H50V User Manual

Original instructions

Boule

Table of Content

1 Introduction 7
1.1 Warranty Limitations 7
1.2 Contact Details 8
1.3 Intended Purpose 9
1.4 Analyzer Overview 10
1.5 Consumables Overview 12
1.5.1 H50V Reagents 12
1.5.2 H50V Detergent 12
1.5.3 H50V Probe cleaner 13
1.5.4 Analyzer Control and Calibrator 13
1.5.5 FCC Declaration of Conformity 13
2 Safety Information 15
2.1 Emergency Procedures 15
2.2 Alerts used in this Manual 15
2.3 Signs on Equipment 16
2.4 Signs on Consumables 18
2.4.1 Hazard Information on Consumables 19
2.5 Safety Requirements 21
2.5.1 Special Requirements 21
2.5.2 General Requirements 21
2.5.3 Limitations 21
2.5.4 Infection Prevention 21
2.5.5 Electromagnetic Compatibility (EMC) Information 22
2.5.6 Laser 22
2.5.7 Installation 23
2.5.8 Operation 23
2.5.9 Maintenance 23
2.5.10 Consumables 24
3 System and Function 26
3.1 Specification 26
3.2 Performance 27
3.3 Analysis Parameters 28
3.4 System parts 29
3.5 User Interface 29
3.6 Test Interface 29
4 Installation 33
4.1 Overview 33
4.1.1 Installation Checklist 33
4.2 Unpacking and Inspection 34

4.3 Space Requirements 35
4.4 Power Supply Requirements 35
4.5 Environment Requirements 36
4.6 Waste Requirements 36
4.7 Tubing Installation 37
4.8 Changing Reagent 38
4.9 Printer Setup 39
4.10 Date and Time 40
4.11 Adding User 40
4.12 Changing Language 40
4.13 Transport and Storage Condition 41
5 Principles of Operation 42
5.1 Overview 42
5.2 Sample Aspiration 42
5.3 WBC Test Principle 43
5.3.1 Laser based Flow Cytometry 43
5.3.2 Interpreting Scatter diagrams 44
5.4 Test Principle of Hemoglobin Concentration 45
5.4.1 Colorimetry Principle 45
5.5 RBC /PLT Test Principle 46
5.5.1 Electrical Impedance Principle 46
5.5.2 Volumetric Metering 47
5.5.3 RBC Parameters 47
5.5.4 PLT Parameters 48
5.6 WOC, WIC functions and RRBC mode 49
5.7 Principles of Reticulocyte Analysis 49
5.7.1 RETIC_ABS 50
5.7.2 IRF 50
6 Daily Operation 51
6.1 Overview 51
6.2 Preparations 52
6.3 Startup 52
6.3.1 Background Test 53
6.4 Quality Control 54
6.5 Collection of Blood Samples 54
6.5.1 Whole blood collection 54
6.5.2 Pre-dilute sample preparation 54
6.5.3 Blood tube mixer 55
6.6 Data input 55
6.7 Running a Sample test 57
6.7.1 Sample mode 57

6.7.2 Animal settings 57
6.7.3 Limit 58
6.7.4 Counting and Analysis 59
6.8 Data Query 59
6.8.1 Data Query 60
6.8.2 Data Selection 60
6.8.3 Data Export 61
6.8.4 Data Deletion 61
6.9 Reticulocyte Analysis 62
6.9.1 Preparation of Reticulocyte samples 62
6.9.2 Reticulocyte background test 63
6.9.3 Reticulocyte test 63
6.10 CV Value and Trend graph 64
6.11 Shutdown and Logout 65
7 Quality Control 66
7.1 Overview 66
7.2 Quality Control Options 67
7.3 Levey-Jennings QC 68
7.3.1 L-J QC Setup 68
7.3.2 L-J QC Graph 71
7.3.3 L-J QC List 72
7.4 X-B QC 72
7.4.1 X-B QC Edit 72
7.4.2 X-B QC Run 73
7.4.3 X-B QC Review 73
7.5 X-R QC 74
7.5.1 X-R QC Setup 74
7.5.2 X-R QC Graph 75
7.5.3 X-R QC List 76
7.6 X QC 76
7.6.1 X QC Setup 76
7.6.2 X QC Graph 77
7.6.3 X QC List 77
8 Calibration 78
8.1 Overview 78
8.2 Calibration Frequency 79
8.3 Handling of Calibrator and Control 79
8.3.1 Summary and Principle 79
8.3.2 Indication of deterioration 79
8.3.3 Mixing and handling of Calibrator and Control 79
8.4 Preparation 80
8.5 Calibration Modes 81

Publ. Date: October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

8.5.1 Principles of the new Calibration coefficient 81
8.5.2 Validation of Calibration coefficient 81
8.5.3 Manual Calibration 81
8.5.4 Standard Calibration 83
8.5.5 Blood Calibration 84
9 Maintenance 86
9.1 Routine Maintenance 86
9.1.1 Maintenance Procedures 87
9.1.2 Maintenance Setup 89
9.2 Intermittent maintenance 90
9.2.1 Prime Reagent 91
9.2.2 Cauterize Aperture 91
9.2.3 Flush Aperture 91
9.2.4 Soak Impedance Transducer 92
9.2.5 Prepare Shipping 92
9.2.6 Other Maintenance Functions 93
9.3 Maintenance by Service technician 93
9.3.1 Components Maintenance 93
9.3.2 Components Replacement 93
9.4 Disposal Information 93
10 Advanced Setup 95
10.1 Parameter 95
10.2 Display 95
10.3 Transmit 95
10.4 Version 96
10.5 Service 96
10.6 System log 96
11 Troubleshooting 97
11.1 Troubleshooting Guidance 97
11.2 Troubleshooting 97
11.3 Obtaining Technical Assistance 100
11.4 Abnormal Results 101
12 Appendix 107
12.1 Appendix A: Components and Consumables 107

1 Introduction

This user manual contains instructions for the operation of the H50V Veterinary Hematology System. Read this manual before installing, operating, handling, or performing maintenance on the analyzer. Unauthorized personnel must not operate the analyzer. This manual is intended for those installing, operating, handling, or performing maintenance on the analyzer.

1.1 Warranty Limitations

- Service must be performed by Boule authorized service personnel.
- Use only Boule authorized reagents, cleaners, controls, and calibrators. If these products are substituted, it may void the warranty.
- Operators and laboratory supervisors are responsible that Boule products are operated and maintained according to the procedures described in manuals and control inserts.
- Each H50V Veterinary Hematology System is tested using recommended reagents, controls, calibrators, and cleaners. All performance claims are generated as part of this complete system.

H50V Veterinary Hematology System

Product Code	Product Name
1440101	H50V

Current Software Version

Software version V5.18.230523B001_196_024 or later.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

1.2 Contact Details

Head Office:

Boule Diagnostics AB
DOMNARVSGATAN 4
163 53 Spånga, Sweden

Representative Companies:

(Manufacturer**)**
Boule Medical AB
DOMNARVSGATAN 4
163 53 Spanga, Sweden

USA

Clinical Diagnostic Solutions Inc.
1800 NW 65th Avenue
Plantation, FL 33313, USA

Russia

Boule Medical LLC
142153, Moscow region
Podolsk, Novoselki village. Technopark area, h. 13, bld. 2, office 4, room 107, Russia

E-mail:

info@boule.com

Website:

boule.com

Distributor and Technical Support:

Contact Boule for information.
For distributor contact details, seeboule.com/boule-worldwide/.

1.3 Intended Purpose

Analyzer

H50V Veterinary Hematology System is intended for veterinary diagnostic use under laboratory conditions. The analyzer uses multi-angle laser scattering flow cytometry to differentiate between the 5 types of white blood cells (WBC). To analyze red blood cells (RBC) and platelets (PLT), the analyzer uses the Coulter principle. Hemoglobin (HGB) concentration is determined using colorimetry.

NOTE

- Read this manual carefully before operation, especially the safety information. Keep this manual in a safe place for later use.
- Follow the instructions in this manual when operating the analyzer. Not following the instructions could lead to erroneous analysis results, harm to the operator and/or damage to the analyzer. It will also void any warranty.
- Any changes to the procedures described in this manual, for example attempts to shorten the analysis time, are likely to have negative impact on the precision of the instrument.

Reagents

The H50V Veterinary Hematology Analyzer is interlocked with system specific Boule reagents; H50V Diluent, H50V Lyse, H50V Sheath, and H50V Reticulocyte stain.

Cleaners

Specified Boule cleaners are intended for the cleaning and maintenance of the H50V system; H50V Detergent and H50V Probe cleaner.

Calibrator

The Calibrator is used for the calibration of the H50V Veterinary Hematology System.

Control

The Control is used to monitor the performance of the H50V Veterinary Hematology System.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

1.4 Analyzer Overview

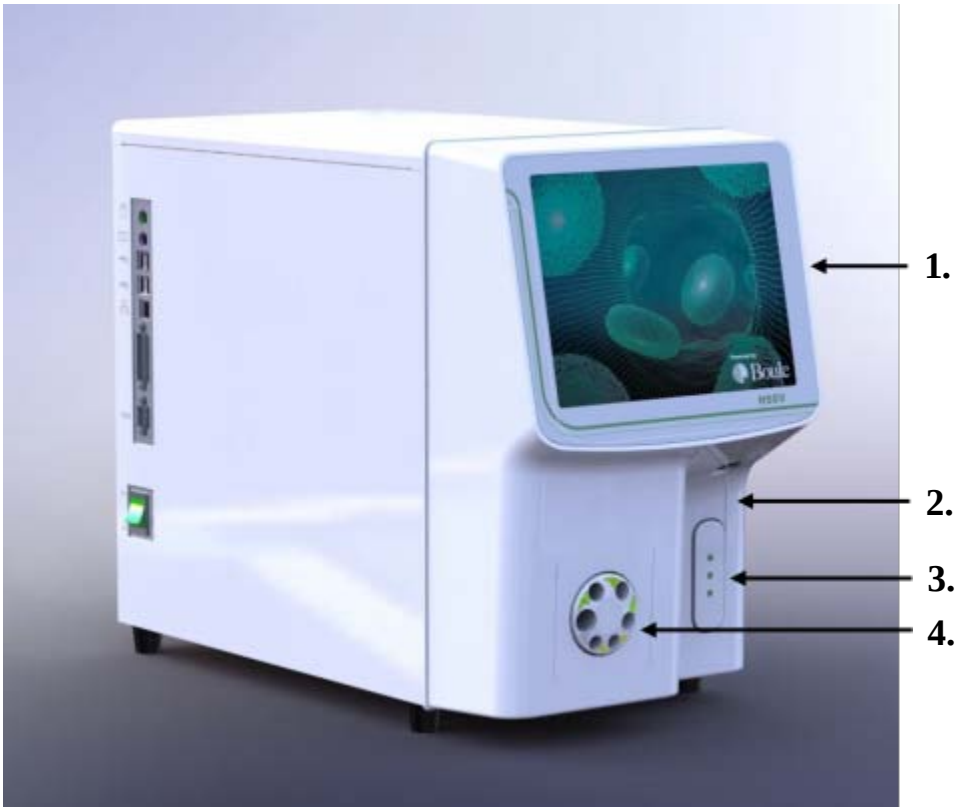


Figure 1-1: Analyzer Front View

	Part	Description/Function
1.	Display	TFT-LCD Touch screen, which displays patient and QC data and allows operator to enter the menu interface. Refer to *Section 6* for menu choices.
2.	Sample probe	Aspirates sample and dispenses diluent.
3.	Start plate	Press to begin sample aspiration.
4.	Sample mixer	Uniformly mixes samples before analysis.

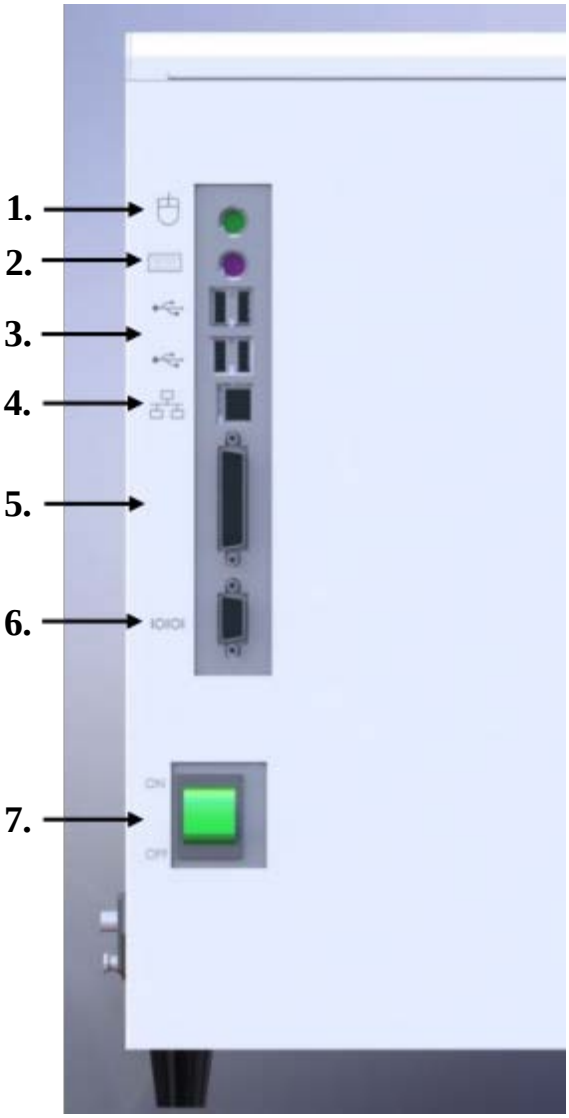


Figure 1-2: Analyzer cable and interface connections

	Part	Description/Function
1.	PS/2 port	Keyboard/mouse.*
2.	PS/2 port	Keyboard/mouse.*
3.	USB host ports	Connects analyzer to USB devices.
4.	LAN port	Connects analyzer directly to network.
5.	Parallel port	Standard IEEE- 1284.
6.	Serial port	RS-232, disabled by default.
7.	Power Switch	Switches power On or Off.

*Restart system after plugging in device.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

1.5 Consumables Overview

1.5.1 H50V Reagents

H50V Veterinary Hematology System reagents are configured specifically for the H50V system to provide optimal system performance. Non-compatible reagents may affect the analyzer performance, result in serious mistakes, or accidents. In this manual, any mention of a reagent refers to the Boule reagents intended for use with the H50V system.

H50V- Lyse, Diluent, Detergent, Sheath, and Probe Cleaner should be kept between 15℃ and 30℃ after opening. Once opened and connected to the instrument, the product shelf life is 60 days.

NOTE

- Always read the Safety Data Sheet (SDS) of the reagent before use.
- Reagents must be stored according to the recommendations to ensure optimal performance. Protected from direct sunlight, undercooling, and overheating during storage.
- The reagent inlet tubes have a cap attached that minimizes evaporation and contamination. Close the cap tightly.
- Ensure all reagents are used before expiration date.
- To ensure open container shelf life, do not keep bottles in dusty environment.

H50V Diluent

Diluent is a transparent isotonic fluid used for diluting the blood sample to enable blood cell counting and classification.

H50V Lyse

Lyse lyses RBC and forms a stable complex with the released hemoglobin (HGB), allowing the absolute count of WBC and the HGB concentration to be determined.

H50V Sheath

Sheath is used together with Lyse and Diluent for determining the WBC cell content, allowing the 5-part differential to be performed on animal blood.

H50V Reticulocyte stain

Reticulocyte stain is used to stain red blood cells, so they can be counted and classified based on their morphology and structure.

1.5.2 H50V Detergent

Detergent is an onboard cleaning function used to clean WBC cups, RBC cups, and liquid system. It also reduces the risk of clogs in the system.

1.5.3 H50V Probe cleaner

Probe cleaner is used as an external system cleaner, aspirated through sample probe.

CAUTION

Detergent and Probe cleaner are alkaline cleaning agents.
(1) Avoid contact of reagent with skin and eyes.
(2) If in contact with skin, rinse with water.
(3) If in contact with eyes, rinse with water and seek medical treatment immediately.
(4) If ingested, induce vomiting, and seek medical treatment immediately.

1.5.4 Analyzer Control and Calibrator

Control and Calibrator are intended for monitoring analyzer performance and for calibrating the analyzer, respectively.

1.5.5 FCC Declaration of Conformity

NOTE

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help.

  This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

  (1) This device may not cause harmful interference, and

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

(2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

RF Exposure Statement

The device has been evaluated to meet general RF exposure requirement. The device can be used in fixed exposure condition without restriction.

2 Safety Information

This section includes information about safety symbols and signs on equipment.

2.1 Emergency Procedures

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

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

2.2 Alerts used in this Manual

Symbol	Indicates
 **WARNING**	Indicates a hazardous situation that, if not avoided, could result in death or serious injury.
 **CAUTION**	Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury. Also used for activities interfering with proper function of the analyzer.
NOTE	Indicates information considered important but not hazard related.
 **WARNING**	Indicates potential biohazard.
 **WARNING**	Indicates a laser hazard which, if non-compliance with procedures or engineering controls, may result in laser damage to eyes.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

2.3 Signs on Equipment

Signs placed on the instrument define areas that need special attention or areas that contain danger. See Figure 2-1.

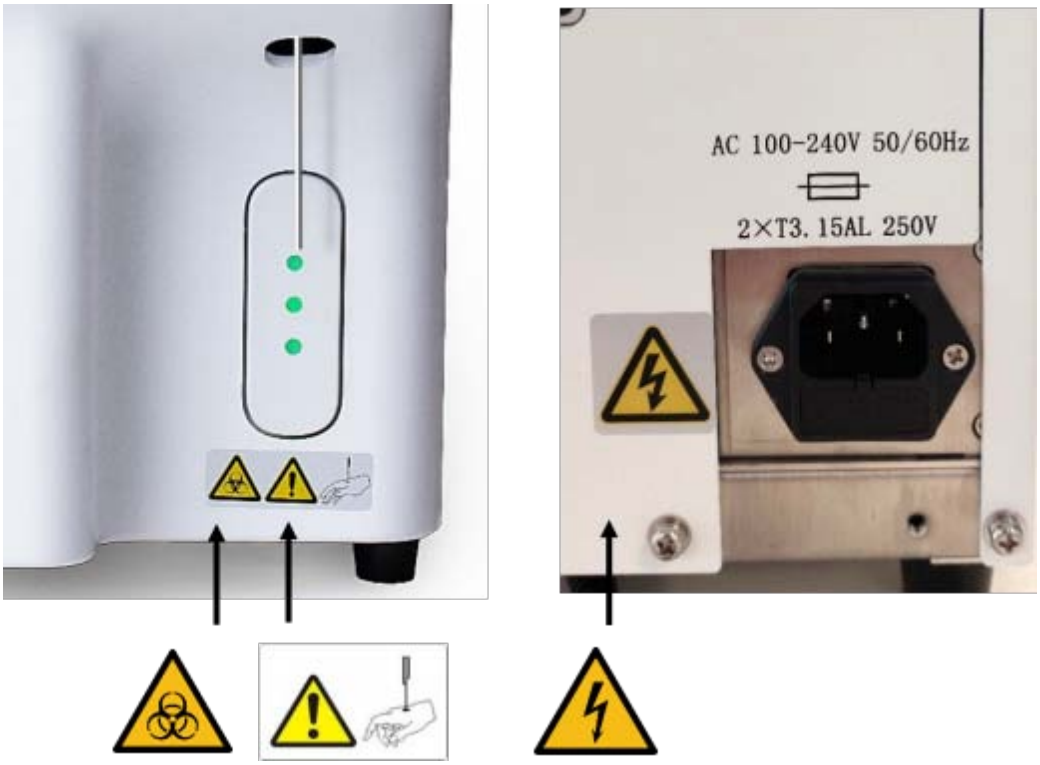


Figure 2-1 Signs present on Analyzer front and back

If any sign comes off, it needs to be replaced by a new one. To obtain new signs, contact your local Boule representative.

	Caution. Refer to the accompanying document		Caution. Electric shock
	Caution. Hot surface		Biohazard
	Laser Hazard		Caution, may cause personal injury
	Protective earthing		Power on

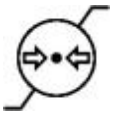
	Power off		Catalogue number
	Serial number		Manufacturer
	WEEE		Keep away from heat and radioactive source
	Consult instructions for use		This side up
	Keep dry		Do not roll
	Handle with care		Stacking limit by number
	CE mark of Conformity		Relative humidity limit
	Atmospheric pressure limit		Temperature limit
	Date of Manufacture		FCC mark of Conformity

Figure 2-2 Symbols Analyzer

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

2.4 Signs on Consumables

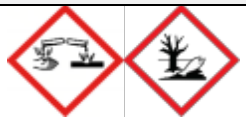
	Temperature limit		Consult instructions for use
	Manufacturer		Batch code
	Use by		Keep away from sunlight
	Catalogue number		This side up
	Single use		Stacking limit by number
	Radio-frequency identification		Keep dry
	Calibrator		Do not roll
	Control		Content
	Corrosive	 boule.com	Electronic instructions for use
	Environmental hazard		Caution
	Warning		

Figure 2-3 Symbols Consumables

2.4.1 Hazard Information on Consumables

Hazard Identification, H50V Diluent, H50V Sheath, H50V Detergent.	
Hazard pictogram	Not applicable.
Signal word	Not applicable.
Hazard code and statement	Not applicable.
Precautionary statements	Not applicable.
Supplemental information	Not applicable.

Hazard Identification, H50V Reticulocyte stain.	
Hazard pictogram	Not applicable.
Signal word	Not applicable.
Hazard code and statement	Not applicable.
Precautionary statements	Not applicable.
Supplemental information	**EUH210** Safety data sheet available on request.

Hazard Identification, H50V Lyse.	
Hazard pictogram	
Signal word	Danger
Hazard code and statement	**H315** Causes skin irritation. **H318** Causes serious eye damage. **H411** Toxic to aquatic life with long lasting effects.
Precautionary statements	**P273** Avoid release to the environment. **P280** Wear protective gloves, protective clothing and eye or face protection. **P305**+**P351**+**P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P310** Immediately call a POISON CENTER. **P391** Collect spillage. **P501** Dispose of contents and container to authorized waste disposal facility.
Supplemental information	Contains: DODECYLTRIMETHYLAMMONIUM CHLORIDE

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Hazard Identification, H50V Probe cleaner.	
Hazard pictogram	
Signal word	Danger
Hazard code and statement	**H314** Causes severe skin burns and eye damage. **H412** Harmful to aquatic life with long lasting effects.
Precautionary statements	**P264** Wash hands thoroughly after handling. **P273** Avoid release to the environment. **P280** Wear protective gloves, protective clothing and eye or face protection. **P303**+**P361**+**P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. **P305**+**P351**+**P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P310** Immediately call a POISON CENTER.
Supplemental information	Contains: SODIUM HYDROXIDE

2.5 Safety Requirements

This section includes the safety requirements for installing, handling, operating, and performing maintenance on the analyzer. Read this section carefully before use.

2.5.1 Special Requirements

- Do not use the analyzer for other purposes than described in this manual, or by Boule technical bulletin covering an application.
- Only use the consumables mentioned in this manual.

2.5.2 General Requirements

- For all procedures and activities, for example starting the analyzer, follow the instructions in the manual. Not doing so may cause erroneous analysis results, damage to the analyzer, or personal injury.
- Keep long hair, fingers, and clothes at a safe distance from rotating parts.
- Do not spill sample, reagents, or other liquids on the analyzer in such a way that it can leak through the analyzer casing.
- Do not drop or place objects on the analyzer.
- Do not touch the circuit.
- The analyzer must be connected to a receptacle with correct voltage, and grounding at the same time.
- Avoid damaging the power cord. Do not put any device upon the power cord. Do not pull the power cord.
- Turn off the power before connecting other devices (host computer, printer).
- Only use the AC adapter provided by Boule. Using other AC adapters may cause erroneous analysis results.
- Do not remove the casing of the H50V analyzer. High voltages inside the analyzer present a risk of electrical shock.
- Do not attempt to modify or rebuild the H50V analyzer. Doing so will void your warranty. Boule takes no responsibility for any personal or material damage resulting from such actions.

2.5.3 Limitations

- Boule products do NOT make diagnoses on patients. Boule products (systems, software, and hardware) are intended for professional use in medical practices, hospitals, and clinical laboratories to support medical diagnoses. This data, in conjunction with other diagnostic information and the evaluation of the patient's condition, can be used by a trained clinician to establish a patient's diagnosis and to define a clinical treatment.

2.5.4 Infection Prevention

- As there is no assurance of the absence of HIV, Hepatitis B or C viruses or other infectious agents in animal blood samples, controls, calibrators and waste, these

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials. This should include use of gloves, lab coat and eye protection.

- All the components and the surface of the analyzer are potentially infectious.
- The sharp sample probe contains residues of clinical specimens, controls, or calibrators. Consider the sample probe as infectious and avoid direct contact.
- Wear protective clothing and rubber gloves during operation, maintenance, service, or repair. Wash hands with disinfectant after work.
- Do not touch the waste and its components without proper protection.
- If you accidentally come into contact with infectious material, immediately wash with water and then sterilize the affected part according to laboratory disinfection procedures.

2.5.5 Electromagnetic Compatibility (EMC) Information

- Evaluate the electromagnetic environment prior to installation.
- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources),as these can interfere with proper operation and result in erroneous analysis results.

2.5.6 Laser

- The analyzer is equipped with a semiconductor laser of wavelength λ 529-535 nm. Class 3B laser product with 11 mW of maximum power output. Do not remove the protective cover of the laser. Only trained maintenance personnel should open the cover. Avoid direct eye exposure to the laser beam.



CAUTION. ELECTRIC SHOCK

- The analyzer has transport protection inserts which should be removed before installation.
- Transport protection must be removed, and analyzer closed before connecting the analyzer to the main power supply.

2.5.7 Installation

- The analyzer must be installed in a dry and dust-free place. Pollution degree 2 according to standard IEC 61010-1.
- Installation site must be well ventilated.
- Only use the analyzer indoors and connect it to a grounded mains supply providing correct voltage.
- Do not expose the analyzer to large temperature differences, or direct sunlight.
- Do not spill liquid on the analyzer.
- Avoid vibration. The analyzer should be put into a Styrofoam box to prevent damage during storage and transport. Improper package may lead to abnormal operation of the instrument.
- The analyzer does not produce ionizing radiation. Placing the analyzer near other equipment that generate strong ionizing radiation, such as X-ray, or γ-ray, may cause erroneous results.
- The equipment should not be installed in a place that stores chemicals or generates gas.
- The applied frequency and voltage should be consistent with that stated in the instruction for use. The analyzer should be equipped with precision power supply or Uninterruptible Power Supply (UPS) as specified.
- The analyzer is heavy. Use two-person lift, proper tools and follow relevant safety code when moving the analyzer.
- Improper use of reagents or incorrect operation may cause erroneous results.

2.5.8 Operation

- H50V Veterinary Hematology System must be operated by well-trained personnel exclusively. Unqualified operators may cause risks of personal injuries and property damage.
- Failing to operate in accordance with the instructions may damage the analyzer and result in erroneous results.
- Maintenance should be carried out by authorized technicians. Non-standard maintenance performed by unauthorized technicians will cause erroneous test results.
- Invalid hardware or software affects the accuracy of test results. The operator needs to contact a Boule local distributor or an authorized service technician as soon as possible.

2.5.9 Maintenance

- Maintenance is necessary for normal operation. Clean the analyzer regularly to avoid erroneous results and to minimize the risk of contamination.
- To prevent infection, electric shock and burn, the operator must wear rubber gloves in maintenance work. Wash hands with disinfectant after work.
- If the analyzer is not used for a long time, empty the liquid system according to

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

the procedure before disuse. Refer to *Section 9.2.5 Prepare Shipping*.

- Always replace with fuses ofthe same rating.

2.5.10 Consumables

- Check the labels on the packaging.
- Read the relevant Safety Data Sheets (SDSs) available at boule.com before handling reagents and cleaners.
- Reagents should only be used by technically qualified personnel.
- Avoid direct contact with reagents, it may irritate eyes, skin, and mucous membranes.
- If a reagent comes in contact with skin, immediately rinse with plenty of water.
- If a reagent comes in contact with the eye, immediately rinse with plenty of water and seek medical advice.
- Follow established emergency measures in the laboratory.
- Protect the reagents from contaminants.
- Reagents must be used before stated expiration date.
- Handle reagents properly to prevent bubbles forming. Do not shake. Do not use the reagent immediately after transport. Let reagents equilibrate to room temperature, according to stated temperature limits before use.
- Do not spill reagents. If it happens, wipe away with a cloth.
- If you accidentally swallow reagents, immediately seek medical attention.
- Diluent is a good conductor. Spilling Diluent next to an electrical cord or an electrical device may result in electric chock. If this happens, turn off the power switch, unplug the power cord, and clean up the Diluent.
- Probe cleaner is strongly alkaline. Do not let it contact the skin or clothes. If this happens, rinse the skin and clothes immediately with plenty of water.
- The Probe cleaner contains sodium hypochlorite and can corrode the analyzer surface. If the cleaner spills on the analyzer, immediately wipe away with a cloth.
- Place the reagents on the same level as the analyzer, or lower.
- Disposal of residual reagents, cleaning agents, and waste must comply with local laws and regulations.

3 System and Function

3.1 Specification

Physical	
Size (Analyzer)	HWL ≤ 410 x 270 x 510 mm
Weight (Analyzer)	≤ 26 kg
Communication interface ports	4 USB ports/1 LAN port that supports LIS/HIS communication through HL7 protocol
Operating Environment	
Temperature	15°C – 35°C
Relative humidity	≤85%
Barometric pressure	80kPa – 106kPa
Storage Environment	
Temperature	-20°C – 55°C
Relative humidity	≤95%
Barometric pressure	50kPa – 106kPa
Electrical	
Fuse specifications	250V/T3.15AL
Overvoltage category	Class II
Maximum sound pressure	65 dBA
Measuring Principles	
WBC, 5Diff	Laser
HGB	Colorimetry
RBC, PLT	Electrical impedance
MCV, HCT, RDW_CV, RDW_SD, MPV, PDW, MCH, MCHC and PCT	Obtained by calculation
Performance	
Aspirated sample volume (Whole blood)	20 µL
Aspirated sample volume (Pre-dilute)	20 µL
Number of samples per hour	Up to 60 / h
Analysis time	<1 min
QC capabilities	Mean, SD, CV%, Levey-Jennings, X-bar
System Information Indicators on parameter abnormalities	Yes

3.2 Performance

Precision

Parameter	Precision Range	CV%
WBC	3.5×10^9/L - 15.0×10^9/L	≤3.0%
RBC	3.00×10^{12}/L - 6.00×10^{12}/L	≤2.0%
HGB	100 g/L - 180 g/L	≤2.0%
PLT	100×10^9/L - 149×10^9/L	≤6.0%
	150×10^9/L - 500×10^9/L	≤5.0%
HCT	35% - 50%（HCT）	≤2.0%
MCV	70fL - 120fL（MCV）	≤1.0%

Carryover

Parameter	Carryover (%)
WBC	≤0.5%
RBC	≤0.5%
HGB	≤0.6%
PLT	≤1.0%

Displayed Range

Parameter	Displayed Range
WBC	0 – 999 × 10^9/L
RBC	0 – 99 × 10^{12}/L
HGB	0 – 35 g/dL
HCT	0 – 99%
PLT	0 – 5000 × 10^9/L

Linearity

Parameter	Linear Range	Correlation (r)
WBC	0 – 400 ×10^9/L	≥0.990
RBC	0 – 8 ×10^{12}/L	≥0.990
HGB	0 – 25 g/dL	≥0.990
PLT	0 – 5000 ×10^9/L	≥0.990

Background Count

Parameter	Acceptable Range
WBC	≤0.20×10^9/L
RBC	≤0.02×10^{12}/L
HGB	≤0.1g /dL
PLT	≤10.0×10^9/L

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

3.3 Analysis Parameters

The analyzer will automatically analyze and arrange sample data to show the RBC count, PLT count and the WBC five-part differential. H50V Hematology Analyzer generates up to 34 test parameters including two histograms and two scatter diagrams.

Abbreviation	Full Name	Unit
WBC	White Blood Cell Count	10^9/L
LYM%	Lymphocyte Percent	%
MON%	Monocyte Percent	%
NEU%	Neutrophil Percent	%
EOS%	Eosinophil Percent	%
BASO%	Basophil Percent	%
LYM#	Lymphocyte Count	10^9/L
MON#	Monocyte Count	10^9/L
NEU#	Neutrophil Granulocyte Count	10^9/L
EOS#	Eosinophil Granulocyte Count	10^9/L
BASO#	Basophil Granulocyte Count	10^9/L
RBC	Red Blood Cell Count	10^{12}/L
HGB	Hemoglobin	g/L
HCT	Hematocrit (relative volume of erythrocytes)	%
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular Hemoglobin	pg
MCHC	Mean Corpuscular Hemoglobin Concentration	g/dL
RDW_CV	Red Blood Cell Distribution Width repeat precision	%
RDW_SD	Red Blood Cell Distribution Width STDEV	fL
PLT	Platelet Count	10^9/L
MPV	Mean Platelet Volume	fL
PDW *	Platelet Distribution Width	fL
PCT *	Plateletcrit	%
P_LCR	Large Platelet Percent	%
P_LCC	Large Platelet Count	10^9/L
ALY% *	Abnormal Lymphocyte Percent	%
ALY# *	Abnormal Lymphocyte Count	10^9/L
LIC% *	Large Immature CellPercent	%
LIC# *	Large Immature CellCount	10^9/L
NRBC% *	Nucleated Red Blood CellPercent	%
NRBC# *	Nucleated Red Blood CellCount	10^9/L
RETIC-ABS *	Reticulocyte absolute value	10^{12}/L

Abbreviation	Full Name	Unit
RETIC *	Reticulocyte	%
IRF *	Immature Reticulocyte Fraction	%

* PCT, PDW, ALY%, ALY#, LIC%, LIC#, NRBC% and NRBC# are the inferred parameters. They and RETIC parameters are for research use. The number of reported parameters may vary according to the animal species. RETIC parameters measurement using Retic mode and Retic reagents may not be locally available. Contact your local supplier for more info.

3.4 System parts

The analyzer consists of analysis part, information management part, result output, and external printer (optional). The analysis part is mainly composed of laser parts, automatic sampler, A/D converter, central control panel, WBC measurement unit, flow system, and screen display.

CAUTION

- The analyzer is heavy. Use two-person lift, proper tools and follow relevant safety code when moving the analyzer.
- Unpack the analyzer and check that the appearance is intact. Ensure that there is no damage during transport.



WARNING

- Do not open the protective cover of the laser. Only trained maintenance personnel should open the cover. Avoid direct eye exposure to the laser beam.

3.5 User Interface

Turn on the power switch located on the left side, the analyzer program starts and enter the startup interface. Refer to *Section 6.3 Startup* for details on how to log in.

3.6 Test Interface

After initialization, the operator may choose to log in as a user or as an administrator. The administrator account is default and gives access to all enabled features. A basic

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

user can for example not delete data, use the export function, or calibrate the analyzer. After logging into the administrator account, the analyzer enters the **Test interface**. See Figure 3-1.



Figure 3-1 Test Interface

This interface can be divided by functions into the following areas:

1. Function button area	Displays function buttons.
2. Parameter information display area	Displays results of each parameter.
3. Information prompt area	Displays image of active animal profile and analyzer warnings.
4. Running mode and Analysis mode	Displays the running mode: Whole Blood or Pre-dilute. Displays the Analysis mode: CBC+5DIFF or CBC+5DIFF+RRBC.
5. Prompt area of abnormal results	Displays abnormal results.
6. Graphic display area	Displays the scatter diagrams (Size and Diff) and histogram.
7. System status area	Displays time, date, operator, next serial number, and printer status.

There are three sets of function buttons.

The first set:



Figure 3-2 Function Button 1

Test: enter **Test** interface to perform sample measurement.
Data: enter **Data** interface and search sample results.
QC: enter the **QC** interface to perform quality control.
Cal: enter the **Cal** interface to perform calibration.
Setup: enter the **Setup** interface to set system parameters.

The second set:



Figure 3-3 Function Button 2

Next sample: add and edit new sample information.
Mode switch: switch the test mode between Background, Whole Blood or Pre-dilute sampling mode. Switch the analysis mode between CBC+5DIFF or CBC+5DIFF+RRBC.
Animal: switch profile settings.
Soak: perform soak cleaning.
Dispense: dispense sheath fluid from sample probe.
Prime: enable new liquid in the liquid system.

The third set:



Figure 3-4 Function Button 3

Pre. record: view the previously recorded sample. The button is gray if the current sample is the first one.
Next record: view the next record. The button is gray if the current sample is the last one.
Audit/Cancel Audit: toggles between Audit and Cancel Audit. Only available with administrator account. Can be used to mark results as approved.
Edit result: Only available with administrator account. Used to modify individual parameter results if adjustment needed after verification by other method. Tap **Recover** to restore original results.
Print: print sample results.
Transmit: transmit sample data.

4 Installation

4.1 Overview

CAUTION

- Environment Requirements
  Temperature: 15℃ – 35℃
  Relative humidity: ≤ 85%
- Place the analyzer on a smooth and stable surface.
- Do not expose the analyzer to large temperature differences, or direct sunlight.
- Use a separate AC receptacle and install a stabilized voltage supply or a UPS (Uninterruptible Power Supply).

CAUTION

- Installation of the analyzer by unauthorized personnel could result in personal injury, and is not covered by the warranty. Never attempt to install or operate the analyzer without an authorized representative.

The analyzer has been thoroughly tested before delivery. It should be carefully packed before transport to avoid damage. Check the package thoroughly to reveal any physical damage at arrival. If damaged, immediately contact the local distributor.

4.1.1 Installation Checklist

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

- ☐ Unpack and check components.
- ☐ Verify analyzer placement and environment instructions.
- ☐ Remove all transport protection. See included instructions.
- ☐ Connect all accessories.
- ☐ Connect all reagents.
- ☐ Connect waste tubing.
- ☐ Connect power cord and start the analyzer.
- ☐ After initialization, prime the system to ensure the liquid system is filled.
- ☐ Verify the background count.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

- ☐ Perform quality control and calibrate if needed. Refer to *Section 8, Calibration.*
- ☐ After initial setup, it is recommended to make a backup of the analyzer database and keep for personal records.

4.2 Unpacking and Inspection

Take out analyzer and accessories from the shipping carton. Keep the packing material for future transport or storage. Check the following:

- Leakage or soakage
- Mechanical damage and bare leads
- Included instructions and inserts
- Quantity of accessories

Contact the local distributor if any problem occurs.

The following items are included *:

Part	Quantity
H50V 5-Part-Diff Auto Hematology Analyzer	1
H50V User Manual	1
H50V User Manual translation	1
H50V Quick Reference Guide	1
Installation checklist	1
Transport protection removal instruction	1
Quality certificate	1
Power Cord	1
Ground Wire	1
Waste Sensor Cable	1
Reagent bottle tray	1
Lyse inlet tubing (500 mL)	1
Lyse inlet tubing (200 mL)	1
Diluent inlet tubing	1
Sheath inlet tubing	1
Detergent inlet tubing	1
Waste outlet tubing	1
Waste container	1
Reagent cap wrench	1
Reagent Barrel Cover support	3
Plastic Test Tube – Predilution	200
Plastic Test tube – Probe cleaner	1
Keyboard	1

A set of touch pen	1
Network Cable	1
Filter	2
O-ring 22X3.5	2
O-ring 18X5	1
Fuse	2

*Local variations may apply. Note that some documents such as SDS, translated SDS and User Manual translations may only be available digitally.

4.3 Space Requirements

Make sure that there is enough space for operation, maintenance, and replacement of reagents.

- Place the analyzer on a clean, stable, and non-vibrating horizontal surface.
- Indoor Use near a grounded mains supply.
- Leave 20 cm of free space behind the analyzer for ventilation.
- Leave 50 cm of free space above analyzer and allow 50 cm on either side of analyzer to be cleared for service access.
- Leave enough space for Reagent bottle tray on the right side of the analyzer. The reagent bottle tray is used only with 1.9 L reagent containers.
- Ensure that there is sufficient space beneath the analyzer for placing reagent and waste containers.

4.4 Power Supply Requirements

Make sure that the H50V system is placed at the desired location before connecting power.

Optimal Voltage	Voltage Range	Frequency
AC 220V	100V – 240V~	50 – 60 Hz

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

WARNING

- Use a ground connection to ensure the accuracy of the analyzer and the safety of the operator.
- A fluctuating voltage could impair the performance and reliability of the analyzer. Proper precautions, such as installation of a voltage stabilizer (not provided by the manufacturer), should be taken before operation.
- Frequent power failure may damage or seriously decrease performance and reliability of the analyzer. Proper precautions, such as use of an Uninterruptible Power Supply (UPS, not provided by the manufacturer), should be taken before operation.

4.5 Environment Requirements

- Ambient Temperature: 15℃ – 35℃ (Optimal temperature is 25℃).
- Professional laboratory use, indoor use only.
- Avoid using the analyzer at extremely high or low temperatures.
- Keep the analyzer away from direct sunlight.
- Choose a well-ventilated place.
- Pollution degree 2 according to standard IEC 61010-1.
- Evaluate the electromagnetic environment prior to installation. Do not place the analyzer in an environment containing high energy sources.
- Electromagnetic compatibility design for class B.
- Keep the analyzer away from communication equipment which may interfere by producing high frequency electric waves.

CAUTION

- Do not use this device near sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation and result in erroneous results.

4.6 Waste Requirements

Always follow the local guidelines for open drain.

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

WARNING

- Follow the established biohazard protection barrier of your lab. This should include gloves, lab coat and eye protection.
- To prevent environmental pollution, follow local guidelines for waste disposal and open drain.

4.7 Tubing Installation

There are five liquid interfaces on the back panel: DETERGENT, DILUENT, LYSE, SHEATH and WASTE. See Figure 4-1. Each of them is wrapped with a cap to avoid contamination before delivery. Uncover and set the caps aside for further use, if needed.



Figure 4-1 Reagent and Waste Interface, back panel

NOTE

- After installation, all tubes should be in a relaxed state and without distortion.
- Using tools for tubing installation is prohibited. Only install by hand.
- The reagent bottle cannot be used if damaged, leaking, expired, or if other anomalies exist. Contact your local distributor.
- Place the reagents on the same level as the analyzer or lower. The reagent bottle tray intended for 1.9 L reagent containers should be placed next to the analyzer.
- Place the end of the waste tube at least 50 cm lower than the analyzer.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Reagent Tubing Installation

1. Connect the Lyse inlet tube to the yellow LYSE interface on the back panel.
2. Connect the Diluent inlet tube to the red DILUENT interface on the back panel.
3. Insert the Detergent inlet tube to the blue DETERGENT interface on the back panel.
4. Connect the Sheath inlet tube to the green SHEATH interface on the back panel.
5. Connect each reagent tube assembly into the corresponding reagent container and fasten the cap properly.

Waste Tubing Installation

1. Connect the Waste outlet tube with black faucet to the black WASTE interface on the back panel.
2. Insert the BNC connector to the SENSOR outlet on the back panel.
3. Properly fasten the waste tubing in your depressurized waste container. Make sure the waste tubing length is maximum 200 cm and the end of the waste tube is placed at least 50 cm lower than the analyzer.

4.8 Changing Reagent

NOTE

- The reagent container lids may be difficult to open. Use the wrench key provided with the analyzer.

1. Insert the reagent inlet tubing into the reagent container. Ensure that the color coding of inlet and reagent corresponds correctly.
2. Tighten the cap. Use cap intended for the size of reagent container used.
3. Select **Setup** to enter **Setup** interface, see Figure 4-2.

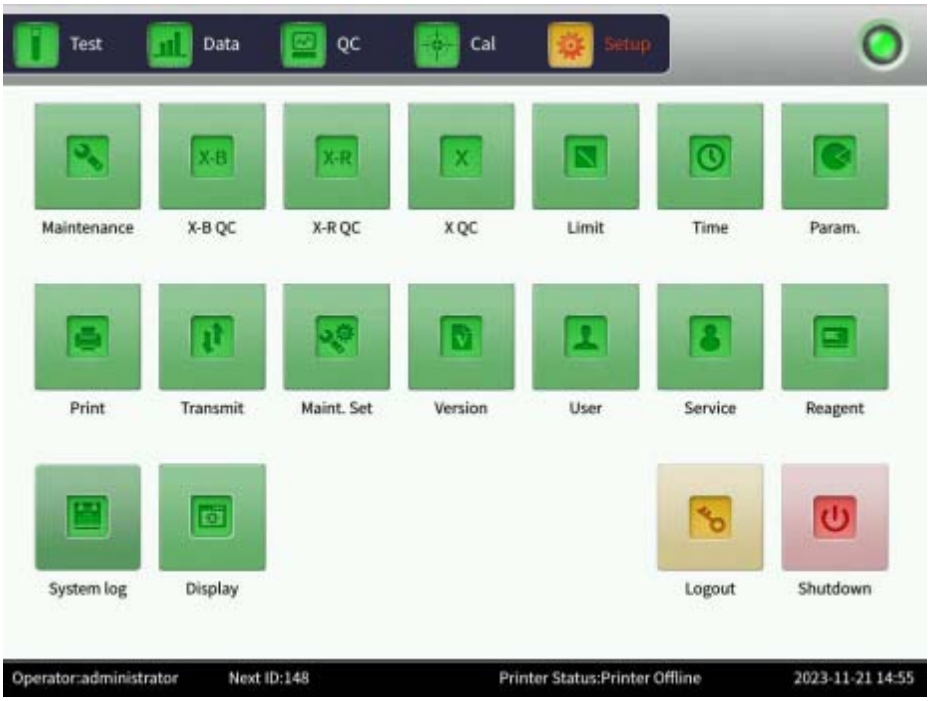


Figure 4-2 Setup Interface

4. In the **Setup** interface**,** select **Reagent**. A popup dialogue appears.
   Activation date, total amount, lot, valid period, and remaining amount are shown for the respective reagents.
5. To change reagent, select **Replace** for the corresponding reagent type. A popup dialogue appears.
6. Select **Activate** to activate the new reagent. A 15 second countdown starts.
7. Scan the RFID card corresponding to the reagent with the RFID reader. A tick sound will indicate a successful card reading.
8. Enter LOT number and verify the expiry date for the open container.
9. A successful activation is displayed in a dialogue box.
10. Perform a background test. Ensure that results are within the recommended range.

CAUTION

- To ensure precision and obtain reliable test results, perform quality control after a reagent has been replaced.

4.9 Printer Setup

To set up a new printer:

1. In the **Setup** interface, select **Service**.
2. Enter password = printer.
3. Connect the printer and search for the correct driver for the connected printer.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

When a printer has been connected:

1. In the **Setup** interface, select **Print**.
2. Choose **Printer type**: USB printer (A5), USB printer (A4), Recorder, or External Recorder.
3. Choose **Print format**: print with histogram or print without histogram.
4. Set **Auto print** to On or Off. If turned on, test result will automatically be printed after counting. If turned off, printing is done manually.
5. Choose **Color**: Color or Grayscale.
6. **Top Margin**: enter a number if you want to have a top margin.
7. Choose **Suffix**: PDF or PNG.
8. Set **Remark** to On or Off.
9. Select **OK** to save the settings.

4.10 Date and Time

1. Enter the **Setup** interface and select **Time**.

   There are three different formats to choose between: YYYY-MM-DD, MM-DD-YYYY and DD-MM-YYYY. Y indicates Year, M indicates Month and D indicates Day.
2. Select **OK** to save the settings.

4.11 Adding User

An administrator can perform modifications in user accounts. Modifications include adding or deleting user accounts and administrating passwords.

To add a new User, do the following:

1. In the **Setup** interface, select **User**.
2. Select **Add** to enter a new user into the system.
3. Enter **Username**, **Name**, **Password**, and **Confirm password**.
4. Select **User Group**: **Basic user** or **Administrator**.

The basic user and the administrator are given different permissions. The administrator has full access to all enabled functions. The basic user cannot for example delete data or edit results.

5. Select **OK** to save settings.

4.12 Changing Language

It is possible to change the language settings.

1. In the **Setup** interface, select **Service**.

2. Enter password **lan**.
3. Select the desired language from the drop-down menu.
4. Select **OK** to save settings.
5. Restart analyzer to activate the new language.

For requests to have the software interface in an additional language, contact your sales representative.

4.13 Transport and Storage Condition

It is important that the H50V system is emptied and cleaned to avoid reagent crystallization in the fluid system tubing. If this is not done it may lead to complicated and expensive repairs.

Perform the **Prepare Shipping** operation when:

- the analyzer will be transported.
- the analyzer will not be used for one week or longer.

The following steps gives an overview of the procedure. For detailed instructions, refer to *Section 9.2.5 Prepare Shipping*.

1. From the **Setup** interface, enter the **Maintenance** interface and select **Prepare Shipping**.
2. Remove all reagent inlet tubes from the reagent containers and allow the liquid system to be emptied.
3. Place all reagent inlet tubes into a bottle of distilled water.
4. Repeat step 1 to allow the liquid system to be filled with distilled water.
5. Repeat step 1 and remove reagent inlet tubes from the water bottle.
6. The analyzer empties the liquid system.
7. Turn off the analyzer.
8. Remove reagent tubing from the back of the analyzer and keep them intact and well stored.
9. The analyzer is now ready for transport or storage.

NOTE

- Storage temperature: -20℃ – 55℃
- Relative Humidity: ≤ 95%
- Atmospheric pressure: 50kPa – 106kPa
- Before shipping, perform external disinfection

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

5 Principles of Operation

5.1 Overview

Measurement methods used in the 5-Part H50V analyzer are:

- Electrical impedance method to detect the amount and the volume distribution of RBC and PLT. Also used for total WBC.
- Transmission spectrophotometry for determining HGB.
- Laser-based flow cytometry for total white blood cell (WBC) count, and the five-part differential count of WBC.

During each analysis cycle the sample is aspirated, diluted, and mixed before each parameter is detected.

The analyzer will flag individual parameters that are outside of specific reference ranges, as well as provide sample pathology indicators for specific conditions where manual review by blood smear is recommended.

5.2 Sample Aspiration

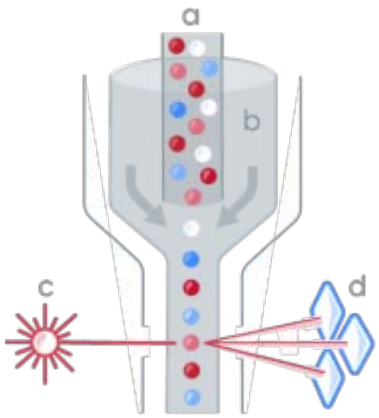
The 5-Part H50V analyzer supports Whole blood sampling mode and Pre-diluted sampling mode.

Sampling Mode	Aspiration volume
Whole Blood	20μL
Pre-dilute	20μL

The whole blood sample is aspirated into the analyzer by a precision stepper motor and distributed into different measuring channels.

5.3 WBC Test Principle

5.3.1 Laser based Flow Cytometry



a. Blood suspension (sample)
b. Sheath flow
c. Laser
d. Light scatter detectors

Figure 5-1 Laser Flow Cytometry Principle

The H50V use a laser-based flow cytometry method for total white blood cell (WBC) count, and differential count of the subpopulations— neutrophils (NEU), lymphocytes (LYM), monocytes (MONO), eosinophils (EOS), and basophils (BASO).

For detection, a laser beam is passed through the sample. See Figure 5- 1. When cells pass through the detection zone, the light is scattered and measured by a photoconductor that converts the light into an electrical impulse. The number of generated impulses correlates with the number of cells, whereas the light scatter is used to determine cell granularity and shape.

The measurements are based on cell size and complexity (granularity) and detected using three angles: Small Angle (SA), High Angle (HA) and Super Wide Angle (SWA). See Figure 5-2.

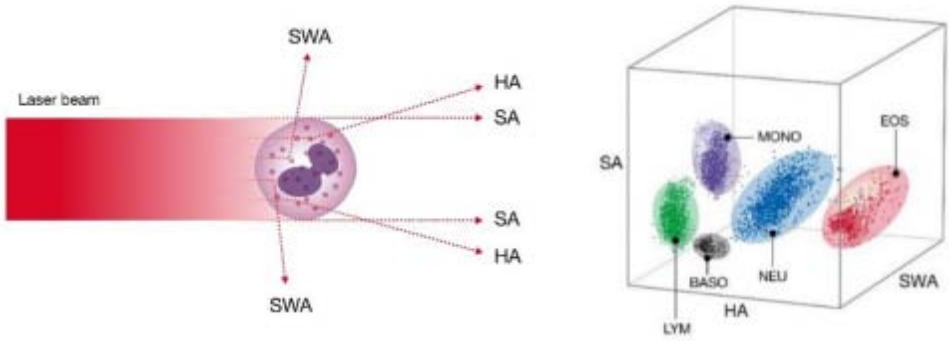


Figure 5-2 Detection Angles

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

SA detects cell volume, HA cellular complexity, and SWA takes the cellular granularity into account. The analyzer displays the results in two scatter diagrams referred to as “Size” and “Diff”. For example, see Figure 3-1.

The Scatter diagram “Size” show scattered light detected by SA (cell volume) on the Y-axis, and HA (cellular complexity) on the X-axis. See Figure 5-3. The Scatter diagram “Diff” show a projection of scattered light detected from all three angles by comparing signals from SWA and HA on the Y-axis, to the signals from SA and HA on the X-axis. See Figure 5-4.

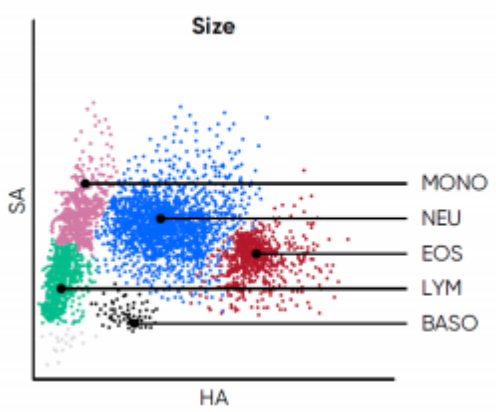


Figure 5-3 Size Scatter diagram

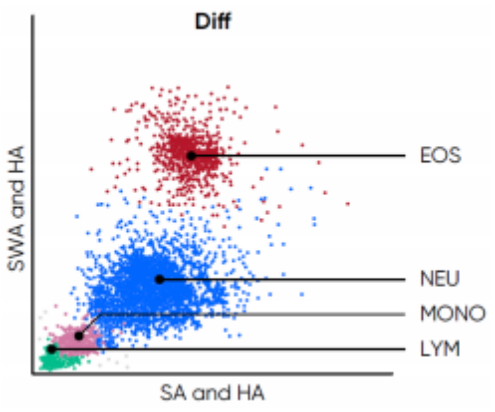


Figure 5-4 Diff Scatter diagram

5.3.2 Interpreting Scatter diagrams

The scatter diagrams provide a snapshot of cellular morphology that complement the numerical results. They can be a valuable tool for a quick interpretation of sample quality, sample results, and the health status of the patient.

Each event in the scatter diagrams represents a particle that has passed through the laser beam. The events come together to form clusters in the scatter diagrams, where each cluster represents a population of cells. The density of the clusters indicates the number of cells in each population. See Figure 5-2 and Figure 5-3.

The analyzer classifies five White Blood Cell (WBC) subpopulations:

Neutrophils (NEU) — are the primary defense against infection and generally the largest of the white blood cell populations. They are found to the right of the monocytes in the scatter diagrams. Depicted in **Blue**.

Lymphocytes (LYM) — make up a relatively large portion of the white blood cells. They are an essential part of the immune system producing antibodies and cytokines. LYM can vary in size but are generally found far down on the y-axis. Depicted in **Green**.

Monocytes (MONO) — are phagocytes involved in the inflammatory response. They are typically larger and more complex than LYM and found above and to the right of these. Depicted in **Pink**.

Eosinophils (EOS) — are associated with allergic disease and parasitic infection and they are often placed high or to the right in the scatter diagrams. However, the granularity of EOS can differ significantly between different species which affects the scatter of light, and their position can vary. Depicted in **Red**.

Basophils (BASO) — are the smallest of the major white blood cell populations that are classified by the analyzer. They are typically found to the right of the monocytes and below the neutrophils. Depicted in **Black**.

Gray events represent ghost cells that appear when the RBCs dissolve into pieces on the scatter diagram.

Increased or decreased density of a cluster can indicate an abnormality that may require further investigation. Distinct clusters mean the analyzer can classify the cells correctly. A slight overlap is normal but if the clusters significantly overlap there is a risk for misclassification. In such cases, it is recommended to take a new sample or confirm results with a manual blood smear count.

5.4 Test Principle of Hemoglobin Concentration

5.4.1 Colorimetry Principle

To determine HGB concentration, the RBCs are lysed so that HGB is released and can be measured using transmission spectrophotometry. Light emitted by a LED lamp is allowed to pass the flow chamber and transmitted light is detected by an optical sensor mounted on the opposite side. Hemoglobin concentration is proportional to the absorbance at 540 nm wavelength.

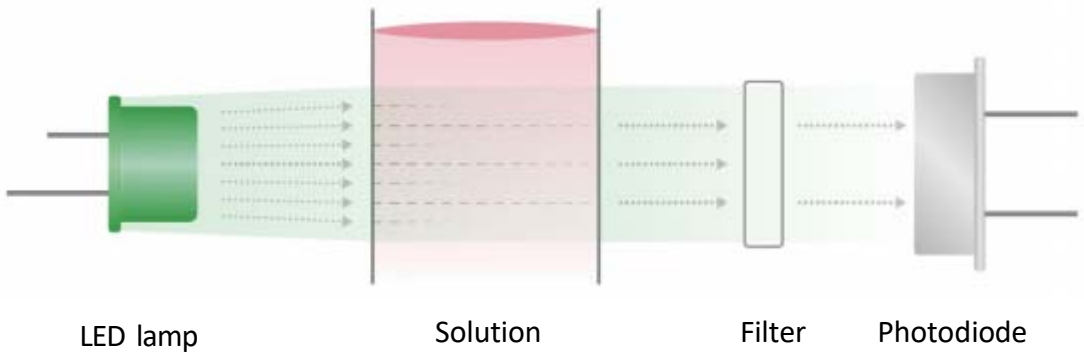


Figure 5-5 HGB detection

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

5.5 RBC /PLT Test Principle

5.5.1 Electrical Impedance Principle

The H50V analyzer uses an impedance method for obtaining red blood cell (RBC) and platelet (PLT) counts. With impedance, each cell that passes through the aperture causes a drop in the electrical current, a pulse. The number of generated pulses correlates with the number of cells that passes the aperture, whereas the amplitude of the pulse is related to the size of the cell. See Figure 5-6.

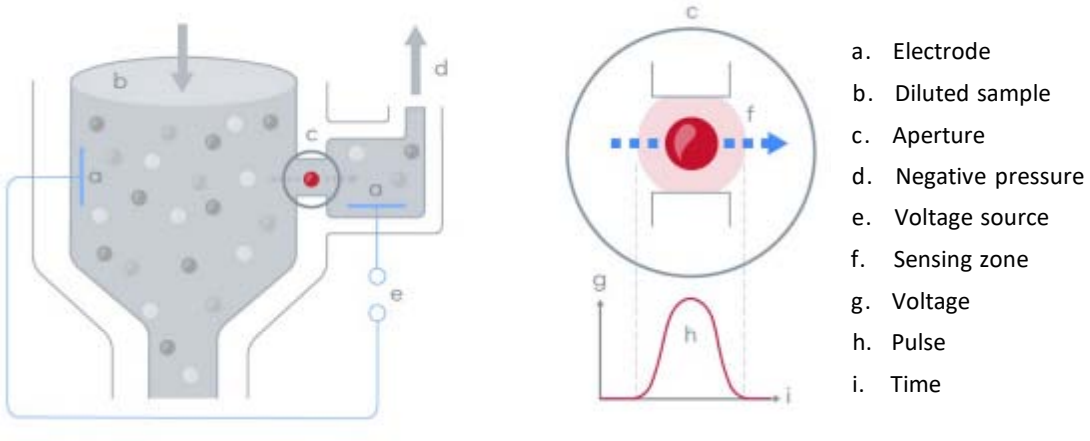


Figure 5-6 Electrical Impedance Method

RBC and PLT counts are displayed in histograms. The x-axis shows cell size and the y-axis number of counted cells. See Figure 5-7. Histograms can be used to interpret measurement results and assess sample quality.

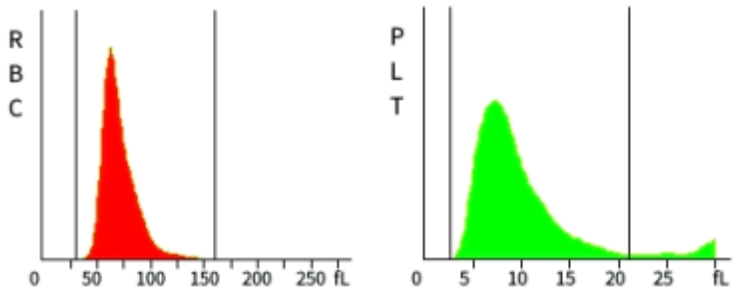


Figure 5-7 RBC and PLT Histograms

5.5.2 Volumetric Metering

The volumetric metering unit controls the sample size that pass the aperture during counting to obtain the exact counts in quantitative samples. The volumetric metering unit includes the metering tube and two photoelectric sensors. See Figure 5-8.

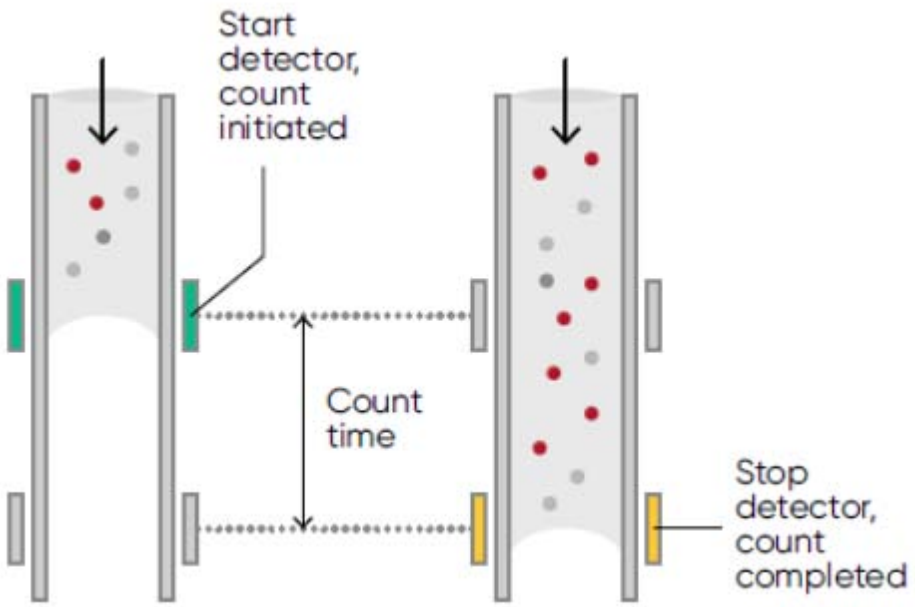


Figure 5-8 Volumetric Metering

The metering tube is emptied before testing. The analyzer starts counting when the liquid level passes the start detector, and an electrical signal is generated. The counting stops when the liquid level reach the stop detector. The analyzer will indicate if bubbles or other abnormalities appear in the flow system, by display of the "Bubble" or "Clog" alarm. Refer to *Section 10 Troubleshooting*.

5.5.3 RBC Parameters

- RBC Count

The analyzer obtains the number of red blood cell (RBC) by directly measuring the corresponding number of electrical pulses. The unit is 10^{12}/L.

- MCV

The mean corpuscular volume (MCV) is the average volume of individual red blood cells. The MCV is derived from the RBC size distribution data. The unit is fL.

- HCT

The hematocrit (HCT) is the ratio of red blood cells to plasma. It is expressed as a

percentage of the whole blood volume. The HCT is calculated from the RBC count and the MCV as follows.

$$HCT = \frac{RBC \times MVC}{10}$$

- MCH

The mean corpuscular hemoglobin (MCH) is the average amount of hemoglobin in the red blood cell and being expressed in pg. The MCH is calculated from the RBC and the HGB as follows.

$$MCH = \frac{HGB}{RBC}$$

- MCHC

The mean corpuscular hemoglobin concentration (MCHC) is the ratio of the weight of hemoglobin to the volume of the average red blood cell. It is expressed in g/dL and calculated from the HGB and the HCT as follows.

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

- RBC Distribution Width

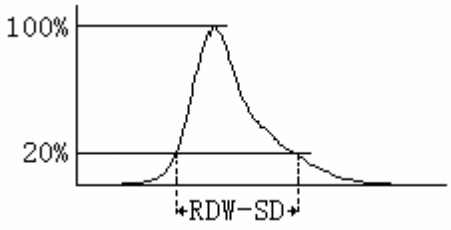
The RBC Distribution Width (RDW), which is obtained from the RBC histogram, is the geometric standard deviation of RBC volume distribution (10 GSD).

- RDW-CV

The RDW-CV is derived from the RBC histogram and being expressed in percent.

- RDW-SD

The RDW-SD is the width of the RBC distribution histogram excluding 20% of the peak value. The unit is fL.



5.5.4 PLT Parameters

- PLT Count

The analyzer obtains the number of platelet (PLT) by measuring the corresponding electrical pulses of RBC directly. The unit is 10^9/L.

- MPV

The mean platelet volume (MPV) is derived from the PLT histogram after the PLT count has been determined. The unit is fL.

- PDW

The platelet distribution width (PDW) is a measure of the heterogeneity of the PLT population. It is expressed as the PLT volume distribution. (10 GSD).

- PCT

The PCT is calculated as follows. The unit of PLT is 10^9/L. The unit of MPV is fL.

$$PCT = PLT \times \frac{MPV}{10000}$$

5.6 WOC, WIC functions and RRBC mode

The H50V analyzer determines the total white blood cell count using both impedance (WIC) and laser-based flow cytometry (WOC). By default, the WOC optical channel is used in all animal profiles, which means that the two scatter diagrams “Size” and “Diff” are shown on the display. See *Section 3.6 Test Interface*.

For each measurement the analyzer compares between WIC and WOC counts. If a significant difference is detected, the analyzer will flag it as a possible presence oflyse-resistant red blood cells (RBCs). If this happens the sample should be re-analyzed in RRBC mode, which involves a longer mixing time with Sheath reagent. See *Section 6.7.1*.

5.7 Principles of Reticulocyte Analysis

Reticulocytes are immature RBCs that exist in transition between nucleated RBCs and mature RBCs. In contrast to mature RBCs, reticulocytes contain ribosomal RNA. The RNA in the immature RBCs can be detected by laser after treatment with a dedicated staining solution.

Illuminated with the polarized light, the stained precipitate will strengthen the scattered light on a wide-angle direction. Reticulocytes are visualized in two scatter plots by detecting signals in super wide angle compared to small and high angle.

In Figure 5-9, **Red** events represent red blood cells (RBC), **Black** events represent white blood cells (WBC) and **Green** events represent reticulocytes (RET). When reticulocytes are present, they appear as a cluster above the mature RBCs.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

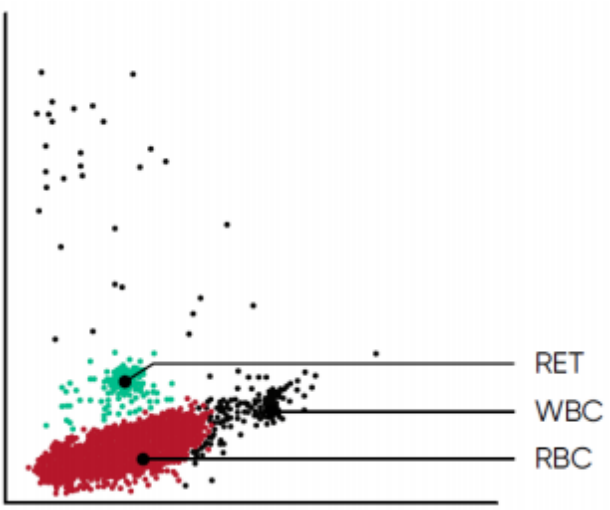


Figure 5-9 RETIC scatter plot

5.7.1 RETIC_ABS

RETIC_ABS is the concentration of RETIC. It corresponds to the ratio of the RETIC to the RBC multiplied by the RBC concentration.

$$\mathrm{RETIC_ABS} = \mathrm{RET} \times \mathrm{RBC}$$

5.7.2 IRF

IRF (Immature Reticulocyte Fraction) contain more RNA than mature reticulocytes, which result in a stronger light scatter signal. The immature reticulocytes are reported as a fraction (or percent) ofthe reticulocytes.

$$\mathrm{IRF} = (\mathrm{IRFPo\,int\,s} / \mathrm{RETICPo\,int\,s}) \times 100\%$$

NOTE

- The reticulocyte test mode might not be available in all analyzer models or relevant in all animal profiles. Contact your local Boule representative for more information.
- When enabled in the H50V analyzer the RETICS method can be used as guideline in anemia investigations. If elevated reticulocyte counts are detected, it is recommended to confirm with manual blood smear count.

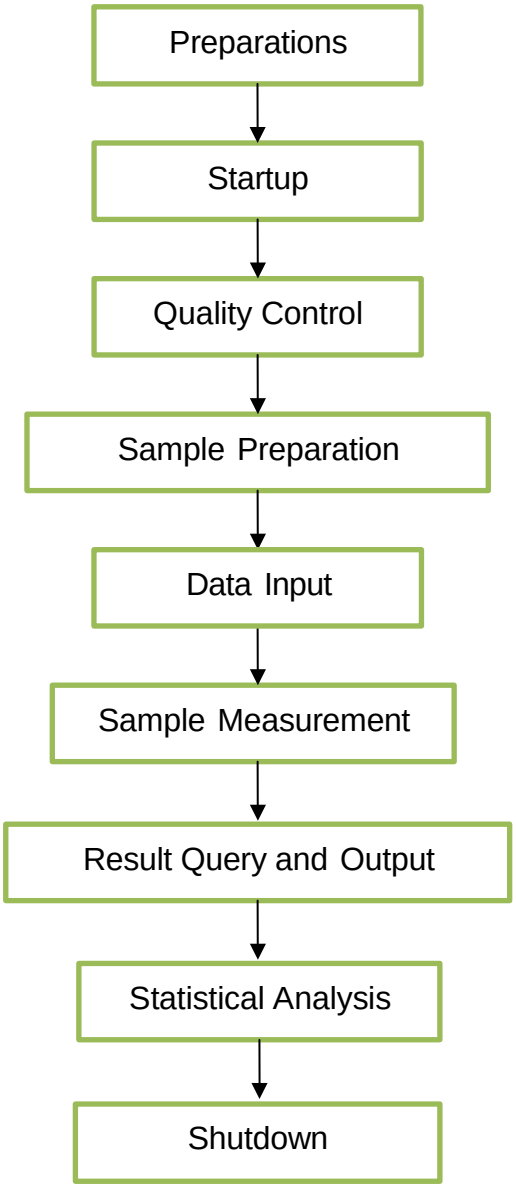
---

6 Daily Operation

6.1 Overview

This section describes the procedures of daily operation from Startup to Shutdown and explains the process of different modes of sample analysis in detail.

Daily Operation Flow Chart as follows:



CAUTION

- Operator must have basic laboratory skills and be aware of good laboratory practice.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

6.2 Preparations

Check the analyzer for the following steps before startup.

Check the Waste Container

- The waste should be processed properly and cleaned up before startup every day.

Check Reagents, Tubing and Power connection

- Ensure that Diluent, Lyse, Detergent and Sheath meet the test requirements.
- Ensure that the tubing of reagents and waste are properly connected, and in a relaxed state.
- Ensure that the power connection of the analyzer and computer are reliable.

Check the Printer

- Ensure that installation is proper, and that paper is stocked.

6.3 Startup

1. Turn **On** the power switch located on the left side of the analyzer. The status indicator on the front panel turns orange.

The analyzer program starts and enters the startup interface. The components of the system are checked, and the liquid system is rinsed. The automatic sequence lasts about four minutes. The status indicator on the start plate turns green after initiation.

2. Enter **Username** and **Password** using the virtual popup keyboard.

Default account and password with all user rights is **admin**. To log in with another account enter the **Setup** interface and select **Log off.**

3. After Startup the **Test** interface opens. See Figure 6-1.



Figure 6-1 Test Interface

6.3.1 Background Test

When startup is complete, perform a background test to make sure that the analyzer and reagents are within range.

1. In the **Test** interface, select **Mode Switch**.
2. Set **Counting Mode** to **BackGround**.
3. Select **OK**.
4. Run a Background test and confirm that the test results are within the acceptable range.

Background Count

Parameter	Acceptable range
WBC	≤0.20×10^9 /L
RBC	≤0.02×10^{12} /L
HGB	≤0.1g /dL
PLT	≤10.0×10^9 /L

If the Background test results are above the limits, repeat the above procedure until it is within range, before proceeding with clinical samples.

The background test can be set to run automatically after startup, refer to *Section 9.1.2 Maintenance Setup* for details.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

6.4 Quality Control

Perform Quality Control before proceeding with clinical samples to ensure accurate results. Refer to *Section 7 Quality Control*.

6.5 Collection of Blood Samples

WARNING

- As there are no assurance of the absence of HIV, Hepatitis B or C viruses or other infectious agents in animal blood samples, controls, calibrators and waste, these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous material. This should include use of gloves, lab coat and eye protection.

CAUTION

- Blood collection and disposal should be performed according to local and national environmental regulations or the laboratory's requirements.
- Ensure that the full procedure of blood collection is clean and contamination-free.
- Venous blood samples should be collected in EDTA-K_2·2H_2O tubes in sufficient quantity and be gently mixed after sampling to obtain accurate results. Follow the recommendation of the EDTA tube supplier.
- Do not shake the sample tube vigorously.
- The sample should be kept at room temperature. Excessive cold or heat could cause erroneous results.
- Samples drawn in an open tube or vacuum tube should be analyzed between 15 minutes and 4 hours after sampling for most accurate results.

6.5.1 Whole blood collection

Collect whole blood samples by venipuncture and store them in clean sample tubes which contains EDTA-K_2·2H_2O (1.5 – 2.2mg/mL). EDTA-K_2·2H_2O maintain WBC and RBC configuration and inhibits PLT aggregation. Gently turn the tube around 5-10 times to ensure the sample is well mixed.

6.5.2 Pre-dilute sample preparation

1. In the **Test** interface, select **Mode Switch**.
2. Set **Counting Mode** to **Rout. Blood**.

3．Set **Blood Mode** to **Pre-dilute**.
4．Set **Analysis Mode** to **CBC+5Diff**.
5．Place a clean test tube under the sample probe and select **Dispense**.

The system automatically drains 500μL diluent from aspiration probe. It is recommended to put the test tube close to the sample probe, to avoid bubbles or spill.

6．Add 20uL peripheral blood into the test tube filled with diluent and mix well.

CAUTION

- Prevent the collected diluent from being contaminated by dust as it may cause analytical error.
- Let the mixture of peripheral blood and diluent stand for 3 minutes, mix again and only thereafter analyze the sample.
- Analyze the sample within 30 minutes after dilution, to ensure reliable analysis results.
- Each laboratory should evaluate the stability of the results in diluent mode according to their own established laboratory protocol.

6.5.3 Blood tube mixer

The H50V analyzer comes with a mixer that uniformly mixes samples before analysis.

1. In the **Setup** interface, select **Maint.Set**.
2. Select **Sample Mixer: On** and then **OK**. The mixer starts to rotate.
3. Select **Sample Mixer: Off** and then **OK**. The mixer will stop.

6.6 Data input

Sample information can be added either before or after sample analysis.

Before sample analysis:

4. In the **Test** interface, select **Next sample** to add sample information.
5. Select desired input box and use the virtual keyboard to add information.

After sample analysis:

1. In the **Data** interface, choose **Sample ID** and select **Edit Info** to access the dialogue box to edit the sample information.
2. Select **OK** to save the edit or **Cancel** to abandon the edit.

When a sample is under audit it cannot be edited. To edit, cancel the audit first.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

If needed, connect an external PS2 or USB interface keyboard to enter information. The following data fields are available:

ID: only accepts numbers. If left blank, the analyzer automatically creates a new Serial number (SN) by increasing the last digit in the SN by one.
Case ID: case number.
BarCode: barcode number.
Pat.Name: name of patient.
Master: name of owner.
Age: year, month, day, and hour can be selected.
Tel.: phone number of owner.
Sampling time: blood sample collection time.
Gender: male or female, the default is blank if not selected.
Sender: name or code of sender.
Sending time: time of sending sample to the department.

NOTE

- SN 0 is used for the background test. Do not enter 0 when processing clinical samples.

CAUTION

- Each sample has a corresponding identification number. Keep track.

6.7 Running a Sample test

6.7.1 Sample mode

1. In the **Test** interface, select **Mode Switch.**
2. Set **Counting Mode** to **Rout.blood** to perform a routine blood test.
3. Set **Blood Mode** to **Whole blood** or **Pre-dilute** depending on how the blood sample was prepared.
4. Set **Analysis Mode** to **CBC+5Diff**.

Only use **CBC+5Diff+RRBC** if the analyzer displays a warning for Resistant red blood cells (RRBC) after performing a test in **CBC+5Diff** mode.

NOTE

- **CBC+5Diff** can be chosen for both Whole Blood and Pre-dilute samples.
- **CBC+5Diff+RRBC** is used to eliminate the interference from resistant red blood cells. When RRBC alarm appears, switch analysis mode to CBC+5Diff+RRBC and repeat the sample test. If WBC total number is far less compared with the first count, it shows that this specimen contains resistant red blood cells.

6.7.2 Animal settings

The analyzer comes with predefined profile settings for several animal species. These include Dog, Cat, Horse, Rat, Mouse, Rabbit, Monkey, Cow, Pig, Buffalo, Sheep, Camel and Goat, Cus 1, Cus 2 and SYS. SYS is used for Quality Control and Calibration.

1. In the **Test** interface, select **Animal**.
2. Choose animal species and select **OK** to confirm.
3. Proceed to sample testing.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

6.7.3 Limit

The analyzer comes with predefined profile settings for several animal species, indicating normal reference range for healthy animals. The settings can be modified and saved to suit local requirements.

1 . In the **Setup** interface, select **Limit**. See Figure 6-2.



Param.	Lower	Upper	Param.	Lower	Upper
WBC	5.00	11.00	HGB	9.0	15.0
LYM%	25.00	62.00	HCT	28.0	46.0
MON%	1.00	8.00	MCV	36.0	55.0
NEU%	38.00	70.00	MCH	13.5	19.5
EOS%	0.10	9.50	MCHC	32.0	39.0
BASO%	0.00	1.20	RDW_CV	15.0	22.0
LYM#	1.320	5.860	RDW_SD		
MON#	0.050	0.820	PLT	90	360
NEU#	2.180	6.360	MPV	5.2	9.0
EOS#	0.010	1.000	PDW		
BASO#	0.000	0.120	PCT		
RBC	4.80	13.00	P_LCR		
RETIC	0.0	2.5	P_LCC		
RETIC_ABS	15	140	IRF	0.00	99.99
NRBC#	0.00	999.99	NRBC%	0.00	99.99
ALY#	0.000	99.999	ALY%	0.00	99.99
LIC#	0.000	99.999	LIC%	0.00	99.99

Figure 6-2 Limits

2 . In the **Limit** interface, **s**elect **Animal** to choose profile settings**.**
3 . Select **OK** to confirm patient group.
4 . Select the desired value under **Lower** or **Upper** to change the limits for individual parameters.
5 . Use backspace to remove the former value and type in the new value.
6 . Select **Save** to save the new setting for the chosen patient group.

Other functions in the **Limit** interface:

- To revert to the factory settings, select the intended group and then select **Default**.
- To export current group limits, select **Export**.
- To print current group limits, select **Print**.
- Select **Return** to go back to **Setup** interface.

6.7.4 Counting and Analysis

WARNING

- The sharp sample probe contains residues of clinical specimens, controls, or calibrators. Consider the sample probe as infectious and avoid direct contact.

CAUTION

- Use recommended vacuum blood tubes, centrifuge tubes, capillary tubes and other disposable products when collecting the blood sample.

NOTE

- Do not reuse disposable items.
- Ensure that the entered ID number corresponds to the sample.

1. Ensure that the sample is well mixed.

Gently invert the blood sample 10-15 times or use the sample mixer, refer to *Section 6.5.3* for details. If an Eppendorf or micro tube is used for sampling, flick the tube with a finger to mix.

2. Hold the sample under the sample probe in an upright position.
3. Press the start plate to aspirate sample.

The sample probe will move up when sample aspiration is finished. Do not remove sample before aspiration is complete. Incomplete aspiration will cause erroneous results.

4. Results are automatically saved.

6.8 Data Query

After each run, results are automatically saved in a database that can store approximately 200 000 sample measurements including results, scatter diagrams and two histograms per sample. All results, scatter diagrams and histograms stored in the database can be reviewed through query and statistics.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

6.8.1 Data Query

1. In the **Data** interface, select **Query**. See Figure 6-3.



Figure 6-3 Data Interface

2. The Query dialogue box opens.
3. Choose between a **Quick query** or a **Conditional query**.

For a **Quick query** choose to display current **Unaudited** samples, **Unprinted** samples or select **No transmitted** to view not transmitted samples.

Use the **Conditional query** to search for a specific run by entering the specified **ID**, **Master**, **Case ID** or **Pat.Name**. A query can also be limited to a range of **Sample number** or **Test date**. The conditional query can be further tailored by using **Sample State.**

6.8.2 Data Selection

1. Enter the **Data** interface.
2. Tap the screen to select a sample to view. Selected samples will have an ***** in front of the sample ID. See Figure 6-3.
3. In the **Data** interface, select **Graph Review** to view detailed data and graphs. See Figure 6-4.

Use **Pre. record** and **Next record** to scroll between samples in the **Graph Review** interface.



Figure 6-4 Graph Review

6.8.3 Data Export

1. In the **Data** interface, select **Export** to access the Export dialogue box.
2. Set **Range** to either **Chosen record** or **All records**, tick relevant items in **Content**.
3. Insert the USB stick before exporting. Select **OK** to start the export. The exported data is in Excel format. Select **Cancel** to cancel the export.

6.8.4 Data Deletion

1. In the **Data** interface, select individual samples or multiple samples for deletion.
2. Select **Delete** to permanently remove data stored in the analyzer.

NOTE

- Be aware that once the data is deleted, it can NOT be recovered. Operate with caution.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

6.9 Reticulocyte Analysis

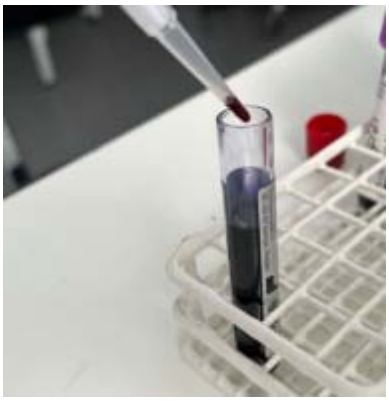
The H50V Analyzer includes an optional mode to analyze presence of immature red blood cells, reticulocytes, in blood samples. The retic mode measurement function may not be locally available or need to be enabled by an authorized service technician prior to use. Contact your local Boule representative for further information.

Reticulocyte samples are prepared from blood samples diluted and dyed with the reticulocyte staining reagent, refer to *Section 6.9.1*. The test result of a reticulocyte sample is Reticulocyte rate, Reticulocyte absolute value and IRF.

6.9.1 Preparation of Reticulocyte samples

Prepare a sample for Retics analysis from a fresh blood sample, maximum 8 hours after collection, refer to *Section 6.5*.

1. Gently invert the blood sample 10-15 times. If an Eppendorf or micro tube is used for sampling, flick the tube with a finger to mix.



2. Add 20µL of whole blood directly into the liquid of one tube of H50V Reticulocyte stain.
3. Place the H50V Reticulocyte stain tube containing the sample, in a dry incubator with a temperature of 37°C for 15 minutes.
4. Take out the sample and gently invert it 10-15 times before analysis.
5. Analyze the sample in Retics test mode, within 10 minutes.

6.9.2 Reticulocyte background test

1. In the **Test** interface**,** select **Mode Switch.**
2. Set **Counting Mode** to **Retic back**. See Figure 6-5.



Figure 6-5 Reticulocyte Background

3. Perform a Retic background test to get the numerical value of the background before proceeding with measurements of samples.

If the Retic background results are above 0.5×10^9 /L repeat the above procedure until it is within range before proceeding with measurements of samples.

6.9.3 Reticulocyte test

A reticulocyte measurement can be performed and saved on its own, or by adding the reticulocyte measurement result to a corresponding sample already collected in regular CBC-5Diff mode.

To collect a Retics sample, do the following:

1. In the **Test** interface**,** select **Mode Switch.**
2. Set **Counting Mode** to **Retic test** to enter the reticulocyte test interface See Figure 6-6.
3. Aspirate a Retics sample by pressing the **Start plate**.
4. Enter a new **ID** and **RBC** value. The RBC value is used for calculating Retics%

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical



Figure 6-6 Reticulocyte Test interface

To collect and add Retics data to an existing sample, do the following:

1. In the **Test** interface**, s**elect **Mode Switch.**
2. Set **Counting Mode** to **Retic test** to enter the reticulocyte test interface See Figure 6-6.
3. In **Data** interface, select a sample previously collected in CBC-5Diff mode.
4. Select **Graph review**.
5. Press the **Start plate**. A pop-up dialogue box opens.
6. The pop-up dialogue box shows the **ID** and **RBC** value of the chosen CBC-5Diff mode measurement. Make sure the correct sample is selected. Data can be overwritten.
7. Select **OK**. Sample is aspirated and measurement values added to the chosen sample.

NOTE

- Avoid contact of skin and clothes with Reticulocyte staining reagent. New methylene blue contained in the reagent can result in skin, clothes, and other surfaces pollution.
- The reticulocyte test mode might not be available in all analyzer models or relevant in all animal profiles.

6.10 CV Value and Trend graph

1. To check the Coefficient of Variation (CV) value, repeat a Sample test with the

control material or the same blood sample 11 times.

2. In the **Data** interface, remove the first test result and select the remaining 10 results.
3. In the **Data** interface, select **CV** to see the CV value or select **Trend graph** to see the trend graph of the parameters.

6.11 Shutdown and Logout

The Shutdown procedure should be performed before turning off the power to clean sample cups and tubing. The Shutdown procedure should be performed as a minimum once per week.

Shutdown Procedure

1. In the **Setup** interface, select **Shutdown** and **OK**.
2. The analyzer asks if soaking shall be performed. Select **OK** or **Cancel**.

Soaking, also referred to as Probe Cleaning with Soak, is a cleaning procedure performed by aspirating H50V Probe Cleaner. Perform soaking after processing 25 samples, or as a minimum once a week if less samples are analyzed. See *Section 9 Maintenance*.

3. Shut off the analyzer or leave it in Standby mode.
4. Alternatively, in the **Setup** interface, select **Logout** and select **OK**.

Log out Procedure

1. In the **Setup** interface, select **Logout** and **OK**.
2. Enter new username and password.
3. Select **OK** to log in.

CAUTION

- Failing to complete the Shutdown procedure properly may result in data loss and abnormal boot.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

7 Quality Control

7.1 Overview

Perform Quality Control (QC) regularly to maintain the analyzer precision and eliminate system errors. The analyzer provides four QC methods, which are Levey-Jennings (L-J) QC mode, X-B QC mode, X-R QC mode and X QC mode.

L-J QC mode is the default mode accessed via the **QC** interface while remaining QC methods are accessed via the **Setup** interface.

Perform Quality Control with the recommended control materials when:

- the daily startup procedure is completed.
- the reagent lot number changes.
- the analyzer has been calibrated.
- a maintenance has been performed or components have been replaced.
- the laboratory or the clinical QC protocol recommend it.
- abnormal parameter values are suspected.



WARNING

- As there are no assurances ofthe absence of HIV, Hepatitis B or C viruses or other infectious agents in animal blood samples, controls, calibrators and waste, these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials. This should include use of gloves, lab coat and eye protection.



CAUTION

- Only use controls authorized by Boule.
- The operator should be thoroughly familiar with the analyzer and the control procedure before analyzing the control.
- Follow the instructions for use and storage of the control.
- Ensure that the control container is undamaged before use.
- Ensure that the control is brought to room temperature and properly mixed before use.
- Do not use the control beyond the stated expiration date.
- Do not use the control if deterioration is suspected.
- Do not pre-mix the control on a mechanical mixer.

- Wipe the aspiration probe with a clean, dry lint-free absorbent cloth before each control run. Not following this technique will impact control accuracy.
- Check the value difference by comparing the current batch and the previous batch of control material.

7.2 Quality Control Options

L-J QC

L-J QC (Levey-Jennings graph) is a visual QC method with which the operator can plot a QC value directly in a graph after getting the Mean, Standard Deviation (SD) and Coefficient of Variation (CV).

The Mean ($\overline{X}$), SD and CV are derived from the following formulas.

$$\overline{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^2}$$

$$CV = \frac{SD}{\overline{X}} \times 100\%$$

X-B QC

X-B QC is a moving average method. It is based on the principle that, the RBC count varies due to blood concentration, blood pathology, and technical factors, while the hemoglobin content, expressed as g/L, is hardly affected. Accordingly, the quality control of samples is performed by examining the value of Mean Cell Volume (MCV), Mean Cell Hemoglobin (MCH) and Mean Cell Hemoglobin Concentration (MCHC).

X-R QC

In X-R QC method, X indicates the mean value, R indicates the range of values. The X graph is mainly used to judge if the mean value reaches the required level. The R graph is mainly used to judge if the value range reaches the required level.

X QC

X QC is a variant ofthe X-R QC. The difference is that the control datapoint in the X graph indicates the mean value of two results rather than one result, and based on this calculates the Mean, the SD and the CV.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

7.3 Levey-Jennings QC

7.3.1 L-J QC Setup

1. Select the **QC** interface to enter the **L-J QC** interface. See Figure 7-1.

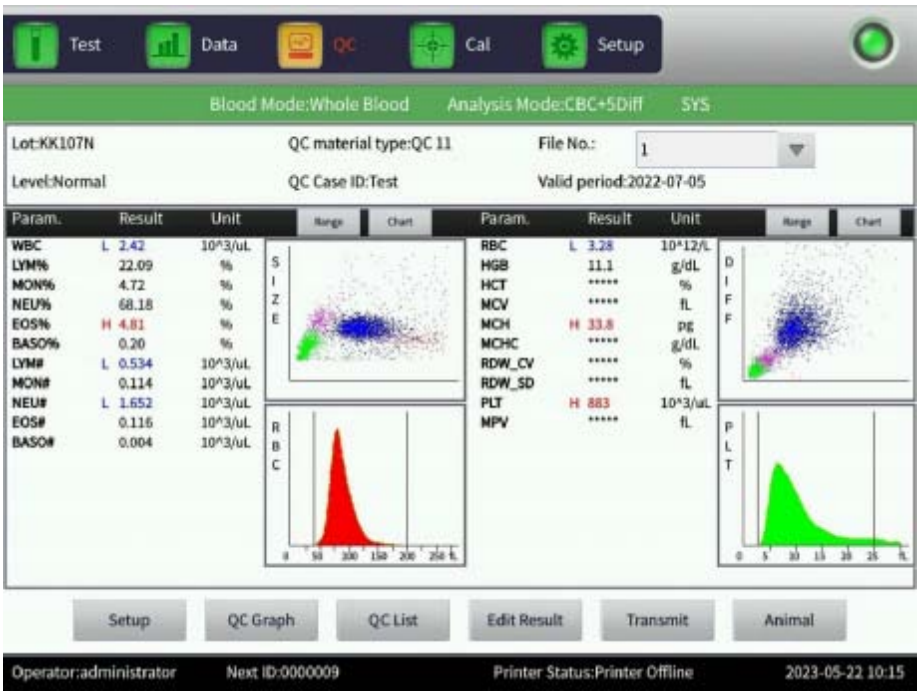


Figure 7-1 L-J QC Interface

2. Select **Setup** to enter the L-J QC setup interface. See Figure 7-2.

There are 14 different QC group sets available. The operator can set several groups if needed. Select **Edit** to make changes to a selected group, select **Delete** to delete the selected group, select **Emptied** to delete all groups.

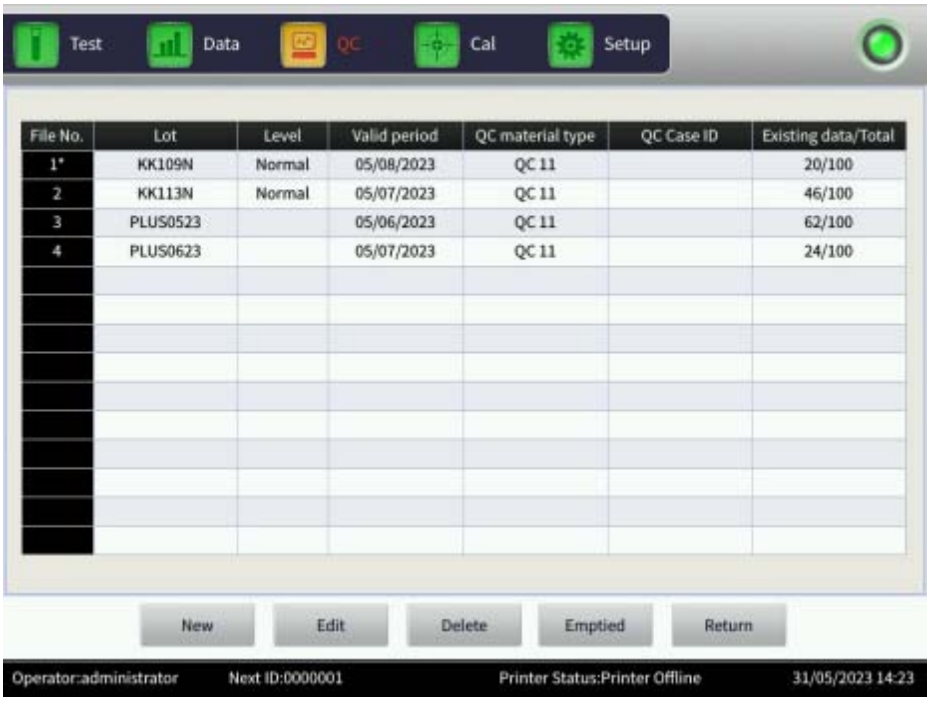


Figure 7-2 L-J QC Setup

3. Select **New** to set up a new group of QC. See Figure 7-3.



Figure 7-3 New QC Group

The L-J QC method is based on QC control material. Enter the relevant information. Information that can be edited is **Lot** number**, QC material type**, **QC case ID**, **Level**, **Runaway mode, Valid period**, **Reference**, and **SD**. Enter the SD values under **Limit(#).**

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

The Reference is the standard value of the QC count. The SD provides the allowed deviation range. Note that the SD cannot be greater than the reference, or it cannot be saved in the database.

NOTE

- Control Assay sheets provides WBC reference values using both WOC and WIC counting methods. The H50V analyzer is set to use WOC counting, hence enter the WOC reference and SD values in QC control.

---

4. Select **Limit setup** to set up the SD. Choose to have SD calculated either as an absolute value or as a percentage.
5. Select **Return** and then **OK** in the popup dialogue box.

To run a QC test:

1. In the **QC** interface, select **Setup**.
2. Select one QC group and select **Return** to go back to the **QC** interface to run a QC test.
3. Ensure that the control sample is well mixed and handled according to the manufacturer's instructions, refer to *Section 8.3.3* for details.
4. Hold the sample under the sample probe in an upright position.
5. Press the start plate to aspirate sample.

The sample probe will move up when sample aspiration is finished. Do not remove the control before aspiration is complete. Incomplete aspiration will cause erroneous results.

7.3.2 L-J QC Graph

QC measurements are viewed in the L-J QC graph.

1. In the **QC** interface, select **QC Graph**, to view the results. See Figure 7-4.



Figure 7-4 L-J QC Graph

2. If a data point is not within the control range, choose this data point and select **Outlier**. Identify the reason for the outlier and select **OK** to save your settings.

QC Graph features

- Each screen displays the QC chart for two parameters at a time, with the Mean, SD and CV of each parameter shown on the right-hand side. Use the arrows to scroll through the parameters.
- The graph displays the number of runs of the QC count on the horizontal axis and the measured result values of the QC count on the vertical axis.
- Every parameter graph displays 20 data points. Use the arrows to scroll through the data points.
- The center line of the graphs corresponds to the Reference value for that parameter.
- The upper and lower line on every parameter graph corresponds to the Reference value ± SD.

If a control value/data point falls in the area between the upper and the lower limits of the corresponding graph, it means that the data point is within the control range. If not, the data point is outside the control range. Each QC graph can accommodate up to 100 data points.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

7.3.3 L-J QC List

1. In the QC interface, select **QC list** to view the test sample data. See Figure 7-5.



	Date	Time	WBC	LYM%	MON%	NEU%	EOS%	BASO%
Reference	/	/	7.76	23.25	6.15	63.30	6.70	0.60
Limit(#)	/	/	0.80	7.00	6.15	8.00	6.50	0.60
17	2023-02-01	14:10	6.18	56.31	11.39	29.07	2.69	0.54
16	2023-02-01	14:06	6.54	55.74	9.65	32.22	2.10	0.29
15	2023-02-01	14:04	6.05	58.14	9.99	29.77	1.64	0.46
14	2023-02-01	14:00	7.31	33.93	9.41	54.92	1.58	0.16
13	2023-02-01	13:58	7.16	33.27	10.14	55.58	0.76	0.25
12	2023-02-01	13:56	0.00	0.00	0.00	0.00	0.00	0.00
11	2022-10-06	15:36	7.99	23.83	5.87	62.61	7.39	0.30
10	2022-10-06	15:34	7.91	23.05	6.52	63.69	6.50	0.24

Figure 7-5 L-J QC List

All generated QC test results are saved in the QC list. Use the arrows to navigate between the test results. A maximum 100 QC test results can be reviewed in the QC list. **Limit(#)**, represent SD. Note that the values for **Reference** and **Limit(#)**, shown in the **QC list** interface are the values that were entered during set up.

7.4 X-B QC

X-B QC is different to the other QC methods. That is, QC control material is not used, and only three parameters, the MCV, MCH and MCHC are managed in this method.

7.4.1 X-B QC Edit

1. In the **Setup** interface, select **X-B QC**. A popup dialogue box opens.
2. Select **XB setup** to edit the setup.
3. Choose the number of samples to be used in **Sample number**. The available range is between 20 and 200.
4. Manually enter the Reference and the SD values of MCV, MCH and MCHC in the corresponding **Reference** and **Limit(#)** columns.
5. Manually enter the Sample validity of RBC, MCV, MCH and MCHC in the **Lower** and **Upper** columns. This provides the range where the SD of the RBC, MCV, MCH and MCHC are valid.

The **Reference** is the standard value of the QC count. The **Limit(#)** corresponds to SD and indicates the allowable deviation range. Note that the Limit cannot be greater than the reference, otherwise, the new SD cannot be saved in the database.

6. Select **Limit setup** in the **XB Setup** interface to choose **Absolute value** or **Percentage**.
7. When setup is complete select **Return** and **OK** to save the settings in the popup dialogue.

7.4.2 X-B QC Run

X-B QC is a QC method that does not use QC control materials. The basic method for measuring the X-B QC is the floating mean method.

1. In the **Setup** interface, select the **X-B QC** and then select **XB setup**. Use the option **On** to start the X-B QC run, and **Off** to stop the X-B QC run.
2. Select **On** to run the X-B QC.

Sample number controls the number of samples in one group. For example, if there are 20 samples in one group, the analyzer will perform X-B QC testing 20 times.

7.4.3 X-B QC Review

Review the QC results of the three parameters through the QC graph review, and the QC list review.

QC graph review

1. In the **Setup** interface, select the **X-B QC** and then select **XB graph**.

Data points of the MCV, MCH and MCHC are plotted in the QC graph after a set of samples have been tested. The X-B QC result is automatically calculated and displayed in the graph.

The three graphs display MCV, MCH and MCHC. The graphs are automatically updated after each set of QC counting. Use the arrows to navigate between the test results. Each data point in a graph has the corresponding date and time. The displayed date and time are subject to the date and time of final data within one group.

QC Graph features

- The screen displays QC charts for three parameters, with the Mean, SD and CV of each parameter on the right-hand side.
- The graph displays the number of runs of the QC count on the horizontal axis, and the obtained result value of the QC count on the vertical axis.
- Every parameter graph displays 20 data points. Use the arrows to scroll through the data points.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

- The center line of the graphs corresponds to the Reference value for that parameter.
- The upper and lower line on every parameter graph correspond to the Reference value ± SD.

If a control value falls in the area between upper and lower limit of the corresponding graph, it means that the data point is within the control range. If not, the data point is outside the control range.

QC list review

1. In the **Setup** interface, select the **X-B QC.**
2. Select **X-B Graph** and then **QC list**.

The average of a set of data is saved after testing. Use the arrows to navigate between the test results. The **Reference** and the **Limit(#)** values shown in this interface are the values entered during setup.

Select **Delete** to delete selected test results. Select **Emptied** to delete all results. Select **Export** to export all data. Select **Return** to go back to the X-B graph interface.

7.5 X-R QC

X-R QC method, or the mean-range QC method, uses QC control material. The analyzer creates an alarm when the QC count result is invalid when a background test is run.

7.5.1 X-R QC Setup

1. In the **Setup** interface, select **X-R QC** interface. A popup dialogue box opens.
2. In the **X-R QC** interface, select **Setup** to enter the QC Setup interface.

The functions in the X-R QC Setup interface are:

- **New** to create a new QC set.
- **Delete** to delete selected test results.
- **Emptied** to delete all results.
- **Edit** to modify QC information which has already been set up.

3. Select **New** to create a new QC set. A popup dialogue box will open.
4. Enter QC control material information related to **Lot**, **QC material type**, **QC Case ID**, **Level** and **Valid period**.
5. Select **OK** to save the information.
6. Select **Return** to go back to the **X-R QC** interface to perform the QC test.

To run a QC test:

1. In the **X-R QC** interface, select **Setup.**

2. Select one QC group and select **Return** to go back to the **X-R QC** interface to run a QC test.
3. Ensure that the control sample is well mixed and handled according to the manufacturer's instructions, refer to *Section 8.3* for details.
4. Hold the sample under the sample probe in an upright position.
5. Press the start plate to aspirate sample.

The sample probe will move up when sample aspiration is finished. Do not remove the control before aspiration is complete. Incomplete aspiration will cause erroneous results.

A maximum of 100 sets of QC data can be tested. The QC run interface displays two QC test results separately, and automatically calculates twice the mean and the range after finishing the second QC count. The mean of the two QC test data is one set of data.

7.5.2 X-R QC Graph

1. In the **Setup** interface, select **X-R QC** and then select **QC graph**, see Figure 7-9.

Use the arrows to navigate between the test results. Select **Return** to go back to the X-R QC interface.

In the **X-R QC Graph** interface, there are two different graphs for each parameter, the X graph, and the R graph. The X graph displays the mean value results while the R graph displays the range results. If the Level Normal is selected during setup and the QC test is performed twice, the data point in the X graph will correspond to that level. The data points for the range are shown in the corresponding R graph.

X-R graph features

- The graph displays the number of runs of the QC count on the horizontal axis and the measured result values of the QC count on the vertical axis.
- Each parameter graph can display 100 data points. Use the arrows to scroll through the data points.
- The center line of each parameter X graph corresponds to X, the overall mean value of the QC results.
- The upper line of each parameter X graph corresponds to X Upper limit ＝X＋A×R.
- The lower line of each parameter X graph corresponds to X Lower limit ＝X－A×R.
- The center line of each parameter R graph corresponds to R, the mean value of the QC result range.
- The upper line of each R parameter graph corresponds to R upper limit ＝B×R.
- The lower line of every R parameter graph corresponds to R lower limit ＝C×R.

If a control data point falls in the area between the upper and the lower lines, it means that the data point is within the control range. If not, the data point is outside the control range.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

7.5.3 X-R QC List

1. In the **X-R QC** interface select **Setup**.
2. In the **Setup** interface, select one QC group and select **Return**.
3. In the **X-R QC** interface**,** select **QC list**. The displayed data is the selected QC data.

A maximum of 100 data results can be reviewed in the QC list. Use the arrows to navigate between test results. The QC data is updated after running two new controls. The data displayed in the QC list is the average of the two QC count results.

The difference between X-R QC and L-J QC Query is that the X-R QC interface displays three QC results that includes the mean value and the range. First page of the first two columns is the total mean and average range in the X-R QC test.

7.6 X QC

The X QC method is used with QC control material. It is possible to generate up to 24 QC parameters depending on need. The method provides QC documents for high, normal, and low Control material for saving.

7.6.1 X QC Setup

1. In the **Setup** interface, select **X QC** and then select **Setup**.

The functions in the X QC Setup interface are:

- **New** to create a new QC set.
- **Delete** to delete selected test results.
- **Emptied** to delete all results.
- **Edit** to modify QC information which has already been set up.

2. Select **New** to create a new QC set and enter the relevant information.

Information that can be edited is **Lot** number**, QC material type**, **QC case ID**, **Level**, **Runaway mode, Valid period**, **Reference**, and SD. SD values are entered under **Limit(#).**

3. Select **Limit setup** to choose to present SD with the **Absolute value** or the **Percentage value** method.

The QC run interface displays two QC test results separately and automatically calculates twice the mean and the range after finishing the second QC count. The mean of two QC test data is one set of data.

7.6.2 X QC Graph

1. In the **X QC** interface, select **QC Graph**.

The results of up to 24 parameters can be viewed via the QC graph. The difference between X QC and L-J QC is that the data point on the X QC Graph indicates the mean value of two QC results.

QC graph features

- The graph displays the number of runs of the QC count on the horizontal axis, and the obtained result value of the QC count on the vertical axis.
- Each parameter graph can display 100 data points. Use the arrows to scroll through the data points.
- The center line of the graphs corresponds to the Reference value for that parameter.
- The upper and lower line on every parameter graph correspond to the Reference value ± SD.

If a control result falls in the area between the upper and the lower lines, it means the data point is within the control range. If not, the data point is outside the control range.

7.6.3 X QC List

1. In the **X QC** interface, select **Setup.**
2. In the **Setup** interface, select a QC group and then select **Return**.
3. In the **X QC** interface, select **QC list.** The displayed data is the selected QC data

Select **Delete** to delete selected test results. Select **Emptied** to delete all results. Select **Edit** to modify QC information which has already been set up.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

8 Calibration

8.1 Overview

Calibration is used to establish a reference point that assists the analyzer to produce accurate results. The H50V analyzer has been factory calibrated prior to shipment. However, good laboratory practice requires regular checks, and recalibration of measured parameters if needed. Only authorized operators with an Administrator account can update or change calibration factors.

The analyzer provides three calibration modes: **Standard**, **Blood** and **Manual**.

Standard calibration mode is recommended when using a Calibrator to calibrate all animal profiles with same adjustments. Blood calibration mode can be used to calibrate each profile individually, should there be a need for it. Use Manual calibration mode to manually set adjustment, to all or each profile separately.

**WARNING**

- As there are no assurances ofthe absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials.

**CAUTION**

- Only use calibrators authorized by Boule.
- Only adjust user calibration, do not adjust factory set Calibration factors.
- The operator should be thoroughly familiar with the analyzer and the calibration procedure before performing calibration.
- Follow the instructions for use and storage of the calibrators.
- Ensure that the calibrator container is undamaged before use.
- Ensure that the calibrators are brought to room temperature and properly mixed before use.
- Do not use the calibrators beyond the stated expiration date.
- Do not use the calibrator if deterioration is suspected.
- Do not pre-mix the calibrator on a mechanical mixer.
- Wipe the aspiration probe with a clean, dry lint-free absorbent cloth before each calibrator run. Not following this technique will impact the accuracy.
- Ensure that the analyzer is in good working condition and that the precision meets the requirements before calibration.
- Do not use the analyzer for clinical samples unless all the parameters are accurately

calibrated.

8.2 Calibration Frequency

To ensure precision and obtain reliable test results, the parameters (WBC, RBC, PLT, HGB and MCV) should be calibrated in the following situations:

- The working environment has significantly changed.
- Test results of one or multiple parameters are not accurate.
- A major component that affects the measurement is replaced.
- If the analyzer is not used for a long time.
- If the laboratory or the clinical protocol requires it.
- Quality control present deviating results.

MCV and HCT are parameters relative to each other, thus one can be obtained from a given value of the other. Only MCV can be calibrated by the analyzer. Usually, the manufacturer provides the value for MCV and HCT at the same time.

8.3 Handling of Calibrator and Control

8.3.1 Summary and Principle

The Calibrator and Control are stable whole blood preparations that can be used to verify and adjust calibration ofthe H50V veterinary hematology analyzer.

8.3.2 Indication of deterioration

After mixing, Calibrator and Control should be similar in appearance to fresh whole blood. In unmixed vials, the supernatant may appear cloudy and reddish; this is normal. Other discoloration, very dark red supernatant, or unacceptable results may indicate deterioration. Do not use the Calibrator or Control if deterioration is suspected.

8.3.3 Mixing and handling of Calibrator and Control

1. Remove the vials from the refrigerator and allow to warm to room temperature (15 – 30°C) for 15 minutes before mixing.
2. To mix, hold the vial horizontally between the palms ofthe hands. Do not pre-mix on a mechanical mixer.
   a) Roll the vial back and forth for 20 – 30 seconds; occasionally invert the vial. Mix vigorously but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Vials stored for a long time may require extra mixing.
   c) Gently invert the vial 8 – 10 times immediately before running each sample.
3. After sampling, carefully wipe the vial rim and cap with a lint-free tissue and replace the cap.
4. Return the vials to the refrigerator within 30 minutes of use.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

8.4 Preparation

Before calibration, check the following:

1. Ensure that reagents are sufficient, uncontaminated, and not past the expiration date.
2. Verify that analyzer maintenance and cleaning is current. Refer to *Section 9*.
3. Run a background test, refer to *Section 6.3.1* for details. Make sure that results are within the acceptable range.

Background Count

Parameter	Acceptable range
WBC	≤0.20x10^9 /L
RBC	≤0.02x10^{12} /L
HGB	≤0.1g /dL
PLT	≤10.0x10^9 /L

4. Verify the precision by checking the Coefficient of Variation (CV) value.
   a) Repeat a Sample test with the control material 11 times with the SYS profile.
   b) In the **Data** interface, remove the first test result and select the remaining 10 results.
   c) In the **Data** interface select **CV** to see the CV value or select **Trend graph** to see the trend graph of parameters.
   d) Make sure that CVs are within the acceptable range.

Coefficient of Variation (CV) value

Parameter	Range	CV
WBC	4.0 ×10^9/L – 15.0×10^9 /L	≤3.0%
RBC	3.00 ×10^{12} /L – 6.00×10^{12}/L	≤2.0%
HGB	100 g/L – 180 g/L	≤2.0%
PLT	100 ×10^9 /L – 149×10^9 /L	≤6.0%
	150 ×10^9 /L – 500×10^9 /L	≤5.0%
HCT /	35% – 50%	≤2.0%
MCV	70 fL – 120 fL	≤1.0%

8.5 Calibration Modes

8.5.1 Principles of the new Calibration coefficient

- Mean value = the sum of the values/the count of the values
- New calibration value = (reference value/mean value) × former calibration value
- If the new calibration value is <70%, consider it equal to 70%, if the new calibration value is >130%, consider it equal to 130%

For example, if the reference value of PLT of the calibrator is 220, the former calibration value is 103% and the mean value is 230, then the new calibration value is

New calibration value =103%×220/230=98.52%

8.5.2 Validation of Calibration coefficient

Follow these steps to validate the Calibration coefficient after calibration.

1. Run the calibrator three times, and check that the results are within the acceptable range. Compare the mean value for each parameter to the assigned value. If the difference is within range, calibration is optimal. If the difference is not within range, recalibration may be needed.
2. It is recommended to run a minimum of three replicas of a control. Check that the results are within the acceptable range.

NOTE

- The acceptable range for the Calibration coefficient is 70% – 130%. If results exceed the limit, then the maximum value in the limit range should be selected as the new coefficient for calibration. If this occurs, the operator should identify the reason and recalibrate. If the problem persists, contact your local Boule representative.

8.5.3 Manual Calibration

1. Select **Manual** in the **Cal** interface. See Figure 8-1.
2. The analyzer will automatically switch the profile to **SYS**.
3. For each parameter enter its reference value under **Reference** and the average obtained value under **Test value**.
4. Select **New Cal%** and the new Calibration coefficient is automatically calculated for the corresponding parameter.
5. When leaving the **Manual** interface, the **Select** pop up menu will open.
6. Choose which profiles to update and select **OK** to save the new Calibration coefficient.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

If the Calibration coefficient has already been obtained simply type in the value for each parameter under **Cal%** and select **OK** to save it. Refer to *Section 8.5.1* for details.



Figure 8-1 Manual Calibration

NOTE

- The analyzer can calibrate a selected parameter or all parameters ofWIC，WOC，RBC，HGB，MCV，MPV, RDW_CV, RDW_SD, PLT and PDW.
- Remember to save the calibration value before exiting the Cal interface.

7. Validate the Calibration coefficient after calibration. Refer to *Section 8.5.2*.

8.5.4 Standard Calibration

1. Select **Standard** in the **Cal** interface. See Figure 8-2.
2. The analyzer will automatically switch the profile to **SYS**.



Figure 8-2 Standard Calibration

3. Enter the Lot number according to the Assay sheet provided with the calibrator under **Lot**.
4. Enter the reference value according to the Assay sheet provided with the calibrator under **Reference**.

Reference values of parameters that do not need to be calibrated are left blank.

5. Hold the well-mixed calibrator under the sample probe and press the button on the front to aspirate the calibrator.

The maximum number of tests that can be performed is 10. It is recommended to analyze at least three to five times. Make sure the sample is mixed between measurements, refer to *Section 8.3.3*.

7. Deselect any unwanted calibrator tests in the list. Always deselect the first run.

   The analyzer will automatically calculate the mean value from the chosen calibrator tests.
8. The new Calibration coefficient is automatically calculated according to the

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

reference value of the calibrators and the computed mean value.

9. When leaving the **Standard** interface, the **Select** popup menu will open.
10. Choose which profiles to update and select **OK** to save the new Calibration coefficient.
11. Select **Print** to print or select **Export** to export a backup of the calibration coefficient data.
12. Validate the Calibration coefficient after calibration, refer to *Section 8.5.2.*

8.5.5 Blood Calibration

1. Select **Blood** in the **Cal** interface. See Figure 8-3.
2. The analyzer will automatically switch the profile to **SYS**.



Figure 8-3 Blood Calibration

2. Prepare five normal whole blood samples.
3. Obtain a mean value to be used as reference value by running each of the prepared samples at least five times on other analyzers or by other reference method.
4. Select the Case ID1 sample and perform sample test on the H50V analyzer. Repeat the counting between five to ten times to get the mean value. Continue in the same manner with the Case ID2 sample, and so on. As a minimum, run five tests for each sample.
5. The analyzer adds the measured values and calculates the average of the parameters. The system automatically calculates a new Calibration coefficient based on the reference value, the mean value, and the former Calibration coefficient.

6. Select **OK** to save the new calibration coefficient.
7. When leaving the **Blood** interface, the **Select** pop up menu will open.
8. Choose which profiles to update and select **OK** to save the new Calibration coefficient.
9. Select **Print** to print or select **Export** to export a backup of Calibration coefficient data
10. Validate the Calibration coefficient after calibration, refer to *Section 8.5.2.*

NOTE

- Remember to save the results before exiting the **Cal** interface.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

9 Maintenance

Routine care and regular maintenance are essential to keep the analyzer at its best, extend its lifetime, and to minimize system problems.

Routine maintenance should be performed by the operator daily to weekly. Intermittent maintenance should be performed by the operator when needed. Additional yearly maintenance should be performed by trained service engineer.

WARNING

- As there are no assurances ofthe absence of HIV, Hepatitis B or C viruses or other infectious agents in animal blood samples, controls, calibrators and waste, these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials. This should include use of gloves, lab coat and eye protection.

CAUTION

- Maintain and follow cleaning procedures. Failing to do so could result in erroneous results.

9.1 Routine Maintenance

The table below summarizes the routine maintenance procedures that should be done by the operator.

Type of maintenance	Recommended frequency
Startup	Daily to weekly
Probe Cleaning with Soak	Daily to weekly
Shutdown	Daily to weekly
Surface Maintenance	When needed
Sample Probe Cleaning (exterior)	When needed

To minimize system problems:

- Perform Shutdown and Startup as a minimum once a week.
- Turn **Auto Soak** on. The system will automatically ask for Probe Cleaning with Soak to be performed after processing a specified number of samples. 25 is the recommended number of cycles. See *Section 9.1.2 Maintenance Setup*.
- Perform Probe Cleaning with Soak, as a minimum once a week and when prompted by the system.

Publ. Date: October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

- Some specimens, for example feline, are more prone to form clots. Adjust maintenance intervals according to the local laboratory protocol.

9.1.1 Maintenance Procedures

Startup

The analyzer goes through an automatic self-test and cleaning procedure. For details, refer to *Section 6.3 Startup*.

**WARNING**

- Probe cleaner is strongly alkaline. Do not let it contact the skin or clothes. If this happens, rinse the skin and clothes immediately with plenty of water.

Probe Cleaning with Soak

Cleaning with H50V Probe Cleaner aspirated through sample probe. The function is also referred to as **Soak**. When prompted by software, aspirate H50V Probe Cleaner through sample probe. If the volume in the Probe Cleaner bottle is too low for the needle to aspirate, transfer the Probe Cleaner into a smaller tube.
It is recommended to perform Probe Cleaning with Soak in any of these three ways:

- In combination with **Shutdown**. When asked by interface to perform **Soak**, select **OK**.
- When prompted by system. Perform Probe Cleaning with Soak, once a week or when 25 samples have been processed. When asked by interface to perform Probe Cleaning with **Soak**, select **OK**.
- From **Test** interface lower function buttons, select **Soak**, to perform a soaking of the whole system.

Auto Prime

The analyzer includes an auto prime cleaning program. The frequency of the **Auto prime** can be adjusted depending on number of samples analyzed, refer to *Section 9.1.2 Maintenance Setup*. After the **Auto prime**, before proceeding with clinical samples, perform a background test. Refer to *Section 6.3.1 Background Test*. **Prime** can also be performed manually from **Test** interface lower function buttons, select **Prime**.

Shutdown

To prevent measurement errors caused by sample residues, it is necessary to clean the counting chambers and to rinse the liquid system. Shutting down the analyzer also reboots the system. It is recommended to perform Shutdown as a minimum once a week.

When selecting **Shutdown**, the analyzer asks if soaking should be performed. It is

recommended to perform Probe Cleaning with Soak, once a week or when 25 samples have been processed. To proceed with soaking, select **OK** and aspirate H50V Probe Cleaner through sample probe. For detailed instructions, refer to *Section 6.11 Shutdown and Logout.*

Surface Maintenance

Clean the analyzer surface carefully with a soft cloth and DI water. Remove possible traces of salt crystals and blood on the sample probe, to prevent protein deposition and mildewing. Wipe the surrounding area of probe with a paper tissue moistened with a 70% alcohol solution.

Sample Probe Cleaning

Clean the sample probe with paper tissue moistened with a 70% alcohol solution. Wipe dry and ensure no alcohol solution is left on the probe before analyzing next sample.

CAUTION

- Never use corrosive acids, alkaline, or volatile organic solvents (such as acetone, ether and chloroforms) to wipe the outside of the analyzer. Only use water and a mild soap.

9.1.2 Maintenance Setup

1. In the **Setup** interface, select **Maint. Set**. See Figure 9-1.

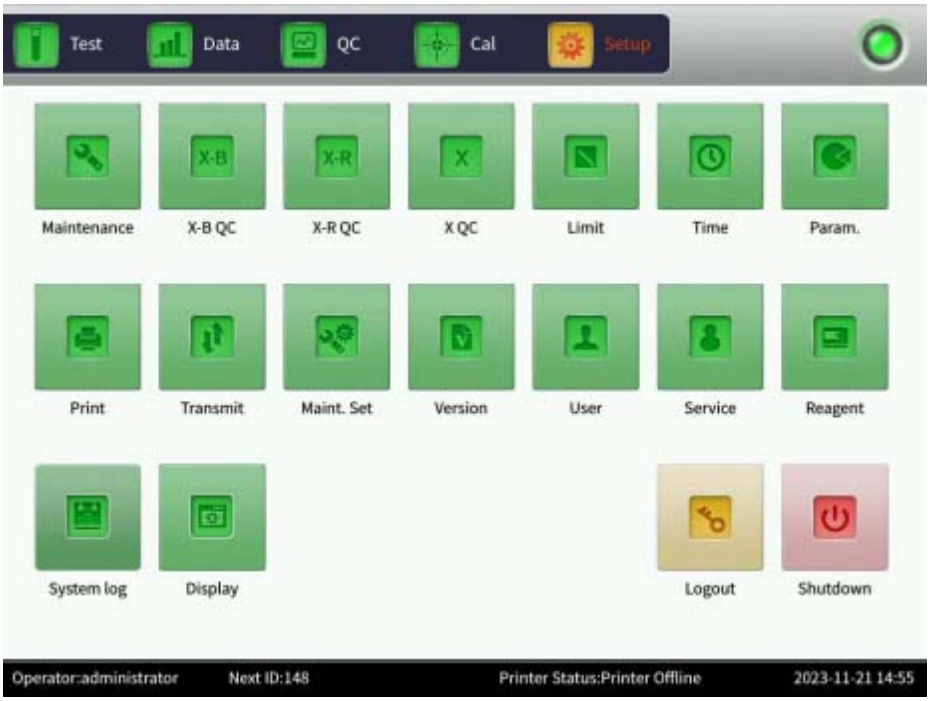


Figure 9-1 Setup Interface

2. A popup dialogue called **Maint. Set** appears with several different settings. The settings are explained below:

Auto blank:

Select **On** or **Off**. Select **OK** to save settings. If **Auto blank** is set to **On**, the analyzer will automatically perform a background test after **Startup** of the analyzer.

Pre-dilute alarm:

Select **On** or **Off**. Select **OK** to save settings.

Soak and exit:

Select **On** or **Off**. Select **OK** to save settings. If **On** is selected, the analyzer will ask if soaking should be performed before shutting down. Aspirate Probe cleaner via the sample probe to clean the system. Shut down the analyzer after soaking.

Audible alarm:

Select **On** or **Off**. When set to **On**, the alarm sounds when an error code appears, and when aspiration of sample probe is done.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Auto prime:

If **Auto prime** is set to **Off,** no automatic prime cleaning is performed. Select the desired number of analyzed samples before the analyzer automatically repeats the prime cleaning. Select **Off**, **50**, **75**, **100**, **125,** or **150 cycles**.

Auto sleep:

The analyzer automatically enters the dormant state after inactivity for a certain time if a time interval has been chosen. Select **Off**, **20**, **40**, **60**, **80**, **100**, or **120 min**.

Auto soak:

If Auto soak is set to **Off**, no automatic probe cleaning is prompted. Select the desired number of analyzed samples (25 is recommended) before the analyzer automatically repeats the soaking. Select **Off**, **25**, **50**, **75**, **100**, or **125 cycles**.

Sample Mixer

Selecting **Sample Mixer On**, the mixer starts to rotate. When you want to turn off the mixer, select **Sample Mixer Off**. Refer to *Section 6.5.3.*

9.2 Intermittent maintenance

There are several maintenance functions that should be done when needed.

1. In the **Setup** interface, select **Maintenance**. See Figure 9-1.
2. The **Maintenance** interface appears, see Figure 9-2.

Each function is described in detail below.

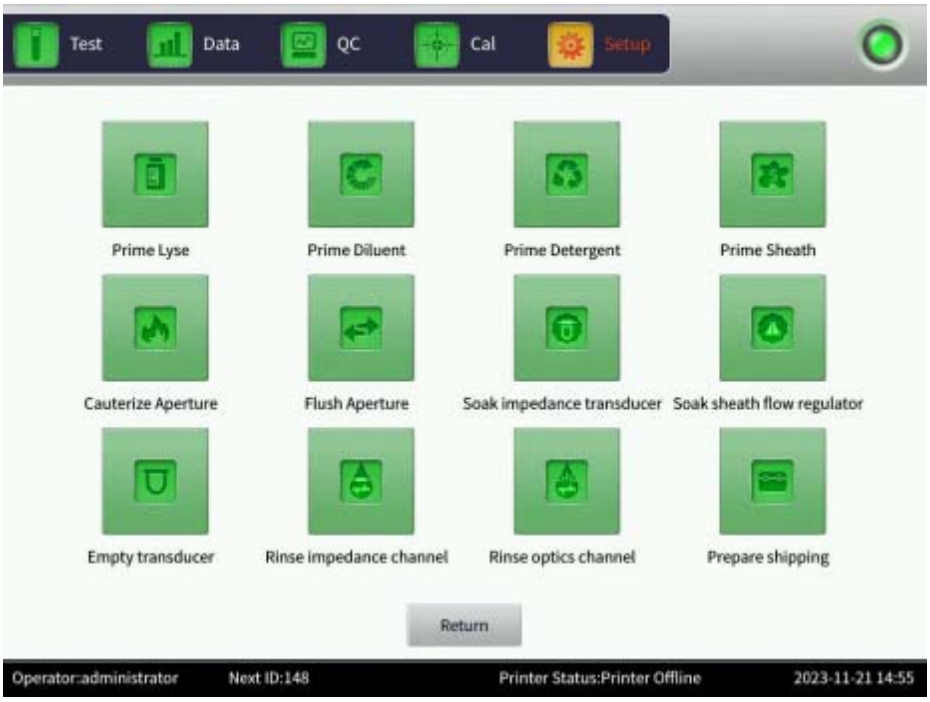


Figure 9-2 Maintenance Interface

9.2.1 Prime Reagent

This function is a priming function, enabling new liquid in the tubing. Perform the priming in the Prime Lyse/Diluent/Detergent, or Sheath reagents in the following situations:

- Bubbles are present in reagent tubing.
- Reagent tubing is contaminated.
- Reagent has expired.
- Reagent has been replaced.

To perform the priming:

1. Select either **Prime Lyse**, **Prime Diluent**, **Prime Detergent**, or **Prime Sheath**.
2. The analyzer executes the operation. All buttons turn gray.
3. Priming is completed, and all buttons return to normal.



WARNING

- Refer to local regulations and established laboratory protocol for handling biohazardous materials. This should include use of gloves, lab coat and eye protection.

NOTE

- Do not shake the reagent. Let it stand to equilibrate before use to ensure it is stable.
- Always perform a background test after replacing a reagent to ensure the background values are within the acceptable range.

9.2.2 Cauterize Aperture

To prevent and eliminate blockage, the Aperture is cauterized with a high voltage to clear protein and dust that adhere or block the aperture.

1. Select **Cauterize Aperture** in the **Maintenance** interface.
2. The analyzer executes the operation. All buttons turn gray.
3. When the operation is completed, buttons return to normal.
4. It is recommended to **Flush Aperture**.

9.2.3 Flush Aperture

The Aperture is flushed to clean it from debris. This prevents and eliminates clogging together with the **Cauterize Aperture** function.

1. Select **Flush Aperture** in the **Maintenance** interface.
2. The analyzer executes the operation. All buttons turn gray.
3. When the operation is completed, buttons return to normal.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

9.2.4 Soak Impedance Transducer

The impedance transducer is soaked in Probe cleaner.

Select **Soak impedance transducer** in the **Maintenance** interface.

1. The analyzer executes the operation. All buttons turn gray.
2. Put probe cleaner under the sample probe when prompted by the analyzer.
3. When the operation is completed, buttons return to normal.

If the aperture is severely clogged, select **Soak impedance transducer**, and put Probe cleaner under the sample probe. The analyzer will automatically aspirate Probe cleaner into the transducer to soak the aperture.

CAUTION

- Probe cleaner contains sodium hypochlorite and is corrosive. Immediately wipe up any spill. Wear protective clothing and rubber gloves.

9.2.5 Prepare Shipping

Perform the **Prepare Shipping** operation when:

- the analyzer will be transported.
- the analyzer will not be used for a week or longer.

It is very important to perform the **Prepare Shipping** operation to avoid crystallization, which can cause complicated and expensive repairs ofthe system.

1. In the **Setup** interface, select **Maintenance**.
2. Select **Prepare Shipping**.
3. Select **OK** in popup dialogue box.
4. Remove all reagent inlet tubes from the containers. The analyzer empties the liquid system, the procedure will take a few minutes.
5. When the operation is complete, put all reagent inlets into a bottle of distilled water.
6. Repeat Steps 1-3. The analyzer fills the liquid system with distilled water.
7. When system is filled, repeat Steps 1-3, and remove the reagent tubes from the water bottle.
8. The analyzer empties the liquid system.
9. When system is empty, turn off the analyzer.
10. Remove all tubes from the back of the analyzer.
11. Keep the tubes intact and well stored.
12. Keep the remaining reagents in their containers and store them as recommended (refer to *Section 1.5 Consumables Overview*).
13. The analyzer is now ready for transport or storage.

9.2.6 Other Maintenance Functions

There are four other maintenance functions.

Soak sheath flow regulator: Sheath flow regulator is soaked in Probe cleaner.

Empty transducer: liquid is emptied from the transducer.

Rinse impedance channel: impedance channel is cleaned.

Rinse optics channel: optics channel is cleaned.

9.3 Maintenance by Service technician

9.3.1 Components Maintenance

Maintenance on the following components by a service technician is required annually.

- Reagent syringes
- Mechanical parts
- Syringe module
- Sample injection mechanism
- Sample cup/Transducer
- Sheath regulator
- Waste filters (should be visually inspected and replaced if needed).

9.3.2 Components Replacement

Replacement of the following components should be performed by service technician every year:

- Probe wiper
- Syringe seals
- Waste filters (should be visually inspected and replaced if needed).

9.4 Disposal Information

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

Disposal Material

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

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Manufacturer Guidelines for Waste Products

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

Always follow local guidelines for open drain.

Decontamination and Disposal

The European Directive 2012/19/EU on Waste Electric and Electronic Equipment (WEEE) aims to minimize the impact on the environment by prevention of waste. The H50V veterinary hematology analyzer has been labeled with the WEEE symbol, and there is a procedure to allow waste collection and recycling of the equipment at the end of its life cycle.

- The instructions for decontamination and disposal, including reagents, can be found at boule.com under Product documents.
- If there are any question on how to follow this procedure, contact your local distributor for more information.
- The analyzer should be considered as infected, and the end user must follow a decontamination procedure before it is safe to hand over to a recycler.

10 Advanced Setup

10.1 Parameter

To change parameter units, do the following:

1. In the **Setup** interface, select **Param**.
2. Choose unit for the listed parameters (**WBC**, **RBC**, **PLT**, **HGB/MCHC**, **IRF**, **HCT** and **MCH**).
3. Select **OK** to save the settings.

To modify the reaction time for lysing RRBC, do the following:

1. In the **Setup** interface, select **Param**.
2. In **RRBC reaction time**, adjust the lysing time.
3. Select **Default** to revert to factory settings.
4. Select **OK** to save the settings.

10.2 Display

The Display function is used to customize which parameters are shown in the Parameter display area. For details on analysis parameters, see *Section 3.3*.

1. In the **Setup** interface, select **Display**.
2. Choose which parameters to be displayed.
3. Select **OK** to save the settings.

10.3 Transmit

The Transmit interface is used to set up the communication between the H50V analyzer and a computer with LIS.

1. In the **Setup** interface, select **Transmit**.
2. In **Ethernet port setup**, enter the IP address of the instrument as **Local IP**. Enter the IP address of the computer as **Server IP**. Enter the **port number** of the computer for the LIS to receive data. Local mask and local gateway can typically be left with default values.
3. In **Transmission setting**, set **Auto Trans** to **On** or **Off** to control automatic data transmission.
4. Select **Save** to save settings.

The **Serial Port** setting is used for connection between the instrument and computer with serial cable instead of ethernet.

Publ. Date: October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

10.4 Version

To view current version information, do the following:

1. In the **Setup** interface, select **Version**.
2. Select **Return** to go back to Set up interface.

10.5 Service

To enter the Service interface, do the following:

1. In the **Setup** interface, select **Service**.
2. Under **Password** enter appropriate command and select **OK**.

Only Boule authorized service engineers can enter the Service interface for maintenance.

10.6 System log

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

1. In the **Setup** interface, select **System log**.
2. Choose which file or files to export. Use the arrows to navigate the list.
3. Insert a USB memory stick into the analyzer.
4. Select **Export**. The chosen files will be downloaded to the USB memory stick.

11 Troubleshooting

This section gives instructions for identifying system problems and how to solve them. If the malfunction cannot be solved according to the instructions, or if more detailed information is needed, contact your local distributor or authorized service technician.



WARNING

- Refer to local regulations and established laboratory protocol for handling biohazardous materials. This should include use of gloves, lab coat and eye protection.

11.1 Troubleshooting Guidance

Troubleshooting guidance is used to assist the operator in identifying and resolving analyzer problems. The first step in the process is to understand normal analyzer operation, and the importance of performing routine maintenance. Good knowledge of the analyzer is essential for identifying and resolving operational problems.
Follow these three steps to troubleshoot:

1) Problem Confirmation

Confirm what the problem is and compare it to how it should be in normal circumstances. It is important to accurately identify the problem, to identify the proper solution.

2) Problem Classification

Problems are divided into three types.

- Hardware-related failures
- Software-related failures
- Failures of sample measurements

3) Troubleshooting

Address sample measurement problems using this guide. If no corrective action can be done, or if the problem is not corrected, contact your local distributor or authorized service technician.

11.2 Troubleshooting

Common error codes, probable causes, and corrective actions are listed below. If the problems cannot be corrected, or if technical assistance is needed, contact your local distributor or authorized service technician.

Publ. Date: October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Some motor functions in analyzer are equipped with transport locking, make sure that these locks have been removed before operating the analyzer.

During troubleshooting, the operator might be recommended to select **Fault clearing**. The function **Fault clearing** means that the analyzer will automatically take action to resolve the issue. The actions taken depend on the problem. For example, if a WBC or RBC Clog is the cause the analyzer will perform a series of cleaning cycles. Once corrected, the error code will disappear.

Error code	**Probable Cause**	**Corrective Action**
• MA motor fault • MB motor fault • MC motor fault • MD motor fault • MG motor fault • MH motor fault	1. Poor contact on motor signal line. 2. Optocoupler limit. 3. Motor fault. 4. Motor drive circuit fault. 5. Motor power fault. 6. Motor guide rod is not lubricated enough.	1. Check that all transport locks have been removed. 2. Select **Fault clearing** to clear faults automatically. 3. If the problem persists, contact your local distributor or authorized service technician.
• Expired Diluent • Expired Sheath • Expired Lyse • Expired Detergent	Reagent has expired.	1. Change reagent (refer to *Section 4.8*). 2. Select **Fault clearing** to clear faults automatically. 3. If the problem persists, contact your local distributor or authorized service technician.
• Diluent Empty • Sheath Empty • Lyse Empty • Detergent Empty	1. Reagent is empty. 2. Tube joint leakage or bubble. 3. Connecting tubes are bent or clogged.	1. Check if the reagent has run out. 2. If finished, change reagent (refer to *Section 4.8).* 2. Tighten the tube joint. 3. Neaten and unchoke tubes. 4. Select **Fault clearing** to clear faults automatically. 5. If the problem persists, contact your local distributor or authorized service technician.

Error code	Probable Cause	Corrective Action
• WBC Clog • RBC Clog	1. Aperture is clogged. 2. Tubes are bent. 3. Reagent replacement error. 4. Solenoid valve problem.	1. Select **Fault clearing** to clear faults automatically. 2. Clean impedance chamber with H50V Probe cleaner. In **Maintenance** interface, select **Setting** and perform **Soak impedance transducer**. Once prompted, aspirate H50V Probe Cleaner through sample probe. 3. If the problem persists, contact your local distributor or authorized service technician.
• WBC Bubble • RBC Bubble	1. Insufficient liquid in sample cup front chamber/ after chamber. 2. Tube joint is leaking. 3. Reagent replacement error. 4. Solenoid valve problem.	1. Select **Fault clearing** to clear faults automatically. 2. If the problem persists, contact your local distributor or authorized service technician.
HGB Blank voltage low	HGB blank voltage is low.	1. Select **Fault clearing** to clear faults automatically. 2. If the problem persists, contact your local distributor or authorized service technician.
HGB Blank voltage high	HGB blank voltage is high.	1. Select **Fault clearing** to clear faults automatically. 2. If the problem persists, contact your local distributor or authorized service technician.
Low vacuum	1. Vacuum tank is leaking. 2. Tubes are leaking.	1. Select **Fault clearing** to clear faults automatically. 2. If the problem persists, contact your local distributor or authorized service technician.
Optical pressure Abnormity	1. Pressure tank is leaking. 2. Tubes are leaking.	1. Select **Fault clearing** to clear faults automatically. 2. If the problem persists, contact your local distributor or authorized service technician.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Error code	Probable Cause	Corrective Action
Low temperature	Temperature is below 15°C.	1. Check if indoor temperature is too low. 2. If indoor temperature is normal, but alarm still rings, restart the analyzer. 3. If the problem persists, contact your local distributor or authorized service technician.
High temperature	Temperature is over 35°C.	1. Check if indoor temperature is too high. 2. If indoor temperature is normal, but alarm still rings, restart the analyzer. 3. If the problem persists, contact your local distributor or authorized service technician.
Waste full	1. Waste container is full. 2. Waste sensor is faulty.	1. Empty waste container or replace it. 2. If the problem persists, contact your local distributor or authorized service technician.
Optical communication error	Optical communication is abnormal. Cannot receive and send data.	1. Select **Fault clearing** to clear faults automatically. 2. If the problem persists, contact your local distributor or authorized service technician.
Printer is not responding	1. Connecting line not working. 2. Printer error.	1. Check the if the printer power cord and USB cable contacts well. Re-plug USB cable and power cord and restart the printer. 2. If the problem persists, contact your local distributor or authorized service technician.

11.3 Obtaining Technical Assistance

Contact your local distributor for orders and support. Have the product number ready for orders. For technical or other assistance, contact your local Boule service representative. Be prepared to provide the following information:

- Analyzer model.
- Serial number and version number.
- Description of the problem and surroundings, including status and operation.
- Lot numbers of reagents (Sheath, Diluent, Lyse, etc.).
- Related data and report of the problem.
- Pictures and videos may be asked for by the Boule service representative.

11.4 Abnormal Results

Alarm information	Interpretation	Measures
Abnormal WBC scatter diagram	WBC scatter diagram is abnormal.	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Neutropenia	Neu# < 1.00×10^9/L Low Neu count	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Neutrophilia	Neu# > 11.00×10^9/L High Neu count	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Lymphopenia	Lym# < 0.80×10^9/L Low Lym count	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Lymphocytosis	Lym# > 4.00×10^9/L High Lym count	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Monocytosis	Mon# > 1.50×10^9/L High Mon count	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Eosinophilia	Eos# > 0.70×10^9/L High Eos	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Basophilia	Baso# > 0.20×10^9/L High Bas	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Alarm information	Interpretation	Measures
Leukopenia	WBC < 2.50×10^9/L Low WBC count	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
Leukocytosis	WBC > 18.00×10^9/L High WBC count	Check the data and repeat the analysis or examine in accordance with the protocol of your laboratory.
NRBC increase	NRBC：Nucleated red blood cells. The following conditions may cause NRBC alarm: • WIC count>WOC count NRBC suspected to exist.	Re-analyze the samples in CBC+5DIFF+RRBC mode. Review the smear for abnormal cell morphology (abnormal RBC and NRBCs). IfNRBCs are present, they should be quantified and excluded from WBC count in accordance with your laboratory's policy.
Immature erythrocyte	Immature erythrocytes might exist.	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.
RRBC appears	RRBC：Refractory red blood cells. The following conditions may cause RRBC alarm: • WOC count >WIC count RRBC suspected to exist.	Re-analyze the samples in CBC+5DIFF+RRBC mode. Review the smear for abnormal cell morphology (abnormal RBC and NRBCs). IfNRBCs are present, they should be quantified and excluded from WBC count in accordance with your laboratory's policy.

Alarm information	Interpretation	Measures
Abnormal WBC results	WBC sign indicates WBC result is abnormal. 1.WBC exceeds linearity range. 2. There is a clinical difference between WIC value and WOC value, and accurate WBC value cannot be determined by algorithm.	1. Dilute the sample (eg 1:10) with Diluent. Re-analyze the samples in CBC+5DIFF. Multiply WBC, RBC and HCT by the dilution factor and determine MCV and MCH directly from the dilution. PLT is determined from the undiluted sample. 2. Perform a manual WBC differential according to your laboratory's policy.
Abnormal WBC differential count	DFLT：Leukocyte categories abnormal (NLMEB：N＝NEU, L =LYM, M ＝MON, E=EOS, B ＝BASO). The following conditions may cause a DFLT alarm: 1. The two cell populations areas overlap. 2. The number of cells in a specific subgroup is abnormally low. Such as WBC increase & decrease, neutrophil increase & decrease, lymphocytes increase & decrease, eosinophils increase & decrease, basophils increase & decrease.	Perform a manual WBC differential according to your laboratory's policy.
Parasitic infected RBC?	RBC might be infected with parasites.	Examine the peripheral smear to evaluate RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Alarm information	Interpretation	Measures
Abnormal LYM?	There might be abnormal LYM.	Perform a manual WBC differential according to your laboratory's policy.
Left shift?	Histogram shifts left.	Perform a manual WBC differential according to your laboratory's policy.
Atypical LYM?	There might be atypical LYM.	Perform a manual WBC differential according to your laboratory's policy.
Abnormal RBC size distribution	Height of histogram at parting line is over 20. Histogram between parting lines distributes double peaks.	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.
Bimodal RBC distribution	Histogram between parting lines distributes double peaks.	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.
Abnormal RET distribution	Scatter histogram distribution is abnormal.	Perform the reticulocyte count by an alternative method.
RETIC increase	RET% > 5% or RET# > 0.2×10^{12}/L High RET count	Perform the reticulocyte count by an alternative method.
Anisocytosis	RDW-SD > 65fL or RDW-CV > 20% Anisocytosis	No actions.
Microcytic RBC	MCV < 70fL Small RBC	No actions.
Macrocytic RBC	MCV > 110fL Large MCV	No actions.
Hypochromic	MCHC < 296g/L Low pigment	No actions.

Alarm information	Interpretation	Measures
Anemia	HGB < 100g/L Anemia	No actions.
Polycythemia	RBC > 6.5×10^{12}/L RBC increase	No actions.
RBC aggregation?	RBC < 3.5×10^{12}/L and MCH > 34 pg Might be due to Macrocytic RBC or Abnormal RBC size distribution	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.
Chylemia affects HGB?	MCHC > 400g/L	Examine the plasma for lipemia, hemolysis or icterus. If sample is lipemic or icteric, perform a plasma replacement, or a dilution to obtain accurate HGB.
Iron deficiency?	MCV < 73fL and MCH < 21pg and MCHC < 320g/L Maybe hypoferric anemia	No actions.
Abnormal HGB?	MCV < 75fL and MCH < 25pg and RDW-SD < 45fL Maybe HGB anomaly or interference factors exist.	No actions.
Fragmented RBC?	Abnormal output sign of PLT size distribution, and microcyte alarm. Doubt erythroclasis.	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.
Light β- thalassemia?	Judge by original signal and test results. Maybe anemia	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

Alarm information	Interpretation	Measures
Sideroblastic anemia?	Judge by original signal and test results. Maybe anemia	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.
Megaloblastic anemia?	Judge by original signal and test results. Maybe anemia	Examine the peripheral smear for the presence of abnormal RBC morphology. Report any clinically significant finding according to individual laboratory guidelines.
Abnormal PLT size distribution	Abnormal PLT size distribution	Examine the peripheral smear for the presence of abnormal PLT morphology. Perform a manual platelet estimate to ensure the count is accurate.
Thrombocytopenia	PLT < 60×10^9/L Thrombocytopenia	Examine the peripheral smear for the presence of PLT aggregation. Perform a manual platelet estimate to ensure the count is accurate.
Thrombocytosis	PLT > 600×10^9/L Thrombocytosis	Examine the peripheral smear for the presence of abnormal PLT morphology. Perform a manual platelet estimate to ensure the count is accurate.
PLT aggregation?	Results might be affected by aggregated PLT.	Examine the peripheral smear for the presence of PLT aggregation.

NOTE

- If there is a request to adjust the limits related to an alarm, contact your local Boule representative.

12 Appendix

12.1 Appendix A: Components and Consumables

This appendix provides additional information about Boule components and consumables. For ordering information, contact your local Boule representative.

Analyzer system

Article name	Article number
H50V Veterinary Hematology System	1440101

Documentation

Article name	Article number
User Manual	1504672
Quick Reference Guide	1504673
Decl. of Conformity H50V	1504647
Installation checklist H50V	1504532
Transport protection removal instruction	1440203

Consumables

Article name	Article number
H50V Diluent 10 L, RFID	1440102
H50V Diluent 5 L, RFID	1440103
H50V Diluent 1.9 L, RFID	1440104
H50V Detergent 5 L, RFID	1440105
H50V Detergent 1.9 L, RFID	1440106
H50V Sheath 5 L, RFID	1440107
H50V Sheath 1.9 L, RFID	1440108
H50V Lyse 500 mL, RFID	1440109
H50V Lyse 200 mL, RFID	1440110
H50V Probe Cleaner, 100 ml	1440111
H50V Reticulocyte stain, 50 x 4 ml	1440112

For further information on which consumables you require for your analyzer, contact your local Boule representative.

October 2025. Article No. 1504672_EN ©2023-2025 Boule Medical

FCC ID: 2BPEL1440101

Produced by Boule Medical AB
DOMNARVSGATAN 4, 163 53 Spanga, Sweden

Publ. date: October 2025. Article no. 1504672_EN. © 2025 Boule Medical