, or container connections

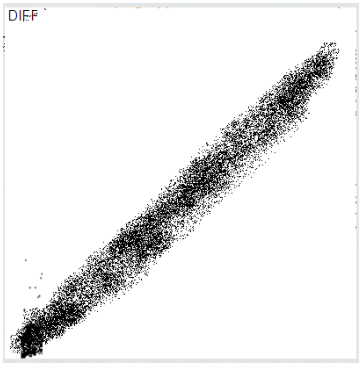

Figure 109. Bad scattergram

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19 Accessories

The following items can be found along with the analyzer:

- Power cord
- Reagent tube kit
- Cleaning tube kit
- Waste container (20L)
- Cardboard box for waste container
- Sample tube adapter
- User's manual

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20 Appendices

20.1 Reagent Consumption

Function	Reagent consumption / function (ml)		
	Erba Lyse-5P	Erba Diff-5P	Erba Dil-Diff
Start Up	13.6	1.7	128
Measure Blank	5.7	0.7	52
Measure 5 part	5.7	0.7	52
Measure Calibration	5.7	0.7	52
Measure QC	5.7	0.7	52
Measure SSM blank	5.7	0.7	60
Measure SSM 5-part	5.7	0.7	60
Measure SSM Calibration	5.7	0.7	60
Measure SSM QC	5.7	0.7	60
Standby	0	0	11.2
Wakeup	0	0	10
Standby in SSM	0	0	11.2
Wakeup in SSM	0	0	11
Cleaning	6.7	0.7	133
Hard cleaning	6.7	0.7	144.2
Clean in SSM	6.7	0.7	138
Hard clean in SSM	6.7	0.7	154
Flow cell cleaning	0	0	63
Shear Valve cleaning	9	1.2	100.2
Offline (overnight) rinsing	6.7	0.7	72.2
**Prime Diluent (full)	0	0	103
**Prime Lyse	7.5	0	2.5
**Prime Diff5P	0	4	0
**Prime all	22	11.5	103
*DrainDilu	0	0	120
*DrainLyse	60	0	0
*DrainDiff5P	0	60	0
*DrainAll	60	60	180
FillUp	22	12	105
Shutdown	7.7	0.7	153.2

* If internal chambers are filled (volume of chambers: 50 ml each, diluent 2x50 + 50 sheath)

** Prime functions fill internal chambers. The following pneumatic function uses reagents from the inside puffer while the inside puffer is continuously refilled to a steady level.

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20.2 Display Range

Parameter	Range	Selectable Dimensions
WBC	1.00 – 99.99 * 10^3 / µl	cells/l, cells/µl
RBC	0.00 – 9.99 * 10^6 / µl	cells/l, cells/µl
HGB	0 – 300 g/l	g/dl, g/l, mmol/l
HCT	0 – 100%	percentage, absolute
PLT	0 – 9999 * 10^3 / µl	cells/l, cells/µl
NEU%	0 -100%	
LYM%	0 -100%	
MON%	0 -100%	
EOS%	0 -100%	
BAS%	0 -5%	
NEU	0.00 –99.99*10^3 / µl	
LYM	0.00 – 99.99*10^3 / µl	
MON	0.00 – 99.99*10^3 / µl	
EOS	0.00 – 99.99*10^3 / µl	
BAS	0.00 – 4.99*10^3 / µl	

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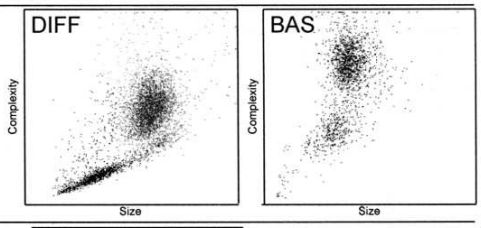
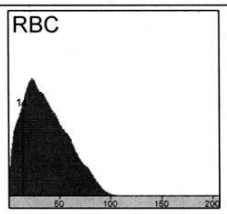
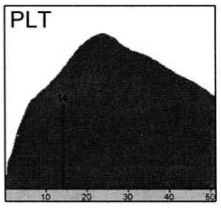
20.3 Printed Report Formats

ELite5 3/24/2011 11:07 AM

Sample ID							Patient ID	1	
Date		3/24/2011 10:37 AM					Name	Michal Huvar	
Mode		Human					Date of birth	1/1/1999	
							Gender	Male	
Parameter			Result			Limit			
WBC	7.37		10^3/µL	5.00	-	10.00			
NEU	5.46		74.1 %	2.00	-	7.50			
LYM	1.53		20.8 %	1.30	-	4.00			
MON	0.20		2.7 %	0.15	-	0.70			
EO	0.18		2.4 %	0.00	-	0.50			
BAS	0.00		0.0 %	0.00	-	0.15			
RBC	4.20		10^6/µL	4.00	-	5.50			
HGB	12.3		g/dL	12.0	-	17.4			
HCT	17.6	--	%	36.0	-	52.0			
MCV	42.0	-	fL	76.0	-	96.0			
MCH	29.3		pg	27.0	-	32.0			
MCHC	69.7	+	g/dL	30.0	-	35.0			
RDWsd	60.0	+	fL	20.0	-	42.0			
RDWcv	30.0	+	%	0.0	-	16.0			
PLT	370		10^3/µL	150	-	400			
PDWcv	39.5		%		-				
PDWsd	14.3		fL		-				
MPV	7.2	-	fL	8.0	-	15.0			
PCT	0.26		%		-				







Warning flags	IxADZ
Morphological flags	G
Interpretive flags	Microcytic RBC?, Hyperchromic?, Anisocytosis?, Microcytic PLT?

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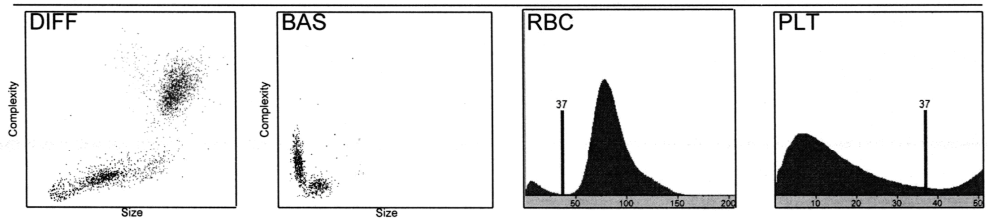
ELite5 3/24/2011 12:29 PM

Sample ID	3	Name	Martina Nemcova
Date	3/24/2011 12:19 PM	Mode	Human

Parameter	Result		Units	Limit
WBC	5.33		$10^3/\mu L$	5.00 - 10.00
NEU	3.44		$10^3/\mu L$	2.00 - 7.50
LYM	1.23	-	$10^3/\mu L$	1.30 - 4.00
MON	0.43		$10^3/\mu L$	0.15 - 0.70
EO	0.20		$10^3/\mu L$	0.00 - 0.50
BAS	0.03		$10^3/\mu L$	0.00 - 0.15
NEU%	64.6		%	40.0 - 75.0
LYM%	23.0		%	21.0 - 40.0
MON%	8.0	+	%	3.0 - 7.0
EO%	3.8		%	0.0 - 5.0
BAS%	0.6		%	0.0 - 1.5
RBC	4.94		$10^6/\mu L$	4.00 - 5.50
HGB	13.0		g/dL	12.0 - 17.4
HCT	43.0		%	36.0 - 52.0
MCV	87.0		fL	76.0 - 96.0
MCH	26.2	-	pg	27.0 - 32.0
MCHC	30.1		g/dL	30.0 - 35.0
RDWsd	50.9	+	fL	20.0 - 42.0
RDWcv	14.0		%	0.0 - 16.0
PLT	206		$10^3/\mu L$	150 - 400
PDWcv	42.8		%	-
PDWsd	32.0		fL	-
MPV	11.3		fL	8.0 - 15.0
PCT	0.23		%	-



Warning flags
Morphological flags
Interpretive flags

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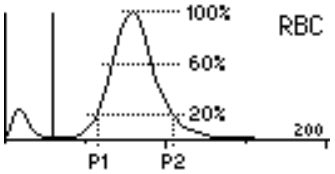
20.4 Specifications

20.4.1 Measured Parameters

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

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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 PCTpercentage = PLT x MPV x 100 PCTabsolute = PLT x MPV
White blood cell, 4 part differential: LYM (%) : lymphocytes MON (%) : monocytes and some eosinophils NEU (%) : neutrophil granulocytes EOS(%):eosinophil granulocytes	Relative value are calculated from the optical 4 diff scatter populations
BAS (%):basophil granulocytes	Relative value is calculated from the basofil optical scatter populations

20.4.2 Technical Data

20.4.2.1 Main Unit

Sample volume	Closed-, and Open-mode: 110 µl
	Sample small module – only open mode: 25 µl
Sample type	Human whole blood (K_3-EDTA anticoagulant)
Tube Identification	By means of the front panel keyboard (enter ID)
	By means of the barcode labels (manual and/or auto-sampler)
Sampling method	Ceramic shear valve with 3 separated primary loops
Measured parameters	CBC+5DIFF mode (24 parameters):
	WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%
	RBC, HCT, MCV, RDWsd, RDWcv HGB, MCH, MCHC
	PLT, PCT, MPV, PDWsd, PDWcv
Throughput	60 tests/hour
Measurement method	Volumetric impedance change for WBC, RBC, PLT
	Spectrophotometry for HGB
	Light scattering 4-diff measurement: LYM, MON, NEU, EOS
	Light scattering BASO measurement
Aperture diameter	WBC: 80 µm, RBC/PLT: 70 µm

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Aperture length	WBC: 80 µm, RBC/PLT: 70 µm
HGB measurement	Light source: green LED with 540 nm wavelength
	Detector: light to frequency converter
Optical measurement	
Light source:	semiconductor laser diode with 650 nm wavelength and 7mW (Class IIIB laser module if the protective housing is closed)
	Quartz flow cell with hydro-dynamic focusing
	Detector: fiber optic coupled PIN Si photodiodes
	Internal safety interlock
Auto-alignment system	Horizontal calibration of laser beam position
	Fine calibration: with calibration material (Polystyrene micro-particle or Polystyrene microsphere, 5µm)
Reagents	Erba Dil-Diff (20 liters) Erba Lyse-5P (5 liters) Erba Diff-5P (1 liter) Erba Hypoclean CC (100 ml) (Emergency cleaner)
Dilution ratios	WBC/BAS 1: 170
	RBC/PLT 1: 21250
	4 DIFF 1: 50
Sheath fluid	Diluent
Quality Control	Levey-Jennings charts, QC database
Flagging	Pathological (diagnostic) flags
	Lab limits (normal ranges)
	Reagents alert (3 measurement pre alert-online reagent replacement), instrument alerts, internal puffer for reagents
Calibration	Manual and SW supported automatic mode
Languages available	English menu and support for other languages
Software upgrade	Via USB
Data storage capacity	100.000 records including flags, scatter- and histograms
Data processing	VIA C7 1.8 GHz processor
Data store	Windows® XP® Embedded
Display	800 x 600 color graphic LCD, portrait layout
External printing	Via USB port, any Windows® XP® compatible printer
External keyboard	Via PS/2 or USB
Bar-Code reader	Optional Manual bar-code reader via USB
	Built in Bar-Code in the Auto-sampler

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Peripheral ports	USB (2.0) 4pc., Ethernet, PS/2
Power requirements	Power supply input: 100-127VAC/200-240 VAC; 47Hz to 63Hz
	Power Consumption: maximum 400 VA
Main fuse	F 10A H 250V
Operating temperature	15-30° C (59-86 °F);
Maximum relative humidity	80%

Guidelines for transport

The instrument in its export package should fulfill the following transport/storage conditions:

- Does not exceed –15°C (5°F) for ≥24 hours.
- Does not exceed a dry heat of 70°C (+158°F) for ≥24 hours.
- Dramatic change of temperature between -15°C (5°F) and 30°C (+86°F).
- Does not exceed a damp heat steady state of 90% RH and 40°C (+104°F) during 48 hours.
- Does not exceed a damp heat cyclic of 90-100% RH and +25°/+40°C (+77°/+104°F) 12+12 hours.

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20.4.3 Performance Data

20.4.3.1 Precision

Parameters	CV	Range
WBC	CV ≤ 3%	4.7 * 10^3 / µl ≤ WBC≤ 38 * 10^3 / µl
		All 5 part parameters (NEU, LYM, MON, EOS, BAS abs and %) at 4.7 * 10^3 / µl ≤ WBC≤ 38 * 10^3 / µl
NEU%	CV ≤ 5%	87.4% ≥ NEU% ≥ 47%
LYM%	CV ≤8%	35.6 % ≥ LYM% ≥ 15%
MON%	CV ≤ 20%	16.3% ≥ MON% ≥5.3%
EOS%	CV ≤ 25%	11% ≥ EOS% ≥1.5%
BAS%	CV≤ 40%	2.4 % ≥ BAS% ≥1%
NEU	CV ≤ 5%	NEU% ≥30%
LYM	CV ≤ 8%	LYM% ≥15%
MON	CV ≤ 20%	MON% ≥5%
EOS	CV ≤ 25%	EOS% ≥ 1.5%
BAS	CV ≤ 40%	BAS% ≥1%
RBC	CV ≤ 1.5%	2.5 * 10^6 / µl ≤ RBC≤ 5.44 * 10^6 / µl
HGB	CV ≤ 1.5%	78.5 g/l ≤ HGB ≤ 184 g/l
HCT	CV ≤ 2%	20-49 HCT%
MCV	CV ≤ 1%	65 fl ≤ MCV ≤ 105 fl
PLT	CV ≤ 5%	100 * 10^3 / µl ≤ PLT ≤ 492 * 10^3 / µl
MPV	CV ≤ 5%	5.6 fl ≤ MPV ≤ 11.3 fl

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20.4.3.2 Accuracy Values And Ranges

Accuracy	Experienced coefficient Against Reference (Cell-Dyn 3700)	Range
WBC	r = 1.00	$0.5*10^3$ / µl ≤ WBC ≤ $56.3*10^3$/µl
RBC	r = 0.99	$2.2*10^6$ / µl ≤ RBC ≤ $6.3*10^6$/µl
HGB	r = 0.99	68.8 g/l ≤ HGB ≤ 173 g/l
HCT	r = 0.99	19.5% ≤ HCT% ≤ 52.6%
PLT	r = 0.98	$12.5*10^3$ / µl ≤ PLT ≤ $699*10^3$/µl
NEU%	r = 0.99	5.8% ≤ NEU% ≤ 94.6%
LYM%	r = 0.99	2.5% ≤ LYM% ≤ 79.5%
MON%	r = 0.90	1.1% ≤ MON% ≤ 28.1%
EOS%	r = 0.95	0.0% ≤ EOS% ≤ 23.6%
BAS%	r = 0.55	0.1% ≤ BAS% ≤ 4.2%

Note 1: the 5part WBC is not reportable if the total WBC count is below 1 $*10^3$ / µl. (The error grows to high.)

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20.4.3.3 Linearity Values and Ranges

Linearity	Coefficient of determination	Range
WBC	r^2 ≥ 0.95	$1*10^3$ / µl ≤ WBC ≤ $100*10^3$/µl
RBC	r^2 ≥ 0.95	0.4 *10^6 / µl ≤ RBC ≤ 7.5 * 10^6/µl
HGB	r^2 ≥ 0.95	13 g/l ≤ HGB ≤ 227 g/l
PLT	r^2 ≥ 0.95	$10*10^3$ / µl ≤ PLT ≤ $2000*10^3$/µl

20.4.3.4 Carryover Values and Ranges

Carryover	High-to-low effect	Range
WBC	0.5% or less	LO ≤ $10*10^3$/µl HI ≥ $75*10^3$/µl
RBC	0.5% or less	LO ≤ 2.3* 10^6/µl HI ≥ 7.5* 10^6/µl
HGB	0.5% or less	LO ≤ 90 g/l HI ≥270 g/l
PLT	0.5% or less	LO ≤ 140 *10^3 / µl HI ≥ $730*10^3$ / µl

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20.4.4 Reagent System

See chapter 4.1.3

20.4.4.1 Diluent

Erba Dil – 5P diluent:	Isotonic solution, used to dilute whole blood and quantitative and qualitative determination of RBC, WBC, PLT and HGB concentration.

20.4.4.2 Lyser

Erba Lyse - 5P WBC-5 Part:	Reagent for stromatolysis of RBC and quantitative determination of WBC 5-part differentiation (LYM, MON, NEU, EOS, BAS) and HGB concentration measurement of human blood.

20.4.4.3 Lyser 2

Erba Diff - 5P:	Quantitative determination of WBC, leukocyte 4-part differentiation (LYM, MON, NEU, EOS).

20.4.4.4 Cleaner

Erba Hypoclean CC:	Capillaries, tubing and chambers, removing blood component precipitates.

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20.4.5 Tab File Format

This file format is composed of a header line and consecutive lines containing records selected for saving. Each parameter is selected by the <TAB> (08h) character, allowing easy interfacing or importing into most data processing applications, like Microsoft® Excel. Scatter diagrams and historgrams, flags are NOT saved in this format.

The header line contains the same column names you can see in the analyzer database.

Data values are saved as they are stored in the analyzer database, alphanumerical or numerical. Decimal separator is defined by the actual operating language of the software.

Example “tab separated file”

ResultID <TAB>Creation time <TAB>Sample Id <TAB>Creation time <TAB>Mode <TAB>WBC <TAB>LYM <TAB>NEU <TAB>MON <TAB>EO <TAB>BAS <TAB>LYM% <TAB>NEU% <TAB>MON% <TAB>EO% <TAB>BAS% <TAB>RBC <TAB>HGB <TAB>HCT <TAB>MCV <TAB>MCH <TAB>MCHC <TAB>RDWsd <TAB>RDWcv <TAB>PLT <TAB>PDWsd <TAB>PDWcv <TAB>MPV <TAB>PCT <TAB>

7538 <TAB>02/04/2009 15:59:05 <TAB>402 <TAB>02/04/2009 15:59:05 <TAB>Human <TAB>70.65 <TAB>56.66 <TAB>2.9 <TAB>11.09 <TAB>0 <TAB>0 <TAB>80.2 <TAB>4.1 <TAB>15.7 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7540 <TAB>02/04/2009 16:11:13 <TAB>402 <TAB>02/04/2009 16:11:13 <TAB>Human <TAB>70.65 <TAB>62.1 <TAB>1.77 <TAB>6.78 <TAB>0 <TAB>0 <TAB>87.9 <TAB>2.5 <TAB>9.6 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7541 <TAB>02/04/2009 16:13:24 <TAB>402 <TAB>02/04/2009 16:13:24 <TAB>Human <TAB>70.65 <TAB>63.09 <TAB>1.7 <TAB>5.86 <TAB>0 <TAB>0 <TAB>89.3 <TAB>2.4 <TAB>8.3 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7542 <TAB>02/04/2009 16:16:53 <TAB>402 <TAB>02/04/2009 16:16:53 <TAB>Human <TAB>70.65 <TAB>64.01 <TAB>1.48 <TAB>5.16 <TAB>0 <TAB>0 <TAB>90.6 <TAB>2.1 <TAB>7.3 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7543 <TAB>02/04/2009 17:31:12 <TAB>402 <TAB>02/04/2009 17:31:12 <TAB>Human <TAB>70.65 <TAB>64.01 <TAB>1.48 <TAB>5.16 <TAB>0 <TAB>0 <TAB>90.6 <TAB>2.1 <TAB>7.3 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

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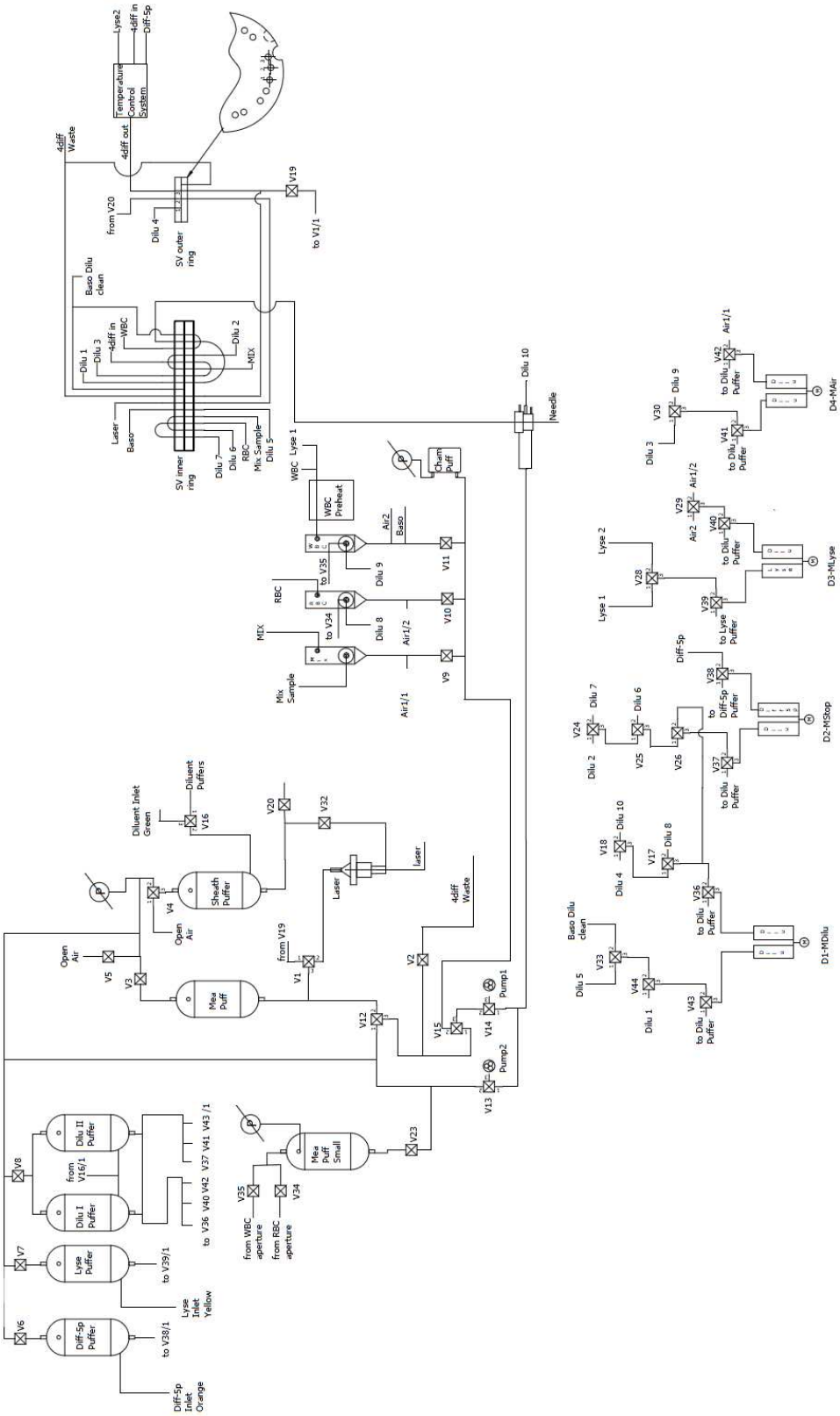
20.5 Fluidic System



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20.6 Summary of Cleaning Products and Procedures for Elite Hematology Analyzers

There are two types of cleaning products:

- **System cleaning products**: these are detergent or enzyme- based solutions and are connected to analyzers all times.

- **Non-system cleaning products**: these are bleach-based solutions and are used for decontamination or thorough cleaning of the analyzer. They are external cleaners and can be used for daily usage and/or for emergencies.

Cleaning recommendations

1. **Daily** – the analyzer must be cleaned **at least once** either with a system or non-system cleaner **as part of a daily cleaning procedure** (Note: for daily cleaning of the analyzer the recommended daily cleaning reagent should be used).
2. **As needed** – when the system has an aperture blockage or is exhibiting a high cell background, the system should be thoroughly cleaned with a non-system bleach-based cleaning reagent – e.g. Erba Hypoclean or Erba Hypoclean CC.

Recommended Cleaning Products / Timetable

Cleaner Type	Description	Recommendation	Usage	Limitations
Erba Cleaner Cat.No.50003767 1 L	The standard detergent-based cleaning solution for ELITE 3 analyzer	It is used as system cleaner and is connected to the analyzer at all times	Daily and/or as needed	None Can be used at any time
Erba Clenz Cat.No.50004375 1 L	Strong, enzymatic cleaning solution	Recommended for systems with high workload for more effective cleaning	Daily and / or as needed	None Can be used at any time
Erba Hypoclean Cat.No. 50004376 1 L	Bleach-based strong cleaning solution	Recommended for thorough cleaning, emergency cleaning or for disinfection of analyzer tubing	As needed	Using as a regular system cleaning solution is not recommended as it can damage the system tubing
Erba Hypoclean CC Cat.No.50003773 100 mL	Concentrated bleach-based cleaning solution for ELITE 5 analyzer	Recommended cleaner for Elite 5 analyzer. Can be used on Elite 3	On ELITE 5: daily On Elite 3: as needed	Excess cleaning may have a long term effect on the tubing

Remarks:
Erba Hypoclean and Erba Cleanz are additional reagents. These are only connected to analyzer in case it is needed.
The reagent which has a connector on three part instrument normally is Erba Cleaner.
Erba Clenz is an enzymatic cleaning solution for removing any lipids, protein sludge from the system.
This can be used as daily cleaner solution as well, connected like Erba Cleaner (Elite 3).
The recommendation is to use this solution as daily cleaner (connected instead of Erba Cleaner) only in case of daily high workload.
Erba Hypoclean is a < 9% hypochlorite solution for cleaning purposes. It should be used in case of massive dirt, dried blood etc. in the system. You can use it in vial and run cleaning cycle from software.

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21 Known Problems

The following problems are known at the time of the releasing of the software and this user manual:

- Long Sample ID is not visible on printout and on display.
- Tooltip info contains square character instead of upper index 6/9/12.
- Sometimes the AS menu is not deactivated when AS is switched off.
- On-screen keyboard remains active while screensaver is running.
- It is necessary to login in multiuser mode to call the shutdown procedure.
- The user is able to log out during pneumatic activities.
- Naming conventions.
- Number of digits on the QC is different.
- The length of some language nodes are longer than expected.
- Patient's SSN is not printed on normal printout.
- If patient data isn't filled out the software could display 'NULL' value.
- Only English characters are accepted as user name.
- Querying statistics/Printing results/Saving to tab separated file is not recommended if more than few hundred results are selected in database view.
- It is not able to print imported data in table view format.

These problems will be fixed in upcoming SW releases.

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23 Contact

For customer and technical support:

Manufacturer:

Erba Lachema s.r.o.,

Karásek 2219/1d, 621 00 Brno

Czech Republic

Tel: +420 517 077 111

e-mail: diagnostics@erbamannheim.com

Website : https://www.erbamannheim.com/en/product-support/

Contact your local technical support: *(Print this page and write or paste contact information for easy access)*

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24 Appendix- package inserts for reagents and cleaning solutions

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Erba Lyse-5P

CE IVD

EN

Lysing reagent for automated analyzers

Name	Cat. No.	Package volume
Erba Lyse-5P	HEM00006	5 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Lyse-5P lyzing reagent is a stabilized and micro-filtered blood lysing agent for stromatolysis of erythtrocytes (RBC), for quantitative determination of leukocytes (WBC), leukocyte 5-part differentiation (LYM, MON, NEU, EOS, BAS) and hemoglobin (HGB) concentration measurement of human blood on hematology analyzer.
Erba Lyse-5P lysing reagent should be used with only Erba Lachema reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.
Please refer to the instrument's User Manual for further information.

INGREDIENTS

Surfactants	< 3.6 %
Buffers	< 1.0 %
Preservative	< 0.4 %
Stabilizers	< 0.4 %

in ion-free water

HANDLING PRECAUTIONS

- Erba Lyse-5P lysing reagent is environmental friendly, cyanide-free and azide-free reagent; does not contain harmful ingredients.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Lyse-5P lysing reagent is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at (+15 to +30) ºC or up to 24 hours after collection when refrigerated (+2 to +8) ºC.

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the colour on each tube, reagent container label and connector in the back of the instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents. Do not pour and mix the remains of a reagent from a container into other one.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store Erba Lyse-5P lysing reagent between +15 and +30°C.
- The shelf life of the Erba Lyse-5P lysing reagent is 24 months from date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Do not use reagent once frozen.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

REF Catalogue Number
Manufacturer
See Instruction for Use
LOT Lot Number
CE Mark - Device comply with the Directive 98/79/EC
Storage Temperature
Expiry date
IVD In vitro Diagnostics
CONT Content

50003765

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

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Erba Diff-5P

CE IVD

EN

WBC differentiation reagentfor automated analyzers

Name	Cat. No.	Package volume
Erba Diff-5P	HEM00002	1 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Diff-5P WBC differentiation reagent is a stabilized and micro-filtered reagent for quantitative determination of leukocytes (WBC), leukocyte 5-part differentiation (LYM, MON, NEU, EOS, BAS) and hemoglobin (HGB) concentration measurement of human blood on hematology analyser.
Erba Diff-5P WBC differentiation reagent should be used with only Erba Lachema reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.
Please refer to the instrument's User Manual for further information.

INGREDIENTS

Sodium salts	< 3.4 %
Buffers	< 1.2 %
Preservative	< 0.5 %
Stabilizers	< 0.5 %

in ion-free water

HANDLING PRECAUTIONS

- Erba Diff-5P differentiation reagent is environmental friendly, cyanide-free and azide-free reagent; does not contain harmful ingredients.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Diff-5P reagent is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at (+15 to +30) ºC or up to 24 hours after collection when refrigerated (+2 to +8) ºC.

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the colour on each tube, reagent container label and connector in the back of the instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents. Do not pour and mix the remains of a reagent from a container into other one.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store Erba Diff-5P WBC-5-part reagent between +15 and +30°C.
- The shelf life of the Erba Diff-5P WBC-5-part reagent is 24 months from date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Do not use reagent once frozen.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

50003766

REF Catalogue Number | Manufacturer | See Instruction for Use | LOT Lot Number | CE Mark - Device comply with the Directive 98/79/EC

Storage Temperature | Expiry date | IVD In vitro Diagnostics | CONT Content

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

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Erba Hypoclean CC

CE

EN

Hypochlorite cleaning concentrate for automated analyzers IVD

Name	Cat. No.	Package volume
Erba Hypoclean CC	HEM00005	100 ml

For *in vitro* diagnostic use only

INTENDED USE

Erba Hypoclean CC cleaning concentrate is a stabilized and micro-filtered concentrated hypochlorite solution for intensive oxidative cleaning, rinsing and washing of hematology analyzers' capillaries, tubing and chambers, removing blood component precipitates and lipoprotein deposits on all hematology analyzers ("emergency cleaning").
Erba Hypoclean CC hypochlorite cleaning concentrate should be use with only Erba Lachema reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.
Please refer to the instrument's User Manual for further information.

INGREDIENTS

Detergents	< 1.0 %
Sodium hypochlorite	< 5.0 %
Sodium hydroxide	< 0.5 %
Stabilizers	< 0.5 %

in ion-free water

HANDLING PRECAUTIONS

Erba Hypoclean contains < 0.5% sodium hydroxide and < 5% sodium hypochlorite.



Danger

Hazard statement:
H314 Causes severe skin burns and eye damage.
EUH031 Contact with acids liberates toxic gas.
Precautionary statement:
P260 Do not breathe vapours.
P280 Wear protective gloves/protective clothing/eye protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- Avoid contact with eyes, skin and clothing.
- In case of eye contact flush eyes with plenty of water for several minutes and seek medical advice.
- In case of skin contact wash the skin area with water.
- If swallowed do NOT induce vomiting. Drink plenty of water and seek medical advice. Beware of aspiration if vomiting does occur.
- Keep the reagent container closed when not in use.
- Avoid any dust or microbial contamination of the reagents.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Please refer to the MSDS associated with the reagent.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Hypoclean CC hypochlorite cleaning concentrate is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at (+15 to +30) ºC or up to 24 hours after collection when refrigerated (+2 to +8) ºC.

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

USE OF THE REAGENT

- Person using the reagent must be a trained laboratory professional.
- During daily maintenance procedure put a proper sample tube containing Erba Hypoclean CC reagent the sample rotor and aspirate the cleanser through the probe. Perform cleaning cycle as specified in the instrument's User Manual.
- If the blank is too high or unacceptable result appears pipette Erba Hypoclean CC directly into the appropriate chamber according to the instrument's User Manual. Wait to perform efficient cleaning and measure the blank.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store Erba Hypoclean CC hypochlorite cleaning concentrate between 15 and 30°C.
- The shelf life of the Erba Hypoclean CC is 15 months from date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

REF Catalogue Number
Manufacturer
See Instruction for Use
LOT Lot Number
CE Mark - Device comply with the Directive 98/79/EC
Storage Temperature
Expiry date
IVD In vitro Diagnostics
CONT Content

50003773

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

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Erba Dil-5P

CE IVD

EN

Diluent for automated analyzers

Name	Cat. No.	Package volume
Erba Dil-5P	HEM00003	20 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Dil-5P diluent is a buffered, stabilized and micro-filtered electrolyte solution for automated dilution of human blood samples, quantitative and qualitative determination of erythrocytes (RBC), leukocytes (WBC) and the leukocyte subpopulations, thrombocytes (PLT) and measurement of hemoglobin (HGB) concentration on hematology analyzer.
Erba Dil-5P diluent should be used with only Erba Lachema reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.
Please refer to the instrument's User Manual for further information.

INGREDIENTS

Sodium chloride	< 1.0 %
Buffers	< 1.1 %
Preservative	< 0.4 %
Stabilizers	< 0.4 %

in ion-free water

HANDLING PRECAUTIONS

- Erba Dil-5P diluent is environmental friendly, azide-free reagent; does not contain harmful ingredients.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Dil-5P reagent is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at (+15 to +30) ºC or up to 24 hours after collection when refrigerated (+ 2 to +8) ºC.

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the colour on each tube, reagent container label and connector in the back of the instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents. Do not pour and mix the remains of a reagent from a container into other one.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store Erba Dil-5P diluent between +15 and +30°C.
- The shelf life of the Erba Dil-5P is 36 months from the date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Do not use reagent once frozen.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

REF Catalogue Number
Manufacturer
See Instruction for Use
LOT Lot Number
CE Mark - Device comply with the Directive 98/79/EC
Storage Temperature
Expiry date
IVD In vitro Diagnostics
CONT Content

50003774

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HEMA/PI/07/17/C

Date of revision: 25.7. 2017

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Erba Clenz

CE IVD

EN

Enzymatic cleaner reagent for automated analyzers

Name	Cat. No.	Package volume
Erba Clenz	HEM00017	1 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Clenz enzymatic cleaner reagent is a stabilized and micro-filtered proteolytic enzyme solution for regular automated cleaning, rinsing and washing of hematology analyzers capillaries, tubing and chambers, removing blood component precipitates and lipoprotein deposits on ELite hematology analyzers.
Erba Clenz enzymatic cleaner reagent should be used only with Erba reagents. Erroneous results may be obtained if the reagent is applied with third party reagents. Please refer to the instrument User Manual for further information.

INGREDIENTS

Sodium chloride	< 1.0%
Proteolytic enzymes	< 1.0%
Preservative	< 0.5%
Stabilizers	< 2.0%

In ion-free water

HANDLING PRECAUTIONS

- Erba Clenz enzymatic cleaner is environmental friendly, azide-free reagent, does not contain harmful ingredients.
- Avoid contact with eye, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Use Good laboratory Practices (GPL) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Clenz reagent is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at 15-30°C or up to 24 hours after collection when refrigerated (2-8°C).

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container, no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the color on each tube, reagent container label and connector in the back of instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents. Do not pour and mix the remains of a reagent from a container into other one.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

Store Erba Clenz enzymatic cleaner reagent between 15 – 30°C.
The shelf life of Erba Clenz is 24 months from the date of manufacture, if stored at the prescribed temperature range.
Do not use reagent beyond the expiration date printed on the container label.
Discard opened container after 120 days.
Do not use reagent once frozen.
Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

REF Catalogue Number
Manufacturer
See Instruction for Use
LOT Lot Number
CE Mark - Device comply with the Directive 98/79/EC
Storage Temperature
Expiry date
IVD In vitro Diagnostics
CONT Content

50004375

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Erba Hypoclean

CE IVD

EN

Hypochlorite cleaning solution for automated analyzers

Name	Cat. No.	Package volume
Erba Hypoclean	HEM00016	1 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Hypoclean hypochlorite cleaning solution is a stabilized and micro-filtered hypochlorite solution for intensive oxidative cleaning, rinsing and washing of hematology analyzers capillaries, tubing and chambers, removing blood component precipitates and lipoprotein deposits on ELite hematology analyzers.
Erba Hypoclean hypochlorite cleaning solution should be used only with Erba reagents. Erroneous results may be obtained if the reagent is applied with third party reagents. Please refer to the instrument User Manual for further information.

INGREDIENTS

Detergents	< 1.0%
Sodium hypochlorite	< 1.0%
Sodium hydroxide	< 0.5%
Stabilizers	< 0.4%

In ion-free water

HANDLING PRECAUTIONS

Erba Hypoclean contains < 0.5% sodium hydroxide and < 1% sodium hypochlorite.



Warning

Hazard statement:
H315 Causes skin irritation.
H319 Causes serious eye irritation.
EUH031 Contact with acids liberates toxic gas.
Precautionary statement:
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- Avoid contact with eyes, skin and clothing.
- In case of eye contact flush eyes with plenty of water for several minutes and seek medical advice.
- In case of skin contact wash the skin area with water.
- If swallowed do NOT induce vomiting. Drink plenty of water and seek medical advice. Beware of aspiration if vomiting does occur.
- Keep the reagent container closed when not in use.
- Avoid any dust or microbial contamination of the reagents.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Please refer to the MSDS associated with the reagent.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

Erba Hypoclean reagent is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at 15-30°C or up to 24 hours after collection when refrigerated (2-8°C).

REAGENT PREPARATION

- This reagent is ready to use and can be applied straight from the container, no special reagent preparation is necessary.
- Leave the reagent at room temperature for at least 12 hours.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the color on each tube, reagent container label and connector in the back of instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents. Do not pour and mix the remains of a reagent from a container into other one.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

Store Erba Hypoclean hypochlorite cleaning reagent between 15 – 30°C.
The shelf life of Erba Hypoclean is 24 months from the date of manufacture, if stored at the prescribed temperature range.
Do not use reagent beyond the expiration date printed on the container label.
Discard opened container after 120 days.
Do not use reagent once frozen.
Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS

REF Catalogue Number	Manufacturer	See Instruction for Use	LOT Lot Number	CE Mark - Device comply with the Directive 98/79/EC
Storage Temperature	Expiry date	IVD In vitro Diagnostics	CONT Content	

50004376

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