pm
product manual

element HT5+
Veterinary Hematology Analyzer

HESKA

Table of Contents

1.1 Introduction

This section explains how to use the Element HT5+® Hematology Analyzer Product Manual, which is available on line at www.heska.com/productmanuals/ and contains reference information about the analyzer and procedures for operating, troubleshooting and maintaining the analyzer. Read this manual carefully before operating the Element HT5+ Hematology Analyzer and operate the Element HT5+ Hematology Analyzer as instructed in this manual.

1.2 Who Should Read This Manual

This product manual is intended to be read by veterinary clinical laboratory professionals. This equipment must only be operated by skilled/trained professionals. This manual contains information for clinical laboratory professionals to:

- Learn about the Element HT5+ Hematology Analyzer.
- Customize system settings.
- Perform daily operating tasks.
- Perform system maintenance and troubleshooting.

1.3 How to Find Information

This operator's manual comprises 11 sections and multiple appendices. Refer to the table below to locate needed information.

If you want to …	See …
Learn about the intended use and parameters of the Element HT5+ Hematology Analyzer	*Section 2: Understanding the Analyzer*
Learn about the Element HT5+ Hematology Analyzer hardware, interface and software	*Section 2: Understanding the Analyzer*
Learn how the Element HT5+ Hematology Analyzer works	*Section 3: Understanding the System Principles*
Learn about the Element HT5+ Hematology Analyzer installation requirements	*Section 4: Analyzer Installation*
Learn about the sample collection and analysis process	*Section 5: Analyzer Operation*
Learn how to use the Element HT5+ Hematology Analyzer to perform daily operating tasks	*Section 5: Analyzer Operation*
Reviewing sample results	*Section 6: Reviewing Sample Results*
Learn how to use the quality control programs for the Element HT5+ Hematology Analyzer	*Section 7: Using the QC Programs*
Calibrate the Element HT5+ Hematology Analyzer	*Section 8: Using the Calibration Programs*
Define/adjust system settings	*Section 9: Customizing the Analyzer Software*
Maintain/service the Element HT5+ Hematology Analyzer	*Section 10: Analyzer Maintenance*
Troubleshoot the Element HT5+ Hematology Analyzer	*Section 11: Troubleshooting*
Know the technical specifications of the Element HT5+ Hematology Analyzer	*Appendix A: Specifications*

1.4 Conventions Used in This Manual

This manual uses certain typographical conventions to clarify meaning in the text:

Format	Indication
xx	Bold letters indicate a key name on the analyzer or external keyboard, such as **ENTER.**
xx	Italicized letters indicate section titles, such as *Section 1: Using This Manual.*

All illustrations in this manual are provided as examples only. They may not necessarily reflect the Element HT5+ Hematology Analyzer's set up or data displayed.

1.5 Safety Information

The following symbols are used to indicate danger and alert information in this manual:

When you see…		Then…
	BIOHAZARD	The statement is alerting you to a potentially biohazardous condition.
	WARNING	The statement is alerting you to an operating hazard that can cause personnel injury.
	CAUTION	The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
	NOTE	The statement is alerting you to information that requires attention.

 BIOHAZARD

All the samples, controls, calibrators, reagents, waste and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (*e.g.*, gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

If the analyzer leaks, the leak liquid is potentially biohazardous.

 WARNING

- Please check the firmness of all the doors and covers before running the analyzer.
- Make sure all the safety measurements are adopted. Disabling any safety device or sensor is prohibited.
- Please take action to address any alarm and problem indication immediately.
- Do not touch the moving parts.
- Contact Heska or Heska-authorized distributors if any damaged part is found.
- Be careful when opening/closing and removing/installing the doors, covers and boards of the analyzer.
- Discard the analyzer according to government regulations.
- Do not contact the patients' sample blood directly.
- Be sure to dispose of reagents, waste, samples, consumables, *etc.*, according to local regulations.
- The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (*e.g.,* gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.
- Keep your clothes, hair and hands away from moving parts to avoid injury.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
- Before maintaining or servicing the analyzer, its surface or the sample probe and other parts concerned must be

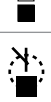
cleaned and sterilized (it is recommend that the parts be wiped with alcohol of which the concentration is 75%) to avoid biohazards or other damages.

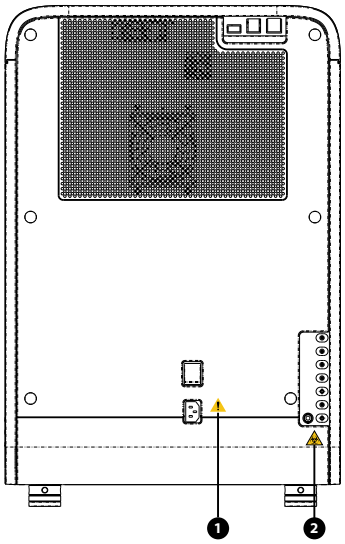
CAUTION

- Please use the analyzer strictly according to this manual.
- Please adopt proper measurements to prevent the reagents from being contaminated.

NOTE: Use the reagents specified by the manufacturer only. Store and use the reagents as instructed by instructions for use of the reagents. Check if the reagent tubes are properly connected before using the analyzer.

1.6 Symbols

You may find the following symbols on the analyzer:			
	**WARNING/CAUTION:** Consult Accompanying Documents		Manufacturer
	BIOLOGICAL RISK		Date of Manufacture
	WARNING: LASER BEAM		Ground
	**CAUTION:** Avoid aspiration probe.		Network Port
	Prohibited		Mandatory Action
	USB Port	LOT	Batch Code
	Alternating Current	SN	Serial Number
	Humidity limitation		Temperature Limitation
	Atmospheric pressure limitation		Use By
	CE Mark		Consult the User Manual
	Power OFF		Power On
	Fragile, Handle with Care		Keep Dry
	Stacking Number Limit		This Way Up
	Do Not Roll		NRTL certification mark
	The device fully conforms with the council directive concerning *In Vitro* diagnostic medical devices 98/79/EC.		
	The following definition of the WEEE label applies to EU member states only: the use of this symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. By ensuring that this product is disposed of correctly, it will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom the product was purchased.		



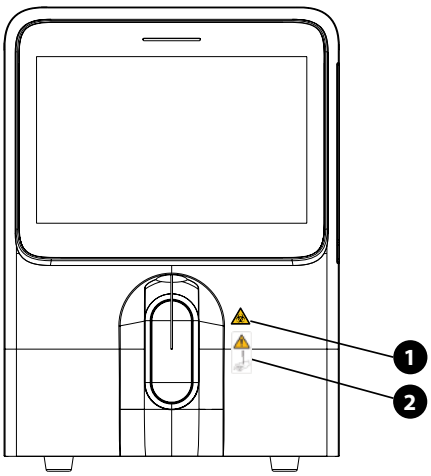
Analyzer Back

CAUTION

Connect only to a properly grounded outlet.
To avoid electric shock, disconnect power cord prior to removing or replacing fuse.
Replace fuse only with the type and rating specified.

BIOHAZARD

Warning, potential biological risk.



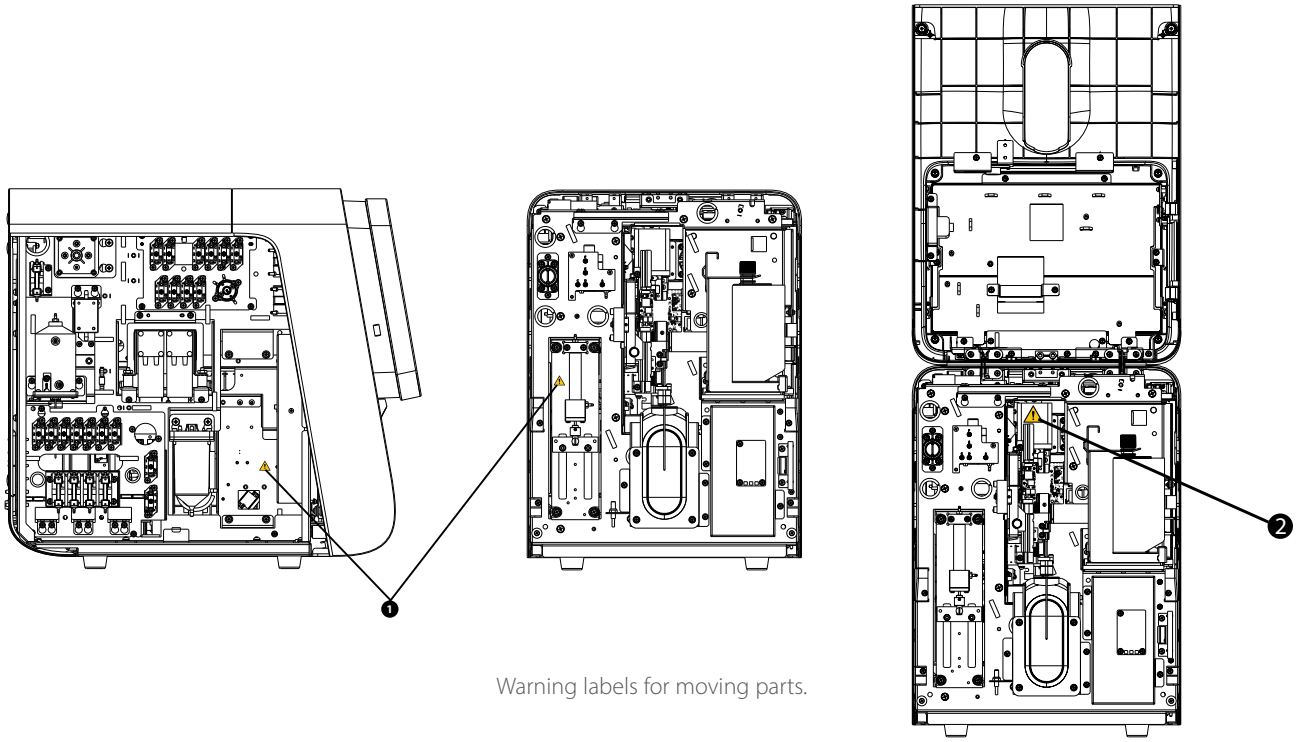
Analyzer Front

BIOHAZARD

Warning, potential biological risk.

WARNING

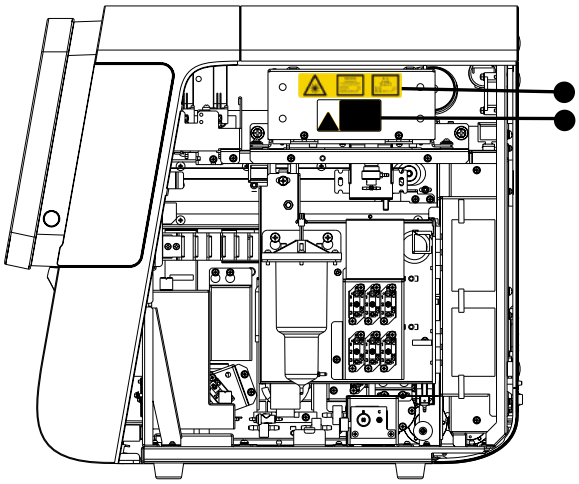
The sample probe is sharp and is a potential biohazard. Exercise caution to avoid contact with the probe when working around it.



Warning labels for moving parts.

⚠ WARNING

1. To avoid personal injury, do not put hand under the syringe or inside the slot.
2. To avoid personal injury, do not put hand under the pipette assembly or inside the moving track.



Optical assembly laser warning labels.

CAUTION

Class 3B laser radiation when open and internal locks defeated. Avoid exposure to the beam.

Laser radiation. Avoid exposure to beam. Class 3B laser product.
Peak power: 10 mW
Wavelength: 635 nm

2.1 Introduction

The Element HT5+ System is a veterinary specific hematology cell counter using proven laser flow cytometry, impedance technology, colorimetric detection, SF Cube cell analysis, and 3rd generation fluorescent dye technology. The Element HT5+ System is pre-programed to provide a complete 26 parameter complete blood count (CBC) including 5-part white blood cell differential, reticulocyte count, flags for abnormal cell morphology, and graphical interpretations including 4 scatterplots and 2 histograms per patient sample.

2.2 Parameters

NOTE: The purpose of this analyzer is to identify the normal patient, with all normal system-generated parameters, and toflag or identify patient results that require additional studies.

The analyzer determines 26 parameters, 2 histograms and 4 scattergrams of blood samples. The parameters under CBC+DIFF mode are listed as follows:

Parameter Group	Name	Abbreviation	CBC and DIFF
WBC group (11)	White blood cell count WBC	WBC	√
	Neutrophils number	Neu#	√
	Neutrophils percentage	Neu%	√
	Lymphocytes number	Lym#	√
	Lymphocytes percentage	Lym%	√
	Monocytes number	Mon#	√
	Monocytes percentage	Mon%	√
	Eosinophils number	Eos#	√
	Eosinophils percentage	Eos%	√
	Basophils number	Bas#	√
	Basophils percentage	Bas%	√
RBC group (10)	Red blood cell count	RBC	√
	Hemoglobin concentration	HGB	√
	Mean corpuscular volume	MCV	√
	Mean corpuscular hemoglobin	MCH	√
	Mean corpuscular hemoglobin concentration	MCHC	√
	Red blood cell distribution width - coefficient of variation	RDW-CV	√
	Hematocrit	HCT	√
	Reticulocyte count	RET#	√
	Reticulocyte percentage	RET%	√
	Reticulocyte hemoglobin expression	RHE	√

Parameter Group	Name	Abbreviation	CBC and DIFF
PLT group (4)	Platelet count	PLT	√
	Mean platelet volume	MPV	√
	Platelet distribution width	PDW	√
	Plateletcrit	PCT	√

Parameter Group	Name	Abbreviation	CBC+DIFF
Auxiliary group (8)	Platelet large cell count	P-LCC	√
	Platelet large cell ratio	P-LCR	√
	Immature platelet fraction	IPF	√
	High fluorescence reticulocytes	HFR	√
	Medium fluorescence reticulocytes	MFR	√
	Low fluorescence reticulocytes	LFR	√
	Immature reticulocyte fraction	IRF	√
	Red blood cell distribution width standard-deviation	RDW-SD	√

NOTE: The 'Auxiliary Group' are parameters still being researched at this time. They will show up on the analyzer display but shouldn't transfer to LIMS patient reports. The P-LCR an d P-LCC parameters are not applicable to feline blood samples.

2.2.1 Histograms

Name	Abbreviation	CBC+DIFF
Red blood cell histogram	RBC histogram	√
Platelet histogram	PLT histogram	√

2.2.2 Scattergrams

Name	Abbreviation	CBC+DIFF
Differential scattergram	Diff scattergram	√
Reticulocyte scattergram	RET scattergram	√
Optical platelet scattergram	PLT-O scattergram	√
Reticulocyte extension scattergram	RET-EXT Scattergram	√

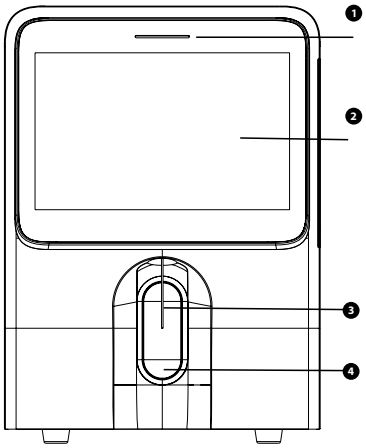
NOTE: √ means, available under the mode; / means, not available under the mode.

2.3 Product Description

Element HT5+ Hematology Analyzer includes the Sample Processing Unit (SPU), Data Managing Unit (DMU), Result Output Unit (ROU) and accessories. The appearance of the product is featured below.

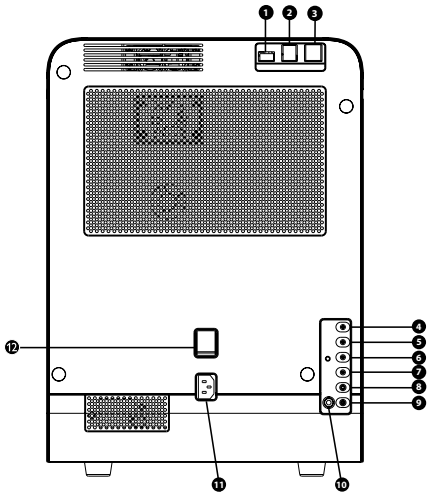
⚠ **WARNING. Ensure dye compartment door is closed before operating the analyzer.**

2.3.1 Analyzer Front



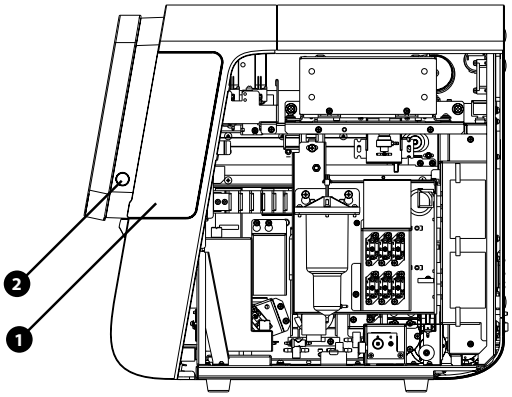
No.	Name	Description
1	Status indicator	The indicator is located on the top of the touch screen; and it displays the status of the instrument including ready, running, error, standby and on/off, *etc*. See *Section 2.4* for more information.
2	Touch screen	The touch screen is located on the front of the main unit, which can be used to operate the instrument and display information.
3	Sample probe	The sample probe is located on the lower front of the main unit, which aspirates samples and adds diluent.
4	Aspirate button	The aspirate button is behind the sample probe. Press the key to aspirate sample, add diluent, or return from standby.

2.3.2 Analyzer Back



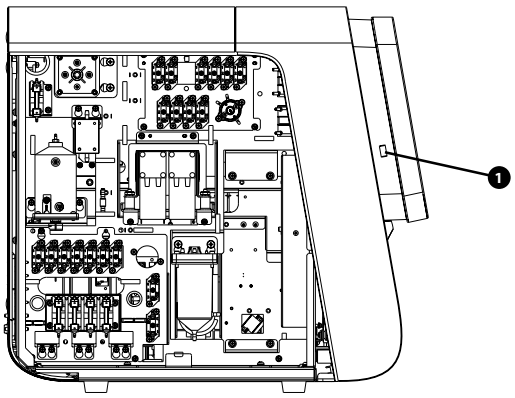
No.	Name	No.	Name
1	USB port (protocol 3.0)	7	Solution reagent inlet
2	USB port (protocol 2.0)	8	DS diluent inlet
3	Network interface	9	Waste outlet
4	DR diluent inlet	10	Waste sensor
5	LD lyse inlet	11	Power inlet
6	LH lyse inlet	12	Main power switch

2.3.4 Analyzer Right Side



No.	Name	No.	Name
1	Dye compartment door	2	Standby button

2.3.5 Analyzer Left Side



No.	Name
1	USB port (protocol 2.0)

Power switch

Main power switch is located on the back of the analyzer.

CAUTION

Do not turn on/off the switch repeatedly in a short time to avoid damaging the analyzer.

Aspirate key

The aspirate key is on the front of the analyzer. Touch it to start analysis, dispense diluent or exit from standby mode.

USB/network port

The USB port and network port are on the back of the analyzer. They can be used to connect the printer and to transmit data.

The supported printer models are the HP Laser Jet Pro M404n and HP Office Jet Pro 8210.

2.4 Status Indicator

The status indicator is on the front of the analyzer; it indicates the ready, running, error and standby status of the analyzer.

The indicator illuminates in 3 colors to indicate the current status of the analyzer; its flashing interval is 2 seconds. See the indicator and status table below.

Status	Indicator	Note
Ready	Solid green	Ready to sequence actions.
Running	Flashing green	Sequence actions in progress.
Running with error	Flashing red	The analyzer is running with error.
Error	Solid red	An error has occurred, and the analyzer is not running.
In standby mode	Solid orange	Analyzer is currently in standby mode.

2.5 System Menu

Icons	Name	Function
	Menu	Touch to display the system menu.
	Count	Touch to enter the Count screen. Displays function buttons related to sample analysis.
	Table review	Touch to enter the Table Review screen. Displays position of the current sample and total number of samples.
	Quality control	Touch to enter to enter the QC screen. When the QC button is lighted in orange, it means the analyzer is out of quality control.
	Reagent setup	Touch to enter the Reagent Setup screen. When the Reagent Setup button lights in orange, it means some reagent is expired or not sufficient.
	Diluent	Touch to enter the Diluent screen.
	Print	• When the analyzer is on the Count screen, touch Print to print the analysis results, histograms and scattergrams of the current sample in accordance with operator-customized print template. • When the analyzer is on the Table Review screen, touch Print to print the analysis results for all or selected samples in the table print or graph print form. • When the analyzer is on the Graph screen, touch Print to print the analysis results, histograms and scattergrams of the current sample in accordance with operator-customized print template. • When the analyzer is on the QC Table screen, touch Print to print all QC results included in the selected QC file. • When the analyzer is on the QC Graph screen, touch Print to print the QC graphs included in the selected QC file. • When the analyzer is on the Manual screen, touch Print to print the manual calibration factors.

2.6 Reagents, Controls and Calibrators

The analyzer, reagents (diluents, lyses, dyes and cleaners), controls, and calibrators are components of a system. Performance of the system depends on the combined integrity of all components. Only Heska-specified reagents (see *Appendix A: Specifications*), which are formulated specifically for the fluidic system of the analyzer in order to provide optimal system performance, should be used. Do not use the analyzer with reagents from any other suppliers. Otherwise, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.

Each reagent package must be examined before use. Product integrity may be compromised in packages that have been damaged. Inspect the package for signs of leakage or damage. If there is evidence of leakage or improper handling, do not use the reagent.

NOTE: Store and use the reagents as instructed:

- When the diluent or lyse has been changed, implement a background test to confirm the results meet the specification.
- Note the expiration dates and open-container stability days of all the reagents. Do not use expired reagents.

2.6.1 Reagents

DS Diluent is used to dilute blood samples and provide an ideal environment for counting and sizing blood cells. Participates in the measurement of RBC, PLT, WBC, and RET parameters.

DR Diluent and FR Dye generate RET parameters.

LH Lyse generates HGB.

LD Lyse is used to to differentiate WBC.

Probe Cleanser and Solution Reagent are used to clean the analyzer.

2.6.2 Controls and Calibrators

The controls are commercially prepared whole-blood products used to verify that the analyzer is functioning properly. They are available in low, normal, and high levels. Daily use of all levels of controls and reticulocyte controls verifies the operation of the analyzer and ensures reliable results are obtained. The calibrators are commercially prepared whole-blood products used to calibrate the analyzer. Store and use the controls and calibrators as instructed.

All references related to controls and calibrators in this manual refer to the controls and calibrators specifically formulated for this Heska analyzer. Purchase these controls and calibrators from Heska or Heska-authorized distributors.

3.1 Introduction

The measurement methods used in this analyzer are: sheath flow impedance, laser scatter, and SF cube cell analysis technology for cell differentiation and counting. Colorimetric method is adopted for HGB measurement. Other parameter results are obtained via calculation.

3.2 Aspiration

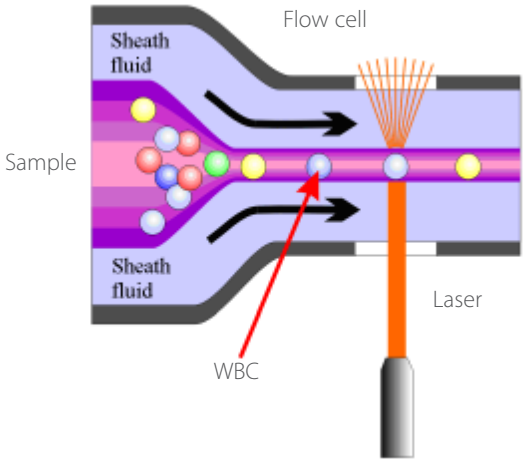
Analyzing a whole blood sample in the open vial sampling mode, the analyzer will aspirate 30–35 µL of the sample.

If analyzing a capillary blood sample in the open vial sampling mode, you will first manually dilute the sample (20 uL of capillary sample needs to be diluted by 100 uL of diluent) and then present the pre-diluted sample to the analyzer, which will aspirate 77.5 uL of the sample.

The aspirated sample will quickly and precisely be diluted in RBC bath and then segmented into two portions. One of these two portions will then be diluted again and processed by lyse reagents. After this, they are ready for analysis.

3.3 WBC Measurement

3.3.1 Laser Flow Cytometry & SF Cube Cell Analysis



Laser flow cytometry

In normal peripheral blood, white blood cells can be classified into five categories: lymphocytes, monocytes, neutrophils, eosinophils and basophils. Analyzing all types of white blood cells will provide a great deal of useful information for the clinical diagnosis of diseases. Under the influence of certain diseases, the peripheral blood may contain various abnormal cells apart from the five subpopulations of normal cells, such as atypical lymphocytes, immature cells, etc. Most of these abnormal cells are different kinds of immature cells in the cell generation process. But what they have in common is they contain a great deal of nucleic acid (DNA and RNA), the content of which decreases as the cell matures. Therefore, normal cells and immature cells can be differentiated by detecting the content of nucleic acid in the cells.

The analyzer adopts the SF Cube cell analysis technology to accurately recognize and detect the immature cells in blood based on WBC 5-part differentiation.

3.3.2 SF Cube Cell Analysis

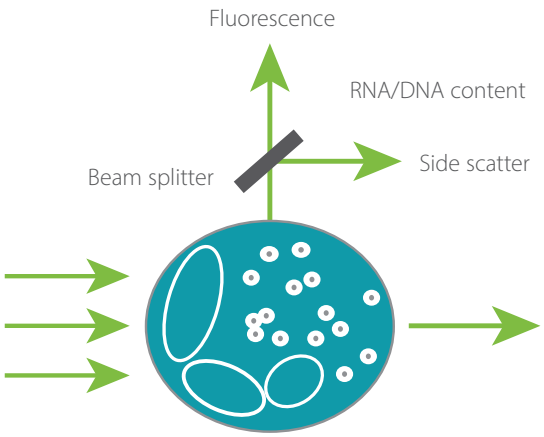
The analyzer adopts SF Cube cell technology to accurately recognize and detect the immature cells in blood.

The analyzer adopts the fluorescent staining technology in its DIFF channels. The RBCs are lysed via lyse diluent resulting in WBC subpopulations made to be different sizes and complexities. The nucleic acid substances in WBCs are marked by the new asymmetric cyanine fluorescent substance. Due to the different content of nucleic acid in different WBC subpopulations, maturity stages or abnormal development status, the volume of fluorescent dye staining the nucleic acid substances is different.

Thus the front scatter reflects the cell size, the side scatter reflects the intracellular granularity, and the intensity of fluorescent signal reflects the degree that the cell is stained. By sensing the difference in signal within three dimensions of the cells processed with lyse, the DIFF channel differentiates the subpopulations of WBCs (lymphocytes, monocytes, neutrophil, eosinophils and basophils). Flags are provided for suspected band cells, atypical lymphocytes, immature granulocytes and nucleated red blood cells.

Lymphocytes are smaller in size with a relative large nucleus . Lymphocytes have a high nucleus-to-cytoplasm ratio, but their nucleic acid content is low. Therefore, these are at a lower position in the direction of fluorescence and side scatter. The monocytes are larger in size, with high nucleus-to-cytoplasm ratio and high nucleic acid content, and less complex in structure. Therefore, these are at a higher position in the direction of fluorescence, and have stronger side scatter. The neutrophils and basophils are larger in size, and have medium nucleus-to-cytoplasm ratio and low nucleic acid content. Therefore, these are at a lower position in the direction of fluorescence, but have stronger side scatter. The volume and nucleus-to-cytoplasm ratio of the eosinophils are similar to those of the neutrophils. Eosinophils have a relatively low nucleic acid content, but they contain a lot of alkaline grains, so they have very strong side scatter.

Internal structure of a cell



SF cube technology

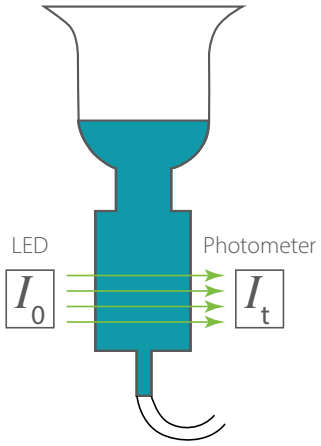
3.4 HGB Measurement

3.4.1 Colorimetric Method

According to the Lambert-Beer Principle, when a beam of monochromatic light passes through a well-proportioned non-scattering light-absorbing solution, the absorbance (A) is proportional to the product of the thickness (L) and the concentration (C). The sample in the HGB channel acts as the light absorbing substance after being treated by reagent, therefore the HGB concentration can be measured by measuring the absorbance.

3.4.2 HGB

The HGB is calculated per the following equation and expressed in g/dL (US) and g/L (SI).
HGB (g/L) = Constant × Ln (Blank Photocurrent/Sample Photocurrent).



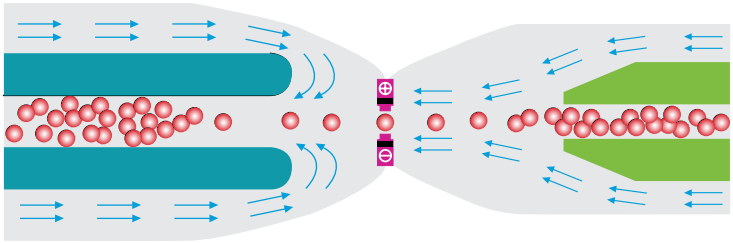
$$A = 1g \frac{I_0}{I_t} k \times C \times L$$

Colorimetry

3.5 RBC/PLT Measurement

3.5.1 Sheath Flow Impedance Method

RBCs/PLTs are counted by the sheath flow impedance method. A sensor is designed to enable the RBCs and PLTs to pass through the aperture one by one in a queue under the "focusing" effect of fluid, during which process pulses will be generated according to the Coulter Principle. The backend processor amplifies the pulses and compares with the voltage thresholds of the RBC/PLT channel, and then the number of pulses in the RBC/PLT channel is calculated. In other words, the pulses collected are sorted per the voltage thresholds of different channels, the number of pulses falling in the range of the RBC/PLT channel is the number of RBC/PLT. The number of cells in each channel defines the volume distribution of cells. The analyzer presents the RBC/PLT histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells. Compared with the common impedance method, the sheath flow impedance method is featured by higher efficiency, better signal quality, more accurate analysis results and lower consumption of reagents.



Secondary sheath flow Primary sheath flow

Sheath flow impedance method

3.6 Deriviation of Parameters

Derivation of RET—Related Parameters

The RET channel also adopts the SF CUBE cell technology. The general measurement principle in RET channel is similar to that of DIFF channel, only the RBCs are not lysed, but spherized and stained by fluorescent dye.

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of certain amplitude. If the pulse generated is above the RBC/PLT lower threshold, it is counted as a RBC/PLT. The analyzer presents the RBC/PLT histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells.

3.6.1 Derivation of WBC—Related Parameters

Parameters	Formula/Test Methods	SI Units	US Units
WBC	WBC = the sum of all particles in the DIFF channel except those in the Ghost region	10^9/L	10^3/μL
Bas#	Bas# = WBC × Bas%	10^9/L	10^3/μL
Bas%	$\text{Bas\%} = \frac{\text{Particles in the Bas region in the DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100$	%	%
Neu#	Neu# = WBC x Neu%	10^9/L	10^3/μL
Neu%	$\text{Neu\%} = \frac{\text{Particles in the Neu region in the DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100$	%	%
Eos#	Eos# = WBC x Eos%	10^9/L	10^3/μL
Eos%	$\text{Eos\%} = \frac{\text{Particles in the Eos region in the DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100$	%	%
Lym#	Lym# = WBC x Lym%	10^9/L	10^3/μL
Lym%	$\text{Lym\%} = \frac{\text{Particles in the Lym region in the DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100$	%	%
Mon#	Mon# = WBC x Mon%	10^9/L	10^3/μL
Mon%	$\text{Mon\%} = \frac{\text{Particles in the Mon region in the DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost region}} \times 100$	%	%

3.6.2 Derivation of RBC—Related Parameters

Parameters	Formula/Test Methods	SI Units	US Units
RBC	Red blood cell (RBCs) number is measured directly by counting the number of pulses in the RBC channel	10^6/μL	10^{12}/L
MCV	Calculated based on the red blood cell histogram	fL	fL
HCT	$\text{HCT} = \frac{\text{RBC} \times \text{MCV}}{10} \times 10$	%	%
MCH (US)	$\text{MCH (US)} = \frac{\text{HGB}}{\text{RBC}} \times 10$	pg	/
MCH (SI)	$\text{MCH (SI)} = \frac{\text{HGB}}{\text{RBC}}$	/	pg
MCHC (US)	$\text{MCHC} = \frac{\text{HGB}}{\text{HCT}} \times 100$	/	g/dL
MCHC (SI)	$\text{MCHC} = \frac{\text{HGB}}{\text{HCT}}$	g/L	/
RDW-CV	Derived from RBC histogram	%	%
RDW-SD	Derived based on standard deviation of red blood cell volume distribution	fL	fL

3.6.3 Derivation of RET—Related Parameters

Parameters	Formula/Test Methods	SI Units	US Units
RET%	$RET\% = \frac{\text{Number of cells in the RET region}}{\text{Number of cells in mature RBC region + Number of cells in RET region}}$	%	%
RET#	RET#= RBC-I × RET%	$10^3/\mu L$	$10^9/L$
HFR*	$HFR\% = \frac{\text{Number of cells in HFR region}}{\text{Number of cells in RET region}} \times 100$	%	%
MFR*	$MFR\% = \frac{\text{Number of cells in MFR region}}{\text{Number of cells in RET region}} \times 100$	%	%
LFR*	$LFR\% = \frac{\text{Number of cells in LFR region}}{\text{Number of cells in RET region}} \times 100$	%	%
IRF*	IRF = MFR + HFR	%	%
RHE	Calculated based on the light scatter information of RET	pg	pg

* Auxiliary parameters

3.6.4 Derivation of PLT—Related Parameters

Parameters	Formula/Test Methods	SI Units	US Units
PLT	The analyzer directly measures the platelet number from RET channel (for dog, cat, horse, rabbit, monkey, and pig) or sheath flow impedance channel (for rat, mouse, camel, alpaca, and llama)	$10^3/\mu L$	$10^9/L$
MPV	Calculated based on PLT histogram	fL	fL
PDW	Derived from the platelet histogram, reported as 10 geometric standard deviation. (10 GSD)	/	/
PCT	$PCT = \frac{PLT \times MPV}{10{,}000}$	%	%
P-LCR*	Derived from the platelet histogram. **NOTE**: Platelet-Large Cell Ratio (P-LCR) is derived from the platelet histogram. It represents the ratio of the number of platelets with a size over a threshold to the total platelets number (the threshold differs in different species).	%	%
P-LCC*	P-LCC= PLT × P-LCR	$10^3/\mu L$	$10^9/L$
IPF*	$IPF = \frac{\text{Immature platelet number in the optical channel}}{\text{Sum of all particles in the optical channel}}$	%	%

* Auxiliary parameters

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4.1 Introduction

⚠ WARNING

Installation by personnel not authorized or trained by Heska may cause personal injury or damage the analyzer. Do not install the analyzer without the presence of Heska-authorized personnel.

The installation, authorization, upgrade and modification of the analyzer software must be performed by Heska-authorized personnel.

The analyzer is tested before it is shipped from the factory. International symbols and special handling instructions tell the carrier how to treat this electronic instrument. When the analyzer is received, carefully inspect the carton. If there are any signs of mishandling or damage, contact Heska customer service department or the local distributor immediately.

4.2 Installation Requirements

4.2.1 Space Requirements

Check the site for proper space allocation. In addition to the space required for the analyzer itself, arrange for:

- Proper height to place the analyzer
- At least 50 cm on each side, which is the preferred access to perform service procedures
- At least 25 cm behind the analyzer for cabling and ventilation
- At least 60 cm above the analyzer
- Enough room on and below the counter top to accommodate the reagents and waste containers
- Diluent container shall be put on the counter or within 1.0 m under the analyzer
- The counter top where the analyzer is placed shall be able to withstand at least 68.34 lbs (31 kg) of weight

4.2.2 Power Requirements

⚠ WARNING

Make sure the analyzer is properly grounded.

Before turning on the analyzer, make sure the input voltage meets the requirements.

⚠ CAUTION

Using pin board may bring the electrical interference and the analysis results may be unreliable. Please place the analyzer near the electrical outlet to avoid using the pin board.

Please use the original power cable shipped with the analyzer. Using other power cable may damage the analyzer or cause unreliable analysis results.

Power Specification Table

	Voltage	Input Power	Frequency
Analyzer	(100 V–240 V~)±10%	300 VA	(50 Hz/60 Hz)±1 Hz

4.2.3 General Environment

- Optimal operating temperature: 50°F~86°F (10°C~30°C)
- Optimal operating humidity: 30%~85%
- Atmospheric pressure: 70 kPa~106 kPa
- The environment shall be as free as possible from dust, mechanical vibrations, loud noises, and electrical interference.
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
- Do not use this analyzer in close proximity to sources of strong electromagnetic radiation (*e.g.*, unshielded intentional RF sources), as these may interfere with the proper operation.
- Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close, such as a lab centrifuge.
- Do not place the analyzer in direct sunlight or in front of a source of heat or drafts.
- The environment must be ventilated.
- Install on a level surface.
- Connect only to a properly earth grounded outlet.
- For indoor use only.

4.2.4 Moving and Installing the Analyzer

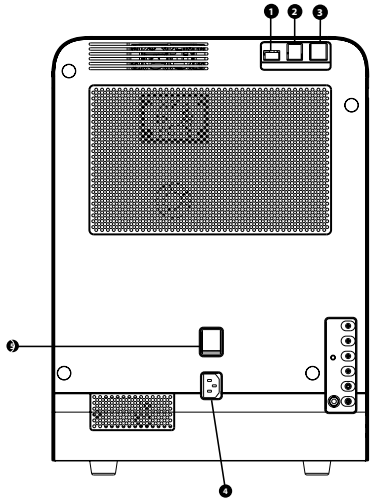
⚠ WARNING

Installation by personnel not authorized or trained by Heska may cause personal injury or damage the analyzer. Do not install the analyzer without the presence of Heska-authorized personnel.

Moving and installation of the analyzer shall be conducted by Heska-authorized personnel. Do not move or install the analyzer without the presence of Heska-authorized personnel.

4.3 Connecting the Analyzer System

Connect the analyzer and the reagents as shown in the following figures. Make sure the connections are correct and firm.



Connecting the analyzer to power outlet

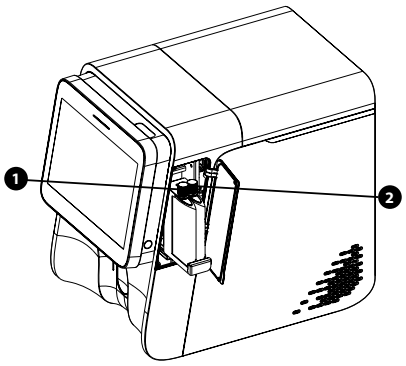
No.	Name	No.	Name
1	USB port (protocol 3.0)	4	Power inlet
2	USB port (protocol 2.0)	5	Power switch
3	Network interface		

⚠ WARNING

Be sure to dispose of reagents, waste, samples, consumables, *etc.*, according to regulations.

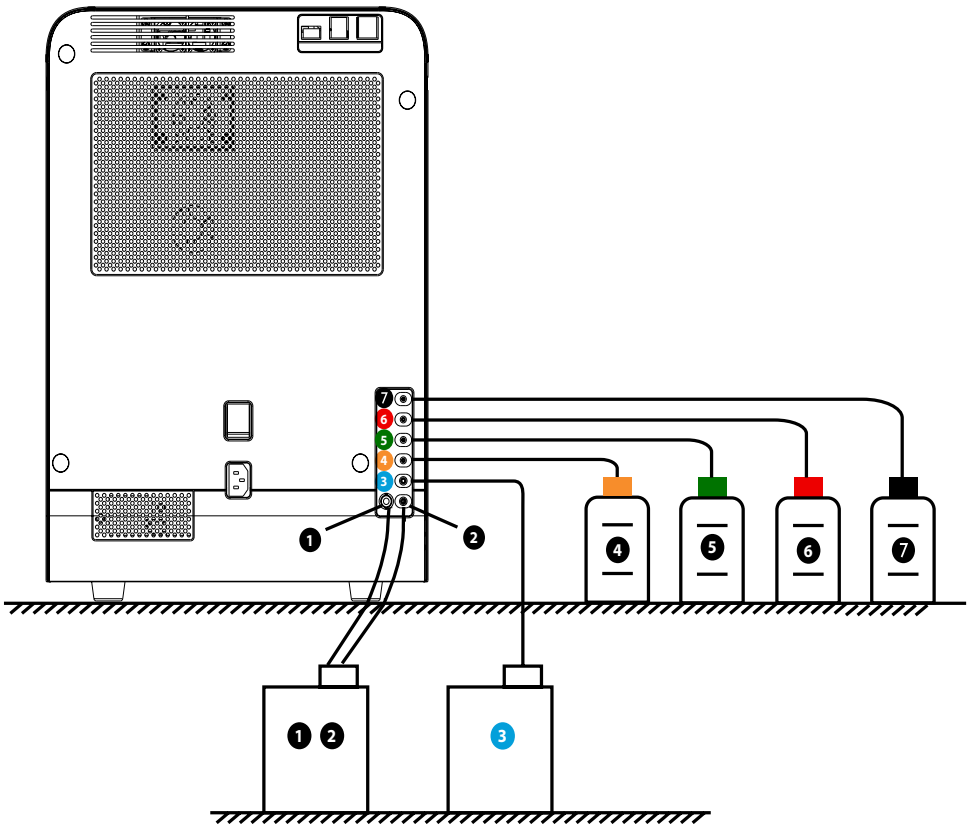
The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (*e.g.*, gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.



Connecting fluorescent dyes.

No.	Name	No.	Name
1	FD Dye	2	FR Dye



Connecting reagents and waste assembly.

No.	Name	No.	Name
1 2	Waste Container Interface 2 is used to connect the waste container, and interface 1 connects to the waste floater sensor to detect whether the waste container is full	5	LH Lyse
3	DS Diluent	6	LD Lyse
4	Solution Reagent	7	DR Diluent

⚠ CAUTION

Make sure the diluent pipe and waste pipe are no longer than 1500 mm.

The waste container must be placed lower than the counter top that accommodates the analyzer. The diluent container can be placed on the counter top or below the analyzer.

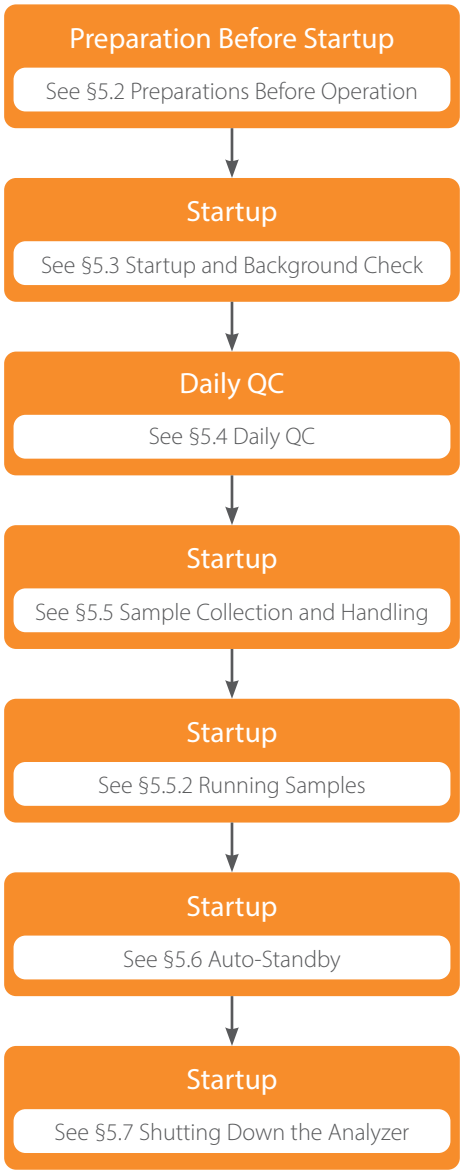
NOTE:

- The analyzer performance may be undermined if it has been placed in contaminated environment.
- The surface of the analyzer shall be cleaned and sterilized regularly with alcohol (75%).
- The probe wipe block of the analyzer (see Figure 2.3.1 Analyzer Front) shall be wiped with alcohol (75%) regularly.
- Sample collection and preparation must be done following standard procedures.
- If any tubing or fluidic components is worn out, stop using the analyzer and contact Heska's Technical Support Services immediately for inspection or replacement.
- Check and make sure the reagents, lyse and waste tubing are not pressed or bent.
- Only use the Heska-specified reagents, otherwise the analyzer may be damaged or provide unreliable results.
- Note the expiration dates and open-container stability days of all the reagents. Do not use expired reagents.

5.1 Introduction

This chapter provides step-by-step procedures for operating the analyzer on a daily basis.

A flow chart presenting the common daily operating process is shown below.



BIOHAZARD

All the samples, controls, calibrators, reagents, waste and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (*e.g.*, gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

⚠ CAUTION

- Do not contact the patients' sample blood directly.
- Be sure to dispose of reagents, waste, samples, consumables, *etc.*, according to local regulations.
- The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (*e.g.*, gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.
- Keep your clothes, hair and hands away from moving parts to avoid injury.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

⚠ CAUTION

Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.

NOTE:

- Use the reagents specified by the manufacturer only. Store and use the reagents as instructed by instructions for use of the reagents.
- Check that the reagent tubes are properly connected before using the analyzer.
- Be sure to use clean EDTAK2 or EDTAK3 anticoagulant collection tubes, fused silica glass/plastic test tubes and centrifugal tubes.
- Be sure to use the evacuated collection tubes recommended in the Appendix.
- Be sure to use the Heska-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes, *etc*.

5.2 Initial Checks

Perform the following checks before removing analyzer from standby.

1. Check the waste container.
   Check and make sure the waste container is not full.
2. Check reagents.
   Check to see if the reagents are expired, empty or frozen. Reagents must be equilibrated for 24 hours before use.
3. Check tubing and power connections.
   Check and make sure the reagents, waste and pneumatic unit tubes are properly connected and not bent.
   Check and make sure the power cord of the analyzer is properly plugged into the power outlet.
4. Check the printer (if applicable).
   Check and make sure enough printer paper is installed. Check and make sure the power cord of the printer is properly plugged into power outlet, and the printer is properly connected to the analyzer.

5.3 Startup and Background Check

1. Resume from Standby.
   1.1 Touch screen at prompt, Touch screen to access menu.
   1.2 Touch **ASPIRATE** key to exit Standby.
2. Run Probe Cleanser if prompted/required.
   2.1 Present Probe Cleanser to sample probe and touch **ASPIRATE** key.
   2.2 Probe Cleanser process takes approximately 13 minutes and is required once weekly..

3. Run Background check.
   3.1 From the Sample Analysis tab, touch **NEXT SAMPLE.**
   3.2 Touch **ASPIRATE** key to run Background.

NOTE:

- Background check is the measurement of particle and electric interference by the analyzer.
- See Appendix C.2: Specifications for the acceptable background range of each parameter.

5.4 Daily Quality Control

Perform daily quality control before running any samples. See *Section 7: Using the QC Programs* for details.

5.5 Sample Collection and Handling

BIOHAZARD

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (*e.g.,* gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

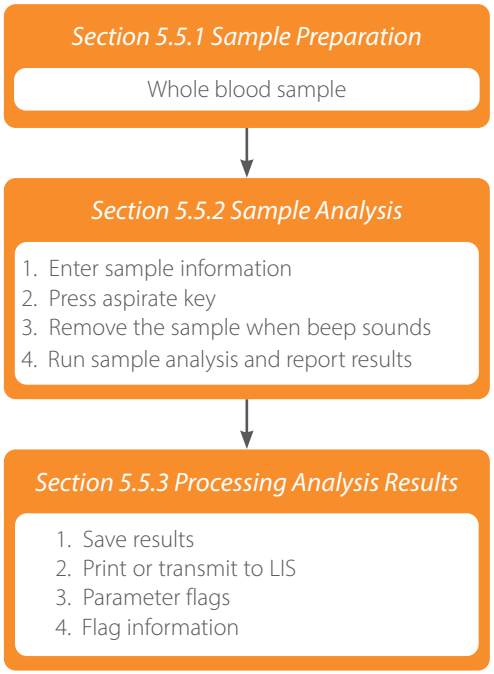
WARNING

The sample probe is sharp and potentially biohazardous. Do not contact the sample probe during operations.

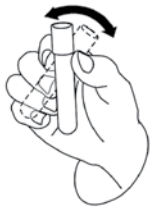
CAUTION

Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.

NOTE: Make sure the probe tip does not contact the sample tube to avoid a potential spill.



The analyzer can run whole blood samples or pre-diluted samples (mouse and rat species only).



5.5.1 Whole Blood Samples

1. Use clean EDTAK2 or EDTAK3 anticoagulant collection tubes to collect venous blood samples.
2. Mix the sample according to laboratory protocol.

⚠ CAUTION

Be sure to fill tubes at least 1/2 full with blood to ensure the accuracy of the results.

Pre-diluted samples

1. Touch **DILUENT** utility button to prepare the analyzer for dispensing diluent. When the preparation completes, a dialog box displays.
2. Present a clean tube under the sample probe.
3. Touch **ASPIRATE** key to dispense 100 µL diluent.
4. To continue with diluent dispensing, repeat step 3.
5. After diluent dispensing is completed, remove the tube and touch **CANCEL**.
6. Add 20 µL venous blood or capillary blood to the diluent, close the tube cap and mix it properly according to the laboratory's protocol.

NOTE:

- Pre-dilute mode is only applicable to rat and mouse species.
- You can also use pipette to aspirate 100 uL of diluent.
- Be sure to keep dust from the prepared diluent.
- After mixing the capillary sample with the diluent, be sure to wait 3 minutes and then re-mix before running the sample.
- Be sure to run the pre-diluted samples within 30 minutes after dilution.
- Be sure to mix any sample that has been prepared for a while before running it. Do not mix the samples with massive force using swirl mixer.
- Be sure to evaluate pre-diluted stability based on your laboratory's sample population and sample collection techniques or methods.

5.5.2 Preparing Body Fluid Samples

⚠ CAUTION

- **To ensure sample stability, process serous cavity fluid (pleural fluid and ascitic fluid) with EDTA anticoagulant.**
- **Do not process cerebrospinal fluid samples with anticoagulant.**
- **The viscosity of synovial fluid can lead to problems with proper fluid flow through the analyzer, preventing accurate cell counts and leading to obstruction of analyzer tubing. Assay of synovial fluid is not recommended.**
- **Ensure acceptable fluid types are free of visible flocculant material in order to prevent obstruction of analyzer tubing.**

NOTE: To attain accurate analysis result, run body fluid samples as soon as possible after collection. The subtype of body fluid supported by the analyzer include cerebrospinal fluid and serous cavity fluid (pleural fluid and ascitic fluid).

1. Use clean collection tube or syringe to collect body fluid samples.
2. Mix the sample according to your laboratory's protocol.

5.5.3 Whole Blood Sample Analysis

Touch **SAMPLE ANALYSIS** to enter the sample analysis screen.

1. Enter sample information.

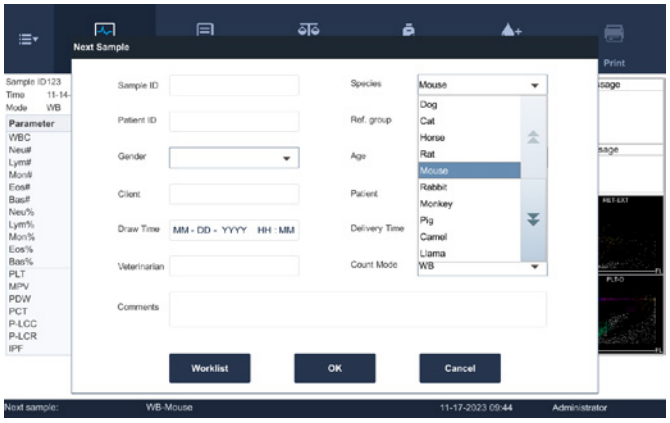
   The analyzer provides two ways to enter sample information: Entering Sample/Patient ID only and entering all sample information.

   To enter sample information after analysis, skip this chapter and enter sample information at the result review screen. See *Section 6: Reviewing Sample Results*.

   First set up the way to enter sample information at the **SETUP ▶ AUXILIARY** screen as instructed in *Section 9.2.8 Auxiliary Setup*, then sample information may be entered at the Analysis screen.

2. Entering patient demographics.

   Touch **NEXT SAMPLE** at the sample analysis screen, the following dialog box will display. Enter complete information of the next sample into the dialog box. The Ref. group will be selected by the system.



   a. Entering Sample ID
   Enter the sample ID in the Sample ID field.

   NOTE: Letters, numerics and all characters (including special characters) supported by the keyboard are allowed for sample ID entering.

   - The allowed length of Sample ID is [1, 20], and the ID cannot be null.

   b. Entering Patient ID
   Enter the Patient ID number in the Patient ID field.

   c. Entering Species
   Select the species from the Species Pull-down list.

   d. Entering Patient Name
   Enter the patient name into the Name field.

   e. Selecting Patient Gender
   Select patient gender from the Gender pull-down list. There are two options: Male and Female.

   f. Entering Patient's Age
   The analyzer provides four ways to enter the patient's age; in years, in months, in days and in hours.

g. Entering Draw Time
Enter the time when the sample is collected into the Draw Time field.

h. Entering Delivery Time
Enter the delivery time of analysis into the Delivery Time field.

i. Entering Clinician
To enter the name of the person who sent the sample for analysis, enter the name into the Clinician field or select the desired name from the Clinician pull-down list (if there are previously saved names in the list). The saved contents will be added in the pull-down list automatically.

j. Entering Comments
Enter comments in the Comments field.

k. OK
When finished entering the work list information, touch **OK** to save the changes and return to the Sample Analysis screen.

l. CANCEL
If the entered work list information is not be saved, touch **CANCEL** to return to the Analysis screen without saving the changes.

3. Aspirate the sample.
Present the sample to the sample probe. Touch **ASPIRATE** to start analysis.

4. Remove the sample.
The sample probe will automatically aspirate sample. When the beep sound is heard, the sample may be removed.

5. Auto analysis and result reporting.
The analyzer will automatically run the sample. When the analysis is finished, the results will be displayed on the screen.

NOTE: During the analysis process, if errors like a clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See *Section 11: Troubleshooting the Analyzer* for the way to remove errors.

- If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) to go out its specified range, the analyzer will alarm for abnormal ambient temperature and the analysis results may be unreliable. See *Section 11: Troubleshooting the Analyzer* for solutions.

5.5.4 Performing Pre-diluted Sample Analysis

1. Present the sample tube under the sample probe.
2. Press **ASPIRATE** key on the analyzer to start sample analysis. The sample probe automatically aspirates sample.
3. Remove the sample tube.

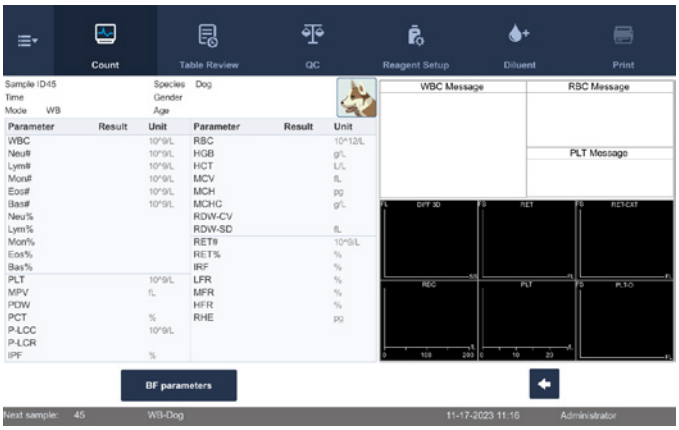
   The analyzer automatically analyzes the sample. When the analysis completes, the analyzer indicator returns to Ready status. The screen will display the current sample results, histograms, scattergrams and flags (if present).

5.5.5 Performing a Single Body Fluid Sample Analysis

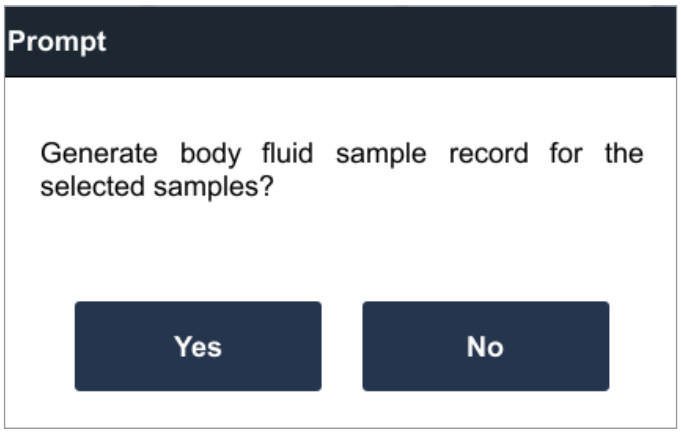
1. Present the sample tube under the sample probe.
2. Press **ASPIRATE** key to start sample analysis.

   The sample probe automatically aspirates sample.
3. Remove the sample tube.

   The analyzer automatically analyzes the sample. When the analysis completes, the analyzer indicator returns to Ready status.
4. When sample analysis finishes, touch **BF PARAMETERS**.



A dialog box pops up.

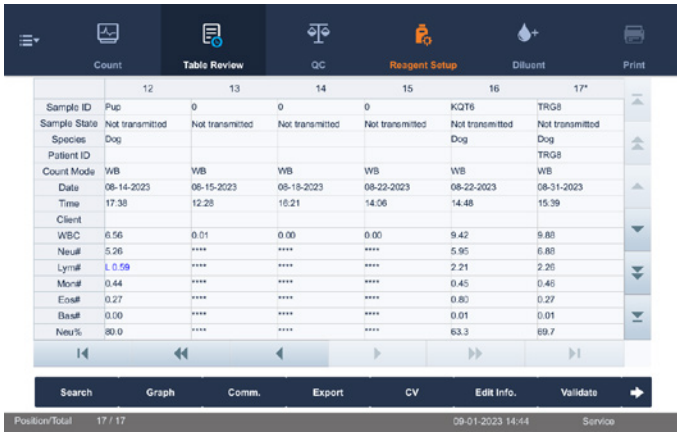


5. Touch **YES** in the dialog box to enter the test result screen of the body fluid sample.
6. Touch **RETURN** to return to the main screen.

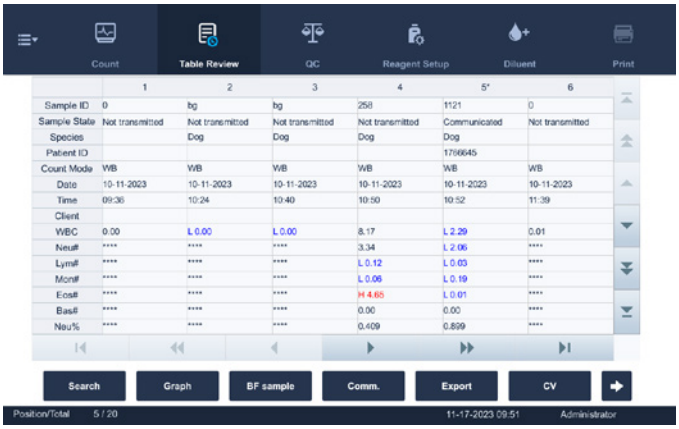
5.5.6 Performing Multiple Body Fluid Sample Analysis

To perform multiple body fluid sample analysis, the operator can follow instructions in " Performing a single body fluid sample analysis" to perform sample analysis one by one. Or the operator can follow below instructions to perform multiple body fluid sample analyses.

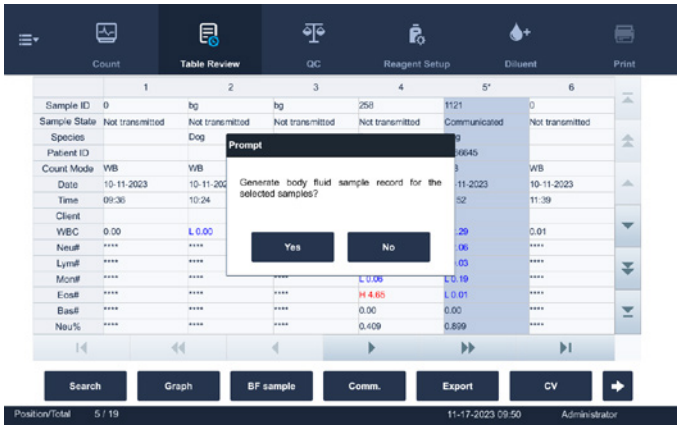
1. Present the sample tube under the sample probe.
2. Press **ASPIRATE** key on the analyzer to start sample analysis. The sample probe automatically aspirates sample.
3. Remove the sample tube. The analyzer automatically analyzes the sample. When the analysis completes, the analyzer indicator will return to Ready status.
4. Repeat steps 1–3 to finish analyses for all body fluid samples.
5. Touch **MENU ►TABLE REVIEW** or touch the Table Review utility button to enter the Table Review"screen.



6. Select one body fluid sample or multiple body fluid samples, and touch **BF SAMPLE**.



A dialog box will display.



7. Touch **YES** to generate results for the selected body fluid samples.
8. Select the desired sample, and touch **GRAPH** to view results.

5.5.7 Processing Analysis Results

1. Automatic saving of analysis results.
   This analyzer automatically saves sample results. When the maximum number of results that can be saved has reached (40,000 records), the newest result will overwrite the oldest.
2. Printing and transmission to LIS.
   If Auto print after sample analysis function is enabled, the analyzer will print reports automatically; and if Auto comm. function is enabled, the analysis results, sample and patient information will be auto transmitted to LIS.
3. Parameter flags.
   See the following section for details about parameter flags.
   - If the parameter is followed by an H or L, or ▲or ▼, it means the analysis result has exceeded the upper or lower limit of the reference range. See *Section 9.2.9 Parameter Setup*.
   - If the parameter is followed by an R, it means the analysis result is questionable.
   - If ***** is displayed, as opposed to the result, it means the result is invalid; if +++++ is displayed as opposed to the result, it means the result is out of the display range. See the following Display Range Table for details.

Display Range Table

Parameter	Reportable Range (SI)	Reportable Range (US)
WBC, Neu#, Lym#, Mon#, Eos#, Bas#	0.00–999.99 $\times 10^9$/L	0.00–999.99 $\times 10^3$/μL
Neu%, Lym%, Mon%, Eos%, Bas%, RET%, IRF, LFR, MFR, HFR*	0.0–100%	0.0–100.0%
RBC	0.00–99.99 $\times 10^{12}$/L	0–99.99 $\times 10^6$/uL
HGB	0–350 g/L	0–99.9%
HCT, P-LCR*, RDW-CV	0.0–99.9%	0–99.9%
MCV	0.0–450.0 fL	0.0–450.0 fL
MCH	0.0–999.9 pg	0.0–999.9 pg
MCHC	0–9999 g/L	0–9999 g/L
RDW-CV	0.0–99.9%	0.0–99.9%

Parameter	Reportable Range (SI)	Reportable Range (US)
RDW-SD*	0–999.9 fL	0–999.9 fL
PLT, P-LCC*	0–9999 $\times 10^9$/L	0–9999 $\times 10^3$/uL
MPV	0.0–99.9 fL	0.0–99.9 fL
PDW	0–99.9	0–99.9
PCT	0–9.999%	0–9.999%
RET#	0–9999.9 $\times 10^9$/L	0–9999.9 $\times 10^3$/uL
RET%	0–999.9 pg	0–999.9 pg

*Auxiliary parameters

4. Abnormal blood cell differential or morphology flags.
   The following Flags of Abnormal Blood Cell Differential or Morphology Table lists all flags and their indications.

5.5.8 Flags of Abnormal Blood Cell Differential or Morphology Table

Flag Type	Pathology Message	Meaning	Criteria
WBC Flag	Leukopenia	Low WBC analysis results	WBC# <3 x 10^9/µL, SI WBC# <3 $\times 10^3$/µL, US
	Leukocytosis	High WBC analysis results	WBC# <3 $\times 10^9$/L for dog, cat and horse, ,SI WBC# <3 $\times 10^3$/µL for dog, cat and horse, US
	Neutropenia	Low neutrophils analysis results	NEUT# <20% below lower normal range limit.
	Neutrophilia	High neutrophils analysis results	NEUT# >20% above upper normal range limit.
	Lymphopenia	Low lymphocytes analysis results	LYMPH# <25% below lower normal range limit.
	Lymphocytosis	High lymphocytes analysis results	LYMPH# >25% above upper normal range limit.
	Monocytosis	High monocytes analysis results	MONO# >40% above upper normal range limit.
	Eosinophilia	High eosinophils analysis results	EOS# >40% above upper normal range limit.
	Basophilia	High basophils analysis results	BASO# >100% above upper normal range limit.
RBC Flag	Anemia	Low hematocrit analysis result	HCT <10% below lower normal range limit.
	Polycythemia	High hematocrit analysis result	HCT >10% above upper normal range limit.
	Microcytosis	MCV low	MCV <10% below lower normal range limit.
	Macrocytosis	MCV high	MCV >10% above upper normal range limit.
	Low MCHC Alert	MCHC low	MCHC <10% below lower normal range limit.
	High MCHC Alert	MCHC high	MCHC >10% above upper normal range limit.
PLT	Thrombocytopenia	PLT low	PLT# <25% below lower normal range limit.
	Thrombocytosis	PLT high	PLT# >50% above upper normal range limit.
Abnormal Cell Morphology			
Immature gran?		Possible presence of immature granulocytes.	Presence of excessive dots in immature granulocyte sensitive region of the scattergram.
Band cell suspected?		Possible presence of band cell.	Presence of excessive dots in Band Cell sensitive region of the scattergram.
RBC lyse resistance?		Possible presence of RBC lyse resistance.	Presence of abnormally distributed dots in the WBC sensitive region of the DIFF scattergram.

Abnormal Cell Morphology		
Atypical lymph?	Possible presence of atypical lymphocytes.	Presence of excessive dots in atypical lymphocyte sensitive region of the scattergram.
PLT clump?	Possibility of platelet clump.	Calculate and compare special parameters.
Lipid particles?	Possible presence of lipid particles.	Presence of excessive dots in lipid particle sensitive region of the scattergram.
WBC abnormal scattergram	DIFF scattergram abnormal.	The DIFF channel scattergram is abnormal.
Band cell suspected?	Possible presence of band cell.	Presence of excessive dots in Band Cell sensitive region of scattergram.
NRBC?	Possible presence of nucleated red blood cells.	Presence of excessive dots in NRBC sensitive region of the scattergram.
RBC abnormal distribution	Abnormal distribution of RBC histogram.	The distribution of RBC histogram is abnormal.
Dimorphic population	Dimorphic population distribution.	Presence of two or more peaks on the RBC histogram.
PLT abnormal scattergram	Abnormal distribution of PLT scattergram.	Abnormal distribution of PLT scattergram.
RET abnormal scattergram	Abnormal distribution of RET scattergram.	Abnormal distribution of the RET scattergram.
RBC abnormal analysis	RBC channel may be abnormal and RBC measurement may be inaccurate.	
HBG abnormal analysis	HGB channel may be abnormal and HGB measurement may be inaccurate.	Analyze and monitor the measurements of the HGB channel.
RET abnormal analysis	RET channel may be abnormal and RET measurement may be inaccurate.	Analyze and monitor the measurements of the RET channel.
RBC agglutination?	RBC results possibly inaccurate.	Calculate and compare special parameters.
PLT abnormal analysis	PLT channel may be abnormal and PLT measurement may be inaccurate.	Analyze and monitor the measurements of the PLT channel.
PLT abnormal scattergram	Abnormal distribution of PLT scattergram.	The distribution of PLT scattergram is abnormal.
PLT clump?	Possibility of PLT clump.	Calculate and compare special parameters.

5.6 Auto-Standby

When the analyzer reaches the time that has been set, at the Setup screen (default setting is 30 minutes) or when it is free from fluidic operations the analyzer automatically enters the standby status.

NOTE: The analyzer will not enter standby status from the Status screen.

- If it is time for auto-standby and the analyzer is reporting error, then the error must be resolved first.
- During this condition, other operations can still be performed (*e.g.,* printing and transmission) other than fluidic operations.
- Under stand-by mode, if there are unfinished printing or communication tasks, the analyzer will continue processing.

On the Maintenance Setup screen, administrators may set the wait time before the analyzer enters Standby status, when the fluidic system stops working.

1. Touch **MENU ► SETUP MAINTENANCE** to enter the Maintenance screen.
2. Set up the wait time before the analyzer entering the standby status.

NOTE: The allowed range is 30 to 150 minutes. Make sure you enter the valid time and in the required format.

Exiting Standby

When the analyzer is free from fluidic operations or when it reaches the set standby time, the analyzer automatically enters the standby status.

When the user starts sample tests, or performs any operation that initiates fluidic system actions or moving parts actions, the analyzer automatically exits standby.

NOTE: When exiting from the standby status, the analyzer will perform different maintenance operations based on the time consumed entering standby status.

- If error occurs when the analyzer is exiting from the standby status, see *Section 11: Troubleshooting the Analyzer* for solutions.
- After exiting the standby status, the analyzer will resume its original status. The Analysis icon will return to solid green. And the analyzer indicator will also turn into solid green.

5.7 Shutdown

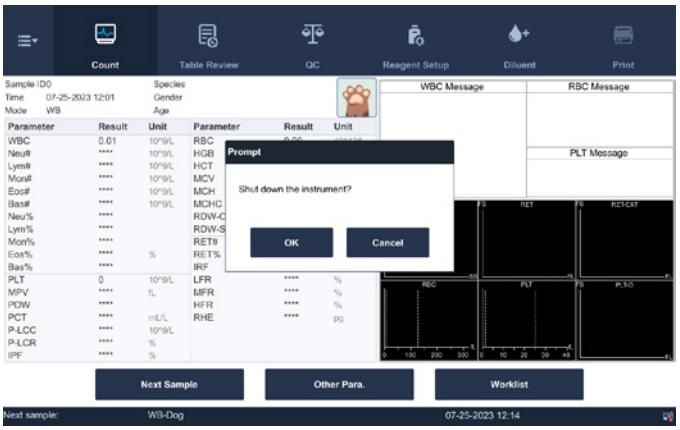
⚠ CAUTION

Do not start up the analyzer immediately after it is shut down. Wait for at least 10 seconds.

NOTE: It is recommended to leave the analyzer powered up.

Perform the shutdown procedure to shut down the analyzer only when needed.

1. On the **COUNT** screen touch **MENU**, then **SHUTDOWN.**



2. Touch **OK** to perform the shutdown procedure .
3. Perform Probe Cleanser maintenance if prompted..
4. Touch screen display will black out and then display a message to power off the analyzer.
5. Check if the waste container is full. If yes, empty the waste container and dispose of the waste properly.

⚠ WARNING

Be sure to dispose of reagents, waste, samples, consumables, *etc*., according to local regulations.

NOTE: Do not disconnect power during the shutdown process.

- If an error that will effect shutdown occurs during the showdown process, the analyzer will resume its original status and report the error. See *Section 11: Troubleshooting the Analyzer* for solutions.

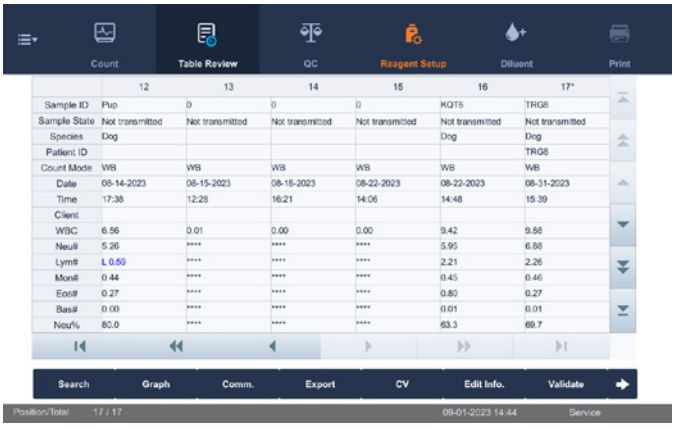
6.1 Introduction

The analyzer automatically saves analysis results. The Element HT5+ Hematology Analyzer can store up to 40,000 analysis results.

Review all the analysis results, scattergrams and histograms either in table or graph mode.

6.2 Browsing in the Table Review Mode

Operators can review, validate, search and export saved results at the Table Review screen. Touch **TABLE REVIEW** to enter the following screen.



6.2.1 Table

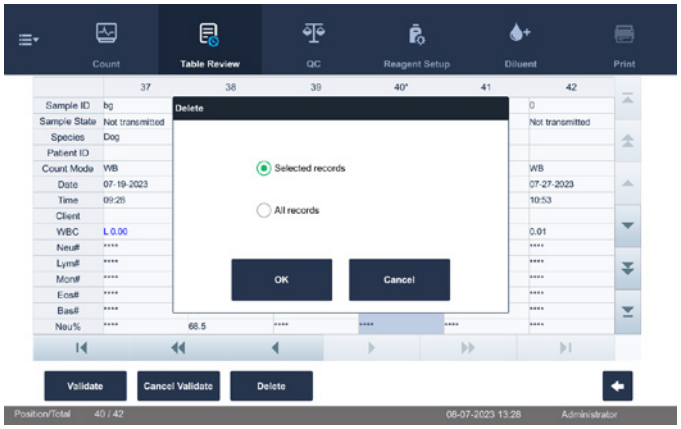
The table lists all analyzed samples, including basic sample information like sample ID, sample state and so on.

6.2.2 Graph Review

1. Touch **GRAPH REVIEW** at the table review screen.
2. Select one or more sample records of which you want to review the graph data. The selected sample record is highlighted.
3. Touch **GRAPH** to go to the Graph screen. The graph of the preceding result may also be viewed by touching **PREVIOUS** at the analysis screen to view the analysis results of samples.

6.2.3 Delete (for administrators only)

1. Select the sample record to be deleted.
2. Touch **DELETE**; the following dialog box will display.



3. Touch **OK** to delete the record, and the dialog box will be closed.

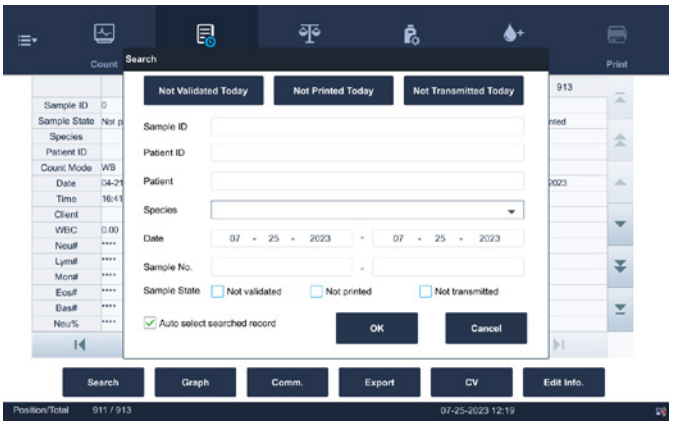
6.2.4 Edit Information (for administrators only)

1. Touch the desired sample result and it will be highlighted. Touch **EDIT INFO** and the following dialog box will display.

2. Edit the sample and patient information, and touch **OK** to save the change. The information on the table review screen will be refreshed.

6.2.5 Search

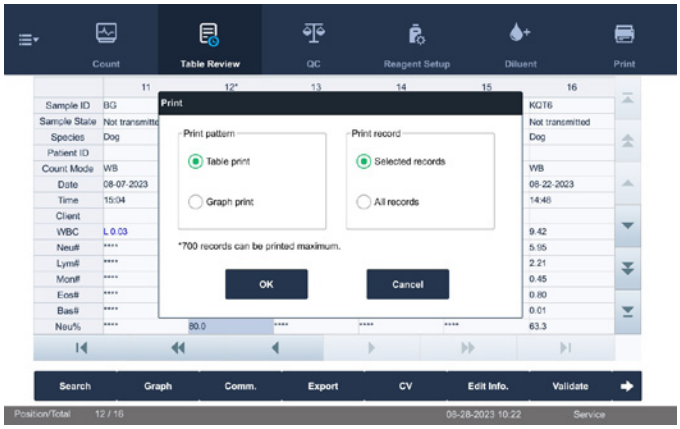
1. Select **MENU** ▶ **TABLE REVIEW** or touch **TABLE REVIEW** utility button to enter the Table Review screen.
2. Touch **SEARCH**, the following dialog box will display.
3. Enter search conditions into the edit boxes or select them from the pull-down lists.
4. Touch **OK** to start search, the results will displayed in the table.



6.2.6 Print

Printing Current Sample Report

1. Touch **MENU** ▶ **TABLE REVIEW** to enter the Table Review screen.
2. (Optional) Touch to select one or more sample records to be printed on the test result report. If you are going to print all sample records, skip this step.
3. Touch **PRINT** in the utility button area. A dialog box for printing displays.



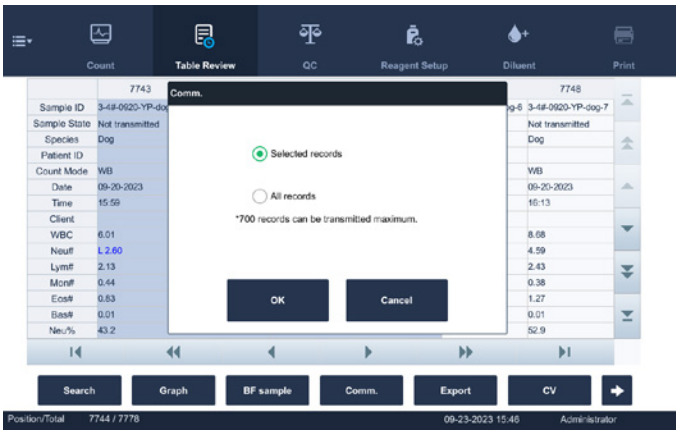
Printing from Graph Review Screen

1. Touch **MENU** ▶ **TABLE REVIEW** to enter the Table Review screen.
2. Select one or more sample records of which you want to review the graph data. The selected sample record is highlighted.
3. Touch **GRAPH** to enter the Graph screen.
4. Touch **PRINT** in the utility button area. The analyzer automatically prints the results of the current sample according to the print setup.

6.2.7 Transmission (requires connection to LIS)

Transmit selected data

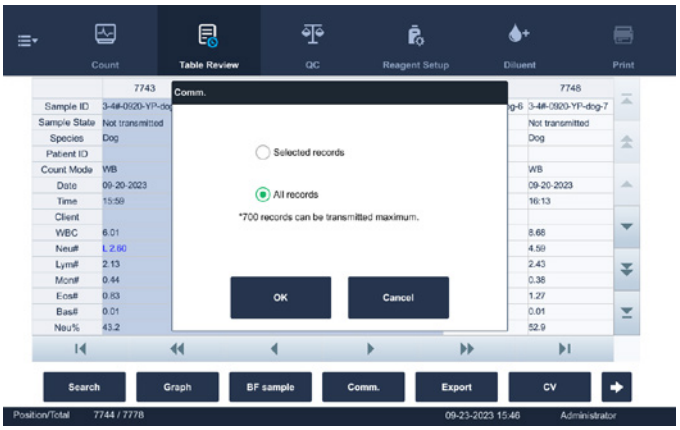
1. Select samples to be transmitted at the table review screen.
2. Touch **COMM** and the following dialog box will display.



3. Touch **SELECTED**.
4. Touch **OK** to start transmitting specified results to the data management software.

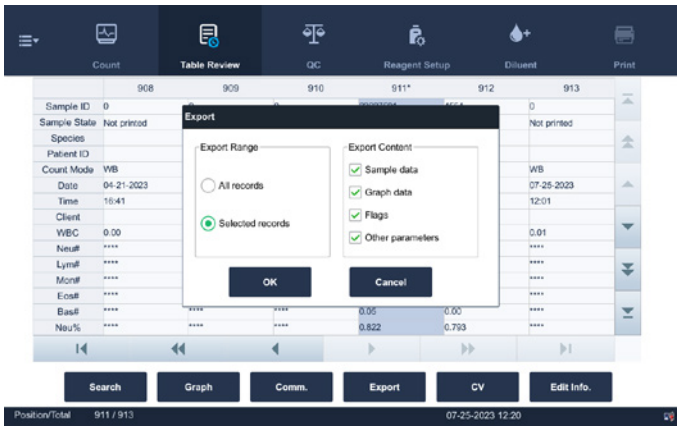
Transmit all data

1. Touch **COMM**, the following dialog box will display.
2. Touch **ALL**.
3. Touch **OK** to start transmitting all results to the data management software.



6.2.8 Export

1. Select **MENU** ▶ **TABLE REVIEW** or touch the Table Review button to enter the Table Review screen.



2. Touch to select one or more sample records to export.
3. Touch **EXPORT**
   The Export dialog box displays. Touch **SELECTED RECORDS** in the Export Range area.
   To export all sample records, touch **ALL RECORDS** in the Export Range area.
4. Touch **OK**
   The analyzer exports the corresponding sample records to USB device.

7.1 Introduction

Quality Control (QC) consists of strategies and procedures that measure the precision and stability of the analyzer. The results imply the reliability of the sample results.

QC involves measuring materials with known, stable characteristics at frequent intervals. Analysis of the results with statistical methods allows the inference that sample results are reliable. Heska recommends running the QC program daily with normal level controls.

A new lot of controls should be analyzed in parallel with the current lot prior to their expiration dates.

This may be accomplished by running the new lot of controls twice a day for five days using any empty QC files. The QC files calculate the mean, standard deviation and coefficient of variation for each selected parameter. The instrument-calculated means of these ten runs should be within the expected ranges published by the manufacturer.

BIOHAZARD

All the samples, controls, calibrators, reagents, waste and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (*e.g.,* gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

WARNING

- **Keep your clothes, hair and hands away from moving parts to avoid injury.**
- **The sample may spill from the uncapped collection tube and create a biohazard. Exercise caution with uncapped collection tubes.**
- **The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (*e.g.*, gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**

CAUTION

- **Running QC sample with error present will lead to unreliable results. If errors are reported during QC analysis, resolve the errors first and then continue with the analysis.**
- **Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.**
- **Sample agglutination may result in inaccurate analysis results. Check the control samples to see if there is any agglutination, if yes, process the samples according to your laboratory's protocols.**

7.2 QC Programs

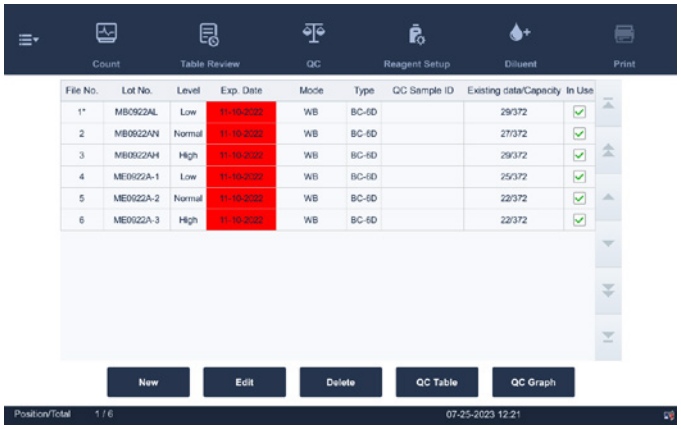
NOTE: Only use the Heska-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents.

- Refer to the instructions for use of the control for its use and storage.
- Be sure to mix any control sample before running it.
- Be sure to use the Heska-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes, *etc.*

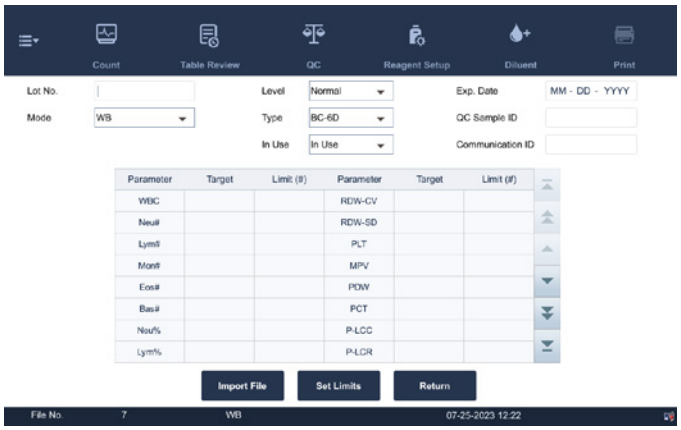
7.2.1 Setting Up New QC Files (for administrators only)

Before running a new lot of controls, a QC file must be setup for each lot of controls.

1. Touch **MENU** ▶ **QC** ▶ **SETUP** to enter the QC file setup screen.
2. Touch **NEW** to enter the new QC file screen.



3. Enter necessary QC file information.
   Set up QC information by either of the following two ways:
   - Manual entry
   - Reading the information provided by the manufacturer (USB download).
     Insert the USB device saving the QC files to the USB port on the analyzer. On the new QC file screen, touch **IMPORT FILE** and follow the software instructions to import the QC file.
4. Define QC Sample ID and Communication ID.
5. As an option, set the QC file to In Use in the In Use pull-down list.
6. Save the QC file.
   Touch **RETURN** or other buttons on the screen. A confirm dialog box will display. Touch **YES** to save the new QC file.



7.2.2 Manual Entry of QC Information

1. Enter lot number located on the vial labels of controls. The lot number field cannot be empty and up to 16 digits can be entered including special characters.
2. Select control level.

   High, medium or low

3.. Enter the lot expiration date.

The expiration date shall not be earlier than the current system date

4. Select the control type.

BC-6D, BC-RET or BC60

5. Select the mode.

WB or PD

6. Select if QC file is in use or not.

In use or Not in use

7. Set QC sample ID.

Controls are analyzed with samples; set a unique ID for the control. The analyzer will recognize the sample as control when it reads the unique ID.

After the analysis completes, the results will be saved into the QC file of the QC sample ID.

8. Enter the target and limits in the edit boxes according to the package insert of the lot of controls.

9. Save QC file.

Touch **RETURN** or other buttons on the screen. A confirm dialogue box will display. Touch **YES** to save new QC file.

7.2.3 Editing QC Files

NOTE: Only edit empty QC files can be edited. QC files that already have QC data cannot be edited.

1. Touch **MENU ► QC ► SETUP** to enter the QC file setup screen.
2. Touch the QC file to edit. The * mark displays next to the File No. of the selected QC file.
3. Touch **EDIT** to enter the QC file editing screen.
4. Edit QC file as necessary.

NOTE: For the introduction of the QC file setup, see previous section.

5. (Optional) If necessary, set the QC file to In Use in the In Use pull-down list.

NOTE: To activate or deactivate QC files, check or uncheck the In Use option on the QC file table screen.

For files having the same QC Sample ID, only one file can be In Use.

For files having the same QC type and level, only one file can be In Use.

6. Save the QC file.

   Touch **RETURN** or other buttons on the screen. A confirm dialog box displays. Touch **YES** to save the new QC file.

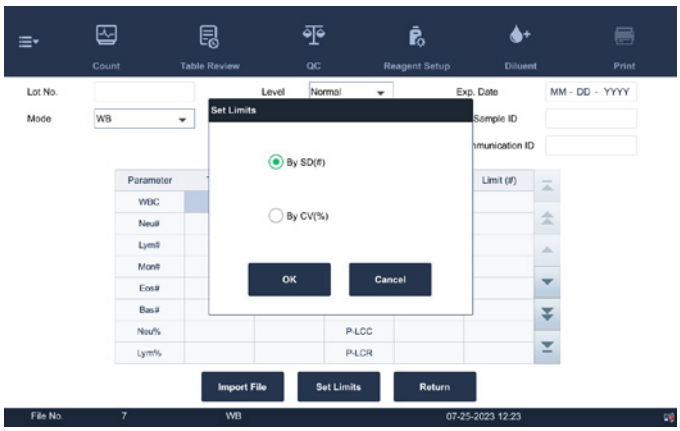
7.2.4 Deleting QC Files

1. Touch **MENU** ▶ **QC** ▶ **SETUP** to enter the QC file setup screen.
2. Select the desired QC file to be deleted. The * mark displays next to the selected QC File No.
3. Touch **DELETE.**
4. Select, Selected records or All records, in the pop-up dialog box, and then touch **OK.**

7.2.5 Setting Limits

Adjust the format of limits:

1. Touch **SET LIMITS.**



2. Touch **By SD** to display the limits in the form of absolute value; or touch **BY CV** to display the limits in the form of percentage.
3. Touch **OK** to save the settings.

7.2.6 QC Run

Run controls under the QC screen.

⚠ CAUTION

Running QC sample with error present will lead to unreliable results. If errors are reported during QC analysis, remove the errors first and then continue with the analysis.

Sample agglutination may result in inaccurate analysis results. Check the control samples to see if there is any agglutination, if yes, process the samples according to laboratory protocols.

Make sure you have set up a suitable and correct QC file for the control to be run, and the QC file is In Use.

1. Touch **QC** to enter the QC count screen.
2. Select the File No. of the desired QC file from the File No. pull-down list.

   Make sure the QC file information displayed on the screen is correct. Make sure the level of the control to be run is the same with the current QC file, and the control is not expired.

NOTE: Be sure that the level of the control to be run is the same with the current QC file, and the control is not expired. The expiration date of expired controls is displayed in red.

3. Prepare the control as instructed by instructions for use of the controls.

   Run QC analysis

4. Make sure analyzer indicator is green.
5. Mix the vial of sample as instructed by the control Instructions for Use to mix the sample thoroughly.
6. Present the control sample to the sample probe. Touch **ASPIRATE** to start QC run.
7. When the beep is heard, remove the control.

When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

Do the above procedures to continue running QC analysis, if necessary.

NOTE: Up to 372 QC results can be saved in each QC file.

7.2.7 Reviewing Results

After QC analysis, QC results can be reviewed in the following ways:

- QC Graph
- QC Table

QC Graph Review

1. Touch **MENU** ▶ **QC** to enter QC file setup.
2. Select QC file to review.

   The asterisk (*) mark displays next to the File No. of selected QC file.

3. Touch **QC GRAPH** to enter QC graph review screen of the selected QC file.

NOTE: If the target/limits of a QC file with QC results have been modified and saved, the modified data will be displayed in yellow.

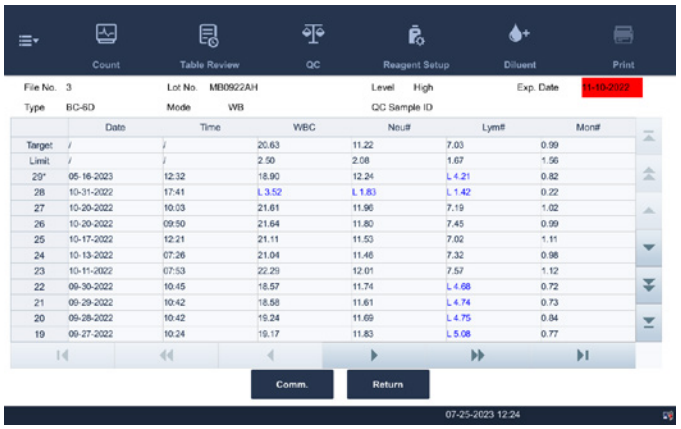
Print

1. Touch **PRINT** in the status bar to print information of the current QC file and the QC graph of all parameters.

NOTE: The green vertical line and values of the corresponding QC points will not be printed.

QC Table Review

1. Touch **QC TABLE** to enter the QC Table screen of the specified QC file. The asterisk (*) mark displays next to the File No. of selected QC file.

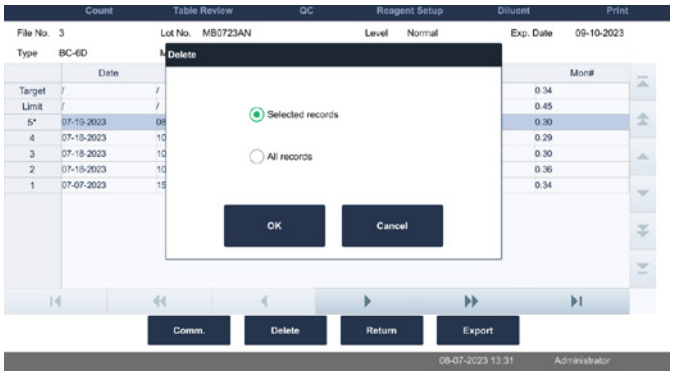


2. Touch the arrow buttons on the right of the graph to browse all QC records. Touch the arrow buttons under the graph horizontally to browse all the parameter results.

NOTE: If the target/limits of a QC file with QC results have been modified and saved, the modified data will be displayed in yellow.

Delete (for administrators only)

1. Touch **DELETE**, the following dialog box will display.



2. Touch to select Selected records and then **OK** to delete selected records.

NOTE: The operation will be recorded in the system log.

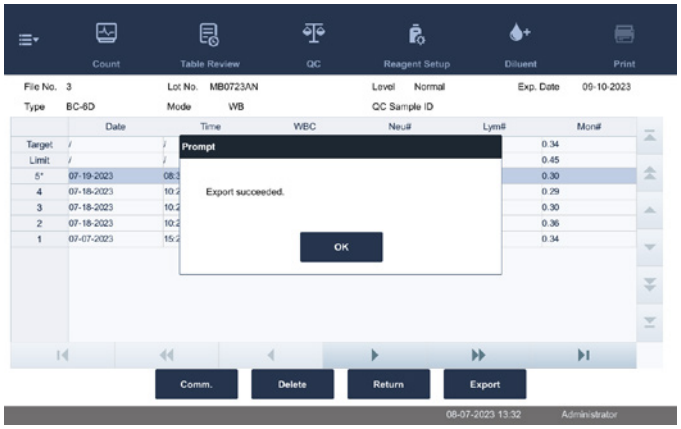
Print

Touch **PRINT** in the status bar to print the QC table.

Transmission

To transmit QC data to external data management software or HIS/LIS/HIS, do as follows.

1. Touch **COMM**; the following dialog box will display.



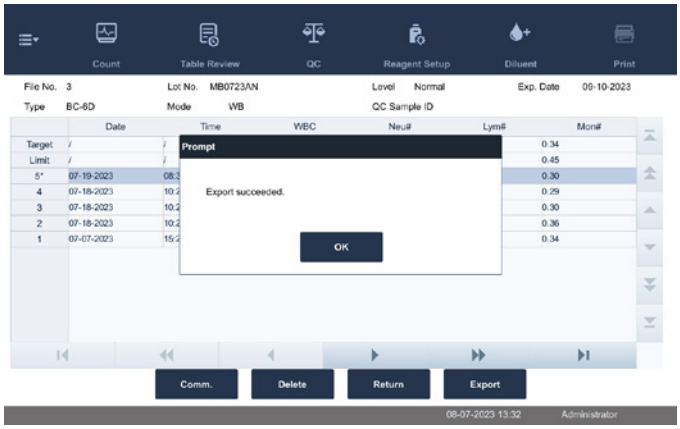
2. Select to transmit Selected or All records.
3. Touch **OK** to start transmitting specified results to the data management software.

NOTE: If auto-communication is enabled and a sample is run during the transmission of the QC data, then only when the QC data transmission finished will the auto-communication of the sample result start. The QC data saved in the process of transmission will not be transmitted.

Export

To Export QC information and results of the current QC file, do as follows.

1. Insert a USB drive ▶ touch **EXPORT**.
2. The system will detect the USB and export data automatically.
3. The prompt, Export succeeded will display.



8.1 Introduction

Calibration is a procedure to standardize the analyzer by determining its deviation under certain specified conditions. In order to get accurate sample analysis results, calibrate the analyzer per the procedure below when necessary.

All the parameters or part of the parameters of WBC, RBC, HGB, MCV and PLT can be calibrated by the calibration programs.

All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (*e.g.*, gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and they contacted areas in the laboratory.

⚠ WARNING

- **The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (*e.g.*, gloves, lab coat, *etc.*) and follow safe laboratory procedures when handling them and they contacted areas in the laboratory.**
- **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**
- **Keep your clothes, hairs and hands away from the moving parts to avoid injury.**
- **Be sure to dispose of reagents, waste, samples, consumables, *etc.*, according to government regulations.**

⚠ CAUTION

Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.

NOTE:

- Be sure to use the Heska-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes, *etc.*
- Calibration procedures can only be performed by users of the administrator-level.
- Only use the Heska-specified calibrators and reagents.
- The analyzer identifies a sample as a calibration sample only if the analysis is started from the Calibration screen.
- Calculation of reproducibility is included in the calibration procedure.

8.2 When to Calibrate

This analyzer is calibrated at the factory just before shipment. It is electronically stable and does not require frequent re-calibration if the analyzer is operated and maintained as instructed in this manual. Re-calibration is only needed for the analyzer if:

- Using this analyzer for the first time (usually done by a Heska-authorized representative when installing the analyzer).
- A major analytical component, including sample probe, syringe, *etc.*, has been changed.
- The quality control results indicate there may be a problem.

NOTE: All of the measured parameters must be calibrated before analyzer readings can be used as valid analysis results.

8.3 How to Calibrate

8.3.1 Analyzer Preparation

Do the following pre-calibration procedures before calibration. If problems are detected during these checks, do not attempt to calibrate the analyzer. If necessary, call Heska's Technical Support Services or the local distributor for assistance.

1. Check and make sure enough reagents have been prepared for the calibration. Restart the calibration if the reagents run out during the process.
2. Check the background (for calibration right after startup) or blank count results. If the analyzer alarm sounds for abnormal background results, see *Section 11: Troubleshooting. See Appendix C2: Background/Blank Count.*

NOTE:

- Be sure to use the evacuated collection tubes recommended in the *Appendix*.
- If fresh blood samples are used for reproducibility test, make sure the sample volume is enough to support the test.

8.3.2 Checking Before Calibration

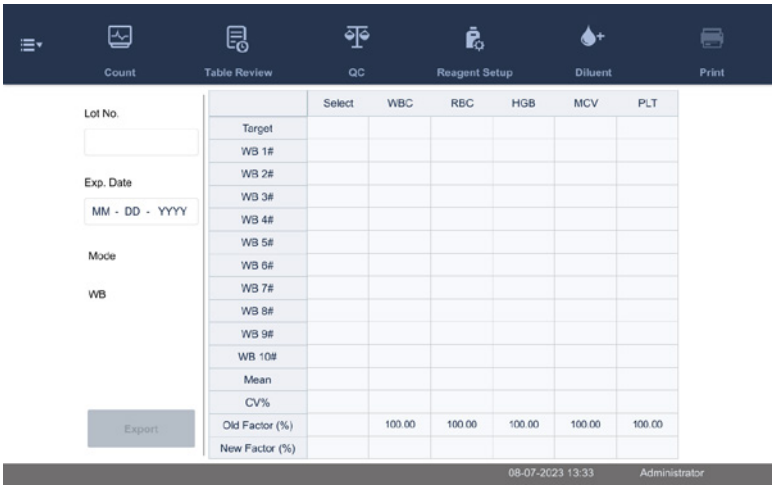
Before calibration, make sure the analyzer's background (blank count) results are within the specified ranges. If results are not in the range, check if the analyzer is in error. Remove errors (if present) and check again. If the problem persists, contact Technical Support Services.

8.3.3 Calibration with Calibrator

BIOHAZARD

All the samples, controls, calibrators, wastes and areas contacting them are potentially biohazardous. Wear proper personal protective equipment (*e.g.,* gloves, lab coat and glasses) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

1. Touch **CALIBRATION ▶ CALIBRATOR** in the menu to enter the following screen.



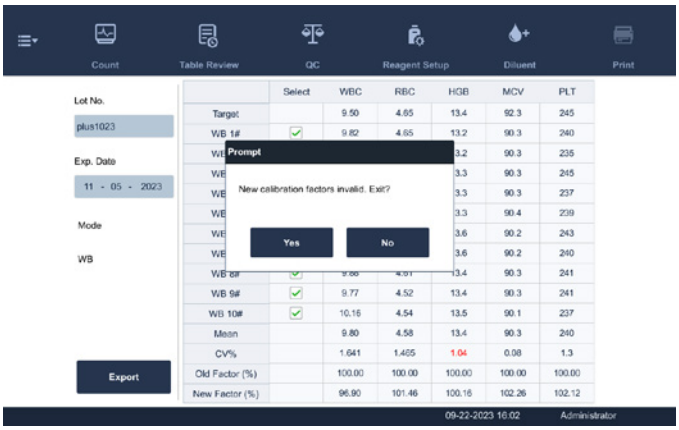
NOTE:

- Only Heska-specified calibrators shall be used. Heska will not be responsible for any erroneous result caused by using other calibrators.
- See the calibrator Instruction for Use for the lot number, expiration date and target.
- The out-of-range CV% does not influence the display of calibration factors.

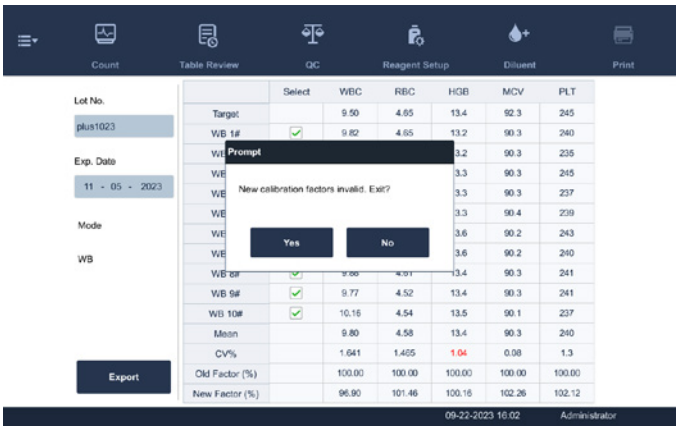
8.3.4 Calibrate the Analyzer with Calibrators

1. Check the mode on the analyzer screen.
2. Enter the lot number of the calibrator into the Lot No. field. Find the lot No. on the label on the vial of the calibrator, or on the target sheet of the corresponding calibrator.
3. Enter the expiration date. The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: The date the container is opened + the open-container stability days.
4. Enter the targets into the Target fields. Find parameter targets on the target sheet of the corresponding calibrator.
5. Prepare the calibrator as instructed by the calibrator's instructions for use.
6. Place the prepared calibrator in a tube, and place the tube under the sample probe.
7. Touch **ASPIRATE** to start calibration and aspirate calibration solution.

   After the analysis, the analyzer will have different responses to different analysis results.
   When the current running is done, if there is a parameter whose calibration data is out of its linearity range but still within the display range, then the calibration data will be displayed in the list and a dialogue box will appear.

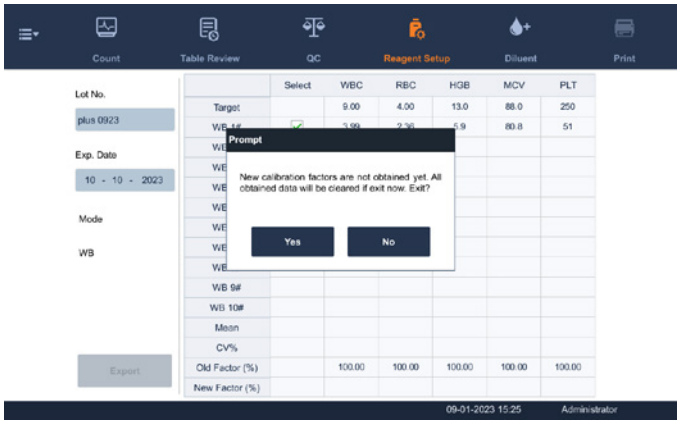


Touch **YES** to close the dialogue box, and the data will be deleted from the table without saving automatically.
When the running is done, if there is a parameter whose calibration data is out of the display range, then the non-numeric parameter values *** will be displayed in the list and a dialogue box will display.



Touch **YES** to close the dialogue box, and the data will be deleted from the table without saving automatically.
The valid results with in the linearity range will be displayed directly. Valid calibration results will be marked with √, per the default setting, and will be taken to calculate calibration factors.

8. Switching to another screen before the calibration factors have been calculated, the following dialogue box will display.



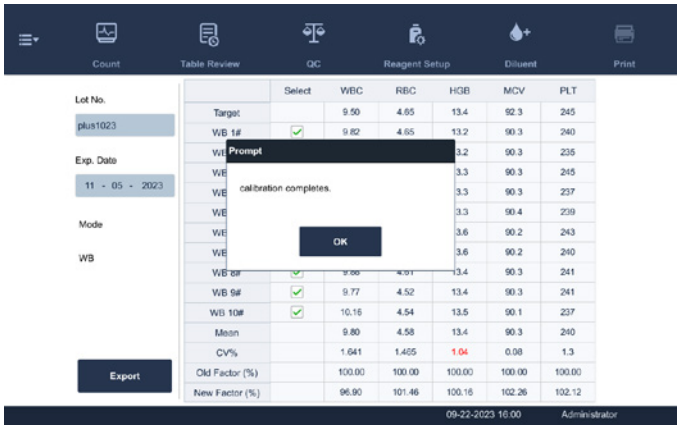
Touch **YES** to switch to another screen while discarding the calibration data and closing the dialogue box. The original calibration factors remain.

9. When calibration count has been performed to a sample for n times (n≥3), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with √ (calibration data of the first run is not marked with √, so it is not included in the calculation).

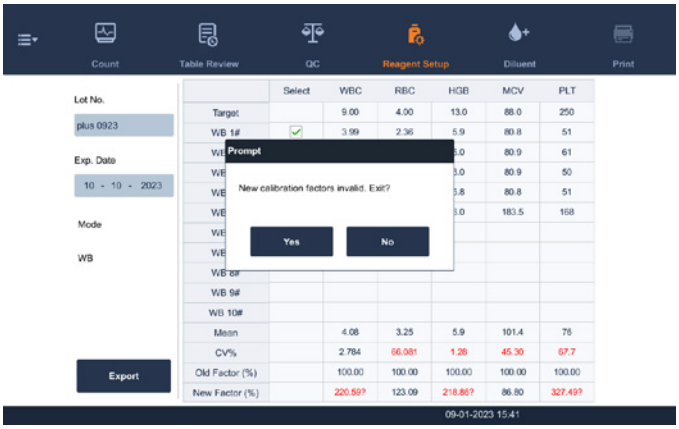
   NOTE: To obtain valid calibration factors, 3 to 10 valid calibration results are required.

   Select several data to calculate the calibration factors, but only after at least 3 groups of the data are marked with √ can the calibration factors be produced. The calibration factors will be refreshed whenever the √ is selected or deselected.

   When the amount of valid calibration data in the list reaches 10, a dialogue box, Calibration complete will display. Then, touch the aspirate key again, the analyzer will beep without starting analysis.

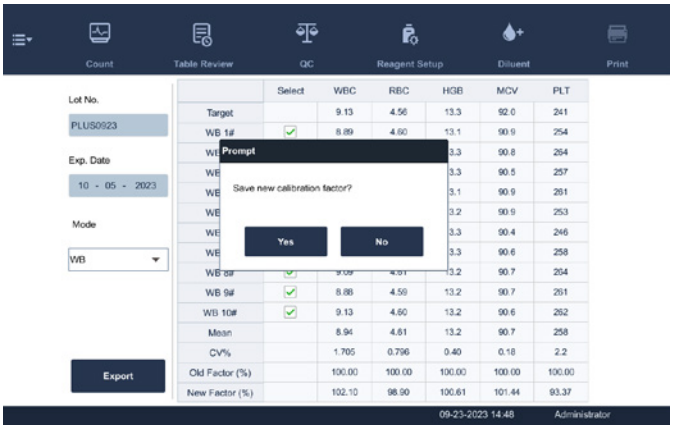


10. There may be two cases when switching to another screen:
    If the calibration factors of any parameter is out of the range [75%–125%] or the CV% of any parameter exceeds the reproducibility range, then the calculated calibration factors of all parameters will not be saved and a message box will also display.



Touch **YES** to close the dialog box and switch to another screen. The calibration factors and dates of all parameters will not be changed.

If the calculated calibration factors of all parameter are within the range [75%–125%] and the CV% of all parameter are also within the reproducibility range, then a dialogue box will display.

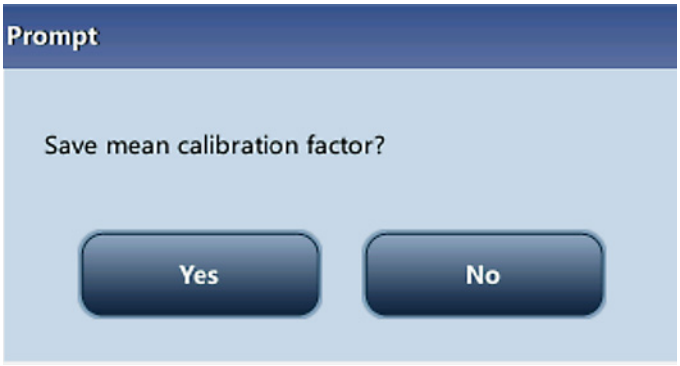


11. Touch **YES** to save the new calibration factors while closing the dialogue box and switching to another screen.

8.3.5 Saving Calibration Results

If the calibration factors are invalid, touch **PRINT,** the dialog box, New calibration factor is invalid, will display.

If the calibration factors are valid but not saved, touch **PRINT**, a dialog box will display to save the factors.



Touch **YES** to close the dialog box, save and print the calibration results. Or touch **NO** to cancel the operation without saving or printing them.

8.3.6 Verifying Calibration Factors

Verify the calibration factors using any of the following methods.

1 Run the calibration at least 3 times, and check if the results are within the allowed range.

2. Run at least 3 fresh blood samples from normal patients, each sample at least 3 times, and check if the results are within the allowed range.

8.3.7 Calibration History

Only administrators can view the calibration history.

1. Touch **MENU** ▶ **CALIBRATION** ▶ **CALIBRATION HISTORY** to enter the Calibration History screen.

- Select **DETAILS** to view detailed calibration information.
- Select **GO TO** to view the calibration history of the specified time period.
- Touch **EXPORT** to export specified or all calibration records to a USB drive.

Manual Calibration

NOTE: If logged in as operator, calibration factors can only be reviewed and not edited.

1. Touch "Menu > Calibration > Manual" to enter the manual calibration screen.

2. Enter the new calibration factors into the factor cell of the parameter that require calibration.

NOTE:

• The calibration factor entered must be in the range of 75.00% - 125.00%, and only two decimal places can be reserved.

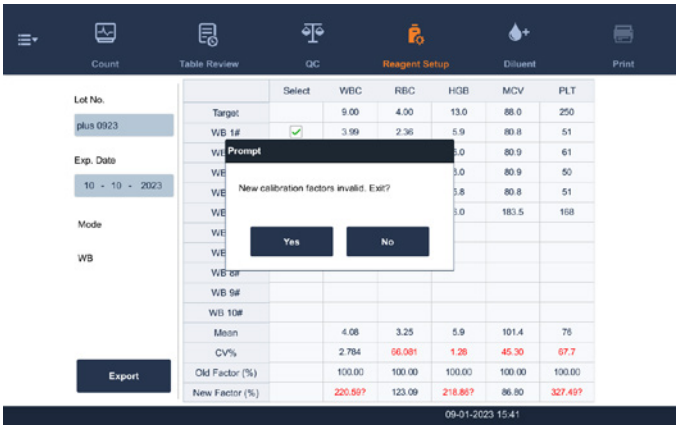
• If the entered calibration factors are invalid, the factors will be highlighted in red.

• The "Date" cells automatically display the date when the new calibration factors are entered.

3. Save calibration factors.

3.1 Touch another button on the software screen and a dialog box displays to remind you to save calibration factors.

3.2 Touch **YES** to save new calibration factors. If the entered calibration factors are invalid, a dialog box will display when you are switching to another screen. Touch **NO** to re-do calibration procedures.



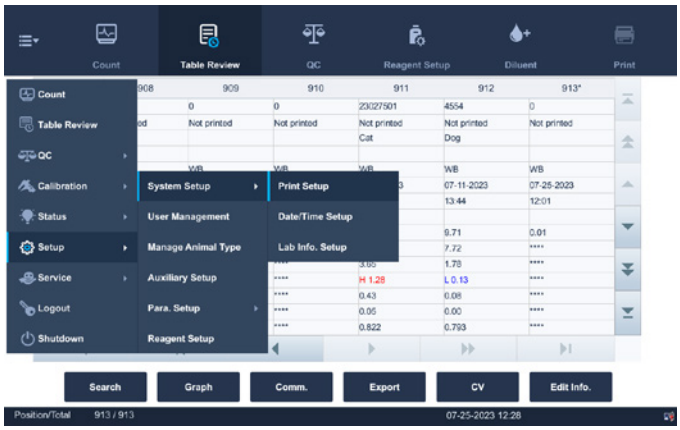
4. Touch **YES** to close the dialog box and switch to another screen without saving the changes. The original calibration factors and dates will remain unchanged.

9.1 Introduction

The Element HT5+ Hematology Analyzer is a flexible laboratory instrument that can be customized to the working environment. Use the Setup program to customize the software options as introduced in this section.

For the security of the settings and data, two access levels are provided to the operator of the analyzer. The administrator access level provides the operator with access to more functions or settings, some of which can be configured to be accessible to operators.

Refer to the following for the Setup menu.

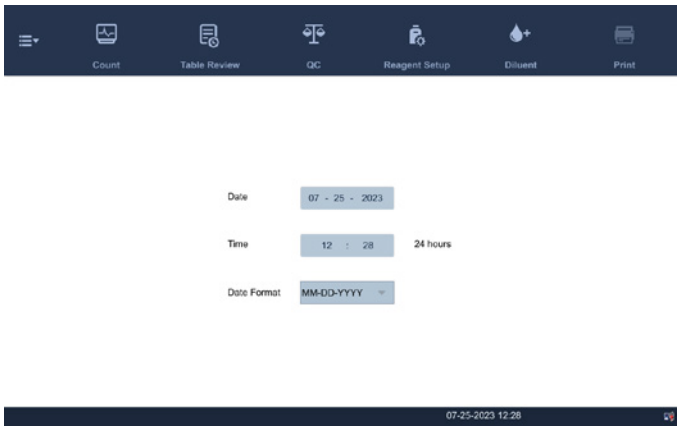


9.2 Setting Up the Analyzer

9.2.1 System Setup

Date/Time

Touch **SETUP ► SYSTEM SETUP ► DATE/TIME SETUP** to enter the Date/Time screen as shown below. Set the date, time and date format of the analyzer at the screen.

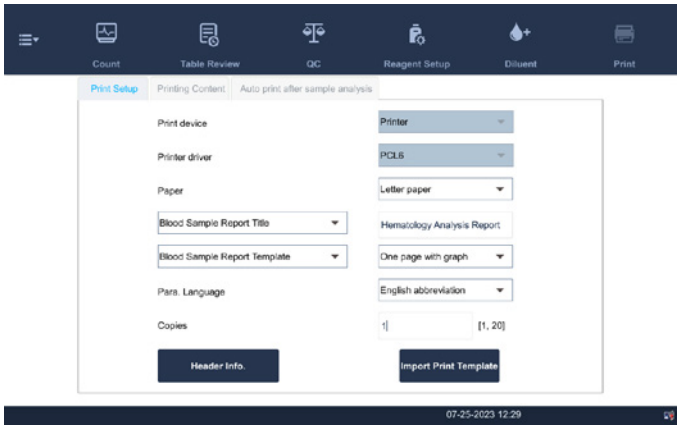


9.2.2 Print

Touch **SETUP** ▶ **SYSTEM SETUP** ▶ **PRINT SETUP** to enter the Print Setup screen as shown below.

Set up the following contents:

- Print setup
- Printing content
- Auto print



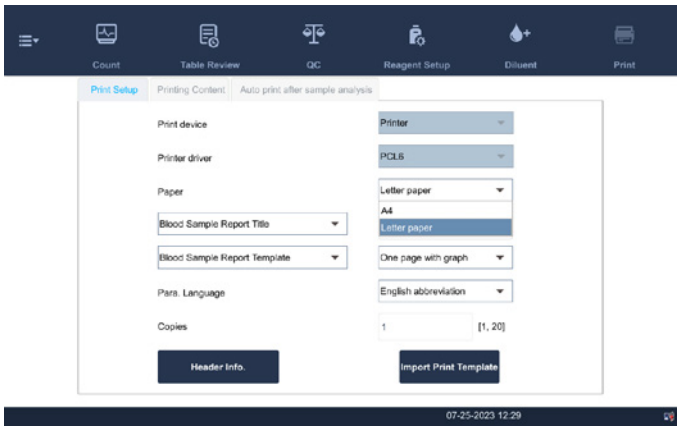
9.2.3 Print Setup

Printer driver

Touch the pull-down list to select printer driver of the analyzer.

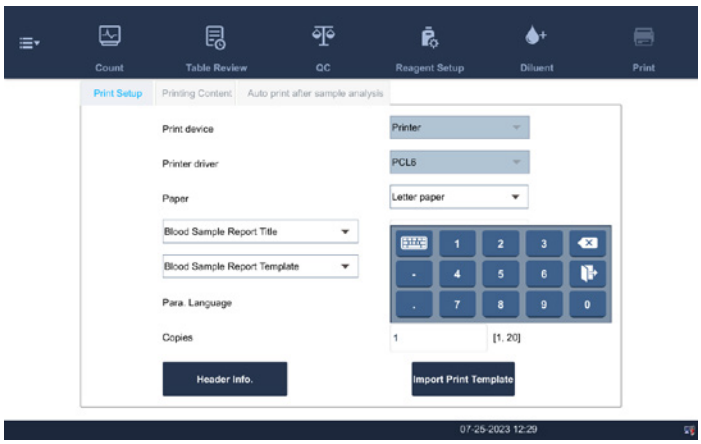
Paper

Touch the pull-down list to select the paper type of the reports to be printed.

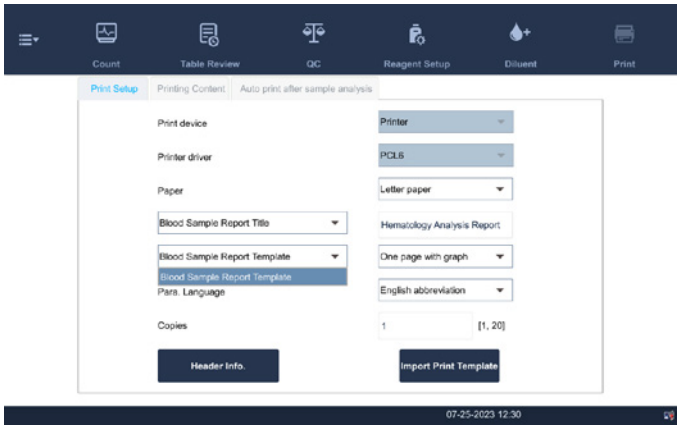


Copies

Enter the number of copies to be printed for each report into the edit box, Copies.

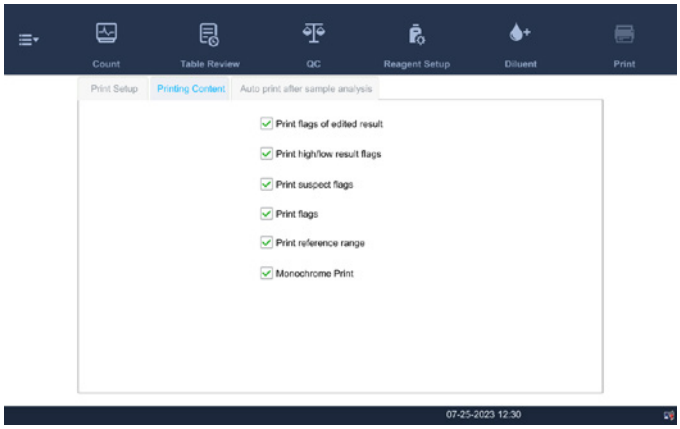


Report Template



Printing Content

Select the functions based on need by touching the check boxes.



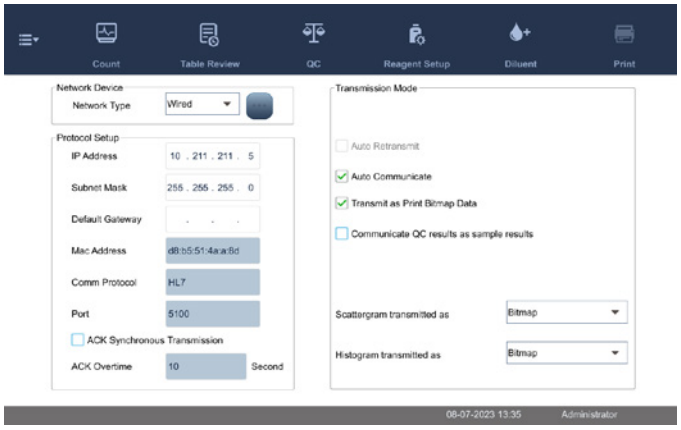
Auto print

Disable auto print or other printing conditions may be setup.

9.2.4 Communication Setup

Touch **SETUP ▶ SYSTEM SETUP ▶ COMMUNICATION** to enter the communication setup screen as shown below. The following contents may be set:

- Protocol setup
- Transmission mode



Protocol Setup

Touch **IP ADDRESS, SUB-NET MASK** and **DEFAULT GATEWAY** edit boxes to enter the contents.

Communication Protocol

Touch **COMM. PROTOCOL** pull-down list to select the communication protocol.

ACK Synchronous Transmission

Touch on the ACK synchronous transmission check box to activate the function.

When the function is activated, ACK overtime is 10 seconds by default. Re-enter the ACK overtime is the edit box.

Transmission Mode

Select the functions based on need by touching on the check boxes.

- Auto retransmit
- Auto communicate
- Transmit as Print Bitmap Data
- Communicate QC results as sample result

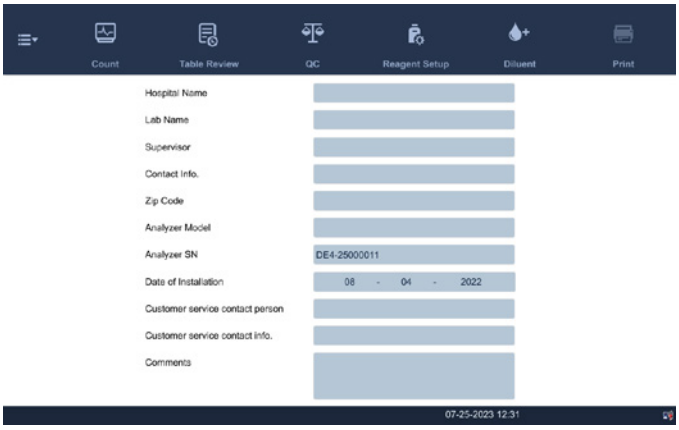
Transmission Mode of Histogram and Scattergram

Touch the pull-down lists to select the transmission modes of histogram and scattergram.

- Not to be transmitted
- Bitmap
- Data

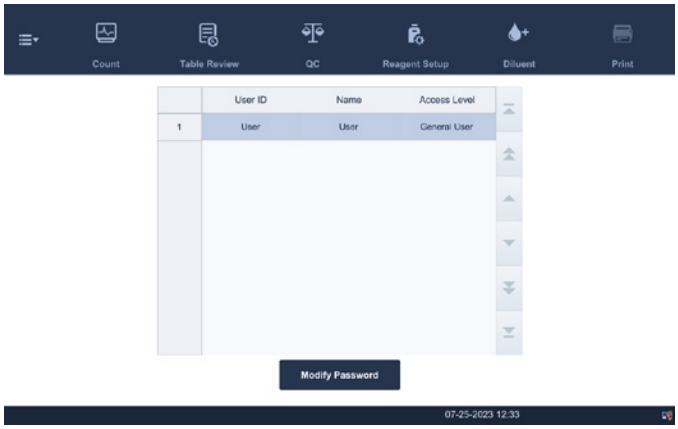
9.2.5 Lab Information Setup

Touch **SETUP ▶ SYSTEM SETUP ▶ LAB INFO.** Setup to enter the screen as shown below. Operators may enter, save and view lab information. Touch the edit boxes to enter the information.



9.2.6 Access Setup

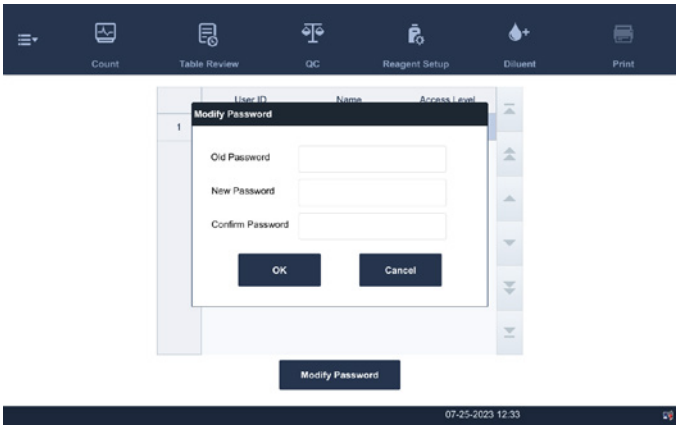
Touch **SETUP ▶ USER MANAGEMENT** in the menu to enter the following screen.



Modify Password

The password may be modified.

1. Select the current user, and then touch **MODIFY PASSWORD** the following dialog box will display.

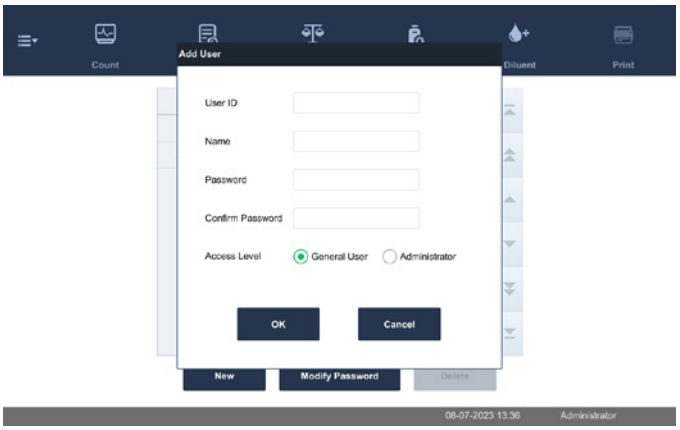


2. Enter the required information in the edit boxes.
3. Touch **OK** to save the change and close the dialog box.

NOTE: The password cannot be null, and 12 characters can be entered at most.

9.2.7 Create New User

1. Touch **MENU** ▶ **SETUP** ▶ **USER MANAGEMENT** to enter the User Management screen.
2. Touch **NEW** and the following dialog box displays.



3. Enter the User ID, Name and Password information.
4. Select access level of the user:
   - Operator
   - Administrator
5. Touch **OK** to save the change and close the dialog box.

NOTE: The user ID cannot be null, and 12 characters can be entered at most. The password cannot be null, and 12 characters can be entered at most. The name cannot be null, and 20 characters can be entered at most.

Delete User

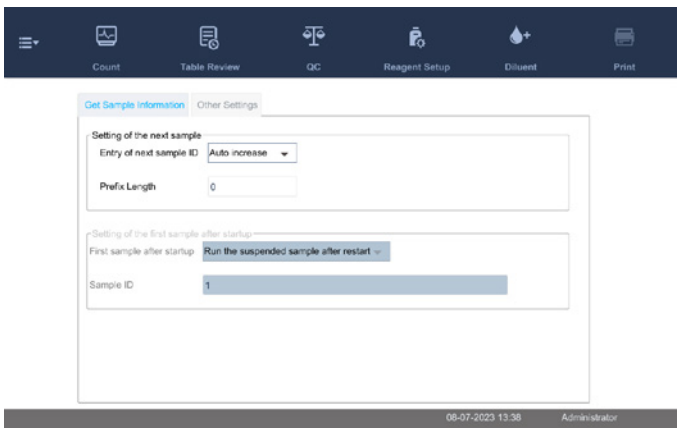
1. Select a user and then touch **DELETE** to delete it. A confirmation box displays.
2. Touch **YES.** The selected user is deleted.

NOTE: The current login user cannot be deleted.

9.2.8 Auxiliary Setup

Touch **MENU** ▶ **SETUP** ▶ **AUXILIARY SETUP** to enter Auxiliary Setup screen. The following contents may be set here.

- Get sample information
- Other settings



Get sample information

MENU ▶ SETUP ▶ AUXILIARY SETUP ▶ GET SAMPLE INFORMATION to enter the Get Sample Information screen. The following options may be set here.

Item		Description
Next sample setting	Enter next sample ID	When Auto Increase is selected for Entry of next sample ID,, after the first sample ID is entered, the subsequent sample IDs of the same batch automatically increase When Manual enter is selected for, Entry of next sample ID, each sample ID will need to be entered manually
	Prefix length	When Auto Increase is selected for Entry of next sample ID, this edit box is activated Enter a number (n) into the edit box of Prefix Length, the first n characters in the sample ID will not be auto increased
Setting first sample after startup	First sample after startup	Default setting is, Run the suspended sample after restart
	Sample ID	Default setting is 1

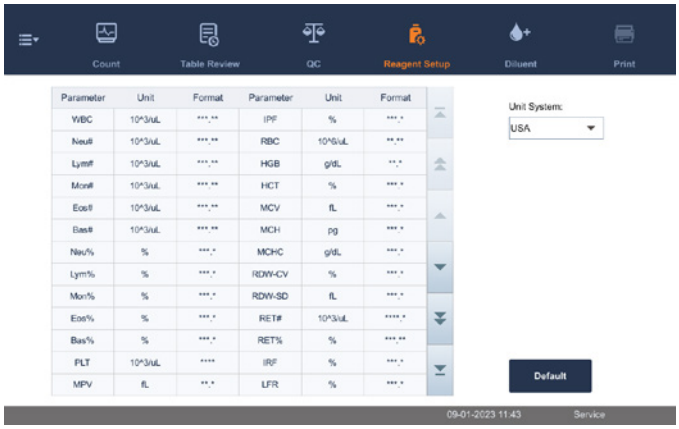
9.2.9 Parameter Setup

Parameter unit setup

Touch SETUP ▶ PARAMETER SETUP ▶ REFERENCE RANGE SETUP to enter the screen as shown below. Set up parameter units using this screen.

Select Unit System

Touch UNIT SYSTEM pull-down list to select unit system.

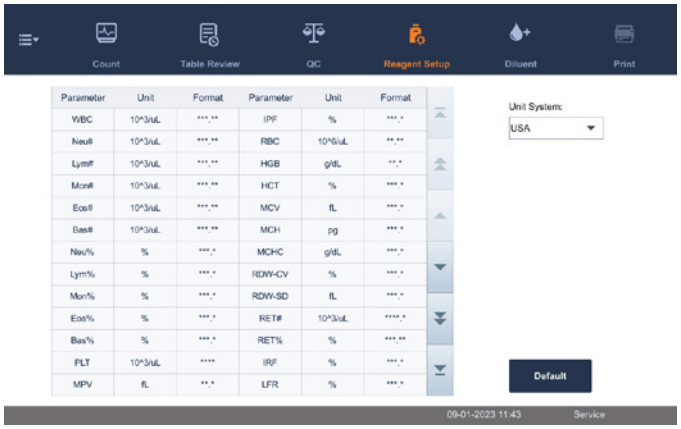


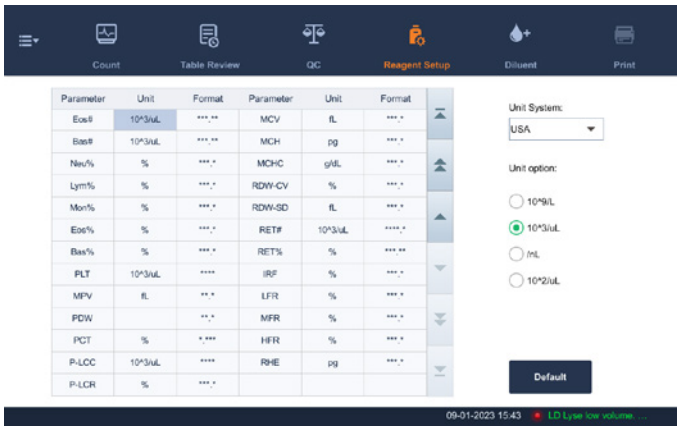
Customizing Parameter Units

Under each unit system, touch the unit cell to customize the parameter unit.

Touch **DEFAULT** to restore the default units.

NOTE: The units displayed will be different when different unit system is selected.





9.2.10 Maintenance Setup (for administrators only)

Touch **SETUP ▶ MAINTENANCE** in the menu to enter the following screen. The following contents may be setup.

Standby

Touch the text box **WAIT** and enter the waiting time before entering the standby status. The range allowed is 30–150 minutes, and the default setting is 30 minutes.

Probe Cleanser Maintenance

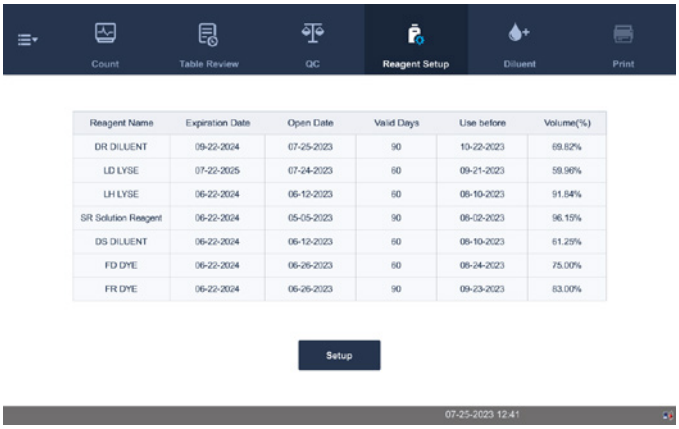
Touch the first text box in the Probe Cleanser Maintenance area to enter the time to start time-based probe cleanser maintenance. Touch the second text box to enter a time in the text box. Then when the operator cancels the time-based maintenance, a reminder dialog box will display after the defined minutes.

1. Touch **SETUP ▶ MAINTENANCE**
2. Set the start time and reminding interval for probe cleanser maintenance as needed.
3. Set the start time of probe cleanser maintenance. The system will perform probe cleanser maintenance for the relevant parts at the specified time according to the operating condition of the analyzer.

NOTE: The allowed range for the start time of probe cleanser maintenance is 00:00 to 23:59. The allowed range for reminding interval is 5 to 60 minutes.

9.2.11 Reagent Setup

Touch **SETUP ▶ REAGENT SETUP** or touch **REAGENT SETUP** tab in the menu to enter the following screen.



It is recommended that the reagents be replaced when their residue volume icons turn from blue to red.

This function may also be used to refill reagent inside the fluidic system when a new container of reagent is loaded.

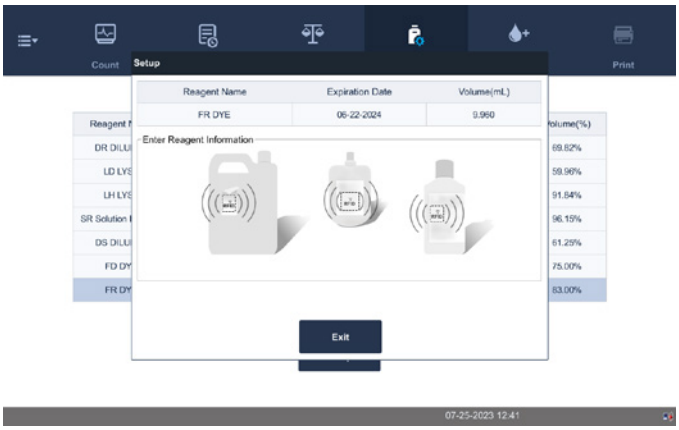
NOTE: The reagents must be kept still for at least a day after long-term transportation.

When the diluents or lyse have been changed, run a background test to see if the results meet the requirement.

Replace reagents when:

- The reagent ran out and a new container of reagent is installed.
- The reagent in the tubing is contaminated.
- There are bubbles in the tubing.

1. Touch the reagent to be replaced, then touch **SETUP**.



2. Read reagent information by swiping RFID card.

   A beep sound occurs if the reagent information is successfully identified.

   Three beep sounds occur if there is a mismatch between the RFID card and the reagent.

3. Touch **APPLY** ▶ **CLOSE** ▶ **OK** to save the exp. date and start to replace the reagent. A progress bar will be displayed in the process.
4. Replace other reagents as per the above procedures, if needed.

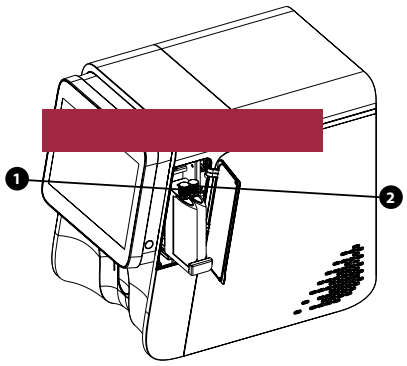
NOTE: Please keep the diluent container from severe shock or impact against other objects. Otherwise, the analyzer performance may be compromised.

Install new reagent

NOTE: When installing new reagents, make sure the color of reagent cap assembly is the same as the color in the rectangle box in reagent label.

Replace Dye

1. Open the dye compartment door and extend the dye support rack.



Connecting fluorescent dyes.

2. Get a new dye bag, open the cap and the aluminum film sealing the bag.
3. Take out the bag to be replaced along the direction of the supporting rack.
4. Turn the cap of the old reagent container counterclockwise, and then take out the cap assembly with caution.

NOTE: If the pickup tube of the cap assembly is stuck when it is taken out of the dye bag, slightly adjust the position of the pickup tube and then take it out without pulling by force.

5. Insert the pickup tube of the cap assembly vertically into the new container, and then turn the cap clockwise until it is secured.

NOTE: During replacement, make sure that the pickup tube of the cap assembly does not reach the bottom of the reagent bag, otherwise the reagent cannot be aspirated normally.

6. Put the sealed new bag back on the support rack, making sure the bag is securely accommodated.
7. Cap the old bag using the cap of the new bag and dispose of the old bag properly.

Replacing other reagent

1. Remove the cap of a new reagent container, and place the container next to the one to be replaced.
2. Turn the cap of the old container counterclockwise, and then take out the cap assembly with caution.
3. Insert the pickup tube of the cap assembly into the new container, and then turn the cap clockwise until it is secured.
4. Cap the old container with the cap of the new container and dispose of the container properly. Touch **REPLACE**.

   After swiping RFID card and installing new reagents, touch **REPLACE** in the Setup dialog box. The analyzer will automatically prime reagent and replace the old reagent.

9.2.12 Discharging waste

 BIOHAZARD

All the samples, controls, calibrators, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment, *e.g.* gloves, lab coat, goggles, *etc.*, and follow safety procedures in the laboratory when handling them and the contacted areas in the laboratory.

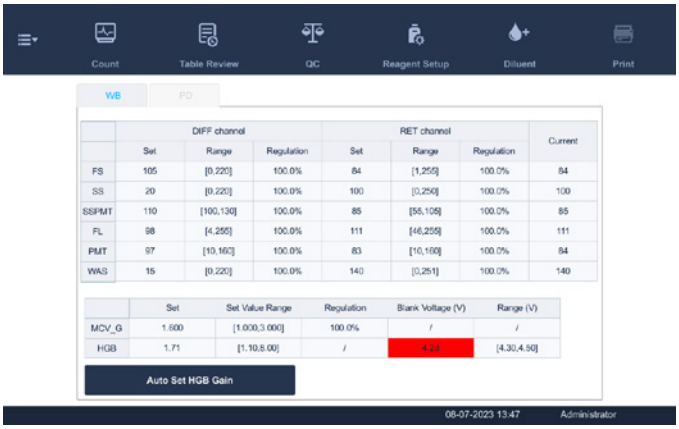
- **Be sure to dispose of reagents, waste, samples, consumables, etc., according to government regulations.**
- **Remove the waste container cap only when the power indicator is not flickering, in order not to make the waste overflow from the container.**
- **If the waste is discharged using the waste container, make sure the pickup tube of the waste container cap assembly is above, and the tube is smooth and not bent.**

If the waste is discharged using the waste container, discharge the waste when the analyzer prompts errors for full waste container. Follow below instructions:

1. Rotate the waste container cap assembly counterclockwise and remove the waste container cap assembly carefully.
2. Discharge the waste.
3. Insert the pickup tube of the waste container cap assembly into the waste container and then rotate the waste container cap assembly clockwise until it is secured.

9.2.13 Gain Setup (for administrators only)

Touch **SETUP ▶ GAIN SETUP ▶ WB** in the menu to enter the following screen. When the analyzer reports the HGB blank voltage abnormal error, and you cannot remove the error by touching the Remove Error button, adjust the HGB gains to correct the HGB blank voltage. The operation shall not be performed frequently.



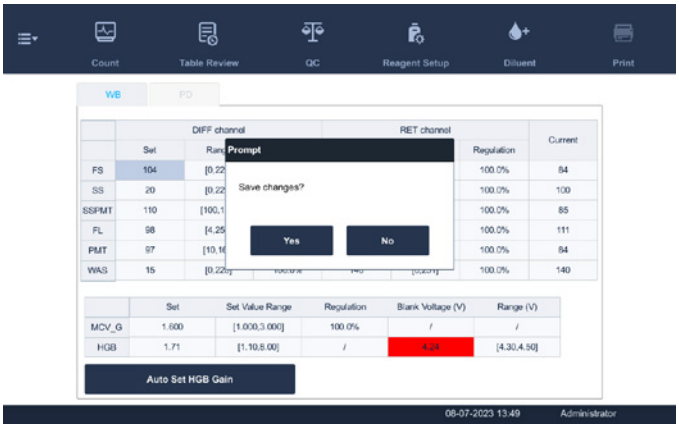
Adjust the HGB default gain by selecting Auto Adjust.

NOTE: When you modify the HGB default gain, the HGB blank voltage will change accordingly.

NOTE: The gains of LAS, MAS and WAS cannot be modified.

9.3 Save the Settings

To save the modified settings switch to another screen, and the following dialog box will display.



Touch **YES** to save the settings and switch to the corresponding screen.

Touch **NO** to switch to the corresponding screen without saving the settings.

10.1 Introduction

Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition. This analyzer provides multiple maintenance functions for this purpose.

This chapter introduces how to use the provided functions to maintain and troubleshoot the analyzer.

BIOHAZARD

All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.

WARNING

The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g., gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.

CAUTION

Improper maintenance may damage the analyzer. Operators must follow the instruction of this Users Manual to perform maintenance operations.

Only Heska-supplied parts can be used for maintenance. For any questions, contact Heska's Technical Support Services. Exercise caution to avoid contact with the sharp sample probe when performing maintenance.

The following are the tools that may be used in maintenance.

- Cross-headed screwdriver
- Slotted head screwdriver
- Medical gloves
- Alcohol

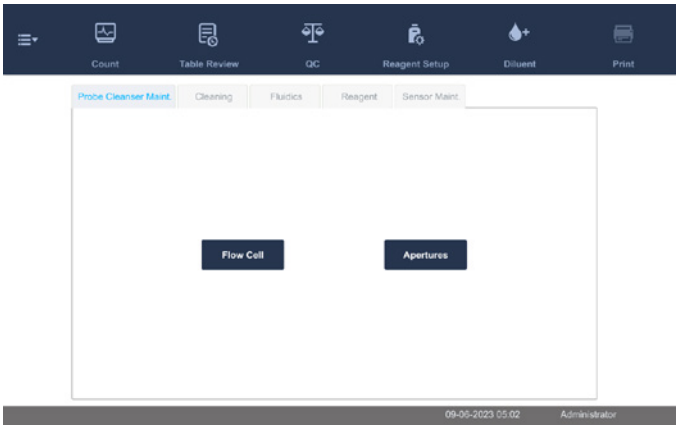
For any questions, contact Heska's Technical Support Services at 800.464.3752, option 3.

10.2 Maintaining the Analyzer

Maintenance options of the analyzer include: maintenance, cleaning and fluidics maintenance.

10.2.1 Maintenance

Touch **SERVICE** ▶ **MAINTENANCE** to enter the following screen.



Routine Probe Cleanser Maintenance

After the probe cleanser maintenance time is set in **SETUP** ▶ **MAINTENANCE,** the analyzer prompts you to maintain the probe cleanser at the set time.

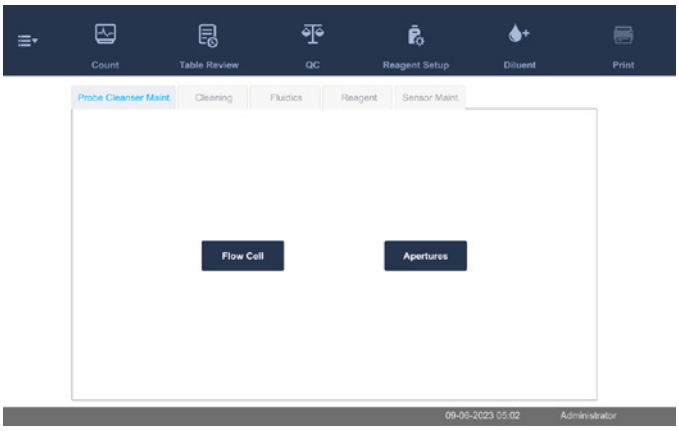
1. When the, Time for maintenance. Perform Probe Cleanser maintenance now?, dialog box displays, touch **YES**.

   The analyzer prepares for Probe Cleanser maintenance. After the preparation for Probe Cleanser maintenance completes, a dialog box will display. The sample probe lowers to the aspiration position.
2. Present the uncapped Probe Cleanser under the sample probe as instructed on the screen.
3. Touch **ASPIRATE** to start probe cleanser maintenance. The analyzer aspirates Probe Cleanser.
4. Remove the Probe Cleanser. The analyzer automatically completes Probe Cleanser maintenance.
5. The full probe cleanse can also be manually entered via **MENU** ▶ **SERVICE** ▶ **MAINTENANCE** ▶ **FLUIDICS** ▶ **PROBE CLEANSE**.

Probe Cleanser Maintenance to Parts and Components

You may perform Probe Cleanser maintenance to parts and components when necessary. This is recommended to clean the apertures when clogging error is reported frequently as well as the flow cell when there is a large amount of bad blood sample differential cases or when there are flow cell errors reported.

1. Touch **MENU ▶ SERVICE ▶ MAINTENANCE ▶ PROBE CLEANSER MAINT.** to enter the Probe Cleanser Maint. screen.



2. Touch the part and component buttons that need Probe Cleanser maintenance either Flow Cell or Aperature.

   The analyzer prepares for probe cleanser maintenance. After the preparation for probe cleanser maintenance completes, a dialog box displays.

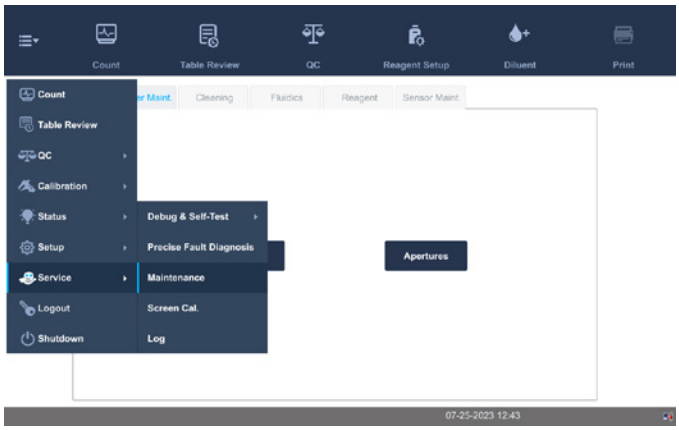
   The sample probe lowers to the aspiration position.

3. Present the uncapped probe cleanser under the sample probe as instructed on the screen.
4. Press **ASPIRATE** to start probe cleanser maintenance. The analyzer aspirates probe cleanser.
5. Remove the probe cleanser. The analyzer automatically completes probe cleanser maintenance.

10.2.2 Auto-cleaning Parts and Components

Fluidics should be cleaned when the background results are unqualified.

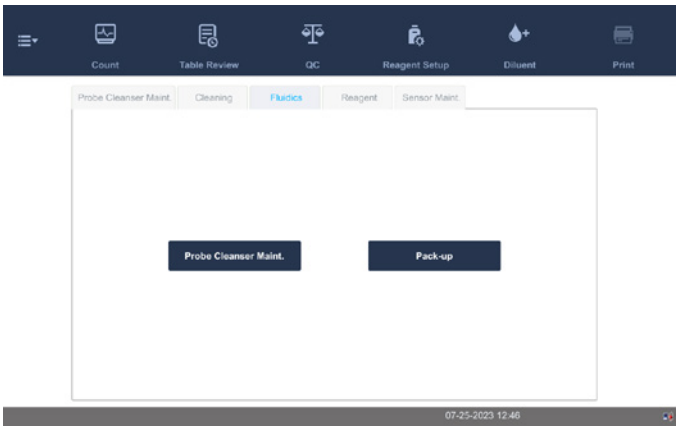
1. Touch **MENU ▶ SERVICE ▶ MAINTENANCE ▶ CLEANING** to enter the Cleaning screen.
2. Touch the corresponding cleaning program. The analyzer automatically completes the operation.



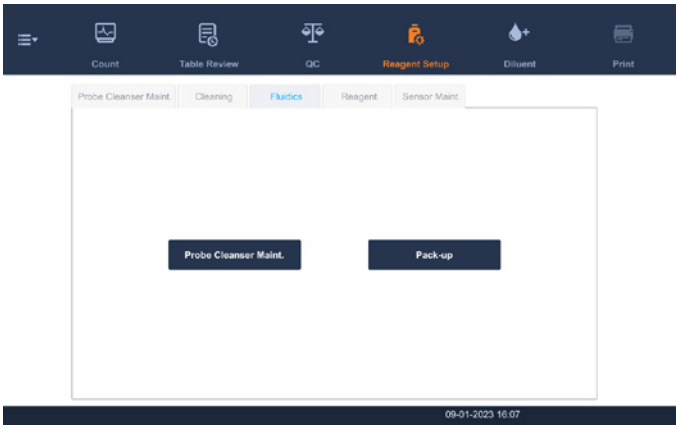
10.3 Preparing for Packup

10.3.1 Packing Up

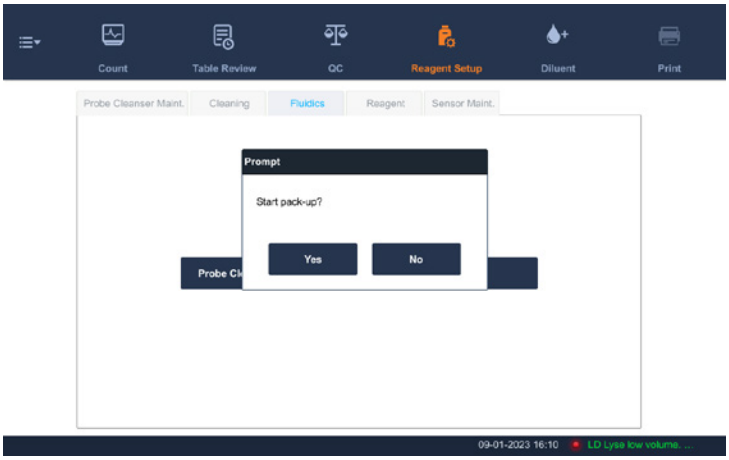
If the analyzer will not be used for over 2 weeks, perform this procedure.



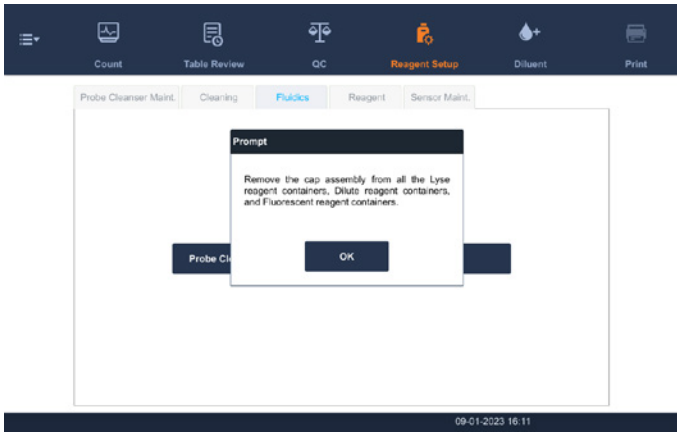
1. Touch **MENU** ▶ **SERVICE** ▶ **MAINTENANCE** ▶ **FLUIDICS** to enter the Fluidics screen.



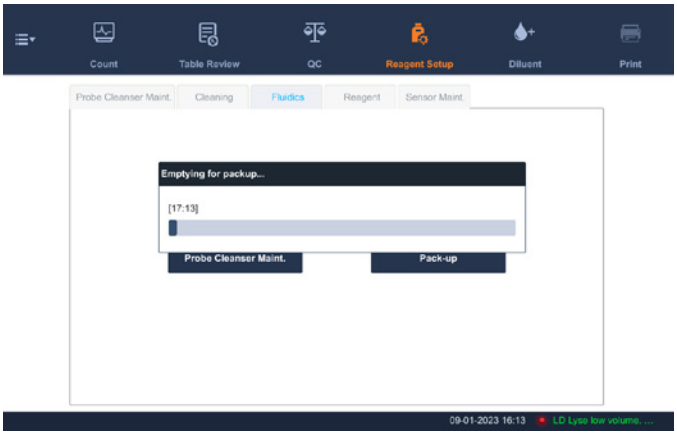
2. Touch **PACK-UP**, the dialog box, Start pack-up?, will display.



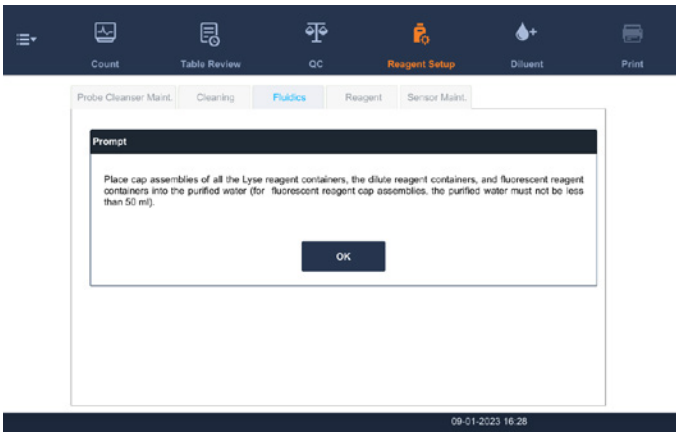
3. Touch **YES** to perform the pack-up procedure. The following dialog box will be displayed.



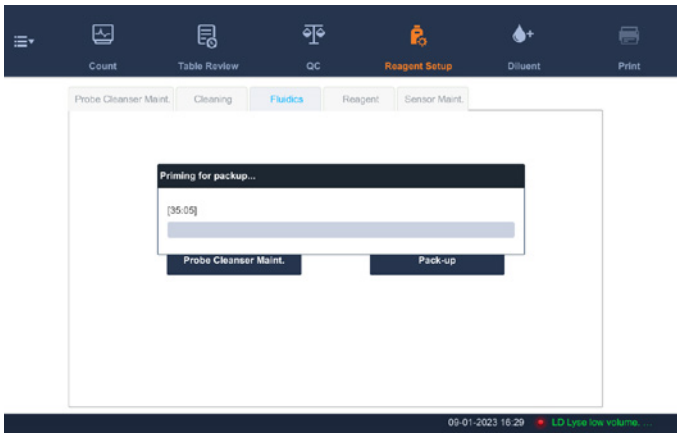
4. Take out the tubes as instructed and then touch **OK** to drain the fluidics.



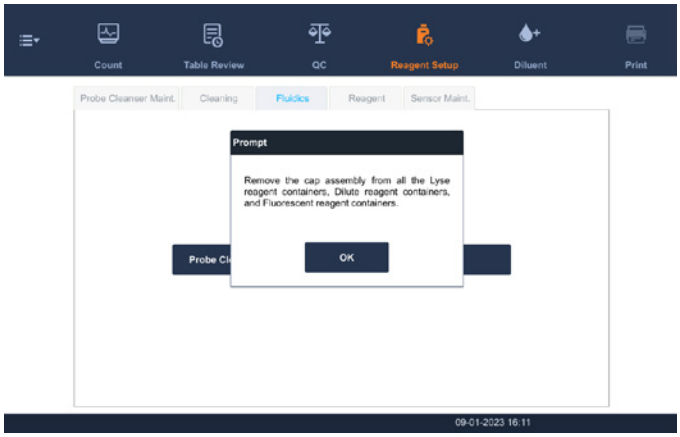
5. The following dialog box will be displayed after draining the fluidics.



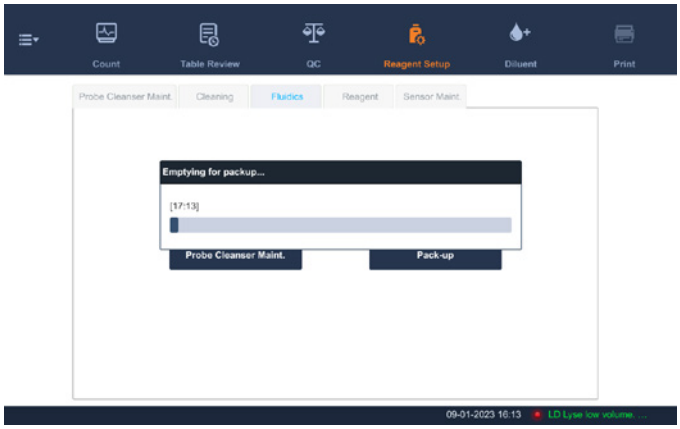
6. Put the tubes into distilled water as instructed, and touch **OK** to start priming.



7. When the priming progress ends, the following dialog box will be displayed.



8. Take out the tubes as instructed and then touch **OK** to drain the fluidics again.



9. The following screen prompt will be displayed after draining the fluidics.

10. When the pack-up is finished, shut down the analyzer as prompted.

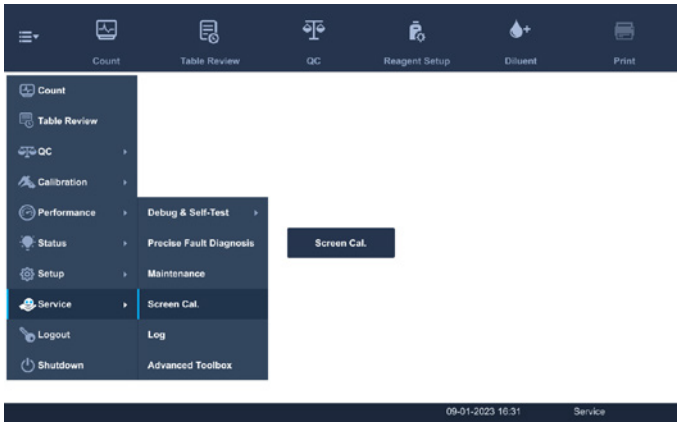
NOTE: This software can still be used after the pack-up.

10.4 Touch Screen Calibration

If the touch screen does not correctly respond to the positions touched, perform the touch screen calibration procedure.

NOTE: Do not touch with the mouse to calibrate the touch screen.

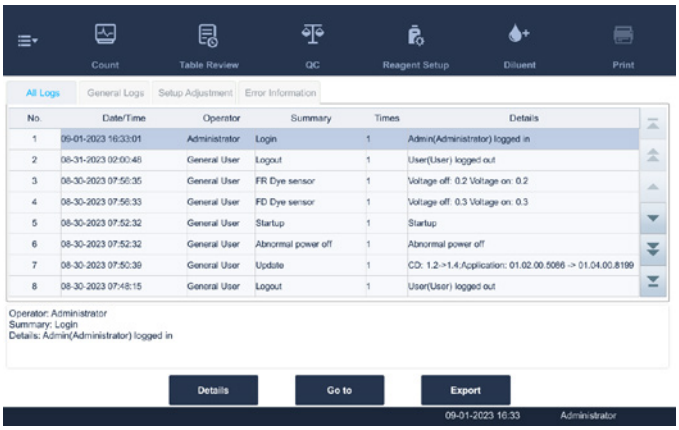
1. Touch **MENU** ► **SERVICE** ► **SCREEN CAL.** to enter the touch screen calibration screen.
2. Touch **SCREEN CAL**. in the middle of the screen.



3. Touch the black ✚ in the upper left corner of the screen as instructed by the screen display to start the calibration. After the calibration is completed, the software displays, Calibration succeeded..

10.5 Viewing and Exploring Logs

1. Touch **MENU** ►**SERVICE** ► **LOG** in the menu to enter the following screen.



2. Touch the type of logs to be viewed.

   (Optional) Review the logs at specified date range.

   Touch **GO TO**. A confirm dialog box displays. In the Date edit box, specify the date on which the logs need to be viewed.

3. Touch **OK**. The screen displays the logs at the specified date.

View the error info, parameter modification info. and records of daily operation in the log.

The Log screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

The analyzer can save logs of the recent two years.

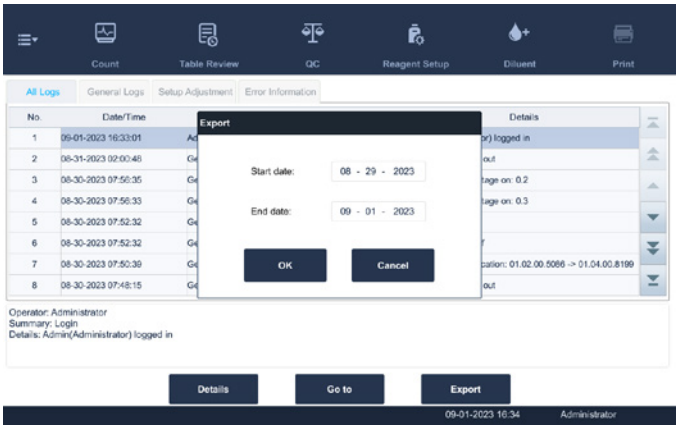
Logs may be browsed and printed but cannot be deleted.

Administrators and common users have different authorities.

NOTE: The oldest record will be overwritten automatically when number of log records reaches the maximum storage capacity. Two year maximum of records can be stored.

Exporting logs (requires connection to computer):

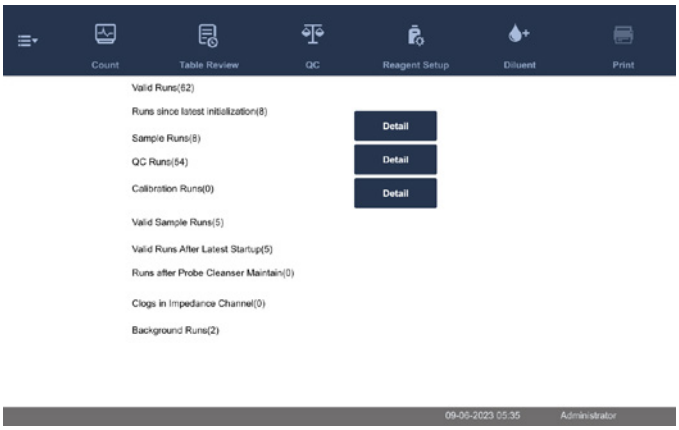
1. Touch **EXPORT** and the following dialog box will display.



2. Select the range of the logs to export.
3. Touch **OK** to close the dialog box and export the logs.

10.6 Checking the Analyzer Status

Touch **STATUS** ▶ **STATISTICS**

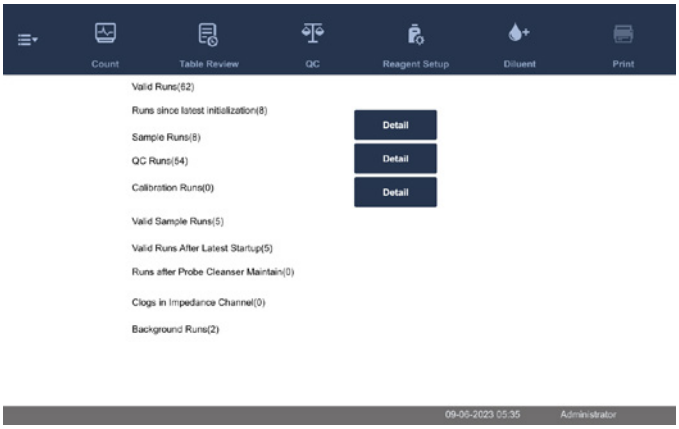


Analyzer information may be checked, including statistics, temperature and pressure, floater status, sensor status, voltage and current, as well as version information. Checking the status information on the Status screen is significant for locating and removing analyzer errors.

NOTE: If the status is outside normal range, it will be highlighted with red background.

10.6.1 Statistics

The counter counts the running times of the analyzer and the occurrence times of some major parameters.



Viewing Details

Touch **DETAIL** following Runs, QC Runs or Calibration Runs to view the related details.

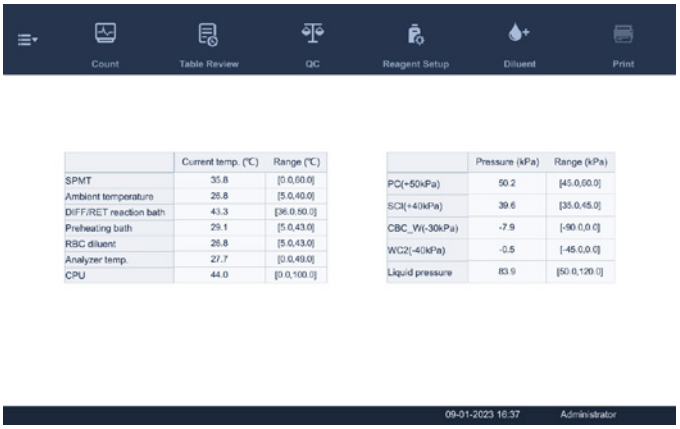
Print

Touch the print icon to print all information on the screen.

10.6.2 Temperature and Pressure

Touch **STATUS ▶ TEMP. & PRESSURE** in the menu to enter the following screen.

Check, export or print the temperature and pressure values of different components of the analyzer.



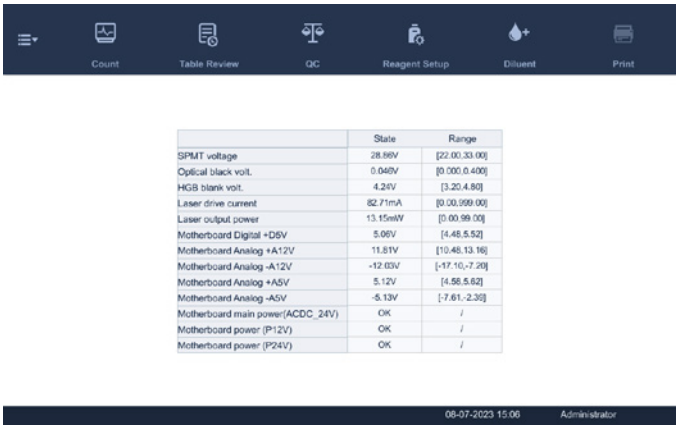
	Current temp. (℃)	Range (℃)
SPMT	35.8	[0.0,60.0]
Ambient temperature	26.8	[5.0,40.0]
DIFF/RET reaction bath	43.3	[36.0,50.0]
Preheating bath	29.1	[5.0,43.0]
RBC diluent	26.8	[5.0,43.0]
Analyzer temp.	27.7	[0.0,49.0]
CPU	44.0	[0.0,100.0]

	Pressure (kPa)	Range (kPa)
PC(+50kPa)	50.2	[45.0,60.0]
SCI(+40kPa)	39.6	[35.0,45.0]
CBC_W(-30kPa)	-7.9	[-90.0,0.0]
WC2(-40kPa)	-0.5	[-45.0,0.0]
Liquid pressure	83.9	[50.0,120.0]

10.6.3 Voltage and Current

Touch **STATUS ▶ VOLTAGE & CURRENT** in the menu to enter the following screen.

Check the voltage and current values of different components of the analyzer.

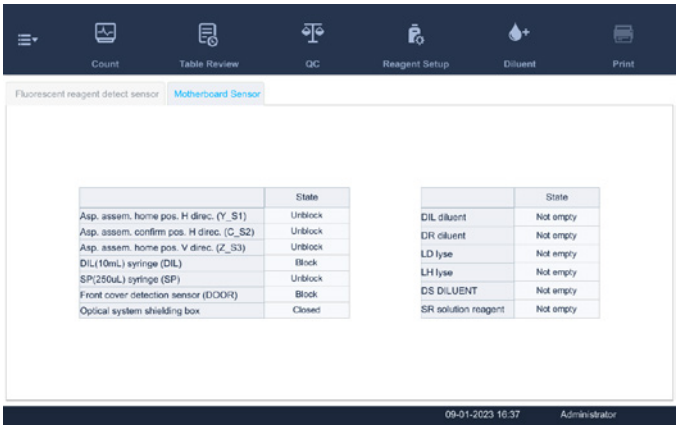


	State	Range
SPMT voltage	28.66V	[22.00,33.00]
Optical black volt.	0.040V	[0.000,0.400]
HGB blank volt.	4.24V	[3.20,4.80]
Laser drive current	82.71mA	[0.00,999.00]
Laser output power	13.15mW	[0.00,99.00]
Motherboard Digital +D5V	5.06V	[4.48,5.52]
Motherboard Analog +A12V	11.81V	[10.48,13.16]
Motherboard Analog -A12V	-12.03V	[-17.10,-7.20]
Motherboard Analog +A5V	5.12V	[4.56,5.62]
Motherboard Analog -A5V	-5.13V	[-7.61,-2.38]
Motherboard main power(ACDC_24V)	OK	/
Motherboard power (P12V)	OK	/
Motherboard power (P24V)	OK	/

10.6.4 Sensor

Touch **STATUS ▶ SENSOR** in the menu to enter the following screen.

Check the sensor status of the analyzer.

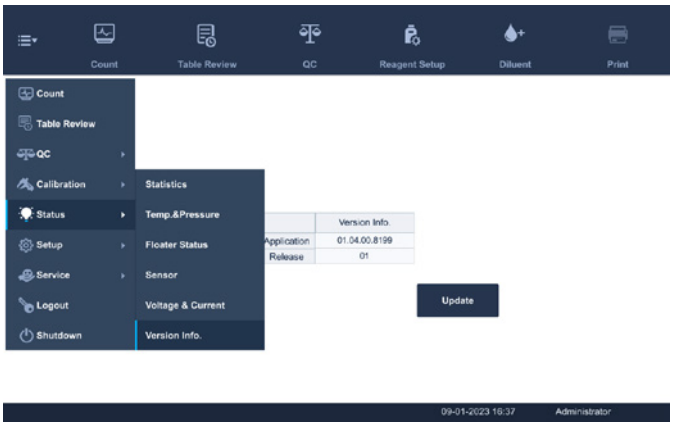


	State
Asp. assem. home pos. H direc. (Y_S1)	Unblock
Asp. assem. confirm pos. H direc. (C_S2)	Unblock
Asp. assem. home pos. V direc. (Z_S3)	Unblock
DIL(10mL) syringe (DIL)	Block
SP(250uL) syringe (SP)	Unblock
Front cover detection sensor (DOOR)	Block
Optical system shielding box	Closed

	State
DIL diluent	Not empty
DR diluent	Not empty
LD lyse	Not empty
LH lyse	Not empty
DS DILUENT	Not empty
SR solution reagent	Not empty

10.6.5 Version Information

Touch **STATUS ▶ VERSION INFO.** in the menu to enter the following screen. View the current version information of the analyzer.



11.1 Introduction

This chapter contains information that is helpful in locating and correcting problems that may occur during analyzer operation.

NOTE: This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer.

11.2 Error Information and Handling

During the operation, if an error is detected, the analyzer will beep and display the corresponding error message in the error information area at the bottom right of the screen. Meanwhile, the indicator will turn red.

According to the severity of the errors, the colors of error messages are red, orange, blue and green.

Red Fatal error. When this kind of error occurs, the analyzer will stop running immediately, and any further operation is prohibited.

Orange Error that stops operation. When this kind of error occurs, the analyzer will stop running immediately.

Blue Error that restricts certain operations. When this kind of error occurs, the analyzer can still continue with the current operation, but any other operations related to the error will be restricted.

Green Prompting error. When this kind of error occurs, the analyzer can still continue with the current operation, and other operations are not restricted.

The following figure is the error info. dialog box.

The name and troubleshooting method of the errors are displayed. Error names are displayed in the order of their occurrence.

Touch **ERROR CODE**, and view its troubleshooting information in the troubleshooting box.

The troubleshooting information of the first error is displayed by default. Please follow the troubleshooting steps in sequence to resolve the error.

11.2.1 Remove Error

Touch **REMOVE ERROR** to clear all errors that can be removed automatically. For the errors that cannot be removed automatically, follow the troubleshooting method to solve them.

1. Touch **CLOSE** to close the dialog box, but the errors will still be displayed in the error info. area on the screen.
2. Touch the error information area again, the dialog box will be displayed.

Error Codes

The possible error(s) and the corresponding troubleshooting information are listed below:

Error ID	Error Message	Description	Actions
0x10103	Waste Container full	Waste Container full	1 Replace the waste container with an empty one. 2. Touch **REMOVE ERROR** to remove this error. 3. If the error still exists, contact Heska's Technical Support Services.
0x10000	No DS Diluent Replace the reagent	No DS Diluent Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10001	No LD Lyse Replace the reagent	No LD Lyse Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10003	No LH Lyse Replace the reagent	No LH Lyse Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10002	No DR Diluent Replace the reagent	No DR Diluent Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10005	No FD Dye Replace the reagent	No FD Dye Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container 3. If the error still exists after replacing the lyse, contact Heska's Technical Support Services.
0x10006	No FR Dye Replace the reagent	No FR Dye Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10200	DS Diluent expires Replace the reagent	DS Diluent expires Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into the reagent setup dialog box 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10201	LD Lyse expires Replace the reagent	LD Lyse expires Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.

Error ID	Error Message	Description	Actions
0x10202	LH Lyse expires Replace the reagent	LH Lyse expires Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE**to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10203	DR Diluent expires Replace the reagent	DR Diluent expires Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10204	FD Dye expires Replace the reagent	FD Dye expires Replace the reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed.. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10205	FR Dye expires Replace reagent	FR Dye expires Replace reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10400	DS Diluent low volume Replace reagent	DS Diluent low volume Replace reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10401	LD Lyse low volume.Replace reagent	LD Lyse low volume Replace reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10402	LH Lyse low volume Replace reagent	LH Lyse low volume Replace reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10403	DR Diluent low volume Replace reagent	DR Diluent low volume Replace reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE t**o prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10404	FD Dye low volume Replace reagent	FD Dye low volume Replace reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x10405	FR Dye low volume. Replace reagent	FR Dye low volume Replace reagent	1. Touch **REMOVE ERROR** and register new reagent information into reagent setup dialog box displayed. 2. Touch **REPLACE** to prime reagent after replacing the reagent container. 3. If the error still exists, contact Heska's Technical Support Services.
0x40003	Import Key file	Import Key file	1. Touch **MENU ► SERVICE ► ADVANCED TOOLBOX ► DEBUG SETUP ► IMPORT PASSWORD**, otherwise, reagents cannot be replaced when built-in authorization runs out.
0x10100	DIL preheating bath sensor abnormal	DIL preheating bath sensor abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.

Error ID	Error Message	Description	Actions
0x10102	Waste cistern floater status abnormal	WC2 waste cistern floater status abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10101	Cistern floater status abnormal	SCI cistern floater status abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30105	FS baseline abnormal	FS baseline abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. Switch off then switch on the instrument power. 3. If the error still exists, contact Heska's Technical Support Services.
0x30106	FS baseline abnormal	SS baseline abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. Switch off then switch on the instrument power. 3. If the error still exists, contact Heska's Technical Support Services.
0x30107	FS baseline abnormal	FL baseline abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. Switch off then switch on the instrument power. 3. If the error still exists, contact Heska's Technical Support Services.
0x30200	HGB baseline abnormal	HGB baseline abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. Switch off then switch on the instrument power. 3. If the error still exists, contact Heska's Technical Support Services.
0x00300	DIL syringe action abnormal	Invalid command to DIL syringe	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00301	DIL syringe action abnormal	Conflicting DIL syringe actions	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00302	DIL syringe action abnormal	Error occurs when DIL syringe returns to home position	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00303	DIL syringe action abnormal	Error occurs when DIL syringe leaves sensor area	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00304	DIL syringe action abnormal	DIL syringe aspiration/ dispensation action failure 2	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00305	DIL syringe action abnormal	DIL syringe aspiration/ dispensation action failure 1	1. Touch **REMOVE ERROR** to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
0x00306	DIL syringe action abnormal	DIL syringe aspiration/ dispensation action not allowed 2	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00307	DIL syringe action abnormal	DIL syringe aspiration/ dispensation action not allowed 1	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00308	DIL syringe action abnormal	DIL syringe aspirated volume too high	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00309	DIL syringe action abnormal	DIL syringe dispensed volume too high	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00310	DIL syringe action abnormal	DIL syringe action time out	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00200	SP syringe action abnormal	Invalid command to SP syringe	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00201	SP syringe action abnormal	Conflicting SP syringe actions	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00202	SP syringe action abnormal	Error occurs when SP syringe returns to home position	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00203	SP syringe action abnormal	Error occurs when SP syringe leaves sensor area	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00204	SP syringe action abnormal	SP syringe aspiration/ dispensation action failure 2	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.

Error ID	Error Message	Description	Actions
0x00205	SP syringe action abnormal	SP syringe aspiration/ dispensation action failure 1	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00206	SP syringe action abnormal	SP syringe action abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00207	SP syringe action abnormal	SP syringe action abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00208	SP syringe action abnormal	SP syringe action abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00209	SP syringe action abnormal	SP syringe dispensed volume too high	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x00210	SP syringe action abnormal	SP syringe action time out	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10308	Auto pressure building out of time	Auto pressure building out of time	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x99800	Startup initiation not performed	Startup initiation not performed	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x20012	Drive board communication out of time	Drive board communication out of time	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10107	SCI priming out of time	SCI priming out of time	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x99805	Background abnormal	Background abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10306	Fluidic system status abnormal	Sampling probe clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10307	Fluidic system status abnormal	Flow cell clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x99801	Exiting standby status failed	Exiting standby status failed	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x99802	Exiting standby status failed	Exiting standby status failed	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x99803	Auto startup failed	Auto startup failed	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10111	SCI priming failed	SCI priming failed	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x20008	Closed-reagent RFID board communication timeout	Closed-reagent RFID board communication timeout	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30109	Optical signal board communication timeout	Optical signal board communication timeout	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x20011	Power supply board communication timeout	Power supply board communication timeout	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10300	50 kPa pressure out of range	50 kPa pressure out of range	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10304	-40 kPa pressure out of range	-40 kPa pressure out of range	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10104	Waste channel abnormal	Waste channel abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10301	Pressure cell pressure release abnormal	Pressure cell pressure release abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10303	SCI bath pressure release abnormal	SCI bath pressure release abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.

Error ID	Error Message	Description	Actions
0x10305	WC2 bath pressure release abnormal	WC2 bath pressure release abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30000	Reaction bath temperature high	Reaction bath temperature high	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30001	Preheating bath temperature control abnormal	Preheating bath temperature control abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30002	Temperature inside analyzer out of range	Temperature inside analyzer out of range	1. Make sure the analyzer is placed in a place with good ventilation, heat dispersion and with no direct sunlight. 2. Touch **REMOVE ERROR** to retest the temperature. 3. If the error still exists, contact Heska's Technical Support Services.
0x30003	Reaction bath temperature low	Reaction bath temperature low	1. Touch **REMOVE ERROR** to retest the temperature. 2. If the error still exists, contact Heska's Technical Support Services.
0x30004	Preheating bath temperature control abnormal	Preheating bath temperature out of the lower limit for counting	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30005	Ambient temperature is high	Ambient temperature is high	1. Make sure the ambient temperature is within acceptable range. 2. Touch **REMOVE ERROR** to retest the temperature. 3. If the error still exists, contact Heska's Technical Support Services.
0x30006	Ambient temperature low	Ambient temperature low	1. Make sure the ambient temperature is within acceptable range. 2. Touch **REMOVE ERROR** to retest the temperature. 3. If the error still exists, contact Heska's Technical Support Services.
0x30007	Ambient temperature is high	Ambient temperature high	1. Make sure the ambient temperature is within acceptable range. 2. Touch **REMOVE ERROR** to retest the temperature. 3. If the error still exists, contact Heska's Technical Support Services.
0x30008	Ambient temperature low	Ambient temperature low	1. Make sure the ambient temperature is within acceptable range. 2. Touch **REMOVE ERROR** to retest the temperature. 3. If the error still exists, contact Heska's Technical Support Services.
0x30009	Reaction bath temperature control assembly is damaged	Reaction bath temperature control assembly is damaged	1. Touch **REMOVE ERROR** to recheck the temperature. 2. If the error still exists, contact Heska's Technical Support Services.
0x30010	Preheating bath temperature control abnormal	Preheating bath does not achieve target temperature after startup procedure	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30100	Optical system working voltage abnormal	PMT voltage abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. Switch off and then switch on the instrument power. 3. If the error still exists, contact Heska's Technical Support Services.
0x30201	HGB blank voltage abnormal	HGB blank voltage abnormal	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30103	Flow cell contaminated	DIFF channel FS blank voltage abnormal	1. On the instrument main unit software, touch **MENU** ▶ **SERVICE** ▶ **MAINTENANCE** ▶ **FLUIDICS** to enter the Fluidics maintenance screen, and perform probe cleanser maintenance procedure. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x30104	Flow cell contaminated	RET channel FS blank voltage abnormal	1. On the instrument main unit software, touch **MENU** ▶ **SERVICE** ▶ **MAINTENANCE** ▶ **FLUIDICS** to enter the Fluidics maintenance screen, and perform probe cleanser maintenance procedure. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x20203	Analyzer fan faulty	Radiator fan in the analyzer is blocked	1. Check the fan on the back of the analyzer main unit for any foreign objects. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.

Error ID	Error Message	Description	Actions
0x99804	Front cover is open	Front cover is open	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30108	Optical system shielding box is open	Optical system shielding box is open	1. Close the Optical system shielding box. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x40001	System time error	System time error	1. On the instrument main unit screen, touch **MENU** ▶ **SETUP** ▶ **DATE/TIME SETUP** to enter the Date/Time Setup screen and set up the correct system time. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x30300	Clog	Aperture voltage abnormal	1. Aperture voltage abnormal. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x30301	Clog	Aperture voltage abnormal	1. Aperture voltage abnormal. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x30302	Clog	RBC sample preparation abnormal	1. RBC sample preparation abnormal. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x30303	Clog	RBC sample preparation abnormal	1. RBC sample preparation abnormal. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x20200	Power fan error	Power fan blocked	1. Check whether the power fan is stuck. 2. If the error still exists, contact Heska's Technical Support Services.
0x20201	Board fan faulty	Board radiator fan is blocked	1. Check the fan located on the back of the analyzer main unit for any foreign objects. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x20202	Board fan faulty	Board radiator fan is blocked	1. Check the fan located on the back of the analyzer main unit for any foreign objects. 2. Touch **REMOVE ERROR** to remove the error. 3. If the error still exists, contact Heska's Technical Support Services.
0x20002	Air pressure detection board error	Air pressure detection board communication error	1. Touch **REMOVE ERROR** to remove the error. 2 Switch off and then switch on the instrument power. 3. If the error still exists, contact Heska's Technical Support Services.
0x20003	Air pressure detection board error	Air pressure detection board calibration parameter error	1. Touch **REMOVE ERROR** to remove the error. 2 Switch off and then switch on the instrument power. 3. If the error still exists, contact Heska's Technical Support Services.
0x30202	Waste channel abnormal	HGB waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30203	Waste channel abnormal	HGB waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30204	Waste channel abnormal	HGB waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30600	Waste channel abnormal	DIFF waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30601	Waste channel abnormal	DIFF waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30602	Waste channel abnormal	DIFF waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30603	Waste channel abnormal	RET waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.

Error ID	Error Message	Description	Actions
0x30604	Waste channel abnormal	RET waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services..
0x30605	Waste channel abnormal	RET waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10108	Waste channel abnormal	Probe wipe waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10109	Waste channel abnormal	Probe wipe waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x10110	Waste channel abnormal	Probe wipe waste channel clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30304	Waste channel abnormal	Cleaning channel of RBC sample preparation clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30305	Waste channel abnormal	Cleaning channel of RBC sample preparation clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.
0x30306	Waste channel abnormal	Cleaning channel of RBC sample preparation clogged	1. Touch **REMOVE ERROR** to remove the error. 2. If the error still exists, contact Heska's Technical Support Services.

A. Specifications

A.1 Classification

According to the CE classification, the Element HT5+ Hematology Analyzer belongs to *in vitro* diagnostic medical devices other than those covered by Annex II and devices for performance evaluation.

A.2 Reagents

Diluents: DR diluent
DS diluent

Lyses: LD lyse
LH lyse

Dyes: FD dye
FR dye

Cleaners: Solution reagent
Probe cleanser

A.3 Applicable Tubes

The following tubes can be used:

- Purple-top EDTA collection tubes filled at least halfway.

A.4 Blood Sample Test Parameters

Parameter	Abbreviation	SI Units	US Units
White blood cell count	WBC	10^9/L	10^3/μL
Neutrophils number	Neu#	10^9/L	10^3/μL
Lymphocytes number	Lym#	10^9/L	10^3/μL
Monocytes number	Mon#	10^9/L	10^3/μL
Eosinophils number	Eos#	10^9/L	10^3/μL
Basophils number	Bas#	10^9/L	10^3/μL
Neutrophils percentage	Neu%	%	%
Lymphocytes percentage	Lym%	%	%
Monocytes percentage	Mon%	%	%
Eosinophils percentage	Eos%	%	%
Basophils percentage	Bas%	%	%
Red blood cell count	RBC	10^{12}/L	10^6/μL
Hemoglobin concentration	HGB	g/L	g/dL
Mean corpuscular volume	MCV	fl	fL
Mean corpuscular hemoglobin	MCH	pg	pg
Mean corpuscular hemoglobin concentration	MCHC	g/L	g/dL

Parameter	Abbreviation	SI Units	US Units
Red blood cell distribution width coefficient of variation	RDW-CV	%	%
Red blood cell distribution width standard deviation*	RDW-SD	fL	fL
Hematocrit	HCT	%	%
Platelet count	PLT	10^9/L	10^3/μL
Mean Platelet Volume	MPV	fL	fL
Platelet distribution width	PDW	10 GSD	10 GSD
Plateletcrit	PCT	%	%
Platelet Large Cell Count	P-LCC	10^9/L	10^3/μL
Platelet Large Cell Ratio*	P-LCR	%	%
Immature platelet fraction*	IPF	%	%
Reticulocyte number	RET#	10^9/L	10^3/μL
Reticulocyte percentage	RET%	%	%
Immature reticulocyte fraction*	IRF	%	%
Low fluorescence reticulocytes*	LFR	%	%
Medium fluorescence reticulocytes*	MFR	%	%
High fluorescence reticulocytes*	HFR	%	%
Reticulocyte hemoglobin	RHE	pg	pg
Red blood cell histogram	RBC histogram	N/A	N/A
Platelet histogram	PLT histogram	N/A	N/A
Differential scattergram	Diff scattergram	N/A	N/A
Reticulocyte scattergram	RET scattergram	N/A	N/A

*Auxiliary parameters

A.5 Body Fluid Sample Test Parameters

Parameter	Abbreviation
White blood cell count-body fluid	WBC-BF
Total nucleated cell count- body fluid	TC-BF#
Mononuclear cell number	MN#
Polymorphonuclear cell number	PMN#
Polymorphonuclear cell %	PMN%
Red blood cell count-body fluid	RBC-BF

B. Sampling Features

B.1 Sample Volumes Required for Each Analysis

Whole blood mode: ≤ 34 µl

Predilute mode: ≤ 20 u/L

B.2 Throughput

Open vial-whole blood: no less than 40 tests per hour.

Prediluted whole blood sample: no less than 29 tests/hour.

C. Performance Specifications

C.1 Reportable (Display) Range

Parameter	Reportable Range–SI Units	Reportable Range–US Units
WBC, Neu#, Lym#, Mon#, Eos#, Bas#	0.00–999.99 × 10^9/L	0.00–999.99 × 10^3/µL
Neu%, Lym%, Mon%, Eos%, Bas% , IPF*, RET%, IRF, LFR, MFR, HFR*	0.0–100.0%	0.0–100.0%
RBC	0–99.99 × 10^{12}/L	0-99.99 × 10^6/µL
HGB	0–350 g/L	0 g/dL ~350 g/dL
HCT, P-LCR*, RDW-CV,	0–99.9%	0–99.9%
MCV	0–450.0 fL	0–450.0 fL
MCH	0–999.9 pg	0–999.9 pg
MCHC	0–9999 g/L	0–999.9 g/dL
RDW-SD*	0–999.9 fL	0–999.9 fL
P-LCC*, PLT	0–9999 × 10^9/L	0–9999 × 10^3/µL
MPV	0–99.9 fL	0–99.9 fL
PDW	0–99.9	0–99.9
PCT	0–9.999%	0–9.999%
RET#	0–9999.9 × 10^9/L	0–9999.9 × 10^3/µL
RHE	0–999.9 pg	0–999.9 pg

*Auxiliary parameters

C.2 Background/Blank Count for Blood Samples

	Background/Blank Count Requirements	
Parameter	SI Units	US Units
WBC	< 0.10 × 10^9/L	≤ 0.10 × 10^3/µL
RBC	< 0.02 × 10^{12}/L	≤ 0.02 × 10^6/µL
HGB	< 1.0 g/L	≤ 1.0 g/dL
PLT	≤ 5 × 10^9/L	≤ 5 × 10^3/µL

C.3 Background/Blank Count for Body Fluid Samples

Parameter	Carryover SI Units	Carryover US Units
WBC-BF	≤ 0.003×10^9/L	≤ 0.003×10^3/μL
RBC-BF	≤ 0.003×10^{12}/L	≤ 0.003×10^6/μL

C.4 Linearity Range and Precision

	Linearity Range		Precision	
Parameter	SI Units	US Units	SI Units	US Units
WBC	0–100.00 × 10^9/L 100.01–350.00 × 10^9/L 350.01–500.00 × 10^9/L	0–100.0 × 10^3/μL 100.01–350.00 × 10^3/μL 350.01–500.00 × 10^3/μL	±0.20 × 10^9/L or ± 3% ± 6% ± 11%	±0.20 × 10^3/μL or ± 3% ± 6% ± 11%
RBC	0–8.0 × 10^{12}/L 8.01–16.99 × 10^{12}/L	0–8.0 × 10^6/μL 8.01–16.99 × 10^6/μL	±0.03 × 10^{12}/L or ± 2% ±0.06 × 10^{12}/L or ± 4%	±0.03 × 10^6/μL or ± 2% ±0.06 × 10^6/μL or ± 4%
HGB	0–260 g/L	0–26 g/dL	±2 g/L or ± 2%	±0.2 g/dL or ± 2%
HCT	0–75%	0–75%	±1.0 (HCT) or ± 2%	±1.0 (HCT) or ± 2%
PLT	0–1000 × 10^9/L 1001–5,000 × 10^9/L	0–1000 × 10^3/μL 1001–5,000 × 10^3/μL	±10 × 10^9/L or ± 5% ± 6%	±10 × 10^3/μL or ± 5% ± 6%
RET#	0–800 × 10^9/L	0–800 × 10^3/μL	15 × 10^9/L or ± 20%	15 × 10^3/μL or ± 20%
RET%	0.00–30.00%	0.00–30.00%	±0.30 (RET%) or ± 20%	±0.30 (RET%) or ± 20%

C.5 Linearity Requirements for Body Fluid Samples

	Linearity Range		Deviation Range	
Parameter	SI Units	US Units	SI Units	US Units
WBC-BF/TC-BF#	0.000–0.050 × 10^9/L 0.051–1.000 × 10^9/L 1.001–10.000 × 10^9/L	0.000–0.050 × 10^3/μL 0.051–1.000 × 10^3/μL 1.001–10.000 × 10^3/μL	+/- 0.010 × 10^9/L ± 20% ± 20%	±0.010 × 10^3/μL ± 20% ± 20%
RBC-BF	0.000–0.100 × 10^{12}/L 0.000–0.100 × 10^{12}/L	0.000–0.100 × 10^6/μL 0.000–0.100 × 10^6/μL	±0.010 × 10^{12}/L or ± 5% ±0.030 × 10^{12}/L or ± 2%	±0.010 × 10^6/μL or ± 5% ±0.030 × 10^6/μL or ± 2%

C.6 Repeatability Requirements for QC in Blood Samples

Parameter	SI Units	US Units	Whole Blood CV/Absolute Deviation d*SD	Predilute CV/Absolute deviation d*SD
WBC	3.50–4.50 × 10^9/L ≥ 4.50 × 10^9/L	3.50–4.50 × 10^3/μL ≥ 4.50 × 10^3/μL	≤ 3.0% ≤ 2.5%	≤ 4.0% ≤ 3.5%
RBC	≥ 3.50 × 10^{12}/L	≥ 3.50 × 10^6/uL	≤ 1.5%	≤ 2.0%
HGB	110–180 g/L	11–18 g/dL	≤ 1.0%	≤ 2.0%
MCV	80.0–100.0 fL	80.0–100.0 fL	≤ 1.0%	≤ 3.0%
HCT	30.0–50.0%	30.0–50.0%	≤ 1.5%	≤ 3.0%
MCH	/	/	≤ 1.5%	/
MCHC	/	/	≤ 1.5%	/
RDW-SD*	/	/	≤ 2.0%	/

Parameter	SI Units	US Units	Whole Blood CV/Absolute Deviation d*SD	Predilute CV/Absolute deviation d*SD
PLT	≥ 100 × 10^9/L	≥ 100 × 10^3/μL	≤ 4%	≤ 8%
PDW	PLT ≥ 100 × 10^9/L	PLT ≤ 100 × 10^3/μL	≤ 10%	/
MPV	PLT ≥ 100 × 10^9/L	PLT ≥ 100 × 10^3/μL	≤ 3.0%	/
P-LCR*	PLT ≥ 100 × 10^9/L	PLT ≥ 100 × 10^3/μL	≤ 15%	/
P-LCC*	PLT ≥ 100 × 10^9/L	PLT ≥ 100 × 10^3/μL	≤ 15%	/
PCT	PLT ≥ 100 × 10^9/L	PLT ≥ 100 × 10^3/μL	≤ 5%	/
RDW-SD*	/	/	≤ 2.0%	/
PLT	≥ 100 × 10^9/L	≥ 100 × 10^3/μL	≤ 4%	≤ 8%
Neu%	Neu% ≥ 30.0% WBC ≥ 4.00 × 10^9/L	Neu% ≥ 30.0% WBC ≥ 4.00 × 10^3/μL	≤ 6.0%	≤ 12.0%
Lym%	Lym% ≥ 15% WBC ≥ 4.00 × 10^9/L	Lym% ≥ 15% WBC ≥ 4.00 × 10^3/μL	≤ 6.0%	≤ 12.0%
Mon%	Mon% ≥ 5.0% WBC ≥ 4.00 × 10^9/L	Mon% ≥ 5.0% WBC ≥ 4.00 × 10^3/μL	≤ 16%	≤ 32.0%
Eos%	WBC ≥ 4.00 × 10^9/L	WBC ≥ 4.00 × 10^3/μL	≤ 20.0% or +/– 1.5% (d)	≤ 40.0% or +/– 3.0% (d)
Bas%	WBC ≥ 4.00 × 10^9/L	WBC ≥ 4.00 × 10^3/μL	≤ 30.0% or +/– 1.0% (d)	≤ 60.0% or +/– 2.0% (d)
Neu#	≥ 1.20 × 10^9/L	≥ 1.20 × 10^3/μL	≤ 6.0%	≤ 12.0%
Lym#	≥ 0.60 × 10^9/L	≥ 0.60 × 10^3/μL	≤ 6.0%	≤ 12.0%
Mon#	≥ 0.20 × 10^9/L	≥ 0.20 × 10^3/μL	≤ 16.0%	≤ 32.0%
Eos#	WBC ≥ 4.00 × 10^9/L	WBC ≥ 4.00 × 10^3/μL	≤ 20.0% or +/– 0.12 x 10^9/L (d) SI ≤ 20.0% or +/– 0.12 × 10^3/μL (d) US	≤ 40.0% or +/– 0.24 × 10^9/μL (d) SI ≤ 40.0% or +/– 0. x 24 × 10^3/μL (d) US
Bas#	WBC ≥ 4.00 × 10^9/L	WBC ≥ 4.00 × 10^3/μL	≤30.0% or +/– 0.06 x 10^9/L (d) SI ≤30.0% or +/– 0.06 × 10^3/μL (d) US	≤60.0% or +/– 0.12 × 10^9/μL (d) SI ≤60.0% or +/– 0.12 × 10^3/μL (d) US
RET#	RBC ≥ 3.00 × 10^{12}/L RET% 1.00%–4.00%	RBC ≥ 3.00 × 10^6/μL RET% 1.00%–4.00%	≤ 15%	≤ 30.0%
RHE	RET# ≥ 0.0200 × 10^{12}/L	RET# ≥ 0.0200 × 10^6/μL	≤ 5%	/
LFR*	RBC ≥ 3.00 × 10^{12}/L RET% 1.00%–4.00% LFR ≥ 20%	RBC ≥ 3.00 × 10^6/μL RET% 1.00%–4.00%	≤ 30%	/
MFR*	RBC ≥ 3.00 × 10^{12}/L RET% 1.00%–4.00%	RBC ≥ 3.00 × 10^6/μL RET% 1.00%–4.00%	≤ 50%	/
HFR*	RBC ≥ 3.00 × 10^{12}/L RET% 1.00%–4.00%	RBC ≥ 3.00 × 10^6/μL RET% 1.00%–4.00% ≤ 100% or +/– 2.0% (d)	≤ 100% or +/– 2.0% (d)	/
IRF*	RBC ≥ 3.00 × 10^{12}/L RET% 1.00%–4.00% IRF ≥ 20.0%	RBC ≥ 3.00 × 10^6/μL RET% 1.00%–4.00% IRF ≥ 20.0%	≤ 30%	/
IPF*	PLT ≥ 50 × 10^9/L IPF ≥ 3.0%	PLT ≥ 50 × 10^6/μL IPF ≥ 3.0%	≤ 25%	/

*Auxiliary parameters

C.7 Repeatability Requirements for QC in Body Fluids

Parameter	Range		Precision or Absolute Deviation (d)
	SI Units	US Units	
WBC-BF	0.015–0.100 × 10^9/µL	0.015–0.100 × 10^3/µL	≤ 30%
RBC-BF	0.003–0.050 × 10^{12}/µL	0.003–0.050 × 10^6/µL	≤ 40% or ≤ 7000/µL (d)

C.8 Deviation of Reading

Parameter	Deviation of Reading
WBC	≤ ± 10%
RBC	≤ ± 6%
HGB	≤ ± 7%
PLT	≤ ± 15%

C.9 Compatibility

Deviation ranges: WBC ≤ ± 5%, RBC ≤ ± 2%, HGB ≤ ± 2%, PLT ≤ ± 8%, HCT/MCV ≤ ± 3%.

C.10 Carryover

Parameter	Carryover
WBC	≤ 1.0%
RBC	≤ 1.0%
HGB	≤ 1.0%
HCT	≤ 1.0%
PLT	≤ 1.0%

C.11 Carryover Requirements for Body Fluid Samples

Parameter	Carryover SI Units	Carryover US Units
WBC-BF	≤ 0.3% or ≤ 0.03 × 10^9/µL	≤ 0.3% or ≤ 0.03 × 10^3/µL
RBC-BF	≤ 0.3% or ≤ 0.03 × 10^{12}/µL	≤ 0.3% or ≤ 0.03 × 10^6/µL

D. External Computer (optional)

Recommended PC configurations: CPU Intel® 1.6 GHz and above.

RAM: 1 G or above.

Hard disk: 160 GB or above.

Recommended resolution of the display 1280 × 1024 (standard), 1680 × 1050 (wide screen).

Operating system: Microsoft Windows® 7 or above, with DVD-ROM.

D.1 Keyboard (optional)

10-key alpha-numeric keyboard.

D.2 Mouse (optional)

E. External Barcode Scanner (optional)

USB port (supporting the protocol of USB 2.0 and above) hand-held barcode scanner.

F. Printer (optional)

USB port (supporting the protocol or USB 2.0 and above) printer.

Supported printer models are: HP Laser Jet Pro M404n and HP Office Jet Pro 8210. Other HP PCL type printers with USB connectivity may work as well.

G. Interfaces

- 4 USB ports
- 1 Ethernet port

H. Power Supply

	Voltage	Input power	Frequency
Analyzer	100V–240 V~ ± 10%	300 VA	50 Hz/60 Hz ± 1 Hz

I. FUSE

WARNING

Use specified fuse only.

Fuse specification: 250 V T3.15 AH

J. EMC Description

Do not use this device in close proximity to sources of strong electromagnetic radiation (*e.g.*, unshielded intentional RF sources), as these may interfere with the proper operation.

This equipment complies with the emission and immunity requirements of the EN61326–1:2006 and EN61326–2–6:2006.

NOTE: It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

NOTE: It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

K. Sound

Maximal sound: 80 dBA

NOTE: Be sure to use and store the analyzer in the specified environment.

L. Operating Environment

Optimal operating temperature: 50°F–86°F (10°C~30°C)

Optimal operating humidity: 30%~85%

Atmospheric pressure: 70 kP~106 kPa

M. Storage Environment

Ambient temperature: 50°F–104°F (-10°C~40°C)

Relative humidity: 10~90%

Atmospheric pressure: 50 kPa ~106 kPa

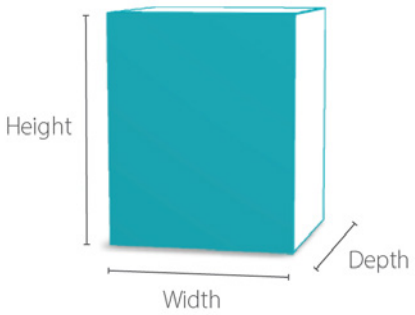
N. Running Environment

Ambient temperature: 50°F–104°F (-10°C~40°C)

Relative humidity: 10%~90%

Atmospheric pressure: 70 kP~106 kPa

O. Dimensions and Weight



Element HT5+ Veterinary Hematology Analyzer			
Dimensions	Width Height (with feet) Depth	≤12.8 in ≤17.7 in ≤23.2 in	325 mm 450 mm 590 mm
Weight		≤68.3 lbs	31 kg

P. Contra-Indications

None

Q. Safety Classification

Level of transient overvoltage: Category II

Rated pollution degree: 2

CE

For this Operator's Manual, the issue date is 2022–12.

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