Swelab Alfa Plus

User's Manual

Swelab

Still counting, since 1956

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SECTION 1. INTRODUCTION

This user manual contains instructions for the operation of the Swelab Alfa Plus system. Please read this guide for the correct safety, installation, and operation instructions before using the analyzer.

Swelab Alfa Plus Systems

Product Code	Product Name
1420041	Swelab Alfa Plus Basic
1420042	Swelab Alfa Plus Standard
1420043	Swelab Alfa Plus Cap
1420044	Swelab Alfa Plus Cap AR
1420045	Swelab Alfa Plus Sampler BD
1420046	Swelab Alfa Plus Sampler BD AR
1420047	Swelab Alfa Plus Sampler SA
1420048	Swelab Alfa Plus Sampler SA AR

Current Software Version:

Software version 2.1

Contact Details

Manufacturer:

Boule Medical AB

Domnarvsgatan 4

SE-163 53 Spånga, Sweden

Websites:

www.boule.se

www.swelab.com

Distributor and Technical Support:

Please contact Boule for information.

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Analyzer Overview



Figure 1: Analyzer front view

	Part	Description/Function
1	Display	TFT-LCD Touch screen which displays patient and QC data, allows operator to enter setup and testing instructions, and prompts operator on next step. See section 7 for menu structure.
2	Blood tube mixer (optional)	Uniformly mixes samples before analysis.
3	Whole blood sample probe	Aspirates whole blood for analysis (Open Tube).
4	Start Plate, Open Tube	Plate pressed to begin Open Tube aspiration.
5	Wash cup	Reservoir where fluid is removed after sample probe is washed.
6	MPA	Micro Pipette Adapter enables analysis using 20 µL of blood.
7	Start Plate, Pre-dilute	Plate pressed to begin Pre-dilute aspiration.
8	Pre-dilute probe/Dispenser	Aspirates pre-diluted samples and dispenses diluent.
9	USB port	Connects analyzer to USB devices.

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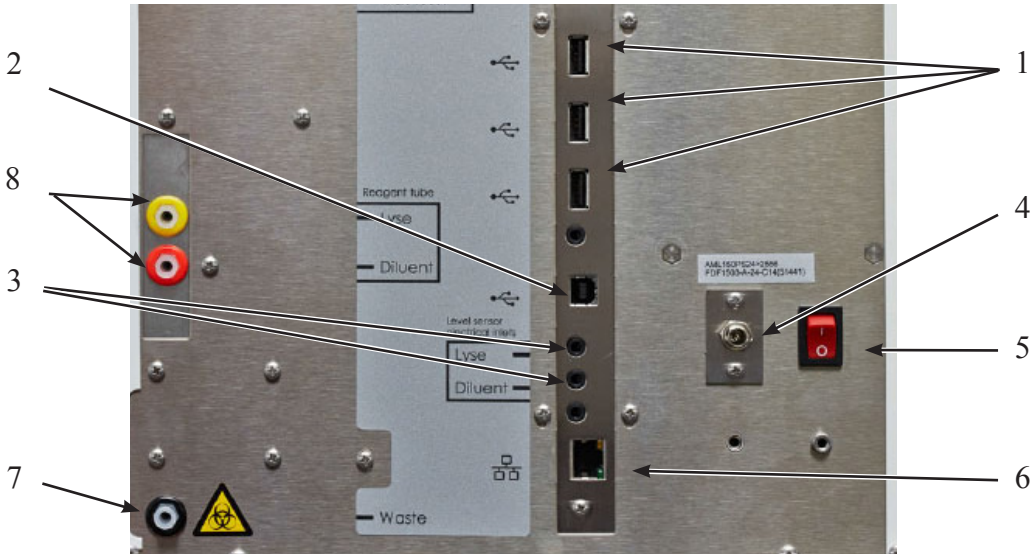

Figure 2: Analyzer cable and interface connections

	Part	Description/Function
1	USB host ports	Connects analyzer to USB devices.
2	USB device port	Connects analyzer to USB host.
3	Electronic sensors	Connects Reagent level sensors to analyzer.
4	Power supply port	Connects Main power outlet to analyzer.
5	Power switch	Switches power On and Off.
6	LAN port	Connects analyzer directly to a computer.
7	Waste tube connection	Connects Waste tube to analyzer.
8	Reagent tube connections	Connects Lyse (yellow) and Diluent (red) to analyzer

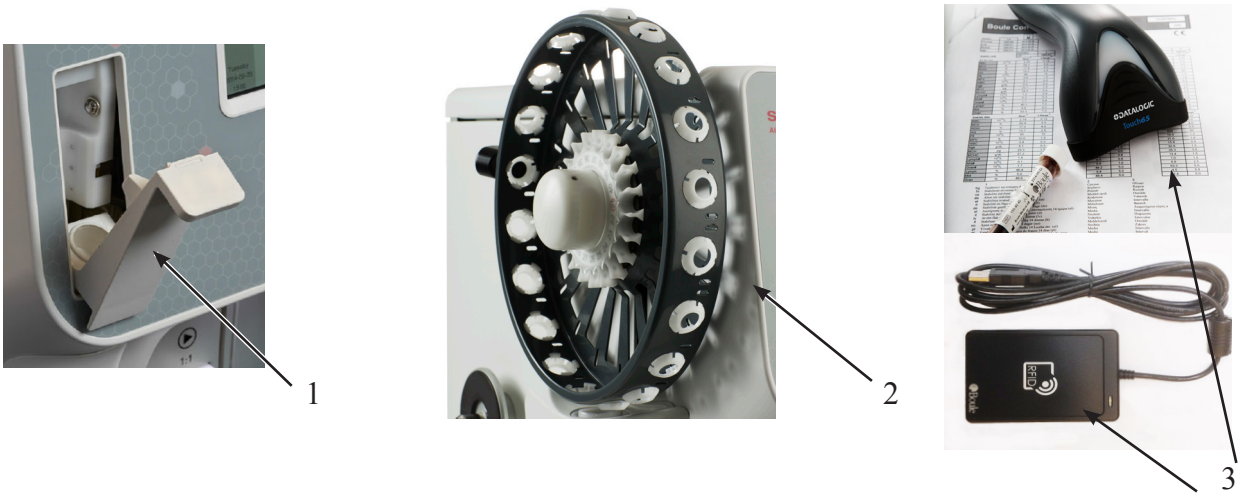

Figure 3: Accessories

	Part	Description/Function
1	Cap Piercer	Analyzes samples with decreased risk of blood contact (Closed Tube).
2	Auto Sampler	Enables consecutive samples to be analyzed automatically (Closed Tube).
3	Barcode Reader	Enables operator to quickly enter patient, sample, reagent and control identifications.
4	RFID Reader	Enables operator to quickly enter Reagent tags.

Consumable Overview

Reagents



Figure 4: Reagents

	Part	Description/Function
1	Diluent	Isotonic diluting solution.
2	Lyse	Lytic solution.

QC Material



Figure 5: QC Material

	Part	Description/Function
1	Boule Control	QC material to verify analyzer operation.
2	Boule Calibrator	QC material to calibrate analyzer.

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Reagent Consumption Specifications

- Diluent Consumption: ~ 21 mL per analysis cycle.
- Lyse Consumption: ~ 4.6 mL per analysis cycle.

For additional information regarding the consumption of cleaning solutions please refer to the Boule Cleaning Kit instruction. (Supplied with the Boule Cleaning Kit).

Regulatory Requirements

The Swelab Alfa Plus system fulfills the following International standards and regulations:

- EN ISO 18113-3
- IVD 98/79/EC
- EN 61326-1
- EN 61326-2
- 2012/19/EU WEEE
- IEC 61010-1
- UL 61010-1:2004 and CAN/CSA-C22.2 No. 61010-1:2004
- EN 61010-2-101
- Standards harmonized with FDA
- 2011/65/EU RoHS-directive

Specifications

Physical	
Size (Instrument versions with sampler)	HWD ≤ 395 × 340 × 475 mm
Size (Instrument version without sampler)	HWD ≤ 395 × 295 × 475 mm
Weight (Instrument)	≤ 18 kg
Weight (Autosampler model)	The weight of the Autosampler including two sample wheels is ≤ 22 kg
Display	Depth: True color (24-bit); Resolution: 800 × 480 pixels
Keyboard	Virtual incorporated keyboard
Communication interface ports	1 USB device/4 USB host/1 LAN port
Barcode reader input	Yes (via USB)
RFID reader input	Yes (via USB)
Operating Environment	
Temperature	18–32 °C
Humidity	10%–90%

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Specifications

Electrical	
Main Voltage	100–240 V
Frequency	50–60 Hz
Noise level	≤ 67 dB(A)
Maximum power consumptions	Running: average 25W, peak 30W Ready: 15W Standby: 10W

Measuring principles	
MCV, MPV, RBC, WBC, and PLT	Impedance
HGB	Photometric
Sampling system	Closed shear valve
Floating RBC/PLT discriminator	Yes (position printed)
Parameters Reported	22 parameters:
	RBC, MCV, HCT, PLT, MPV, HGB, MCH, MCHC, WBC, RDW%, RDW*, PCT*, PDW%*, PDW*, P-LCR*, P-LCC*, LYM, MID, GRAN, LYM%, MID%, GRAN% *Research parameters

Performance	
Sample volume (Open Tube)	≤ 110 µL
Sample volume (Auto Sampler)	≤ 300 µL
Sample volume (Cap Piercer)	≤ 250 µL
Sample volume (Micro Pipette Adapter)	20 µL
Pre-diluted mode	1:200 to 1:300 using min. 20 µL sample e.g. 20 µL sample to 4.5 mL diluent (1:225)
Dispenser precision (CV)	≤ 0.9%
Number of Samples per hour (Open Tube)	≥ 60 samples
Number of Samples per hour (Cap Piercer)	≥ 45 samples
Number of Samples per hour (Auto Sampler)	≥ 43 samples
Built-in test / adjustment programs	Yes
QC capabilities	Mean, SD, CV, Levey-Jennings and Xb
System Information Indicators on parameter abnormalities	Yes

Memory capacity
≤ 50,000 samples

Reagent Shelf Life
36 months

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Performance

Parameter	Correlation (r)	Carry-over (%)	Reproducibility (CV%)
RBC	1.00	≤ 1	0.9
MCV	0.99	N/A	0.4
HGB	1.00	≤ 1	0.5
PLT	0.99	≤ 1	3.0
WBC	1.00	≤ 0.5	1.7

Correlation

Correlation is performed using a reference analyser compared with the Swelab Alfa Plus system run in open tube mode.

Carry-over

Based on CLSI Standard H26-A2, using venous whole blood in open tube mode.

Reproducibility

Measured as an average of 10 measurements each on 9 different venous blood in K2-EDTA collected normal samples, on 3 instruments, in open tube mode.

Parameter Ranges

Parameter	Difference (whichever is greater)	Linearity Range	Displayed Range
RBC	± 0.05 × 10^{12}/L or ± 2%	0.30–7.00 × 10^{12}/L	0.00–14.00 × 10^{12}/L
MCV	N/A	N/A	15.0–250.0 fL
HGB	± 0.2 g/dL or ± 2%	2.0–24.0 g/dL	0.0–35.0 g/dL
PLT	± 10 × 10^{9}/L or ± 3%	10(*20) –1800 × 10^{9}/L	0–5000 × 10^{9}/L
WBC	± 0.40 × 10^{9}/L or ± 3%	0.20–130.0 × 10^{9}/L	0.00–150.0 × 10^{9}/L

*If your analyzer was manufactured before December 2016.

Linear Range

Based on CLSI Standard EP6-A. Control blood material.

Displayed Range

Total range in which results are reported.

Lower Limit of Quantitation

Set to 0.20 × 10^{9}/L for WBC and 10 × 10^{9}/L for PLT. Based on CLSI standard H26-A2 and EP17-A2 with Clinical blood material.

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Safety Instructions

Boule incorporates safety features within the analyzer in order to protect the operator from injury, the analyzer from damage and the test results from inaccuracies.

Intended Use

The Swelab Alfa Plus system is an automated hematology analyzer for in vitro diagnostic use under laboratory conditions. The Swelab Alfa Plus is used for enumeration of white blood cells (WBC); the absolute number and percentage concentration for granulocytes (GRAN), lymphocytes (LYM), mid-sized white cells (MID); red blood cells (RBC); hemoglobin (HGB); mean cell volume of red cells (MCV); hematocrit (HCT); mean cell hemoglobin (MCH); mean cell hemoglobin concentration (MCHC); red cell distribution relative and absolute widths (RDW%, RDWa); platelets (PLT); mean platelet volume (MPV), platelet crit (PCT), platelet distribution relative and absolute widths (PDW%, PDWa) and platelet large cell ratio and concentration (P-LCR, P-LCC) in K2EDTA and K3EDTA anti-coagulated whole blood samples.

Operator Requirements

- Operator must have basic laboratory skills and be aware of good laboratory practice.
- Read user manual prior to use.

Analyzer Restrictions

- Do not use the analyzer outdoors.
- Do not modify the analyzer.
- Do not remove the cover. (Authorized personnel only)
- Do not use the analyzer for other purposes than described in this manual or by Boule technical bulletin covering an application.
- Do not spill liquids on the analyzer in such a way that it can leak through the analyzer casing.
- Do not drop or place objects on the analyzer.
- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.
- Do not use power supply other than supplied by Boule.

Limitations

- Boule products do NOT make diagnoses on patients. Boule intends its diagnostic products (systems, software and hardware) to be used to collect data reflecting the patient's hematological status. This data, in conjunction with other diagnostic information and the evaluation of the patient's condition, can be used by a trained clinician to establish a patient's diagnosis and to define clinical treatment.

Reagent Precautions

- If a reagent comes in contact with eyes, rinse with running water for several minutes. If symptoms occur seek medical attention.
- If the reagent comes into contact with skin, wash affected area with water.
- If swallowed, rinse out mouth. If persistent symptoms occur seek medical attention.

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- SDS sheets are available for all reagents.

Biohazards

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in human blood samples, controls, calibrators and waste these products should be handled as potentially biohazardous.
- Handle any exposure according to established laboratory protocol regulations.
- The instructions for analyzer decontamination and disposal can be found on the Swelab home page, www.swelab.com under Support.

Emergency Procedure

If there are any obvious signs of malfunction such as smoke or liquid leaking out of the analyzer proceed as follows:

- **Disconnect the main power supply immediately by pulling out the power cord from the main supply outlet and contact your authorized distributor.**

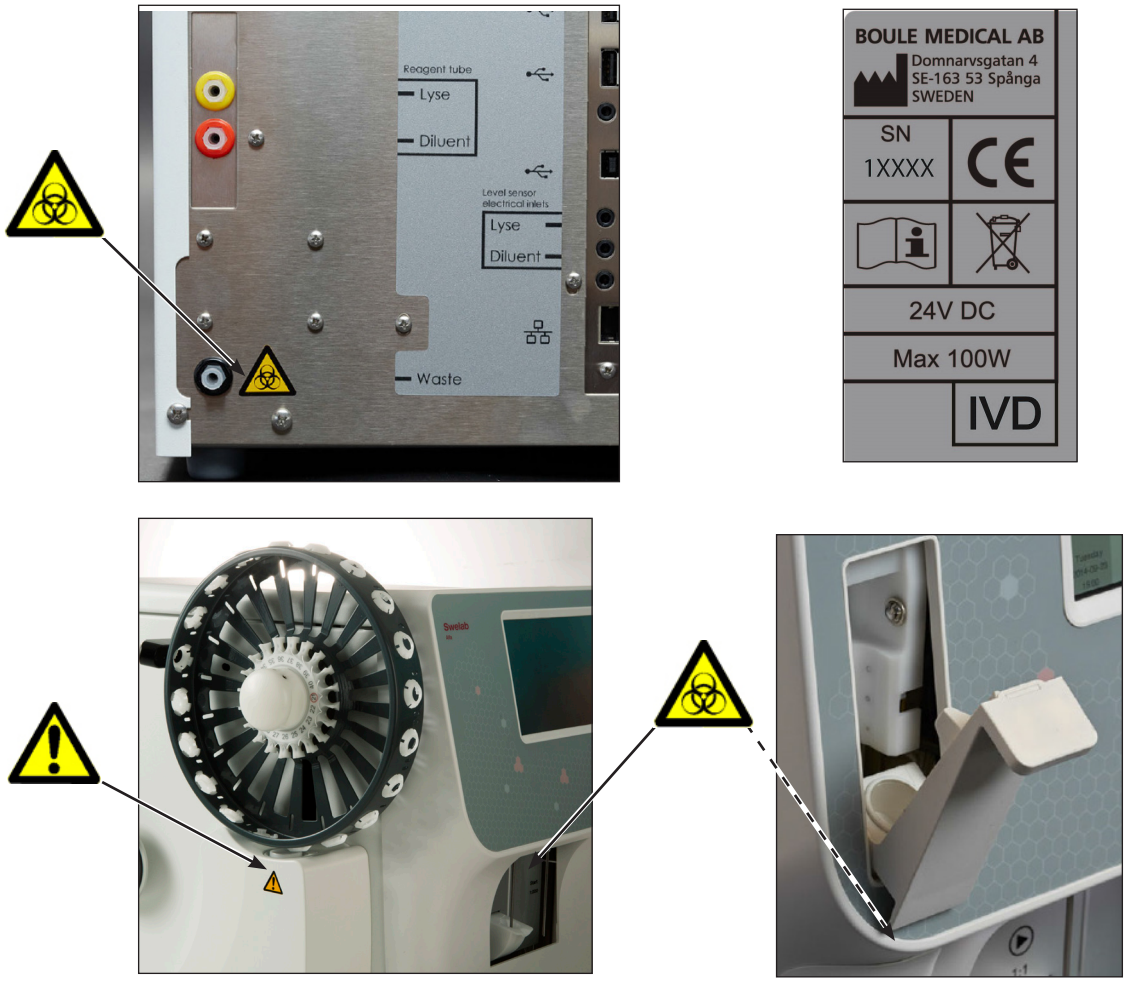


Figure 6: Signs on Equipment

Signs on Equipment and Consumables

Signs placed on the instrument define areas that need special attention or areas that contain danger. See *figures 6* and *7.*



Batch code



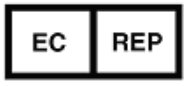
Serial number



Catalogue number



Manufacturer



Authorized Representative in the European Community



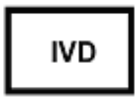
Biological Risk



Fragile, handle with care



Use by



In vitro diagnostic medical device



Lower limit of temperature



Upper limit of temperature



Temperature limitation



Consult instructions for use



Control



Low control, 16 parameters



Normal control, 16 parameters



High control, 16 parameters



Calibrator



Content



Recycling



WEEE



Warning or Caution



Radio-frequency identification

Figure 7: IVD Symbol Table

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Warranty Limitations

- Service must be performed by Boule authorized service personnel.
- Use only Boule authorized reagents, controls, and calibrators. (If these products are substituted it may void the warranty)
- Operators and laboratory supervisors are responsible that Boule products are operated and maintained according to the procedures described in manuals and control inserts.
- Each Swelab Alfa Plus system is tested using recommended reagents, controls, calibrators and cleaners. All performance claims are generated as part of this complete system.

1. Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition. CLSI H26-A2

2. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. CLSI EP6-A

3. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition. CLSI EP17-A2

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SECTION 2. INSTALLATION AND REAGENT SETUP

Unpack and Check Components



Figure 8: Analyzer packaging components

Please open the analyzer box and check all the components against those in *figure 8*.

- Should any of these components be missing or if packaging is damaged please contact your local distributor.
- The analyzer is packed in a specifically designed protective box, please save this original packaging.

*Not included in Basic model.**Optional.

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Analyzer Placement and Environment

The analyzer should be placed in a laboratory environment according to the guidelines below:

- Place the analyzer on a clean horizontal surface.
- Avoid direct exposure to sunlight.
- Make sure the analyzer has access to proper ventilation: 5 cm of free space above it and 10 cm of free space behind it.
- Indoor Use with grounded mains supply
- Evaluate the electromagnetic environment prior to installation.
- Temperature: 18 – 32 °C
- Humidity: 10% – 90%

Installation Checklist and Menu

Follow the quick Installation Checklist and Installation Menu step by step for best installation results.

Installation Checklist
❑ Complete Unpack and Check Components / Analyzer Placement and Environment instructions.
❑ Connect the power adapter to the power supply port on the back of the analyzer, but do not plug in power cord yet.
❑ Connect the barcode/RFID reader to one of the USB host ports on the back of the analyzer.
❑ Connect the printer to either the USB host port or USB device port (depending on printer type) on the back of the analyzer (if applicable).
❑ Connect the analyzer to computer system using either one of the USB host ports or USB device port (depending on computer connection type) on the back of the analyzer (if applicable).
❑ Connect the waste tube to the analyzer and plumb to waste container or drain.
❑ Connect the Diluent reagent tube assembly (red) and electronic sensor to the analyzer.
❑ Connect the Lyse reagent tube assembly (yellow) and electronic sensor to the analyzer.
❑ Plug one end of the power cord to the power adapter and the other to a surge protected power outlet, then turn power switch to ON position.
❑ After system initialization, follow Installation Menu instructions below.

Post-Installation Recommendations
❑ After initial setup, it is recommended to print all analyzer settings and keep for personal records. Select **System Info** from Main Menu and then **Print All Settings**.
❑ All sample analysis modes (Open Tube and MPA) are factory calibrated. However, calibration should always be checked upon installation. See *section 5* for more details.

After completing the following eight Installation Menu steps, the system will be ready for the first sample analysis.

▶ Installation Menu

1 Set Language — Choose language and press **Save**.

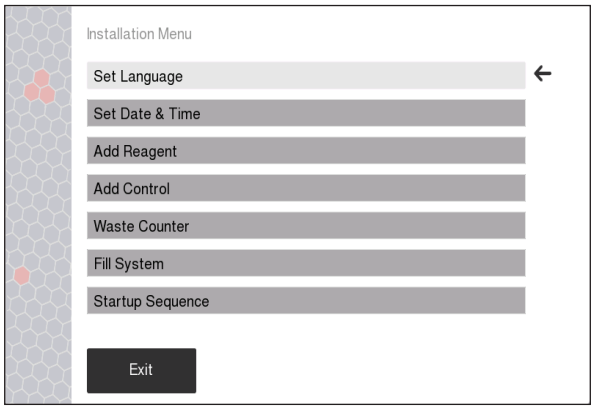

Figure 9: Installation menu

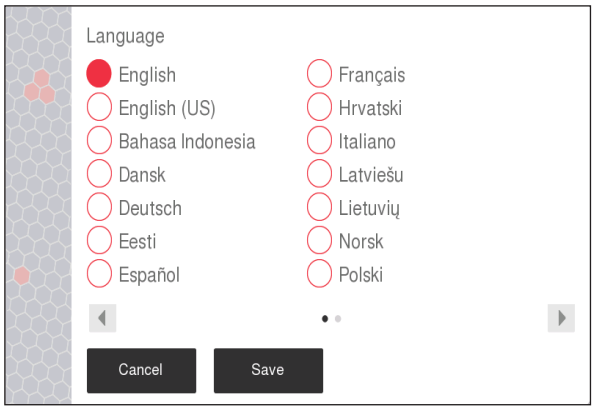

Figure 10: Language menu

2 Set Time

In this menu 4 different options are available:

- Select either **12h** or **24h**.
- To change the time select the hour or minute box and use the ✚ or ▬ signs to change.
- To change the divider select the divider box and use the use the ✚ or ▬ signs to change.
- Select the time zone box and click in the circle next to the correct time zone and then press **Save**.

3 Set Date

In this menu 3 different options are available:



Figure 11: Date and Time menu

- To change the date format select the date format box and use the ← or → arrows to change.
- To change the date select the year, month, or day box and use the ← or → arrows to change.
- To change the divider select the divider box and use the use the ✚ or ▬ signs to change.
- Press **Save** and return to Installation Menu.

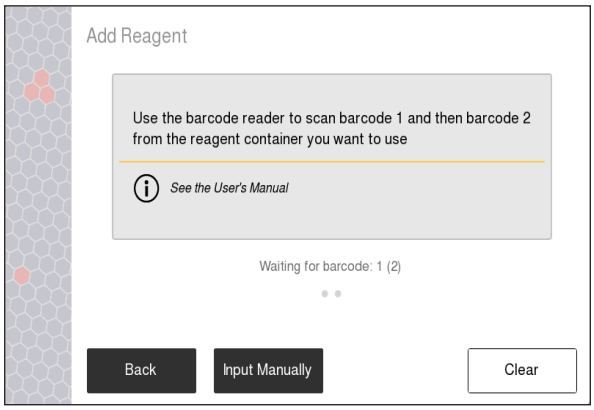

Figure 12: Reagent barcode entry

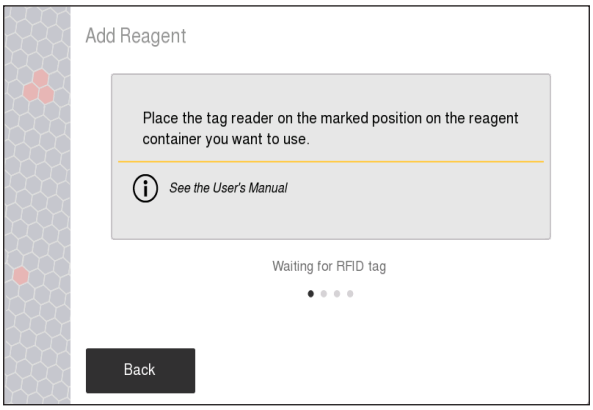

Figure 13: Reagent RFID entry

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4 Enter Reagent barcodes/RFID tags

For *Barcode entry* with a *Barcode reader*:
Scan in barcodes on reagent box. When all barcodes are entered a screen will display that reagent barcodes have been accepted.

- Scan barcode 1 and then barcode 2 on the Diluent container. (Press and hold the ACTIVE or ON button, on the barcode reader, each time a barcode is scanned.)
- Press **Enter another barcode** and scan barcode 1 and then barcode 2 on the Lyse container.
- Press **Exit** to return to the Installation Menu.

For *RFID tag entry* with a *RFID reader*:

- Place the tag reader on the marked position on the reagent container you want to use. When the reagent tag has been read a screen will display that the tag has been accepted.
- After a RFID tag has been accepted it is now possible to read another reagent, **Enter another tag**, or to exit to previous menu, **Exit**.

5 Connect Reagent tube assemblies to reagents

After reagents are scanned, loosen reagent container caps and connect the reagent tube assembly to respective container based on color-coding.

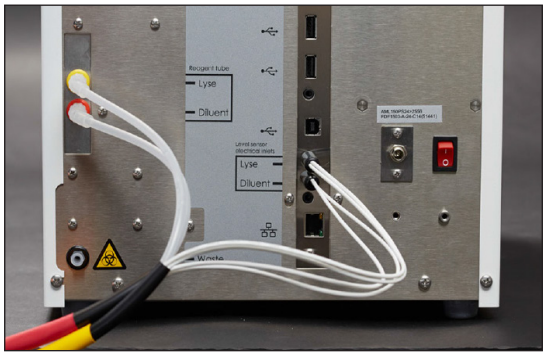

Figure 14: Connect Reagents

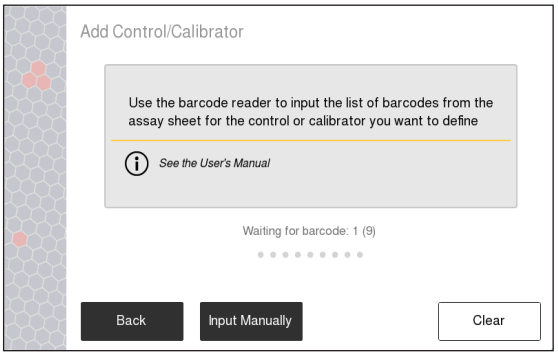

Figure 15: Enter Control barcodes

6 Enter Control barcodes

Scan Control Assay Sheet to enter assay value ranges into the system for the lot of Control being used.

- Scan barcodes 1–9, in that order, from the assay sheet.
- Once accepted, press **Exit** to return to Installation Menu.

7 Fill the liquid system

To fill the system with reagents, select **Fill System**. This cycle will last for approximately 3 minutes.

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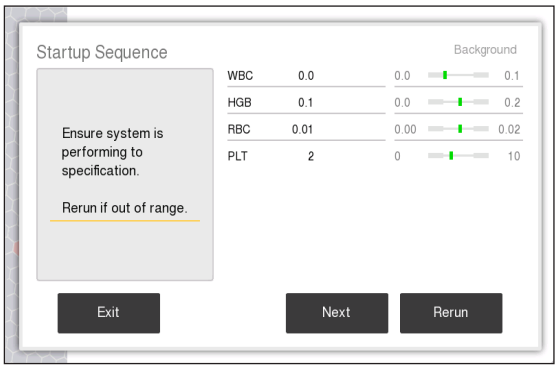

Figure 16: Daily Startup

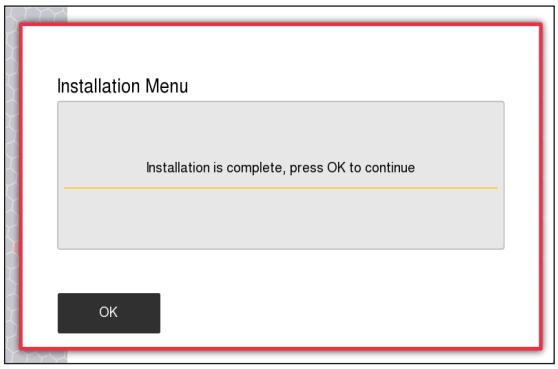

Figure 17: Completed Installation Menu

8 The installation sequence is now complete.

To prepare the Swelab Alfa Plus to analyze a sample perform one of the following:

Option 1 (recommended):

- Select **Startup Sequence**. This sequence guides the operator through the beginning of the day startup routine for the analyzer.
- There are two simple steps to follow which take the user through a background and control analysis sequence with detailed guidance at each step.
- When complete select **OK** to return to **Start Menu** and analyze sample.

Option 2:

- Select **Exit** to return to **Start Menu** .
- Go to *section 3* and follow instruction for Background analysis.
- Go to *section 5* and follow instruction for analyzing Controls.
- Return to *section 3* to analyze a sample.

■

Reagent Setup

The Swelab Alfa Plus system is interlocked with specified Boule reagents, AlfaDiluent and AlfaLyse (hereafter referred to as Diluent and Lyse), for optimal performance. The reagent containers must be identified by the analyzer before analysis of samples can begin.

Reagent Installation

This section describes the placement and connection of reagent containers:

- It is recommended that both the Diluent and the Lyse reagents are placed at the instrument level or below.

Placing the reagent containers above the instrument level could cause system flow issue and is not recommended.

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▶ Reagent Installation

1 Connect the Diluent reagent tube assembly (red) and electronic sensor to the analyzer.

2 Connect the Lyse reagent tube assembly (yellow) and electronic sensor to the analyzer.

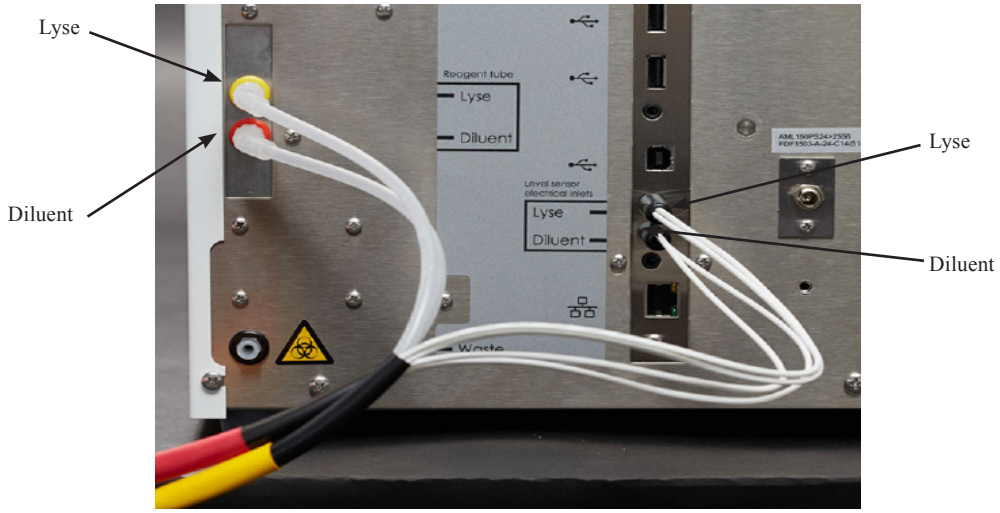

Figure 18: Reagent tubing installation

3 Insert each reagent tube assembly into the corresponding reagent container.



Figure 19: Reagent tubing installation

■

▶ Waste Tube Installation

Connect the waste tube to the analyzer. Place the other end of the waste tube directly into the drainage system or into a waste container, following local regulations. See *section 10* for Disposal information.

The end of the waste tube must be at a lower level than the analyzer itself. Not following this may lead to improper analyzer functions and/or waste liquid flowing backwards into the analyzer.

Always use protective gloves when working with the waste container and the waste tube.

If using waste container, press Reset Waste Container to reset the counter and OK to save.

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▶ Fill System with New Reagents

1 Select **Main Menu** tab, then **Maintenance Menu**, and then press **Fill**.

2 The system is now filling up with reagents. This cycle will last for approximately 3 minutes.

Changing Reagents

The interlocked reagent system displays indicator and warning messages to alert the operator when reagents are running low and need to be changed. When this occurs perform the following:

▶ Changing Reagents

1 Select **Quick Functions Menu** and then select **Add Reagent**.

2 Scan in barcodes/RFID tags on reagent box, and when all reagent barcodes/RFID tags are entered a screen will display that reagent barcodes/RFID tags have been accepted.

3 Select **Exit** to return to the **Quick Functions Menu**.

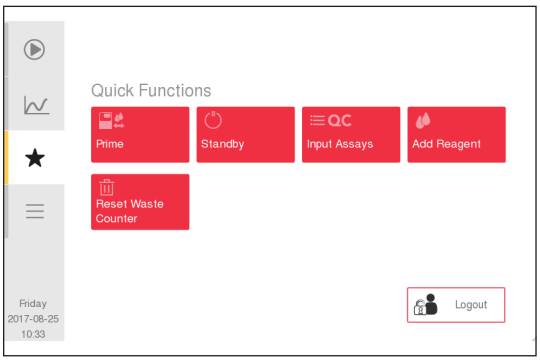

Figure 20: Reagent Setup

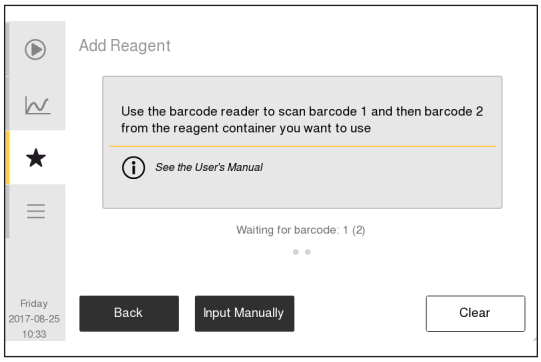

Figure 21: Enter New Reagents via barcode reader



Figure 22: Enter New Reagents via RFID tag reader

Note: To view current/activated reagent container select Main Menu, then Setup, and then Reagents.

4 Remove the cap on the new reagent container.

5 Transfer the reagent tube assembly from the used container to the new reagent container.

6 The analyzer is now ready to resume operation or analyze samples. No priming or fill cycle is necessary when putting on a new reagent container, if indicator and warning messages are followed.

A reagent alarm will display when at least one of the reagent containers is running low, empty, or expired. Once alarm is displayed it will continue to display after each sample run until the indicated container is changed.

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SECTION 3. OPERATION (SAMPLE ANALYSIS)

Preparations before Analysis

See section 4, **"Sample Collection"**.

Startup Sequence

The following sequence describes the daily startup routine for the analyzer including background and control analysis.

The startup sequence is optional and must be activated to follow this procedure, alternatively follow the manual background and quality control checks.

▶ Startup Sequence

1

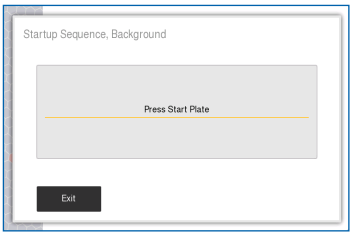

Figure 23: Startup Menu

Wake-up Analyzer

- Touch display or switch on power to the analyzer.
- Press **Exit Standby** or **Power-up**, depending on how the analyzer was shutdown previously, to "wake up" the analyzer.

2

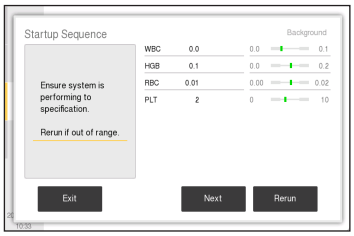

Figure 24: Startup Background

Parameter	Values
RBC	≤ 0.02 (10^{12}/L)
WBC	≤ 0.1 (10^{9}/L)
HGB	≤ 0.2 (g/dL)
PLT	≤ 10 (10^{9}/L)

Figure 25: Values accepted

Press Start Plate

When "wake up" cycle is complete, press start plate to begin the first step of the startup sequence.

Check Background

The background count is performed to check that the analyzer and reagents are within specifications.

- When complete the background results are displayed. Results should not be higher than values shown in *figure 23*.
  - If the results are within range proceed to final step and analyze controls.
  - If results are too high, analyze background count again and check values.

3

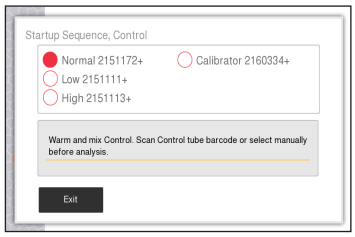

Figure 26: Select Control

Analyze Control

Control samples are analyzed to verify the performance of the Swelab Alfa Plus system. Follow the instructions on the screen:

- Either scan in barcode on control vial or choose the circle next to the desired lot number and level of control.
- Follow control handling instructions to ensure control sample is brought to room temperature and mixed properly, and press Start Plate.

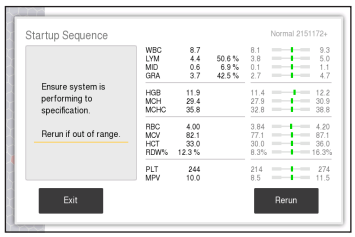

Figure 27: Analyze Control

- Analyzer will now analyze the control sample.
- When complete the control results are displayed.
  - If control results are acceptable, press Rerun, and repeat steps above with next level of control.
  - If control results are not acceptable, press Rerun, and repeat steps above with same level of control.

The Startup sequence is complete when all control results are acceptable.

Background Count

The following sequence is performed to check that the background count is low enough to run a sample. It is recommended to run a background check at the beginning of each day and when switching between different analysis modes.



Figure 28: Start Plate

Parameter	Accepted Values
RBC	≤ 0.02 (10^{12}/L)
WBC	≤ 0.1 (10^{9}/L)
HGB	≤ 0.2 (g/dL)
PLT	≤ 10 (10^{9}/L)

Figure 29: Acceptable Background Count

▶ Background Count

1 From **Start Menu** select **Background** tab, in upper right-hand corner.

2 Press the whole blood start plate, which is located behind whole blood sample probe.

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For Open Tube (OT), Closed tube devices (Autoloader/Cap Piercing Device) and Micro Pipette Adapter (MPA) use air as a sample. For the Pre-Dilute (PD) inlet background analysis, use diluent as sample through the dispensing function. Note that for the CAP device a dark tube or black tape around the tube is required for the initiation of an analysis.

Refer to Dispense Function under ***"Analyzing Sample (Pre-dilution Procedure)"*** for further instruction.

3 The aspiration time is approximately 10 seconds. After ~ 10 seconds the analyzer will time out due to no detection of blood, and continue its cycle.

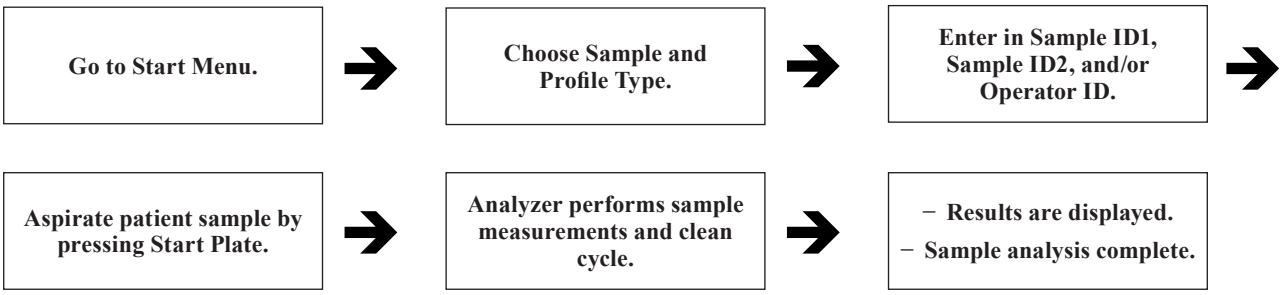
4 The background count should not be higher than the values shown in *figure 27*

- The Micro Pipette inlet is acceptable at ≤ 0.2 (10^9/L) on WBC due to potential pre-analytical contributions.
- Rerun sample if values are not acceptable.

Analyzing Sample (Open Tube)

The following steps will guide the operator through analyzing a blood sample using the "Open Tube" mode, which aspirates the blood sample through the sample probe.

▶ Sample Analysis Flowchart



▶ Analyzing Sample (Open Tube)

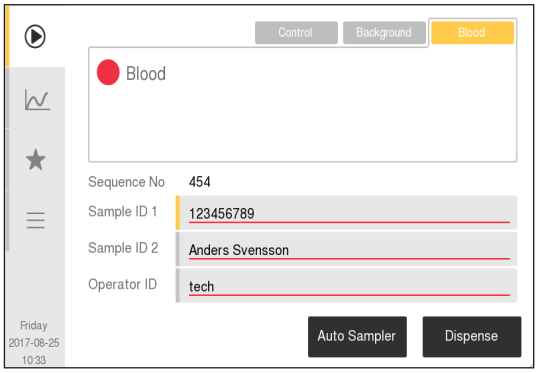


Figure 30: Start Menu



Figure 31: Sample Entry Keyboard

1 Enter Sample Analysis Mode Go to **Start Menu**.

2 Choose Sample type

Choose **Blood** tab, in upper right-hand corner, for sample type.

3 Choose Profile type

The analyzer can hold ≥ 20 different profiles.

- Choose profile by selecting the circle next to desired profile type.
- To see more profiles use left and right arrows to scroll to more profile types.

4 Choose Sample ID 1 and Sample ID 2

Sample IDs can be entered either manually or by barcode. Operator can enter up to 50 characters for each ID. The yellow indicator next to the fields shows which field the next barcode can be entered into.

- Sample ID1 is automatically highlighted, either scan in the ID using the barcode reader or use the keyboard to manually type in ID and press ☑ to save.
- Repeat to enter in Sample ID2.

5 Enter Operator ID

The Operator ID is an optional feature and, once set, will stay the same until Operator ID is changed, analyzer enters Standby, or analyzer is switched off.

- Press the field next to Operator ID and enter up to a 25-digit numerical or alphabetic ID.



Figure 32: Sample Aspiration

Make sure that the blood sample tube is not touching the upper part of the sample probe.

Do not remove sample prior to instruction, incomplete aspiration could occur, causing erroneous result.

Not removing the sample tube could result in incorrect washing sequence of the sample probe.

6 Sample Aspiration

Aspirate the sample through the sample probe by gently inserting sample probe into the sample tube and then press the whole blood start plate behind the sample probe.

- Follow the instruction on the display when to remove the sample tube. A beep is also an audible indication the sample should be removed from the sample probe.

7 Sample Measurement

The analyzer now switches to the sample analysis screen.

- Sample ID1/ID2 and profile can be changed up until results are displayed.
- If any changes are made, press ☑ to save, and then **Confirm**. Results will not be shown until change is confirmed.

8 Results Displayed

Sample results will be displayed after 45 seconds.

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Analyzing Sample (Micro Pipette Adapter, MPA)

The following steps will guide the operator through analyzing a whole blood sample with the use of the Micro Pipette Adapter (MPA).

ONLY Boule supplied, plastic, high precision EDTA micropipettes should be used when running MPA. Glass micropipettes can cause damage to analyzer if inserted incorrectly.

Read *section 4* on **"Capillary Blood Sample Collection"** before commencing.

▶ Analyze Capillary Sample (Micro Pipette Adapter, MPA)

1 Enter Sample Information

Follow instructions 1–5 under **"Analyzing Sample (Open Tube)"** to enter sample and ID information.

2 Preparing MPA device

- Pull out the MPA device. (The analyzer will give an instruction to put back the loaded MPA device to start the analysis cycle).
- Remove the previous sample micropipette. (If applicable)
- Place the adapter on the table.

3 Sample Collection

Once again, see *section 4*, **"Capillary Blood Sample Collection"** for this step.



Figure 33: Micropipette insertion into MPA



Figure 34: MPA insertion into analyzer

4 Micropipette insertion to device and analyzer

- Insert the micropipette into the MPA device as shown above, using the micropipette holder.
- Insert the MPA device into the analyzer which automatically starts the analyzing sequence.

5 Sample Measurement

The analyzer now switches to the sample analysis screen.

- Sample ID1/ID2 and profile can be changed up until results are displayed.
- If any changes are made, press ☑ to save, and then **Confirm**. Results will not be shown until change is confirmed.

6 Results Displayed

Sample results will be displayed after 45 seconds.

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Note: Do not remove MPA device during sample aspiration or analysis. Removal prior to completion of analysis may cause erroneous results.

Read *section 4* on **"Venous Blood Sample Collection"** before commencing.

▶ Analyze Venous Sample (Micro Pipette Adapter, MPA)

1	Enter Sample Information	Follow instructions 1–5 under **"Analyzing Sample (Open Tube)"** to enter sample and ID information.
2	Preparing MPA device	• Pull out the MPA device. (The analyzer will give an instruction to put back the loaded MPA device to start the analysis cycle). • Remove the previous sample micropipette. (If applicable) • Place the adapter on the table.
3	Sample Collection	Once again, see *section 4*, **"Venous Blood Sample Collection"** for this step.
4	Fill micropipette with venous sample	• Use the micropipette holder to grasp a micropipette (holding it on one end and not the middle will facilitate filling of blood). • Using your other hand tilt the sample vial so the blood nears the opening of the tube. • Place the micropipette end into the sample vial and aspirate blood via capillary action. • When the micropipette is completely filled, remove it from the vial. • Wipe off any excess blood on the outside surface without removing any blood from the inside of the capillary tube.
5	Micropipette insertion to device and analyzer	• Insert the micropipette into the MPA device as shown above, using the micropipette holder. • Insert the MPA device into the analyzer which automatically starts the analyzing sequence.
6	Sample Measurement	The analyzer now switches to the sample analysis screen. • Sample ID1/ID2 and profile can be changed up until results are displayed. • If any changes are made, press ☑ to save, and then **Confirm**. Results will not be shown until change is confirmed.
7	Results Displayed	Sample results will be displayed after 45 seconds.

Note: Do not remove MPA device during sample aspiration or analysis. Removal prior to completion of analysis may cause erroneous results.

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Analyzing Sample (Cap Piercing Device)

The following steps will guide the operator through analyzing a venous blood sample using the Cap Piercing Device.

Sample tube description:

- Most standard 5.0 mL tubes, with a maximum length of 82 mm, can be used in the Cap Piercing device. The minimum volume in the closed tube should be approximately 1 mL.

The Cap Piercer can be damaged if incorrect sized tube is used.

▶ Analyze Sample (Cap Piercing Device)

1	Enter Sample Information	Follow instructions 1–5 under **"Analyzing Sample (Open Tube)"** to enter sample and ID information. • If the Cap Piercing Device has a mounted internal barcode reader, for Step 4, the operator can simply place the tube into the Cap Piercing Device and the ID will be read automatically. – It is very important to line up the barcode on tube with the barcode reader, facing inwards as seen in figure 34. • If the Cap Piercing Device does not have a mounted internal barcode reader, follow instructions 1–5, as stated above.
2	Preparing Cap Piercing Device	Open door to Cap Piercer and insert vacuum tube upside down, pressing the tube in place, aligning with lower support.
3	Close Cap Piercing Device	Close the door to the Cap Piercer to begin sample analysis.



Figure 35: Sample tube insertion



Figure 36: Sample tube alignment

Follow your lab established biohazard barrier protection. This may include gloves, lab coat and/or eye protection.

Caution should be applied when handling the Cap Piercer. Handling and operation by unauthorized personnel may result in injury.

Insert the sample tube with lid facing downwards. Ignoring this instruction may damage the aspiration needle.

4	Sample Measurement	The analyzer now switches to the sample analysis screen. • Sample ID1/ID2 and profile can be changed up until results are displayed. • If any changes are made, press ☑ to save, and then **Confirm**. Results will not be shown until change is confirmed.
5	Results Displayed	Sample results will be displayed after 45 seconds.

Analyzing Sample (Pre-dilution Procedure)

This section describes how to analyze a pre-diluted sample through the "pre-dilute" aspiration probe and how to use the dispense function.

Dilution Rates and Ratios: 1:200–1:300 (Recommended: 1:225 (20 µL sample in 4.5 mL diluent)).

▶ Recommended Method

The recommended pre-dilute method is using the dispense function, which uses the factory calibrated dilution ratio of 1:225 (20 µL sample in 4.5 mL diluent).

Dispense Function

1	Select Dispense Button	Go to **Start Menu** and choose **Dispense**.
2	Fill Pre-dilute Beaker	• Place a beaker for waste under the pre-dilute aspiration probe (the probe in front of the pre-dilute start plate). • Press the pre-dilute start plate to begin dispense mode. • The instrument will fill the beaker with a small amount of diluent, this is to be discarded. • Now place your beaker for sample analysis under the pre-dilute aspiration probe, and fill with 4.5 mL diluent by pressing the start plate again. – If more than one beaker is to be filled repeat this step. • Leave dispense function by pressing Exit.

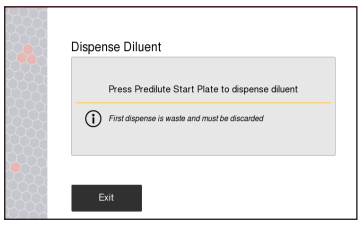

Figure 37: Dispense Menu

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3	Prepare Pre-dilute Sample	• To make the 1:225 dilution add 20 µL of sample to be analyzed, into the beaker. • Make sure to mix the contents. • Prepare pre-dilute sample according to your laboratory procedures and the **time limitations** section below.

Pre-dilute Aspiration Procedure

1	Enter Sample Information	• Re-enter analysis mode by going back to the Start Menu. • Follow instructions 1–5 under **"Analyze Sample (Open Tube)"** to enter sample and ID information.
2	Sample Mixing	• Make sure the contents of the pre-dilute beaker is fully mixed and no sedimentation is observed.
3	Aspirate Pre-dilute Sample	• Aspirate the pre-diluted sample through the pre-dilute aspiration probe by pressing and holding the pre-dilute start plate until aspiration starts. • When the complete sample is aspirated remove the pre-dilute beaker.



Figure 38: Pre-dilute aspiration

4	Sample Measurement	The analyzer now switches to the sample analysis screen. • Sample ID1/ID2 and profile can be changed up until results are displayed. • If any changes are made, press ☑ to save, and then **Confirm**. Results will not be shown until change is confirmed.
5	Results Displayed	• Sample results will be displayed after 45 seconds.

▶ Externally Pre-diluted volumes and preparation

- There is a possibility of externally preparing pre-dilution. However, pre-dilute volumes of 4.5 mL–5.0 mL must be used.
- Always calibrate the pre-diluted inlet with your chosen pre-dilute volume, if recommended method is not used.
- Prepare pre-dilute sample according to your laboratory procedures and the **time limitations** section below.
- In order to get accurate results always use the same dispenser for calibration and sample analysis.

Do not analyze a whole blood sample in the pre-dilute mode, this will cause erroneous results.

If this happens follow the instructions below, as soon as possible, to return analyzer to normal operation status:

Step 1: Use dispense mode to dispense diluent into waste beaker until diluent has no traces of blood left. Then dispense two more times and discard waste.

Step 2: Next, dispense clean diluent into beaker and run diluent in pre-dilute mode.

Step 3: Check background results. If results pass, instrument is now ready to use. If results do not pass, repeat Step 2 until background results pass.

▶ Time Limitations

Pre-dilute procedures are generally less precise than open and closed tube procedures and results may vary depending on local laboratory procedures and conditions. Blood cells may shrink and/or swell during the time between mixing in the beaker and the actual analysis, resulting in compromised values of MCV, MPV and the distribution between lymphocytes/mid-cells/ granulocytes (with indirect effect on calculated parameters, e.g. HCT). Thus, the time between mixing and analysis should be minimized and under no circumstances exceed 60 minutes, since RBC, PLT, HGB and WBC may also be affected.

Analyzing Sample (Auto Sampler)

The following steps guide the operator through analyzing a venous blood sample using the Auto Sampler.

Sample tube description:

- Only standard 4.0 to 5.0 mL tubes can be used in the Auto Sampler. A sample wheel adapted for Sarstedt tubes is available as an option. The minimum volume in the closed tube should be approximately 1 mL.

▶ Analyze Sample (Autosampler)

1 Load Wheel



Figure 39: Sample Wheel

- To unlock the sampling wheel, turn it counterclockwise and lightly pulling it away from analyzer.
- Load the vacuum tube samples by placing the capped end towards outer edge of sample wheel and fitting it into designated slot. (The first positions of sample wheel (Position 1 and 21) are recommended to be left open for emergency samples.) Lock in samples by turning center piece clockwise.
- It is important that tubes are positioned correctly.
  - If the instrument is equipped with an internal bar code reader, position tubes with barcodes facing TOWARDS analyzer and tubes without barcodes so that label on tube is facing AWAY from analyzer.
- Place the sampling wheel back on the analyzer.

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2 Select Wheel Number

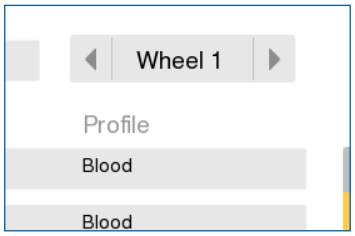

Figure 40: Wheel Selection

When numerous samples are being analyzed, an additional wheel may be needed. Additional wheel entry can begin before or after previous wheel has begun analysis.

- Press arrows on either side of **Wheel** field to select wheel number.
- Scroll through position number on selected wheel to match the position number on the wheel with the sample that the operator is currently loading.
- Follow steps for **Selecting Sample ID**.
- Wait for previous wheel to finish before placing new wheel on front position of analyzer.

3 Select Sample ID

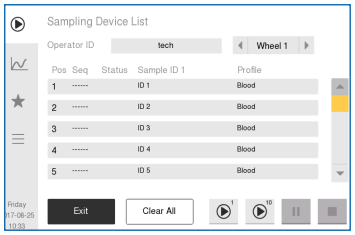

Figure 41: Auto Sampler Menu

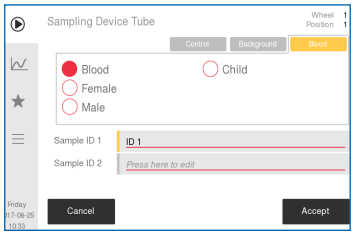

Figure 42: Select Sample

There are several ways to select the samples:

Method 1:

If Auto Sampler model has a mounted internal barcode reader, and if a barcode is used for the ID, the operator can simply place the tube in sample wheel and the ID will be read automatically. It is very important to line up the barcode on tube with the barcode reader.

Method 2:

Another option is to manually enter in IDs, using the external barcode reader or the touch screen keyboard.

- To manually enter ID press **Auto Sampler,** choose wheel number**,** and then press the desired position sequence field.
- Press the field next to Sample ID1 and/or Sample ID2 and either scan in the ID using the barcode reader or use the keyboard to manually type in ID, then select **Accept** to save.
- After ID is entered the next position for entry will automatically be highlighted.

Method 3:

If Sample ID 1 is not specified and no barcode read from the tube, the instrument will use "NO BARCODE" as Sample ID 1.

4 Select Operator ID (optional)

- Operator ID– Select the field next to **Operator ID** to enter optional Operator ID and then **Accept** to save.

5 Start Sample Device

- Verify that correct wheel number is selected.
- Make any needed Setup changes.
- Choose/Follow Sample ID Method from Step 3.
- Press ▶ button on the left to immediately begin analysis.
- Auto Sampler begins analysis with the sample tube placed in the lowest position number.

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Do not touch sample wheels or samples during operation.

Handling and operation by unauthorized personnel may result in injury.

6 Auto Sampler Setup

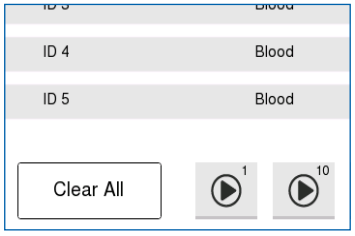

Figure 43: Auto Sampler Mixing Setup

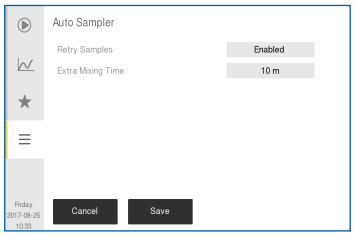

Figure 44: Auto Sampler Retry Setup

Most of the Auto Sampler functions are preset, so that the user can simple press a button to start the desired function.

- Mixing time – When ready to analyze samples select the ▶ button on the right if longer mixing time is prefered.
  - ▶ on the left is the standard mixing time of 1 minute.
  - ▶ on the right is the settable extra mixing time.
  - Currently set mixing time is written as superscript to the right of each ▶ button.
  - To change Extra Mixing Time go to System Setup Menu and then select Auto Sampler.
  - Select the field next to Extra Mixing Time.
  - Extra Mixing Time can be set from 1 to 15 minutes.
  - Press ☑ to accept the new values and then Save.
- Clear All – Press **Clear All** button to clear all samples from all wheels.
- Retry sample – Go to **System Setup Menu** and then select **Auto Sampler**.
  - Select the field next to Retry Samples.
  - Default setting = Enabled
  - To deactivate setting select Disabled and then Save.

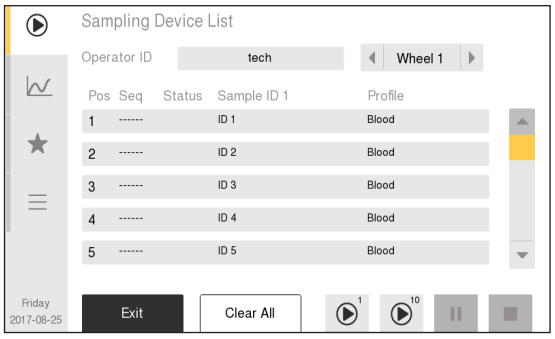

Figure 45: Pre-Sample Analysis

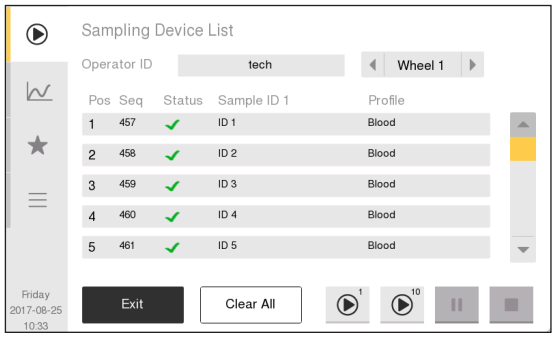

Figure 46: Post-Sample Analysis

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7 Sample Status

= A tube is in the position but not yet analyzed.

= Count cycle is complete, good analysis obtained.

= Failure to complete a good count cycle.

= The sample tube will be re-analyzed.

= Failure to find sample that has been entered into a position.

= No sample tube in this position.

Figure 47: Sampler symbols

Position (Pos), Sequence (Seq), Status, Sample ID, and Profile will appear in **Sampling Device List** as they are analyzed.

- Position Sequence will display either the position number of the samples being analyzed/entered or a dashed line (------) if there is no tube in that position.
- Sample Status has six indicators, see *figure 45*.
- Sample ID will be displayed in this column, unless no ID is entered.
- Profile column will display profile type of sample analysis.

8 View Sample

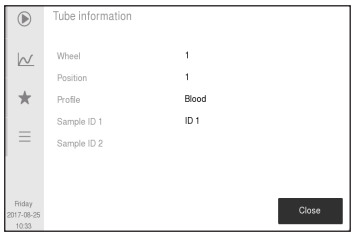

Figure 48: During Analysis

Sample information can be viewed before, during, and after **Start** is selected. The following can be viewed when desired position sequence field is selected.

- Before – If the sample has not yet been analyzed, the user will see the configuration of the tube.
- During – If the sample is currently being analyzed, the user can view a read-only version of the tube configuration.
- After – When the sample analysis is complete, the user can view the result.

▶ Editing Sample ID

Changing a Sample ID for position is allowed as long as analysis of that position has not started yet.

- Press **Auto Sampler** and then press the desired position sequence field.
- Manually enter in new ID, using the external barcode reader or the touch screen keyboard.

▶ Emergency Sample Analysis

Emergency (STAT) samples can be analyzed after the Auto Sampler has been started or during Auto Sampler ID entry. There are several ways to analyze an emergency sample.

Method 1:

- Emergency sample can be analyzed through OT, pre-dilute, or MPA mode.
  - Press ⏸, wait for current sample to finish, select Start Menu, and then analyze sample in preferred mode.
  - There may be a slight delay after pressing ⏸ button before emergency sample can be analyzed. This is because analyzer will complete the counting cycle of the last sample run on sample wheel before continuing with emergency sample analysis.

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- When emergency sample is complete, select Auto Sampler button, and then ▮▶ to restart sampling in next position on the wheel.

Method 2:

- Emergency sample can also be analyzed using the sample wheel.
  - Press ■, unlock sample wheel and place emergency sample in Position 1 or 21.
  - If a sample is already occupying Position 1 or 21 and has already been analyzed, remove sample and place emergency sample in its place.
  - If emergency sample has a barcode for ID, align barcode correctly, lock sample wheel and press ▮▶.
  - See Editing Sample ID if manual entry of sample is desired, and lock sample wheel and press ▮▶.
  - Analyzer will automatically analyze emergency sample and then continue sampling where it left off prior to pressing ■ button.

DO NOT press START after Auto Sampler has been paused or stopped unless operator wants to rerun all samples on wheel.

Results

After a sample has been analyzed the result information will be displayed on the screen. The operator can also search for previous sample analyses, look at statistics, and print and export them.

▶ New Sample Analysis Results

The Sample Result screen can be divided into four main sections.

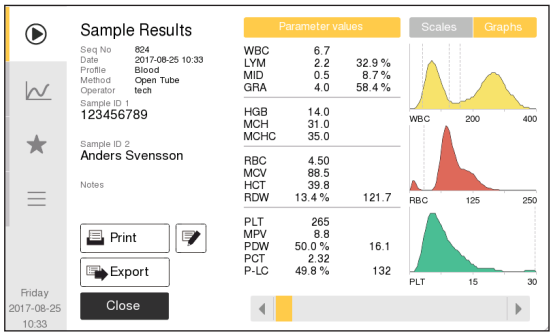

Figure 49: Result Screen with graphs

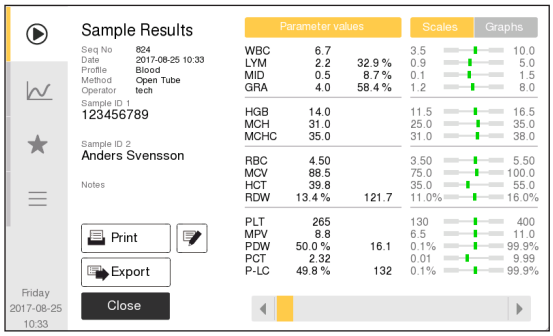

Figure 50: Result Screen with scales

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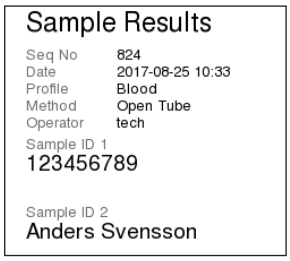

Figure 51: Analysis Information

Section 1: Sample Analysis Information

- Sequence number
- Date and time
- Profile type
- Method
- Operator ID
- Sample ID1
- Sample ID2
- Notes (if applicable)

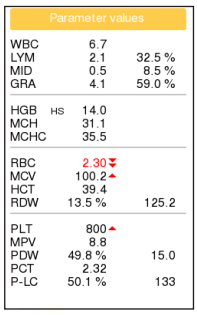

Figure 52: Parameters Values

Section 2: Parameter Values

- Parameter names
- Parameter values
- Parameter flag, more information from System Information message
- Red arrow = Result that is either higher or lower than preset normal range
- Double red arrow = Result outside of Alert Limits

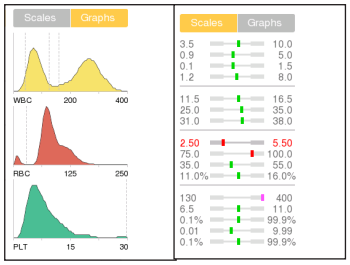

Figure 53: Distribution Curves and Scales

Section 3: Parameter Scales and Graphs

- Normal range display bars with sample results
  - Green bar = Result within normal range
  - Red bar = Result Out-of-Range
  - Purple bar = Result outside of visible bar range
- RBC, PLT, and WBC distribution curves

Note: If the light gray horizontal bar becomes darker = Alert Limits are used instead of normal ranges.

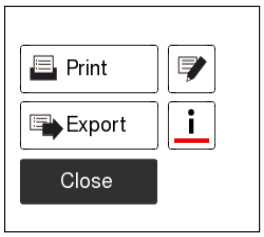

Figure 54: Function/Info button

Section 4: Function/Information Buttons

- Note: **i-button** is only visible when a message is present.
- Press button to add notes to the sample results.
- Press the **i-button** to see System Information and/or Pathology Messages.
- Press **Print** button to Print the sample results.
- Press **Export** button to Export the sample results to a USB device or host.
- Press **Close** button to return to **Start Menu**.

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PLT Extended Count

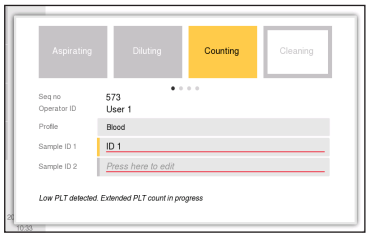

Figure 55: PLT extended counting time counting phase

If *PLT extended counting time* is enabled (see section 7) and a low PLT is detected during analysis, the extended counting time will be displayed firstly in the counting phase screen and will then be indicated by an asterix (*) adjacent to the PLT parameter name on the result screen, printouts and exported PDFs.

Sample Results List and Search

In the Results List Menu the operator can search for previous sample analyses, view statistics, and print/send samples and summary reports.

▶ Sample Result List and Search Function

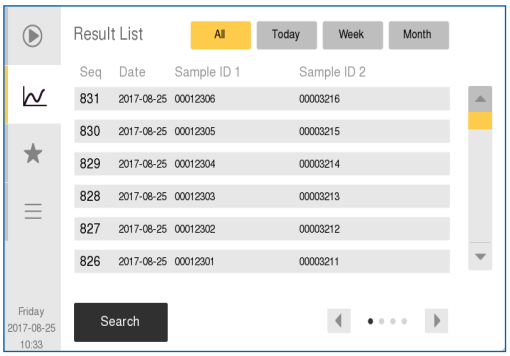

Figure 56: Result List Screen

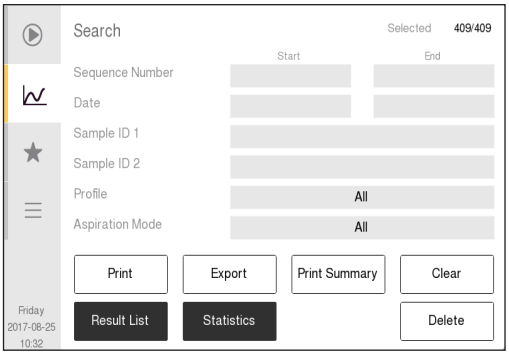

Figure 57: Search Screen

1 Enter Result List Mode

Go to **Result List** screen to view list of results.

2 View Results

To view a specific sample result from the list use the scroll arrows to scroll to sample and then press on field with desired sample result.

3 Quick View of Results

Quick View buttons have been setup to view the following groups of sample analyses.

- All
- Today
- Week
- Month

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4 Search Function

In Search mode the operator can search for samples using specific search criteria.

- Select the **Search** field, in lower left-hand corner.
- Press the field to the right of the following criteria to narrow search and then press **Accept** to view search criteria.
  - Start Sequence number – End Sequence number
  - Start date – End date
  - Sample ID1
  - Sample ID2
  - Profile type
  - Aspiration Mode
- Press **Clear** button to Clear search criteria.
- Press **Result List** button to cancel and return to list.
- Search function will automatically clear search criteria when another sample is analyzed or analyzer is turned OFF.

5 View Sample Statistics

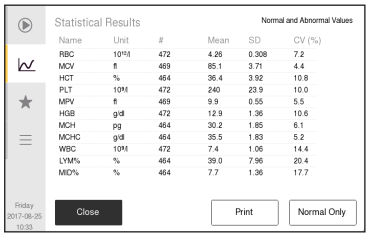

Figure 58: Sample Statistics

- For a quick view of all sample statistics press **Statistics** button.
- In the Sample Statistics Menu the operator will be able to view:
  - Parameter
  - Number of samples used in statistics
  - Mean value of selected samples
  - Standard Deviation (SD) of selected samples
  - Coefficient of Variation (CV) of selected samples.
- To view specified samples, select samples using the **Search** mode in **Result List** screen. Press **Close** button to return to search screen and view current search criteria.
- To view only normal statistic values, press **Normal Only** button.

6 View Summary Reports

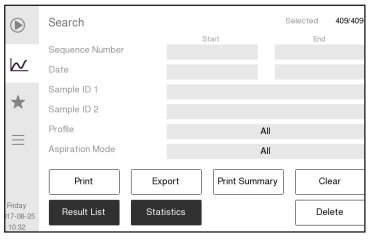

Figure 59: Print Summary Report

- To view specified samples, select samples using the **Search** mode in **Result List** screen.
- Select **Print Summary** to print or send report.
- Summary reports will print on a horizontal sheet of paper.

To manually enter **Standby** mode, go to **Maintenance** menu and press **Standby.**

SECTION 4. SAMPLE COLLECTION

Venous Blood Sample Collection

- Venous blood samples should be collected in a K2EDTA or K3EDTA tubes in sufficient quantity and be gently mixed after sampling in order to obtain accurate results. Please follow the recommendation of the EDTA tube supplier.
- Obtain the sample by means of a clean venipuncture to minimize platelet aggregation.

Limitations

- Samples drawn in an open tube or vacuum tube should be analyzed between 15 minutes and 8 hours for most accurate results.
- The sample should be kept at room temperature. Excessive cold or heat could cause erroneous results.

Handling of venous blood samples

- It is recommended that the sample should be allowed to equilibrate to the EDTA for 10–15 minutes after collection.
- The sample should be thoroughly and gently mixed before analysis.
- A sample not correctly handled may give erroneous results.

Handling of capillary blood samples

- The sample in the EDTA micropipette can be analyzed directly after collection and for optimal results not longer than 10 minutes from collection.
- For capillary samples collected in EDTA micro tubes follow the "Handling of venous blood samples" section above.

Capillary Blood Sample Collection

Performing a Fingerstick

For capillary collection, follow steps below and the procedure for optimal collection of capillary blood specimens given in the CLSI standard GP42-A6 "Procedures and devices for the collection of diagnostic capillary blood specimens". (For latest edition of this standard go to www.clsi.org.)

- Due to PLT adhesion to tissue and capillary walls and imprecision in preparation and blood draw procedures, discrepancies between capillary and venous blood values may occur on the following parameters:
  PLT may be lower in capillary blood by 5–10%
  WBC may be slightly elevated if PLT clumping occurs, affecting the lymphocyte count.

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Wash hands, put on gloves, and any other safety equipment specified by established local laboratory protocol, for coming in contact with potentially biohazardous materials.

▶ Capillary Blood Sample Collection

1	Choose site for skin puncture	See CLSI standard GP42-A6 for details on recommended site for finger and heel punctures.
2	Warm the site	Warm the skin site for 3–5 minutes before puncture to increase blood flow to the site (arterialization). This can be done using a warm, moist towel or other warming device.
3	Disinfect site and dry	Cleanse site with 70% aqueous solution of isopropanol or appropriate disinfectant. Allow the skin to dry before puncture.
4	Remove MPA adapter	Remove MPA adapter from the analyzer by gently pulling the handle.
5	Perform the puncture	Follow lancet packaging insert for instructions on proper preparation and use.



Figure 58: Puncture with lancet

- Position lancet firmly against the puncture site and puncture skin.
- It is important to perform a deep and firm puncture to obtain free flowing drops of blood, which decreases incorrect or non-reproducible results.
- Properly discard lancet per laboratory protocol.

6 Collect specimen



Figure 59: Collect Specimen

- After puncture, wipe away the first drop of blood with a clean tissue or gauze pad. (First drop of blood often contains excess tissue fluid.)
- By holding puncture site downwards and applying gentle, intermittent pressure above the site, the blood flow will be enhanced. Do not use scooping motion or strong repetitive pressure, "milking", to the site. (This can cause hemolysis or contaminate sample with excess tissue fluid.)

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7

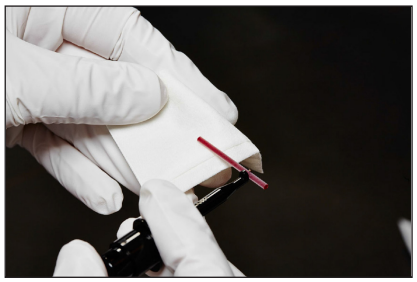

Figure 60: Preparing micropipette

- When second drop forms either:
  - Use the micropipette holder to grasp a micropipette. (Holding the micropipette towards one end or the other, instead of in the middle, is best for filling and insertion.) Aspirate the sample, holding the micropipette at a slightly downward angle, for quickest fill, and being careful to only allow the tip of the pipette to touch the drop of blood (not the finger directly).
  - Or turn the patient's palm downward and position micro collection tube directly under puncture site to collect blood drops.

Important to fill micropipette completely, to ensure correct and reproducible results.

- Dispose of all materials according to laboratory protocol.

Fill the micropipette completely with fresh whole blood and wipe off excessive blood on the outside surface.

Be careful not to wick blood from open ends of the micropipette.

Ignoring these instructions might cause incorrect and non-reproducible results.

8 Complete procedure

- Transport sample to analyzer for processing by inserting filled micropipette into the MPA adapter using the micropipette holder. Insert the holder into the analyzer and an analysis cycle with automatically begin.
- Samples should be analyzed directly after collection and for optimal results not longer than 10 minutes from collection.

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SECTION 5. QUALITY CONTROL

Analyzing Control Sample

It is advisable that the performance of the Swelab Alfa Plus system is checked daily with a certified blood control authorized by Boule. Comparing the analyzer results to the known values on the Boule control assay sheet is a good assurance that the system is functioning properly.

Control Handling Recommendations

- Handle and prepare controls in accordance to control package insert.
- Never use an open vial longer than recommended by the manufacturer, past the expiration date, or subject any vial to excessive heat or agitation.
- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials.
- Wipe the aspiration needle with a clean, dry lint free absorbent cloth before each control run. Not following this technique will impact control accuracy.

Control Use Recommendations

It is recommended to use a control for the following:

- Daily analyzer system check.
- With a new lot or shipment of reagents to check for damage during transport or storage.
- If required by operator's laboratory protocol or local, state, or federal guidelines.
- Possible troubleshooting purposes.

Enter New Control Lot

Follow the instruction below to access the QC menu and to input Control/Calibrator Assay Values from the Assay sheet.

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▶ Enter New Control Lot

1 Enter QC Mode — Go to **Main Menu** and then select **Quality Control**.

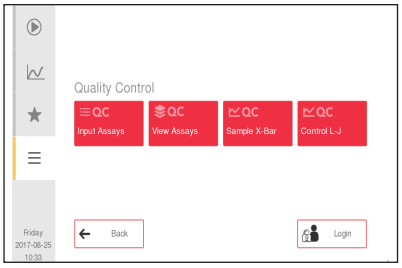

Figure 63: QC Menu

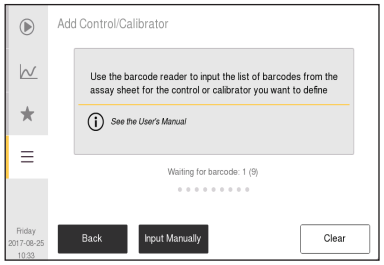

Figure 64: New Control Entry

2 Enter New Control Lot

- Choose **Input Assays**.
- Refer to the Assay sheet for instructions on how to input control assay values. (These pages are delivered with authorized Boule controls).
- Assay values for a control lot will be automatically removed from the system 30 days after the expiration date.
  - For everyday use this means that the user registers new controls and the system removes the old controls.
  - A maximum of 100 control lots can be registered at the same time. If more than 100 control lots exist on the system, the user will be prompted to OK removing the oldest control lot before the new control lot can be registered.

Analyze Control

Control samples are analyzed to verify the performance of the Swelab Alfa Plus system. Three levels of control can be checked. Follow the instructions below to analyze controls.

▶ Analyze Control

1 Enter Control Analysis Mode — Go to **Start Menu**.

2 Choose Sample type — Choose **Control** tab, in upper right-hand corner, for sample type.

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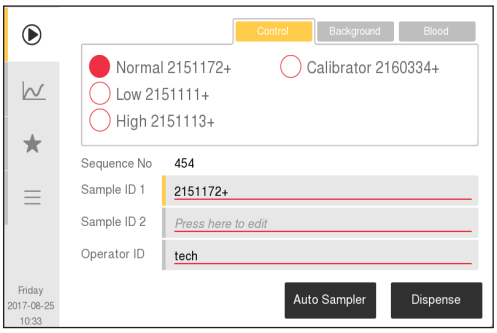

Figure 65: Select Control

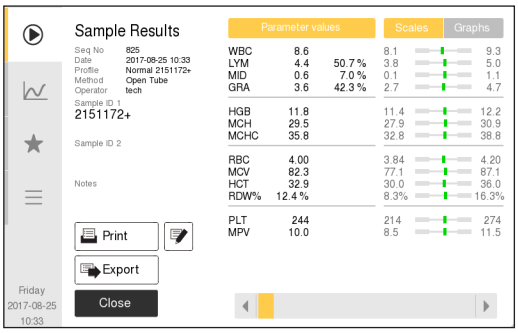

Figure 66: Control Results

3	Enter barcode	Either scan in barcode on control vial or choose the circle next to the desired lot number and level of control.
4	Analyze Control	Press Start Plate, analyzer will now analyze the control sample.
5	Results Displayed	When complete the control results are displayed. • If control results are acceptable, repeat steps above with next level of control. • If control results are not acceptable, repeat steps above with same level of control.

▶ Control Sample Analysis (Auto Sampler)

If analyzing samples using the Auto Sampler mode it is recommended to also run daily control samples using the sample wheel.

- Follow instruction in *section 5* for control handling and assay sheet input.
- Firmly press capped end of control sample into control tube adapter.
- Load the control sample by placing the adapter towards the outer edge of the sample wheel and fitting it into Position 1 for all tubes except if using Sarstedt wheel. If Sarstedt wheel, place control sample in Position 40.
  - Position control tube barcode facing TOWARDS analyzer and centered in slot.
  - If using all three levels of control, add adapters to all levels and fit them into Positions 1, 2, and 3.
- Follow instructions in *section 3*, **"Operation (Sample Analysis)"**.

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Quality Assurance Functions

The Swelab Alfa Plus system includes numerous Quality Assurance functions to ensure that the analyzer and reagents are working properly and that the operator procedures are performed correctly.

The Swelab Alfa Plus system has been designed and manufactured according to Boule Medical ISO 13485 quality system procedures.

Analyzer Quality Assurance

- Before and during each measurement the analyzer performs a self-test to verify correct operation on both the sub-system and system levels.
- A system check using blood control is recommended on a daily basis to assure the system is functioning properly. The system uses barcodes to identify that the control materials are Boule certified products.
- The analyzer has been factory calibrated prior to shipment, and has calibration functionality, if necessary.

Reagent Quality Assurance

- Each lot of reagents have specific lot information assigned to them with the information encoded in the barcode.

Software Quality Assurance

- The software has been designed with a variety of control features such as:
  - Result memory storage – Allowing results to be stored, reviewed, printed, and sent to USB devices and hosts.
  - Barcodes – Restricting only Boule certified consumables and accessories to be used with the analyzer.
  - QC flagging – If expired reagents, controls and/or calibrators are used, results will be flagged.
  - Blocked results – Possible erroneous results cannot be viewed by operator if specified QC/ analysis conditions are not met.
- The software has several parameter and system information messages related to the measured parameters and the analyzer. These messages alert the operator of possible pathologic samples and parameter value and analyzer errors.
- For information on Third-party software see Appendix C.

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Control and Calibrator Search Function

The operator can search for previous control and calibrator analyses, view statistics, and print/send QC samples and summary reports.

▶ QC Results and Search Function

1 Enter QC Search Mode

- Go to **Main Menu** and select **Quality Control Menu**.
- Select **Control L-J** and then **Search**.

2 View Results

To view a specific QC sample result, select **Sample List**, and then press on field with desired sample result.

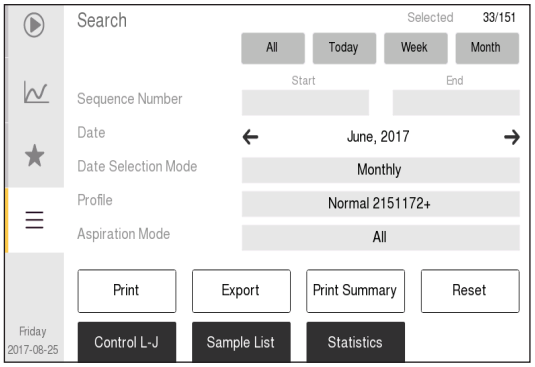

Figure 67: Search Menu

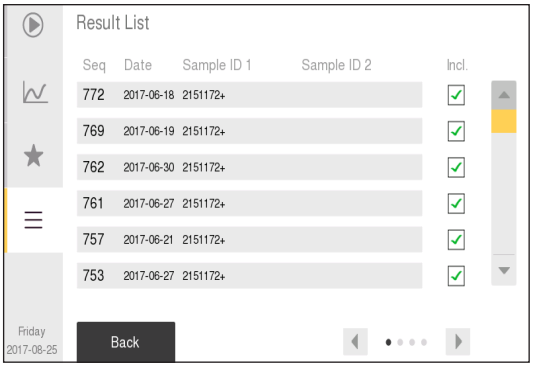

Figure 68: Sample List

3 Quick View of Results

Quick View buttons can be used to group QC samples into specific time periods.

- All
- Today
- Week
- Month

4 QC Search Function

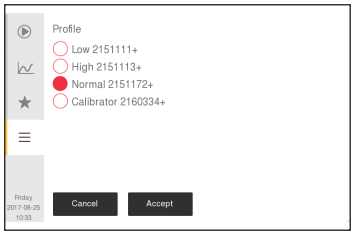

Figure 69: Profile selection

In Search mode the operator can search for QC samples using specific search criteria.

- Select the **Search** field, in lower right-hand corner.
- Press the field to the right of the following criteria to narrow search and then press **Accept** to view search criteria.
  - Start Sequence number – End Sequence number
  - Date (Either Start Date – End Date or Month/Year)
  - Date Selection – Choose Continuous or Monthly
  - Profile (Selecting Profile allows the user to search by Lot number.)
  - Aspiration Mode
- Press **Reset** button to return to default search criteria.
- Press **Sample List** button to return to list.

5 Print/Send Results

- To print a specific QC sample result, select **Print**.
- To Send a specific QC sample result, select **Export**.

6 View QC Statistics

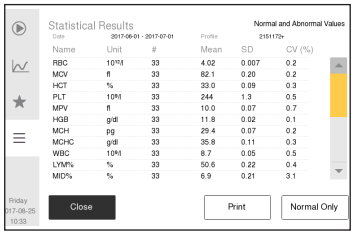

Figure 70: QC Statistics

- For a quick view of all sample statistics press **Statistics** button.
- In the Sample Statistics Menu the operator will be able to view:
  - Parameter
  - Number of samples used in statistics
  - Mean value of selected samples
  - Standard Deviation (SD) of selected samples
  - Coefficient of Variation (CV) of selected samples.
- To view specified control lot, select samples using the **Search** mode in **Control L-J** screen.
- To view only normal statistic values, press **Normal Only** button.
- To exclude a specific sample from the statistics, uncheck the box to the right of the sample when viewing it in **Sample List**.

7 View Summary Reports

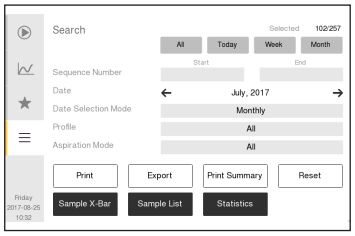

Figure 71: Summary Reports

Once QC samples are displayed they can also be printed out in a Monthly QC summary report.

- In **Search** menu, select **Monthly** under **Date Selection Mode** and then choose the desired control lot under **Profile**.
- Select **Print Summary** button to print report.

8 Clear Search Results

- Search criteria are reset when leaving the function.

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Levey-Jennings Plots

Levey-Jennings (L-J) plots are used to monitor the long term stability of the analyzer using Boule controls. Plots are auto-scaled to the expected ranges defined in the assay. To select, display and/or print the L-J plots, follow the instructions below:

▶ Levey-Jennings Plots



Figure 72: QC Menu

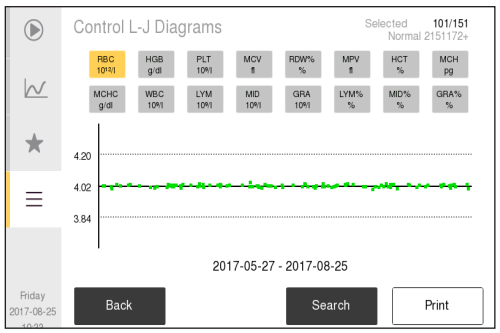

Figure 73: L-J Plot Results

1	Enter QC Mode	Go to **Main Menu** and then select **Quality Control Menu**.
2	Enter Levey-Jennings Mode	Select **Control L-J**.
3	L-J Plot Results	Samples during the latest 90 days are shown as a default for the L-J plots. Monthly View • Select **Search** button and change **Date Selection Mode** to **Monthly**. • Select **Accept** to save and then **Control L-J** button to return to previous screen and select desired parameter. Selected Search • Select **Search** button and choosing desired search criteria. • Select **Control L-J** to return to previous screen and select desired parameter. • To exclude a specific sample from the L-J Plot, uncheck the box to the right of the sample when viewing it in **Sample List**. Print L-J Plots • To print the plots on the displayed page, press **Print** button.
4	L-J Plot Limitations	• The L-J plot is constructed from several samples and will not be shown as above until at least one accepted control sample has been analyzed. • If a control shows a system information indicator, the parameter values of such a control will not be included in the L-J plots. • Plots are scaled to expected ranges defined in the assay.

Initialization and Use of Xb Function

The Xb function in the Swelab Alfa Plus follows strictly the Bull algorithm* for the parameters MCV, MCH and MCHC. These parameters should not drift as a function of time within a large patient population. The recommended range setting is ± 3% from the expected mean value of these parameters.

▶ Xb Function



Figure 74: QC Menu

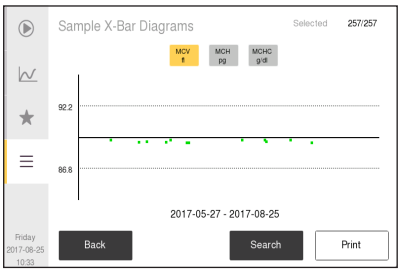

Figure 75: Xb Diagrams

- Enter the QC menu and press **Sample X-Bar**.
- Samples during the latest 90 days are shown as a default for the Xb L-J diagrams.
- Select Xb points pressing the **Search** button, choose desired search criteria, and then select **Sample X-Bar** button to return to previous screen.
- Xb L-J diagrams are displayed, choose MCV, MCH or MCHC buttons to see corresponding parameter diagram.
  - The image above represents several sample results where each point represents a mean value for 20 samples.
- To print the plots on the displayed page, press **Print** button.

*Reference: Bull BS, Hay KL. The blood count, its quality control and related methods: X-bar calibration and control of the multichannel hematology analysers. In: Clangoring I. editor. Laboratory Hematology: An account of Laboratory Techniques. Edinburgh.

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SECTION 6. CALIBRATION

Calibration

The analyzer has been calibrated by Boule prior to shipment. Good laboratory practice, however, requires regular checks and calibration of the measured parameters. Only authorized operators can update or change calibration factors.

Calibrator Handling Recommendations

- Handle and prepare calibrator in accordance to calibrator package insert.
- Never use an open vial longer than recommended by the manufacturer, past the expiration date, or subject any vial to excessive heat or agitation.
- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials.
- Wipe the aspiration probe with a clean, dry lint free absorbent cloth before each calibrator run. Not following this technique will impact the accuracy.

Before Calibration

- Verify that analyzer maintenance/cleaning is current. (See *section 10.*)
- The operator should be thoroughly familiar with the analyzer and the calibration procedure before performing calibration.
- An Advanced Login is required to perform any type of calibration (Guided and Advanced).

Enter New Calibrator Lot

- Follow instructions for Enter New Control Lot, except use calibrator. (See *section 5.*)

▶ Calibration

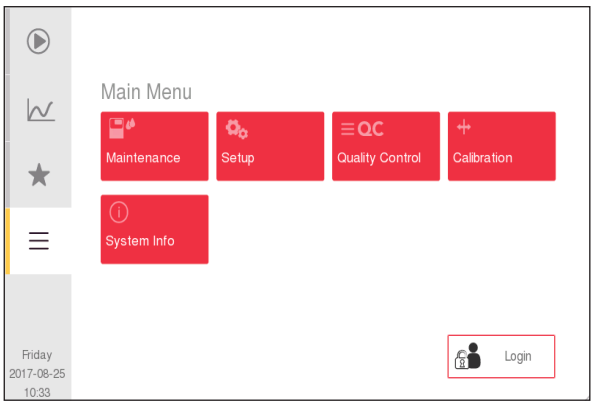

Figure 74: Main Menu

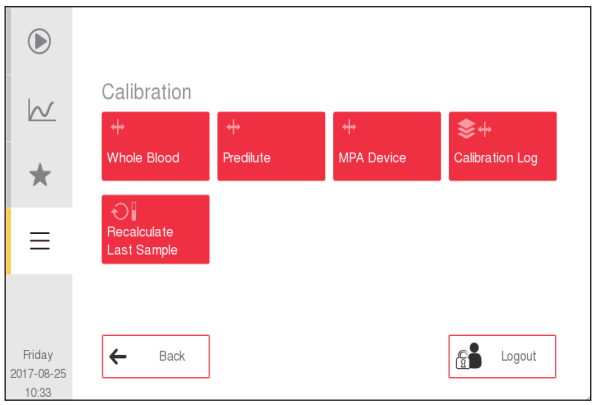

Figure 75: Calibration Menu

▶ Guided Calibration

The Guided Calibration is a step-by-step assisted calibration, usable for all inlets (except Closed Tube Devices) and always required 5 Boule Calibrator runs.

Note: It is possible to exit the Guided Calibration at any time, and already analysed samples can be used in *Advanced Calibration*.

1	Select Mode to be Calibrated	Go to **Main Menu** and login using Authorization Code. Select **Calibration** and then choose mode to be calibrated: • **Whole Blood** • **Predilute** • **MPA** Select **Guided Calibration**
2	Background Analysis	Operator is guided through a background analysis prior to start of calibration sequence.
3	Scan in or choose Calibrator	Dialog is shown prompting to select or scan calibrator to start analysis 1/5.

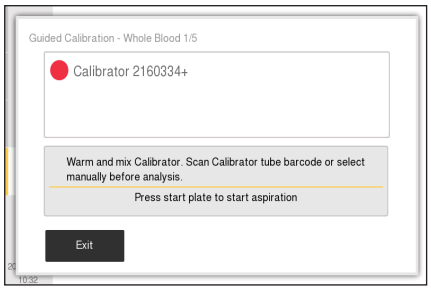

Figure 76: Select or Scan in Calibrator

4	Calibrator Analysis	For OT analysis: • Press **Start Plate** to aspirate calibrator sample. (For Predilute or MPA analysis follow instructions for how to prepare and run a sample in *Chapter 3*.)
5	First Results	After analysis 1/5, results are presented together with a textbox stating if analysis is **OK** or not. If analysis is: • **OK:** Two buttons **Reject Analysis** and **Accept Analysis** are shown. If pressing: – Reject Analysis: same proceedure as for Not OK analysis below occurs – Accept Analysis: New dialog prompting start of analysis 2/5 appears. • **Not OK:** A **Rerun** button is shown, which if pressed will prompt start of analysis 1/5 again.

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6 Continuation of Calibrator Analysis

Repeat steps 2 to 4 above until all 5/5 samples have been analysed.

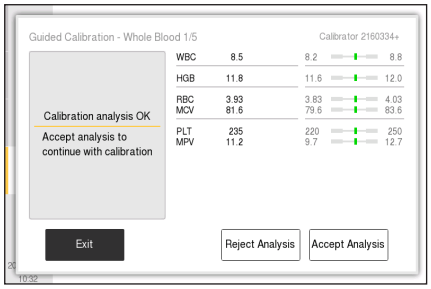

Figure 77: Consecutive Guided Calibration Analysis

7 Completion of Guided Calibration

When pressing button **Accept Analysis** for sample 5/5 a calibration result screen is displayed showing results for all parameters together with a pass/fail status column. Press button **Save** to save all new calibration factors (only those that are indicated pass will be updated).

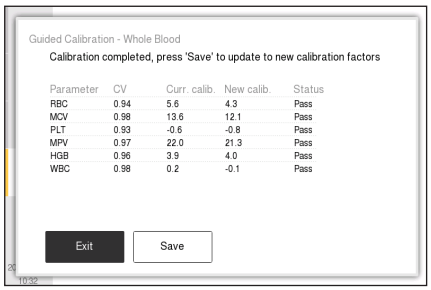

Figure 78: Guided Calibration Results

Note: It is only possible to update and save new Calibration factors for parameters that have passed.

▶ Advanced Calibration

1 Select Calibration Procedure

Calibration of the analyzer can be performed in three different ways:

- **Method 1**: The recommended method is to use Boule calibrator which will automatically calculate the new calibration factor using target values from assay values.
- **Method 2**: If no calibrator is available, use a sample with target values from an assay sheet or determine target values using a reference analyzer or microscope method with an in-house sample.
- **Method 3**: Is to manually calculate and enter in the calibration factor. This method should only be used with instruction from an authorized technician.

Parameter	OT CV%	MPA CV%
RBC	≤ 2.2	≤ 3.2
MCV	≤ 1.8	≤ 1.8
PLT	≤ 5.8	≤ 6.2
MPV	≤ 4.0	≤ 4.0
HGB	≤ 1.8	≤ 2.9
WBC	≤ 4.2	≤ 4.8

Figure 79: Calibration CV % Values

- RDWa, PDWa and PDW% have default preset calibration factors. If the parameters are clinically used it is recommended to calibrate. RDW% is however factory calibrated and should remain.

Method 1

For this method it is recommended that five calibration analyses be performed through the open tube mode.

2 Scan in Calibrator

- Make sure the Calibrator assay sheet has been entered and scanned into the instrument before calibration. (If not, see first page of *section 5,* **"Enter New Control Lot"**).
  - The scanned in controls can be viewed either in Main Menu, then QC, and then View Assays or in the Start Menu under the control profile.
- Go to Start Menu and scan in calibrator tube
  - Calibrator lot number will automatically be displayed.

3 Calibrator Analysis

- Press Start Plate to aspirate calibrator sample.
- Analyze the calibrator five times.

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Calibration

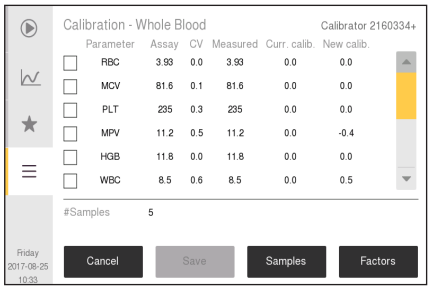

Figure 80: Calibration Results

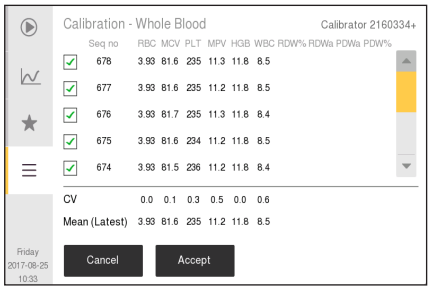

Figure 81: Calibration Parameter Values

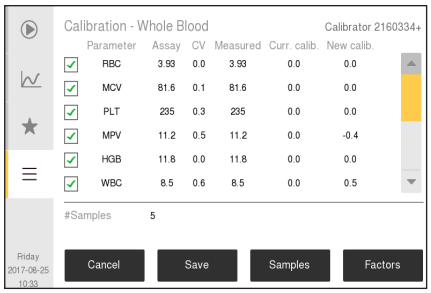

Figure 82: Accepted Calibration

- Go to **Main Menu** and login using Authorization Code **2006**.
- Select **Calibration** and then **Whole Blood**.
- Analyses will be displayed, along with the following for each parameter:
  - Assay Value
  - CV%
  - Measured Value
  - Current Calibration Factors
  - New Calibration Factors - displayed if CV and measured values are within acceptance limits.
- Select **Samples** button to view your sample results.
- Verify that the CVs for the parameters given are within the stated limits, as shown in *figure 69*.
  - This step is only needed if some parameters don't have new calibration factors showing, otherwise the mean and CV are acceptable and no verification is needed.
  - If the Mean or CV% are outside of the limits they will be displayed in red and operator will be unable to perform calibration.
  - Analyses that had a system information indicator will have been automatically inactivated as an analyses from the CV calculation. Depending on the indicator it may not be stored on the list at all.
  - If a known sample handling error or erroneous result is present, then that specific sample may be inactivated by pressing the checked box on the left.
- If CV% are acceptable, select **Accept**.
- If a CV% is red and not acceptable, rerun calibration.
- New calibration factors will now be displayed.
- Mark the parameters to be calibrated.
- Select **Save** to accept and store these calibration factors.

Note: After the new calibration factors have been saved, the last patient sample analyzed can be recalculated with the new calibration factors by selecting **Recalculate Last Sample**. (The recalculated sample will be stored with the next sequence number and the text "Recalculated" for Sample ID 1.)

Method 2

- Follow Method 1 but replace the calibrator with reference sample and analyze it in blood profile.

Calibration

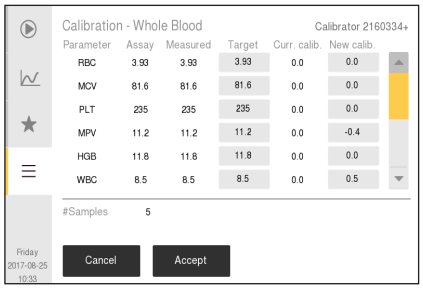

Figure 83: Set Target Values

- Log in as in Method 1, enter **Calibration** and then **Whole Blood** but then select **Factors**.
- Enter target values under the heading **Target**.
- Once all target values have been entered, press **Accept** and the analyzer will calculate and display the new factors.
- Mark the parameters to be calibrated.
- Select **Save** to accept and store these calibration factors.

Method 3



Figure 84: Manual Input Menu

- Go to **Main Menu**.
- Enter Authorization Code [2006].
- Select **Calibration** and then **Whole Blood**.
- Select **Factors** and enter calibration factor under **New Calib.** header.
- Calibration factors for each parameter can range from −50.0 to +50.0. (Values outside this range result in an error message).
- Once all target values have been entered press **Accept**.
- Mark the parameters to be calibrated.
- Select **Save** to accept and store these calibration factors.

It is recommended to analyze controls after calibration to verify that all parameters have been calibrated correctly.

▶ MPA Device Calibration

To calibrate MPA, follow **Method 1** except select **MPA Device** instead of **Whole Blood** and use MPA mode for analysis. (See *section 3* for details on capillary analysis).

▶ Pre-dilute Calibration

To calibrate PD inlet, follow **Method 1** except select **Pre-dilute** instead of **Whole Blood** and use pre-dilute mode for analysis. (See *section 3* for details on pre-dilute sample analysis).

▶ Closed Tube Device Calibration

The closed tube device (Cap Piercer or Autosampler) uses the same calibration as the Open Tube inlet. However, if the same systematic differences are seen on RBC, HGB, WBC and PLT when analyzing blood in the closed tube device compared to the open tube, a calibration factor can be calculated. This should only be performed with instructions from local distributor or authorized technician.

DO NOT use Cap Piercer or Autosampler mode to aspirate calibrator when calibrating with Whole Blood.

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SECTION 7. MENU STRUCTURE AND ADVANCED SETUP

Menu Structure

Display screens may vary pending on user login level.

- Advanced User menus highlighted in gray.
  - = Start Menu
  - = Result List
  - = Quick Functions
  - = Main Menu
  - = Service Login

Start Menu Flowchart

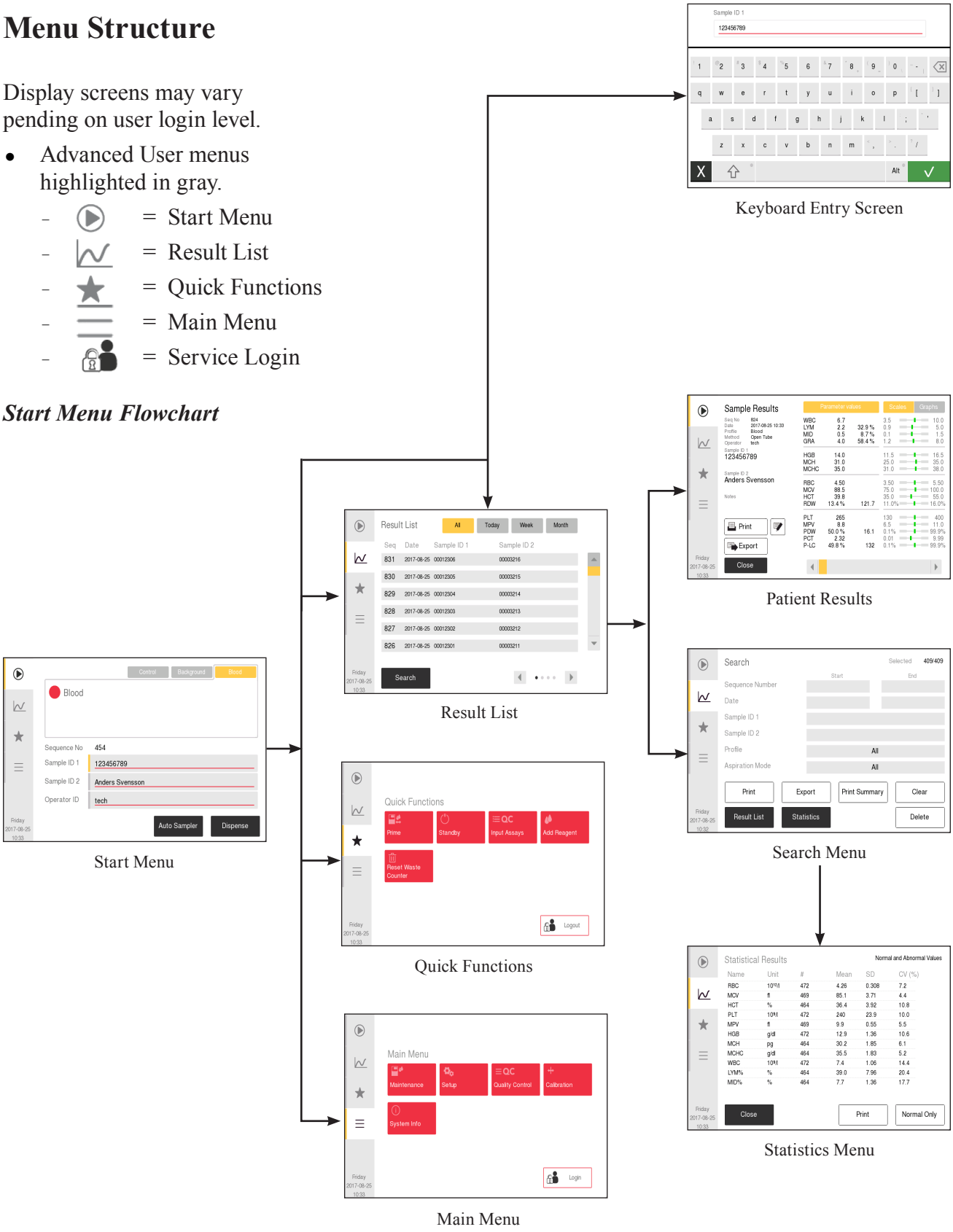

Figure 85: Start Menu Flowchart

Main Menu Flowchart



Figure 86: Main Menu Flowchart

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Setup Flowchart



Figure 87: Setup Flowchart

Advanced Setup Flowchart



Figure 88: Advanced Setup Flowchart

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Advanced Parameter Setup

Initial advanced setup of the analyzer has been factory set to default values. However, other operator definable formats may be preferred. Details on how to install and configure these parameter are provided in this section. See *figure 81–figure 84* for guidance to specific menus.

Quick Functions

In this screen, a set of Quick Function buttons have been selected for the user to be able to select common occurring functions quickly. Simply select the required function button and the action will automatically begin.

Setup Menus

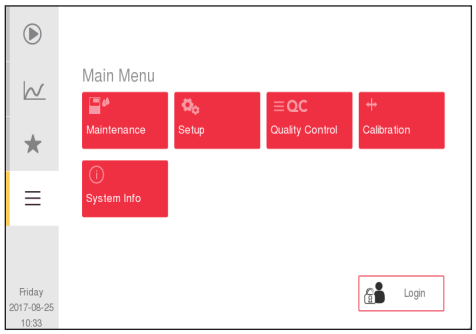

Figure 89: Main Menu

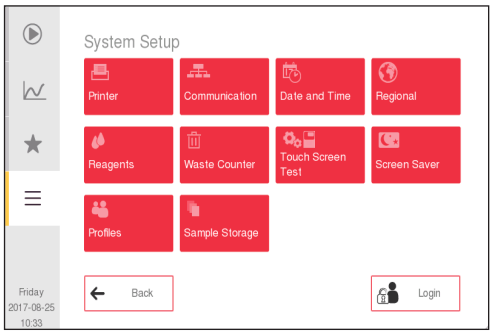

Figure 90: Setup Menu

▶ Printer Setup

In the Printer Setup menu the user is able to further define print format settings:

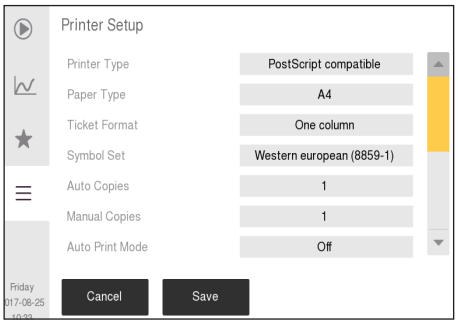

Figure 91: Printer Menu A

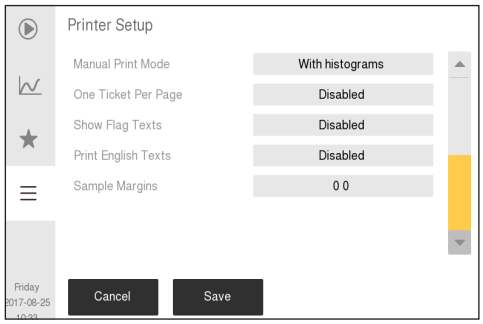

Figure 92: Printer Menu B

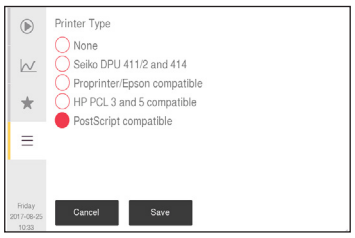

Figure 93: Printer Type

Printer Type

- Printer Type affects available selections for Paper Type, Ticket Format, Symbol Set, Auto Copies and Manual Copies. When changing Printer Type these settings could be changed automatically to valid selections.
- To change the setting, select the circle next to the printer type and press **Accept**, and then **Save**.

- When using a printer that is PostScript compatible, select PostScript Compatible.
- If using a printer other than that specified by distributor, the printer must be HP PCL 3 and 5 or Proprinter/Epson compatible.
- Note: for chinese, only postscript is supported and PDF report must be selected for in ticket format.

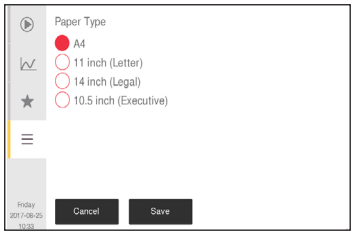

Figure 94: Paper Type

Paper Type

- This function allows the user to choose the type (size) of paper used for the printout.
- Select **Paper Type** button, select the circle next to desired paper size, press **Accept**, and then **Save**.

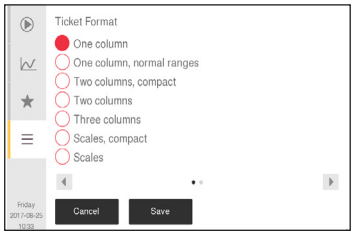

Figure 95: Ticket Format

Ticket Format

- This function allows the user to change the column layout of the printout.
- Select **Ticket Format** button, select the circle next to desired ticket format, press **Accept**, and then **Save**.
- For ticket format PDF report, settings are changed under **PDF setup**.

Symbol Set

- This function allows the user to choose which symbol set to use.
- Select **Symbol Set** button, select the circle next to desired symbol set, press **Accept**, and then **Save**.

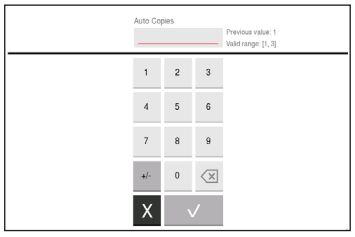

Figure 96: Print Copies

Print Copies

- This function allows the user to choose how many manual or automatic copies to print with each analysis.
- Select **Auto Copies**, select the number of copies wanted, press ☑ to accept, and then **Save**.
- Select **Manual Copies**, select the number of copies wanted, press ☑ to accept, and then **Save**.

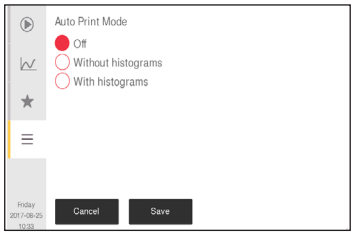

Figure 97: Printer Mode

Print Mode

- This function allows the user to choose whether a printout is manually or automatically printed, with or without histograms, and how many analyses per page.
- Select **Auto Print Mode**, select a circle next to each category, press **Accept**, and then **Save**.
- Select **Manual Print Mode**, select a circle next to each category, press **Accept**, and then **Save**.

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One Ticket Per Page

- This function allows the user to print more than one analysis per page.
- Select **One Ticket Per Page**, select **Enabled** to print one analysis per page or **Disabled** to print more than one analysis per page, press **Accept**, and then **Save**.

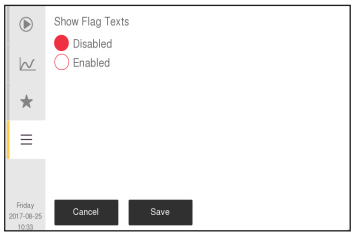

Figure 98: Show Flag Text

Flag Text Options

- This function allows the user to choose whether or not flag text is displayed on the printout.
- Select **Show Flag Text,** select either **Enabled** to show flag text on printout or **Disabled** to not show flag text on printout, press **Accept**, and then **Save**.

Print English Texts

- If enabled, all headers and descriptions will be printed in English regardless of selected system language.
- Select **Print English Texts**, select either **Enable** to use English in printouts or **Disable** to use selected system language.

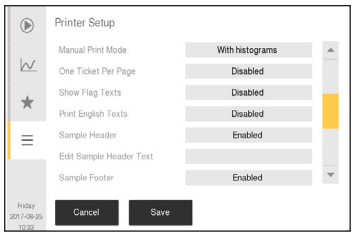

Figure 99: Add Header Text

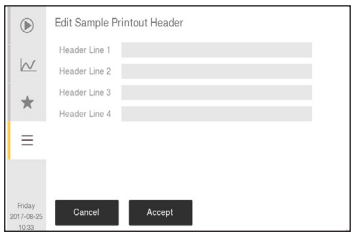

Figure 100: Edit Header Text

Text Options (Advanced User)

- This function allows the user to choose whether or not header and footer text is displayed on the sample printout.
- Select **Sample Header,** select either **Enabled** to show header text on printout or **Disabled** to not show header text on printout, press **Accept**, and then **Save**.
  - To input text select Edit Sample Header Text. Up to four lines of header text can be added.
  - Select field next to header and type in header text.
  - To save select ☑ and then Accept.
- Select **Sample Footer,** select either **Enabled** to show footer text on printout or **Disabled** to not show footer text on printout, press **Accept**, and then **Save**.
  - To input text select Edit Sample Footer Text. Up to four lines of footer text can be added.
  - Select field next to footer and type in footer text.
  - To save select ☑ and then Accept.

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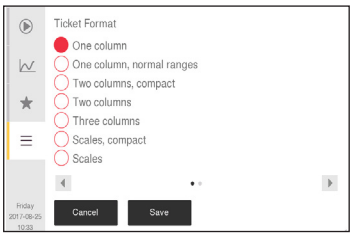

Figure 101: Edit Customized Ticket

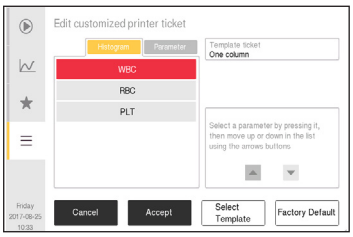

Figure 102: Edit Customized Histogram Order

Parameter and Histogram order for custom ticket format

- This function allows the user to choose the order of the parameters and histograms on the printouts.
- Firstly make sure the Printer Setup, Ticket Format is set to **Customized.** Go to Printer Setup and Edit Customized Ticket:
- To change the **Parameter order:**
  - Select the tab Parameter and press the button Select Template to select a template to base the customized ticket on.
  - Select the parameter to change order for by pressing it which will highlight it.
  - Simply move the parameter up and down the list to a new prefered position using the up/down arrows.
  - Repeat for all desired parameters.
  - Note: to insert a space before a parameter press New Line, Insert.
  - If a ticket with multiple columns has been used as a template, it will be indicated by Column Delimeter in the parameter list, and can then be highlighted and moved in the same way as all parameters.
- To change the **Histogram order**:
  - Select the tab Histogram.
  - Press the histogram to be moved, highlighting it.
  - Move the histogram up and down in the list to the prefered position using the up/down arrows.
  - Repeat for all desired histograms.

▶ Communication Setup

In the Communication Setup menu the user is able to further define communication format settings:



Figure 103: Communication Menu

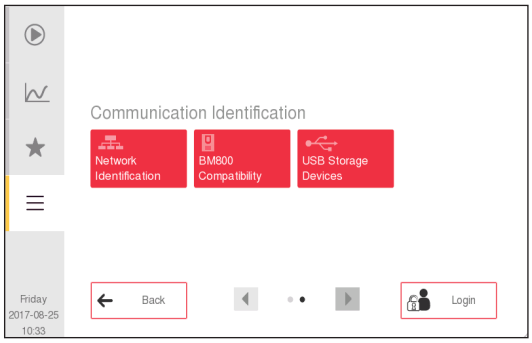

Figure 104: Communication Menu 2

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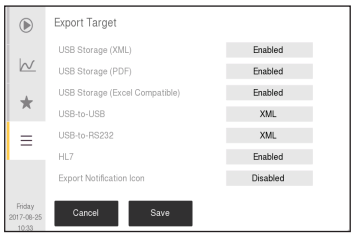

Figure 105: Export Target Setup

Export Target

This function allows the user to choose how and where data is exported.

- USB Storage (XML) – To activate the export of data to a USB memory stick, choose **USB Storage (XML)** button, then **Enabled**, and then press **Save**.
- USB Storage (PDF) allows a single sample result to be exported to a single PDF file.
- USB Storage (Excel Compatible) exports sample results to an Excel compatible CSV file. All samples exported on a specific day will be stored on a single CSV file.
- USB-to-USB – To activate the export of data to a host computer via USB, choose **USB-to-USB** button, then select **XML** or **HL7**, and press **Save**.
- USB-to-RS232 – To activate the export of data to a host computer via RS232, choose **USB-to-RS232** button, then select **XML** or **HL7**, and press **Save**.
- HL7 – Check with Service Contact for more information.

Export Notification Icon – Allows the user to specify whether or not to see if a sample has been exported to a specific target or not.

- To activate the export icon, choose Export Notification Icon button, then choose the export target to be tracked, and then press Save.
- There are two different icons that can show up in the Result List for each sample when this function is activated:
  - Samples prior to activation are indicated with the icon  which indicates that it is unknown if the user wants to export them or not.
  - After the setting is enabled, all samples successfully exported will have no indication, while samples where the export has failed will be indicated with the icon .

Note: Restart of instrument may be required if USB memory is removed during export.

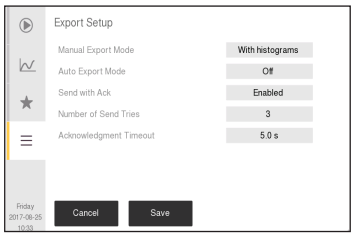

Figure 106: Export Setup

Export Setup

General settings for export of data can be found here.

- Manual Export Mode – Setup the manual export mode of samples by either selecting **Without histograms** or **With histograms**, and then press **Save**.
- Auto Export Mode – To automatically export of sample results after analyzing a sample choose either **Without histograms** or **With histograms,** and then press **Save**.
- Send with Ack – If the host computer should send a message acknowledging the successful transfer of data during export, set **Send with Ack** to **Enabled** and then press **Save**.
  - When Enabled and the analyzer does not receive the acknowledgment before Acknowledgment Timeout, the instrument resends the data for Number of Send Tries before reporting an error to the user.
- Number of Send Tries – To change the number of tries to export data, choose **Number of Send Tries**, and then set from 1 to 5
  - To save, select ☑ and then press Save.
- Acknowledgment Timeout - To change the amount of time before timeout, choose **Acknowledgment Timeout**, and then set from 1 to 30 seconds.
  - To save, select ☑ and then press Save.

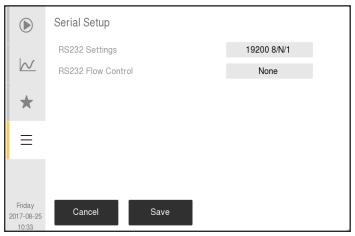

Figure 107: Serial Setup

Serial Setup

- RS232 Settings – If Send by USB-to-RS232 has been **Enabled**, the RS232 communication setup can be done here.
  - To setup RS232 baud rate, choose RS232 Settings button, choose baud rate, and then press Save.
- RS232 Flow Control – To setup RS232 flow control, choose **RS232 Flow Control** button, choose flow control, and then press **Save**.

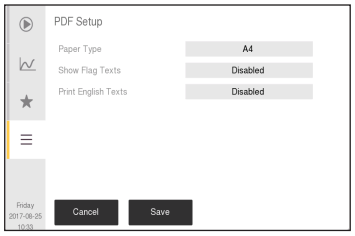

Figure 108: PDF Setup

PDF Setup

This function allows user to change paper formats, settings, show flag texts, header/footers, print enlish text for PDF.

- For **header text** – set header type to Text, then go to Edit PDF Header and set Header Line 1-4 to desired text.
- For **header/footer image** - insert a USB memory with a header image max 500x110 pixels named header.xx (chosen file format) - or footer.xx for footer image. Set header type to Image. Set Edit PDF Header, Header Image Alignment to desired alignment (Left, Center, Right). Set Header Image File to User image and press Edit PDF Header Image from USB Storage and the image file will be uploaded.

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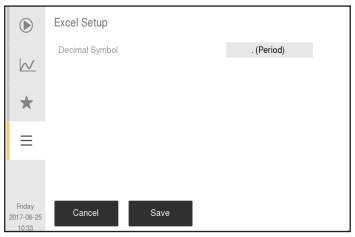

Figure 109: Excel Setup

Excel Setup

This function allows the user to define what to use as a decimal symbol in a csv file.

- The Decimal Symbol can be set to either **.(Period)** or **,(Comma)**.

Network Identification

Check with Technical Support for more information.

BM800 Compatibility

Check with Technical Support for more information.

▶ Date and Time Setup

See description under **"Unpack and Check Components"** in *section 2*.

▶ Screen-saver

This function allows the screen-saver timeout to be changed to operator preference.

- The default screen-saver is set at 15 minutes.
- To change the screen-saver timeout press **Screen-saver** button.
- The screen-saver can be set from 2 to 240 minutes.
- Press ☑ to save

▶ Keyboard Setup

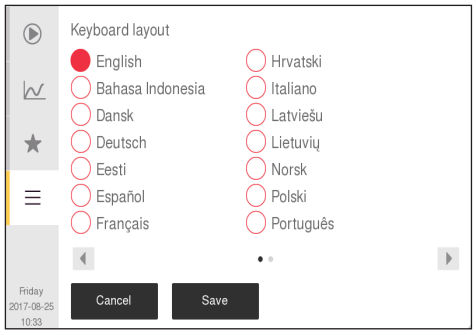

Figure 110: Keyboard Setup

This function allows the on-screen keyboard layout to be changed to operator preference.

- Choose **Regional** and then **Keyboard**.
- To change keyboard type, choose desired keyboard type and press **Save**.

▶ Language

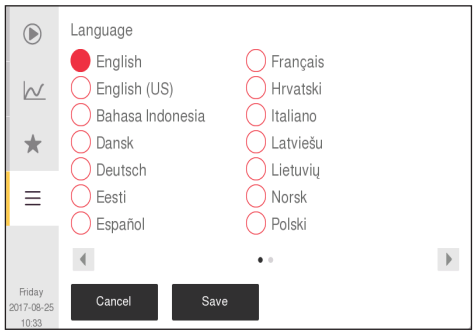

Figure 111: Language Setup

This function allows the language be changed to operator preference.

- Choose **Regional** and then **Language**.
- Choose language and press **Save**.

▶ Waste Counter Setup

In this setup menu the user can choose preferences for utilization of a waste container and the associated preferences: waste container volume, warning level, and counter reset.

- If **Waste Counter** is disabled, then preferences are grayed out.

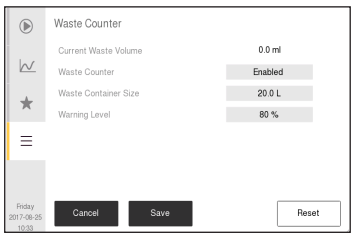

Figure 112: Waste Counter Setup

Waste Counter

- This function allows the user to choose whether or not to use a waste container for reagent waste.
- Select **Waste Counter,** select either **Enabled** to use a waste container or **Disabled** if waste tubing is plumbed directly into a drain.
- To save press **Accept**, and then **Save**.

Waste Container Size

- This function allows the user to choose the size of the waste container.
- The waste container volume can be set to values between 1.0 and 25.0 L.
- To save, select ☑ and then press **Save**.

Warning level

- This function allows the user to choose the percentage of waste in the container to activate warning level message.
- To activate a warning, the waste container warning level can be set to values between 50% and 95%.
- To save, select ☑ and then press **Save**.

Reset Waste Counter

- The waste container can be reset to **"0"** by selecting **Reset**.

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▶ Sequence Number Setup

To reset the sequence number, enter **Sample Storage,** choose desired sequence number, and then press ☑ to save.

▶ Profile Default Setup

During routine daily operation often the same patient type or patient profile is analyzed. The operator has the option to select a default profile.

- Choose **Setup** and then **Profile**.
- Choose desired profile and press the circle next to **Default** to select this profile, and then **Save**.

▶ Touch Screen Test

To test the alignment of the touch screen perform the following:

- By touching any of the four circles, the error in pixels will be shown in the X and Y boxes. If the error in pixels is too large, the user can calibrate the touch screen under **Touch Screen Calibration** in **Advanced Setup**.
- Press **Back** to exit.

Advanced Setup Menus with Login

These are advanced menus which are password protected. To enter go to **Main Menu**, then **Service login** and enter password **2006**.

- The operator should be thoroughly familiar with the analyzer and the setup procedure before performing function.

▶ Regional Setup

In this setup menu the operator can choose preferences for parameter names and units, keyboard and language.

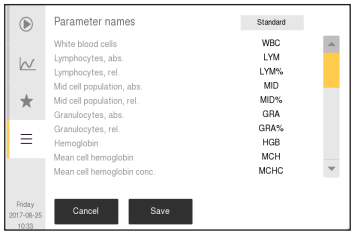

Figure 113: Parameter Name Setup

Parameter Names

- The first screen shows the currently selected parameter names and units.
- The parameter names are in settable groups.
- To view parameter group press **Name** button and then select name group by pressing the button to the right of **Parameter names**.
- A list will be displayed with group names.
- To choose specified name group press circle next to desired Group and then **Accept** to view changes, and then **Save**.

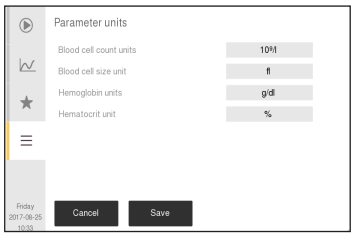

Figure 114: Parameter Unit

Parameter Units

- The first screen shows the currently selected parameter units.
- The parameter units are in 4 settable groups.
- To view parameter group press **Unit** button.
- A list will be displayed with unit group parameters and the what units different parameters will receive with selection.
- To choose specified unit group press button to the right of the unit group to be viewed/changed, then select circle next to the desired unit and then **Accept** to view changes, and then **Save**.

▶ Analysis Profile Setup

Analysis profiles have been predefined in the Swelab Alfa Plus analyzer. Each analysis profile has many different formatting options, including profile name, default settings, normal ranges, analysis constants, blocking parameters, etc. To add or change analysis profile settings follow these step by step instructions below.

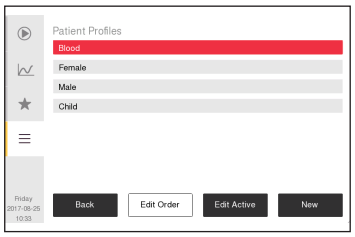

Figure 115: Profile Settings

Select **Accept** on each menu to save changes:

- Choose **Setup** and then **Profile**.
- Choose profile to change or select **New**.
  - A keyboard will pop-up to name the new profile. Enter in new profile name and select ☑ to save.
  - Maximum number of analysis profiles are 100.
- The next screen will have a number of settings that can be changed, depending on instrument model and configuration.

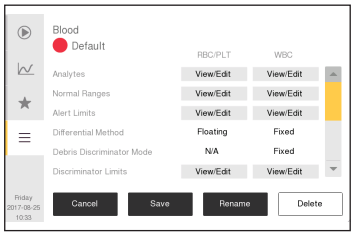

Figure 116: Profile Parameters A

Default Setup

- During routine daily operation often the same patient type or patient profile is analyzed. The operator has the option to select a default profile. Press the circle next to **Default** to select this profile.

Analyte Setup

- To show or hide certain analytes press buttons to the right of **Analytes** to view and edit. Select either **Hide** or **Show** depending on what parameters you want visible in this profile.

Rename Profile

- To rename a user created profile select **Rename**.
  - A keyboard will pop-up to rename the profile. Enter in new profile name and select ☑ to save.

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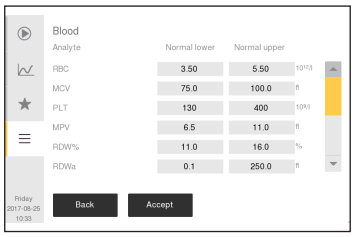

Figure 117: Normal Ranges

Normal Range Setup

Indicative normal ranges are provided in this instrument based on clinical data. It is recommended to establish local reference ranges (normal ranges) for your laboratory. (See CLSI standard EP28-A3C for guidance on how to establish these ranges and examples of normal ranges in the reference documents listed at the end of this section.)

- To change Normal Range values press buttons to the right of **Normal Ranges** to view and edit. Select **Normal Lower** or **Normal Upper** buttons to edit specified value.

Alert Limit Setup

- To change Alert Limit values press buttons to the right of **Alert Limits** to view and edit. Select **Alert Lower** or **Alert Upper** buttons to edit specified value.
- In addition to normal ranges, alert limit are optional for indication of abnormally high or low values.

Differential Method Setup

- This mode is factory set and unable to be changed by operator.

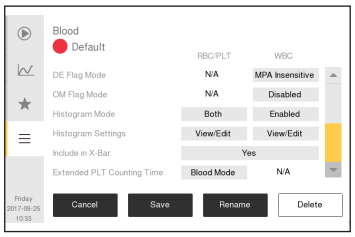

Figure 118: Profile Parameters B

Discriminator Limits Setup

- To change discriminator limits press buttons to the right of **Discriminator Limits** and choose desired values.

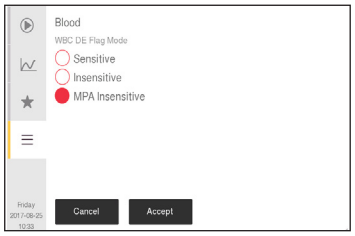

Figure 119: DE Flag Mode Setup

DE Flag Mode Setup

- Choose circle next to the setting that is appropriate for your laboratory:
  - Sensitive
  - Insensitive
  - MPA Insensitive (default)
- For more info regarding DE flag see section 9, Troubleshooting and System Messages.
- DE Flag mode is only settable for WBC parameters.

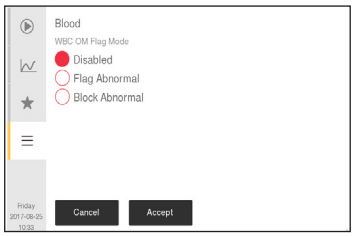

Figure 120: OM Flag Mode Setup

OM Flag Mode Setup

- Choose circle next to the setting that is appropriate for your laboratory:
  - Disabled (default)
  - Flag Abnormal
  - Block Abnormal
- OM Flag mode is only settable for WBC parameters.



Figure 121: PLT extended count Setup

PLT Extended Count Setup*

This function allows for extended count time when detecting low PLT samples (approximately below 50×10^9/L).

The function is settable in Setup, Profiles, *Selected Profile*, PLT Extended Count Time and can be set to:

- **Disabled**
- **Blood Mode** = Use extended PLT count time if PLT is approximately below 50×10^9/L and RBC >0.5×10^{12}/L
- **Other Fluids** (for research use only) = Always use extended PLT count time

*not applicable to analyzers manufactured before December 2016.

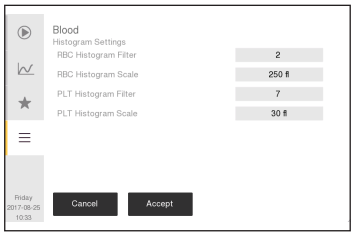

Figure 122: Histogram Settings

Histogram Mode Setup

- Distribution curves can either be turned ON or OFF for viewing on both display or printout. Press buttons to the right of **Histogram Mode** to select desired presentation.

Histogram Settings Setup

- To change the distribution curve configuration press buttons to the right of **Histogram Settings** and choose desired values.

Include in X-Bar L-J Setup

- To change X-Bar setting buttons to the right of **Include in X-Bar L-J** and choose either Yes or No for whether or not samples analyzed with this profile should be included in X-Bar L-J diagrams.

- This setting affects all samples analyzed, even if they were run prior to the change.

When all desired parameters have been setup press **Save** on Profile Settings menu to save new profile.

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▶ Advanced Setup

Blood Detector Setup

This function allows the operator to enable and disable the blood detector for each aspiration type.

- Setting this function to **Automatic Detection** enables the blood detector function. When enabled, aspiration stops when blood is detected by blood detector sensor.
  - Aspiration time is grayed out if automatic detection is selected.
- To change the setting to a fixed aspiration type choose button next to aspiration type and then select **Fixed Aspiration Time**.
  - The blood detector can be set from 0.1 to 19.9 seconds.
  - Press ☑ to accept the new values and then Save.

High Altitude Setup

This function only needs to be activated if various HF, HH, HL, or HN indicators repeatedly appear (see *section 9*), then mode may need to be changed to Moderate or Maximum compensation in higher elevations.



Figure 123: High Altitude Setup

- Select **High Altitude** Setup.
- Choose the circle next to the setting that is appropriate for your location:
  - None = No Compensation (default)
  - Moderate Compensation
  - Maximum Compensation
- Select **Save**.
- By choosing a compensation, the software incorporates some minor timing sequences for the wash cycles, no other functions are affected. Guidelines for Compensation setup are:

Altitude range (meters above sea level)	Compensation factor
-400 to 1000	None
1000 to 2500	Moderate
Over 2500	Maximum

PLT Setup

The function of the PLT offset is to set a background count for PLT. It is recommended to keep PLT offset value at 0. (This function should not be used for the purpose of forcing QC background count acceptance.)

PLT Offset Setup

- To change the default press PLT Offset button.
- Offset can be set from 0 to 50.
- Press ☑ to accept the new values and then Save.

X-Bar Range Setup

Indicative X-Bar ranges are provided in this instrument.

- To change range values select buttons to edit specified value.
- Press ☑ to accept the new values and then **Save**.

Standby Setup

These functions allow standby to be changed to user preferences.

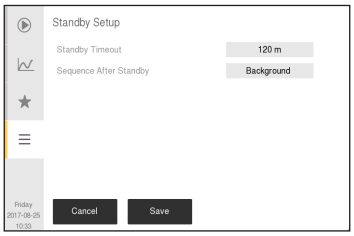

Figure 124: Standby Setup

Minutes before Standby

- To change the default press **Standby Timeout** button. It can be set from 10 to 240 minutes.
- Press ☑ to accept the new values and then **Save**.

Sequence after Standby

- When activated this function will either perform an automatic background count or the Startup sequence when the analyzer comes out of Standby.
- Choose the circle next to the setting that is appropriate:
  - None – Neither Background count nor Startup Sequence will be performed after Standby.
  - Background – Only Background count will be performed after Standby.
  - Full – Startup Sequence will be performed after Standby.
- Press **Accept** and then **Save**.

Barcode Setup

To enable the barcode reader to scan ISBT-128 barcodes change to **Enabled** and then **Save**.

Instrument ID Setup

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If multiple analyzers are used in a laboratory, a specific ID can be used for ease of identification.

- To enter a new ID press **Instrument ID** button and assign specific ID.
- Press ☑ to accept the new values and then **Save**.

Touch Screen Calibration

- To calibrate the touch screen, touch the center of the two circles. The instrument will then automatically calculate new calibration factors. Save them by pressing **Calibrate**.

Predilute Delay Setup

The default setting for the pre-dilute start plate is a 0.3 second delay. This is a precautionary measure so that it is not accidentally pressed when running Open Tube Samples.

- To change the default press **Predilute Delay** button.
- Choose **Long** to change it from 0.3 second default to 2.5 seconds.
- Press **Save**.

Mixer Setup

The default for the mixer is set to Enabled. Upon sample aspiration mixer will discontinue rotation until sample analysis is complete.

- To deactivate the mixer choose **Mixer Setup** button, then **Disabled**, and then press **Save**.

Internal Barcode Setup

An Internal barcode reader is also available on some models.

- To change the mode for the internal barcode reader, choose the circle next to the setting that is appropriate:
- Press **Accept** and then **Save**.

Sample ID2 Setup

The default for Sample ID2 is enabled. However it is possible to disable Sample ID2 in Advanced setup, Sample ID2.

Parameter Order

1

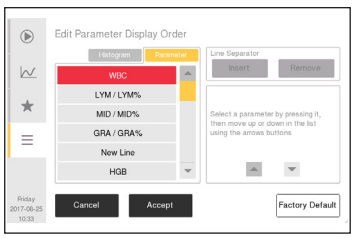

Figure 125: Parameter Display Order Setup

Change Parameter Order

1. Click tab *Parameter* and select desired parameter to change the order for.
2. Press the up/down arrow on the right hand side until selected parameter is in the desired position.
3. Line separators can be used to group parameters. They are called **New Line**. Their positions can be changed in the same way as for the parameters.
4. Line separators can be inserted (maximum 3) by button **Insert** and can also be removed by selecting **Remove**.
5. Press button **Accept** to store the new order.

2

Change Histogram Order

1. Click tab *Histogram* and select desired histogram to change the order for.
2. Press the up/down arrow until selected histogram is in the desired position.
3. Press button **Accept** to store the new order.

3

Factory Default

Press button Factory Default to restore parameter and histogram order to the factory default.

Custom Profile Order/Active Profiles

1

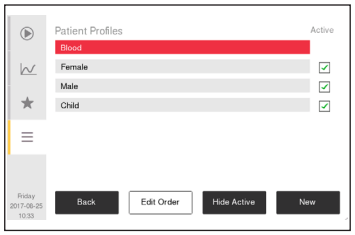

Figure 126: Activate/Deactivate profiles

Activate/Deactivate profiles

Note: you need more than 1 profile on the instrument to view this setting. A default set profile is not possible to deactivate until a new default profile is selected.

1. Click button **Edit Active**. A checkbox is now visible after each profile in the profile list except for the profile that is default (*blue*).
2. To make a profile inactive, uncheck the checkbox for desired profile.
3. To make a profile visible, check the checkbox for desired profile.
4. Activating/Deactivating a profile can affect several instrument settings, except when used as a search parameter for samples.

2

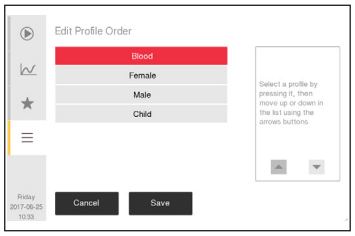

Figure 127: Edit Profile Order

Change profile order

Note that profiles that are *inactivated* (see In-activated profiles Step 2 above), will not be visible in the *Edit Profile Order* list.

1. Click button **Edit Order**.
2. Click on the profile you want to change position of.
3. Press the up/down arrow until selected profile is in desired position.
4. Press button **Save** to store the new profile order.

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Custom Quick Menu

Note: What functions are visible and the user is able to move depends on the current login level.

1

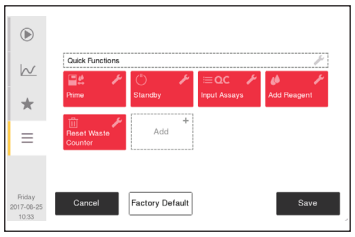

Figure 128: Quick Function Setup

Addition of a Functional Button

1. Press outlined button Add+.
2. Press button Button.
3. In the left list select from which *Main Menu* the function resides in.
4. In the right list, highlight desired function by clicking on it and pressing **Accept**.
5. Repeat steps 1-5 for each function to add to quick menu.
6. Press button **Save** to store new quick menu.

2

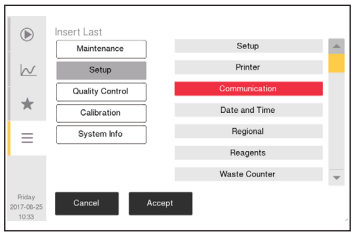

Figure 129: Add Function to Quick Function

Insert of a Functional Button

1. Click button at desired position where you want to add a new button.
2. Click button **Insert Before** or **Insert After.**
3. Add button according to Steps 3-4 above in *Addition of a Functional Button*.
4. Press button **Save** to store the new quick menu.

3

Moving of a Functional Button

1. Click button desired to move position.
2. Click button **Move Left** or **Move Right**
3. Repeat Steps 1-2 until button is in desired position (Note: it is only possible to move a button within its *Group*).
4. Press button **Save** to store new quick menu.

4

Removing of a Functional Button

1. Click button for removal.
2. Click button **Remove**.
3. Press button **Save** to store new quick menu.

5

Change function of a Functional Button

1. Click button for editing and press **Edit**.
2. Select new function according to Steps 3-5 under *Addition of a Functional Button* above.
3. Press button **Save** to store new quick menu.

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6 **Addition of a Group Header**

Group headers are for grouping buttons in functional areas (see S*ystem Setup/Advanced Setup* in *Main Menu Setup*)

1. Press button **Add+** then button **Group** and input desired name for the group.
2. Press button **Save**.
3. Add buttons to this group according to Steps 1-5 under *Addition of a Functional Button* above.
4. Press button **Save** to store new quick menu.

7 **Editing of a Group Header Name**

1. Click the group header you want to edit and press **Edit**.
2. Input the new name.
3. Press button **Save** to store new quick menu.

8 **Removal of a Group Header**

1. Click the group header you want to remove and press **Remove**.
2. Press button **Save** to store new quick menu.

9 **Restore Factory Default**

1. Press button **Factory Default**.
2. Press button **Save** to store factory default quick menu.

User/Level Login

The analyzer allows for different levels of Login for a User and the various Login Levels have different restrictions on performing various functions on the Swelab Alfa Plus. Below is an overview of the Login Levels authorities.

Note: The Admin can change password for all users (Admin does not need to know other users old passwords). All users can change their own respective passwords (but the old passwords are required in order to perform this function).

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Login Level	Description
Basic User	- Analyse, view and search samples - View sample statistics - Run Prime - Manual standby - View instrument information (About) - Change own Password
User	*Basic User* as well as: - System Setup - Maintenance
Advanced User	*User* as well as: - Advanced Setup - Calibration - Deletion of Selected Samples - Change Login Type (User/Level)
Admin	*Advanced User* as well as: - Manage Users - Change other users Passwords

1

Change Login Type to Old Level Login System

1. Press menu button **Login**.
2. Set Login Type = Level Login
3. Press button **Save** to store login type.

2

Change Login Type to New User Login System

1. Press menu button **Login**.
2. Set Login Type = User Login, and press **Accept.**
3. Press button **Save** (an administrator user "Admin" will be automatically created).
4. Input and then verify the new password for user Admin.
5. Press keypad **OK** button (resulting in an automatic log out).

3

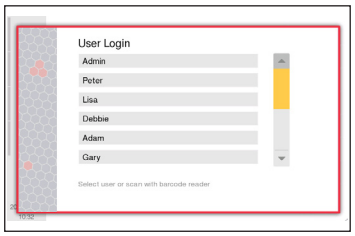

Figure 130: User Login

Log in with User Login

1. Select which user to log in from User Login list.
2. Input password and press **OK** button.

4

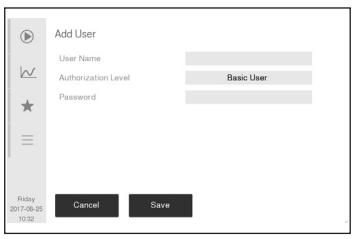

Figure 131: Add User

Add User

1. Login as Admin and go to Setup > Page 2 > Administrate Users.
2. Press button **New** and input User Name.
3. Set Authorization Level (same levels as for level login, except new Basic User which only can run/view/print/ export samples and perform manual standby and prime).

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1. Press **Accept.**
2. Input new password and press button **Save**.

5

Delete User

1. Login as Admin and go to Setup > Page 2 > Administrate Users.
2. Select user to delete and press button **Delete.**
3. Press button **Yes** when asked to confirm.

6

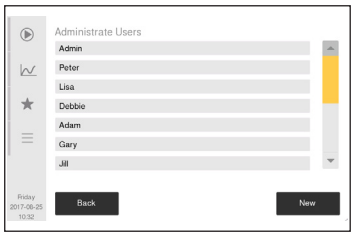

Figure 132: Administrate Users

Edit User

1. Login as Admin and go to Setup > Page 2 > Administrate Users.
2. Select user to edit and edit *User Name, Authorization Level* and *Password*.
3. Press button **Save.**

7

Change Password

1. Login as user for which to change password.
    - For users with login level *Basic User*: Go to Main Menu > Change Password
    - For all other login levels: Go to Setup > Page 2 > Change Password
2. Enter old password, then enter new desired password.
3. Verify the new chosen password.

Service Log

This function is used to export instrument data useful for Service.

Export service log, standard usage:

From System Info > Page 2:

1. Insert USB memory into instrument.
2. Press button **Export Service Log**.

Normal Range References

1. Cheng C, Chan J, Cembrowski G, van Assendelft O. Complete Blood Count Reference Interval Diagrams Derived from NHANES III: Stratification by Age, Sex, and Race Laboratory Hematology 10:42-53

2. Nordin G, et al. A multicentre study of reference intervals for haemoglobin, basic blood cell counts and erythrocyte indices in the adult population of the Nordic countries Scand J Clin Lab Invest 2004; 64: 385-398

3. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI EP28-A3C

4. Mayo Clinic, Mayo Medical Laboratories. Rochester 2016 Interpretive Handbook. 2016 Mayo Foundation for Medical Education and Research (MFMER)

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SECTION 8. TECHNOLOGY

Measuring Principles

The measuring principles of the Swelab Alfa Plus analyzer are based on impedance and spectrophotometer principles.

Whole Blood Dilution

The RBC and WBC concentration values are determined by counting cells in whole blood dilutions of 1:40,000 for the RBC and 1:400 for the WBC.

Theoretical Principles (RBC Example)

If a sample contains 5 million red blood cells per µL, a dilution of 1:40 000 will give a final concentration of 5 million divided by 40,000 = 125 cells per µL. Each µL containing 125 cells, drawn through the aperture, will generate 125 pulses.

Measured Volumes (Example)

The measured volume drawn through the aperture is 270 µL (manufacturer calibrated). Based on the assumption made above, the system will count 270 × 125 = 33,750 pulses, which is equivalent to 5.0×10^6 cells/µL in the concentrated blood.

Theoretical Principles (WBC Example)

The measurement principle for white blood cells is the same as in RBC example but with a difference in dilution ratio and cell quantity. An example of this could be as follows: 5,000 cells/µL diluted 1:400 = 12.5 cells/µL.

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Counting Time RBC and WBC

The counting time is defined as being the time needed for the sample to fill the metering unit from the start to the stop detector.

Counting Time Limits

- The normal counting time limits for the RBC and WBC metering units are between 21–30 seconds and 10–13 seconds respectively. If the counting time is below or exceeds the above mentioned limits, the flag ST, TL and TU will be displayed.
- The Counting Time is not related to the actual result. Atmospheric pressure variations, protein built up within the orifice (aperture) and other secondary effects that might cause pressure changes will NOT affect the counted parameters RBC, PLT and WBC.

WBC Differentials

The Swelab Alfa Plus system uses a fixed discriminator technology. The differentiation of the WBC cells into lymphocytes, mid-cells and granulocytes is presented in the number of cells per liter or cubic millimeter and in the percentage of the total number of WBC cells. The MID discriminator of WBC is set to 140 and 180 fL. The WBC histogram is automatically adjusted depending on the number of cells, i.e. expanded for low values and compressed for high values. See *figure 115*.

Differential Parameters

- LYM region (small size cells): Ranges from 30 to 140 fL. Cells in this area typically correlate to lymphocytes. Other cell types that could locate in this region are nucleated red blood cells, clumped platelets, macrocyte platelets, variant (atypical) lymphocytes or blasts.
- MID region (mid size cells): Ranges from 140 to 180 fL. Cells in this area typically correlate to monocytes, eosinophils and basophils and also degranulated neutrophils, precursor cells, blasts and plasmacytes.
- GRA region (large size cells): Ranges from 180 to 600 fL. Cells in this area typically correlate to neutrophils as well as the majority of the eosinophil population. Precursor granulocytic cells, especially bands, have a tendency to locate close to the mid cell region.

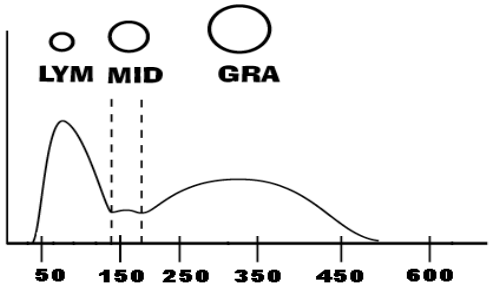

Figure 132: Volume lysed WBC (fL)

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Photometric Method – HGB Hemoglobin

The hemoglobin is determined from the same dilution as the WBC. For each sample a blank is measured as a reference, this means that any drift in reagent, cuvette-absorption, or diode is eliminated. The photometer system consists of a photodiode, a cuvette with a length of 15 mm and a filter at a wavelength of 535 nm (bandwidth 20 nm). The HGB readings are slightly corrected for turbidity in case of extreme WBC counts. The diode is switched off if the instrument is in standby mode, giving it an extended lifetime. See *figure 116* below.

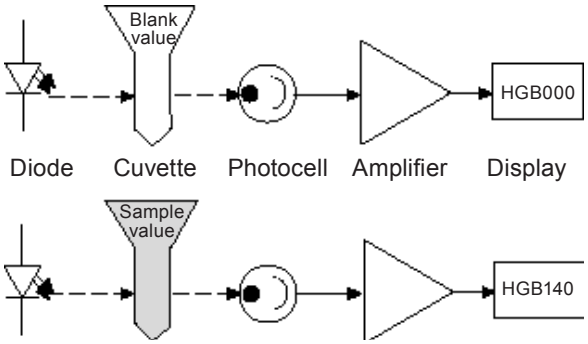

Figure 133: HGB method

SECTION 9. TROUBLESHOOTING AND SYSTEM MESSAGES

Troubleshooting

General Information Displays

General information displays are informative screen displays that appear after a function has been completed. Instruction is then displayed for the operator on next step or function to be performed.

Warning Displays

Warning displays appear after a function has been performed incorrectly or to inform the operator that further action is needed to complete the desired task. The warning display describes the situation and instructs the operator on next step or function to resolve the issue.

Indication Error Codes

Indications error codes are specific instrument situations that in most cases need the attention of the operator or might need service action.

- The first indication display is the most important as it describes the issue and how to solve the problem. The 300 indication series displayed after a two digit indication is added information for the user.
- In most cases, the instrument is stopped and the operator has to confirm with **OK** to continue. Once **OK** is pressed and instrument returns to display menus, user should repeat previous actions again (e.g. re-analyze sample, printing results, etc.)
- If indication error appears again or a three digit indication was displayed as the first indication message, contact local distributor or authorized service technician.

Indication Series	Description
1–19	Indication series for auxiliary errors like battery faults or similar.
20–29	Indication series for ‘Liquid’ errors.
30–39	Indication series for Communication errors between the PCBs (CAN bus).
40–49	Indication series for Printer and serial output errors.
50–59	Indication series for General Memory errors.
60–69	Indication series for EEPROM/HPC errors.
70–79	Indication series for Shear Valve problems.
80–89	Indication series for Cap Piercer errors.
90–99	Indication series for Sampling device errors.
100–255	Indication series for internal hardware and software problems, and messages during sub-board firmware upgrades.

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Indication Series	Description
300–399	Indication series for cycle aborted indication numbers.

Communication Issues

This section contains information regarding errors associated with printers.

Issue	Solution	Cause
The printout has unusual layout or strange characters.	• Verify that printer type matches the printer being used. • Verify that the correct paper format has been selected for the printer paper.	• New printer was connected but not matched with analyzer setup. • Printer may need maintenance or to be reset.
Results are not printing out after sample or control analysis.	Verify that Auto Print Mode is NOT set to OFF.	Auto Print Mode was turned off and not reset.
Printer Alarm: Printer not ready!	• Printer Alarm message is displayed. • Printer is not ready to print, wait unit printer has finished with previous printout. • Verify that printer is connected the analyzer. • Verify that the setup of the analyzer is correct for the printer in use.	• The printer is not connected to the analyzer or the printer setup is incorrect. • The printer has not completed last printout.
Printer Alarm: Printer timed out!	• The Printer is connected to the analyzer and on, but not activated. • Verify that printer is not in standby or off-line. • Verify that printer is set to print and not serial port only setup.	• The printer has timed out. • Printer paper may need to be refilled. • Incorrect setup for information transmission.

Aspiration Issues

This section contains information regarding errors associated with aspiration and the sample probe.

Issue	Solution	Cause
No aspiration of sample is taking place.	• Verify that there are no leaks and tubing is connected properly and not kinked. • Perform valve check in Service Menu. • Perform clot prevention. See *section 10*. • If clot prevention cycle does not work perform clot removal procedure. See *"Clot Removal" on page 82*.	• Blockage of tubing or leak causes sample to not be pulled correctly through shear valve. • Valve malfunction. • Clot in sample caused by incorrect sample handling or pathologic sample.

No cleaning of aspiration probe	• Suggest cleaning upper area of sample probe. • Verify that there are no leaks and tubing is connected properly and not kinked.	• Sample tube is touching the upper part of the sample probe when analyzing. • Diluent is not flowing correctly through tubing to sample probe.

System Information Messages

As samples are analyzed, the system software may produce two types of intelligent information messages. The information is designed to guide and aid the user in the practice of complete hematology. The categories of information are:

- Low & High Abnormal Results – message of abnormal patient results or out-of range control results with a ▼ or ▲ notation
- Out of Alert Limits Results – an indicator and double triangle is used if the value is out of alert limits.
- System Information – messages for checking some aspect of the analyzer system.

Description of Information Indicators

Information is indicated on the touch screen with the results and is printed on the patient report. For System Information messages, the touch screen's **i-button** becomes active when a message is present. The information is automatically included in the printed report. The user has the preference to access this information detail by either touching the **i-button** on the touch screen or reviewing the printed sample report. Further detail and background information may also be obtained by referring to this section of the user manual.

Low and High Abnormal Results

Reference ranges may be stored in the system software for each profile configuration. When a patient sample in analyzed, the system software will compare each parameter value to its corresponding reference range stored in the system software. Any value that is outside the reference range will result in display of a ▼ for Low or ▲ for High next to the value. This information is included on the printed patient report. The printed report also shows the reference range for all values.

Specific Assay Value Ranges: The Low and High abnormal results messages are also applied to results of control samples compared with lot specific assay value ranges. The barcode reader enters assay value ranges into the system memory for each lot of control material. The barcode reader is used to identify the control lot by scanning the tube each time a control is analyzed. The assay value ranges are designed to demonstrate that the system is both calibrated to a reference standard and operating to specification. Control sample results are expected to be within these ranges 99% of the time. A sporadic value slightly outside the limits may occur normally. Troubleshooting action should be taken when control values are either consistently out of range or when values are markedly out of range.

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Out-of-Range Indicators

Values that are out of measurement range are indicated by MH (out of upper range) and ML (out of lower range) indicators, and the value will not be shown on the patient report. This means the count is too high or too low to measure. If it is expected that the parameter is too high, the sample can be diluted and re-analyzed, and then the dilution factor can be multiplied with the result to calculate the correct value.

Abnormalities

All samples with anomalies and/or abnormal distributions signaled by the analyzer should be analyzed manually by a blood smear. Pathological cells may vary in their stability towards lysing of their cytoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments.

System Information Messages

The system software monitors a number of analytical and system functions and will display information that indicates the possible attention of the operator. This information will alert the operator to check the system or sample, or institute selected troubleshooting procedures. This information is presented on the touch screen as a code next to one or more parameters. Additional detail and recommendations may be accessed by either pressing the **i-button** on the touch screen or reviewing the printed report.

Sample Pathology Messages

The sample analysis software is capable of displaying intelligent information messages related to pathology that may be present in the sample.

Triggering mechanisms

The Sample Pathology information includes a short message defining the sample abnormality followed by recommendation(s) for that sample. The information may be triggered by the following mechanisms:

- Histogram shape abnormalities detected by system software calculations.
- Selected values that exceed defined limits outside the reference range. These messages occur when selected values are moderately to markedly abnormal. Values slightly outside the reference range are typically treated as cautionary by the clinician, as described above.

Aspiration Indicators (Sample Probe)

Indicator	Message	Description	Action
AF	Aspiration failed	Possible reasons for AF flag include a short sample, clogging or air bubbles in sample tube. This flag is also displayed when running a background count without selecting the background analysis profile.	Check profile type is correct and then re-analyze sample.

Control and Reagent Indicators (RBC, PLT, WBC, LYM/MID/GRAN)			
Indicator	Message	Description	Action
EC	Control is expired	A control blood was used past its expiry date.	Use a fresh blood control.
ER	Reagent is expired	The reagent was used past its expiry date.	Use a new lot of reagents.
NR	Not enough reagent left	The analyzer's capacity counter has gone below zero.	Open and scan in new reagent pack.

Distribution Indicators (RBC, PLT, WBC)			
Indicator	Message	Description	Action
DE	Small particle interference	The size distribution of the cell pulses departs from the expected one. Possible reasons might be pathological blood sample (e.g. nRBCs), PLT clumps, lipemic sample interferences, air bubbles, electrical disturbances, incomplete lysing or incorrect gain setting.	Blood sample too old or pathological sample. Re-analyze sample, if still flagged an alternative methodology such as e.g. slide review, is adviced.
FD	Irregular distribution	It was not possible to find the correct position for the floating RBC/PLT distribution curve. This flag may occur on low PLT counts.	Re-analyze sample.

HGB Indicators (HGB)			
Indicator	Message	Description	Action
HF	HGB measuring problem	The instrument detected a problem during the filling of liquid in WBC counting chamber during HGB blank.	Run a **Prime Cycle**, before re-analyzing the sample.
HH	HGB measuring problem	The HGB blank or sample readings reported a too high light level.	
HL	HGB measuring problem	The HGB blank or sample readings reported a light level that was too low.	
HN	HGB measuring problem	The HGB sample reading reported more light than the blank reading. This gives a negative HGB value.	Wait one minute, and then re-analyze sample.
HO	HGB measuring problem	The HGB dark (offset) reading reported a light level that was too high or too low.	Switch off the analyzer and switch it back on after 3 seconds, and then re-analyze sample.

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HS	HGB measuring problem	Individual HGB readings vary too much, possibly due to noise interference.	Run a **Prime Cycle**, before re-analyzing the sample.
HT	Instrument temperature outside limits	The instrument temperature reading is outside the limits (10–50 °C) or the temperature sensor is nonfunctional.	Ensure instrument is within operating temperature (18–32 °C). If HT continues, contact service technician.
HW	High WBC	HGB can be slightly too high due to extremely high WBC.	Re-analyze sample. Dilute if necessary.

Note: If various HF, HH, HL or HN Indicators repeatedly appear check High Altitude Compensation, mode may need to be changed to Moderate or Maximum compensation in higher elevations.

Measuring Chamber Indicators (RBC, PLT, WBC)

Indicator	Message	Description	Action
OR	Measurement warning	• The cell pulses arrived faster than the analyzer could process them. Possible reasons might be air bubbles, electrical disturbances or incomplete lysing. • Filtered away cell pulses might raise the OR flag, so it might not be possible to see them in the histograms or the result parameters. This is a hard limit determined by the software.	Re-analyze sample.
SE	Measurement statistics warning	• The rate of cell pulses per time unit varies too much. Possible reasons might be clogging, air bubbles, electrical disturbances or difficult to lyse cells. • Filtered away cells might raise the SE flag, so it might not be possible to see them in the histograms or the result parameters.	Re-analyze sample.

Mixing Beaker Indicators (RBC, PLT, WBC)

Indicator	Message	Description	Action
TE	Liquid system problem	The analyzer detected an abnormality during the emptying of the first dilution from the mixing beaker. Reasons for flagging might be timeout, or too short of a transfer time.	Run a **Prime Cycle**, before re-analyzing the sample.

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Out-of-Range Indicators (RBC, PLT, WBC)			
Indicator	Message	Description	Action
MH	Parameter above measurement range	A parameter value is above the measurement range for the analyzer.	Re-analyze sample. Dilute if necessary.
ML	Parameter below measurement range	A parameter value is below the measurement range for the analyzer.	Re-analyze sample.

PLT Indicators (PLT)			
Indicator	Message	Description	Action
MB	Missing blank	A sample with high PLT has been run previously without a blank afterwards, which could lead to high PLT background for current sample.	Run Background after sample with high PLT (> = 1000 10^9/L)
XF	Extended counting time failure	Extended counting time failure if the RBC from the first count cycle does not correspond to the RBC from the extended PLT counting time.	Re-analyze sample

Reagent Pipette Indicators (RBC, PLT, WBC)			
Indicator	Message	Description	Action
DF	Diluent system problem	The analyzer detected an abnormality during one of the fill cycles of the diluent pipette. Reasons for flagging might be timeout, short time or bubbles at the upper detector.	Verify analyzer is filled, run a **Prime Cycle** and then re-analyze sample.
DP	Diluent system problem	The analyzer detected an abnormality during one of the empty cycles of the diluent pipette. Reasons for flagging might be timeout, short time or liquid not detected at the lower detector.	Verify analyzer is filled, run a **Prime Cycle** and then re-analyze sample.
LF	Lyse system problem	The analyzer detected an abnormality during the fill cycle of the lyse pipette. Reasons for flagging might be timeout, short time or bubbles at the upper detector.	Verify analyzer is filled, run a **Prime Cycle** and then re-analyze sample.
LP	Lyse system problem	The analyzer detected an abnormality during the empty cycle of the lyse pipette. Reasons for flagging might be timeout, short time or liquid not detected at the lower detector.	

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ST	Air bubbles	The time for the liquid meniscus to pass from the lower to the upper detector is unreasonably short.	Run a **Prime Cycle**, before re-analyzing the sample.
TB	Air bubbles	Air bubbles were detected by the start detector in the diluent column.	
TL	Possible orifice blockage	The liquid meniscus in the measuring tube never passed the lower detector.	
TU	Possible orifice blockage	The liquid meniscus in the measuring tube passed the lower detector but never passed the upper one.	

WBC Differential Abnormalities (LYM, MID, GRAN)			
Indicator	Message	Description	Action
OM	Only one WBC population found	There was only one mode in the WBC distribution between the LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended.	Blood sample too old or pathological sample. Re-analyze sample, if still flagged an alternative methodology such as e.g. slide review, is adviced.

Prime Cycle

The prime cycle is used to reset the analyzer after an error has been indicated or a failure in running a sample occurs.

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SECTION 10. ANALYZER CARE AND MAINTENANCE

Cleaning

Daily Cleaning

The majority of the Swelab Alfa Plus system's cleaning procedures are automated to keep routine cleaning to an absolute minimum, increase the longevity of the analyzer and decreases maintenance procedures.

- Clean the sample probe using a paper tissue moistened with a 70% alcohol solution.
- Remove possible traces of salt crystals or blood at the top of the sample probe and probe rinse cup using a paper tissue moistened with the alcohol solution.
- When necessary, gently clean the display and/or outside of the analyzer with a soft cloth, slightly moistened with water and a mild soap. Dry carefully.

Important: Follow your lab established biohazard barrier protection. This may include gloves, lab coat and/or eye protection.

Orifice Cleaning

Check with your local Service Contact for more information.

Monthly Cleaning

There are two cleaning procedures to secure the correct function of the instrument on a monthly basis. The Monthly Cleaning procedure takes approximately 10 minutes and the Clot Prevention procedure takes approximately 15 minutes.

▶ **Monthly Cleaning**

1 Clean the aspiration probes using a paper tissue with a 70% alcohol solution.

2 Fill a cup with 10 mL 2% hypochlorite, from Boule Cleaning Kit, and one cup with 18 mL diluent. (Recommend use of dispense function for obtaining diluent, see **"Dispense Function"** in *section 3*.)

3 Aspirate the hypochlorite as a pre-dilute sample.

4 Run 2 blank samples by aspirating diluent as a pre-diluted sample.

5 Perform a background check, in pre-dilute mode, to verify all values are within range. See *section 3* for more details.

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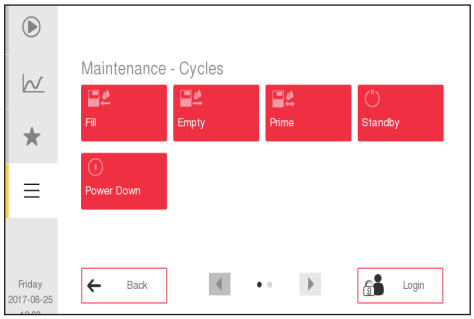

Figure 134: Maintenance Menu

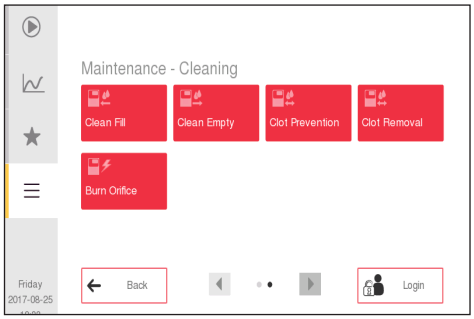

Figure 135: Cleaning Menu

▶ Clot Prevention

This process will decrease the risk of debris material building up in the analyzer system. This should be performed at least once a month or every 1000 samples.

- Once this procedure is started the operator will be unable to abort the cycle until it is completed.
- Prematurely aborted the cycle could cause erroneous patient results if system is not cleaned properly.

1 Fill a small container with 5 mL of Enzymatic Cleaner from Boule Cleaning Kit.

- If system has the optional Cap Piercer or Auto Sampler, fill a CLEAN standard 4.0–5.0 mL tube half full with Enzymatic Cleaner.

2 From Main Menu press **Maintenance** and then press **Clot Prevention**.

3 For Cap Piercer: Place filled cleaner tube into cap piercer, same as a normal sample analysis, close the door, and go to Step 4.

- For Auto Sampler: Place filled cleaner tube into Position 1 on wheel, lock wheel into place, and follow instructions for **Maintenance** and then **Clot Prevention**.

4 Hold the container (with cleaner) under the OT probe, submerged in cleaner, press **OK** to confirm. Do not remove container (with cleaner) for at least 5 seconds after aspiration has stopped. (This is important as Cap Piercer and Auto Samplers will take a few extra seconds to perform aspiration before the OT begins to aspirate.)

5 The system will then perform the cleaning process for all analysis modes simultaneously, and upon completion analyzer is ready for next analysis.

6 Perform a background check to verify all values are within range. See *section 3* for more details.

Clot Removal

Check with your local Service Contact for more information.

Boule Cleaning Kit Procedure

To increase the life of the analyzer's internal tubing, the following cleaning procedure is strongly recommended. The Boule Cleaning Kit procedure takes approximately one hour and 15 minutes to complete.

Depending on daily sample analyses, it is recommended that the following cleaning intervals be followed:

- Less than 50 samples/day = every six months
- More than 50 samples/day = every three months
- 100–200 samples/day = every month

▶ Cleaning Procedure

1 Select **Main Menu**, then **Maintenance**, and arrow over to next page to enter the Cleaning Menu.

2 Follow the instruction for the Boule Cleaning Kit to clean the analyzer. (Instructions for use are supplied with the Boule Cleaning Kit solutions).

The Boule Cleaning Kit contains the following items:

- Hypochlorite (2%)
- Enzymatic cleaner
- Detergent cleaner

Transport (Short-term and Long-term)

Relocation of analyzer (within the laboratory)

This section describes the procedure performed to move the analyzer over very short distances (From table to table).

▶ Analyzer Relocation

1 Before Relocation

- If the analyzer is in **Standby** mode **do not** unplug analyzer. Use the **Power Down** button in the **Maintenance Menu** to turn the instrument off.
- D**o not** detach the reagent tube assemblies or the electronic sensors.
- Remove the waste tube from waste container or drain, but do not detach tube from analyzer.
- Disconnect all electrical connections.

2 Relocation

- Make sure that the analyzer is lifted from beneath to avoid unnecessary stress on the front cover.

3 After Relocation

- Place the waste tube in waste container or drain.
- Reconnect the electrical connections.
- Power on analyzer.
- Perform Prime.
- Verify Background.

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- It is recommended that the performance of the Swelab Alfa Plus system is checked with certified blood controls authorized by Boule.

Short–Term Shutdown (< 12h)

This section describes the procedure performed before transporting the analyzer over short distances outside the usual facility. This procedure only describes the preparations performed before transporting the analyzer for less than 12 hours.

▶ **Short-Term Shutdown**

1 Select **Maintenance Menu**,and then press **Power Down** button.

2 If system is filled, a pop-up dialog will ask the user to empty the system by removing the reagent tube assemblies from the reagent containers and then pressing the **Empty** button. (System will not perform empty cycle if reagent tube assemblies are not removed from the containers.)

3 Press the **Power Down** button and wait for the screen to go blank.

4 Switch off power and then unplug analyzer.

5 After analyzer is powered off, detach reagent tube assemblies waste tube, electronic sensors and all electrical connections. Package all components carefully for transport.

6 Transport Conditions

- The analyzer should be transported in temperature conditions between 5 to 40 °C.
- Humidity should be less than 80%.

■

Repackaging, Long–Term Transport and Storage (> 12h)

This section describes the procedure when transporting or shutting down the analyzer for a longer period of time (> 12 hours).

- It is very important to follow the below instructions for preparing the analyzer for long term transport or repackaging, to avoid erroneous results upon re-installation.
- The main difference between Relocation/Short-Term Shutdown and Long-Term Shutdown is the importance of cleaning the instrument with the Boule cleaning kit and distilled water, prior to repackaging to avoid contaminates.

▶ **Repackaging, Long-Term Transport and Storage**

1 Select **Main Menu**, then **Maintenance**, and arrow over to next page to enter the Cleaning Menu.

2 Follow the instructions for the Boule Cleaning Kit (Instruction is supplied with the Boule Cleaning Kit solutions).

3 After completing the cleaning of the analyzer, insert the reagent tube assemblies into distilled water. Select **Clean Fill** from **Cleaning Menu**.

4 When the analyzer has been filled with distilled water, select **Clean Empty** from **Cleaning Menu**.

5 When system is emptied, enter **Maintenance Menu** and press the **Power Down** button. After the power down is completed turn the power off and disconnect the main supply cable and all other connections such as reagent tube assemblies and waste tube.

6 Make sure that the analyzer is lifted from beneath to avoid unnecessary stress on the cover.

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7 If transporting instrument, pack securely using the original shipping container.
   - If original packaging is not available, cushion and surround analyzer as best as possible and place in double corrugated cardboard shipping box.
   - Mark the container with DELICATE ANALYZER, FRAGILE and THIS SIDE UP.

8 Follow Guidelines for transport.

Note: If system was not emptied according to guidelines before storage, salt deposition might build up in the liquid system causing system instabilities. If this occurs try to recover system by running two primes, three backgrounds and then verify with three control analyses. If not within specification, contact service.

Guidelines for transport

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

- Does not exceed −40 °C for ≥ 24 hours.
- Does not exceed a Dry heat of +70 °C for ≥ 24 hours.
- Does not exceed a dramatic change of temperature between −40 °C and + 30 °C.
- Does not exceed a Damp heat steady state of 90% RH and +40 °C during 48 hours.
- Does not exceed a Damp heat cyclic of 90–100% RH and +25°/+40 °C 12+12 hours.

Return Procedure

When maintenance or service is required, contact a Boule authorized service technician or local distributor to determine if an analyzer should be returned and the details necessary for the packaging and shipment of the analyzer.

Maintenance/Service

When service or maintenance is required for the analyzer contact an authorized service technician or local distributor. The maintenance should be performed at the following intervals by local distributor or authorized service technician:

- 1 year or 20,000 samples
- Refer to local distributor for specific warranty requirements.

Disposal Information

Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer systems or recycling decontaminated equipment.

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Disposal Material

- Used reagents
- Reagents mixed with potentially biohazardous material
- Instrument and instrument components
- Controls and calibration material
- Li-Ion battery

Manufacturer Guidelines for Waste Products

- Place the instrument close to a waste container or drain suitable for disposal of used reagents.
- Check that the drainage is suitable for disposal of chemical and biological waste.
- Check that the waste tube is securely fastened in the drain.

Always follow local guidelines for open drain

Decontamination and Disposal

The European Directive 2012/19/EU on Waste Electric and Electronic Equipment (WEEE) aims to minimize the impact on the environment by prevention of waste. The Swelab Alfa Plus hematology analyzer has been labeled with the WEEE symbol, and there is a procedure to allow waste collection and recycling of the equipment at the end of it's life cycle.

- The instructions for decontamination and disposal, including reagents, can be found on the Swelab home page www.swelab.com under Support, Downloads, SDS (MSDS), Waste Electric and Electronic (WEEE).
- If there are any question on how to follow this procedure, contact your local distributor for more information.
- The analyzer should be considered as infected and the end user must follow a decontamination procedure before it is safe to hand over to a recycler.

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SECTION 12. APPENDIX

Appendix A: Parameter Limitations

Parameters presented in alphabetical order. All measured parameters except HGB are based on the principle of impedance. HGB measurements are based on photometry. The expression of very low values of some parameters has been limited due to low statistical significance. The limits are given as information.

HCT (Hematocrit)

The HCT is defined as being the packed volume of red cells in whole blood and is measured through integration of total red blood cell count and the mean cell volume of the red blood cells. RBC counts lower than around 0.20 do not generate an HCT.

HGB (Hemoglobin Concentration)

The hemoglobin is determined using a non-cyanide analytical method from a dilution of whole blood.

MCH (Mean Cell Hemoglobin)

The MCH is a calculated value and is defined as HGB/RBC giving the mean HGB concentration in the red cells.

MCHC (Mean Cell Hemoglobin Concentration)

The MCHC is a calculated value and is defined as HGB/HCT.

MCV (Mean Cell Volume)

The MCV parameter is derived from the RBC size distribution curve of diluted blood. RBC counts lower than around 0.20 do not generate an MCV value.

MPV (Mean Platelet Volume)

The mean cell volume of the platelets is determined from the PLT size distribution curve of diluted blood. PLT counts lower than around 30 do not generate an MPV.

PLT (Platelets)

The number of cells for determining PLT values are counted from a dilution of whole blood.

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PDW (Platelet Distribution Width)

The PDW parameters, both relative (PDW%) and absolute (PDWa), are calculated from the PLT size distribution curve and only presented if the MPV value is displayed.

PCT (Packed Platelet Volume)

The PCT is defined as being the packed volume of platelets in whole blood and is measured through integration of the PLT count and the MPV. PLT counts lower than around 30 do not generate a PCT value.

P-LCC & P-LCR (Platelet Large Cell Concentration and Ratio)

The P-LCC is the concentration of PLT with MPV larger than 12 fl. The P-LCR parameter is calculated from the PLT size distribution curve. The ratio of platelets that are larger than 12fl are expressed as a % to the total PLT count. The parameter is only presented if the MPV value is displayed.

RBC (Red Blood Cell)

The number of cells for determining RBC values are counted from a dilution of whole blood.

RDW (Red Cell Distribution Width)

The RDW parameters, both relative (RDW%) and absolute (RDWa) are calculated from the RBC size distribution curve and are only presented if the MCV value is displayed.

WBC (White Blood Cell)

The number of cells for determining WBC values are counted from a dilution of whole blood.

WBC Differential: Granulocytes, Lymphocytes, MID cells

- LYM region (small size cells): Ranges from 30 to 140 fL. Cells in this area typically correlate to lymphocytes. Other cell types that could locate in this region are nucleated red blood cells, clumped platelets, macrocyte platelets, variant (atypical) lymphocytes or blasts.
- MID region (mid size cells): Ranges from 140 to 180 fL. Cells in this area typically correlate to monocytes, eosinophils and basophils and also degranulated neutrophils, precursor cells, blasts and plasmacytes.
- GRA region (large size cells): Ranges from 180 to 600 fL. Cells in this area typically correlate to neutrophils as well as the majority of the eosinophil population. Precursor granulocytic cells, especially bands, have a tendency to locate close to the mid cell region.

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Appendix B: Parameter Limitations

This section describes the different factors that may interfere with HCT, HGB, MCV, MPV, PLT, RBC, RDW, WBC and WBC differential determination.

HGB Limitations

Turbidity, in the blood sample, due to any number of physiological and/or therapeutic factors may produce falsely elevated HGB results. The analyzer however, is compensated throughout the linear range of the analyzer.

Limitation	Description
Unlysed Red Blood Cells	Increased turbidity may be seen in cases where the red blood cells are resistant to lysing. This condition will cause a falsely elevated HGB result but can be detected by monitoring the MCHC.
Leukocytosis	Extremely elevated WBC may produce falsely elevated HGB results due to turbidity. In case of extreme WBC counts, the following is recommended: Dilute the sample and re-analyze.
Lipemia, hyperproteinemia and hyperbilirubinemia	Elevated lipids in the blood sample will give the plasma a "milky" appearance which may disturb the spectrophotometric measurement of HGB. Similar problems may occur with hyperproteinemia (high protein concentration) and hyperbilirubinemia (high bilirubin concentration). Accurate HGB determination can be achieved by using reference methods and a plasma blank.
Fetal blood	The mixing of fetal and maternal bloods may produce a falsely elevated HGB value.

MCV / HCT Limitations

As HCT is the product of MCV x RBC, any erroneous result in MCV and/or RBC will produce an equal error in the HCT parameter.

Limitation	Description
Red Blood Cell Agglutination	Agglutination of RBC may produce an erroneous MCV value and therefore a false HCT.
WBC	An excessive number of WBCs might cause interference within the RBC population and therefore a false MCV value.
Thrombocytosis (elevated PLT)	Excessive numbers of PLT, in most cases, do not interfere with the MCV parameter due to the use of the floating discriminator technology in the analyzer.
Decreased plasticity Red Blood Cells	Increased MCV may be seen in rare cases where the red blood cell membrane is less rigid (resistant to lysing). This condition may cause a falsely elevated MCV result but can be detected by monitoring the MCHC parameter.

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PLT / MPV Limitations

Measurement of low PLT levels may influenced by circulating RBCs, which may cause falsely high results. Measurement of high PLT levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The analyzer is compensated for these effects by separate algorithms to produce linearity ranges according to the specifications.

Limitation	Description
Microcytosis (small RBC, low MCV)	Very small RBCs might falsely elevate a PLT count and affect the MPV. This effect is minimized in the analyzer due to the use of a floating threshold (discriminator). By observing the PLT and RBC histograms, this effect is seen as an overlapping PLT/RBC area.
Agglutinated RBCs	Agglutinated RBCs might trap platelets and may give an erroneous low PLT count and affect the MPV. The presence of agglutinated RBCs is detected by monitoring the MCHC parameter and by careful examination of the stained blood film.
Giant platelets	Excessive numbers of giant platelets may cause a low PLT count since they might fall within the RBC region.
Chemotherapy	Cytotoxic and immunosuppressive drugs may increase the fragility of these cells, which may cause low PLT counts. Reference (manual) methods may be necessary to obtain an accurate platelet count.
Hemolysis	Hemolyzed specimens contain red cell stroma, which may elevate platelet counts.
A.C.D. blood	Blood anti coagulated with Acid Citrate Dextrose may contain platelet aggregates, which could depress the platelet count.
RBC inclusions	Erythrocyte inclusions may also produce a spuriously increased platelet count. (e.g. Howell-Jolly bodies, siderotic and basophilic granules)
Platelet agglutination	Clumped platelets due to poor collection techniques or platelet satellitosis caused by EDTA activation of immunoglobulins may cause a decreased platelet count and/or an elevated WBC count. The specimen should be recollected in sodium citrate anticoagulant and re analyzed for only the platelet count. The final PLT result must be corrected for the sodium citrate dilution effect.

MPV Limitations

Limitation	Description
Giant platelets	Large platelets counted as RBCs will fall outside the PLT range and therefore lower the MPV.
Small erythrocytes	Very small RBCs might fall into the PLT region and might be counted as PLTs and therefore influence the MPV parameter.
Agglutinated erythrocytes	This may trap platelets and therefore affect the MPV parameter. Note that agglutinated erythrocytes may be detected by carefully examine the MCHC parameter and/or the stained blood film.
Chemotherapy	May also effect the size of the PLTs.

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RBC Limitations

The red blood cell dilution contains all the cellular elements of the blood: RBC, WBC, and PLT. Platelets are not counted since the size falls below the discriminator threshold. Leukocytes are included in the RBC count, but since the ratio of RBCs to WBCs is approximately 1000:1, the introduced WBC count is almost negligible. Exceptions are noted below.

Measurement of high RBC levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The analyzer is compensated for this effect by an algorithm to produce a linearity range according to the specifications.

Limitation	Description
Leukocytosis with concurrent anemia	In samples where the WBC is very high and at the same time the RBC is low, the WBC may cause a false increase in the RBC count. The WBC is always included in the RBC count, but the contribution is not significant under normal circumstances. The RBC count may be corrected by simply subtracting the WBC from RBC.
Agglutinated Red Blood Cells	This might cause a falsely decreased RBC count. Blood samples containing the agglutinated red blood cells may be identified by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film.
Cold Agglutinins	IgM immunoglobulins which are elevated in cold agglutinin disease may lower RBC and PLT counts and increase the MCV.
Fragile Red Blood Cells	Fragile RBCs might cause falsely low RBC values due to lysis between sampling and counting. This condition can be detected by monitoring the MCHC parameter.

RDW Limitations

The red cell distribution width is a function of the RBC count and derived from the RBC histogram. In most cases, any error introduced in the MCV may also cause the RDW to be erroneous.

Limitation	Description
Blood transfusions	Blood transfusions may raise the RDW significantly due to the presence of bi-modal populations.

WBC Limitations

Measurement of high WBC levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The analyzer is compensated for this effect by an algorithm to produce a linearity range according to the specifications.

Limitation	Description
Leukocytosis	WBC in concentrations that exceeds the linearity limits of the system will require dilution of the blood sample. Re-assaying the diluted sample will help to obtain the correct assay value.

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Nucleated Red Blood Cells, NRBC Giant Platelets PLT Clumps	Immature, nucleated red blood cells are large and not lysed like mature RBCs, thus they will be classified as a WBC and may cause falsely elevated WBC and lymphocyte results. If the number of the NRBC is sufficient to activate the DE alarm, such interference will be detected. An overview of a stained blood film can reveal the presence of NRBCs, PLT clumps or giant platelets.
Unlysed Red Blood Cells	In particularly rare instances, the RBC in the blood sample may not completely lyse like expected. These non-lysed cells may be detected on the WBC histogram with a DE alarm, or as an elevated baseline on the side of the lymphocyte population. Non-lysed RBCs will cause a falsely elevated WBC and lymphocyte count. (See also NRBC above)
Hemolysis	Hemolyzed specimen contains red cell debris, which may falsely elevate the WBC and/or PLT count. Hemolysis can be detected by looking at the color of the plasma in an EDTA-sample that has been allowed to sediment.
Leukemias	This disease state may result in a spurious low WBC count, if the leukocytes are more fragile than normal and becomes destroyed in the sample. The cell fragments will also interfere with the WBC differential parameters (LYM, GRAN and MID). A falsely low WBC count may also be seen in patients with lymphocytic leukemias due to the presence of abnormally small lymphocytes, which may not be counted by the analyzer.
Chemotherapy	Cytotoxic and immunosuppressive drugs may increase the fragility of the leukocytes, which may cause falsely low WBC counts.
Cryoglobulins	Increased levels of cryoglobin may cause elevated levels of WBC, RBC or PLT counts as well as HGB. Cryoglobulins may be associated with myeloma, carcinoma, leukemias, macroglobulinemia, lymphoproliferative disorders, metastatic tumors, autoimmune disorders, infections, idiopathic disease, aneurism, pregnancy, thromboembolic phenomena, diabetes, etc. The specimen can be brought up to 37 °C and re-analyzed immediately or a manual WBC, RBC or PLT count can be performed.
Multiple myeloma	The precipitation of proteins in multiple myeloma patients may give falsely elevated WBC counts.
Large lymphocytes, atypical lymphocytes, blasts, and basophils in excessive numbers	The presence of large or atypical lymphocytes, blasts, or an excessive number of basophils may interfere with the MID cell area which otherwise consists mainly of monocytes.
Metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells in excessive numbers	The presence of excessive numbers of metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells may interfere with an accurate granulocyte count.

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Appendix C: Third-Party Software

This product uses some software which are distributed under the GPL and/or the LGPL licences.

Accordingly, Boule Medical AB makes the source code (including changes made by Boule Medical AB) for the following GPL and/or LGPL licensed software available: U-boot, Linux Kernel, Busybox, Glibc, Glib, GTK. Contact info@boule.se using the Subject line "BM850 GPL source code request" for information about access to the source codes. Please refer to http://en.wikipedia.org/wiki/Gpl, http://www.gnu.org/licenses/old-licenses/gpl-2.0.html and http://www.gnu.org/licenses/old-licenses/lgpl-2.1.html for further info.

"This software is based in part on the work of the Independent JPEG Group."

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