

Swelab™ Alfa Plus hematology system

A complete blood count is commonly requested to monitor patients' health status, and the results form the basis for decision-making regarding further testing, diagnosis, and treatment.

With its short analysis time, capillary sample inlet, and low maintenance needs, Swelab Alfa Plus contributes to efficient health assessments, from patient screening to monitoring of treatment efficacy.

Swelab Alfa Plus - equipped to deliver results you can trust:

- Complete blood count from a fingerstick sample.
- Rapid results to support early diagnosis and initiation of treatment.
- Robust equipment design helps that ensure instrument uptime.

System overview

Swelab Alfa Plus is an automated hematology analyzer tailored to the clinic or smaller hospital laboratory (Fig 1). The analyzer features a high-precision shear valve for accurate sample aspiration and dilution. A closed shear valve design minimizes leakage risk, ultimately reducing maintenance requirements.

Swelab Alfa Plus employs well-proven and robust measurement technologies. The analyzer uses impedance for white blood cell (WBC), red blood cell (RBC), and platelet (PLT) counts, while hemoglobin (HGB) is determined spectrophotometrically. The analyzer provides quantitative results for 22 parameters, with histograms for WBC, RBC, and PLT (Fig 2).

The sample analysis software displays information messages related to pathology that might be present in the sample. The sample pathology information includes a short message, defining the sample abnormality followed by



Fig 1. Swelab Alfa Plus hematology analyzer.

recommendations for that sample. The information can 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 interval are typically treated as cautionary by the clinician.

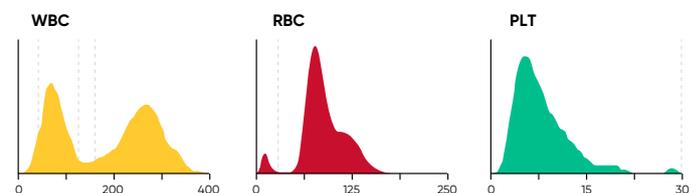


Fig 2. Swelab Alfa Plus analysis results visualized in histograms for WBC, RBC, and PLT.

Key components

Shear valve technology

Every Swelab Alfa Plus analyzer comes equipped with a high-precision shear valve that cuts out an absolute sample volume to be used for analysis (Fig 3). The closed design minimizes user maintenance needs, thereby maximizing instrument uptime. The closed design prevents entry of environmental impurities that might cause contamination and leakage. Additionally, the shear valve is automatically flushed with Diluent to prevent build-up of salt deposits that might also cause leakage. To avoid wear and tear of the shearing discs, the shear valve is soaked in Diluent, ultimately mitigating the need for replacement.

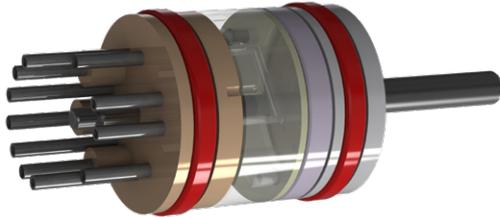


Fig 3. Swelab Alfa Plus shear valve design secures accurate results and lowers maintenance costs.

Atmospheric pressure variations will not affect the blood cell count. High altitude compensation only needs to be activated if various indicators related to HGB measurement problems repeatedly appear (see Section 9 in User manual). At higher elevations, the mode might need to be changed to Moderate or Maximum compensation. For high altitude compensation, the software incorporates some minor timing sequences for the wash cycles, no other functions are affected.

A blood sensor prevents inaccurate results caused by air in the sample. When enabled, aspiration stops when blood is detected by the blood detector sensor. This functionality can be disabled by the operator to instead employ a fixed aspiration type.

Sample aspiration modules

To maximize utilization of the Swelab Alfa Plus analyzer, sample aspiration can be performed with a variety of aspiration modes (Fig 4). The whole blood sample probe aspirates from open tube for analysis. For samples with high cell concentrations, the pre-dilute inlet can be used to dispense diluent and thereafter aspirate the pre-diluted samples for analysis. Analysis from closed tubes can be performed with analyzer models equipped with a cap piercer device or an autosampler. Most standard 5 mL tubes can be used. After aspiration, the analyzer will perform an automatic probe flush for cleaning of the sample probe.

Aspiration fails can be caused, for example, by sample shortage, clogging, or air bubbles in sample tube. Ensure that there is no blockage of tubing or leakage that might cause sample not to be aspirated properly, using built-in maintenance tools.

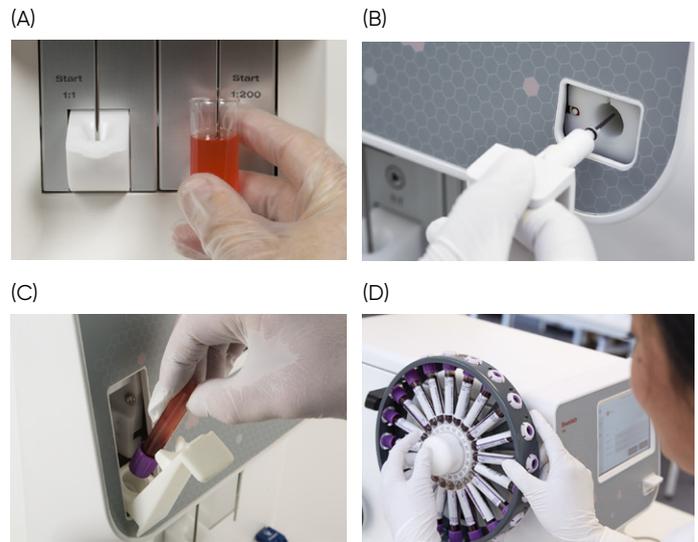


Fig 4. Swelab Alfa Plus allows sample aspiration from (A) open tubes (whole blood or predilute), (B) micro-pipette adapter (capillary whole blood), or closed tubes, using (C) the cap-piercing device or (D) autosampler.

Micro-pipette adapter (MPA) inlet

The micro-pipette adapter (MPA) enables a complete blood count (CBC) from one drop of blood using a capillary sample tube. Only use Boule supplied, plastic, high precision EDTA capillary tubes with the MPA inlet. Glass tubes can cause damage to the analyzer if inserted incorrectly.

As the MPA inlet bypasses the shear valve sample aspiration, it is of utmost importance to ensure correct volume is collected by making sure the whole capillary is filled with blood and by wiping of any excess blood outside of the capillary before sliding it into the MPA module (Fig 5).

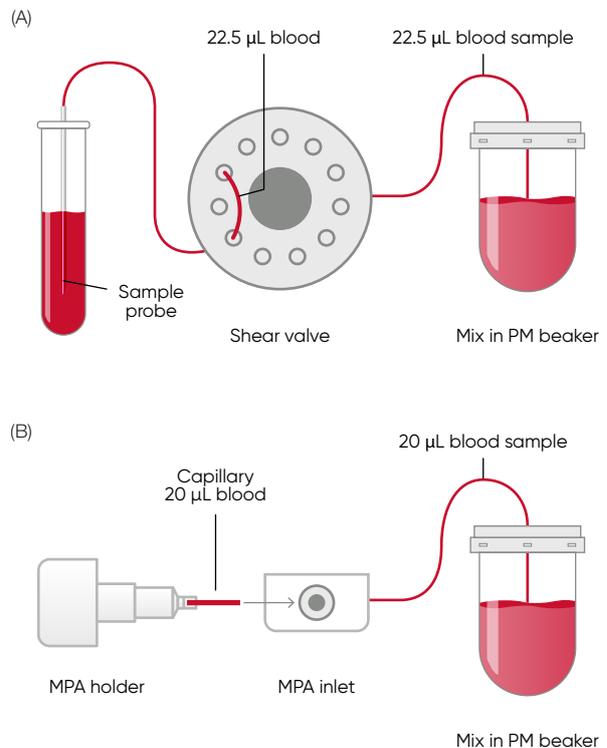


Fig 5. Sampling for (A) tube inlets, using the shear valve, as well as for (B) the MPA inlet, bypassing the shear valve. The difference in sample volume is compensated for in the instrument software.

Measurement chambers

RBC and PLT counts are conducted in the RBC chamber, using floating discriminators. For samples with low PLT levels, the extended PLT counting time functionality can be enabled. In case of a patient sample with a severe thrombocytopenia detected, the analyzer will activate PLT extended counting time, counting three times as many platelets as in normal count mode, to be able to provide a more accurate result in the critically low PLT range (Fig 6).

Sample Result		Parameter values		Scales	Graphs
Seq No	347	WBE	DE 10.2	3.5	10.5
Date	2018-11-28 14:32	LYM*	1.4 14.4 % ▼	0.9	2.9
Profile	Blood	MID	0.6 6.2 %	0.3	0.9
Method	Open Tube	GRA	8.2 ▲ 79.4 %	1.2	8.0
Operator		HGA	11.2 ▼	11.5	16.5
Sample ID 1		MCH	31.5	25.0	35.0
30261084		MCHC	35.7	31.0	38.0
		RBC	3.57 ▼	3.90	5.72
		MCV	88.0	81.2	98.3
		HCT	31.4 ▼	35.0	55.0
		RDW	13.5 % 62.7	11.8 %	15.6 %
		PLT*	24 ▼	150	450
		MPV		6.5	11.0
		PDW%		0.1 %	99.9 %
		PCT		0.01	9.99
		P-LCR		0.1 %	99.9 %

Fig 6. If PLT extended counting time is enabled and a low PLT is detected during analysis, the extended counting time will be displayed on the counting phase screen, and then indicated by an asterisk (*) adjacent to the PLT parameter on the result screen and in printouts and exported PDFs.

WBC count is conducted in the WBC chamber, and the differentiation into lymphocytes (LYM), granulocytes (GRA), and mid-sized (MID) cell is performed using fixed discriminators (Fig 7). The WBC histogram is automatically adjusted depending on the number of cells, that is, expanded for low values and compressed for high values.

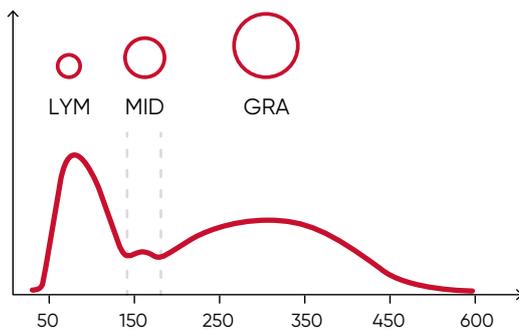


Fig 7. Swelab Alfa Plus uses fixed discriminators for the differentiation of the WBC cells into LYM, MID-cells and GRA. The LYM region ranges from 30 to 140 fL, the MID discriminator of WBC is set to 140 and 180 fL, and the GRA region ranges from 180 to 600 fL.

HGB is determined from the same dilution as the WBC (Fig 8). The HGB reading is slightly corrected for turbidity in case of extreme WBC counts. When the analyzer is in standby mode, the LED lamp is switched off to extend its lifetime.

$$\text{HGB (g/L)} = \text{Constant} \times \ln \left(\frac{\text{Blank photocurrent}}{\text{Sample photocurrent}} \right)$$

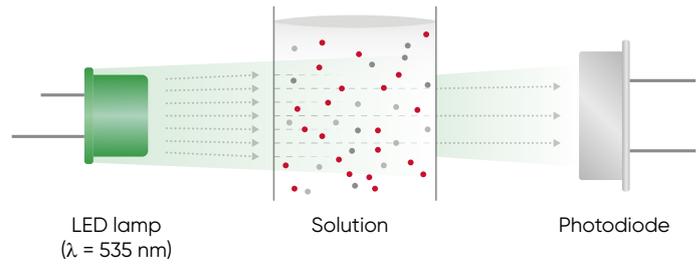


Fig 8. HGB is determined spectrophotometrically, using a LED lamp mounted on one side of the WBC chamber. The light is allowed to pass the flow chamber and transmitted light is detected by an optical sensor mounted on the opposite side. HGB concentration is calculated as a difference of a blank and a blood measure with and without illumination to reduce the effect of liquid refraction and disturbing light.

Liquid system

The fluidic system is controlled by pumps that generate pressure and vacuum. Reagent pipettes, featuring optical sensors, ensure accurate dilution of the sample. No pistons or other moving parts are used in the dilution system to minimize the maintenance and service needs. For the cell count, measuring pipettes equipped with liquid start and stop sensors ensure that a correct volume is used for analysis. The air pump generates a pressure that pushes the finally diluted sample through the aperture in the measuring chambers. To reduce risk for clogging, high voltage burning of the aperture (based on generated air bubbles) is automatically carried out, but only when needed to reduce wear and tear.

To minimize user intervention, the analyzer performs automatic cleaning every 12 hours. Boule designed low-maintenance valves automatically relieve upon standby or after a power down cycle to prevent wearing of the tubing.

It is recommended to keep the analyzer switched on at all times. The instrument will automatically enter standby after a user-settable idle time. In case the analyzer needs to be turned off, for example, for transportation (< 12 h), use the **Power Down** button in the **Maintenance** menu. Power down ensures proper shutdown of the software and preparation of the liquid system prior to power off. When the display goes blank, the analyzer can be securely turned off. For long-term storage (> 12 h), the analyzer should be cleaned and emptied before power down. For more information, please refer to Section 10 "Analyzer care and maintenance" in the user manual.

When put into use after being turned off, use the **Power-up** function to prime the analyzer. Upon selecting **Power-up** or **Exit standby**, the valves will close and the analyzer will be ready for use.

In the event of an error message, verify that the analyzer is filled and run a prime cycle, using built-in maintenance tools. The prime cycle is used to reset the analyzer after an error has been indicated or a failure in running a sample occurs.

Reagents

Only two reagents are required for the Swelab Alfa Plus analyzer—Diluent and Lyse—which greatly facilitates handling and logistics and helps reduce running costs. Simply scan the RFID card on the reagent container and the analyzer stores key information such as lot number, open and expiry dates, and remaining volume. The measurement principle is depicted in Figure 9.

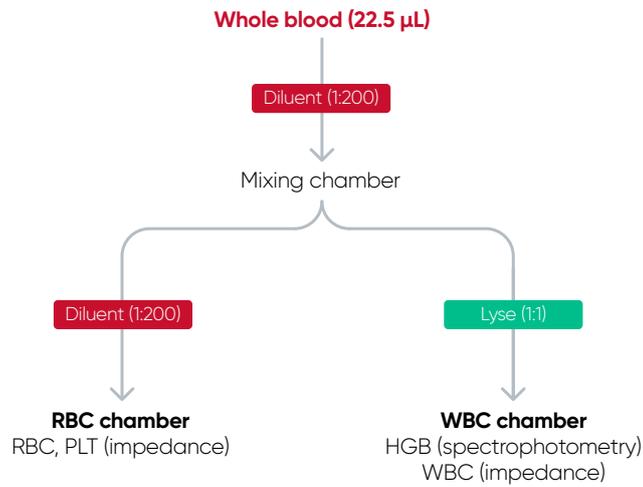


Fig 9. Swelab Alfa Plus measurement principle.

Not only is the blood dilution ratio critical for an accurate count. The reagent composition is also of utmost importance for reliable results. The Diluent should provide an isotonic environment for the RBCs and PLTs, while the Lyse reagent should be capable of lysing the RBCs to release HGB and shrink the WBCs to allow differentiation of these cells into their subgroups. Boule's cell count processes have been tested and optimized for decades for robust and reliable analysis results. The use of the reagents designed by Boule Diagnostics for the specific instrument ensures analytical quality and performance of the hematology system.

To avoid reagent shortage and to ensure an exact sample dilution each time, Boule adds a small extra volume to each reagent container. To prevent air from entering the system, the small volume that is left in the container when all cycles are consumed should not be used. To mitigate the contamination risk, the left-over volume should not be mixed with reagent in a newly opened container.

System performance

Swelab Alfa Plus provides a robust performance, with analysis results comparable with those from a more advanced reference instrument (Fig 10).

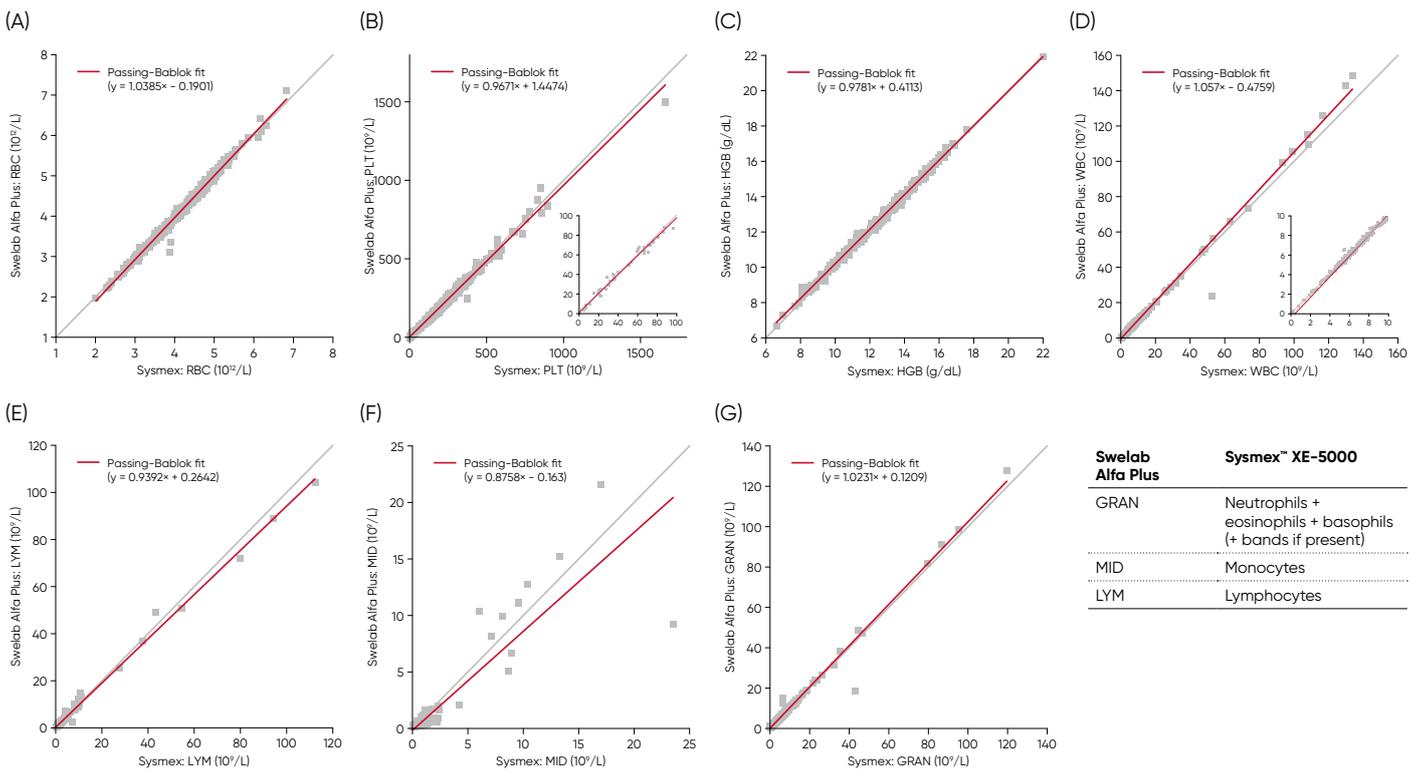


Fig 10. Agreement between Swelab Alfa Plus hematology system and a Sysmex XN-5000 reference systems intended for the larger hospital laboratory. For comparison with the Swelab Alfa Plus 3-part differentiation of the WBCs, results from the Sysmex 5-part differentiation of the WBCs were combined into GRAN, MID and LYM. Correlation plots for (A) RBC, (B) PLT (C) HGB, (D) WBC, (E) LYM, (F) MID, (G) GRAN. In the regression plots, the gray line corresponds to identity ($x = y$) and the red line corresponds to best fit.

Instrument maintenance

Designed with few moving parts, a maintenance-free closed shear valve design, and with the majority of the instrument cleaning procedures being automated, the user maintenance of Swelab Alfa Plus analyzer is kept to a minimum. However, some user intervention is still required. Section 10 "Analyzer care and maintenance" in User manual contains information on how to maintain the Swelab Alfa Plus analyzer. An overview of maintenance procedures is given in Table 1.

Good practice also dictates keeping the instrument clean from dust and other impurities. Regularly, check if there is dust inside the instrument. At the same time, check that reagent connection or waste tubes are not bent or squeezed. Also, regularly check for possible leakages from components inside the instrument. The system software monitors a number of system functions and will display information that alerts the operator to check the system or sample, or institute selected troubleshooting procedures.

Table 1. Scheduled maintenance

Procedure	Description	Frequency
Sample probe cleaning	Clean with 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.	Daily
Surface cleaning	Gently clean the display and/or outside of the analyzer with a soft cloth, slightly moistened with water and a mild soap. Dry carefully.	When necessary
Monthly cleaning	Fill a cup with 10 mL 2% hypochlorite, from Boule Cleaning Kit, and one cup with 18 mL Diluent. Aspirate the hypochlorite as a pre-dilute sample. Run 2 blank samples by aspirating Diluent as a pre-diluted sample. Perform a background check, in pre-dilute mode, to verify all values are within range.	Monthly
Clot prevention	Fill a small container with 5 mL of Enzymatic Cleaner from Boule Cleaning Kit. If analyzer has the optional cap piercer or autosampler, fill a clean standard 4.0–5.0 mL tube half full with Enzymatic Cleaner. From Main Menu , press Maintenance and then press Clot Prevention . <ul style="list-style-type: none"> For cap piercer: place filled cleaner tube into cap piercer, same as a normal sample analysis, close the door. For autosampler: place filled cleaner tube into Position 1 on wheel, lock wheel into place, and follow instructions. For open tube, hold the cleaner container under the OT probe, submerged in cleaner, press OK to confirm. The system will perform the cleaning process for all analysis modes simultaneously, and upon completion, the analyzer is ready for next analysis. Perform a background check to verify that all values are within range.	Monthly or every 1000 samples
Cleaning procedure	Select Main Menu , then Maintenance , and arrow over to next page to enter the Cleaning Menu . Follow instruction for use (IFU) for the Boule Cleaning Kit to clean the analyzer.	Less than 50 samples/day = every six months More than 50 samples/day = every three months 100–200 samples/day = every month.
Preventive maintenance (PM)	Inspection, and adjustments upon need, performed by an authorized service technician. PM kit available and included components should be exchange by an authorized service technician.	Every year or 20 000 samples

Quality control

Swelab Alfa Plus hematology analyzer is part of Boule's Total Quality Concept that is designed to increase the value of reported hematology results. Controls and calibrator are key elements of this initiative. Boule QC materials (Boule Con-Diff and Boule Cal) ensure that Swelab Alfa Plus performs accurately and delivers quality-controlled hematology results. Advanced quality control capabilities built into the Swelab Alfa Plus software include Mean, SD, CV, Levey-Jennings charts, XB-function, and QC reports.

The analyzer has been factory calibrated prior to shipment. If necessary, however, a calibration functionality is available. Good laboratory practice dictates regular checks and calibration of the measured parameters. Only authorized operators can update or change calibration factors.

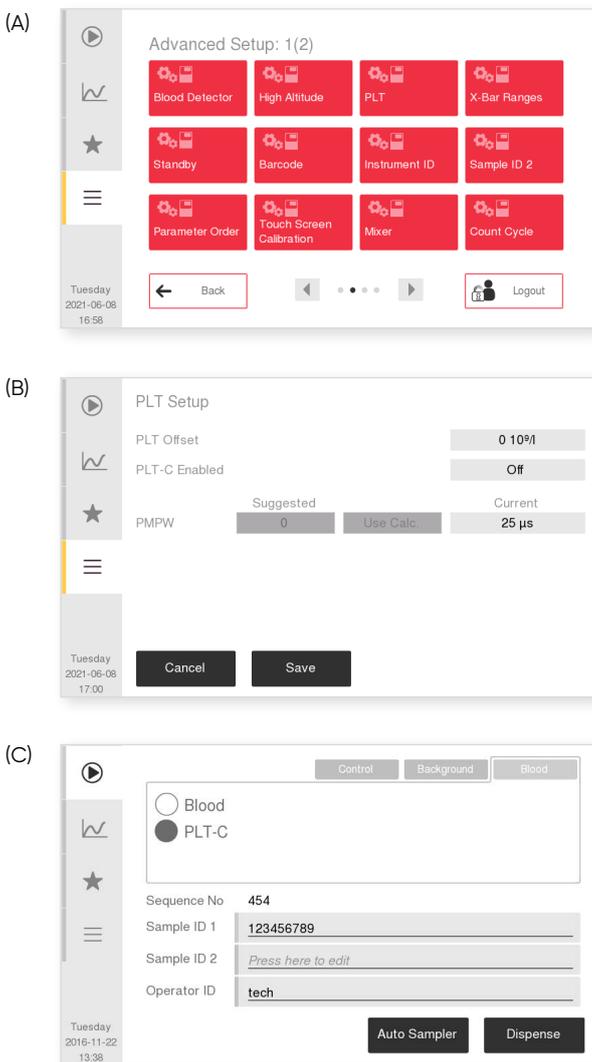


Fig 11. PLT-C profile is available in all analyzers with software version 1.3 or higher. (A) The profile is activated in **Advanced Setup**. (B) After entering the login code, go to **PLT Setup** menu and (C) enable **PLT-C**. In the **Start** menu, the PLT-C profile will thereafter be available as an option.

Blood bank application for PLT concentrates

The Swelab Alfa Plus blood bank application resides in the Swelab Alfa Plus analyzer as a special analysis profile. The factory default blood bank profile is named PLT-C (i.e., PLT concentrate). This profile is pre-installed in the instrument and can be activated by the service technician upon delivery of the instrument (Fig 11).

The PLT linearity range in the PLT-C profile is 10–5000 × 10⁹/L, as compared with 10–1800 × 10⁹/L in the normal blood profile. RBC concentrates are analyzed in the normal blood profile, with a linearity range of 0.30–7.00 × 10¹²/L. Plots of recovered versus theoretical values show good conformity over the linearity range for both PLT and RBC concentrates (Fig 12).

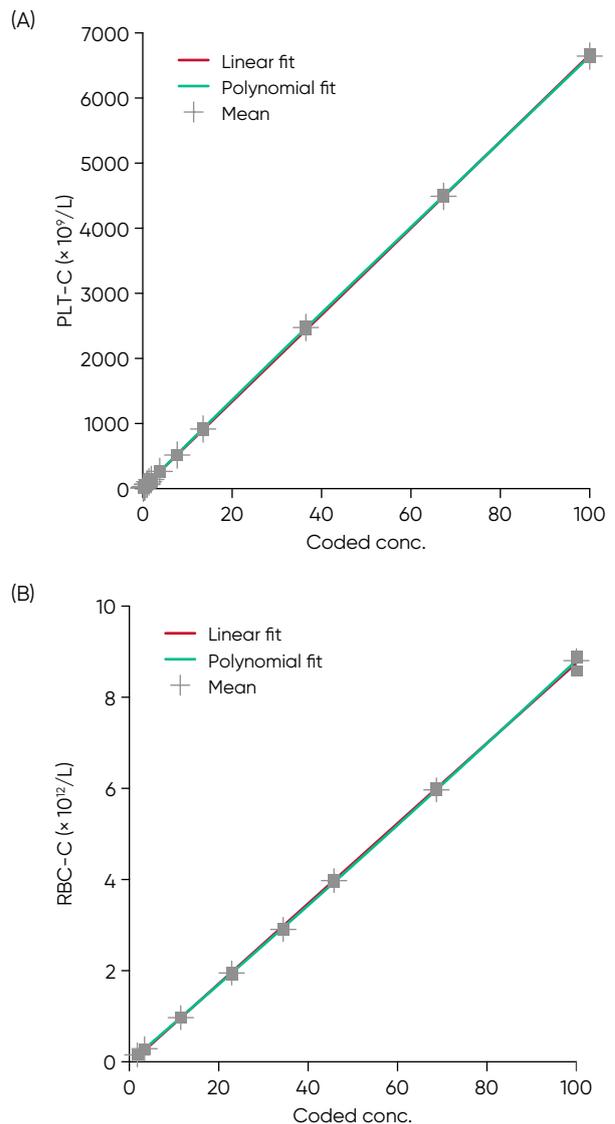


Fig 12. Recovered vs theoretical values for (A) PLT linearity and (B) RBC linearity. PLT concentrates were analyzed using the PLT-C profile, while RBC concentrates were analyzed using the normal blood profile.

Specifications

Swelab Alfa Plus is available in multiple models to fit the needs of various users (Table 2).

Main system specifications are listed in Table 3.

Table 2. Swelab Alfa Plus analyzer models



Model characteristics	Basic	Standard	Cap	Sampler
Built-in tube mixer		•		•
Micro-pipette adapter (MPA)		•	•	•
Shear valve sample aspiration	•	•	•	•
Pre-dilution mode	•	•	•	•
Cap-piercing device			•	•
Autosampler				•

Table 3. Swelab Alfa Plus system specifications

Parameters	16 for diagnostic use 6 for research use	WBC, LYM, MID, GRAN, LYM%, MID%, GRAN%, RBC, MCV, HCT, PLT, MPV, HGB, MCH, MCHC, RDW% RDW, PCT, PDW%, PDW, P-LCR, P-LCC
Throughput	60 samples/hour 50 seconds, time to results, OT inlet	
Sample volume	Open tube (OT) Capillary (MPA) Prediluted Cap piercer Autosampler	110 µL 20 µL 20 µL 250 µL 300 µL
Reagents	2 RFID locked reagents are used for analysis:	<ul style="list-style-type: none"> • Swelab AlfaDiluent • Swelab AlfaLyse
Display	7 inch TFT touch screen	
Data storage capacity	50 000 samples	
Interface ports	4 USB ports, 1 LAN port that supports LIS/HIS communication through HL7 protocol	
Printout	Postscript-compatible printers supporting PCL 3/5e	
Precision	WBC CV ≤ 3.5% RBC CV ≤ 1.8% MCV CV ≤ 1.5% HGB CV ≤ 1.5% PLT CV ≤ 5.2%	
Dimension	295 (W) × 475 (D) × 395 (H) mm (Basic/Standard/Cap) 340 (W) × 475 (D) × 395 (H) mm (Sampler)	
Weight	≤ 18 kg (Basic/Standard/Cap) ≤ 22 kg (Sampler)	

Ordering information

Product	Product code	
	EU*	US*
Swelab Alfa Plus Basic	1420041	
Swelab Alfa Plus Standard	1420042	
Swelab Alfa Plus Cap	1420043	
Swelab Alfa Plus Cap AR	1420044	
Swelab Alfa Plus Sampler BD AR	1420046	
Swelab Alfa Plus Sampler SA AR	1420048	
Swelab AlfaDiluent, RFID, > 900 cycles	1504462	
Swelab AlfaLyse, RFID, > 900 cycles	1504463	
Swelab Alfa ComboPack, RFID, > 200 cycles	1504464	
Swelab AlfaDiluent (21 kg) > 900 cycles	1504124	501-208
Swelab AlfaLyse (6 kg) > 900 cycles	1504125	501-207
Swelab Alfa ComboPack (7 kg) > 200 cycles	1504127	
Boule Cleaning Kit, 3 × 450 ml	1504111	501-036
Boule Enzymatic Cleaner, 100 mL	1504112	
Boule Hypochlorite 2,0% Cleaner, 500 mL	1504113	
Boule Con-Diff Normal, 1 × 4.5 mL	1504019	
Boule Con-Diff Low, 1 × 4.5 mL	1504020	
Boule Con-Diff High, 1 × 4.5 mL	1504021	
Boule Con-Diff Tri-Level, 2 × 3 × 4.5 mL	1504022	502-012
Boule Con-Diff Normal, 6 × 4.5 mL	1504043	
Boule Con-Diff Low, 6 × 4.5 mL	1504176	
Boule Con-Diff High, 6 × 4.5 mL	1504216	
Boule Cal, 1 × 3 mL	1504025	502-018
Boule Cal, 2 × 3 mL	1504045	

* Location of manufacturing. For availability in your country, please contact your local Boule representative.

AR = automatic barcode reader

BD = autosampler for BD tubes

SA = autosampler for Sarstedt tubes

Product	Product code
User manual: Swelab Alfa Plus	1504492
Flyer: Swelab Alfa Plus	38939
Application Note: Clinical performance of Swelab Alfa Plus 3-part hematology analyzer compared with a reference 5-part instrument	31785
Application Note: Comparison of capillary and venous blood samples on Swelab Alfa Plus hematology analyzer	31783
Application Note: Swelab Alfa Plus hematology analyzer helps ensure secure and efficient use of blood donations	32007

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