

Element HT5

Veterinary Hematology Analyzer



**USER
MANUAL**

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1.1 Introduction

This chapter explains how to use your Element HT5 Hematology Analyzer User Manual, which is shipped with your Element HT5 Hematology Analyzer and contains reference information about the analyzer and procedures for operating, troubleshooting and maintaining the analyzer. Read this manual carefully before operating your Element HT5 Hematology Analyzer and operate your Element HT5 Hematology Analyzer as instructed in this manual.

1.2 Who Should Read This Manual

This 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 find the information you need.

If you want to ...	See ...
Learn about the intended use and parameters of the Element HT5 Hematology Analyzer	<i>Section 2: Understanding Your Analyzer</i>
Learn about the Element HT5 Hematology Analyzer hardware, interface and software	<i>Section 2: Understanding Your Analyzer</i>
Learn how the Element HT5 Hematology Analyzer works	<i>Section 3: Understanding the System Principles</i>
Learn about the Element HT5 Hematology Analyzer installation requirements	<i>Section 4: Installing Your Analyzer</i>
Learn about the sample collection and analysis process	<i>Section 5: Operating Your Analyzer</i>
Learn how to use the Element HT5 Hematology Analyzer to perform your daily operating tasks	<i>Section 5: Operating Your Analyzer</i>
Review sample results	<i>Section 6: Reviewing Sample Results</i>
Learn how to use the quality control programs for the Element HT5 Hematology Analyzer	<i>Section 7: Using the QC Programs</i>

If you want to ...	See ...
Calibrate the Element HT5 Hematology Analyzer	<i>Section 8: Using the Calibration Programs</i>
Define/adjust system settings	<i>Section 9: Customizing the Analyzer Software</i>
Maintain/service the Element HT5 Hematology Analyzer	<i>Section 10: Maintaining Your Analyzer</i>
Troubleshoot the Element HT5 Hematology Analyzer	<i>Section 11: Troubleshooting Your Analyzer</i>
Know the technical specifications of the Element HT5 Hematology Analyzer	<i>Appendix A: Specifications</i>

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 .
	Letters included in brackets indicate text you may find on the screen of Element HT5 Hematology Analyzer, such as [CLEAN].
xx	Italicized letters indicate section titles, such as <i>Section 1: Using This Manual</i> .

All illustrations in this manual are provided as examples only. They may not necessarily reflect setup of the Element HT5 Hematology Analyzer 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 your 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:



CAUTION: Consult Accompanying Documents



WARNING: Laser Beam



BIOLOGICAL RISK



Ground



USB Port



Network Port



Alternating Current



Batch Code



Use By



Serial Number



Serial Number



Temperature Limitation



Manufacturer



Date of Manufacture



CAUTION: Avoid aspiration probe.



Consult the User Manual



The device fully conforms with the council directive concerning In Vitro diagnostic medical devices 98/79/EC.

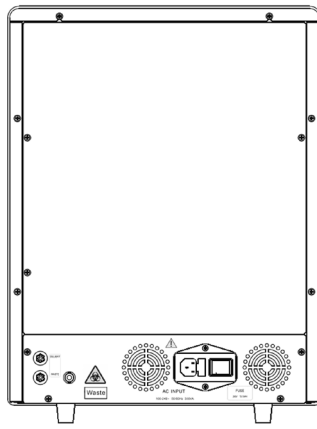


Figure 1.1 Analyzer Back

 **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.

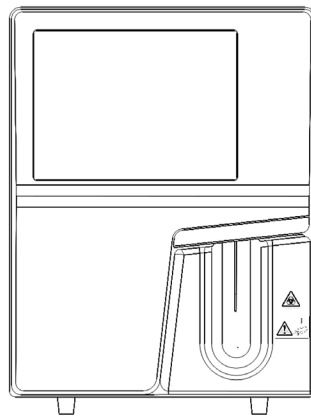


Figure 1.2 Analyzer Front

  **WARNING**

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

 **BIOHAZARD**

Warning, potential biological risk.

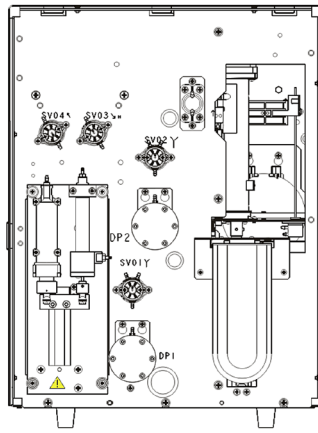


Figure 1.3 Analyzer Front with Cover Open



WARNING

Do not put hands under the syringe or in the guide slot when the analyzer is running.

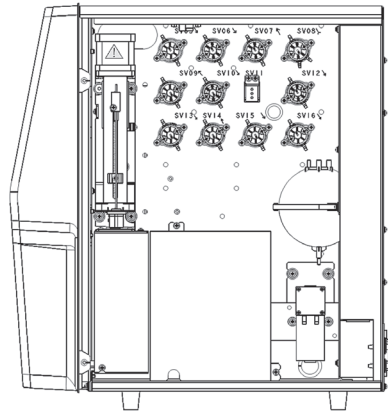


Figure 1.4 Analyzer Right Side



WARNING

Do not put hands under the syringe or in the guide slot when the analyzer is running.

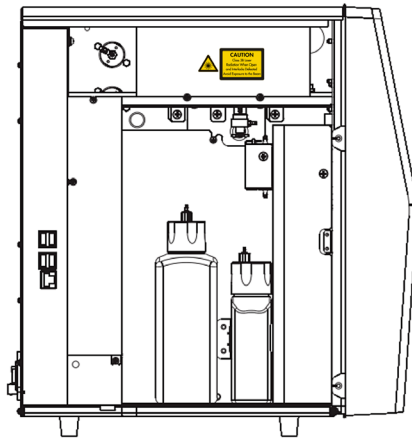


Figure 1.5 Analyzer Left Side



CAUTION

Class 3B Laser radiation when open and interlocks defeated avoid exposure to the beam.

2.1 Introduction

This chapter introduces the parameters, major components, interfaces, buttons, menus, software help system, operation information and reagent system of the Element HT5 Hematology Analyzer.

2.2 Parameters

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

The analyzer determines 23 parameters, 3 histograms and 1 scattergram of blood samples. The parameters under CBC+DIFF mode are listed as follows:

Parameter Group	Name	Abbreviation	CBC+DIFF
WBC group (11)	White Blood Cell count	WBC	√
	Basophils number	Bas#	√
	Basophils percentage	Bas%	√
	Neutrophils number	Neu#	√
	Neutrophils percentage	Neu%	√
	Eosinophils number	Eos#	√
	Eosinophils percentage	Eos%	√
	Lymphocytes number	Lym#	√
	Lymphocytes percentage	Lym%	√
	Monocytes number	Mon#	√
	Monocytes percentage	Mon%	√
RBC group (7)	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	√
PLT group (2)	Platelet count	PLT	√
	Mean Platelet Volume	MPV	√

2.2.1 Histograms

Name	Abbreviation	CBC+DIFF
White Blood Cell Histogram	WBC Histogram	√
Red Blood Cell Histogram	RBC Histogram	√
Platelet Histogram	PLT Histogram	√

2.2.2 Scattergram

Name	Abbreviation	CBC+DIFF
Differential Scattergram	Diff 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 (ROP) and accessories. The appearance of the product is featured below.

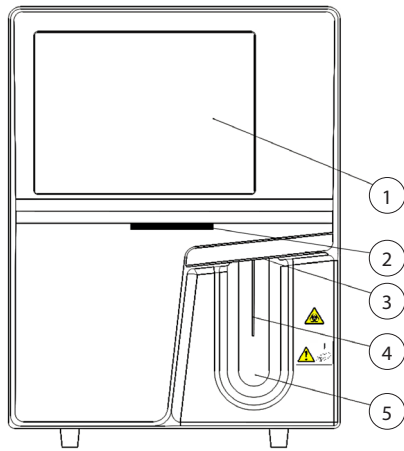


Figure 2.1 Element HT5 Hematology Analyzer



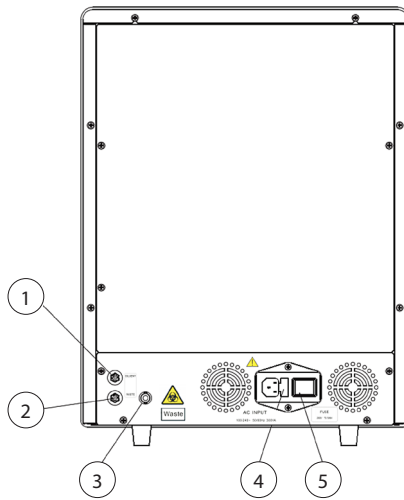
WARNING

Ensure reagent door is closed before operating the analyzer.



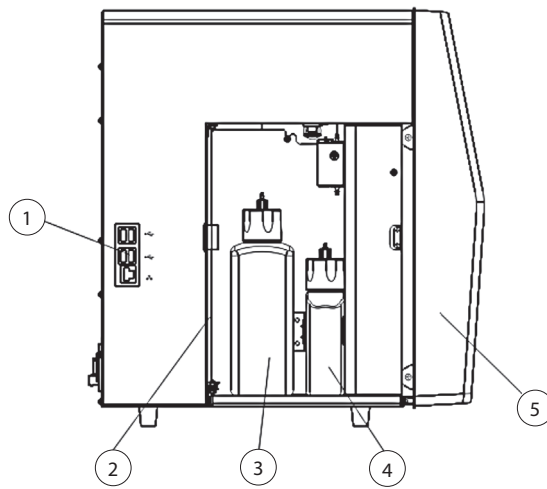
2.2 Analyzer Front

- | | | |
|-----------------|---------------------------|---------------------|
| 1. Display | 2. Power/Status indicator | 3. Probe wipe block |
| 4. Sample probe | 5. Aspirate key | |



2.3 Analyzer Back

- | | | |
|------------------------|-----------------|-----------------|
| 1. M-52D diluent inlet | 2. Waste outlet | 3. Waste sensor |
| 4. AC input | 5. Power switch | |



2.4 Analyzer Side

- | | | |
|---------------------------|-------------------------|-----------------------------|
| 1. Network port, USB port | 2. Lyse reagent door | 3. DIFF lyse reagent bottle |
| 4. LH lyse reagent bottle | 5. Front cover assembly | |

Power switch

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 left of the analyzer. They can be used to connect the printer, barcode scanner, *etc.* and to transmit data.

The supported printer models are: EPSON LQ-590K, HP Laser Jet P1505n, HP OfficeJet Pro K5300 and HP LaserJet P1606dn.

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:

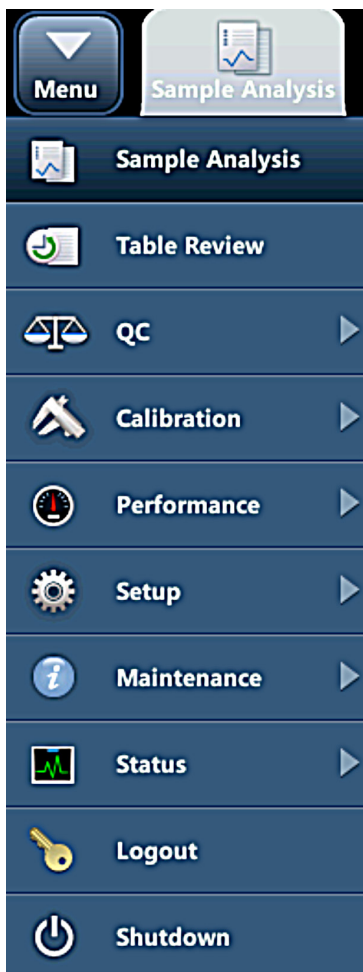
Status	Indicator	Note
Ready	Solid green	Ready to sequence actions
Running	Flashing green	Sequence actions in progress
Running with error	Flashing red	The analyzer is running with error
Error	Solid red	An error has occurred, and the analyzer is not running
No error, fluidic actions are not available	Solid yellow	Initializing (not involving sequence actions) in startup process, standby status
Entering/exiting standby status	Flashing yellow	Entering/exiting standby status

2.5 Buzzer

The buzzer indicates analyzer errors. When you touch the screen or the error is cleared, the buzzer can be cleared.

When...	How...	Note
The startup process completes.	1 short beep	The startup process completes and the analyzer is ready to run analysis.
Open vial sample aspiration finishes.	2 short beeps	
Press the aspirate key at the analysis screens (including sample analysis, QC, calibration, Reproducibility, carryover, background, aging, optical gain calibration screens) when analysis cannot be started.	1 long beep	When dialog box message is given, the buzzer may not beep.
Error	Long beeps at intervals	Touch the touch screen to turn off the buzzer.
The analyzer enters ready status.	1 short beep	The analyzer enters ready status from another status.
When the analyzer screen turns black and the message "Please power off the analyzer" appears.	Turn off the buzzer.	If error occurs during the shutdown process, please turn off the buzzer when the screen turns black.

2.6 System Menu



2.7 Reagents, Controls and Calibrators

The analyzer, reagents (diluent, lyses, and probe cleanser), 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 your 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 you have changed the diluent or lyse, 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.

2.7.1 Reagents

Diluent

Used to dilute blood samples and provide an ideal environment for counting and sizing blood cells.

DIFF Lyse

Used to lyse red blood cells and differentiate WBCs.

LH Lyse

Used to lyse red blood cells, count and differentiate WBCs, and determine the HGB.

Probe Cleanser

Probe cleanser is used to clean the analyzer regularly.

2.7.2 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 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: Electrical Impedance method for determining the RBC and PLT data; colorimetric method for determining HGB and flow cytometry by laser for determining the WBC differential data. 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 15 μL (CBC+DIFF mode) of the sample.

If analyzing a capillary blood sample in the open vial sampling mode, you will first manually dilute the sample (20 μL of capillary sample needs to be diluted by 480 μL of diluent, dilution ratio: 1:25) and then present the Pre-Diluted sample to the analyzer, which will aspirate 200 μL of the sample.

3.3 Dilution

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.

This analyzer can process two types of blood samples—whole blood samples and Pre-Diluted sample.

3.3.1 Whole Blood Mode

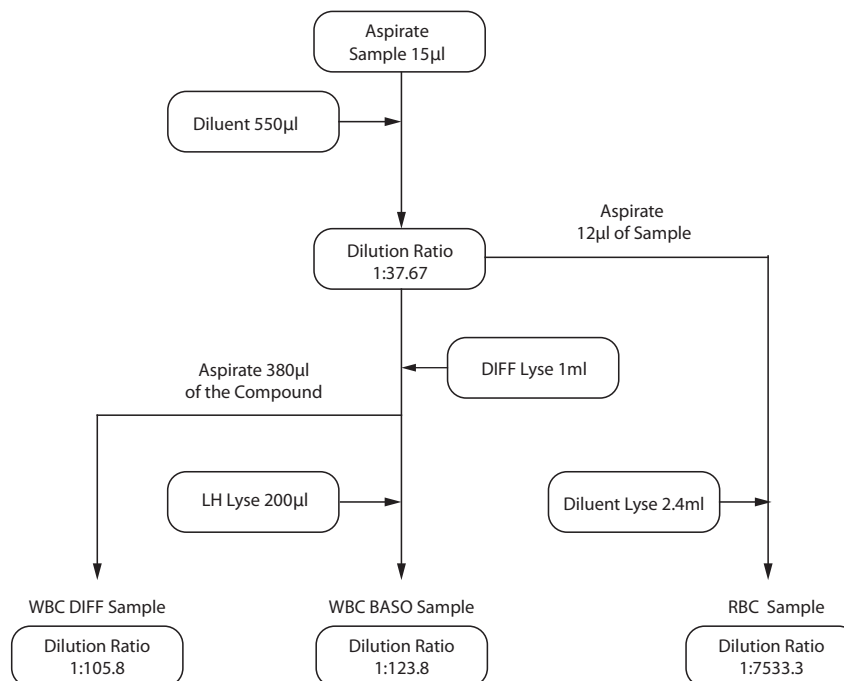


Figure 3.1 Dilution procedure of whole blood CBC+DIFF mode

3.3.2 Pre-Diluted Mode

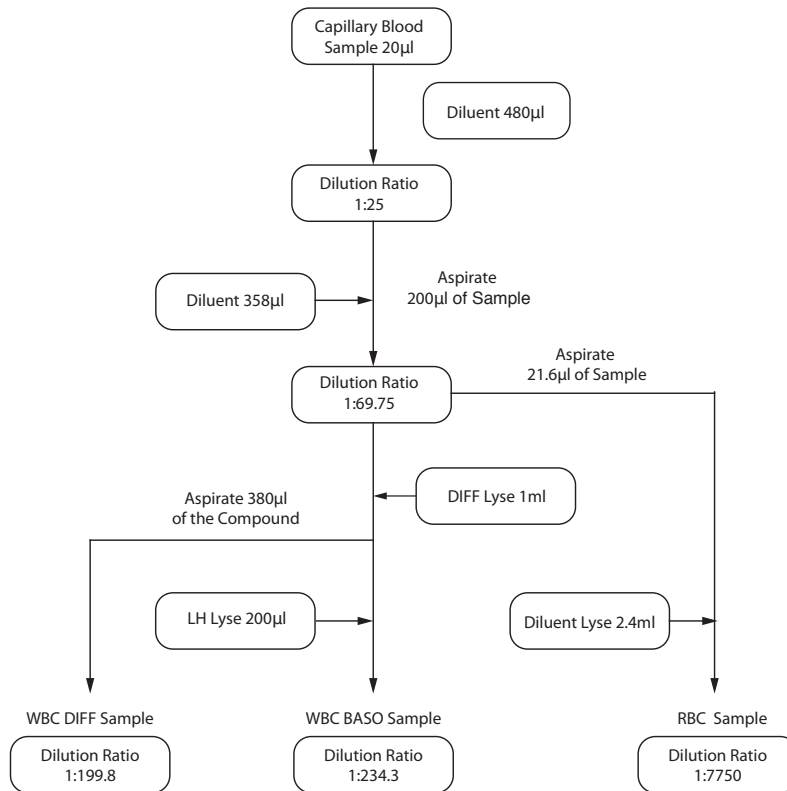


Figure 3.2 Dilution procedure of Pre-Diluted CBC+DIFF mode

3.4 WBC Measurement

3.4.1 Flow Cytometry by Laser

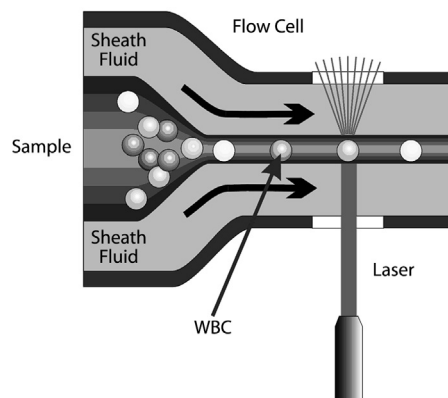


Figure 3.3 WBC measurement

After a predetermined volume of blood is aspirated and diluted by a specific amount of reagent, it is injected into the flow cell. Surrounded with sheath fluid (diluent), the blood cells pass through the center of the flow cell in a single column at a faster speed. When the blood cells suspended in the diluent pass through the flow cell,

they are exposed to a laser beam. The intensity of scatter light reflects the blood cell size and intracellular density. The low-angle scattered (LAS) light reflects cell size, and the high-angle scattered light (HAS) reflects intracellular density (nucleus size and density). The optical detector receives this scatter light and converts it into electrical pulses. Pulse data collected can be used to draw a 3-dimensional distribution (scattergram).

3.5 HGB Measurement

3.5.1 Colorimetric Method

The WBC/HGB dilution is delivered to the HGB bath where it is bubble mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 530 nm. An LED is mounted on one side of the bath and emits a beam of monochromatic light, whose central wavelength is 530 nm. The light passes through the sample and is then measured by an optical sensor that is mounted on the opposite side. The signal is then amplified and the voltage is measured and compared to the blank reference reading (readings taken when there is only diluent in the bath), and the HGB is measured and calculated in the analyzer automatically.

3.5.2 HGB

The HGB is calculated per the following equation and expressed in g/dL.

$$\text{HGB (g/dL)} = \text{Constant} \times \log_{10} (\text{Blank Photocurrent} / \text{Sample Photocurrent})$$

3.6 RBC/PLT Measurement

3.6.1 Electrical Impedance Method

RBCs/PLTs are counted and sized by the Electrical Impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. A pair of electrodes are submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated represents the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle.

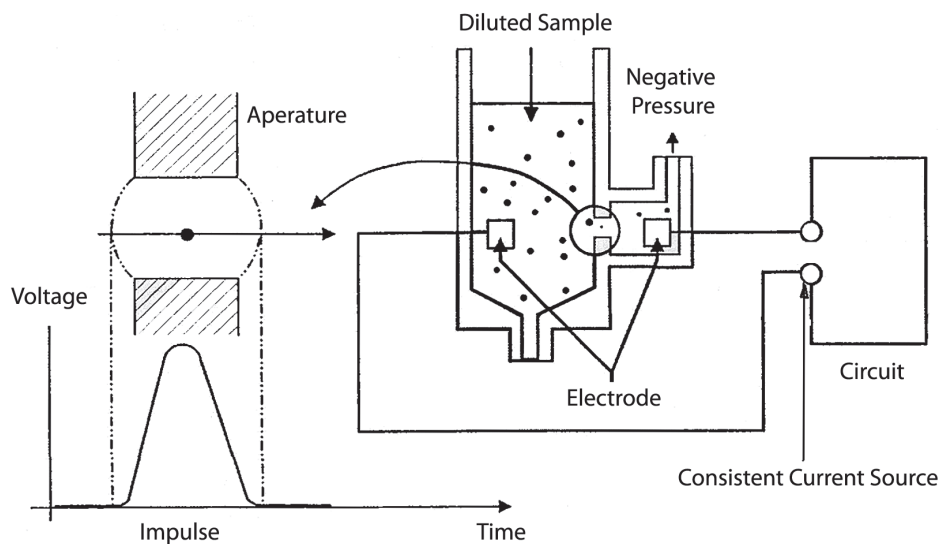


Figure 3.4 Electrical Impedance method

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.

3.6.2 Derivation of RBC—Related Parameters

RBC

RBC ($10^6/\mu\text{L}$) is the number of erythrocytes measured directly by counting the erythrocytes passing through the aperture.

MCV

Based on the RBC histogram, this analyzer calculates the mean cell volume (MCV) and expresses the result in fL.

HCT, MCH and MCHC

This analyzer calculates the HCT(%), MCH (pg) and MCHC (g/dL) as follows:

$$\text{HCT} = \frac{\text{RBC} \times \text{MCV}}{10}$$

$$\text{MCH} = \frac{\text{HGB}}{\text{RBC}} \times 10$$

$$\text{MCHC} = \frac{\text{HGB}}{\text{HCT}} \times 100$$

Where the RBC is expressed in $10^6/\mu\text{L}$, MCV in fL and HGB in g/dL.

RDW-CV

Based on the RBC histogram, this analyzer calculates the CV (Coefficient of Variation) of the erythrocyte distribution width, expressed in %..

3.6.3 Derivation of PLT-Related Parameters

PLT

PLT ($10^3/\mu\text{L}$) is measured directly by counting the platelets passing through the aperture.

MPV

Based on the PLT histogram, this analyzer calculates the mean platelet volume (MPV, fL).

4.1 Introduction



WARNING

Installation by personnel not authorized or trained by Heska may cause personal injury or damage your analyzer. Do not install your 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.

Your 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 you receive your analyzer, carefully inspect the carton. If you see any signs of mishandling or damage, contact Heska customer service department or your 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 10 cm behind the analyzer for cabling and ventilation;
- 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, lyse containers are placed inside the analyzer.
- The counter top where the analyzer is placed shall be able to withstand at least 40 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: 20%~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 your analyzer. Do not install your 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 your 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.

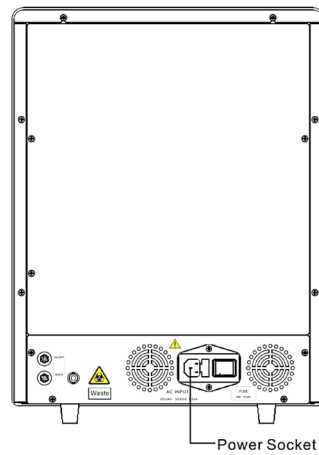


Figure 4.1 Connecting the analyzer to power outlet

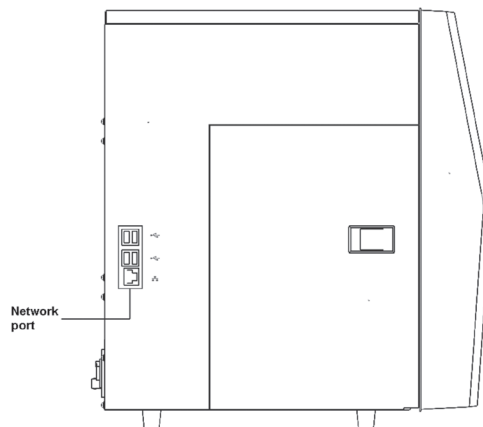


Figure 4.2 Connecting the analyzer network cable

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.

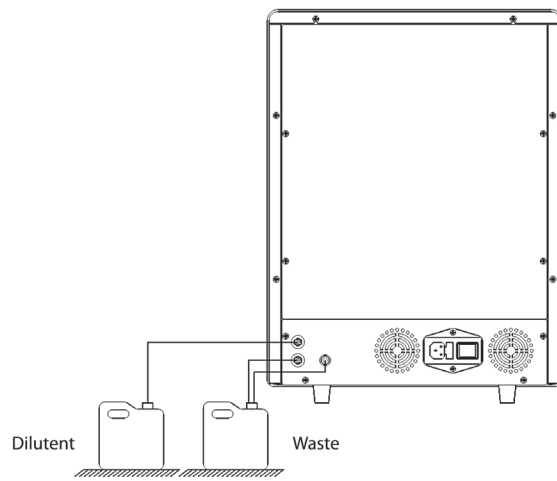


Figure 4.3 Connecting reagents placed outside the analyzer

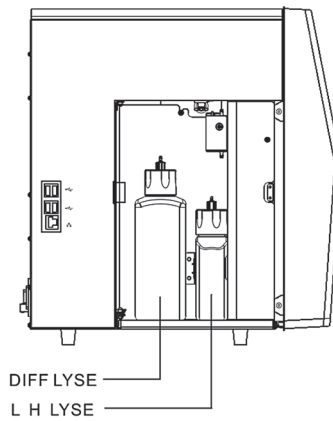


Figure 4.4 Connecting reagents placed inside the analyzer

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.

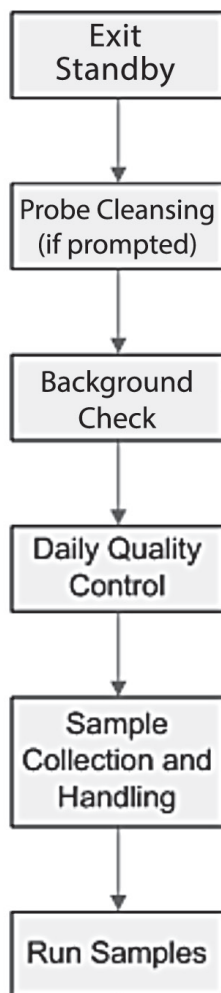
NOTE:

- 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 2.2 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.
- You must 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 your 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, centrifugal tubes and borosilicate glass capillary 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 and capillary 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

- Resume from Standby.
 - Touch screen at prompt, "Touch screen to access menu".
 - Press the aspirate key to exit Standby.
- Run Probe Cleanser if prompted/required.
 - Present Probe Cleanser to sample probe and aspirate by pressing aspirate key.
 - This process takes approximately 2 minutes.
- Run Background check.
 - From the Sample Analysis tab, touch **[NEXT SAMPLE]**
 - If desired, enter sample and/or Patient ID.
 - Touch down arrow next to species and select Background. Touch **[OK]**.
 - Press aspirate key to run Background.



NOTE:

- Background check is the measurement of particle and electric interference by the analyzer.
- See *Appendix A: 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

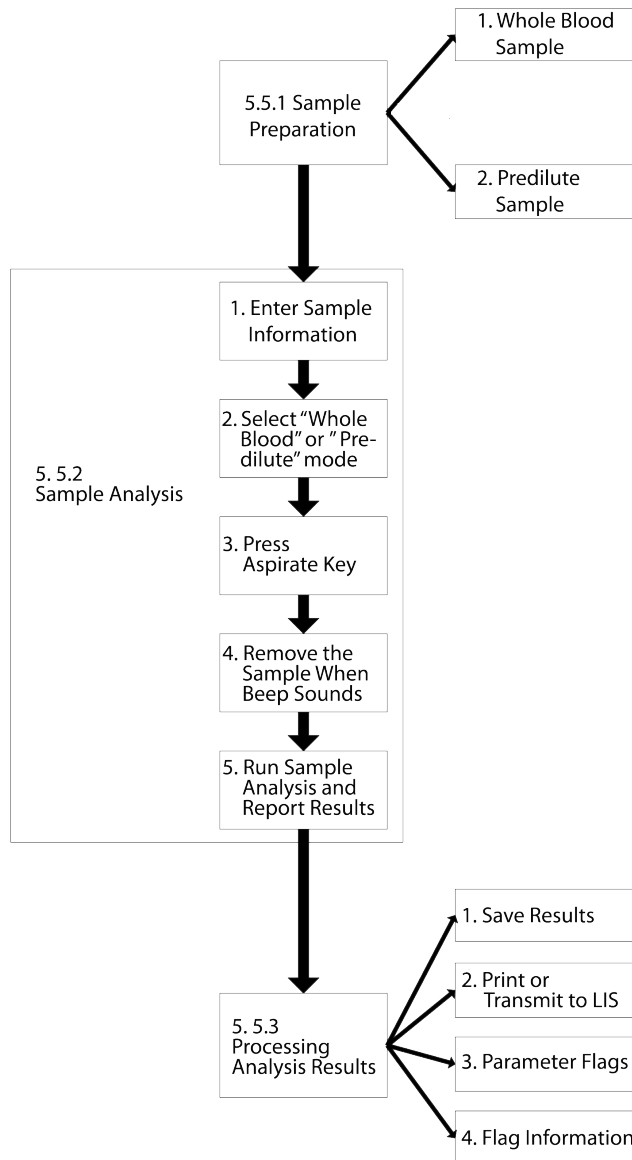
The sample probe is sharp and potentially biohazardous. Do not contact the sample probe during operations.



CAUTION

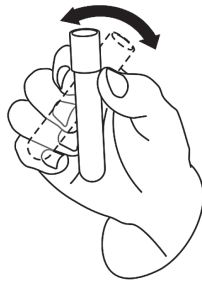
Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.

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



5.5.1 Sample Preparation

The analyzer can run 2 types of samples: whole blood samples and Pre-Diluted samples.



Whole blood samples

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



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

Pre-Diluted Samples

1. Touch the diluent tab.
2. Present a clean tube to the sample probe, press the aspirate key to dispense diluent (480 μ L). The dispensing progress bar will be displayed on the screen.
3. To continue with diluent dispensing, repeat steps 1–2.
4. Add 20 μ L of venous blood or capillary blood to the diluent, close the tube cap and mix it properly according to your laboratory's protocol.
5. Touch **[CANCEL]** after preparing all the samples, the analyzer will clean the sample probe automatically.

NOTE:

- You can also use pipette to aspirate 480 μ L 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 remix before running the sample.
- Be sure to run the Pre-Diluted samples within 30 minutes after the mixing.
- 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 Sample Analysis

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

1. Enter Sample Information

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

If you want to enter sample information after analysis, you may skip this chapter, and enter sample information at the result review screen (see *Section 6: Reviewing Sample Results*).

You may first set up the way to enter sample information at the **[SETUP ► AUXILIARY]** screen as instructed in *Section 9: Customizing the Analyzer Software*, then you may enter sample information at the Analysis screen.

2. Entering Patient Demographics

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

Next Sample

Sample ID Species Dog

Patient: Patient ID Patient Background

Time: Patient ID Patient Dog

Param: Gender Age Cat

WBC: Owner Last Name Ref. Group Dog Default

Neu #: Draw Time MM - DD - YYYY HH : MM Delivery Time MM - DD - YYYY HH : MM

Lym #: Veterinarian Mode Whole Blood

Mon #: Comments

Eos #: * Required field

Bas #: LIS Fetch OK Cancel

Next Sample: Dog Whole Blood open 01-02-2015 14:38

Species Dog

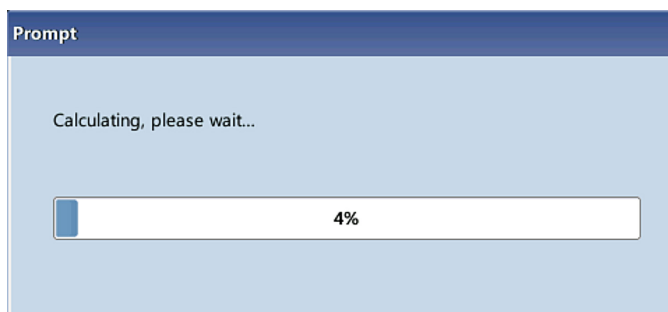
Patient Background

Age Cat

Ref. Group Dog Default

- a. Entering the 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 the Patient ID
Enter the Patient ID number in the Patient ID field.
- c. Entering the Species
Select the species from the Species pull-down list.
- d. Entering the 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 the patient's age
The analyzer provides four ways for you to enter the patient's age – in years, in months, in days and in hours.
- g. Entering the draw time
Enter the time when the sample is collected into the Draw Time field.
- h. Entering the delivery time
Enter the delivery time of analysis into the Delivery Time field.
- i. Entering the 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 you have finished entering the work list information, click **[OK]** to save the changes and return to the Sample Analysis screen.
- l. **[CANCEL]**
If you do not want to save the entered work list information, click **[CANCEL]** to return to the Analysis screen without saving the changes.

3. Aspirate sample
Present the sample to the sample probe. Press aspirate key to start the analysis.
4. Remove the sample
The sample probe will automatically aspirate sample. When you hear the beep sound, you may remove the sample.
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 Your 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 Your Analyzer* for solutions.

5.5.3 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 (20,000 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, it means the analysis result has exceeded the upper or lower limit of the reference range. See *Section 9.2.4 Parameter Setup*.
 - If the parameter is followed by an "R", it means the analysis result is questionable.
 - If you see *****, as opposed to the result, it means the result is invalid; if you see +++++ 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	Display Range
WBC, Bas#, Neu#, Eos#, Mon#, Lym#, ALY#, LIC #	0.00 ~ 999.99 × 10 ⁹ /L
Bas%, Neu%, Eos%, Mon%, Lym%, ALY%, LIC %	0.0 ~ 99.9%
RBC	0.00 ~ 18.00 × 10 ¹² /L
HGB	0 ~ 300 g/L
HCT	0.0 ~ 80.0%
MCV	0.0 ~ 250.0 fL
MCH	0.0 ~ 999.9 pg
MCHC	0 ~ 9999 g/L
RDW-CV	0.0 ~ 99.9%
PLT	0 ~ 9999 × 10 ⁹ /L
MPV	0.0 ~ 99.9 fL

4. Flags of Abnormal Blood Cell Differential or Morphology

The following table lists all flags and their indications.

Flags of Abnormal Blood Cell Differential or Morphology Table

Flag Type	Pathology Message	Meaning	Criteria
WBC Flag	Leukopenia	Low WBC analysis results	WBC < 3,000 x 10 ³ /μl
	Leukocytosis	High WBC analysis results	WBC > 20% above upper normal range limit.
	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.

5.6 Auto-Standby

When the time for which the analyzer is free from fluidic operations reaches that you have set at the Setup screen of the analyzer (default setting is 30 minutes), a dialog box will pop up, with the prompt, "Entering standby status...".



After entering standby status, the message, "Standby. Press the aspirate key to exit" will be displayed at the bottom left of the screen.

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, you can still perform any other operations (e.g., printing and transmission) other than fluidic operations.
- Refer to *Section 9: 9.2.5 Maintenance Setup* for how to edit waiting time before entering standby mode.
- Under stand-by mode, if there are unfinished printing or communication tasks, the analyzer will continue processing.

Aspirate key

Press aspirate key to exit the standby status.



After the auto-standby is canceled, the dialog box above will close automatically.

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 Your 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



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. Click [**SHUTDOWN**] on the menu and the following shutdown dialog box will display.



2. Click [**OK**].
3. When dialog box prompting probe cleanser maintenance displays, present probe cleanser to the sample probe, press aspirate key. The probe will aspirate probe cleanser automatically.
4. After shutdown is complete, the message, "Please power off the analyzer!" will be displayed. Touch [**POWER**] on back of the instrument to power off.

 **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 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 Your Analyzer* for solutions.

6.1 Introduction

The analyzer automatically saves analysis results. The Element HT5 Hematology Analyzer can store up to 20,000 analysis results.

You can 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.

	3	4	5	6	7	8
Sample ID	1	RY	H	Background	Background	1
Patient ID						
Patient						
WBC	8.15	L 0.05	6.78 E	0.10	0.05	L 0.03
Neu #	5.62	*****	L 3.36 e			*****
Lym #	1.52	*****	1.02 e			*****
Mon #	0.70	*****	0.14 e			*****
Eos #	0.30	*****	1.37 e			*****
Bas #	0.01	*****	H 0.88 e			*****
Neu %	69.0	*****	L 49.6			*****
Lym %	18.6	*****	15.1			*****
Mon %	8.6	*****	2.1			*****

Pos./Total 8 / 8 TSS 12/19/2014 18:17

6.2.1 Table

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

	3	4	5	6	7	8
Sample ID	1	RY	H	Background	Background	1
Patient ID						
Patient						
WBC	8.15	L 0.05	6.78 E	0.10	0.05	L 0.03
Neu #	5.62	*****	L 3.36 e			*****
Lym #	1.52	*****	1.02 e			*****
Mon #	0.70	*****	0.14 e			*****
Eos #	0.30	*****	1.37 e			*****
Bas #	0.01	*****	H 0.88 e			*****
Neu %	69.0	*****	L 49.6			*****
Lym %	18.6	*****	15.1			*****
Mon %	8.6	*****	2.1			*****

6.2.2 Graph Review

Touch [GRAPH REVIEW] at the table review screen or touch [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)

Click the desired sample result and it will be highlighted. Click **[EDIT INFO]** and the following dialog box will display.

Pos./Total 5 / 8 Administrator : Admin 12/19/2014 18:21

You may 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. Touch **[SEARCH]**, the following dialog box will display.

Pos./Total 8 / 8 TSS 12/19/2014 18:22

2. Enter search conditions into the edit boxes or select them from the pull-down lists.
3. Touch **[OK]** to start search, the results will displayed in the table.

6.2.6 Print

Print reports as per the default report template

Select sample records to be printed, and then touch **[PRINT]** to print them. In the table review interface, a "printed" sign will be applied to each printed sample in the sample state sector.



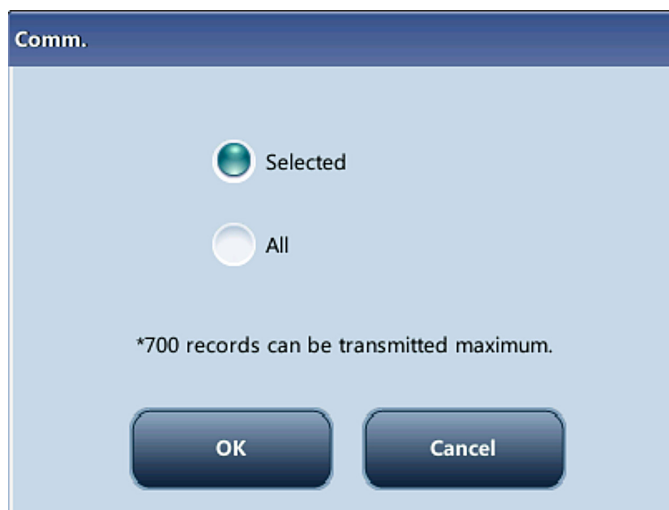
The screenshot shows the 'Table Review' interface with a table of sample data. The table has 7 columns (3-8) and 13 rows (Sample ID to Mon %). The 'Print' button is visible in the top right corner of the interface.

	3	4	5	6	7	8
Sample ID	1	RY	H	Background	Background	1
Patient ID						
Patient						
WBC	8.15	L 0.05	6.78 E	0.10	0.05	L 0.03
Neu #	5.62	*****	L 3.36 e			*****
Lym #	1.52	*****	1.02 e			*****
Mon #	0.70	*****	0.14 e			*****
Eos #	0.30	*****	1.37 e			*****
Bas #	0.01	*****	H 0.88 e			*****
Neu %	69.0	*****	L 49.6			*****
Lym %	18.6	*****	15.1			*****
Mon %	8.6	*****	2.1			*****

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]**; the following dialog box will display.



The screenshot shows a dialog box titled 'Comm.' with two radio button options: 'Selected' (which is selected) and 'All'. Below the options is a note: '*700 records can be transmitted maximum.' At the bottom are 'OK' and 'Cancel' buttons.

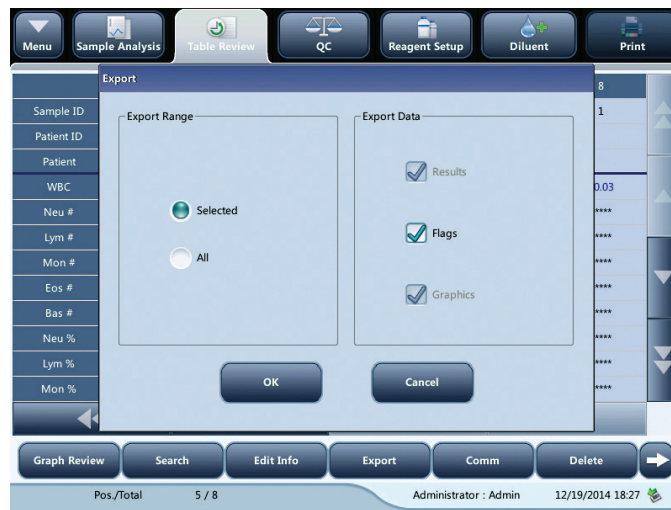
3. Touch **[SELECTED]**.
4. Touch **[OK]** to start transmitting specified results to the data management software.

Transmit all data

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

6.2.8 Export

1. Touch [EXPORT], the following dialog box will display.



2. Select "Selected" or "All" in the "Export range" area.
3. Check the type of information to be exported in the "Export data" area.

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 you run 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: You should 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 Editing QC Settings (for administrators only)

Before running a new lot of controls, you must set up a QC file for each lot of controls.

1. Touch the menu option [QC] ► [SETUP].
2. You will enter the following QC setup screen.

File No.	Lot No.	Level	Exp. Date	Mode	Control Type	QC Sample ID	Data/Capacity
1	BC411L	Low	01/10/2015	Whole Blood	BC-5D	BC411L	1/100
2	BC411N	Normal	01/10/2015	Whole Blood	BC-5D	BC411N	0/100
3*	BC411H	High	01/10/2015	Whole Blood	BC-5D	BC411H	0/100

New Edit Delete Clear All Count

Whole Blood Administrator : Admin 12/19/2014 18:28

You may set up QC information by any of the following two ways.

- Reading the information provided by the manufacturer—USB download.
- Manual entry

Reading the information provided by the manufacturer

1. Enter the QC setup screen.
2. Touch [NEW].
3. Insert USB memory stick and touch [IMPORT FILE].

Lot No. Level **Normal** Exp. Date

Mode **Whole Blood** Control Type **B55** QC Sample ID

Parameter	Target	Limit (#)	Parameter	Target	Limit (#)
WBC			Bas %		
Neu #			RBC		
Lym #			HGB		
Mon #			HCT		
Eos #			MCV		
Bas #			MCH		
Neu %			MCHC		
Lym %			RDW-CV		

Import File **Set Limits** **Return**

File No. 4 Whole Blood Administrator: Admin 12/19/2014 18:30

4. Select the QC file to be imported.
5. Touch **[OK]** to read the selected QC information to the current QC file.
6. Select "Control type" from the pull-down list.
7. Select the mode.
8. Set QC sample ID.
9. Touch other icons to switch screen and save QC information.

Manual entry

1. Enter the QC setup screen.
2. Touch **[NEW]**.
3. Enter the lot No. of the controls in the edit box manually.

NOTE: The lot No. shall not be empty and up to 16 digits can be entered. You can enter characters, numbers, letters and special characters.

4. Select the control level.
5. Enter the expiration date of the lot.
6. Select the control type.
7. Select the mode.
8. Set QC sample ID.

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

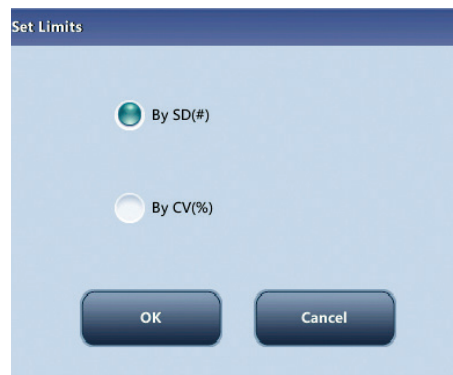


10 Touch other icons to switch screen and save the QC information.

Setting limits

You can adjust the format of limits as per the following procedure:

1. Touch [SET LIMITS].



2. Touch [By SD] to display the limits in the form of absolute value; or click [BY CV] to display the limits in the form of percentage.

3. Click [OK] to save the settings.

7.2.2 QC Run

Run controls under the QC screen

After editing the QC information, you can start QC analysis by one of the following ways according to the selected QC mode.

- Whole blood
- Pre-Diluted



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 your laboratory's protocols.

NOTE: When switching mode from "Pre-Diluted" to "Whole Blood", a progress bar will be displayed while the analyzer runs mode switching sequence.

1. Touch [QC] to enter the QC count screen.

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.



2. Prepare the control as instructed by instructions for use of the controls.
3. Run QC analysis:
 - a. Make sure the analysis mode is Whole Blood or Pre-Diluted and the analyzer indicator is green.
 - b. Mix the vial of sample as instructed by the control "Instructions for Use" to mix the sample thoroughly.
 - c. Present the control sample to the sample probe. Press aspirate key to start QC run.
 - d. When you hear the beep, remove the control.
4. When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE: Up to 100 QC results can be saved in each QC file.

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

7.2.3 Reviewing Results

After QC analysis, you can review the QC results in the following ways:

- QC Graph
- QC Table

QC graph review

1. Touch **[GRAPH]** on the QC screen to enter the QC graph screen.



2. You can touch the arrow buttons on the right of the graph to browse graphs of the parameters. You can touch the arrow buttons under the graph horizontally to browse all the QC 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.

Print

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 [TABLE] on the QC screen to enter the QC table screen.

Mode	Whole Blood	Control Type	BC-5D	QC Sample ID				BC411L		
	Date	Time	WBC	Neu #	Lym #	Mon #	Eos #	Bas #		
Target	/	/	3.30	1.46	1.23	0.40	0.11	0.10		
Limit (#)	/	/	0.50	0.40	0.40	0.14	0.11	0.10		
*1	12/16/2014	14:29	3.23	1.44	1.22	0.44	0.12	0.01		

2. You can touch the arrow buttons on the right of the graph to browse all QC records. You can 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.

Mode	Whole Blood	Control Type	BC-5D	QC Sample ID				BC411L		
	Date	Time	WBC	Neu #	Lym #	Mon #	Eos #	Bas #		
Target	/	/	3.30	1.46	1.23	0.40	0.11	0.10		
Limit (#)	/	/	0.50	0.40	0.40	0.14	0.11	0.10		
*1	12/16/2014	14:29	3.23	1.44	1.22	0.44	0.12	0.01		

2. Touch [YES] to delete the selected records.

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

Print

You can touch the [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.



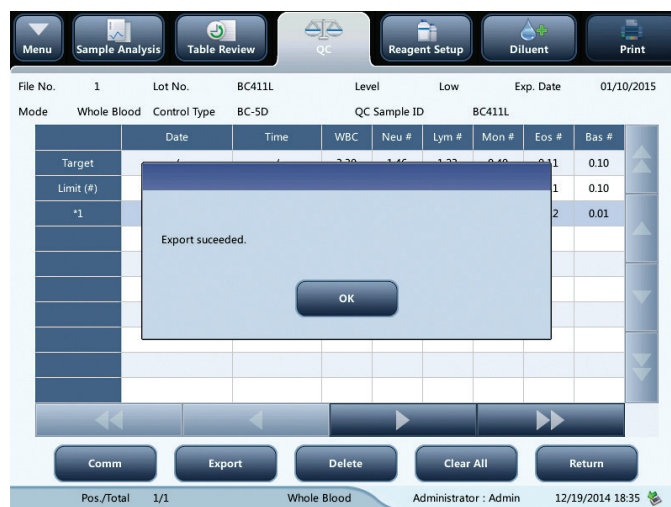
2. Select to transmit "Selected" or "All" records.
3. Touch [OK] to start transmitting specified results to the data management software.

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 an USB and then 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, you should 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.
- You should 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 you operate and maintain it as instructed by this manual. You only need to recalibrate this analyzer if:

- You are going to use this analyzer for the first time (usually done by a Heska-authorized representative when installing the analyzer).
- An analytical component has been changed.
- You are going to re-use the analyzer after a long-term storage.
- The quality control results indicate there may be a problem.
- Use environment changes significantly.

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

8.3 How to Calibrate

8.3.1 Preparing Your Analyzer

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 your local distributor for assistance.

1. Check and make sure enough reagents have been prepared for the calibration. You need to start over 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 *Chapter 11: Troubleshooting for Solutions*. See *Appendix C: Specifications for Background Range*.

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 Calibration with Calibrator

Touch [CALIBRATION] ► [CALIBRATOR] in the menu to enter the following screen.



NOTE:

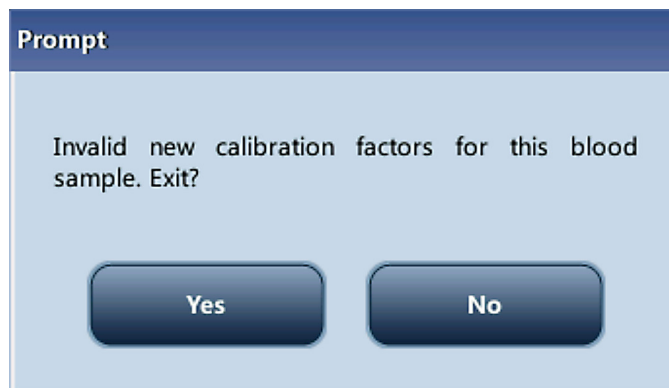
- The calibrator calibration can be performed under Whole Blood -CBC+DIFF and Pre-Diluted CBC+DIFF mode.
- Only Heska-specified calibrators shall be used. Heska will not be responsible for any erroneous result caused by using other calibrators.
- See the calibrator Instruction for Use for the lot number, expiration date and target.
- The out-of-range CV% does not influence the display of calibration factors.

Do as follows to 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.
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 that container is opened + the open-container stability days.
4. Enter the targets into the Target fields.
5. Prepare the calibrator as instructed by the calibrator's instructions for use .
6. Press aspirate key to start calibration and aspirate calibration solution.

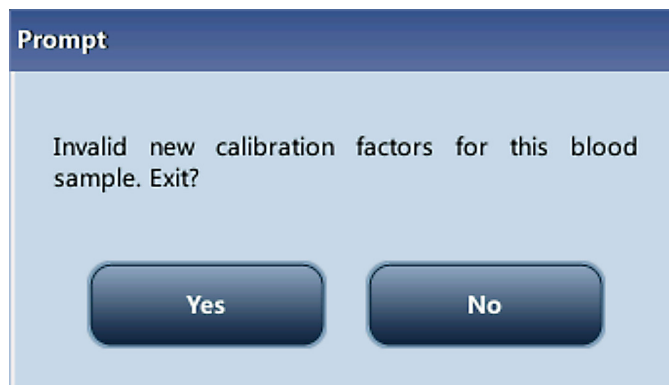
After the analysis, the analyzer will have different responses to different analysis results.

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 **[OK]** to close the dialogue box, and the data will be deleted from the table without saving automatically.

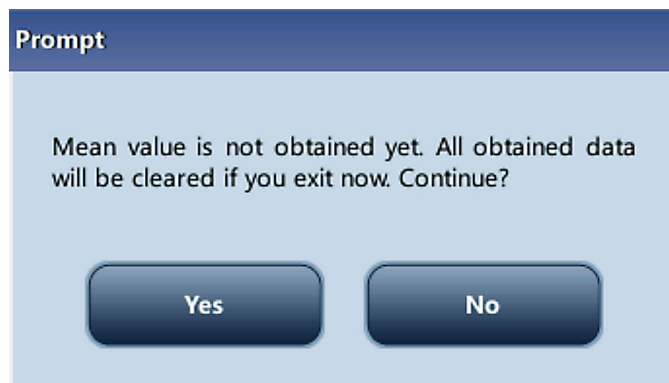
When the running is done, if there is a parameter whose calibration data is out of the display range, then the non-numeric parameter values "****" will be displayed in the list and a dialogue box will pop up.



Touch **[OK]** 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.

7. If the calibration factors have not been calculated, and you switched to another screen, the a dialogue box will appear.

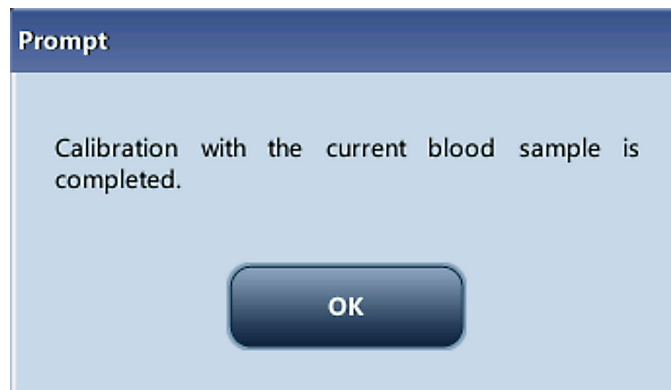


Touch **[YES]** to switch to another screen while discarding the calibration data and closing the dialogue box. The original calibration factors remain.

- When calibration count has been performed to a sample for n times ($n \geq 5$), 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).

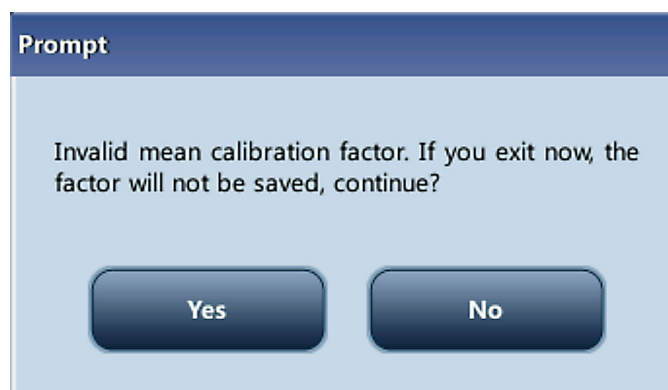
You can select several data to calculate the calibration factors, but only after at least 5 groups of the data are marked with "√" can you get the calibration factors. The calibration factors will be refreshed whenever you select "√" or deselect "√".

When the amount of valid calibration data in the list reaches 10, a dialogue box "Calibration is completed!" will pop up. Then, if you press aspirate key again, the analyzer will beep without starting analysis.



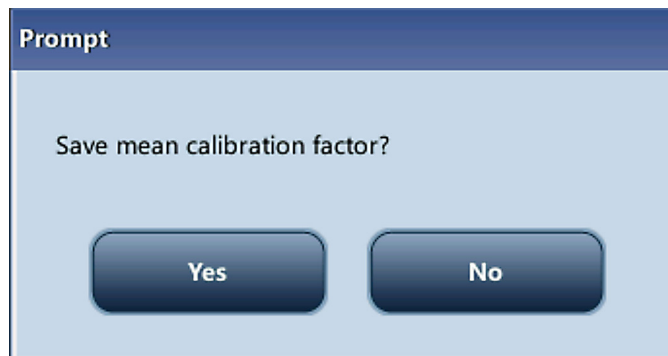
- There may be two cases when you are switching to another screen:

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 pop up.



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 pop up.

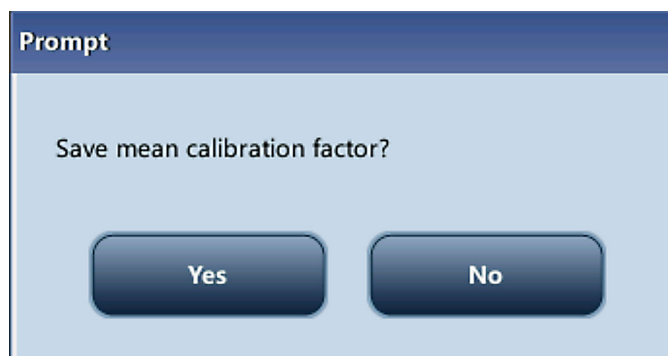


Touch **[YES]** to save the new calibration factors while closing the dialogue box and switching to another screen.

8.3.3 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 asking you to save the factors.



Click **[YES]** to close the dialog box, save and print the calibration results. Or click **[NO]** to cancel the operation without saving or printing them.

9.1 Introduction

The Element HT5 Hematology Analyzer is a flexible laboratory instrument that can be customized to your working environment. You can 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 figure for the Setup menu.



9.2 Setting Up the Analyzer

9.2.1 System Setup

Date/Time

Touch the menu option [SETUP] ► [SYSTEM SETUP] ► [DATE/TIME SETUP] to enter the Date/Time screen as shown below. You can set up the date, time and date format of the analyzer at the screen.

Date: 12 / 19 / 2014

Time: 18 : 45 24 Hour

Date Format: MM/DD/YYYY

Administrator : Admin 12/19/2014 18:45

Print

Touch the menu option [SETUP] ► [SYSTEM SETUP] ► [PRINT SETUP] to enter the Print Setup screen as shown below. You can set up the following contents:

- Print setup
- Printing content
- Auto print

Print Setup

Print Device: Printer

Printer Driver: Auto Identification

Paper: Letter paper

Report Title: Hematology Analysis Report

Report Template: One page with histogram

Language: English abbreviation

Copies: 1 [1, 20]

Header Info Customized Template

Printing Content

Print reference range flags

Print suspect flags

Print flags

Print reference range

Auto print after sample analysis

Auto print off

Auto print after analysis

Administrator : Admin 12/19/2014 18:45

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.

Paper	Letter paper
Report Title	A4
Report Template	A5
Language	Continuous paper
	Letter paper
	English abbreviation

Copies

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

Copies	1	[1, 20]
--------	---	---------

Report title

Report Title	Hematology Analysis Report
--------------	----------------------------

Report template

The screenshot shows the 'Print Setup' interface with a top navigation bar containing icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. The 'Print Setup' section includes:

- Print Device: Printer
- Printer Driver: Auto Identification
- Paper: Letter paper
- Report Title: Hematology Analysis Report
- Report Template: One page with histogram (with a dropdown menu showing options: One page with histogram, One page without histogram, Half page with histogram, Half page without histogram)
- Language: One page without histogram
- Copies: (input field)

The 'Printing Content' section includes:

- Print reference range flags
- Print suspect flags
- Print flags
- Print reference range

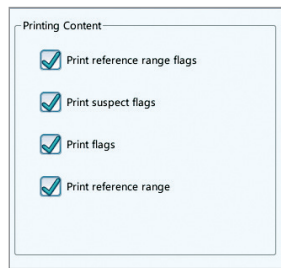
The 'Auto print after sample analysis' section includes:

- Auto print off
- Auto print after analysis

Buttons at the bottom: Header Info, Customized Template. Footer: Administrator : Admin 12/19/2014 18:46

Printing content

You can choose to select the functions based on your needs by touching on the check boxes.



Printing Content

- Print reference range flags
- Print suspect flags
- Print flags
- Print reference range

Auto print

You can choose to disable auto print or set up printing conditions.

Communication setup

Touch the menu option [SETUP] ► [SYSTEM SETUP] ► [COMMUNICATION] to enter the communication setup screen as shown below. You can set up the following contents:

- Protocol Setup
- Transmission Mode



Menu Sample Analysis Table Review QC Reagent Setup Diluent Print

Network Device

Network Type: Wired

Protocol Setup

IP Address: 10 . 0 . 0 . 2

Subnet Mask: 255 . 255 . 255 . 0

Default Gateway: . . .

Mac Address: c8-00-00-00-00-00

Comm Protocol: HL7

Transmission Mode

ACK Synchronous Transmission

ACK Overtime: 10 Second

Auto Retransmit

Auto Communicate

Auto Fetch Info From LIS

Transmit as Print Bitmap Data

Histogram transmitted as: Not to be transmitted

Scattergram transmitted as: Not to be transmitted

Administrator : Admin 12/19/2014 18:47

Protocol setup

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

Communication protocol

Touch the [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. You can re-enter the ACK overtime in the edit box.

Transmission mode

You can choose to select the functions based on your needs by touching on the check boxes.

- Auto retransmit
- Auto communicate
- Transmit as Print Bitmap Data

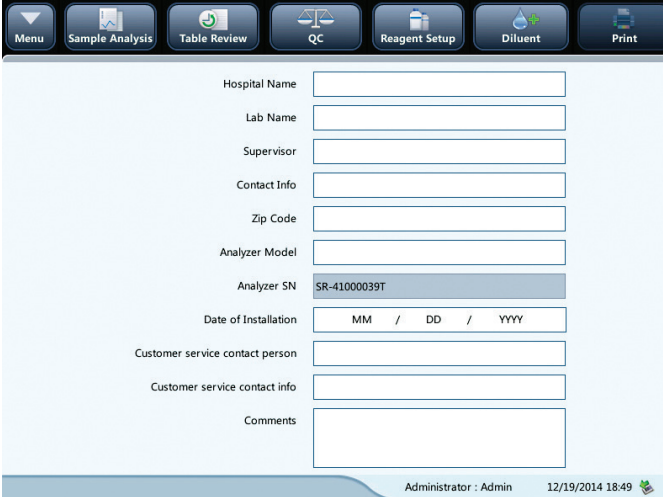
Transmission mode of histogram and scattergram

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

- Not to be transmitted
- Bitmap
- Data

Lab info. setup

Touch the menu option [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.



The screenshot displays the 'Lab Info. Setup' screen. At the top, there is a navigation bar with icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. Below the navigation bar, the screen contains several input fields for lab information:

- Hospital Name:
- Lab Name:
- Supervisor:
- Contact Info:
- Zip Code:
- Analyzer Model:
- Analyzer SN: SR-4100039T
- Date of Installation: MM / DD / YYYY
- Customer service contact person:
- Customer service contact info:
- Comments:

At the bottom of the screen, the status bar shows 'Administrator : Admin' and the date/time '12/19/2014 18:49'.

9.2.2 Access Setup

Touch [SETUP] ► [ACCESS SETUP] in the menu to enter the following screen.



Modify password

You can modify your own password.

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.

Create new user

1. Touch **[NEW]**, the following dialog box displays.



The screenshot shows a software interface with a top navigation bar containing icons for Menu, Sample Anal, Add User, and Print. The 'Add User' dialog box is open, featuring four text input fields for User ID, Name, Password, and Confirm Password. Below these fields are two radio buttons for Access Level: 'Operator' (selected) and 'Administrator'. At the bottom of the dialog are 'OK' and 'Cancel' buttons. The background interface shows a status bar at the bottom with the text 'Administrator : Admin' and the date/time '12/19/2014 18:50'.

2. Enter the User ID, Name and Password information.
3. Select access level of the user:
 - Operator
 - Administrator
4. 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

Select a user and then touch **[DELETE]** to delete it.

NOTE: The current login user cannot be deleted.

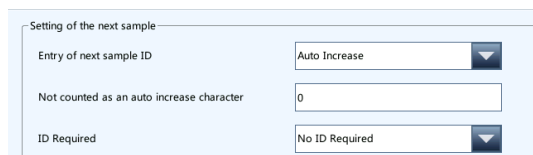
9.2.3 Auxiliary Setup

Touch [SETUP] ► [AUXILIARY SETUP] in the menu to enter the following screen. You can set up the following contents:

- Setting of the next sample
- Setting of the first sample after startup
- Other settings



Setting of the next sample



Entry of the next sample ID

Touch the pull-down list to select the way to enter the next sample ID.

- Auto increase
- Manual entry

Not counted as an auto increase character

Operators can set up the number of characters in the sample ID that will not be auto increased.

When "Auto Increase" is selected as the way to enter the next sample ID, this edit box will be activated.

Enter a number n into the edit box. The first n characters in the sample ID will not be auto increased.

Setting of the first sample after startup

Operators may customize the first sample ID after startup by entering it into the edit box. Or select to continue with the sample ID before last shutdown.

Setting of the first sample after startup

First sample after startup Custom

Sample ID Mode WB-CBC+DIFF

Other settings

Other settings

Predilute Mode Prompt On Off

Pop-up keyboard On Off

Flags Suspect R High H Low L

On/off radio buttons

Select On or Off to activate or deactivate the functions.

Flags

Operators may set up the suspect flag by entering a character into the edit box, or selecting a letter from the pull-down list (the default character is R).

Operators may set up the high/low flag by entering two characters into the edit boxes, or selecting two letters from the pull-down lists (the default character of high flag is H, and that of low flag is L).

9.2.4 Parameter Setup

Parameter unit setup

Touch the menu option [SETUP] ► [PARAMETER SETUP] ► [REFERENCE UNIT SETUP] to enter the screen as shown below. You can set up parameter units at this screen.

Parameter	Unit	Format	Parameter	Unit	Format
WBC	10 ³ /uL	***	Bas %	%	**
Neu #	10 ³ /uL	***	RBC	10 ⁶ /uL	**
Lym #	10 ³ /uL	***	HGB	g/dL	**
Mon #	10 ³ /uL	***	HCT	%	**
Eos #	10 ³ /uL	***	MCV	fL	**
Bas #	10 ³ /uL	***	MCH	pg	**
Neu %	%	**	MCHC	g/dL	**
Lym %	%	**	RDW-CV	%	**
Mon %	%	**	PLT	10 ³ /uL	**
Eos %	%	**	MPV	fL	**

Unit System: USA

Default

Standby. Press the aspirate key to exit. Administrator : Admin 12/19/2014 18:53

Select unit system

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

Parameter	Unit	Format	Parameter	Unit	Format
WBC	10 ³ /uL	***.##	Bas %	%	**.##
Neu #	10 ³ /uL	***.##	RBC	10 ⁶ /uL	**.##
Lym #	10 ³ /uL	***.##	HGB	g/dL	**.##
Mon #	10 ³ /uL	***.##	HCT	%	**.##
Eos #	10 ³ /uL	***.##	MCV	fL	***.##
Bas #	10 ³ /uL	***.##	MCH	pg	***.##
Neu %	%	**.##	MCHC	g/dL	***.##
Lym %	%	**.##	RDW-CV	%	**.##
Mon %	%	**.##	PLT	10 ³ /uL	****
Eos %	%	**.##	MPV	fL	**.##

Unit System: USA

China
International
Netherlands
UK
USA
Canada

Default

Standby. Press the aspirate key to exit. Administrator : Admin 12/19/2014 18:53

Customizing parameter units

Under each unit system, you can 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.

Parameter	Unit	Format	Parameter	Unit	Format
WBC	10 ³ /uL	***.##	Bas %	%	**.##
Neu #	10 ³ /uL	***.##	RBC	10 ⁶ /uL	**.##
Lym #	10 ³ /uL	***.##	HGB	g/dL	**.##
Mon #	10 ³ /uL	***.##	HCT	%	**.##
Eos #	10 ³ /uL	***.##	MCV	fL	***.##
Bas #	10 ³ /uL	***.##	MCH	pg	***.##
Neu %	%	**.##	MCHC	g/dL	***.##
Lym %	%	**.##	RDW-CV	%	**.##
Mon %	%	**.##	PLT	10 ³ /uL	****
Eos %	%	**.##	MPV	fL	**.##

Unit System: USA

Unit option:

10¹²/L
 10⁶/uL
 10⁴/uL
 /pL

Default

Standby. Press the aspirate key to exit. Administrator : Admin 12/19/2014 18:53

9.2.5 Maintenance Setup (for administrators only)

Touch [SETUP] ► [MAINTENANCE] in the menu to enter the following screen. You can set up the following contents:



Standby

Touch the text box [WAIT] and enter the waiting time before entering the standby status. The range allowed is 10–30 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 pop up after the defined minutes.

9.2.6 Reagent Setup

Touch [SETUP] ► [REAGENT SETUP] in the menu to enter the following screen.



It is recommended that you replace the reagents 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 you have changed the diluents or lyse, run a background test to see if the results meet the requirement.

You should 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.

You can replace the following reagents in the fluidics:

- Diluent
- DIFF lyse
- LH lyse

1. Touch the reagent you want to replace, and then touch **[SETUP]**.

The screenshot shows a software interface for reagent management. At the top, there is a navigation bar with icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. The main window is titled 'Reagent Information' and is divided into two sections: 'Reagent Information' and 'Barcode Entry'. The 'Reagent Information' section contains three input fields: 'Reagent Name' with the value 'Diluent', 'Exp. Date' with the value '10 / 13 / 2016', and 'Residual Volume' with the value '4.949' and a unit dropdown set to 'L'. The 'Barcode Entry' section contains a text box for the barcode and the instruction 'Scan reagent barcode directly, or enter the numbers under the barcode.' Below these sections are two buttons: 'Apply' and 'Close'. At the bottom of the screen, there are two more buttons: 'Setup' and 'Replace'. The status bar at the very bottom displays 'Standby. Press the aspirate key to exit.', 'Administrator : Admin', and the date/time '12/19/2014 18:57'.

2. Enter reagent information at the screen.

3. Or scan in the barcode. If the barcode is valid, the corresponding reagent information will automatically display.

4. Touch **[APPLY]** ► **[CLOSE]** ► **[OK]** to save the exp. date and start to replace the reagent. A progress bar will be displayed in the process.

5. 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.

9.2.7 Gain Setup (for administrators only)

Touch [SETUP] ► [GAIN SETUP] in the menu to enter the following screen. Gain setup function allows you to adjust the digital potentiometers. The operation shall not be performed frequently.



The screenshot displays the Gain Setup interface with a top navigation bar containing icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. Below the navigation bar are two tables. The first table lists gain factors and adjustment rates for LAS, MAS, WAS, and Width. The second table lists set values, adjustment rates, and blank voltages for MCV_G and HGB. The status bar at the bottom indicates the user is Administrator - Admin and the date/time is 12/19/2014 18:58.

	Gain Factor (%)	Adjustment Rate (%)
LAS	144.40	100.0
MAS	130.60	100.0
WAS	116.50	100.0
Width	100.10	100.0

	Set Value	Adjustment Rate (%)	Blank Volt.
MCV_G	74	100.0	/
HGB	92	/	4.65V

RBC gain

Touch the [MCV-G SET VALUE CELL], and enter the new value of RBC gain.

HGB gain

The purpose of adjusting HGB gain is to change HGB blank voltage.

Enter the new value in to the HGB "Set Value" cell to modify HGB gain.

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

9.3 Save the Settings

To save the modified settings, you may switch to another screen, 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 your 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.

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

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

10.2 Maintaining Your Analyzer

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

10.2.1 Maintenance



Touch [MAINTENANCE] ► [MAINTENANCE] to enter the following screen.



Unclog aperture

Unclogging includes zapping and flushing the aperture. When a clog error is reported, you should unclog the aperture.

The unclogging procedures are:

1. Touch [ZAP] ► [FLUSH] to start unclogging.
2. When the progress ends, a message will display indicating "Maintaining finished!".
3. Do the above procedures to continue unclogging aperture if necessary. If the error persists, perform probe cleanser maintenance of the related channels.

Probe cleanser maintenance

You should perform the probe cleanser soaking procedure when:

- Background results are out of range, QC results abnormal or scattergram abnormal due to long term idleness of the analyzer; or when other maintenance operations fail to solve the clog error.
- The analyzer shuts down due to loss of power; probe cleanser maintenance must be performed after it is started up again.

The probe cleanser maintenance procedures are:

1. Touch **[OVERALL SOAK]**, the following dialog box will display.
2. Touch **[YES]**, the analyzer starts to prepare for the maintenance.



3. When the preparation is done, the following dialog box will display.



4. After aspirating probe cleanser, the analyzer performs probe cleanser soak automatically, and a progress bar will display indicating the progress.



5. When the progress ends, the following dialog box will display, touch [OK] to close the dialog box.



10.2.2 Cleaning

You should clean the following components when:

- WBC and/or HGB background results exceed their limits, perform WBC bath cleaning. If WBC bath cleaning does not solve the problem, perform WBC probe cleanser maintenance.
- RBC and/or PLT background results exceed their limits, perform RBC bath cleaning. If RBC bath cleaning does not solve the problem, perform RBC probe cleanser maintenance.
- There are too many particles in the scattergram of background results, perform WBC bath cleaning. If WBC bath cleaning does not solve the problem, perform WBC probe cleanser maintenance.
- Sample probe is dirty, perform sample probe cleaning.

Touch **[MAINTENANCE]** ► **[MAINTENANCE]** and select the Cleaning tab to enter the following screen.



You may perform cleaning operation to the following components:

- Fluidics
- Flow cell
- Sample probe
- Clear flow cell
- WBC bath
- RBC bath

The cleaning procedures are:

1. Touch the component button you want to clean. The message, "Cleaning in process. Please wait..." will display.
2. When the progress ends a message will display indicating, "Cleaning finished!".
3. Clean other components as per the above procedures if needed.

10.2.3 Servicing the Fluidics

Touch [MAINTENANCE] ► [MAINTENANCE] and select the "Fluidics" tab to enter the following screen.

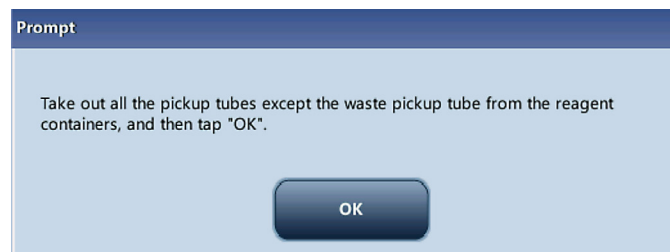


Pack-up

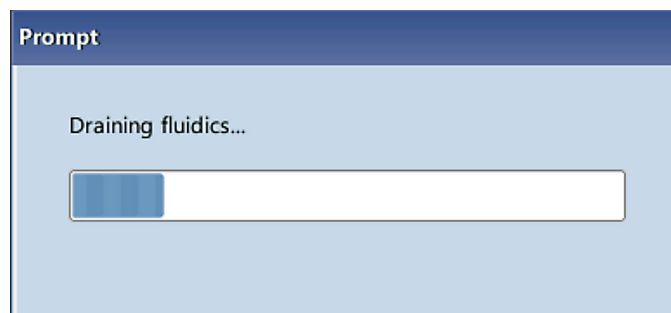
If the analyzer will not be used for over 2 weeks, you should perform this procedure.

Do as follows to pack up:

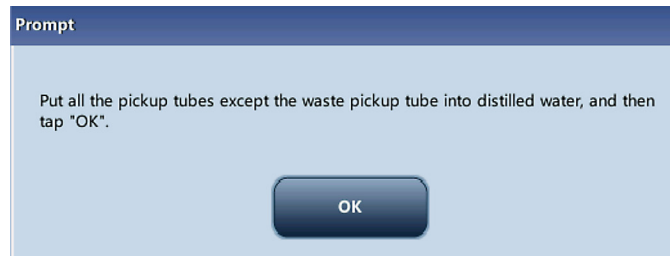
1. Touch [PACK-UP], the dialog box "Start pack-up?" will pop up.
2. Touch [Yes] to perform the pack-up procedure. The following dialog box will be displayed.



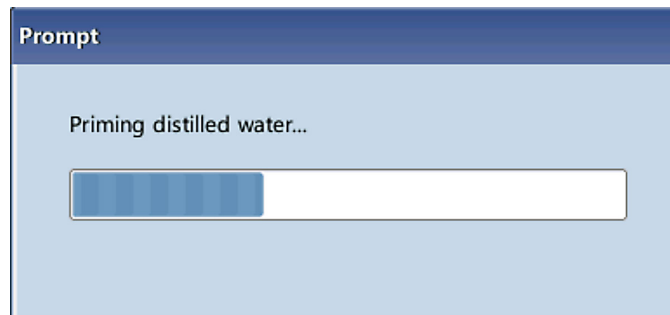
3. Take out the tubes as instructed and then touch [OK] to drain the fluidics.



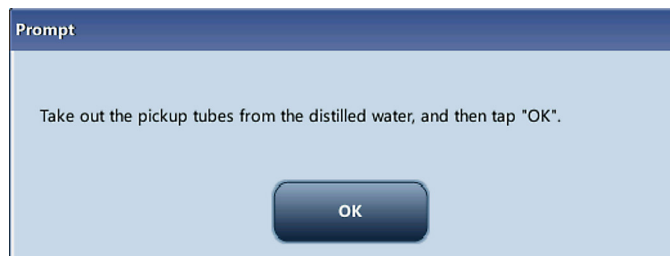
4. The following dialog box will be displayed after draining the fluidics.



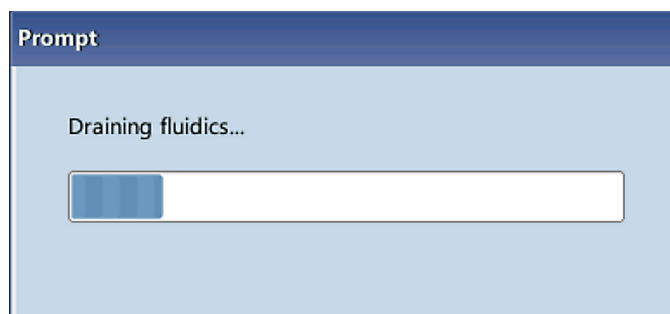
5. Put the tubes into distilled water as instructed, and touch [OK] to start priming.



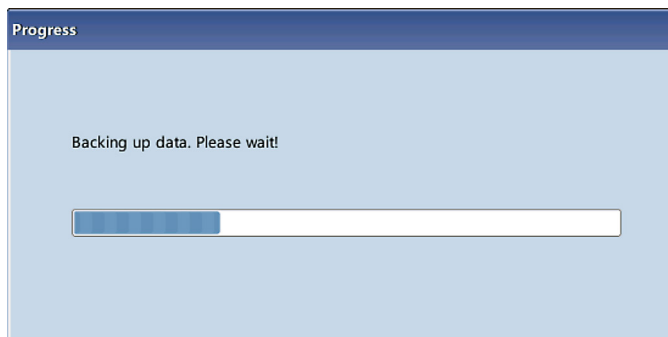
6. When the priming progress ends, the following dialog box will be displayed.



7. Take out the tubes as instructed and then touch [OK] to drain the fluidics again.



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



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

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

Reset

When major components of the analyzer have been replaced, or the fluidic system has been serviced, you must reset the fluidics.

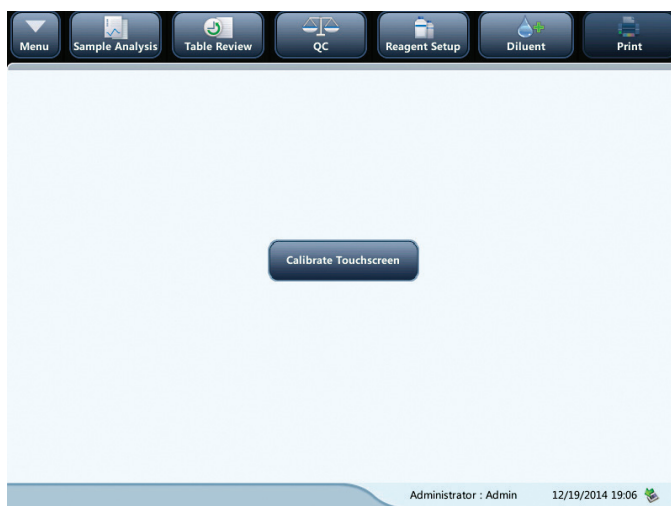
Do as instructed below:

1. Touch **[RESET FLUIDICS]**, a dialog box will pop up asking you to confirm the operation.
2. Touch **[OK]** to start initialization, the message, "Resetting fluidics. Please wait..." will be displayed.
3. When the progress ends, a dialog box will display indicating, "Resetting fluidics finished!".
4. Do the above procedures to continue resetting fluidics if necessary.

10.4 Touch Screen Calibration



Touch [MAINTENANCE] ► [CALIBRATE TOUCH SCREEN] in the menu to enter the following screen.



10.5 Viewing Logs

Touch [MAINTENANCE] ► [LOG] in the menu to enter the following screen.



You may 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.

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 that you want to export.
3. Touch [OK] to close the dialog box and export the logs.

10.6 Checking the Analyzer Status

Touch [STATUS] ► [COUNTER]

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

10.6.1 Counter

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



Viewing details

You may 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 & Pressure

Touch [STATUS] ► [TEMP. & PRESSURE] in the menu to enter the following screen.

You may check, export or print the temperature and pressure values of different components of the analyzer.

	Temperature (°C)	Range
Diluent Temperature	25.9	[10.0, 40.0]
Reagent Preheating Temperature	42.3	[40.6, 45.1]
Optical System Temperature	29.4	[15.0, 40.0]

	Pressure (KPa)	Range
Liquid Pressure	82.3	[70.0, 110.0]
Vacuum	-29.1	[-35.0, -26.0]

Administrator : Admin 12/19/2014 19:09

10.6.3 Voltage and Current

Touch [STATUS] ► [VOLTAGE & CURRENT] in the menu to enter the following screen.

You may check the voltage and current values of different components of the analyzer.

	Volt (V)	Range
Power +12V	12.0	[11.5, 12.5]
Power +24V	25.3	[22.0, 29.0]
Analog +12V	11.9	[11.5, 12.5]
Analog -12V	-11.8	[-12.5, -11.5]
Digital +56V	56.9	[47.0, 60.0]
HGB Blank Voltage	4.5	[3.2, 4.9]
FS Blank Voltage	0.4	[0.0, 0.5]

	Current(mA)	Range
Laser Diode Current	39	[20, 70]

Administrator : Admin 07-18-2013 15:01

10.6.4 Sensor

Touch **[STATUS]** ► **[SENSOR]** in the menu to enter the following screen.

You may check the sensor status of the analyzer.

Component		Status
Float Sensor	Waste	Off
Syringe Photocoupler	Sample Syringe	Block
Aspiration Module Photocoupler	Vertical Photocoupler	Unblock
	Inboard Photocoupler	Block
	Outboard Photocoupler	Unblock
Other	Aspirate Key	On

Administrator : Admin 12/19/2014 19:10

10.6.5 Version Information

Touch **[STATUS]** ► **[VERSION INFO.]** in the menu to enter the following screen. You may view the current version information of the analyzer.

Software Version	Boot Software	1.4
	Kernel	V1.03.75
	System Software	V01.03.00.3605
	Print Drive	1.4.1
	Print Template	01.03
	Sequence	1.2.258GENERAL
	Language	English
Hardware Version	Algorithm	1.0.0.390
	Data Board FPGA	3.0.1.46
	Drive Board FPGA	1.0.3.12
Drive Board MCU	01.03.00.2819	
Version Info	CD	1.3

Administrator : Admin 12/19/2014 19:10

11.1 Introduction

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

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.

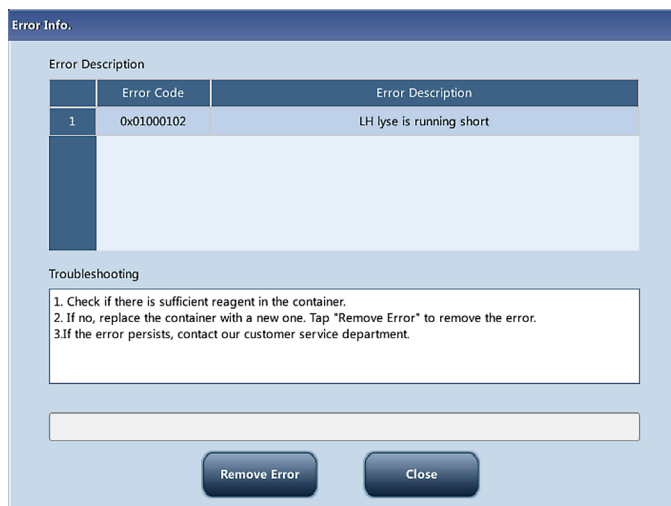
According to the severity of the errors, the colors of error messages are red, orange, blue and green.

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.

The following figure is the error info. dialog box.



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

You may touch to select the error, and view its troubleshooting information in the troubleshooting box. The troubleshooting information of the first error is displayed by default. Please follow the troubleshooting to resolve the error in sequence.

Remove error

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

Close the error info. dialog box

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

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

Error Name	Actions
Communication error	<ol style="list-style-type: none">1. Touch [REMOVE ERROR] to see if the error can be removed.2. If the error still exists, contact Heska's Technical Support Services.
Digital board error	Power the analyzer off and then contact Heska's Technical Support Services.
System clock error	Power the analyzer off and then contact Heska's Technical Support Services.
Diluent ran out	<ol style="list-style-type: none">1. Touch [REMOVE ERROR] and enter the new barcode of the diluent into the reagent setup dialog box.2. After replacing the reagent container, touch [APPLY] to prime diluent.3. If the error still exists after replacing diluent, contact Heska's Technical Support Services.
LH lyse ran out	<ol style="list-style-type: none">1. Touch [REMOVE ERROR] and enter the new barcode of the LH lyse into the reagent setup dialog box.2. After replacing the lyse container, touch [APPLY] to prime the lyse.3. If the error still exists after replacing the lyse, contact Heska's Technical Support Services.
DIFF lyse ran out	<ol style="list-style-type: none">1. Touch [REMOVE ERROR] and enter the new barcode of the DIFF lyse into the reagent setup dialog box.2. After replacing the lyse container, touch [APPLY] to prime the lyse.3. If the error still exists after replacing the lyse, contact Heska's Technical Support Services.
Diluent expired	<ol style="list-style-type: none">1. Touch [REMOVE ERROR] and enter the new barcode of the diluent into the reagent setup dialog box.2. After replacing the diluent container, touch [APPLY] to prime diluent.3. If the error still exists after replacing the diluent, contact Heska's Technical Support Services.
LH lyse expired	<ol style="list-style-type: none">1. Touch [REMOVE ERROR] and enter the new barcode of the lyse into the reagent setup dialog box.2. After replacing the lyse container, touch [APPLY] to prime the lyse.3. If the error still exists after replacing the lyse, contact Heska's Technical Support Services.

Error Name	Actions
DIFF lyse expired	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] and enter the new barcode of the lyse into the reagent setup dialog box. 2. After replacing the lyse container, touch [APPLY] to prime the lyse. 3. If the error still exists after replacing the lyse, contact Heska's Technical Support Services.
Waste container full	<ol style="list-style-type: none"> 1. Empty the waste container or use a new waste container. 2. Touch [REMOVE ERROR] to see if the error can be removed. 3. If the error still exists, contact Heska's Technical Support Services.
Power source error	Power the analyzer off and then contact Heska's Technical Support Services.
Preheat bath temperature sensor error	Power the analyzer off and then contact Heska's Technical Support Services.
Optical assembly temperature sensor error	Power the analyzer off and then contact Heska's Technical Support Services.
Diluent temperature sensor error	Power the analyzer off and then contact Heska's Technical Support Services.
Preheat assembly error	Power the analyzer off and then contact Heska's Technical Support Services.
Laser error	Power the analyzer off and then contact Heska's Technical Support Services.
Syringe assembly error	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Aspiration module lift mechanism error	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Aspiration module rotary mechanism error	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Background abnormal	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Exiting standby mode failed	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Replacing diluent failed	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Replacing DIFF lyse failed	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.

Error Name	Actions
Replacing LH lyse failed	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
HGB blank voltage abnormal	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Liquid pressure overloaded	<ol style="list-style-type: none"> 1. Perform "Probe Cleanser Maintenance". 2. Perform "Unclog Flow Cell". 3. Power off the analyzer and power on later. 4. If the error persists, contact Heska's Technical Support Services.
Vacuum pressure abnormal	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Preheat bath temperature error	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Analyzer temperature too high	<ol style="list-style-type: none"> 1. The ambient temperature shall be within 50°F–86°F [10°C–30°C] 2. Diluent temperature shall be within 50°F–86°F [10°C–30°C]. 3. Touch [REMOVE ERROR] to see if the error can be removed.
Diluent temperature too high	Diluent temperature shall be within 50°F–86°F [10°C–30°C].
Diluent temperature too low	Diluent temperature shall be within 50°F–86°F [10°C–30°C].
Clogging	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed. 2. If the error still exists, contact Heska's Technical Support Services.
Aperture voltage too low	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to see if the error can be removed 2. If the error still exists, contact Heska's Technical Support Services.
Impedance channel signal abnormal	<ol style="list-style-type: none"> 1. Eliminate sources of electromagnetic interference. 2. Touch [REMOVE ERROR] to see if the error can be removed.
Analysis is abnormal	<ol style="list-style-type: none"> 1. Touch [REMOVE ERROR] to remove the error. 2. If the error persists, power the analyzer off and then power back on. 3. If the error persists, contact Heska's Technical Support Services.
RBC channel is abnormal	<ol style="list-style-type: none"> 1. Please check the analysis mode. 2. Touch [REMOVE ERROR] to remove the error. 3. If the error persists, power the analyzer off and then power back on. 4. If the error persists, contact Heska's Technical Support Services.

Error Name	Actions
DIFF channel is abnormal	<ol style="list-style-type: none"> 1. Please check the DIFF lyse volume remaining and the analysis mode. 2. Touch [REMOVE ERROR] to remove the error. 3. If the error persists, power the analyzer off and then power back on. 4. If the error persists, contact Heska's Technical Support Services..
BASO channel is abnormal	<ol style="list-style-type: none"> 1. Please check the LH lyse residue and the analysis mode. 2. Touch [REMOVE ERROR] to remove the error. 3. If the error persists, power the analyzer off and then power back on. 4. If the error persists, 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

Diluent: Diluent

Lyse: DIFF lyse
LH lyse

/: Probe cleanser

A.3 Applicable Tubes

The following tubes can be used:

- Purple top EDTA collection tubes filled at least halfway.

A.4 Parameters

Parameter	Abbreviation	Default Unit
White Blood Cell count	WBC	$10^3/\mu\text{L}$
Basophils number	Bas#	$10^3/\mu\text{L}$
Basophils percentage	Bas%	%
Neutrophils number	Neu#	$10^3/\mu\text{L}$
Neutrophils percentage	Neu%	%
Eosinophils number	Eos#	$10^3/\mu\text{L}$
Eosinophils percentage	Eos%	%
Lymphocytes number	Lym#	$10^3/\mu\text{L}$
Lymphocytes percentage	Lym%	%
Monocytes number	Mon#	$10^3/\mu\text{L}$
Monocytes percentage	Mon%	%
Red Blood Cell count	RBC	$10^6/\mu\text{L}$
Hemoglobin Concentration	HGB	g/dL
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/dL
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV	%

Parameter	Abbreviation	Default Unit
Hematocrit	HCT	%
Platelet count	PLT	$10^3/\mu\text{L}$
Mean Platelet Volume	MPV	fL
White blood Cell Histogram	WBC Histogram	None
Red blood Cell Histogram	RBC Histogram	None
Platelet Histogram	PLT Histogram	None
Differential Scattergram	Diff Scattergram	None

B. Sampling Features

B.1 Sample Volumes Required for Each Analysis

Whole blood mode: $\leq 15 \mu\text{L}$ for CBC+DIFF mode

Pre-diluted mode: $\leq 20 \mu\text{L}$ for CBC+DIFF mode

B.2 Throughput

Open vial-whole blood and open vial-pre-diluted: no less than 60 samples per hour.

C. Performance Specifications

C.1 Display Range

Parameter	Display Range
WBC	$0.00 \times 10^9/\text{L} \sim 999.99 \times 10^9/\text{L}$
RBC	$0.00 \times 10^{12}/\text{L} \sim 18.00 \times 10^{12}/\text{L}$
HGB	0 g/L \sim 300 g/L
PLT	$0 \times 10^9/\text{L} \sim 9999 \times 10^9/\text{L}$
HCT	0% \sim 80%

C.2 Background/Blank Count

Parameter	Background/Blank Count Requirements
WBC	$\leq 0.30 \times 10^3/\mu\text{L}$
RBC	$\leq 0.03 \times 10^6/\mu\text{L}$
HGB	$\leq 0.1 \text{ g/dL}$
HCT	$\leq 0.5\%$
PLT	$\leq 10 \times 10^3/\mu\text{L}$

C.3 Linearity Range

Parameter	Linearity Range	Deviation Range (Whole Blood)	Deviation Range (Pre-Diluted)
WBC	0.00 × 10 ⁹ /L 100.00 × 10 ⁹ /L	±0.30 × 10 ⁹ /L or ±5%	±0.60 × 10 ⁹ /L or ±6%
RBC	0.00 × 10 ¹² /L 8.00 × 10 ¹² /L	±0.05 × 10 ¹² /L or ±5%	±0.10 × 10 ¹² /L or ±10%
HGB	0 g/L 250 g/L	±2g/L or ±2%	±4g/L or ±4%
PLT	0 × 10 ⁹ /L 1,000 × 10 ⁹ /L	±10 × 10 ⁹ /L or ±8%	±20 × 10 ⁹ /L or ±16%

C.4 Deviation of Reading

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

C.5 Compatibility

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

C.6 Reproducibility

Parameter	Condition	Whole Blood Reproducibility	Pre-Diluted Reproducibility
WBC	4.00 × 10 ⁹ /L ~ 15.00 × 10 ⁹ /L	(CV/absolute deviation d)	(CV/absolute deviation d)
Neu%	50.0% ~ 70.0%	≤2.5%	≤4.0%
Lym%	20.0% ~ 40.0%	±4.0(d)	±8.0(d)
Mon%	5.0% ~ 10.0%	±3.0(d)	±6.0(d)
Eos%	2.0% ~ 5.0%	±2.0(d)	±4.0(d)
Bas%	0.5% ~ 1.5%	±1.5(d)	±2.5(d)
RBC	3.50 × 10 ¹² / L ~ 6.00 × 10 ¹² /L	±0.8(d)	±1.2(d)
HGB	110 g/L ~ 180 g/L	≤1.5%	≤3.0%
MCV	70 fL ~ 120 fL	≤1.5%	≤3.0%
PLT	100 × 10 ⁹ /L ~ 149 × 10 ⁹ /L	≤1.0%	≤2.0%
	150 × 10 ⁹ /L ~ 500 × 10 ⁹ /L	≤6.0%	≤10.0%
MPV	–	≤4.0%	≤8.0%

C.7 Carryover

Parameter	Carryover
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
HCT	≤0.5%
PLT	≤1.0%

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)

F. Printer (Optional)

Supported printer models are: EPSON LQ-590K, HP Laser Jet P1505n, HP OfficeJet Pro K5300 and HP LaserJet P1606dn. 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: 65 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: 20%~85%

Atmospheric pressure: 70 kPa ~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

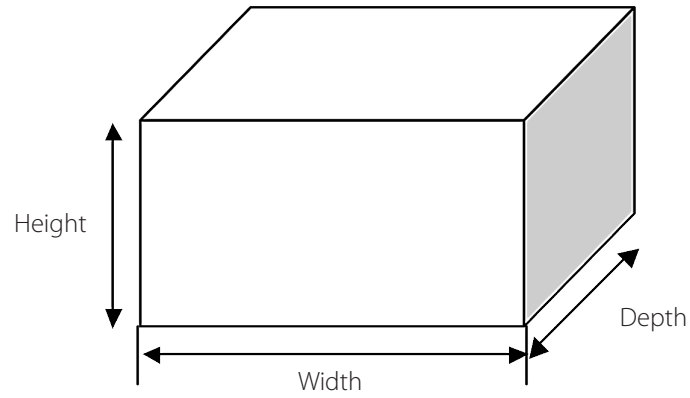
N. Running Environment

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

Relative humidity: 10%~90%

Atmospheric pressure: 70 kPa~106 kPa

O. Dimensions and Weight



Element HT5	Analyzer
Dimensions	Width(mm) \leq 325 Height (mm) \leq 435 (with foot) Depth (mm) \leq 410
Weight	\leq 25Kg

P. Contra-Indications

None

Q. Safety Classification

Level of transient overvoltage: Category II

Rated pollution degree: 2



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