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1.1 Introduction

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

1.2 Who Should Read This Manual

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

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

1.3 How to Find Information

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

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

1.4 Conventions Used in This Manual

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

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

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

1.5 Safety Information

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

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



BIOHAZARD

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

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



WARNING

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

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



CAUTION

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

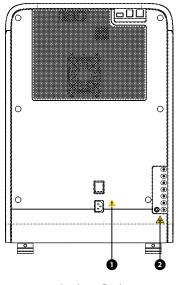
NOTE: Use the reagents specified by the manufacturer only. Store and use the reagents as instructed by instructions for use of the reagents. Check if the reagent tubes are properly connected before using the analyzer.

1.6 Symbols

product was purchased.

| ou ma | y find the following symbols on the analyzer: | | |
|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------------------------------------------------------------------------|
| | WARNING/CAUTION: Consult Accompanying Documents | | Manufacturer |
| | BIOLOGICAL RISK | M | Date of Manufacture |
| | WARNING: LASER BEAM | | Ground |
| 1 | CAUTION: Avoid aspiration probe. | _ | Network Port |
| 2 | Prohibited | | Mandatory Action |
| \leftarrow | USB Port | LOT | Batch Code |
| \sim | Alternating Current | SN | Serial Number |
| Ø | Humidity limitation | 1 | Temperature Limitation |
| | Atmospheric pressure limitation | \square | Use By |
| (| CE Mark | []i | Consult the User Manual |
| \supset | Power OFF | | Power On |
| Ţ | Fragile, Handle with Care | · j · | Keep Dry |
| | Stacking Number Limit | <u> </u> | This Way Up |
| ∀ . | Do Not Roll | SGS C 801341 | NRTL certification mark |
| (| The device fully conforms with the council directive concerning <i>In Vitro</i> diagnostic medical devices 98/79/EC. | | |
| X | The following definition of the WEEE label applies to EU member sta electronic equipment must not be disposed of as unsorted municip product is disposed of correctly, it will help prevent bringing potent For more detailed information with regard to returning and recycling | oal waste and ial negative | d must be collected separately. By ensuring that the consequences to the environment and human he |

For more detailed information with regard to returning and recycling this product, please consult the distributor from whom the



Analyzer Back



CAUTION

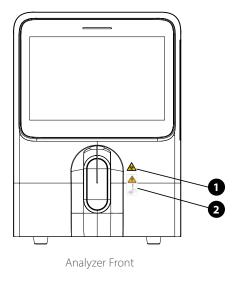
Connect only to a properly grounded outlet.

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.





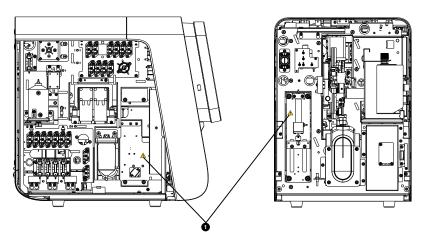
BIOHAZARD

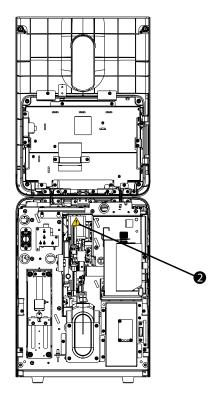
Warning, potential biological risk.



⚠ WARNING

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



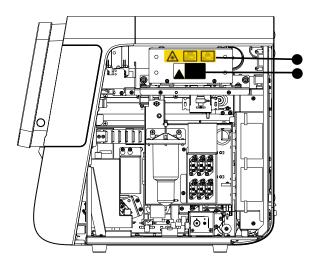


Warning labels for moving parts.



WARNING

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



Optical assembly laser warning labels.



CAUTION

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

Laser radiation. Avoid exposure to beam. Class 3B laser product.

Peak power: 10 mW Wavelength: 635 nm



2.1 Introduction

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

2.2 Parameters

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

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

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

| Parameter Group | Name | Abbreviation | CBC and DIFF |
|-----------------|-----------------------------|--------------|--------------|
| | Platelet count | PLT | $\sqrt{}$ |
| DIT (4) | Mean platelet volume | MPV | $\sqrt{}$ |
| PLT group (4) | Platelet distribution width | PDW | √ |
| | Plateletcrit | PCT | √ |

| Parameter Group | Name | Abbreviation | CBC+DIFF |
|---------------------|------------------------------------------------------|--------------|-----------|
| | Platelet large cell count | P-LCC | $\sqrt{}$ |
| | Platelet large cell ratio | P-LCR | $\sqrt{}$ |
| | Immature platelet fraction | IPF | $\sqrt{}$ |
| Auvilianu graup (0) | High fluorescence reticulocytes | HFR | $\sqrt{}$ |
| Auxiliary group (8) | Medium fluorescence reticulocytes | MFR | $\sqrt{}$ |
| | Low fluorescence reticulocytes | LFR | $\sqrt{}$ |
| | Immature reticulocyte fraction | IRF | $\sqrt{}$ |
| | Red blood cell distribution width standard-deviation | RDW-SD | |

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

2.2.1 Histograms

| Name | Abbreviation | CBC+DIFF |
|--------------------------|---------------|-----------|
| Red blood cell histogram | RBC histogram | $\sqrt{}$ |
| Platelet histogram | PLT histogram | V |

2.2.2 Scattergrams

| Name | Abbreviation | CBC+DIFF |
|------------------------------------|---------------------|-----------|
| Differential scattergram | Diff scattergram | $\sqrt{}$ |
| Reticulocyte scattergram | RET scattergram | √ |
| Optical platelet scattergram | PLT-O scattergram | √ |
| Reticulocyte extension scattergram | RET-EXT Scattergram | $\sqrt{}$ |

NOTE: $\sqrt{\text{means}}$, available under the mode; / means, not available under the mode.

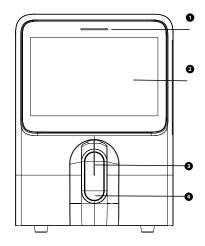
2.3 Product Description

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



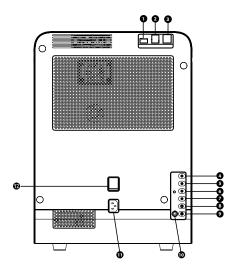
WARNING. Ensure dye compartment door is closed before operating the analyzer.

2.3.1 Analyzer Front



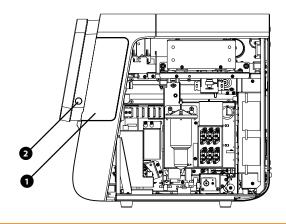
| No. | Name | Description |
|-----|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Status indicator | The indicator is located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

2.3.2 Analyzer Back



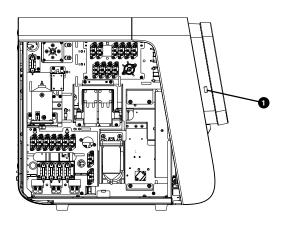
| No. | Name | No. | Name |
|-----|-------------------------|-----|------------------------|
| 1 | USB port (protocol 3.0) | 7 | Solution reagent inlet |
| 2 | USB port (protocol 2.0) | 8 | DS diluent inlet |
| 3 | Network interface | 9 | Waste outlet |
| 4 | DR diluent inlet | 10 | Waste sensor |
|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

2.3.4 Analyzer Right Side



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

2.3.5 Analyzer Left Side



| No. | Name |
|-----|-------------------------|
| 1 | USB port (protocol 2.0) |

Power switch

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



CAUTION

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

Aspirate key

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

USB/network port

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

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

2.4 Status Indicator

The status indicator is on the front of the analyzer; it indicates the ready, running, error and standby status of the analyzer. The indicator illuminates in 3 colors to indicate the current status of the analyzer; its flashing interval is 2 seconds. See the indicator and status table below.

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

2.5 System Menu

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

2.6 Reagents, Controls and Calibrators

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

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

NOTE: Store and use the reagents as instructed:

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

2.6.1 Reagents

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

DR Diluent and FR Dye generate RET parameters.

LH Lyse generates HGB.

LD Lyse is used to to differentiate WBC.

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

2.6.2 Controls and Calibrators

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

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



3.1 Introduction

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

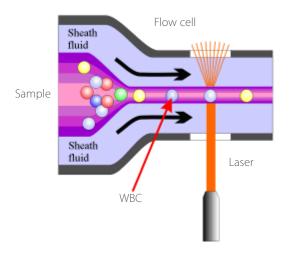
3.2 Aspiration

Analyzing a whole blood sample in the open vial sampling mode, the analyzer will aspirate $30-35~\mu\text{L}$ of the sample. If analyzing a capillary blood sample in the open vial sampling mode, you will first manually dilute the sample (20 uL of capillary sample needs to be diluted by 100 uL of diluent) and then present the pre-diluted sample to the analyzer, which will aspirate 77.5 uL of the sample.

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

3.3 WBC Measurement

3.3.1 Laser Flow Cytometry & SF Cube Cell Analysis



Laser flow cytometry

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

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

3.3.2 SF Cube Cell Analysis

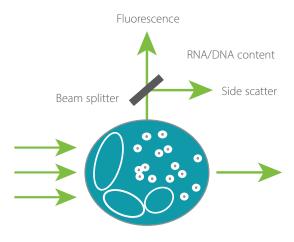
The analyzer adopts SF Cube cell technology to accurately recognize and detect the immature cells in blood.

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

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

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

Internal structure of a cell



SF cube technology

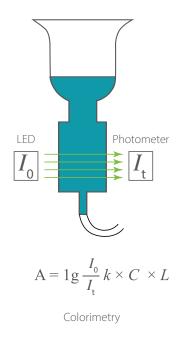
3.4 HGB Measurement

3.4.1 Colorimetric Method

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

3.4.2 HGB

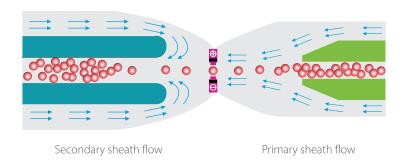
The HGB is calculated per the following equation and expressed in g/dL (US) and g/L (SI). HGB (g/L) = Constant \times Ln (Blank Photocurrent/Sample Photocurrent).



3.5 RBC/PLT Measurement

3.5.1 Sheath Flow Impedance Method

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



Sheath flow impedance method

3.6 Deriviation of Parameters

Derivation of RET—Related Parameters

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

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

3.6.1 Derivation of WBC—Related Parameters

| Parameters | Formula/Test Methods | US Units | SI Units |
|------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|
| WBC | WBC = the sum of all particles in the DIFF channel except those in the Ghost region | 10 ³ /μL | 10 ⁹ /L |
| Bas# | Bas# = WBC × Bas% | 10 ³ /μL | 10 ⁹ /L |
| Bas% | Bas% = Particles in the Bas region in the DIFF channel Sum of all particles in DIFF channel except those in Ghost region × 100 | % | % |
| Neu# | Neu# = WBC x Neu% | 10 ³ /μL | 10 ⁹ /L |
| Neu% | Neu% = Particles in the Neu region in the DIFF channel Sum of all particles in DIFF channel except those in Ghost region × 100 | % | % |
| Eos# | Eos# = WBC x Eos% | 10 ³ /μL | 10 ⁹ /L |
| Eos% | Eos% = Particles in the Eos region in the DIFF channel Sum of all particles in DIFF channel except those in Ghost region × 100 | % | % |
| Lym# | Lym# = WBC x Lym% | 10 ³ /μL | 10 ⁹ /L |
| Lym% | Lym% = Particles in the Lym region in the DIFF channel Sum of all particles in DIFF channel except those in Ghost region × 100 | % | % |
| Mon# | Mon# = WBC x Mon% | 10 ³ /μL | 10 ⁹ /L |
| Mon% | Mon% = Particles in the Mon region in the DIFF channel Sum of all particles in DIFF channel except those in Ghost region × 100 | % | % |

3.6.2 Derivation of RBC—Related Parameters

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

3.6.3 Derivation of RET—Related Parameters

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

^{*} Auxiliary parameters

3.6.4 Derivation of PLT—Related Parameters

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

^{*} Auxiliary parameters

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4.1 Introduction



WARNING

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

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

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

4.2 Installation Requirements

4.2.1 **Space Requirements**

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

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

4.2.2 **Power Requirements**



WARNING

Make sure the analyzer is properly grounded.

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



CAUTION

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

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

Power Specification Table

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

4.2.3 General Environment

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

4.2.4 Moving and Installing the Analyzer



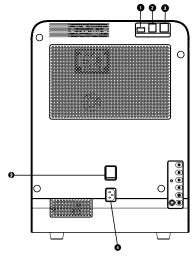
WARNING

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

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

4.3 Connecting the Analyzer System

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



Connecting the analyzer to power outlet

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

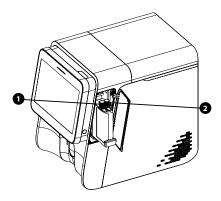


WARNING

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

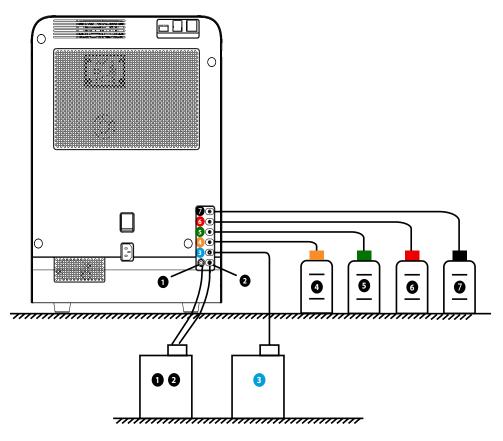
The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g., gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

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



Connecting fluorescent dyes.

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



Connecting reagents and waste assembly.

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



CAUTION

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

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

NOTE:

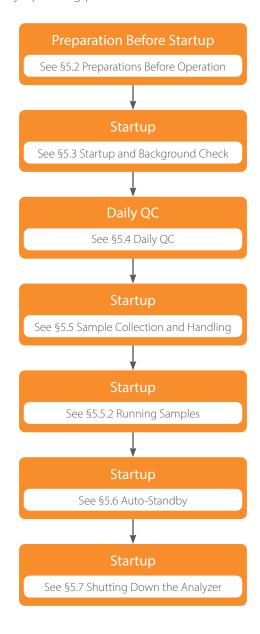
- The analyzer performance may be undermined if it has been placed in contaminated environment.
- The surface of the analyzer shall be cleaned and sterilized regularly with alcohol (75%).
- The probe wipe block of the analyzer (see Figure 2.3.1 Analyzer Front) shall be wiped with alcohol (75%) regularly.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



5.1 Introduction

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

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





BIOHAZARD

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



CAUTION

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



CAUTION

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

NOTE:

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

5.2 Initial Checks

Perform the following checks before removing analyzer from standby.

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

5.3 Startup and Background Check

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

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

NOTE:

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

5.4 Daily Quality Control

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

5.5 Sample Collection and Handling



BIOHAZARD

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



WARNING

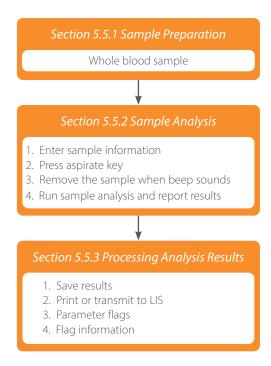
The sample probe is sharp and potentially biohazardous. Do not contact the sample probe during operations.



CAUTION

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

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



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



5.5.1 Whole Blood Samples

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



CAUTION

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

Pre-diluted samples

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

NOTE:

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

5.5.2 Preparing Body Fluid Samples



CAUTION

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

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

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

5.5.3 Whole Blood Sample Analysis

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

1. Enter sample information.

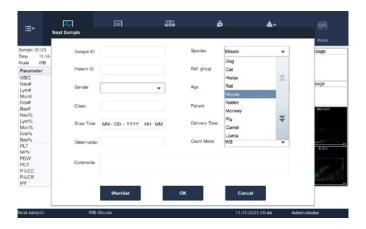
The analyzer provides two ways to enter sample information: Entering Sample/Patient ID only and entering all sample information.

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

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

2. Entering patient demographics.

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



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

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

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

 Enter the Patient ID number in the Patient ID field.
- c. Entering Species
 Select the species from the Species Pull-down list.
- d. Entering Patient Name Enter the patient name into the Name field.
- e. Selecting Patient Gender Select patient gender from the Gender pull-down list. There are two options: Male and Female.
- f. Entering Patient's Age
 The analyzer provides four ways to enter the patient's age; in years, in months, in days and in hours.

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

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

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

Enter comments in the Comments field.

k. OK

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

I. CANCEL

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

- 3. Aspirate the sample.
 - Present the sample to the sample probe. Touch ASPIRATE to start analysis.
- 4. Remove the sample.

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

5. Auto analysis and result reporting.

The analyzer will automatically run the sample. When the analysis is finished, the results will be displayed on the screen.



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

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

5.5. Performing Pre-diluted Sample Analysis

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

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

5.5.5 Performing a Single Body Fluid Sample Analysis

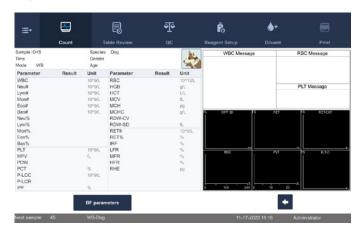
- 1. Present the sample tube under the sample probe.
- 2. Press ASPIRATE key to start sample analysis.

The sample probe automatically aspirates sample.

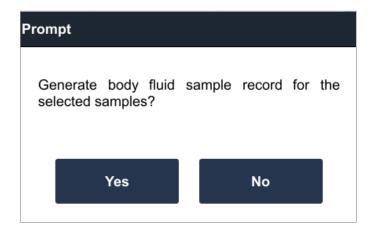
3. Remove the sample tube.

The analyzer automatically analyzes the sample. When the analysis completes, the analyzer indicator returns to Ready status.

4. When sample analysis finishes, touch BF PARAMETERS.



A dialog box pops up.

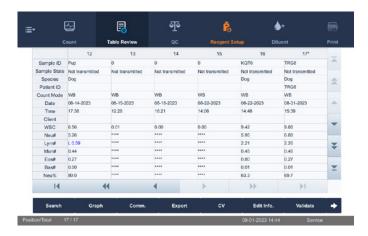


- 5. Touch YES in the dialog box to enter the test result screen of the body fluid sample.
- 6. Touch **RETURN** to return to the main screen.

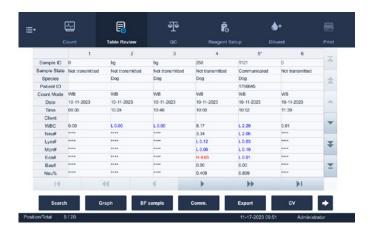
5.5.6 Performing Multiple Body Fluid Sample Analysis

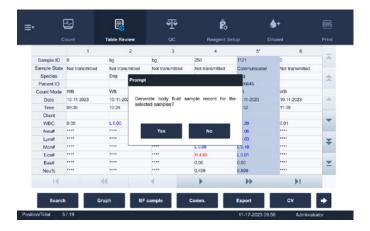
To perform multiple body fluid sample analysis, the operator can follow instructions in "Performing a single body fluid sample analysis" to perform sample analysis one by one. Or the operator can follow below instructions to perform multiple body fluid sample analyses.

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



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





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

5.5.7 Processing Analysis Results

- 1. Automatic saving of analysis results.

 This analyzer automatically saves sample results. When the maximum number of results that can be saved has reached (40,000 records), the newest result will overwrite the oldest.
- 2. Printing and transmission to LIS.

 If Auto print after sample analysis function is enabled, the analyzer will print reports automatically; and if Auto comm. function is enabled, the analysis results, sample and patient information will be auto transmitted to LIS.
- 3. Parameter flags.

See the following section for details about parameter flags.

- If the parameter is followed by an H or L, or ▲or ▼, it means the analysis result has exceeded the upper or lower limit of the reference range. See Section 9.2.9 Parameter Setup.
- If the parameter is followed by an R, it means the analysis result is questionable.
- If ***** is displayed, as opposed to the result, it means the result is invalid; if +++++ is displayed as opposed to the result, it means the result is out of the display range. See the following Display Range Table for details.

Display Range Table

| Parameter | Display Range (US Units) | Display Range (SI Units) |
|---------------------------------------------------------|---------------------------------|---------------------------------|
| WBC, Neu#, Lym#, Mon#, Eos#, Bas# | $0.00-999.99 \times 10^3/\mu$ L | 0.00-999.99 ×10 ⁹ /L |
| Neu%, Lym%, Mon%, Eos%, Bas%, RET%, IRF, LFR, MFR, HFR* | 0.0-100.0% | 0.0-100% |
| RBC | 0-99.99 × 10 ⁶ /uL | 0.00-99.99 ×10 ¹² /L |
| HGB | 0-35 g/dL | 0-350 g/L |
| HCT, P-LCR*, RDW-CV | 0-99.9% | 0.0-99.9% |
| MCV | 0.0-450.0 fL | 0.0-450.0 fL |
| MCH | 0.0-999.9% | 0.0-999.9% |
| MCHC | 0-9999 g/L | 0-9999 g/L |
| RDW-CV | 0.0-99.9% | 0.0-99.9% |

| Parameter | Display Range (US Units) | Display Range (SI Units) |
|-------------|--------------------------------|-------------------------------|
| RDW-SD* | 0-999.9 fL | 0-999.9 fL |
| PLT, P-LCC* | 0-9999 × 10 ³ /uL | 0-9999 ×10 ⁹ /L |
| MPV | 0.0-99.9 fL | 0.0-99.9 fL |
| PDW | 0-99.9 | 0-99.9 |
| PCT | 0-9.999% | 0-9.999% |
| RET# | 0-9999.9 × 10 ³ /uL | 0-9999.9 × 10 ⁹ /L |
| RET% | 0-999.9% | 0-999.9% |

^{*}Auxiliary parameters

4. Abnormal blood cell differential or morphology flags.

The following Flags of Abnormal Blood Cell Differential or Morphology Table lists all flags and their indications.

5.5.8 Flags of Abnormal Blood Cell Differential or Morphology Table

| Flag Type | Pathology Message | Meaning | Criteria |
|--------------------------|----------------------|---------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| | Leukopenia | Low WBC analysis results | WBC# $< 3 \times 10^9 / \mu$ L, SI WBC# $< 3 \times 10^3 / \mu$ L, US |
| | Leukocytosis | High WBC analysis results | WBC# $< 3 \times 10^9 / L$ for dog, cat and horse, ,SI WBC# $< 3 \times 10^3 / \mu L$ for dog, cat and horse, US |
| | Neutropenia | Low neutrophils analysis results | NEUT# <20% below lower normal range limit. |
| WBC Flag | Neutrophilia | High neutrophils analysis results | NEUT# >20% above upper normal range limit. |
| WDCTIag | 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. |
| | Anemia | Low hematocrit analysis result | HCT <10% below lower normal range limit. |
| | Polycythemia | High hematocrit analysis result | HCT >10% above upper normal range limit. |
| DDC El- | Microcytosis | MCV low | MCV <10% below lower normal range limit. |
| RBC Flag | 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. |
| DIT | Thrombocytopenia | PLT low | PLT# <25% below lower normal range limit. |
| PLT | Thrombocytosis | PLT high | PLT# >50% above upper normal range limit. |
| Abnormal Cell Morphology | | | |
| Immature gran | 1? | Possible presence of immature granulocytes. | Presence of excessive dots in immature granulocyte sensitive region of the scattergram. |
| Band cell suspected? | | Possible presence of band cell. | Presence of excessive dots in Band Cell sensitive region of the scattergram. |
| RBC lyse resistance? | | Possible presence of RBC lyse resistance. | Presence of abnormally distributed dots in the WBC sensitive region of the DIFF scattergram. |

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

5.6 Auto-Standby

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

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

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

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

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

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

Exiting standby

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

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

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

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

 And the analyzer indicator will also turn into solid green.

5.7 Shutdown



CAUTION

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

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

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

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



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



WARNING

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

NOTE: Do not disconnect power during the shutdown process.

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



6.1 Introduction

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

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

6.2 Browsing in the Table Review Mode

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



6.2.1 Table

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

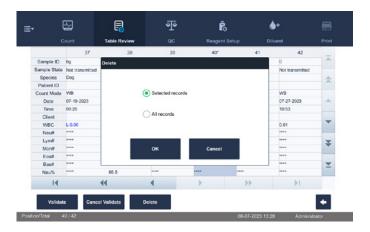
6.2.2 Graph Review

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



6.2.3 Delete (for administrators only)

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



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

6.2.4 Edit Information (for administrators only)

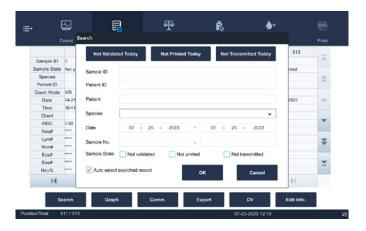
1. Touch the desired sample result and it will be highlighted. Touch EDIT INFO and the following dialog box will display.



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

6.2.5 Search

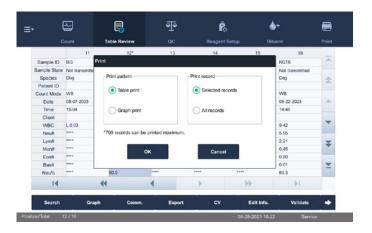
- 1. Select MENU ► TABLE REVIEW or touch TABLE REVIEW utility button to enter the Table Review screen.
- 2. Touch **SEARCH**, the following dialog box will display.
- 3. Enter search conditions into the edit boxes or select them from the pull-down lists.
- 4. Touch **OK** to start search, the results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



6.2.6 Print

Printing current sample report

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



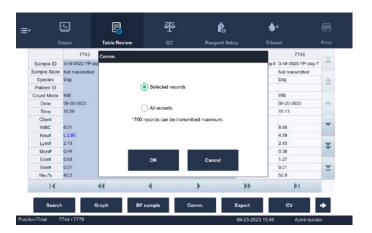
Printing from graph review screen

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

6.2.7 Transmission (requires connection to LIS)

Transmit selected data

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



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

Transmit all data

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



6.2.8 Export

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



- 2. Touch to select one or more sample records to export.
- 3. Touch **EXPORT**

The Export dialog box displays. Touch **SELECTED RECORDS** in the Export Range area. To export all sample records, touch **ALL RECORDS** in the Export Range area.

4. Touch **OK**

The analyzer exports the corresponding sample records to USB device.



7.1 Introduction

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

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

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

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



BIOHAZARD

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



WARNING

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



CAUTION

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

7.2 QC Programs

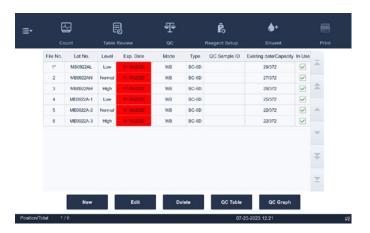
NOTE: Only use the Heska-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents.

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

7.2.1 Setting Up New QC Files (for administrators only)

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

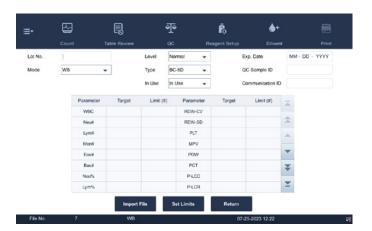
- 1. Touch MENU ▶ QC ▶ SETUP to enter the QC file setup screen.
- 2. Touch **NEW** to enter the new QC file screen.



- 3. Enter necessary QC file information.
 - Set up QC information by either of the following two ways:
 - Manual entry
 - Reading the information provided by the manufacturer (USB download).

 Insert the USB device saving the QC files to the USB port on the analyzer. On the new QC file screen, touch IMPORT FILE and follow the software instructions to import the QC file.
- 4. Define QC Sample ID and Communication ID.
- 5. As an option, set the QC file to In Use in the In Use pull-down list.
- 6. Save the QC file.

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



7.2.2 Manual Entry of QC Information

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

High, medium or low

3.. Enter the lot expiration date.

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

4. Select the control type.

BC-6D, BC-RET or BC60

5. Select the mode.

WB or PD

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

In use or Not in use

7. Set QC sample ID.

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

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

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



9. Save OC file.

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

7.2.3 Editing QC Files

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

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

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

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

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

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

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

6. Save the OC file.

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

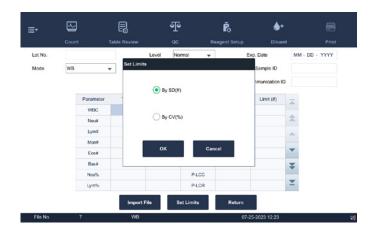
7.2.4 Deleting QC Files

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

7.2.5 Setting Limits

Adjust the format of limits:

1. Touch **SET LIMITS**.



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

7.2.6 QC Run

Run controls under the QC screen.



CAUTION

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

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

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

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

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

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



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

When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically. Do the above procedures to continue running QC analysis, if necessary.

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

7.2.7 Reviewing Results

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

- QC Graph
- QC Table

QC Graph Review

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

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

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



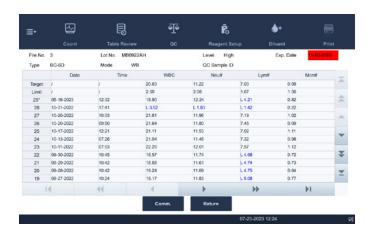
NOTE: If the target/limits of a QC file with QC results have been modified and saved, the modified data will be displayed in yellow.

Print

1. Touch **PRINT** in the status bar to print information of the current QC file and the QC graph of all parameters. **NOTE:** The green vertical line and values of the corresponding QC points will not be printed.

QC Table review

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



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

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

Delete (for administrators only)

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



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

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

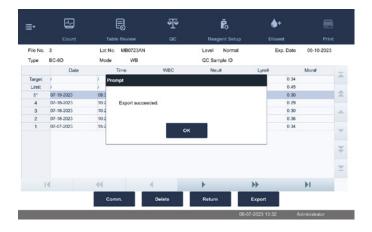
Print

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

Transmission

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

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



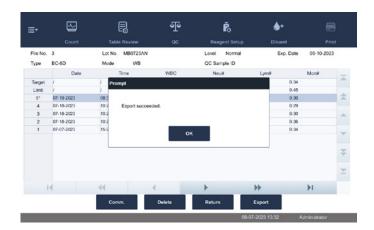
- 2. Select to transmit Selected or All records.
- 3. Touch **OK** to start transmitting specified results to the data management software.

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

Export

Export QC information and results of the current QC file as follows:

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





8.1 Introduction

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

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

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



WARNING

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



CAUTION

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

NOTE:

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

8.2 When to Calibrate

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

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

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

8.3 How to Calibrate

8.3.1 Analyzer Preparation

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

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

NOTE:

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

8.3.2 Checking Before Calibration

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

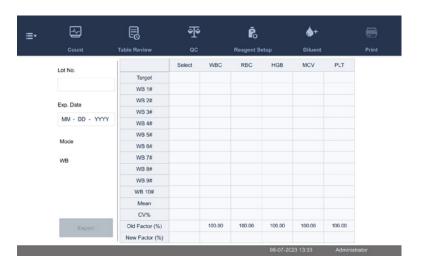
8.3.3 Calibration with Calibrator



BIOHAZARD

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

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



NOTE:

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

8.3.4 Calibrate the Analyzer with Calibrator

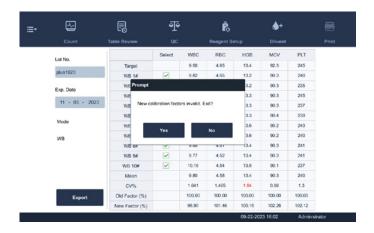
- 1. Check the mode on the analyzer screen.
- 2. Enter the lot number of the calibrator into the Lot No. field. Find the lot No. on the label on the vial of the calibrator, or on the target sheet of the corresponding calibrator.
- 3. Enter the expiration date. The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows:

 The date the container is opened + the open-container stability days.
- 4. Enter the targets into the Target fields. Find parameter targets on the target sheet of the corresponding calibrator.
- 5. Prepare the calibrator as instructed by the calibrator's instructions for use.
- 6. Place the prepared calibrator in a tube, and place the tube under the sample probe.
- 7. Touch **ASPIRATE** to start calibration and aspirate calibration solution.

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

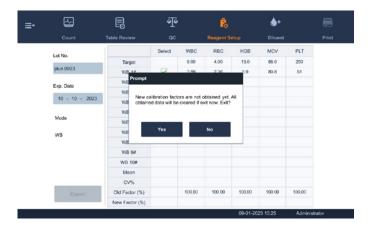


Touch **YES** to close the dialogue box, and the data will be deleted from the table without saving automatically. When the running is done, if there is a parameter whose calibration data is out of the display range, then the non-numeric parameter values *** will be displayed in the list and a dialogue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



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

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



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

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

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

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

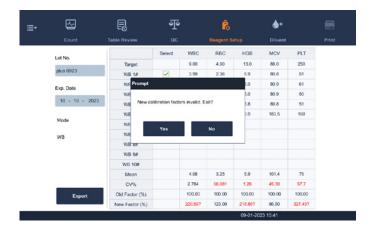
When the amount of valid calibration data in the list reaches 10, a dialogue box, Calibration complete will display. Then, touch the aspirate key again, the analyzer will beep without starting analysis.



10. There may be two cases when switching to another screen:

If the calibration factors of any parameter is out of the range [75%–125%] or the CV% of any parameter exceeds the

reproducibility range, then the calculated calibration factors of all parameters will not be saved and a message box will also display.



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

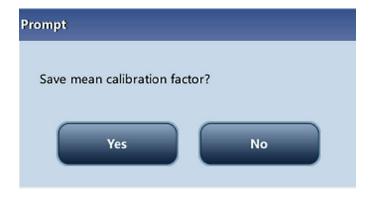
If the calculated calibration factors of all parameter are within the range [75%–125%] and the CV% of all parameter are also within the reproducibility range, then a dialogue box will display.



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

8.3.5 Saving Calibration Results

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



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

8.3.6 Verifying Calibration Factors

Verify the calibration factors using any of the following methods.

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

8.3.7 Calibration History

Only administrators can view the calibration history.

- 1. Touch MENU ► CALIBRATION ► CALIBRATION HISTORY to enter the Calibration History screen.
 - Select **DETAILS** to view detailed calibration information.
 - Select **GO TO** to view the calibration history of the specified time period.
 - Touch **EXPORT** to export specified or all calibration records to a USB drive.

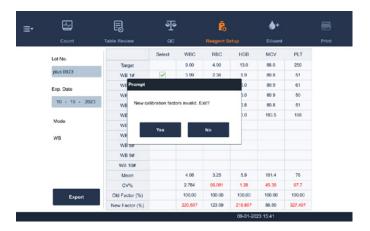
Manual calibration

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

- 1. Touch "Menu ▶ Calibration ▶ Manual" to enter the manual calibration screen.
- 2. Enter the new calibration factors into the factor cell of the parameter that require calibration.

NOTE:

- The calibration factor entered must be in the range of 75.00% 125.00%, and only two decimal places can be reserved.
- If the entered calibration factors are invalid, the factors will be highlighted in red.
- The Date cells automatically display the date when the new calibration factors are entered.
- 3. Save calibration factors.
 - 3.1 Touch another button on the software screen and a dialog box displays to remind you to save calibration factors.
 - 3.2 Touch **YES** to save new calibration factors. If the entered calibration factors are invalid, a dialog box will display when you are switching to another screen. Touch **NO** to re-do calibration procedures.



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



9.1 Introduction

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

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

Refer to the following for the Setup menu.

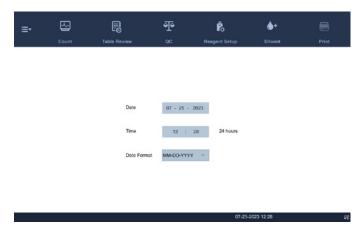


9.2 Setting Up the Analyzer

9.2.1 System Setup

Date/Time

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

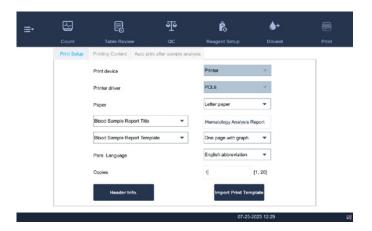


9.2.2 Print

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

Set up the following contents:

- Print setup
- Printing content
- Auto print



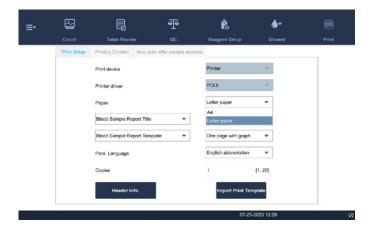
9.2.3 Print Setup

Printer driver

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

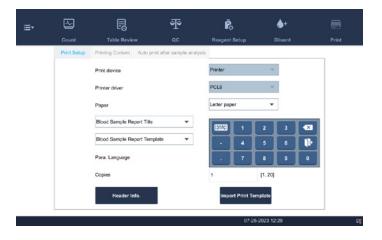
Paper

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

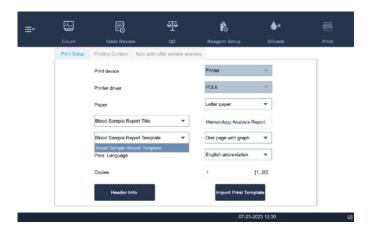


Copies

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

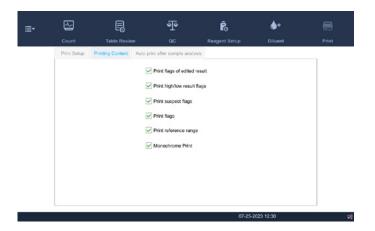


Report template



Printing content

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



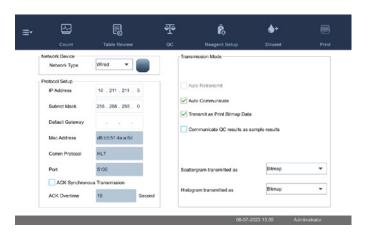
Auto print

Disable auto print or other printing conditions may be setup.

9.2.4 Communication Setup

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

- Protocol setup
- Transmission mode



Protocol setup

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

Communication Protocol

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

ACK synchronous transmission

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

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

Transmission mode

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

- Auto retransmit
- Auto communicate
- Transmit as print bitmap data
- · Communicate QC results as sample result

Transmission mode of histogram and scattergram

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

- Not to be transmitted
- Bitmap
- Data

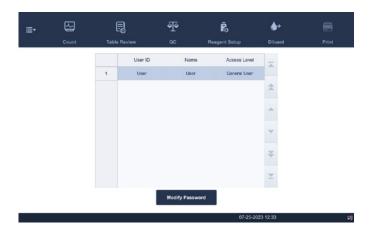
9.2.5 Lab Information Setup

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



9.2.6 Access Setup

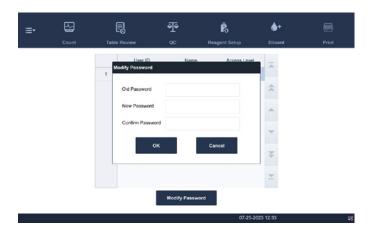
Touch **SETUP** ► **USER MANAGEMENT** in the menu to enter the following screen.



Modify password

The password may be modified.

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

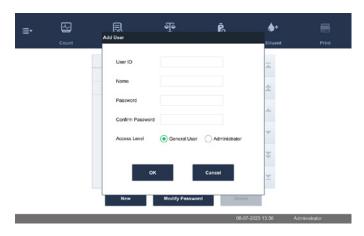


- 2. Enter the required information in the edit boxes.
- 3. Touch **OK** to save the change and close the dialog box.

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

9.2.7 Create New User

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



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

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

Delete User

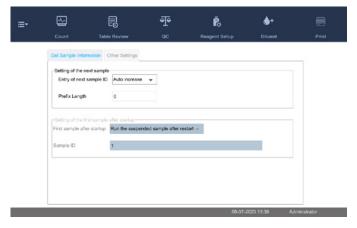
- 1. Select a user and then touch **DELETE** to delete it. A confirmation box displays.
- 2. Touch **YES.** The selected user is deleted.

NOTE: The current login user cannot be deleted.

9.2.8 Auxiliary Setup

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

- Get sample information
- Other settings



Get sample information

MENU ► SETUP ► AUXILIARY SETUP ► GET SAMPLE INFORMATION to enter the Get Sample

Information screen. The following options may be set here.

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

9.2.9 Parameter Setup

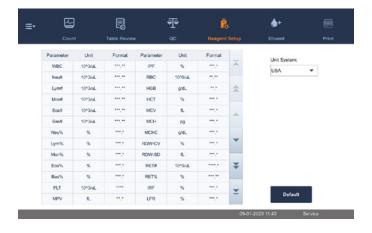
Parameter Unit Setup

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



Select Unit System

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





Customizing arameter Units

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

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

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



9.2.10 Maintenance Setup (for administrators only)

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

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

Probe Cleanser Maintenance

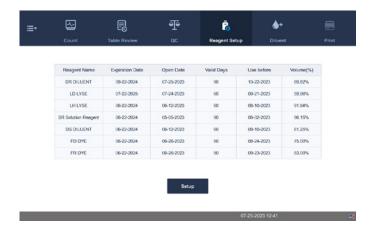
Touch the first text box in the Probe Cleanser Maintenance area to enter the time to start time-based probe cleanser maintenance. Touch the second text box to enter a time in the text box. Then when the operator cancels the time-based maintenance, a reminder dialog box will display after the defined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

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

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

9.2.11 Reagent Setup

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



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

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

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

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

Replace reagents when:

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

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



2. Read reagent information by swiping RFID card.

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

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

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

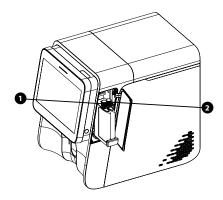
NOTE: Please keep the diluent container from severe shock or impact against other objects. Otherwise, the analyzer performance may be compromised.

Install new reagent

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

Replace dye

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



Connecting fluorescent dyes.

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

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

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

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

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

Replacing other reagent

- 1. Remove the cap of a new reagent container, and place the container next to the one to be replaced.
- 2. Turn the cap of the old container counterclockwise, and then take out the cap assembly with caution.
- 3. Insert the pickup tube of the cap assembly into the new container, and then turn the cap clockwise until it is secured.
- 4. Cap the old container with the cap of the new container and dispose of the container properly. Touch **REPLACE**. After swiping RFID card and installing new reagents, touch **REPLACE** in the Setup dialog box. The analyzer will automatically prime reagent and replace the old reagent.

9.2.12 Discharging Waste



BIOHAZARD

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

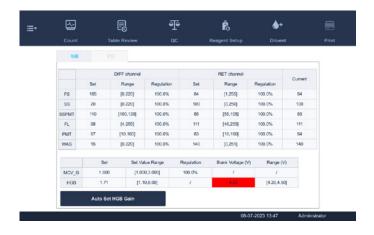
- Be sure to dispose of reagents, waste, samples, consumables, etc., according to government regulations.
- Remove the waste container cap only when the power indicator is not flickering, in order not to make the waste overflow from the container.
- If the waste is discharged using the waste container,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

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

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

9.2.13 Gain Setup (for administrators only)

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



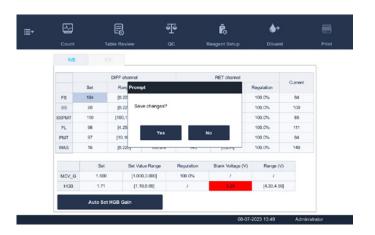
Adjust the HGB default gain by selecting Auto Adjust.

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

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

9.3 Save the Settings

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



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

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



10.1 Introduction

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

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



BIOHAZARD

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



WARNING

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

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



CAUTION

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

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

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

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

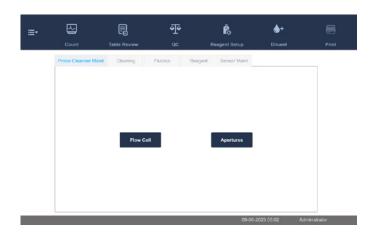
For any questions, contact Heska's Technical Support Services at 800.464.3752, option 3.

10.2 Maintaining the Analyzer

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

10.2.1 Maintenance

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



Routine probe cleanser maintenance

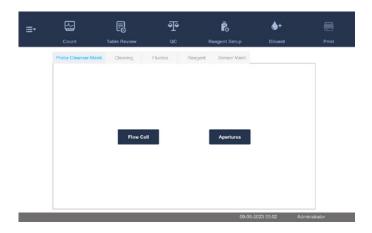
After the probe cleanser maintenance time is set in **SETUP** ▶ **MAINTENANCE**, the analyzer prompts you to maintain the probe cleanser at the set time.

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

Probe cleanser maintenance to parts and components

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

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



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

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

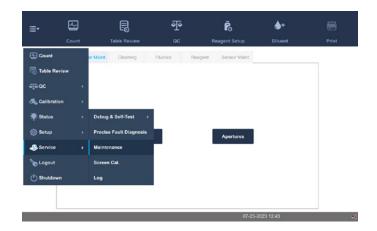
The sample probe lowers to the aspiration position.

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

10.2.2 Auto-cleaning Parts and Components

Fluidics should be cleaned when the background results are unqualified.

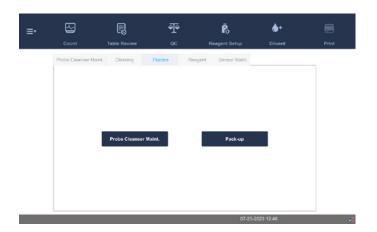
- 1. Touch MENU ► SERVICE ► MAINTENANCE ► CLEANING to enter the Cleaning screen.
- 2. Touch the corresponding cleaning program. The analyzer automatically completes the operation.



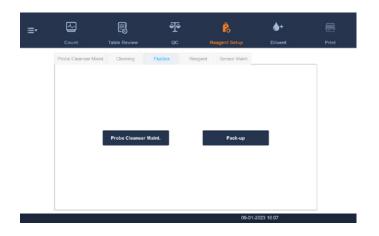
10.3 Preparing for Packup

10.3.1 Packing Up

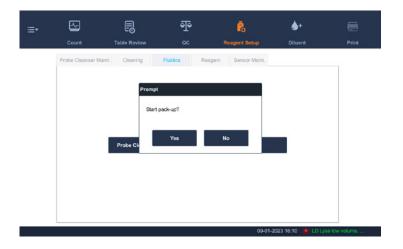
If the analyzer will not be used for over 2 weeks, perform this procedure.



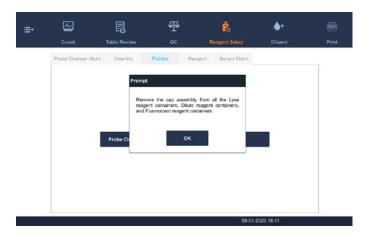
1. Touch MENU ▶ SERVICE ▶ MAINTENANCE ▶ FLUIDICS to enter the Fluidics screen.



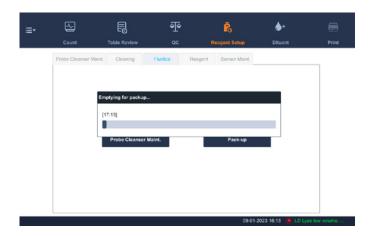
2. Touch PACK-UP, the dialog box, Start pack-up?, will display.



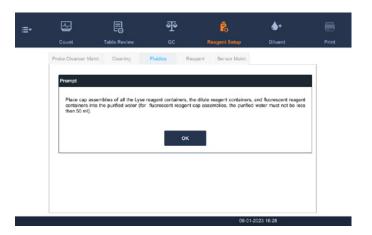
3. Touch YES to perform the pack-up procedure. The following dialog box will be displayed.



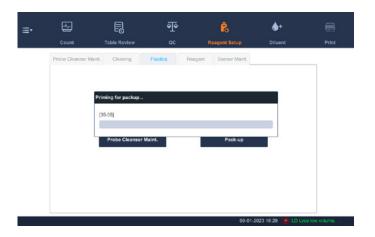
4. Take out the tubes as instructed and then touch **OK** to drain the fluidics.



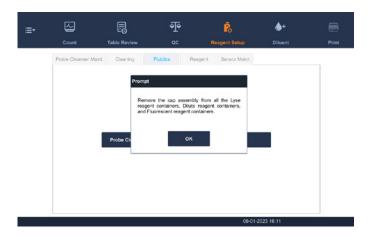
5. The following dialog box will be displayed after draining the fluidics.



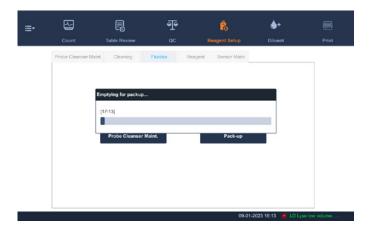
6. Put the tubes into distilled water as instructed, and touch **OK** to start priming.



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



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



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



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

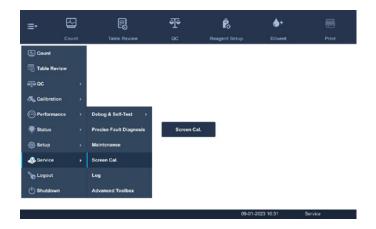
NOTE: This software can still be used after the pack-up.

10.4 Touch Screen Calibration

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

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

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

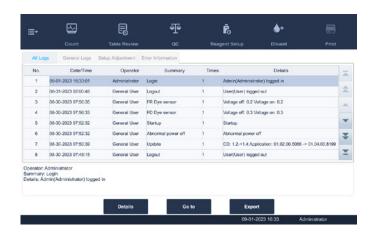


3. Touch the black + in the upper left corner of the screen as instructed by the screen display to start the calibration.

After the calibration is completed, the software displays, Calibration succeeded..

10.5 Viewing and Exploring Logs

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



2. Touch the type of logs to be viewed.

(Optional) Review the logs at specified date range.

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

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

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

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

The analyzer can save logs of the recent two years.

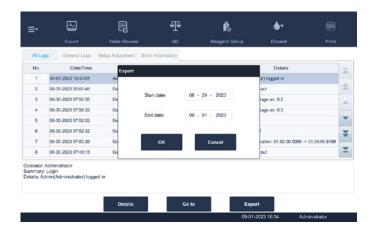
Logs may be browsed and printed but cannot be deleted.

Administrators and common users have different authorities.

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

Exporting logs (requires connection to computer):

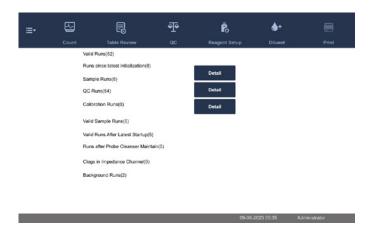
1. Touch **EXPORT** and the following dialog box will display.



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

10.6 Checking the Analyzer Status

Touch **STATUS** ► **STATISTICS**

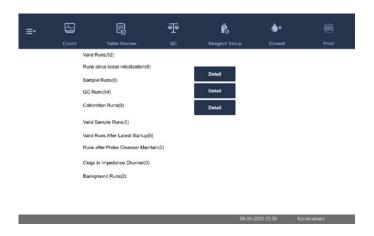


Analyzer information may be checked, including statistics, temperature and pressure, floater status, sensor status, voltage and current, as well as version information. Checking the status information on the Status screen is significant for locating and removing analyzer errors.

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

10.6.1 Statistics

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



Viewing Details

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

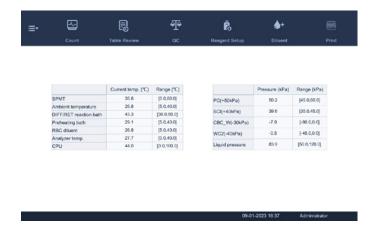
Print

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

10.6.2 Temperature and Pressure

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

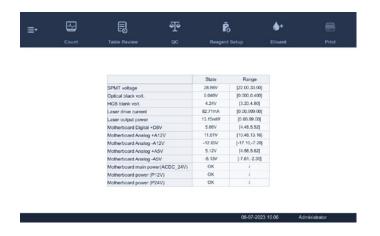
Check, export or print the temperature and pressure values of different components of the analyzer.



10.6.3 Voltage and Current

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

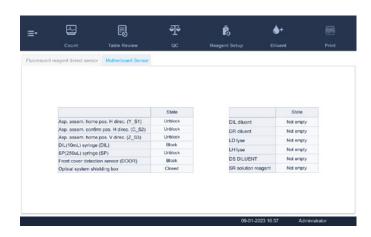
Check the voltage and current values of different components of the analyzer.



10.6.4 Sensor

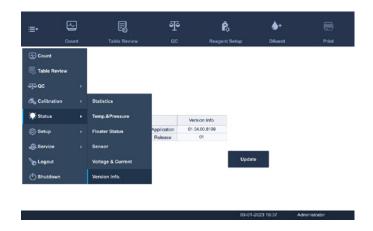
Touch **STATUS** ► **SENSOR** in the menu to enter the following screen.

Check the sensor status of the analyzer.



10.6.5 Version Information

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





11.1 Introduction

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

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

11.2 Error Information and Handling

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

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

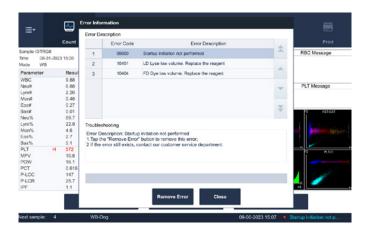
Red Fatal error. When this kind of error occurs, the analyzer will stop running immediately, and any further operation is prohibited.

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

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

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

The following figure is the error info. dialog box.



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

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

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

11.2.1 Remove Error

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

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

Error codes

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

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

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

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

| Error ID | Error Message | Description | Actions |
|----------|-------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| 0x00205 | SP syringe action abnormal | SP syringe aspiration/ dispensation action failure 1 | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x00206 | SP syringe action abnormal | SP syringe action abnormal | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x00207 | SP syringe action abnormal | SP syringe action abnormal | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x00208 | SP syringe action abnormal | SP syringe action abnormal | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x00209 | SP syringe action abnormal | SP syringe dispensed volume too high | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x00210 | SP syringe action abnormal | SP syringe action time out | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10308 | Auto pressure building out of time | Auto pressure building out of time | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x99800 | Startup initiation not performed | Startup initiation not performed | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x20012 | Drive board communication out of time | Drive board communication out of time | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10107 | SCI priming out of time | SCI priming out of time | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x99805 | Background abnormal | Background abnormal | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10306 | Fluidic system status abnormal | Sampling probe clogged | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10307 | Fluidic system status abnormal | Flow cell clogged | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x99801 | Exiting standby status failed | Exiting standby status failed | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x99802 | Exiting standby status failed | Exiting standby status failed | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x99803 | Auto startup failed | Auto startup failed | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10111 | SCI priming failed | SCI priming failed | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0×20008 | Closed-reagent RFID board communication timeout | Closed-reagent RFID board communication timeout | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x30109 | Optical signal board communication timeout | Optical signal board communication timeout | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x20011 | Power supply board communication timeout | Power supply board communication timeout | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10300 | 50 kPa pressure out of range | 50 kPa pressure out of range | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10304 | -40 kPa pressure out of range | -40 kPa pressure out of range | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10104 | Waste channel abnormal | Waste channel abnormal | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10301 | Pressure cell pressure release abnormal | Pressure cell pressure release abnormal | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |
| 0x10303 | SCI bath pressure release abnormal | SCI bath pressure release abnormal | Touch REMOVE ERROR to remove the error. If the error still exists, contact Heska's Technical Support Services. |

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

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

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



A. Specifications

A.1 Classification

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

A.2 Reagents

Diluents: DR diluent

DS diluent

Lyses: LD lyse

LH lyse

Dyes: FD dye

FR dye

Cleaners: Solution reagent

Probe cleanser

A.3 Applicable Tubes

The following tubes can be used:

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

A.4 Blood Sample Test Parameters

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

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

^{*}Auxiliary parameters

A.5 Body Fluid Sample Test Parameters

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

B. Sampling Features

B.1 Sample Volumes Required for Each Analysis

Whole blood mode: ≤ 34 µl Predilute mode: ≤ 20 u/L

B.2 Throughput

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

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

C. Performance Specifications

C.1 Reportable (Display) Range

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

^{*}Auxiliary parameters

C.2 Background/Blank Count for Blood Samples

| | | Background/Blank Count Requirements |
|-----------|---------------------------------|----------------------------------------|
| Parameter | US Units | SI Units |
| WBC | $\leq 0.10 \times 10^{3}/\mu L$ | $< 0.10 \times 10^9 / L$ |
| RBC | $\leq 0.02 \times 10^6 / \mu L$ | $< 0.02 \times 10^{12}/L$ |
| HGB | ≤ 1.0 g/dL | < 1.0 g/L |
| PLT | $\leq 5 \times 10^3 / \mu L$ | ≤ 5 × 10 ⁹ /L |

C.3 Background/Blank Count for Body Fluid Samples

| Parameter | Carryover US Units | Carryover SI Units |
|-----------|----------------------------------|-------------------------------|
| WBC-BF | $\leq 0.003 \times 10^3 / \mu L$ | $\leq 0.003 \times 10^9 / L$ |
| RBC-BF | $\leq 0.003 \times 10^6 / \mu L$ | $\leq 0.003 \times 10^{12}/L$ |

C.4 Linearity Range and Precision

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

C.5 Linearity Requirements for Body Fluid Samples

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

C.6 Repeatability Requirements for QC in Blood Samples

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

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

^{*}Auxiliary parameters

C.7 Repeatability Requirements for QC in Body Fluids

| Parameter | US Units | Range SI Units | Precision or Absolute Deviation (d) |
|-----------|-----------------------------------|------------------------------------|----------------------------------------|
| WBC-BF | $0.015-0.100 \times 10^3/\mu$ L | $0.015-0.100 \times 10^9/\mu$ L | ≤ 30% |
| RBC-BF | 0.003-0.050 × 10 ⁶ /μL | 0.003-0.050 × 10 ¹² /μL | ≤ 40% or ≤ 7000/µL (d) |

C.8 Deviation of Reading

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

C.9 Compatibility

Deviation ranges: WBC \leq \pm 5%, RBC \leq \pm 2%, HGB \leq \pm 2%, PLT \leq \pm 8%, HCT/MCV \leq \pm 3%.

C.10 Carryover

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

C.11 Carryover Requirements for Body Fluid Samples

| Parameter | Carryover US Units | Carryover SI Units |
|-----------|--------------------------------------------------------|--------------------------------------------------------|
| WBC-BF | $\leq 0.3\% \text{ or } \leq 0.03 \times 10^3 / \mu L$ | $\leq 0.3\% \text{ or } \leq 0.03 \times 10^9 / \mu L$ |
| RBC-BF | $\leq 0.3\% \text{ or } \leq 0.03 \times 10^6 / \mu L$ | $\leq 0.3\%$ or $\leq 0.03 \times 10^{12}/\mu$ L |

D. External Computer (optional)

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

RAM: 1 G or above.

Hard disk: 160 GB or above.

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

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

D.1 Keyboard (optional)

10-key alpha-numeric keyboard.

D.2 Mouse (optional)

E. External Barcode Scanner (optional)

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

F. Printer (optional)

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

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

G. Interfaces

- 4 USB ports
- 1 Ethernet port

H. Power Supply

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

I. FUSF



WARNING

Use specified fuse only.

Fuse specification: 250 V T3.15 AH

J. EMC Description

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

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

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

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

K. Sound

Maximal sound: 80 dBA

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

L. Operating Environment

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

Optimal operating humidity: 30%~85% Atmospheric pressure: 70 kP~106 kPa

M. Storage Environment

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

Relative humidity: 10~90%

Atmospheric pressure: 50 kPa ~106 kPa

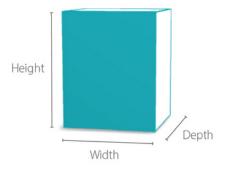
N. Running Environment

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

Relative humidity: 10%~90%

Atmospheric pressure: 70 kP~106 kPa

O. Dimensions and Weight



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

P. Contra-Indications

None

Q. Safety Classification

Level of transient overvoltage: Category II

Rated pollution degree: 2





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