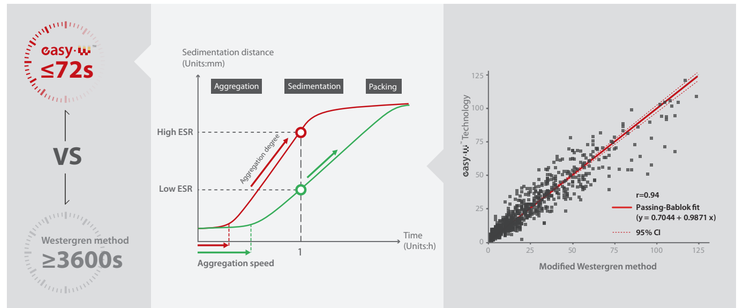
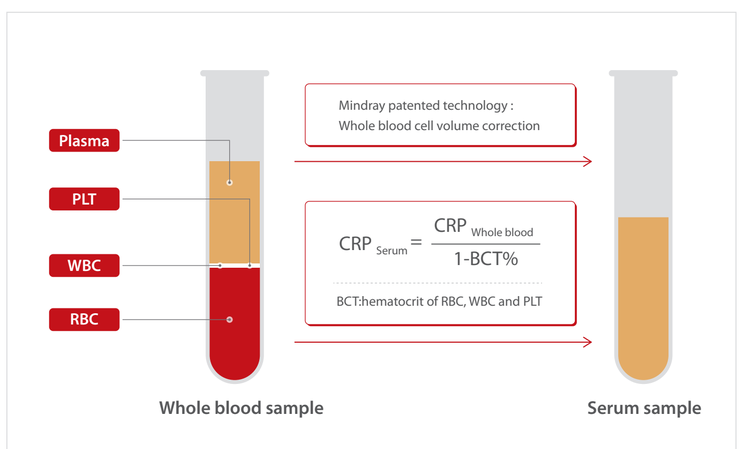
ESR
All in 6™



CRP
All in 6™

The function of CRP modification ensures that the result of CRP $_{Serum}$ and CRP $_{whole\ blood}$ are consistent.



BC-760 CS

Auto Hematology Analyzer with ESR and CRP

Principles
WBC (IMG/Neu/Mon/Lym/Eos/Bas)/PLT-H/IPF
SF Cube ^ Cell Analysis Technology (^S: Scatter; F: Fluorescence; Cube: 3D analysis)

RBC, PLT
Focusing Flow-DC Impedance Method

HGB
Colorimetric method

ESR
Photometric method

CRP
Latex Particle-Enhanced Immunonephelometry Method

Kokybės kriterijus Nr.1
ENG matavimo greitis

Parameters
Number of measuring parameters (whole blood): 44+68
Number of reportable parameters: 44
WBC Bas# Bas% Neu# Neu% Eos# Eos% Lym# Lym% Mon# Mon% IMG# IMG% RET%* RET#* RHE* IRF* LFR* MFR* HFR* RBC HGB MCV MCH MCHC RDW-CV RDW-SD HCT NRBC# NRBC% PLT PLT-I PLT-H MPV PDW PCT P-LCR P-LCC IPF ESR CRP FR-CRP hs-CRP
Number of research parameters:68

Number of measuring parameters (body fluid): 7+11
Number of reportable parameters: 7
WBC-BF TC-BF# MN# MN% PMN# PMN% RBC-BF
Number of research parameters: 11

4. Matuojami parametrai

Kokybės kriterijus Nr.3
NRBC("#", "%") atliekamas diagnostinis tyrimas

Kokybės kriterijus Nr. 1
ENG mėginio tūris

Sample volume
CD (whole blood): ≤25ul
ESR (whole blood): ≤140ul
CD+CRP (whole blood): ≤34ul
CD+ESR+CRP (whole blood): ≤160ul
CD (predilute): ≤20ul

7. Mėginio tūris
CD (visas kraujas): ≤25 ul
ESR (visas kraujas): ≤140 ul
CD+CRB (visas kraujas): ≤34 ul
CD+ESR+CRB (visas kraujas): ≤160 ul
CD (praskiestas): ≤20 ul

Data storage capacity
Up to 130,000 results including numeric and graphical information

Throughput
CD (whole blood): up to 80t/h
CDR (whole blood): up to 45t/h
CRP (whole blood): up to 60t/h
ESR (whole blood): up to 50t/h
CD (body fluid): up to 50t/h
CD+CRP(whole blood): up to 60t/h
CD+ESR(whole blood): up to 40t/h
CD+CRP+ESR(whole blood): up to 30t/h

3. Analizatoriaus našumas skirtinguose režimuose

Sample Type
Whole blood
Predilute
Body fluid

Main Unit Dimensions and Weight
Width (autoloader included)≤411mm
Height (autoloader included)≤600mm
Depth (autoloader included)≤728mm
Weight (autoloader included)≤73kg

Power Requirements
Voltage:100V-240V~ (±10%)
Frequency:50Hz/60Hz (±1Hz)
Power input:600VA

External output
LANx1 , USB x 4 (Specifications: DC 5V; 500mA; USB2.0 ; USB3.0)

Normal Operating Environment
Ambient temperature:10℃ ~ 35℃
Relative humidity: 30% ~ 85%
Atmospheric pressure:70.0kPa ~ 106.0kPa^
^Note : Required altitude for normal operation: -400m ~ +3000m

www.mindray.com

P/N:ENG-BC-760 CS-210285X6P-20220628

mindray
healthcare within reach

Kokybės kirterijus Nr. 1

Eritrocitų nusėdimo tyrimas

mindray

BC-760 CS

Auto Hematology Analyzer with ESR and CRP

Above and Beyond

1. Analizatoriaus pavadinimas, modelis ir gamintojas: Mindra, Hematologinis analizatorius su ENG ir CRB, BC-760CS

Above your expectations

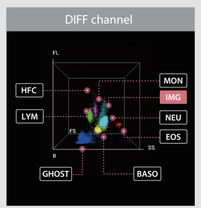
- **SF Cube fluorescent technology allows reliable counting and differentiation of abnormal samples.**

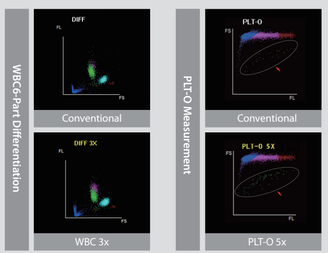
CBC All in 5 Diff™

More refined and reliable cell differentiation

3D fluorescent analysis technology allows reliable differentiation of immature and other abnormal cells, such as immature granulocytes (IMGs), reticulocytes (RETs*), and immature platelet fraction (IPF).

SF Cube™



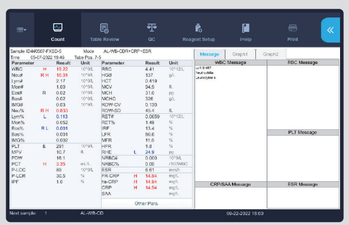


More reliable measurements for low-value samples

The BC-760 3D fluorescence analysis platform is designed with multiple counting analysis modes to help ensure higher reliability for low-value WBC and PLT.

More comprehensive alarm messages for abnormalities

The analyzer provides a detailed list of over 40 prompt messages, including WBC message, RBC message, and PLT message. This allows laboratory technicians to intuitively and quickly identify abnormal samples and proceed further with the samples in a timely manner. This in turn helps to avoid missed diagnosis of blood disease and false reports.

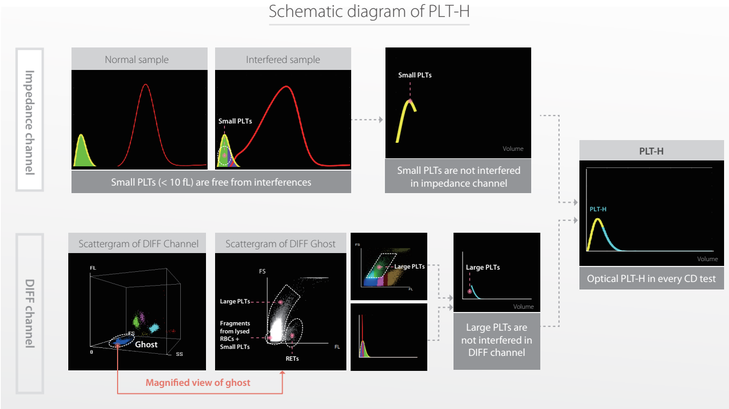


Optical PLT-H in every CBC+DIFF test

In the traditional impedance method, PLTs are subject to interferences that may lead to falsely high or falsely low results. Once an error report is generated, it will directly affect the judgment and decision-making of clinicians. The results reported at the clinical decision level are related to patient safety. Therefore, accurate PLT results are critical in clinical practice.

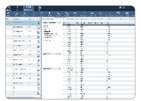
PLT-H combines small PLTs from the conventional impedance method and large PLTs from the optical method. The solution can resist the interferences in conventional PLT detection without requiring extra reagents.

Schematic diagram of PLT-H



Beyond your expectations

RFID
Encryption key management



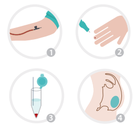
labXpert
Coming as standard configuration
Same software as BC-6 series

Floating screen
Switching between different analysis modes with a single touch

- **Excellent performance, high reliability, and ease of use**

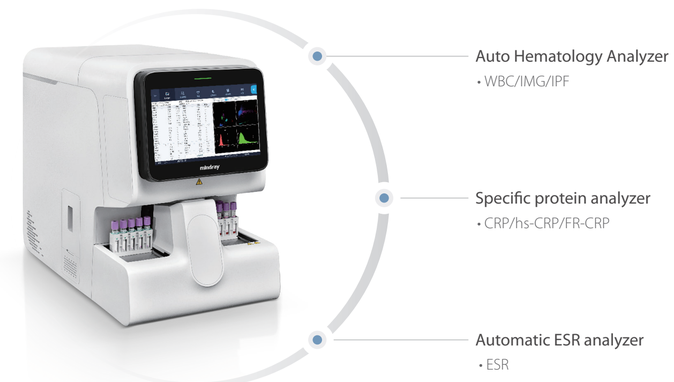
Full-automatic
Capillary blood autoloading and mixing

Cap piercing STAT
Supports STAT samples and capillary blood samples; minimizes bio-safety hazards



Applicable to different sample types
Peripheral blood/Capillary blood
Pre-diluted blood/Body fluid

Excellent performance — **Superior functionality** — **Interactive excellence**



B.5 Sampling Features

B.5.1 Sample modes, test panel, and applicable model

Table B-8 List of sample modes, test panel, and applicable models

Sample mode		Test Panel	Applicable Model
Whole blood samples	CT-WB	CBC,CD,Ret,CR,CDR; CRP,SAA,CRP+SAA; CD+CRP,CD+SAA,CD+CRP+SAA; CDR+CRP,CDR+SAA,CDR+CRP+SAA; ESR; CBC+ESR,CD+ESR,CD+CRP+ESR,CD+CRP+SAA+ESR; CDR+ESR,CDR+CRP+ESR,CDR+CRP+SAA+ESR	BC-760[R] CS
		CBC,CD; CRP,SAA,CRP+SAA; CD+CRP,CD+SAA,CD+CRP+SAA; ESR; CBC+ESR,CD+ESR,CD+CRP+ESR,CD+CRP+SAA+ESR	BC-760[B] CS
	CT-Low WBC	CD/WBC-3X	BC-760[B] CS
		CD/WBC-3X, CDR/WBC-3X	BC-760[R] CS
	CT-Low PLT	CR/PLT-5X, CDR/PLT-5X	BC-760[R] CS
CT-PD		CBC,CD,Ret,CR,CDR; CRP,SAA,CRP+SAA; CD+CRP,CD+SAA,CD+CRP+SAA; CDR+CRP,CDR+SAA,CDR+CRP+SAA	BC-760[R] CS
		CBC,CD; CRP,SAA,CRP+SAA; CD+CRP,CD+SAA,CD+CRP+SAA	BC-760[B] CS
CT-BF		CD	General
Whole blood samples	AL-WB	CBC,CD,Ret,CR,CDR; CRP,SAA,CRP+SAA; CD+CRP,CD+SAA,CD+CRP+SAA; CDR+CRP,CDR+SAA,CDR+CRP+SAA; ESR; CBC+ESR,CD+ESR,CD+CRP+ESR,CD+CRP+SAA+ESR; CDR+ESR,CDR+CRP+ESR,CDR+CRP+SAA+ESR	BC-760[R] CS
		CBC,CD; CRP,SAA,CRP+SAA; CD+CRP,CD+SAA,CD+CRP+SAA; ESR; CBC+ESR,CD+ESR,CD+CRP+ESR,CD+CRP+SAA+ESR	BC-760[B] CS

2.
CD = CBC+ DIFF
Matavimo rėžimai:
Kokybės kriterijus Nr. 2
Matavimo rėžimas CBC+DIFF+CRB +ENG (CD=CBC+DIFF)

NOTE

- **The SAA test panel is applicable to models configured with SAA channel.**

4.3.2 Derivation of HGB

Hemoglobin Concentration (HGB) is calculated using the following equation and expressed in g/L.

Parameters	Name	Formula/Test Methods	Unit
HGB	Hemoglobin Concentration	$HGB = Constant \times Ln\left(\frac{Blank\ Photocurrent}{Sample\ Photocurrent}\right)$	g/L

4.4 RBC/PLT Measurement

4.4.1 Sheath Flow Impedance Method

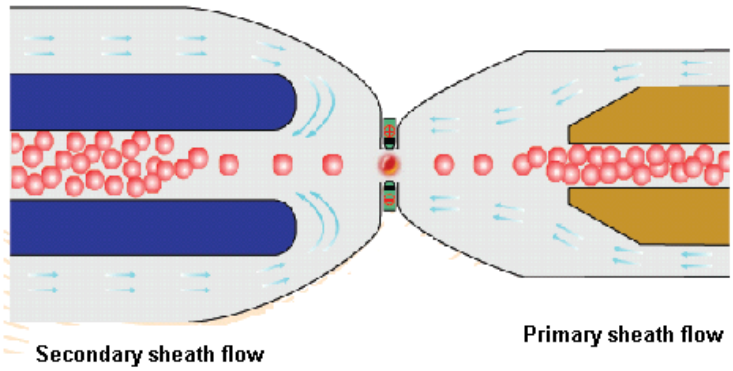


Figure 4-4 Sheath flow impedance method

RBCs/PLTs are counted by the sheath flow impedance method. A sensor is designed to enable the RBCs and PLTs to pass through the aperture one by one in a queue under the "focusing" effect of fluid, during which process pulses will be generated according to the Coulter Principle. The backend processor amplifies the pulses and compares them with the voltage thresholds of the RBC/PLT channel, and then the number of pulses in the RBC/PLT channel is calculated. That is to say, the pulses collected are sorted per the voltage thresholds of different channels, the number of pulses falling in the range of the RBC/PLT channel is the number of RBC/PLT. The number of cells in each channel defines the volume distribution of cells. The analyzer presents the RBC/PLT histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells.

5. Analizatorius pateikia RBC/PLT histogramą

Compared with the common impedance method, the sheath flow impedance method is featured by higher efficiency, better signal quality, more accurate analysis results and lower consumption of reagents.

4.4.2 Measurement Principle of Platelets in DIFF Channel (PLT-H)

Traditional impedance method counts platelets by sorting and detecting the pulses fall in the PLT channel per cell size. However, as microcytes and fragments are similar in size with platelets with relatively large size, when there are microcytes/fragments present, the impedance method may deliver not so accurate PLT results. To solve the problem, the analyzer lyses the erythrocytes in the DIFF channel, so the count of platelets in relatively large sizes in DIFF channel will not be affected by erythrocytes. By combining the large-size platelet count result in DIFF channel and the small-size platelet count result in the impedance channel, the analyzer provides more accurate PLT results.

4.4.3 SF CUBE Cell Analysis Technology

The RET channel also adopts the SF CUBE Cell Analysis Technology. The general measurement principle in RET channel is similar to that of DIFF channel, only that in the RET channel, the RBCs are not lysed, but are spherized by RET diluent. Then the nucleic acid of the spherized RBCs and the PLTs are stained by fluorescent dyes.

4 Understanding the System Principles

4.1 Overview

Ląstelių diferenciacijai ir skaičiavimui skirta apvalkalo srauto impedanso metodas, lazerio sklaida ir SF Cube ląstelių analizės technologija (3D analizė, naudojant informaciją iš lazerio šviesos sklaidos dviem kampais ir fluorescencijos signalus);

The principles used by the analyzer are:

5.

- Sheath flow impedance method, laser scatter and SF Cube cell analysis technology (3D analysis using information from scatter of laser light at two angles and fluorescence signals) for cell differentiation and counting;
- Colorimetric method for HGB measurement.
- Latex particle-enhanced immunonephelometric method for C-reactive protein concentration and Serum Amyloid A (SAA) concentration measurement.

Based on the above data, the analyzer calculates other parameters.

4.2 WBC Measurement

4.2.1 SF CUBE Cell Analysis Technology

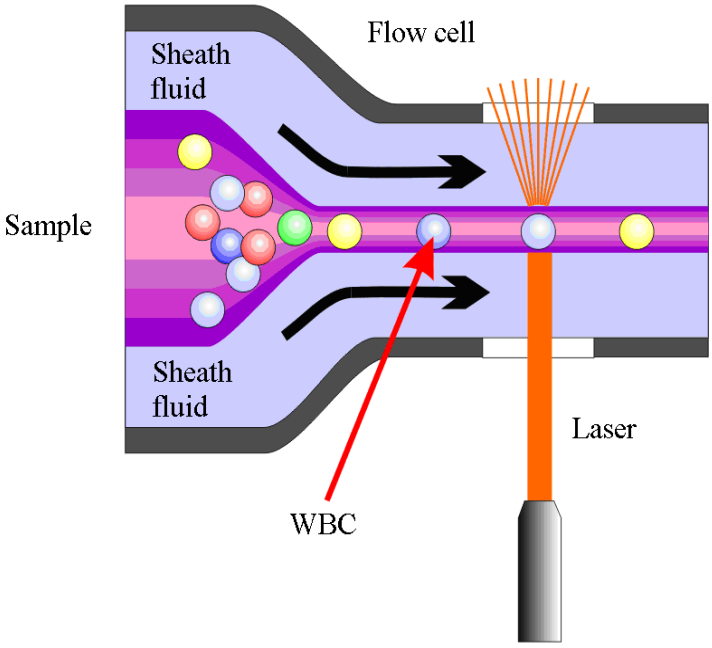


Figure 4-1 Laser flow cytometry

In normal peripheral blood, white blood cells can be classified into five categories: lymphocytes, monocytes, neutrophils, eosinophils and basophils. Analyzing all types of white blood cells will provide a great deal of useful information for the clinical diagnosis of diseases. Under the influence of certain diseases, the peripheral blood may contain various abnormal cells apart from the five subpopulations of normal cells, such as

atypical lymphocytes, immature cells, etc. Most of these abnormal cells are different kinds of immature cells in the cell generation process. But what they have in common is they contain a great deal of nucleic acid (DNA and RNA), the content of which decreases as the cell gets maturer. Therefore, normal cells and immature cells can be differentiated by detecting the content of nucleic acid in the cells.

Body fluid refers to the fluid in side body cavities except blood vessels. There are many sub-types of body fluid, among which the most commonly seen sub-types are cerebrospinal fluid, pleural fluid, ascitic fluid, and synovial fluid. Both cerebrospinal fluid and serous cavity fluid are colorless and transparent in normal case, but in abnormal cases, there could be increase of cells (including leukocytes and erythrocytes). Leukocytes in body

B.6.2 Linearity Ranges

6.

Matavimo ribos

Table B-12 Linearity requirements for blood samples

Parameters	Linearity Range	Acceptable Deviation Range (WB)	Acceptable Deviation Range (PD)	Correlation Coefficient
WBC	(0 ~ 100.00)×10^9/L	±0.20×10^9/L±2%	±0.50×10^9/L±5%	≥ 0.990
	(100.01 ~ 350.00)×10^9/L	±6%	±6%	≥ 0.990
	(350.01 ~ 500.00)×10^9/L	±11%	±11%	≥ 0.990
RBC	(0 ~ 8.60)×10^{12}/L	±0.03×10^{12}/L±2%	±0.05×10^{12}/L ±5%	≥ 0.990
HGB	(0 ~ 260) g/L	±2g/L±2%	±2g/L or ±3%	≥ 0.990
HCT	(0.0 ~ 75.0)%	±1.0% (HCT) or ±2% (percentage error)	±2.0% (HCT) or ±4% (percentage error)	/
PLT	(0 ~ 1000)×10^9/L	±10×10^9/L±5%	±10×10^9/L±10%	≥ 0.990
	(1001 ~ 5000)×10^9/L	±6%	±10%	≥ 0.990
RET%	(0.00 ~ 30.00)%	±0.30% (RET% value) or ±20% (percentage error)	/	/
RET%	(0.0000~0.8000)×10^{12}/L	±0.0150×10^{12}/L±20%	/	/
*FR-CRP	0.20mg/L~10.00mg/L	±1.00mg/L	/	≥ 0.990
	10.01mg/L~100.00mg/L	±15%	/	≥ 0.990
	100.01mg/L~320.00mg/L	±20%	/	≥ 0.990
SAA	5.00~20.00mg/L	±3.00mg/L or ±15%	/	≥ 0.990
	20.01~350.00mg/L	±15%	/	≥ 0.990

*Note: FR-CRP covers CRP and hs-CRP.

Table B-13 Linearity requirements for body fluid samples

Parameters	Linearity Range	Deviation range
WBC-BF/TC-BF#	(0~0.050)×10^9/L	±0.010×10^9/L
	(0.051~1.000)×10^9/L	±20%
	(1.001~10.000)×10^9/L	±20%
RBC-BF	(0.000~0.100)×10^{12}/L	±0.010×10^{12}/L or ±5%
	(0.101~5.000)×10^{12}/L	±0.030×10^{12}/L or ±2%

B.6.3 Accuracy

B.6.3.1 Blood parameter accuracy

Table B-14 Accuracy requirements

Parameters	Measurement Range	Acceptable Relative Deviation Range/%
WBC	3.50×10^9/L~9.50×10^9/L	Within ±10.0
RBC	3.80×10^{12}/L~5.80×10^{12}/L	Within ±6.0

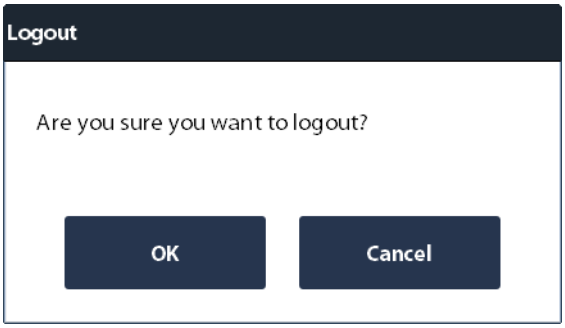
7.3.2 Switching Login Account

If logged in as an administrator's account, the lower right corner of the screen displays "**Administrator**".

If necessary, perform the following steps to switch the login account. To set an account or change the password, refer to ***6.3.2User Management ("Menu > "Setup" > "User Management")***.

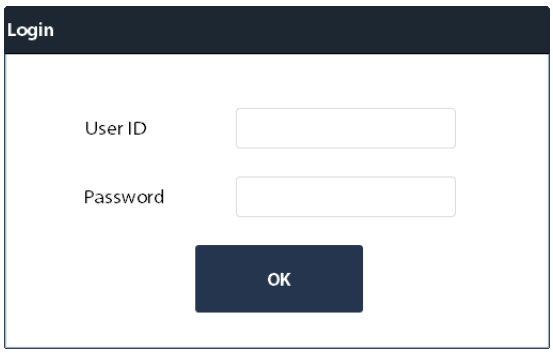
1. Tap "**Menu**" > "**Logout**" in turn.

√ A dialog box displays



2. Tap "**OK**".

√ The login dialog box displays



3. Enter the new "**User ID**" and "**Password**", and tap "**OK**" to log in.

7.4 Daily QC

Before running any samples, run the controls to ensure reliable results of the analyzer. Please see ***9Using the QC Program*** for details.

7.5 Preparing Samples

7.5.1 Preparing Whole Blood Samples (For WB Mode)

To attain accurate analysis results, make sure the venous blood sample volume meets the following requirements:

Table 7-1 Whole Blood Sample Volume

Sampling and sample modes	Tube Position	Cap open?
CT-WB	Regular tube/Micro-WB tube	Either
AL-WB	Tube rack	No

7. ir Kiekybinis kriterijus Nr.2

Iš įprasto ir mikro mėgintuvėlių kapiliariniam kraujui tyrimai yra atliekami iš uždarų ir atvirų mėgintuvėlių

13. Automatiniame rėžime tyrimai yra atliekami iš uždaro mėgintuvėlio

- **When the sample mode or sampling mode changes, the analyzer will switch the mode automatically and a message will be displayed.**
- **Up to 372 QC results can be saved in each QC file.**

9.2.3 Reviewing L-J QC Results

After QC analysis, you can review the QC results in the "**QC Table**" review or "**QC Graph**" review.

9.2.3.1 QC Graph Review

Reviewing QC Graph

1. Tap "**Menu**"-"**QC**"-"**L-J QC**"-"**Setup**" in turn, and then tap"**Blood Routine Test ESR QC**" to enter the L-J QC file setup screen.
2. Select the desired QC file to review.

√ The "*" mark displays next to the "**File No.**" of the selected QC file.

3. Tap "**QC Graph**" to enter the QC graph review screen of the selected QC file.

8.

Levey - Jehnings kokybės kontrolės grafikai

Introduction to the L-J Blood QC Graph Screen

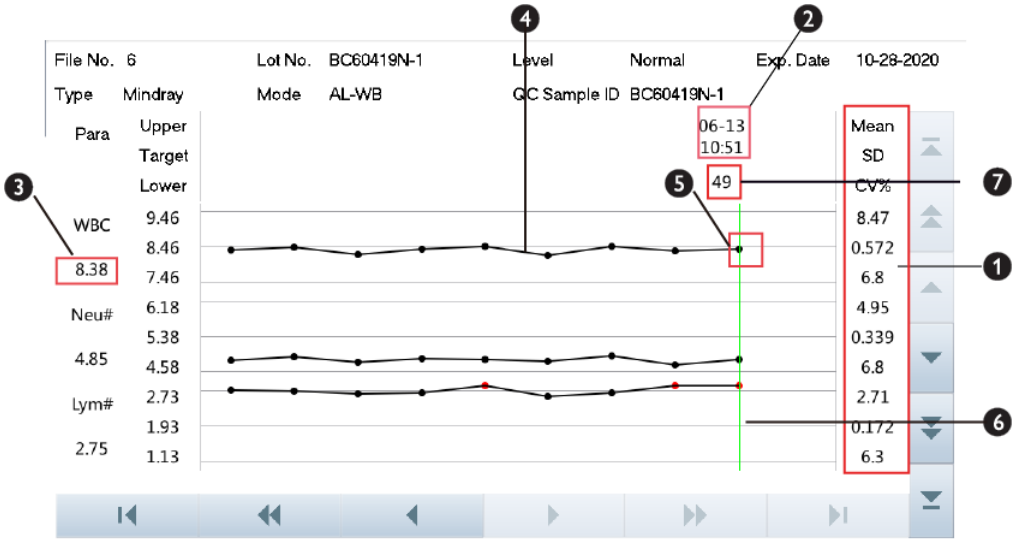


Figure 9-2 L-J Blood QC Graph

1—The Mean, SD and CV% of all the QC results of each parameter in the current graph.

2— The saving date and time of the QC point on the green line.

3— The QC result of the QC point on the green line.

4—The line connecting all QC points of the same parameter to show the trend. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest.

5— Currently selected QC point. The analysis result of the selected QC point is displayed under the parameter. A black QC point indicates the value is within the limit; a red QC point indicates the value is out of the limit.

6— The green vertical line is used to identify a selected QC point and all parameter values of the QC point.

7— The sequence number of the QC point on the green line among all the QC points in the current QC file.

Set Limits	Tap "**Set Limits**" and select "By SD (#)" or "By CV (%)"	When "**By SD**(#)" is selected, the limits are displayed in the format of SD value; When "**By CV**(%)" is selected, the limits are displayed in the format of CV percent.

BIOLOGICAL RISK

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

After editing X-B setup, the system will start X-B QC automatically.

After every 20 to 200 valid sample results (determined by the "**Samples/Batch**" setup, the system will perform the X-B calculation once automatically. You can review the result in X-B QC graph or X-B QC table.

9.4.3 Reviewing X-B QC Results

After QC analysis, you can review the QC results in the "QC Table" review or "QC Graph" review.

9.4.3.1 QC Graph Review

Tap "**Menu**" > "**QC**" > "**X-B QC**" > "**Graph**" in turn to enter the X-B QC Graph screen.

8.

Paciento kokybės (XB) grafikai

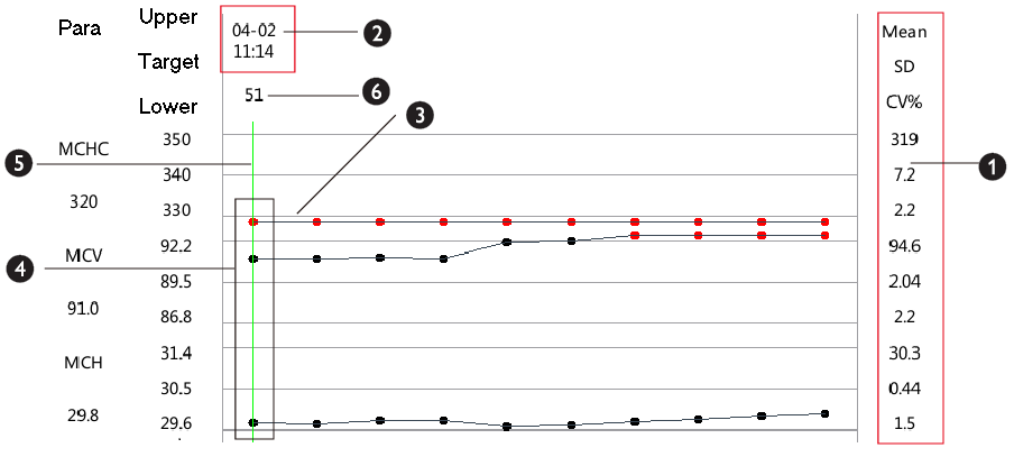


Figure 9-7 X-B QC Graph Screen

1—The Mean, SD and CV% of all the QC results of each parameter in the current graph.

2— The saving date and time of the QC points on the green line.

3—The line connecting all QC points of the same parameter to show the trend. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest.

4— Currently selected QC point. The analysis result of the selected QC point is displayed under the parameter. A black QC point indicates the value is within the limit; a red QC point indicates the value is out of the limit.

5—The green vertical line is used to identify the QC points of the same analysis, all of which are displayed on the line when you select one of them.

6—The relative position of the QC point where the green vertical line is located in all QC points of the current QC file.

9.4.3.2 QC Table Review

1. Tap "**Menu**" > "**QC**" > "**X-B QC**" > "**Graph**" in turn to enter the X-B QC Graph screen.

- **If "Auto-Scan sample ID" is selected and the tube No. scanned is invalid, then "??" will be the tube No.. For the information of enabling or disabling "Auto-Scan sample ID", refer to *6.3.3.1Getting sample information*.**
- **For the information of enabling or disabling "Display summary after autoloading finished", refer to *6.3.7Setting up Functions for the Auto-Loading of Samples (Menu > "Setup" > "Auto-loading") (administrators)*.**

7.7.3 Stop Count

If you need to stop auto-loading analysis during the analysis process, follow below instructions.

During the analysis process, tap the "**Stop Count**" button on the pop-up window.

√ The analyzer will stop running after the current sample is analyzer,

√ The rack of the sample will move to the left tray of the autoloader.

7.8 STAT

Use this function to insert STAT samples during the auto-loading analysis process.

1. On the "**Count**" screen, tap « and then tap the "**STAT**" button on the pop-up window.

√ After the current sample has been analyzed, the analyzer will stop the autoloading operation and switch from AL Mode to CT Mode.

9.

Naudokite šią funkciją STAT mėginiams įterpti automatinio įkrovimo analizės proceso metu.
1. Ekrane „Count“ (Skaičiavimas) palieskite , tada iššokančiajame lange palieskite mygtuką „STAT“.
√ Išanalizavus dabartinį mėginį, analizatorius sustabdys automatinio įkrovimo operaciją ir persijungs iš AL režimo į CT režimą.

√ The pop-up window is switched to "**CT Mode**" page.

√ The sample compartment reaches out.

2. Enter the sample information and select the desired sample mode and analysis mode.
3. Place STAT samples in the sample compartment.
4. Select "**Start Count**" to start STAT samples analysis.
5. When STAT samples analysis completes, the sample compartment reaches out. Take out STAT samples.
6. (Optional) Repeat steps 2 to 5 to complete all STAT samples analysis.
7. Exit STAT using either of the following methods.

■ Exit STAT manually.

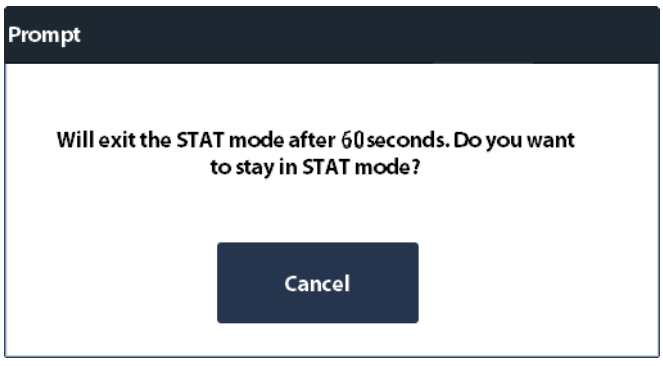
Select "**Exit STAT**".

■ Exit STAT automatically.

NOTE

- **For the instruction of enabling "Auto exit STAT" function, refer to *6.3.3Auxiliary Setup ("Menu" > "Setup" > "Auxiliary Setup")*.**

a When you do not place STAT samples in the sample compartment during the pre-defined time range, a prompt as shown in the figure below is displayed.



b (Optional) To continue STAT samples analysis, select "**Cancel**".

c The analyzer automatically exits STAT when count-down ends.

■ If you are running a venous blood sample collected in an evacuated blood collection tube, shake the tube as instructed by the picture below to mix the sample thoroughly.

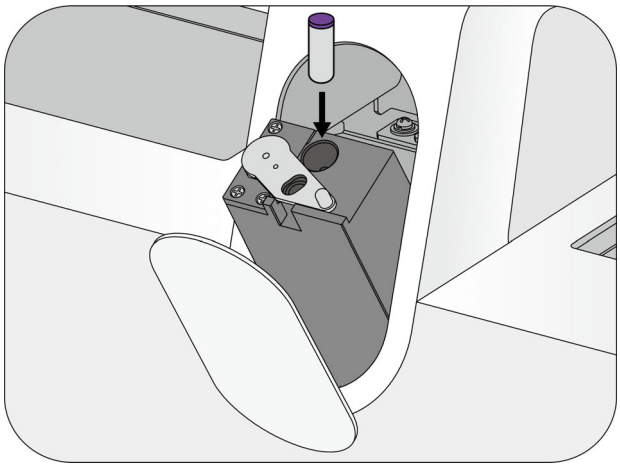
■ If you are running a capillary blood sample collected in a centrifugal tube, cap the tube and shake the capped tube to mix it thoroughly.

2. Place the sample tube into the appropriate tube position in the sample compartment.

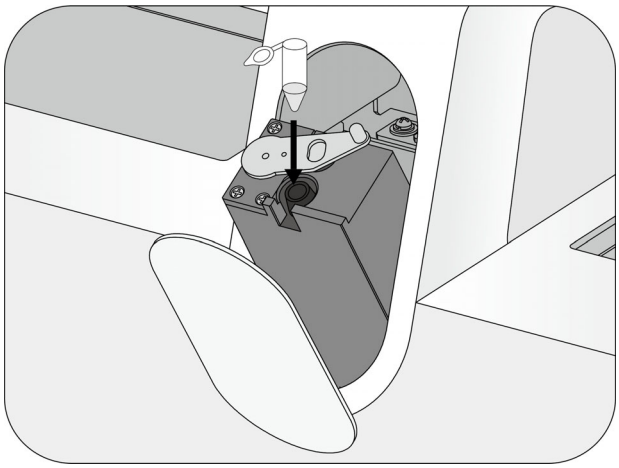
Jei naudojate mėginį, surinktą į vakuuminį surinkimo mėgintuvėlį, įsitikinkite, kad mėgintuvėlio padėties jungiklis yra „Micro WB“ mėgintuvėlio padėties pusėje. Tada įdėkite vakuuminius surinkimo mėgintuvėlius į įprastą mėginių skyriaus padėtį.

9.

■ If you are running a sample collected in an evacuated collection tube, make sure the tube position switch is at the Micro WB tube position side. Then place the evacuated collection tubes into the regular position of sample compartment..



■ If you are running capillary whole blood sample collected in centrifuge tubes, make sure the tube position switch is at the regular tube side and proper adapter is installed, then uncap the centrifuge tube and place it at Micro-WB tube position.



NOTE

- **When the sample compartment is reaching out, do not block it.**

3. Press the "**Start Count**" key on screen to start sample analysis.

√ The sample compartment closes, and the sampling probe automatically aspirates sample.

4. After the analyzer finishes aspirating sample, the sample compartment opens. You can remove the sample safely.

√ The analyzer automatically analyzes the sample, the analyzer indicator is flickering in green.

√ When the analysis completes, the analyzer indicator returns to "Ready" status (stay in green).

√ The screen displays the current sample results, histograms, scattergrams and flags (if there is).

B.7.1 Keyboard

USB port (supporting the protocol of USB2.0 and above) keyboard.

B.7.2 Mouse

USB port (supporting the protocol of USB2.0 and above) mouse.

B.7.3 External barcode scanner

USB port (supporting the protocol of USB2.0 and above) hand-held barcode scanner.

10. Išorinis brūkšninių kodų skaitytuvas
Rankinis brūkšninių kodų skaitytuvas su USB prievadu (palaikantis USB 2.0 ir naujesnius protokolus).

B.7.4 Printer

USB port (supporting the protocol of USB2.0 and above) printer.

B.7.5 USB Drive

Supporting the protocol of USB2.0 and above.

B.7.6 Electronic Interface Specifications

NOTE

- **Connection of the electronic interface to an IT network that includes other equipment could result in previously unidentified risks to patients, users or third parties; the responsible organization should identify, analyse, evaluate and control these risks.**

	Specifications	
Communication format (protocol) and relevant standards	USB ports	Type A interface, complied with USB 2.0/3.0 standard.
	Network ports	TCP/IP protocol bottom layer. DICOM/HL7 protocol application layer. RJ45 interface, supporting wired network 10 M/100 M/ 1000 M, and complied with technical standard IEEE802.3. NTP/SNTP Calibration protocol of TCP/IP.
Time setting	The time on the analyzer should be set to the correct local time.	

B.8 Interfaces

NOTE

- **The USB interfaces on the back of the analyzer shall only be used to connect the peripheral devices specified in this manual. See Appendix *B.7 Requirements for Input/Output Devices* for details about supported devices and models.**

- One network port (compatible with 10/100/1000M Ethernet and complying with the 802.3u/802.3ab standard)
- Four USB ports including three supporting USB2.0 and one supporting USB3.0 (specification: DC 5V; 500 mA)

B.9 Power supply

	Voltage	Input power	Frequency
Main unit	100V-240V~ (±10%)	600 VA	50 Hz/60 Hz (±1 Hz)

Enter a number (n) into the edit box of "**Prefix Length**". The first n characters in the sample ID will not be auto increased.

NOTE

- **Prefix Length cannot exceed 20 digits.**

Setting of the first sample after startup

Set the test panel for the first sample after startup in accordance with the real needs in your laboratory.

Follow below instructions:

1. Tap "**Menu**" > "**Setup**" > "**Auxiliary Setup**" > "**Get Sample Information**" to enter the "**Get Sample Information**" screen.
2. In the "**Setting of the first sample after startup**" area, set the test panel for the first sample after startup.

■ Define the mode for the first sample after startup:

1. In the "**First sample after startup**" pull-down list, select "**Custom**".
2. In the "**Mode**" pull-down list, select the desired mode.
3. In the "**Sample ID**" edit box, enter the ID (1 by default) of the first sample after startup.

√ After each startup, the first sample is analyzed according to the set sample ID and mode by default.

■ Test the sample according to the mode of the last sample before shutdown:

1. In the "**First sample after startup**" pull-down list, select "**Run the suspended sample after restart**".

√ The sample ID of the first sample after each startup increases by 1 on the basis of the ID of the last sample before shutdown; the sample is tested according to the mode of the last sample before shutdown.

10. **Getting sample information**

The setup is applicable to the analyzer with built-in rotary scanner.

Mėginio informacijos gavimas
Sąranka taikoma analizatoriui su integruotu rotaciniu skaitytuvu.

This function is for "Auto-Scan rack No." setup under autoloading mode. Select "Auto-Scan rack No.", and the analyzer starts to scan rack No. automatically.

Follow below instructions:

1. Tap "**Menu**" > "**Setup**" > "**Auxiliary Setup**" > "**Get Sample Information**" to enter the "**Get Sample Information**" screen.
2. Tap "**Auto-Scan rack No.**" in the "**Get Sample Information**" area.

6.3.3.2 Protein module setup (administrators)

On "**Protein Module Setup**" screen, you can：

■ set the CRP report parameters to be displayed;

■ set the display thresholds for protein parameters measurement values.

1. Tap "**Menu**" > "**Setup**" > "**Auxiliary Setup**" > "**Protein Module Setup**" to enter the "**Protein Module Setup**" screen.
2. Define the settings as needed.

See below for setting descriptions:

Report parameters	Set the CRP report parameters to be displayed as needed: If a C-Reactive Protein(CRP) Kit (Latex Particle-Enhanced Immunonephelometry Method) is used, available report parameters are CRP and FR-CRP.
CRP threshold settings	Set the display threshold for CRP parameters: • When C-Reactive Protein(CRP)Kit(Latex Particle-Enhanced Immunonephelometry Method) is used, you can set the display thresholds of CRP test values (the default lower display threshold of CRP is 6 mg/L). • CRP, hs-CRP and FR-CRP test result values in the range of<0.20mg/L are displayed as <0.20 and the actual value will not be displayed. and the actual value will not be displayed.

9.2.1 Setting up L-J QC Files (Administrators)

9.2.1.1 Introduction to the L-J QC file setup

You can set up L-J QC files on the QC file setup screens, as shown in ***Figure 9-1L-J QC File Setup Screen***.

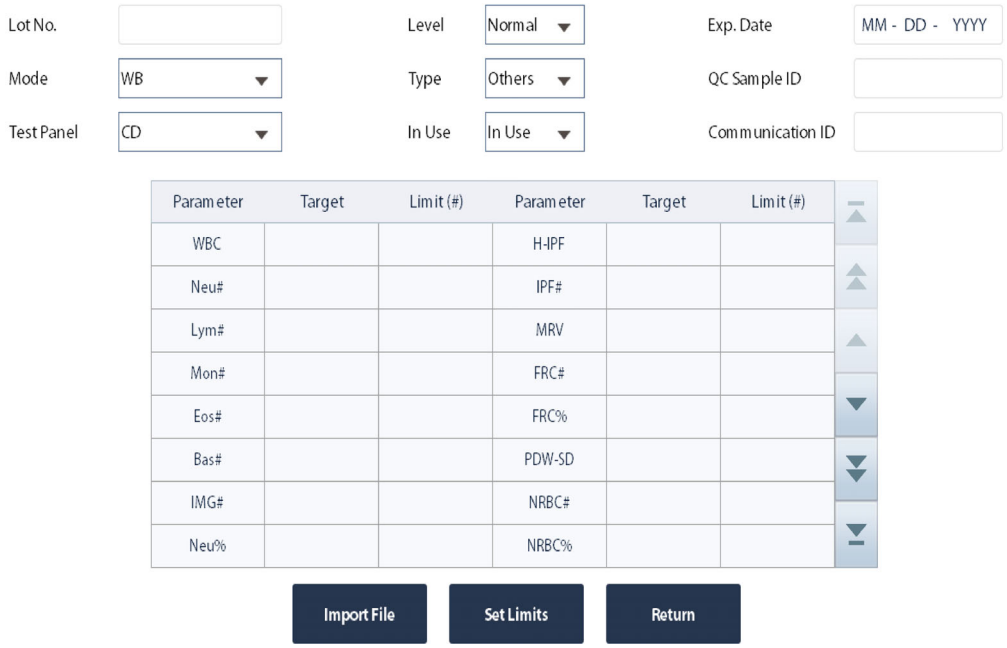


Figure 9-1 L-J QC File Setup Screen

Įveskite kontrolinių medžiagų partijos numerį vienu iš šių būdų: rankiniu būdu arba naudodami išorinį brūkšninių kodų skaitytuvą.

Table 9-1 L-J QC File

Items	Description	Note
Lot No.	Find the Lot No. of controls on the vial labels of the controls	• Up to 16 digits can be entered for the lot No. You can enter characters, numbers, letters and special characters. Chinese characters are not supported. • The lot No. is required. • Enter the lot No. of the controls by one of the following ways: Manual entry, or using an external barcode scanner.
Level	Levels of controls "**High**", "**Normal**", "**Low**"	/
Exp. Date	Expiration dates of the controls	The expiration date shall not be earlier than the current system date.
Mode	The loading and sample modes in QC tests: "**AL-WB**" "**CT-WB**" "**CT-BF**"	/

10.

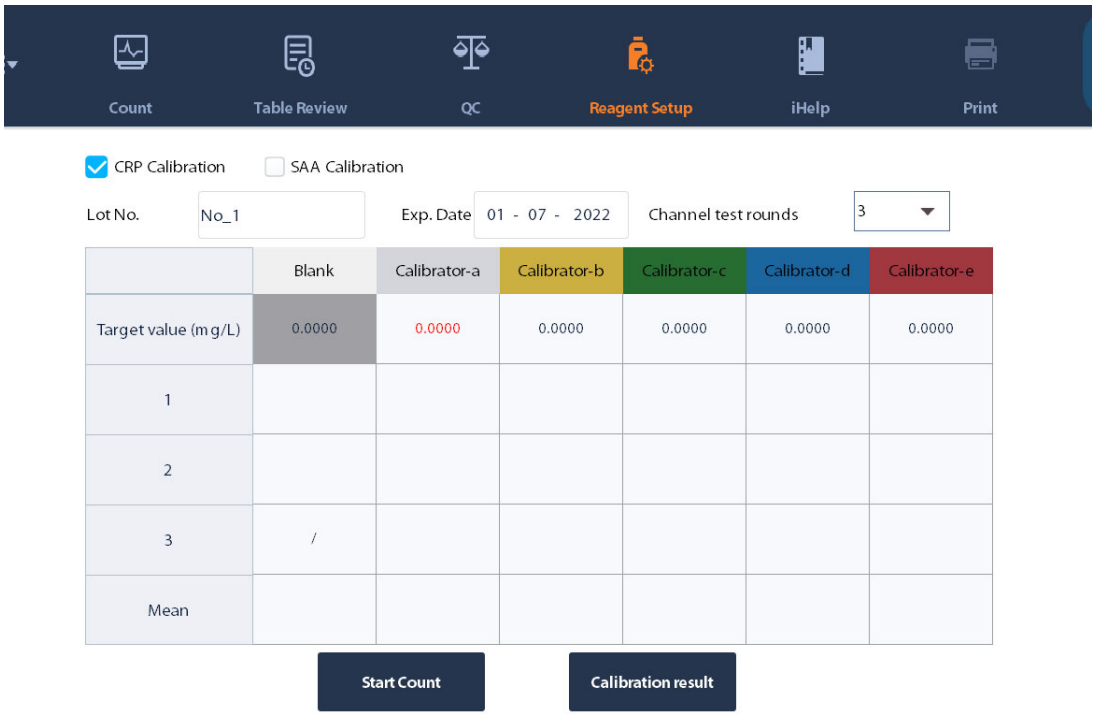


Figure 10-1 Protein multi-point calibration screen

3. Check the calibration type: "**CRP Calibration**" or "**SAA Calibration**".
4. Enter the protein calibrator information.

NOTE

- **For models configured with SAA channels, selecting the calibration type is required**.

Options	Description	Note
Lot No.	Find the lot No. on the vial label of the calibrator. Kalibratoriaus partijos numerį įveskite vienu iš šių būdų: rankiniu būdu arba naudodami išorinį brūkšninių kodų skaitytuvą.	■ The lot No. shall not be empty and up to 16 digits can be entered. You can enter characters, numbers, letters and special characters. ■ The lot No. cannot be null. ■ Enter the lot No. of a calibrator by one of the following ways: Manual entry or using an external barcode scanner. 10.
Exp. Date	Expiration date of the calibrator	■ The entered expiration date should be either the expiration date printed on the labeling or the open-vial expiration date, whichever is earlier. ■ The open-vial expiration date is calculated as follows: the date that container is opened + the open-vial stability days.
Channel test rounds	Number of rounds for a multi-point calibration measurement	■ 1–3 rounds can be selected. ■ For example, if the number of test rounds is "3", the calibrator of a proper concentration is tested three times on channel.

Palieskite redagavimo laukelį „Įveskite reagento informaciją“ ir iššokančia klaviatūra įveskite reagento brūkšninį kodą arba nuskaitykite reagento brūkšninių kodų etiketes išoriniu brūkšninių kodų skaitytuvu.

2. Enter the reagent information in one of the following ways:

16.

If...	Then...
Barcode entry is selected	Tap "**Enter Reagent Information**" edit box and use a pop-up keyboard to enter the reagent barcode; or scan the reagent barcode labels with an external barcode scanner.
Information entry through RFID is selected	Swipe the reagent on RFID region of "**Reagent Setup**" screen.

NOTE

- **If you want to change the way of entering reagent information, please contact Mindray Customer Service Department.**
- **Only when replacing the dye or ESR cleanser, reagent information can be entered through RFID.**

√ If the barcode is valid, the reagent information will be refreshed.

NOTE

- **If the barcode is entered/scanned in the "Barcode Entry" edit box of the "Reagent Setup" dialog box, and the reagent corresponding to the barcode is not in the reagent list displayed at the top of the dialog box, the software will prompt an alarm. Check and make sure that you have selected the correct reagent for replacement.**
- **If necessary, you can manually modify the reagent validity period and reagent volume information, and the software will automatically save and refresh the information.**

3. (Optional) If more than one reagent needs to be replaced, repeat step 3 to complete the setup of all reagents.
4. Replace the old reagent in the pipelines.

■ If "**Auto replace reagent after setup**" is checked on the "**Setup**" > "**Auxiliary Setup**" > "**Other Settings**" screen, the analyzer will automatically start the program to replace the old reagent in the pipelines at defined time.

NOTE

- **After the latex reagent is replaced but the reagent lot has not changed, the analyzer will not replace the old reagent in the pipelines.**

As shown in the figure below, when "**Auto replace reagent after setup**" is enabled, the count-down timer displays on the "**Replace**" button after the reagent setup is completed. After the countdown ends, the analyzer automatically starts the program to replace the old reagent in the fluidic system.

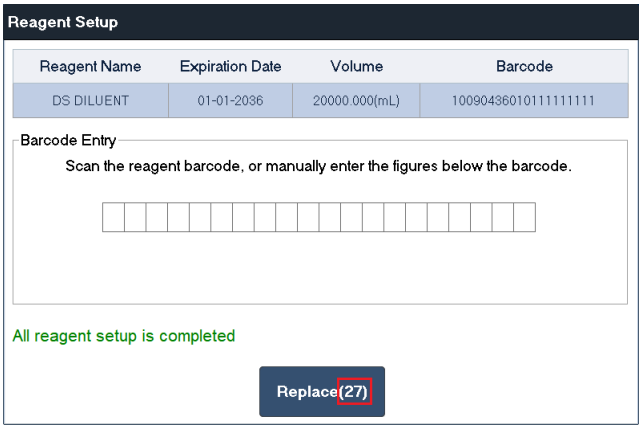


Figure 12-1 Countdown - replacing reagents through barcode entry

Table 3-8 Body fluid sample test scattergrams

Name	Abbreviation	3D Scattergram	Applicable Model
Differential scattergram	DIFF scattergram	Available	General
Differential-extension scattergram	DIFF-EXT scattergram	Unavailable	General

3.3 Device Description

3.3.1 Structure and Components

BC-760[B] CS/BC-760[R] CS Auto Hematology Analyzer consists of the sample processing unit, data management unit, result output unit, and the accessories.

3.3.2 Modules and Components

⚠ CAUTION

- **Do not use anything sharp on the touch screen or strike on it.**
- **Clean the touch screen with a clean and soft cloth, as well as clean water, rather than chemical solution, acid or alkali solution.**

3.3.2.1 Front of the analyzer

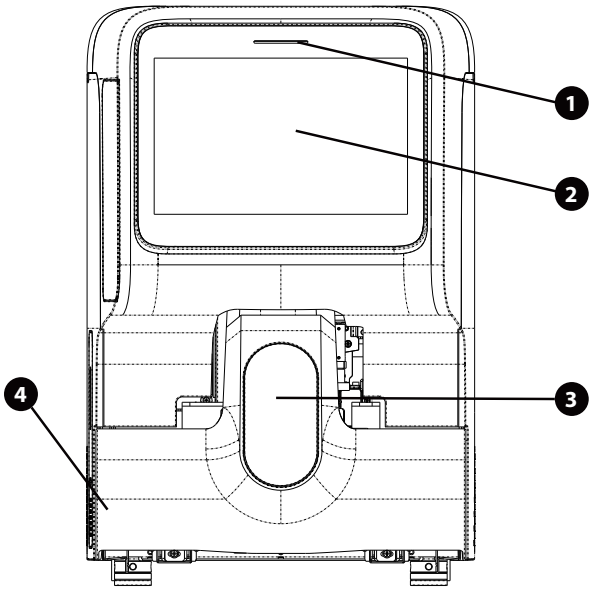


Figure 3-1 Front of the analyzer

① Status indicator
②Touch screen
③ Sample compartment
④Autoloader

11. Automatinis mėginių krautuvas

①	Status Indicator	The indicator locates on the top of the touch screen; and it tells you about the status of the instrument including ready, running, error, standby and on/off, etc.	Ready: indicator stays in green
			Running: indicator flickers in green
			Sampling probe piercing: indicator flickers fast
			Error: indicator stays in red
			Sleep: indicator stays in orange
			Off: indicator off
②	Touch screen	The touch screen locates on the front of the main unit, which can be used to operate the instrument and display information.	/
③	Sample compartment	Tap closed-tube sampling mode on touch screen, and the analyzer opens the sample compartment automatically. Place applicable adapters in the compartment and sample tubes to perform analysis tests.	/
④	Autoloader	The autoloader is in the front of the analyzer. You can use it to load tubes automatically.	/

11.

3.3.2.2 Back of the analyzer

Automatinis įkroviklis yra analizatoriaus priekyje. Jį galite naudoti mėgintuvėliams automatiškai įkelti.

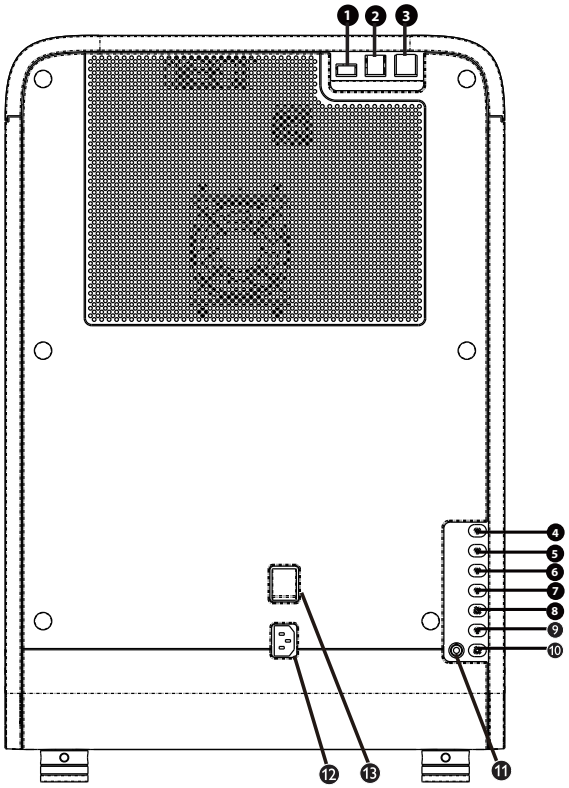


Figure 3-2 Back of the analyzer

① USB port (protocol 3.0)
② USB port (protocol 2.0)
③ Network interface
④ LS Lyse
⑤ DR Diluent inlet (applicable to the BC-760[R] CS model)
⑥ LD Lyse inlet
⑦ LH Lyse inlet
⑧ ESR solution reagent inlet

7.7 Running Samples

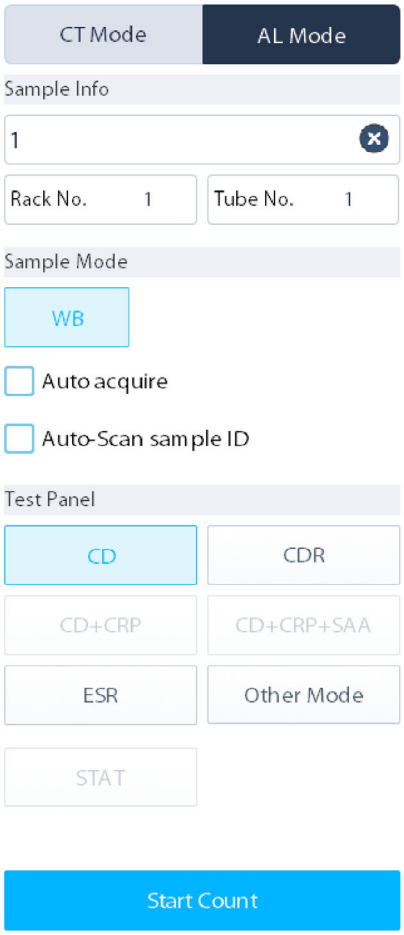
7.7.1 Setting up Analysis Orders

You can set analysis order information on the main unit of Auto Hematology Analyzer.

1. Tap " « " on the "**Count**" screen.

√ The pop-up window appears.

2. Select "**AL Mode**".



Jei jūsų analizatoriuje sukonfigūruotas integruotas brūkšninių kodų skaitytuvas, analizatorius automatiškai nuskaitys mėginio ID, kai pažymėsite „Automatiškai nuskaityti mėginio ID“. Įsitikinkite, kad brūkšninių kodų etiketės yra nepažeistos ir įskaitomos.

3. Enter the sample ID, rack No., and tube No. as needed.

14.

NOTE

- **If built-in barcode scanner is configured on your analyzer, the analyzer will scan the sample ID automatically after you check “Auto-Scan sample ID”. Make sure that the barcode labels are intact and readable.**
- **If you uncheck "Auto-Scan Sample ID", manually enter the first Sample ID, and the following sample IDs will automatically increase. For more details, refer to *6.3.3.1Getting sample information*.**
- **Totally 20 characters are allowed for sample ID maximally (including prefix); the ID must end with a number, and must not be consisted of "0" only.**

4. Select the desired test panel according to your model.

Test panel	Meaning	Description
CBC	CBC	Complete blood count
CD	CBC+DIFF	Complete blood count + WBC differentiation tests

D Communication

The LIS/HIS function of this analyzer enables the communication between the analyzer and the PC in laboratory through Ethernet, including sending analysis results to and receiving worklist from PC.

In the LIS/HIS communication process of the analyzer involves the HL7 communication protocol. For details about the connection control, and the introduction, message definition and examples, please contact Mindray Customer Service Department or your local distributor.

15. Šio analizatoriaus LIS/HIS funkcija leidžia analizatoriui ir laboratorijos kompiuteriui bendrauti per Ethernet, įskaitant analizės rezultatų siuntimą į kompiuterį ir darbo sąrašo gavimą iš jo.

Analizatoriaus LIS/HIS ryšio procese naudojamas HL7 ryšio protokolas. Dėl išsamesnės informacijos apie ryšio valdymą, įvadą, pranešimų apibrėžimą ir pavyzdžius kreipkitės į „Mindray“ klientų aptarnavimo skyrių arba vietinį platintoją.

B.7.1 Keyboard

USB port (supporting the protocol of USB2.0 and above) keyboard.

B.7.2 Mouse

USB port (supporting the protocol of USB2.0 and above) mouse.

B.7.3 External barcode scanner

USB port (supporting the protocol of USB2.0 and above) hand-held barcode scanner.

B.7.4 Printer

USB port (supporting the protocol of USB2.0 and above) printer.

B.7.5 USB Drive

Supporting the protocol of USB2.0 and above.

B.7.6 Electronic Interface Specifications

NOTE

- **Connection of the electronic interface to an IT network that includes other equipment could result in previously unidentified risks to patients, users or third parties; the responsible organization should identify, analyse, evaluate and control these risks.**

	Specifications	
Communication format (protocol) and relevant standards	USB ports	Type A interface, complied with USB 2.0/3.0 standard.
	Network ports	TCP/IP protocol bottom layer. DICOM/HL7 protocol application layer. RJ45 interface, supporting wired network 10 M/100 M/ 1000 M, and complied with technical standard IEEE802.3. NTP/SNTP Calibration protocol of TCP/IP.
Time setting	The time on the analyzer should be set to the correct local time.	

15.

Tinklo prievadai.
TCP/IP protokolo
apatinis sluoksnis.

B.8 Interfaces

NOTE

- **The USB interfaces on the back of the analyzer shall only be used to connect the peripheral devices specified in this manual. See Appendix *B.7 Requirements for Input/Output Devices* for details about supported devices and models.**

- One network port (compatible with 10/100/1000M Ethernet and complying with the 802.3u/802.3ab standard)
- Four USB ports including three supporting USB2.0 and one supporting USB3.0 (specification: DC 5V; 500 mA)

B.9 Power supply

	Voltage	Input power	Frequency
Main unit	100V-240V~ (±10%)	600 VA	50 Hz/60 Hz (±1 Hz)

Parameters	Range	Whole Blood (CV/Absolute Deviation d*/SD)	Predilute (CV/Absolute Deviation d*)
Mon%	Mon %≥5.0% WBC≥ 4.00×10^9/L	≤16.0%	≤32.0%
Eos%	WBC≥ 4.00×10^9/L	≤20.0% or ±1.5%(d)	≤40.0% or ±3.0%(d)
Bas%	WBC≥ 4.00×10^9/L	≤30.0% or ±1.0%(d)	≤60.0% or ±2.0%(d)
Neu#	≥1.20×10^9/L	≤6.0%	≤12.0%
Lym#	≥0.60×10^9/L	≤6.0%	≤12.0%
Mon#	≥0.20×10^9/L	≤16.0%	≤32.0%
Eos#	WBC≥ 4.00×10^9/L	≤20.0% or ±0.12×10^9/L(d)	≤40.0% or ±0.24×10^9/L(d)
Bas#	WBC≥4.00×10^9/L	≤30.0% or ±0.06×10^9/L(d)	≤60.0% or ±0.12×10^9/L(d)
IMG%	WBC≥4.00×10^9/L IMG%≥2.0%	≤25.0% or ±1.5%(d)	/
IMG#	≥0.10×10^9/L	≤25.0% or ±0.12×10^9/L(d)	/
NRBC%	WBC≥ 4.00×10^9/L	≤25.0% or ±1.5%(d)	/
NRBC#	WBC≥4.00×10^9/L	≤25.0% or ±0.12×10^9/L(d)	/
RET%	RBC≥ 3.00×10^{12}/L RET%: 1.00% ~ 4.00%	≤ 15%	≤ 30%
RET%	RBC≥ 3.00×10^{12}/L RET%: 1.00% ~ 4.00%	≤ 15%	≤ 30%
RHE	RET#≥ 0.0200×10^{12}/L	≤ 5%	/
LFR	RBC≥ 3.00×10^{12}/L RET%: 1.00% ~ 4.00% LFR≥20%	≤ 30%	/
MFR	RBC≥ 3.00×10^{12}/L RET%: 1.00% ~ 4.00% MFR≥20%	≤ 50%	/
HFR	RBC≥ 3.00×10^{12}/L RET%: 1.00% ~ 4.00%	≤ 100% or ±2.0%(d)	/
IRF	RBC≥ 3.00×10^{12}/L RET%: 1.00% ~ 4.00% IRF≥20%	≤ 30%	/
IPF	PLT ≥ 50×10^9/L IPF≥3.0%	≤ 25%	/
ESR	0 ~ 20mm/h	≤1.8(SD)	/
	> 20mm/h	≤ 9%	/
FR-CRP	≤10mg/L	≤0.5(SD)	/
	10.01 ~ 320.00mg/L	≤ 4%	
SAA	≤10.00mg/L	≤1.0(SD)	/
	10.01 ~ 350.00mg/L	≤ 8%	

Kokybės kriterijus Nr. 1

ENG matavimo ribos

Note:

1. *Absolute deviation d = MAX|Measured value - measured mean|
2. **Range = Maximum measurement value – Minimum measurement value
3. FR-CRP covers CRP and hs-CRP.

B Specification

B.1 Classification

According to the CE classification, the device belongs to Class B in vitro diagnostic medical device according to rule 6, annex VIII of REGULATION (EU) 2017/746.

B.2 Reagent

The analyzer can be used with the following reagents, controls, and calibrators.

NOTE

- **The item with + only applies to the models configured with SAA channels.**
- **For any questions related to reagents, controls, and calibrators, please consult your local distributor.**

Kokybės kriterijus nr. 4

Analizatoriaus naudojamų reagentų sarašas

Table B-1 Reagents

Applicable Channel	BC-760[B] CS	BC-760[R] CS
HGB channel	LH Lyse	LH Lyse
DIFF channel	LD Lyse	LD Lyse
	FD Dye	FD Dye
RET channel	/	DR Diluent
	/	FR Dye
/	DS Diluent	DS Diluent
	Probe Cleanser	Probe Cleanser
CRP channel SAA channel	C-Reaction Protein(CRP)Kit(Latex Particle-Enhanced Immunonephelometry Method)	C-Reaction Protein(CRP)Kit(Latex Particle-Enhanced Immunonephelometry Method)
	+Serum Amyloid A (SAA) Kit (Latex Particle-Enhanced Light Scattering Immunoturbidimetric Method)	+Serum Amyloid A (SAA) Kit (Latex Particle-Enhanced Light Scattering Immunoturbidimetric Method)
	LS Lyse	LS Lyse
ESR channel	ESR Solution Reagent	ESR Solution Reagent

Table B-2 Controls/calibrators for complete blood tests

Name	Model	Applicable Model
Hematology control	BC-6D	BC-760[B] CS/BC-760[R] CS
Hematology control	BR60	BC-760[B] CS/BC-760[R] CS
Hematology control	BC-RET	BC-760[R] CS
C-reaction protein control	/	BC-760[B] CS/BC-760[R] CS
+Serum amyloid A control	/	BC-760[B] CS/BC-760[R] CS

Name	Model	Applicable Model
Hematology calibrator	SC-CAL PLUS	BC-760[B] CS/BC-760[R] CS
C-reactive protein (CRP) calibrator	/	BC-760[B] CS/BC-760[R] CS
+Serum amyloid A calibrator	/	BC-760[B] CS/BC-760[R] CS

Table B-3 Controls for body fluid tests

Name	Model	Applicable Model
Hematology control	BC-BF	BC-760[B] CS/BC-760[R] CS

Table B-4 Controls/calibrators for ESR tests

Name	Model	Applicable Model
Hematology control	BC-6D	BC-760[B] CS/BC-760[R] CS
Hematology calibrator	SC-CAL PLUS	BC-760[B] CS/BC-760[R] CS

Kokybės kriterijus nr. 4

Reagentų modelis pritaikytas šiam analizatoriui

Table B-5 Part number for reagent controls/calibrators

Name	Model	Part Number
LH Lyse	M-6	105-012291-00 (4L*1)
		105-012292-00 (1L*4)
LD Lyse	M-6	105-012287-00 (4L*1)
		105-012288-00 (1L*4)
FD Dye	M-6	105-012297-00 (48mL*1)
		105-012298-00 (12mL*4)
*DR Diluent	M-6	105-012285-00 (4L*1)
		105-012286-00 (1L*4)
*FR Dye	M-6	105-012295-00 (48mL*1)
		105-012296-00 (12mL*4)
DS Diluent	/	105-012283-00 (20L)
		105-012284-00 (10L)
Probe Cleanser	/	105-002225-00 (50 mL*1)
		105-009432-00 (25mL*6)
C-Reaction Protein(CRP)Kit(Latex Particle-Enhanced Immunonephelometry Method)	C-II	105-025161-00 (50 tests*1)
		105-025162-00 (50 tests*2)
		105-025163-00 (125 tests*1)
		105-025164-00 (125 tests*2)