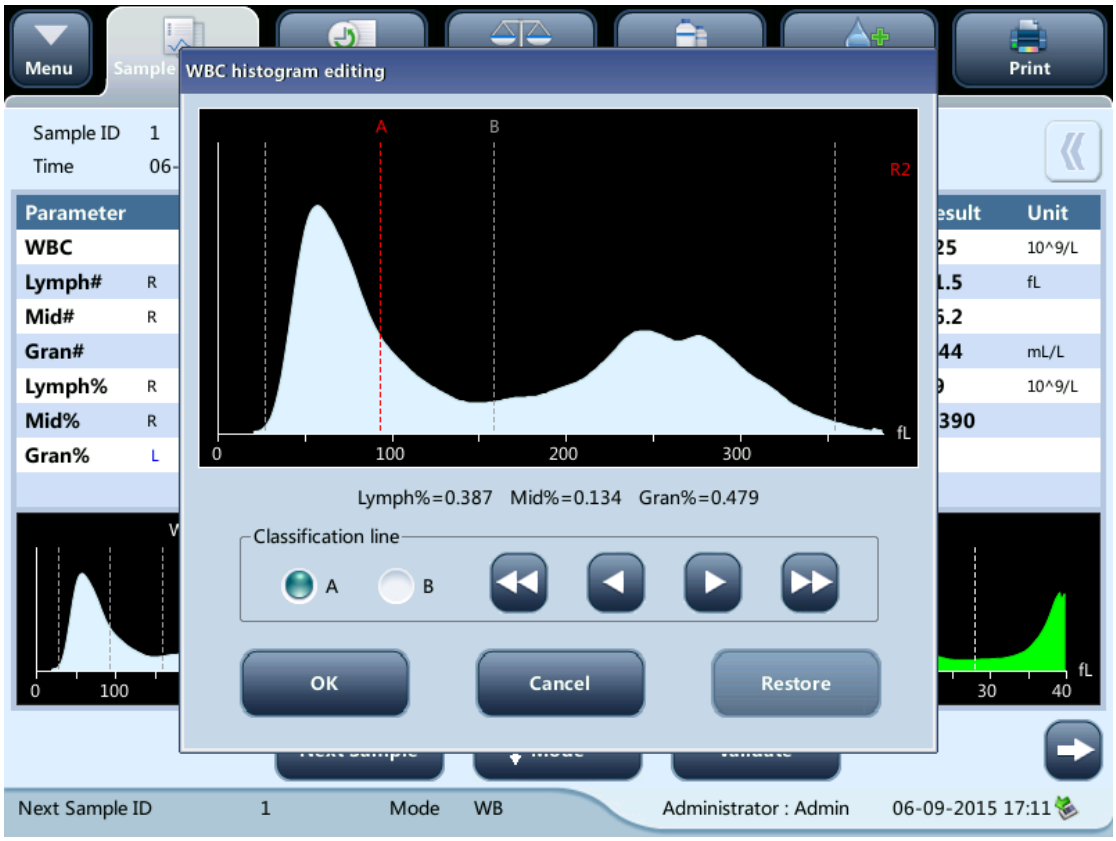
re-calculate the differential results.



PLT histogram flags

Abnormal PLT histograms will be flagged by the marking Pm, PS, PL.
The indication of the marking is as follows:

- Pm: indicates blur demarcation between the platelet area and red blood cell area and possible presence of large platelet, platelet clump, small red blood cell, cell debris or high molecular weight protein.
- PS: small platelet possibly high notice.
- PL: giant platelet possibly high notice.

Parameter flags

3.2.1.9 punktas Table 1 Flags of abnormal blood cell differential or morphology

Pranešimai apie nenormalias kraujo ląstelių diferenciacijas ar morfologiją

Flag type	Inform	
WBC Flag	Leuco	
	Leucocytosis	High WBC count
	Granulocyte decreased	Low granulocyte number
	Granulocyte increased	High granulocyte number
	WBC abnormal	NRBCs, abnormal/atypical lymphocytes, immature or blast cells may present

Graph review

You can either tap the "**Graph Review**" button on the "**Table Review**" screen or tap "**Previous**" on the "**Sample Analysis**" screen to review the detailed results of each sample.

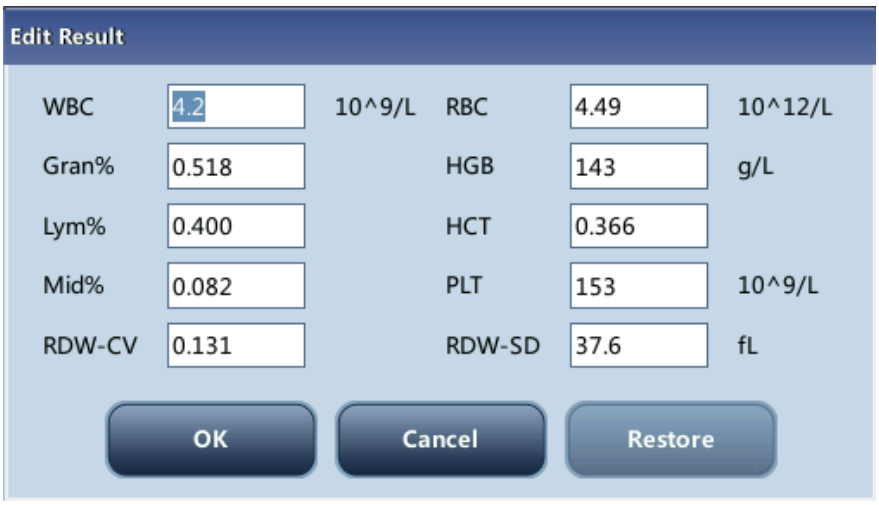
3.2.1.9 punktas

Tap the bu

Analizatoriaus monitoriuje rezultatai rodomi skaitiniai rezultatai ir histogramos, pažymėti rezultatai už norminių dydžių ribų.

Edit results

Tap the desired sample result and it will be highlighted. Tap the "**Edit Result**" button and the following dialog box will display.



Modify the results and tap "**OK**" to save the changes. The information on the graph review screen will be refreshed.

7 Using the QC Programs

7.1 Introduction

Quality Control (QC) consists of strategies and procedures that measure the precision and stability of the analyzer. The results reflect the reliability of the sample results. QC involves measuring materials with known, stable characteristics at frequent intervals.

Analysis of the results with statistical methods allows the inference that sample results are reliable. Mindray recommends you run the QC program daily with low, normal and high level controls. A new lot of controls should be analyzed in parallel with the current lot prior to their

3.2.1.7 punktas

Mndray rekomenduoja kasdieninę kontrolę atlikti su žemo, normlaus ir aukšto lygio kontrolėmis.

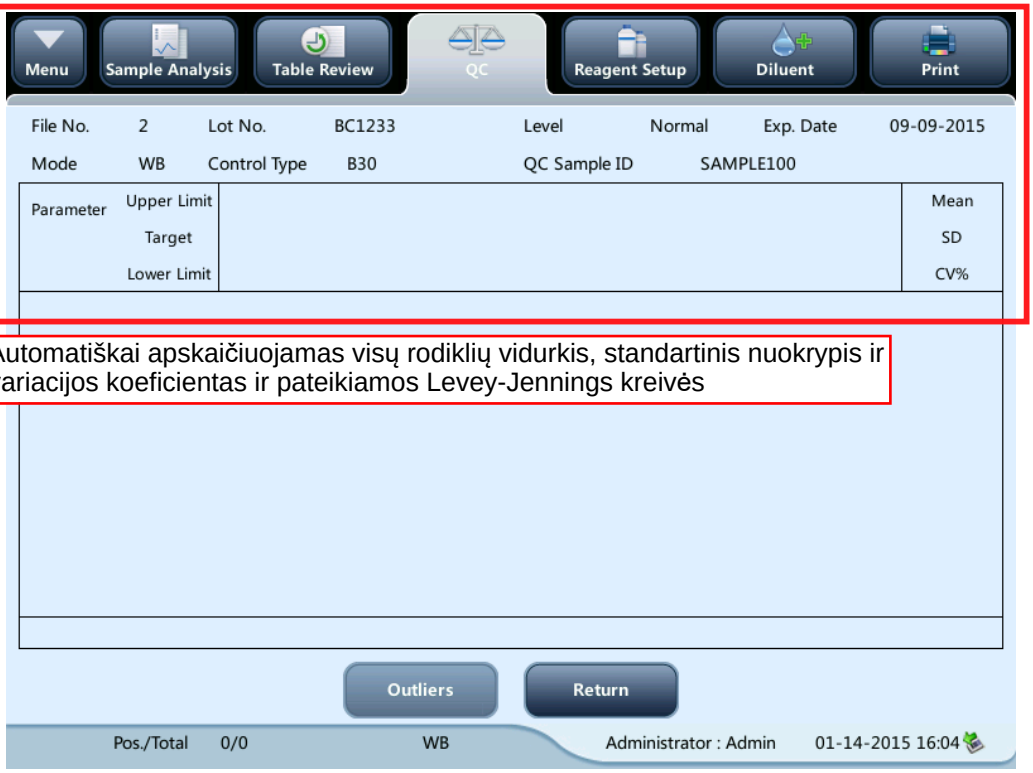
coefficient of variation for each selected parameter. The instrument-calculated means of these ten runs should be within the expected ranges published by the manufacturer.

This analyzer provides two QC programs: L-J QC and X-B QC.

NOTE

- **Use the controls and reagents specified by the manufacturer only. Store and use the controls and reagents as instructed by their instructions for use.**

3.2.1.7 punktas
2.3.5. punktas



Automatiškai apskaičiuojamas visų rodiklių vidurkis, standartinis nuokrypis ir variacijos koeficientas ir pateikiamos Levey-Jennings kreivės

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

NOTE

- **If a parameter target/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters changes accordingly, those changed data will be highlighted in yellow.**

Print

Tap the "**Print**" icon in the status bar to print information of the current QC file and the QC graph of all parameters.

NOTE

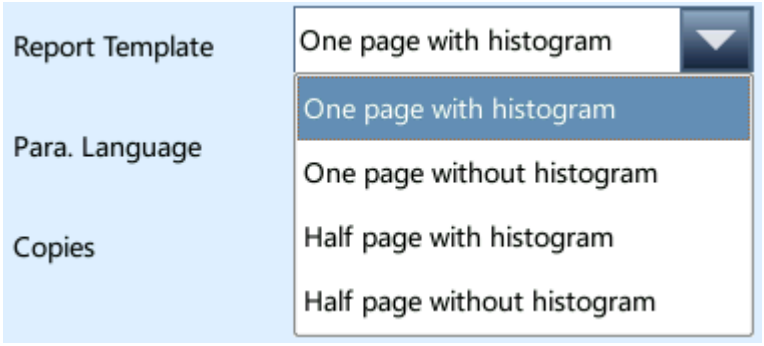
- **The green vertical line and values of the corresponding QC points will not be printed.**

L-J QC table review

1. Tap the "**QC Table**" button on the **"L-J QC Run**" screen to enter the L-J QC table screen.

Report title

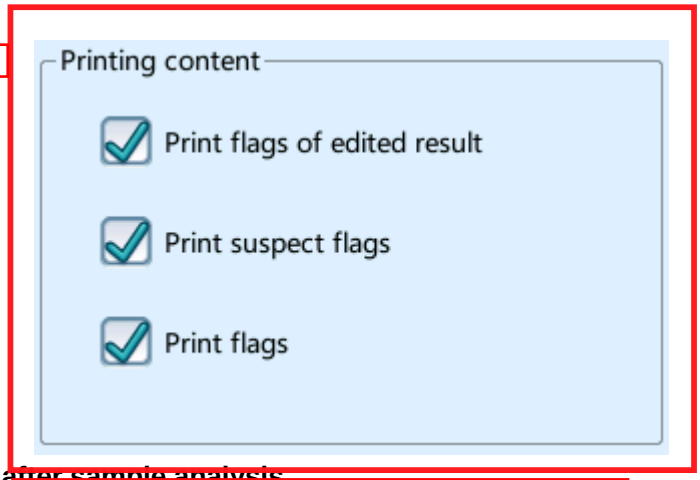
Report template



- **Printing content**

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

3.2.1.9 punktas



- **Auto print after sample analysis**

  You can choose

Sapusdinimo turinys:
Spausdinti pranešimus apie koreguotus rezultatus
Sapusdinti įspėjamuosius pranešimus
Spausdinti pranešimus

Communication setup

Tap the menu option "**Setup**" > "**System Setup**" > "**Communication**" to enter the communication setup screen as shown below. You can set up the following contents:

- Communication
- Network Device
- Protocol Setup
- Transmission Mode

9.2.2 User Management

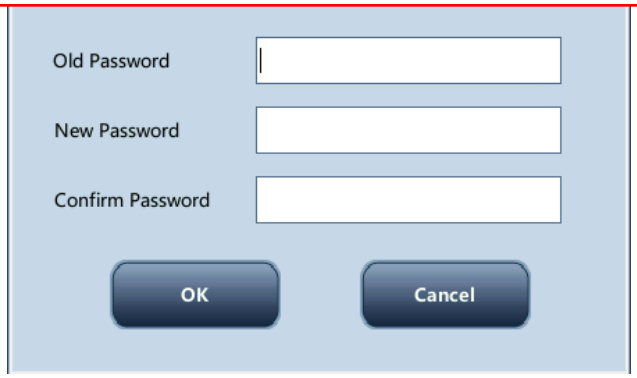
Tap "**Setup**" > "**Access Setup**" in the menu to enter the following screen.

3.2.1.6 punktas **Modifying password** Keisti slaptažodį

You can modify your own password.

1. Select the current user, and then tap "**Modify Password**", the following dialog box will display.

Galite keisti savo slaptažodį
Pasirinkite esantį vartotoją ir paspauskite "Modify Password", sekantis langas pasirdys.



2. Enter the required information in the text boxes.
3. Tap "**OK**" to save the change and close the dialog box.

9.2.4 Setting Parameters

Parameter unit setup

Tap the menu option "**Setup**" > "**Parameter Setup**" > "**Reference Unit Setup**" to enter the screen as shown below. You can set up parameter units on this screen.

Parameter	Unit	Format	Parameter	Unit	Format
WBC	10^9/L	***.*	MCH	pg	***.*
Lym#	10^9/L	***.*	MCHC	g/L	****
Mid#	10^9/L	***.*	RDW-CV		*.***
Gran#	10^9/L	***.*	RDW-SD	fL	***.*
Lym%		*.***	PLT	10^9/L	****
Mid%		*.***	MPV	fL	**.*
Gran%		*.***	PDW		**.*
RBC	10^12/L	*.**	PCT	mL/L	**.**
HGB	g/L	***	P-LCC	10^9/L	****
HCT		*.***	P-LCR		*.***
MCV	fL	***.*			

2.4.5.punktas
Tyrimo rezultai pateikiami SI sistemos vienetais

■ **Selecting unit system**

Tap the "**Unit System**" pull-down list to select unit system.

■ **Customizing parameter units**

Under each unit system, you can tap the "**Unit**" cell to customize the parameter unit.
Tap the "**Default**" button to restore the default units.

NOTE

- **The units displayed will be different when different unit system is selected.**

Reference range setup

Tap the menu option "**Setup**" > "**Parameter Setup**" > "**Reference Range Setup**" to enter the screen as shown below.

3.2.1.8 punktas
Five factory reference groups and 10 customized reference groups are provided for your choice. Each laboratory shall select a proper reference range of its own based on its patient demographics. The reference range differs among races, genders, ages and geographic

Penkios gamyklinės atraminės grupės ir 10 konfiguruojamų atraminių grupių pasrinkti

NOTE

- **The name of the reference group cannot be null.**
- **The names of the customized reference groups shall not repeat the names of the five default groups (General, Adult male, Adult female, Child, and Neonate) and they shall not repeat each other either.**

For factory reference groups, you can tap the "**Default**" button to restore the default parameter settings.

NOTE

- **The name, lower and upper limits of age and gender of the factory reference groups cannot be modified.**
- **The input range of age is [0,999].**

■ **Setting as default reference group**

Select a reference group and then tap "**Set to Default**" to set it as default reference group.

3.2.1.8 punktas

■ **Modifying reference range(s)** Keisti kritines ribas

To modify the reference range of a reference group, select the group from the reference group list on the left, and then:

9.2.6 Reagent Management

Tap "**Setup**" > "**Reagent Setup**" in the menu to enter the following screen.

3.2.1.5 ir 2.3.6 punktai

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

NOTE

- **The diluent must be kept still for at least a day after long-term transportation.**
- **When you have changed the diluent, lyse or rinse, run a background to see if the results meet the requirement.**

You should replace reagents when:

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

You can replace the following reagents in the fluidics:

- Diluent

BC-30

Auto Hematology Analyzer

Technical Specifications:

Principles

Impedance method for WBC, RBC and PLT counting

Cyanide free reagent for hemoglobin test

Be cianidiniai reagentai hemoglobino testui

Parameters

21 parameters: WBC, Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR,P-LCC

3 histograms for WBC, RBC and PLT

3 histogramos WBC, RBC ir PLT

Sample Volume — Mėginio tūris

Prediluted mode ≤20μL

Whole blood mode ≤9 μL — Pilno kraujo režimas 9uL

Performance

Parameter	Linearity Range	Precision (CV %)	Carryover
WBC(109/L)	0-300	≤3.5% (4.0-6.9)	≤0.5%
		≤2.0% (7.0-15.0)	
RBC(1012/L)	0-8.00	≤1.5% (3.50-6.5)	≤0.5%
HGB(g/L)	0-280	≤1.5% (100-180)	≤0.5%
MCV(fL)		≤0.5% (70.0-110.0)	≤0.5%
PLT(109/L)	0-4000	≤5.0% (100-149)	≤1.0%
		≤4.0% (150-500)	

Throughput — Našumas

60 samples per hour — 60 mėginių per valandą

Display — Ekranas

10.4 inch TFT Touch Screen — 10.4 colių TFT liečiamas spalvotas ekranas

Multi-language

Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity

Up to 400,000 results including numeric and graphical information

Communication

LAN Port supports HL7 protocol — LAN portas palaiko HL7 protokolas

Support bi-directional LIS — Palaiko dvikryptį LIS

Interface

4 USB ports (for external printer, software upgrade, barcode reader, external WIFI, keyboard and mouse), LAN port (1)

4 USB portai (išoriniam spausdintuvui, programinės įrangos atnaujinimui, barkodo skaitytuvui, išorinis WIFI, klaviatūra ir pelė), LAN portas (1)

External printer optional

Power Requirement

Temperature: 15℃~30℃

Humidity: 10%~90%

Air pressure: 70kPa～106kPa

Power Requirement

(100V-240V)±10%

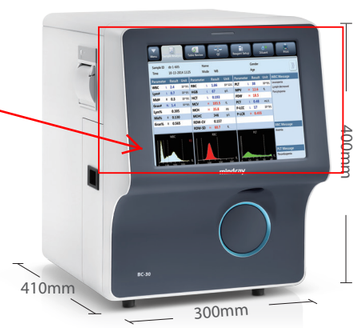
≤180VA

(50Hz/60Hz) ±1Hz

Dimension and Weight

Dimension: Depth (410 mm) x width (300 mm) x height (400 mm)

Weight: ≤20Kg



Weight (kg)≤20Kg

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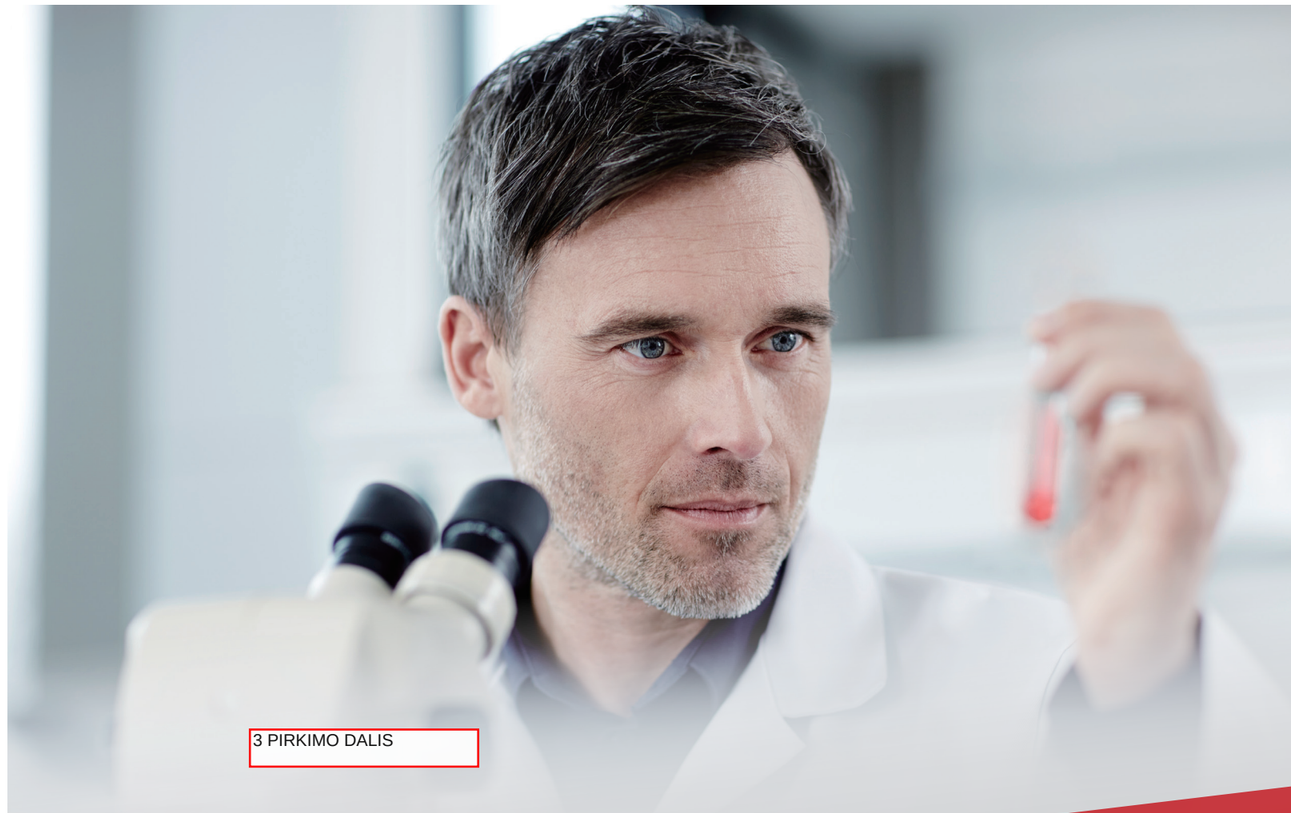
E-mail: intl-market@mindray.com www.mindray.com

P/N:ENG-BC-30-210285x4P-20170725

mindray



3 PIRKIMO DALIS

BC-30

Auto Hematology Analyzer

Minimum Size, Maximum Capability

mindray

healthcare within reach

Gives you **confidence in results**

Advanced detailed flag information provides warning in case of abnormal cell results. High quality original reagent calibrator and quality controls maintain your work at a high level. We integrate technologies into our products to fulfill your clinical needs, therefore, today, Mindray products and services are used by healthcare facilities in over 190 countries and regions. More and more customers choose Mindray products and trust Mindray's quality.

- CBC+3-DIFF,21 parameters+3Histograms
- Throughput :up to 60 samples per hour
- 10.4 inch TFT touch screen
- Only three reagents needed

3.2.1.5 punktas

Naudoja tik tris reagentus

- Detailed flag information
- Large storage capacity: up to 400,000 samples
- Sample volume is only 9μL which is ideal for pediatrics

Gives you **more time to work**

Smart and intuitive software bring your productivity to a new level. The 10.4 inch TFT touch screen makes operations easy and flexible, maximizing your productivity. The incredible 400,000 storage capacity gives you a worry-free solution to managing previous patients' data. The smart software can detect and remove operational errors, as well as run automatic maintenance with a single click.

Gives you **less downtime**

Quality and user experience are top priorities for Mindray. We design and manage our manufacturing processes in compliance with FDA, ISO and CE. Complete quality control systems in Mindray's manufacturing centers ensure we exceed the most stringent criteria and traceability throughout the entire process. Our professional and responsive support team makes sure your systems are kept at full capability.

Smallest

Convenience fast

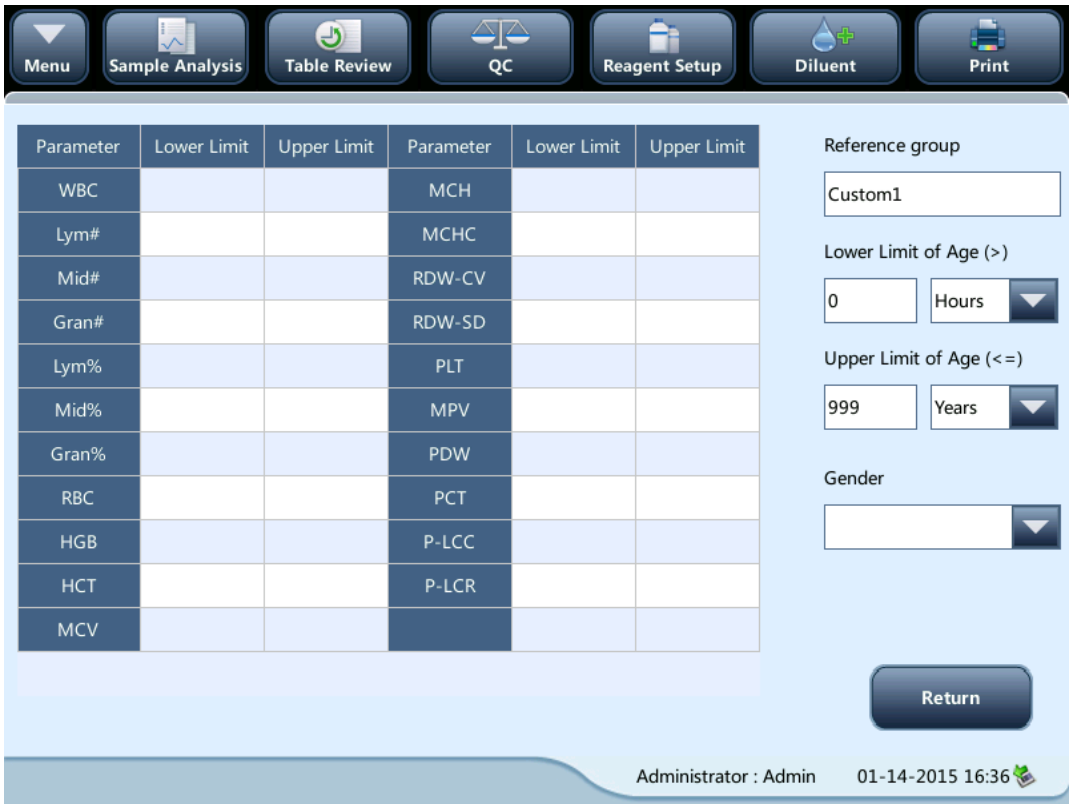
Perfect for pediatric samples

locations.

2.3.3 punktas
Analizatoriuje pateikiamos 5 gamintojo rekomenduojamos normų reikšmės, taikomos suaugusiems ir vaikams

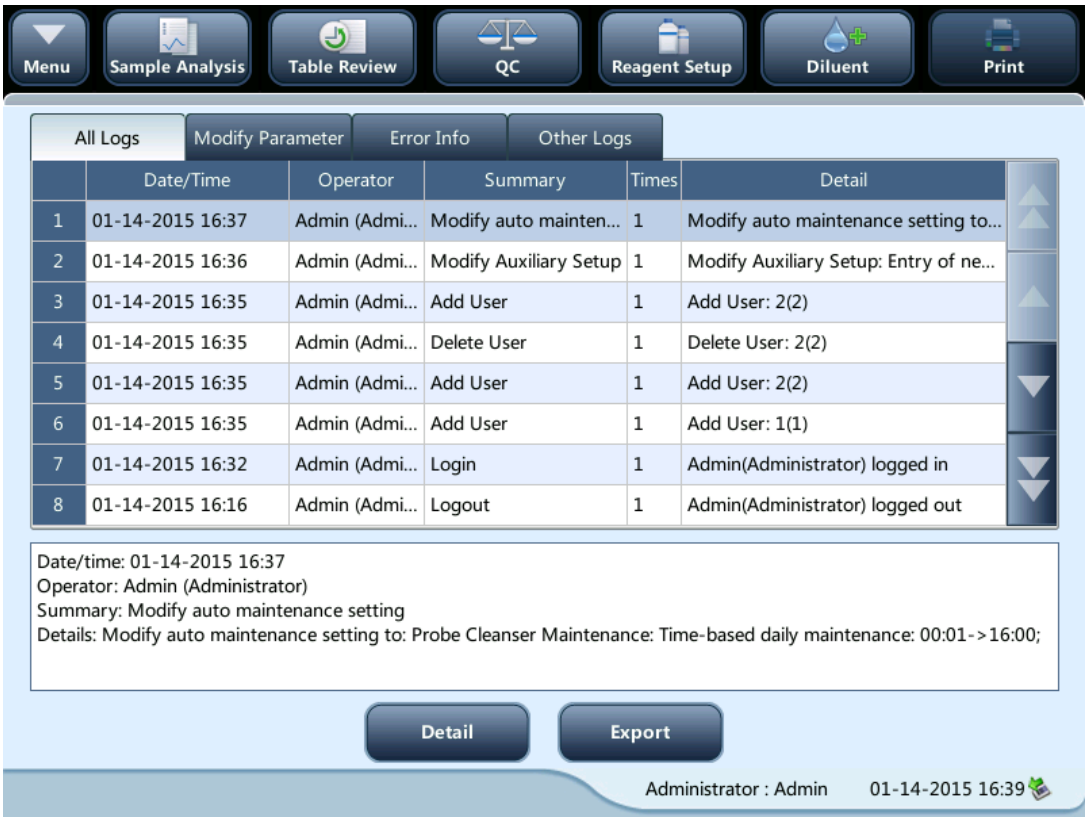
■ Customizing reference groups

Tap "**New**", or select a reference group and "**Edit**", to enter the reference group setup screen. You can set up the name, lower and upper limits of age, gender, and parameter reference range.



10.8 Viewing Logs

Tap "**Maintenance**" > "**Log**" in the menu to enter the following screen.



2.2.7 punktas You may view the error info., parameter modification info. and records of daily operation in the log. Galima peržiūrėti klaidų informaciją, parametrų keitimo informaciją ir kasdieninių operacijų įrašus log ekrane.

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

NOTE

- **The oldest record will be overwritten automatically when number of log records reaches the utmost.**
- **Records of two years can be stored at most.**

The following functions are provided:

Clearing the errors

Tap the "**Remove** " button to clear all the errors that can be removed automatically. For the errors that cannot be removed automatically, follow the troubleshooting method to solve them.

Closing the fault prompt dialog box

Tap "**Close**" to close the fault prompt dialog box, but the errors will still be displayed in the error info. area on the screen. Tap the error info. area again, the fault prompt dialog box will be displayed again.

3.2.1.5 punktas

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

Klaidos pavadinimas monitoriuje

Error name	Actions
Main board error	1. Power off the analyzer directly and contact our customer service department.
System clock error	1. Power off the analyzer directly and contact our customer service department.
Diluent ran out Diluentas pasibaigė	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the diluent container, tap "**Apply**" to prime the diluent. 3. If the problem still persists after replacing the diluent, contact our customer service department.
Diluent ran out	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the diluent container, tap "**Apply**" to prime the diluent. 3. If the problem still persists after replacing the diluent, contact our customer service department.
Lyse ran out Lyse pasibaigė	1. Tap "**Remove**", and enter the new barcode of the lyse into the reagent setup dialog box. 2. After replacing the lyse container, tap "**Apply**" to prime the lyse. 3. If the problem still persists after replacing the lyse, contact our customer service department.
Lyse ran out	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box. 2. After replacing the lyse container, tap "**Apply**" to prime the lyse. 3. If the problem still persists after replacing the lyse, contact our customer service department.
Diluent expired	1. Tap "**Remove**", and enter the new barcode of the diluent into the reagent setup dialog box.

EU-DL-L1370-170229

Date: 1st March 2017

To whom it may concern,

3.2.1.5 punktas
3.1.1.6 punktas

DECLARATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd., ("Mindray")** with business office at Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China.

As a reputable manufacturer of BC-series Hematology analyzers, BS-series Chemistry analyzers, Immunoassay analyzer, ELISA analyzer, Urine analyzers, Blood coagulation analyzer, and their Reagents, Consumables, Spare part, Quality control and Calibrators **("Products"),** hereby declares that the reagent used on our Hematology, Chemistry, Immunoassay, Urine and Coagulation Analyzer is ready for use and its on board stability continues till validity date.

, Europe

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

SHENZHEN MINDRAY
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Fax: +86 755 26582680
Website: www.mindray.com

Data: 2017 kovo 1d

Vertimas iš amglų kalbos į lietuvių kalbą

Tiems kam tai aktualu

DEKLARACIJA

Mes, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., ("Mindray") su verslo biuru Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen 518057, Kinijos Liaudies Respublika.

Kaip patikimas BC-serijos hematologinių analizatorių, BS serijos chemijos analizatorių, Imunologinių tyrimų analizatorių, ELISA analizatorių, šlapimo analizatorių, kraujo krešėjimo analizatorių, ir jų reagentų, medžiagų, atsarginių dalių, kokybės kontrolės ir kalibrantų ("Produktai") gamintojas, patvirtiname, kad reagentai naudojami mūsų Hematologijos, Chemijos, Imunologinių tyrimų, šlapimų ir krešėjimo analizatoriuose yra paruošti naudoti ir jame stabilus išlieka iki galiojimo datos pabaigos.

Labai Nuoširdžiai

/Parašas/

Yandong YIN

Direktorius Tarptautinių Pardavimų ir Rinkodaros Sistemos, In-Vitro diagnostikos skyriaus, Europa

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Vertimą tvirtino UAB „GRAINA‘

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
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Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com

4.4.2 Special information

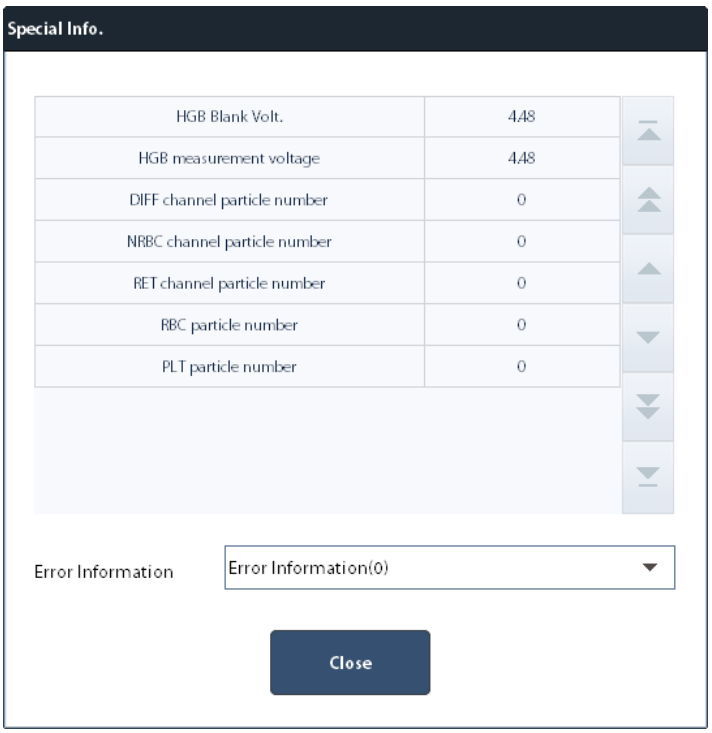

Figure 4-6

3.1.1.2 punktas

Meanings of special information

HGB background voltage	The voltage when diluent is added to the HGB reaction bath
HGB measurement voltage	The voltage when blood sample and lyses are added to the HGB reaction bath
DIFF channel particle number	Total particle count at the DIFF channel
WNB channel particle number	Total particle count measured at the WNB channel
RET channel particle number	Total particle count at the RET channel
RBC particle number	Total RBC particle count at the impedance channel
PLT particle number	Total PLT particle count measured at the impedance channel

HGB fono įtampa. Įtampa, kai diluetas yra įpilamas į reakcijos vonelę.

HGB matavimo įtampa. Įtampa kai kraujo mėginys ir lyse yra įpilamos į reakcijų vonelę

4.5 Setup screen

4.5.1 Maintenance

Menu Setup-Maintenance

- Set the wait time before the analyzer entering standby.
- Set up the auto probe cleanser maintenance time

BC-6000

Auto Hematology Analyzer

Principles
SF Cube* method to count WBC, 5-Part diff and NRBC
DC impedance method for RBC and PLT
Cyanide free reagent for hemoglobin test
*S: Scatter; F: Fluorescence; Cube: 3D analysis

Parameters 3.1.1.3 punktas
3.1.2.1 punktas
29 Reportabl ole blood): WBC, Lym%, Mon%, Neu%, Bas%, Eos%, IMG%, Lym#, Mon#, Neu#, Eos#, Bas#, IMG#; RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, NRBC#, NRBC%; PLT, MPV, PDW, PCT, P-LCR, P-LCC
20 Research parameters (whole blood): HFC#, HFC%, WBC-D, TNC-D, IME%, IME#, H-NR%, L-NR%, NLR, PLR, WBC-N, TNC-N, InR#, InR‰, Micro#, Micro%, Macro#, Macro%, PDW-SD, PLT-I
7 Reportable parameters (body fluid): WBC-BF, TC-BF#, MN#, MN%, PMN#, PMN%, RBC-BF
11 Research parameters (body fluid): Eos-BF#, Eos-BF%, Neu-BF#, Neu-BF%, HF-BF#, HF-BF%, RBC-BF, LY-BF, LY-BF%, MO-BF#, MO-BF%

2 Histograms for RBC and PLT
2 Three-dimension scatter grams: DIFF, WNB
2 Two-dimension scatter grams: DIFF, WNB

Mode
CBC, CBC+DIFF

Data storage capacity
Up to 10,0000 results including numeric and graphical information

Operating environment
Temperature: 15 ℃~32 ℃
Humidity: 30%~85%

Performance

Parameter	Linearity Range	Precision	Carryover
WBC	0-500×10⁹/L	≤2.5% (≥4×10⁹/L)	≤1.0%
RBC	0-8.60×10¹²/L	≤1.5% (≥3.5×10¹²/L)	≤1.0%
HGB	0-260g/L	≤1.0% (110-180g/L)	≤1.0%
HCT	0-75%	≤1.5% (30%-50%)	≤1.0%
PLT	0-5000×10⁹/L	≤4.0% (≥100×10⁹/L)	≤1.0%

Sample volume 3.1.1.10 punktas

Whole blood (Autoloader, Closed Tube)	80uL
Capillary blood (Closed Tube)	35uL
Predilute (Closed Tube)	20uL
Body fluid (Closed Tube)	85uL

Pilno kraujo ir Kapiliarinio kraujo mėginys (uždaras pavienių mėginių padavimo įrenginys)

3.1.1.5 punktas

Throughput
Up to 110 samples per hour (CBC+DIFF)
Up to 40 samples per hour (Body fluid)

Našumas. 110 mėginių per valandą (CBC+DIFF)

3.1.1 1 punktas

Loading capacity
Up to 50 sample tubes

Užkrovimo talpa iki 50 mėgintuvėlių

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P/N:ENG-BC-6000-210285X12P-20170526

mindray

Yra galimybė tirti skubius mėginius po vieną (uždarus arba atvirus)

4.PIRKIMO DALIS

BC-6000

Auto Hematology Analyzer

High Performance for ALL

mindray
healthcare within reach

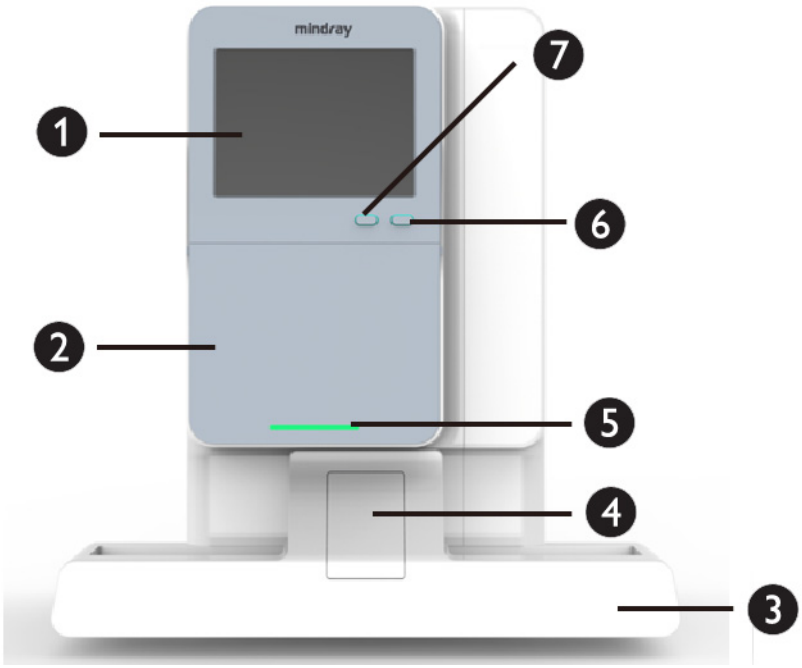


Figure 3-2 Closed-sampling type, front of the analyzer

3.1.1.1 punktas

❶ ---- Touch screen Liečiamas ekranas ❷ ----Fluorescent dye compartment

❸ ----- Autoloader ❹ ---- Sample probe

❺ ---- Status indicator ❻ --- [Run] key

❼ ---- Mode switch key

❶	Touch screen	The touch screen displays all alphanumeric and graphic data. You can use it to operate your analyzer	
❷	Status indicator	The indicator tells you about the status of the instrument including ready, running, error, standby and on/off, etc.	Ready: indicator stays in green
			Running: indicator lights in green
			Error: indicator lights in red
			Sleep: indicator stays in orange
			Off: indicator off
❸	[Aspirate] key	The [Aspirate] key is behind the sample probe. Press the key to start analysis or add diluent	
❹	Sample probe	The sample probe aspirates samples and adds diluent	
❺	Autoloader	The autoloader is in the front of the analyzer. You can use it to load tubes automatically.	

4 Understanding the System Principles

4.1 Introduction

The Impedanco metodas, lazerio sklaidos ir SF Cube ląstelės analizės technologija (3D analizė naudojant informaciją iš dviejų kampų lazerio šviesos sklaidos ir fluorescencinio signalo) ląstelių diferenciavimui ir skaičiavimui.

3.1.1.2 punktas

- 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;
- the colorimetric method for HGB measurement.

Kolometrinis metodas HGB matavimui

4.2 WBC Measurement

4.2.1 SF CUBE Cell Analysis Technology

In normal peripheral blood, white blood cells can be classified into 5 categories: lymphocytes, monocytes, neutrophils, eosinophils and basophils. Analyzing both 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 and serous cavity 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 fluid can be categorized into mononuclear cells (MN) and polymorphonuclear cells (PMN). The analysis of the cells in body fluid can provide useful information for clinical diagnosis.

The analyzer adopts the SF Cube cell analysis technology to recognize and detect the immature cells in blood accurately besides doing WBC 5-part differentiation, as well as identify the nucleated cells in body fluid.

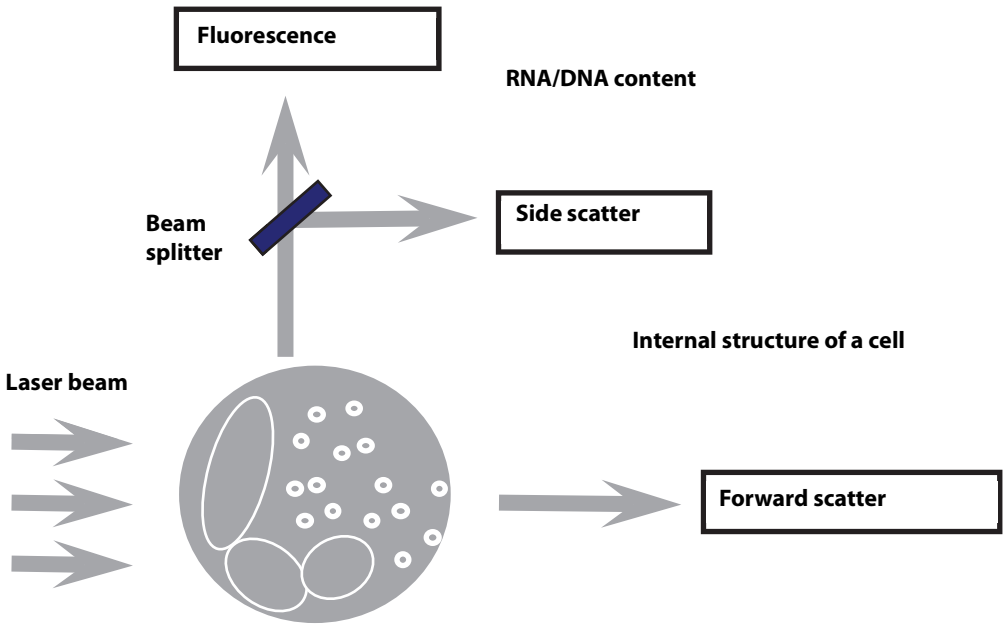


Figure 4-1 SF Cube Technology

The analyzer adopts the fluorescent staining technology in its DIFF and WNB channels. The RBCs are lysed and the WBC subpopulations are made different in size and complexity by the lyse; the nucleic acid substances in WBCs are marked by the new asymmetric cyanine fluorescent substance. Due to the different content of nucleic acid in different WBC subpopulations, maturity stages or abnormal development status, the volume of fluorescent dye staining the nucleic acid substances can be different; the low-angle light scatter reflects cell size, the high-angle light scatter reflects intracellular granularity, and the intensity of fluorescent signal reflects the degree that the cell is stained. By sensing the difference in signal in three dimensions of the cells processed with lyse, the DIFF channel differentiates the subpopulations of WBCs (lymphocytes, monocytes, neutrophil and eosinophils), as well as identifies and flags abnormal cells like immature granulocytes, abnormal lymphocytes and blast cells. In the meanwhile, the WNB channel differentiates basophils and nucleated red blood cells and counts the WBCs.

3.1.1.3 punktas

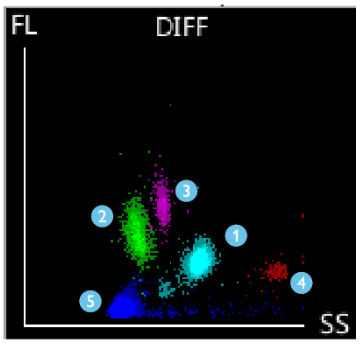
Registruojant skirtingus signalus trijose dimensijose ląstelių pakitimuose su lyse, DIFF kanalas diferencijuoja WBC į subpopuliacijas (limfositai, monocitai, neutrofilų ir eozinofilai), taip identifikuoja ir praneša apie nenormalias ląsteles kaip nesubrendę granuliocitai, pakitę limfostai ir blastai. Tuo tarpu WNB kanalas diferencijuoja basofilus ir branduolėti raudonieji kraujo kūnelliai ir skaičiuoja WBC.

and high nucleic acid content, and less complex in structure, therefore they are at a higher position in the direction of fluorescence, and have stronger side scatter. The neutrophils and basophils are larger in size, and have medium nucleus-to-cytoplasm ratio and low nucleic acid content, therefore they are at a lower position in the direction of fluorescence, but they have stronger side scatter. The characteristics of the eosinophils are similar to those of the neutrophils, but they contain a lot of alkaline grains, so they have very strong side scatter. The blast cells, atypical lymphocytes and immature granulocytes have high nucleic acid content, so they are at a higher position in the direction of fluorescence on the scattergram.

In body fluid samples, the mononuclear cells (MN) are less complex in intracellular granularity, so the side scatter is weaker, while polymorphonuclear cells are more complex in intracellular granularity, so the side scatter is stronger.

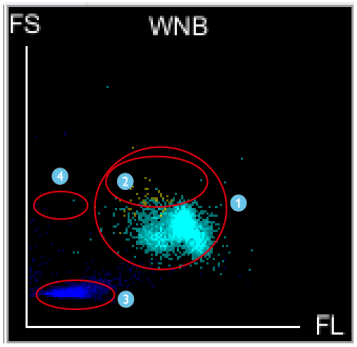
4.2.2 Derivation of WBC-Related Parameters

DIFF Scattergram



1. Neu and Bas region
2. Lym region
3. Mon region
4. Eos region
5. Ghost region

WNB Scattergram



1. WBC region
2. Bas region
3. Ghost region
4. NRBC region

NOTE

- **Users at operator's level can only review the unit system and the parameter units.**
- **Tap "Default" to restore the default units for all parameters.**

Setting up parameter reference range (administrators)

3.1.1.6 punktas

The “Reference Range Setup” screen provides 5 factory reference groups for your selection. In addition, you can set up to 10 custom reference groups. Users at administrator's level may select and customize reference ranges and reference groups.

"Reference Range Setup" ekranas suteikia 5 gamyklines atramines grupes pasirinkimui. Ppildomai galima nustatyti 10 individualių atraminių grupių. Vartotojas su administratoriaus įgaliojimais gali pasirinkti ir keisti atraminius rėžius ir atramines grupes.

6.3.14 Setting up Flag Alarm Sensitivity ("Menu" > "Setup" > "System Setup ">"Flag Alarm Sensitivity") (administrators)

3.1.1.6 punktas

The analyzer provides 14 flags for abnormal blood cell morphology.

Analizatorius suteikia 14 pranešimų apie nenormalią kraujo ląstelių morfologiją.

Information	It means...	Conditions
Blasts?	Possible presence of blast cells	Presence of excessive dots in blast sensitive region of the scattergram
Abn. Lymph/blast?	Possible presence of abnormal lymphocytes or blasts	Presence of excessive dots in abnormal lymphocyte/blast sensitive region of the scattergram
Immature Gran?	Possible presence of immature granulocytes	Presence of excessive dots in immature granulocyte sensitive region of the scattergram
Left Shift?	Possibility of left shift	Presence of excessive dots in left shift sensitive region of the scattergram
Atypical Lymph?	Possible presence of atypical lymphocytes	Presence of excessive dots in atypical lymphocyte sensitive region of the scattergram
RBC Lyse Resistance?	Possibility of RBC lyse resistance	Presence of abnormally distributed dots in WBC sensitive region of the DIFF or WNB scattergram
RBC Agglutination?	RBC results possibly inaccurate	Calculate and compare special parameters
Turbidity/HGB Interference?	Hemoglobin abnormal or there is HGB interference	Calculate and compare special parameters
Iron Deficiency?	May indicate iron deficiency anemia	Calculate and compare special parameters
Fragments?	Possible presence of RBC fragments	Presence of abnormally distributed dots in sensitive region of the RET channel
PLT Clump?	Possibility of PLT clump	Calculate and compare special parameters
Lipid Particles?	Possible presence of lipid particles	Presence of excessive dots in lipid particle sensitive region of the scattergram
Infected RBC?	Possible presence of infected RBC	Presence of excessive dots in infected RBC sensitive region of the scattergram
WBC Fragments?	Possible presence of WBC fragments.	Presence of abnormally distributed dots in WBC fragment sensitive region

*Only applies to BC-6000Plus. During sample analysis, the analyzer evaluates and scores the possibility of the presence of all types of abnormal blood cell morphology. When the score for a certain type of abnormal blood cell morphology exceeds the set threshold, the analyzer reports the flag accordingly.

Administrators may tap "Menu" - "Setup" - "System Setup"- "Flag Alarm Sensitivity" to set up the flag alarm threshold values. The higher the threshold value, the lower the alarm sensitivity of the flag.

Follow below instructions:

7.8 STAT

3.1.1.10 ir 2.3.7 punktai

Naudoti šią STAT funkciją įdėti skubūs mėginiai testuojami nesustabdant automatinio padavimo analizės proceso (mėginiai toliau automatiškai testuojami atlikus STAT mėginį .

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

1. Tap "STAT" on the "Count" screen, or press the [Mode Switch] key on the front cover of the analyzer.

   √ After the current sample has been analyzed, the analyzer will stop the autoloading operation and convert from AL to OV (for open-sampling type analyzer)/CT (for closed-sampling type analyzer) mode.

   √ The "Mode" dialog box displays.

2. Set the analysis order.

   a Enter the sample information and select the desired analysis mode.

   b Tap "OK" to save the settings and exit the "Mode" screen.

3.1.1.10

3. Start STAT sample analysis. Testuoti STATmėginį

4. When the analysis for all STAT samples completes, tap "Exit STAT" on the "Count" screen, or press the [Mode Switch] key on the front cover of the analyzer.

   √ The analyzer switches back to auto-loading mode, then you can proceed with analysis under auto-loading mode.

NOTE

- **For the information of setting analysis order under OV (for open-sampling type analyzer)/CT (for closed-sampling type analyzer) mode, refer to 7.6.1 Setting up Analysis Orders.**
- **For the information of running samples under OV (for open-sampling type analyzer)/CT (for closed-sampling type analyzer) mode, refer to 7.6.2 Performing Sample Analysis.**
- **During the STAT analysis mode, when the operator does not continue to run another STAT sample for a defined period of time, the analyzer automatically exits the STAT mode, and resumes the autoloading analysis that has been paused. Check "Enable Auto Exit STAT", and set up the time.**

7.9 Other Operations

7.9.1 Entering and Exiting Standby

When the time for which the analyzer is free from fluidic operations reaches that you have set on the "Setup"-"Maintenance" screen of the analyzer, the analyzer automatically enters the standby status.

Tap the screen to exit standby.

NOTE

- **Refer to 6.3.11 Setting up the Waiting Time before Analyzer Entering Standby Status (Menu > "Setup"> "Maintenance") (administrators) for how to edit waiting time before entering the standby mode.**

7.10 Shutdown

BIOHAZARD

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

⚠ WARNING

- **The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.**

- parameter flags;
- flags of abnormal blood cell differential or morphology

8.3.1 Parameter Flags

The analyzer provides the following parameter flags.

3.1.1.6 punktas

Labeling	Messages	Meaning
"H" and "L" (default)	High and low result flags	The analysis result exceeds the upper or lower limit of the reference range, but still within the display range
"H" ir "L" (numatytos) or "↑" and "↓"	Aukštų ir žemų rezultatų pranešimai	Analizės rezultatas viršija aukštesnę arba žemesnę ribą atraminės ribos, bet vis dar esantis rodymo diapozone.
"R" (default) or "r"	Suspicious flag	The analysis result is suspicious
"&"	Algorithm-rectified flag	The analysis result is rectified by the algorithm of the instrument
"@"	Out of linearity range flag	The analysis result is out of the linearity range
"++++"	Out of parameter result display range flag	The analysis result is out of the parameter result display range
"****"	Screened results	When the analyzer deems that some parameter results are not reliable (for example, the DIFF results for certain types of abnormal samples), the results of the parameters would be screened from the report screen and display as "****".

NOTE

- **The results of background check will not be flagged for abnormal parameters, abnormal blood cell differential or morphology.**
- **For the linearity range of each parameter, refer to B.6.3 Linearity Range.**
- **For the display ranges of the major parameters, refer to B.6.1 Display Ranges for Major Parameters.**

8.3.2 Flags of Abnormal Blood Cell Differential or Morphology

⚠ CAUTION

- **Abnormal cells may not necessarily trigger the flags during the analysis process, it is recommended**

Pranešimai apie nenormalias kraujo ląstelių diferenciacijas ar morfologiją

The analyzer reports the flags for the following abnormal blood cell differential or morphology.

3.1.1.6 punktas

Flag Message	Indication	Criteria
WBC scattergram abnormal	WBC scattergram abnormal	The distribution of DIFF channel scattergram is abnormal
WNB Scattergram Abn.	WNB channel scattergram is abnormal	The distribution of WNB channel scattergram is abnormal
Neutropenia	Neu# low	Neu# < 1.00×10^9/L
Neutrophilia	Neu# high	Neu# > 11.00×10^9/L
Lymphopenia	Lym# low	Lym# < 0.80×10^9/L
Lymphocytosis	Lym# high	Lym# > 4.00×10^9/L
Monocytosis	Mon# high	Mon# > 1.50×10^9/L

Flag Message	Indication	Criteria
Thrombopenia	PLT low	PLT<60×10^9/L
Thrombocytosis	PLT high	PLT>600×10^9/L
PLT Clump?	There may be PLT clump	Calculation and comparison of special parameters
Pancytopenia	WBC, RBC and PLT low	WBC< 4.0 and RBC< 3.5 and PLT< 100
Lipid Particles?	Possible presence of lipid particles	Presence of excessive dots in lipid particle sensitive region of the scattergram
Infected RBC?	Possible presence of infected RBC	Presence of excessive dots in infected RBC sensitive region of the scattergram
WBC Fragments?	Possible presence of WBC fragments.	Presence of abnormally distributed dots in WBC fragment sensitive region
Aspiration abnormal	The sample probe is clogged or sample volume is insufficient	Insufficient sample aspiration due to clogging of the sample probe, or insufficient sample volume

3.1.1.9 punktas

Nenormalus paėmimas

*: Only applies to BC-6000Plus..

Mėginių adata užsikišusi arba mėginių tūris nepakankamas

10 Calibrating Your Analyzer

10.1 Introduction

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

3.1.1.8 punktas

There are three calibration programs available on this analyzer : manual calibration, auto calibration using calibrators and auto calibration using fresh blood samples.

Yra galimos trys kalibravimo programos šiam analizatoriui: rankinė kalibracija, automatinė kalibracija naudojant kalibratorius ir automatinė kalibracija naudojant žviežio kraujo mėginius.

⚠ CAUTION

- **Use the calibrators and reagents specified by the manufacturer only. Store and use the calibrators and reagents as instructed by their instructions for use.**

10.2 When to Calibrate

Your analyzer is calibrated at the factory just before shipment. It is electronically stable and does not require frequent recalibration if you operate and maintain it as instructed by this manual. It is recommended that you run the calibration program every half year. You only need to recalibrate this analyzer if:

- you are going to use this analyzer for the first time (usually done by a Mindray-authorized representative when installing the analyzer).
- a major analytical component (including sample probe, syringe, etc.) has been changed;
- you are going to re-use the analyzer after a long-term storage.
- the quality control results indicate there may be a problem.

⚠ CAUTION

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

10.3 Checking before Calibration

Before calibration, follow the CLSI standards or your laboratory protocol to do tests, and make sure the analyzer's background (blank count) results, repeatability results and carryover results are all within the specified ranges.

If any of the above items is not in the range, check if the analyzer is in error. Remove the errors (if there are) and check again. If the problem cannot be solved, contact Mindray Customer Service Department.

NOTE

- **For information of the blank count, repeatability and carryover specifications, refer to *B.6 Performance Specifications***

	Blood Sample/ Body Fluid Sample Report Templates	1. Select "Blood Sample Report Template" or "Body Fluid Sample Report Template" from the pull-down list; 2. Select the desired format from the pull-down list: • One page with histogram • One page without histogram	• When "One page with histogram" is selected, the printed report includes the parameter results and the graphs; • When "One page without histogram" is selected, the printed report includes only the parameter results
	Para, language	Select the language to display the parameters: • English abbreviation	When "English abbreviation" is selected, the printed report displays the abbreviated parameter names.
	Copies	• Enter the number of copies to be printed when the "Print" button is pressed • The default setting is 1 copy, and the allowed range is [1-20]	
3.1.1.6 punktas	Printing Content Spausdinimo turinys	Check the items you want to display on the printed report: • Print flags of edited result • Print high/low results flags • Print suspect flags • Print flag • Print reference ranges Spausdinti aukštų/žemų rezultatų pranešimus Spausdinti įtariamus pranešimus Spausdinti pranešimus Spausdinti atramines ribas	• For the information of setting up high/low results as well as suspect results flags,
			setting up reference ranges, refer to 6.3.9 Setting up for Parameters (Menu > "Setup" > "Para. Setup") Setting up parameter reference range (administrators)
	Auto printing after analysis	Check to enable one or more desired auto print settings: • Auto Print after Analysis • Auto print after validating • Auto print after QC count	• When "Auto print after analysis" is enabled, the analyzer automatically print sample results after each analysis • When "Auto print after validating" is checked, the analyzer automatically print validated sample results • When "Auto print after QC count" is checked, the analyzer automatically print QC count results.

⚠ WARNING

- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
- **The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective instrument (e.g. gloves, lab coat, goggles, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water, and seek medical attention immediately.**

⚠ CAUTION

- **Do not mix the new container of reagent with the residue in the replaced container to ensure accurate measurement.**
- **Please keep the diluent container from severe shock or crashing against other object. Otherwise, the alarming would be unreliable.**

12.3.1 Review Reagent Information (Menu > "Setup" > "Reagent Setup")

You may review the expiration dates, use before dates, open dates, valid days and remaining volumes on the "Reagent Setup" screen.

Tap Menu - "Setup" - "Reagent Setup" to enter the reagent setup screen.

√ You may review the expiration dates, use before dates, open dates, valid days and remaining volumes of the analyzing reagents on the "Reagent Management" screen.

3.1.1.11 ir 2.2.7 punktai

Replace	Reagent Name	Expiration Date	Open Date	Valid Days	Use before	Volume(%)
☐	DS DILUENT	2036-01-01	2017-04-12	90	2017-06-10	100.00%
☐	M-6DR DILUENT	2036-01-01	2017-04-12	60	2017-06-10	100.00%
☐	M-6LH LYSE	2036-01-01	2017-04-12	60	2017-06-10	100.00%
☐	M-6LN LYSE	2036-01-01	2017-04-12	60	2017-06-10	100.00%
☐	M-6LD LYSE	2036-01-01	2017-04-12	60	2017-06-10	100.00%
☐	M-6FN DYE	2036-01-01	2017-04-12	60	2017-06-10	100.00%
☐	M-6FD DYE	2036-01-01	2017-04-12	60	2017-06-10	100.00%
☐	M-6FR DYE	2036-01-01	2017-04-12	90	2017-06-10	100.00%

Reagentų kiekio stebėjimas

12.3.2 Replace the Reagents

Replace the reagent when the reagent runs out, is insufficient or expired

The whole reagent replacing procedure includes 3 steps:

1. install a new reagent;
2. enter the new reagent information into the analyzer
3. replace the old the reagent in the fluidic

⚠ CAUTION

- **Do not mix the new container of reagent with the residue in the replaced container to ensure accurate measurement.**

Item/Software access	Status	Path	Account level requirements
Voltage and current	Display the voltage and current information Out-of-range values are highlighted in red background.	Menu - Status - Voltage & Current	Administrator's level
Version information	Review the analyzer software version information	Menu - Status - Version Info.	All

13.3 Error Messages and Solutions

3.1.1.11 punktas

During the operation, if error(s) is detected, the analyzer will beep and display the corresponding error message in the pop-up dialog box.

Jei atiekant operaciją yra fiksuojama klaida, analizatorius pradeda pypsėti ir ekrane pasirodo pranešimas apie esanančią klaidą.

order of their occurrence.

You may tap to select the error, and view its troubleshooting information in the troubleshooting box. The troubleshooting information of the first error is displayed by default. The troubleshooting information of the first error is displayed by default.

The following functions are provided:

■ Remove error

Tap the "Remove Error" button to clear all the errors that can be removed automatically. For the errors that cannot removed automatically, follow the troubleshooting method to solve them.

■ Close the error info. dialog box

Tap "Close" to close the dialog box, but the errors will still be displayed in the error info. area on the screen. Tap the error info. area again, the dialog box will be displayed.

Error ID	Error Message	Description	Solutions
0x32060001	Waste container full	Waste container full	1.Replace the waste container with an empty one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department.
0x32060010	No DS Diluent	No DS Diluent	1.Replace the DS Diluent with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department.
0x32060011	No LD Lyse	No LD Lyse	1.Replace the LD Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department.
0x32060012	No LH Lyse	No LH Lyse	1.Replace the LH Lyse with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department.

B.7.2 Keyboard (Optional)

USB keyboard

B.7.3 Mouse (Optional)

USB mouse.

2.1.3 punktas

B.7.4 External bar-code scanner (optional) Išorinis barkodų skaitytuvas

External USB barcode scanner (hand-held)

3.1.1.1 punktas

B.7.5 Printer (optional) Spausdintuvas pasirinktinai

B.7.6 USB Device (Optional)

B.8 Interfaces

NOTE

- **The USB ports on the left side of the analyzer shall only be used to connect the peripheral devices specified in this manual. See Section B.7 Input/output device for details about supported devices and models.**

2.3.1 punktas

- 1 network port 1 tinklo portas
- 4 USB ports

B.9 Power supply

	Voltage	Frequency	Power
Main Unit (Analyzer)	100V-240V~	50Hz/60Hz	500VA

B.10 Fuse

⚠ WARNING

- **The fuse used in the equipment is not a replaceable one. If there is any problem with the fuse, contact Mindray Customer Service Department or your local distributor.**

B.11 EMC Description

- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.
- This IVD medical equipment complies with the emission and immunity requirements described in IEC 61326-1:2012 / EN 61326-1:2013 and IEC 61326-2-6:2012 / EN 61326-2-6:2013..
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.

NOTE

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

D Transmission

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

2.3.1 punktas

There are 3 types of communication protocol involved in the LIS/HIS communication process of the analyzer: 15ID protocol, HL7 protocol, and ASTM protocol. For details about the connection control, and the introduction, message definition and examples, please contact Mindray Customer Service Department or your local distributor.

Yra 3 tipai komnikacijos prtokolų skirtų LIS/HIS komunikacijos procesams su analizatoriumi: 15ID protokolas, HL7 protokolas ir ASTM protokolas.

3. Manually enter the Sample ID, or use an eternal barcode scanner to scan the barcode label on the tube to enter Sample ID into the "**Sample ID**" field.

NOTE

- **Make sure the Sample ID you entered is the same with the QC sample ID you set in the QC file for the control.**

4. Run the samples in accordance with the normal sample analysis procedure.

√ After the analysis, the QC results will be automatically saved to the corresponding QC file.

4.2.3 L-J QC Review

On the labXpert software, click **Menu**- "**QC**" to review the QC results.

labXpert software supports 4 kinds of QC results review methods:

- L-J Graph
- L-J Table
- Parameter QC Graph
- Monthly QC Graph

4.2.3.1 L-J QC Graph Review

1. On the labXpert data management end, click "**Menu**"-"**QC**" to enter the "QC" screen.
2. Select an analyzer from the "Analyzer" pull-down list;
3. and select "**L-J QC**" for "QC Type".
4. Click "**Graph**" to enter the QC graph review screen.

3.1.1.7 ir 2.2.6 punktas

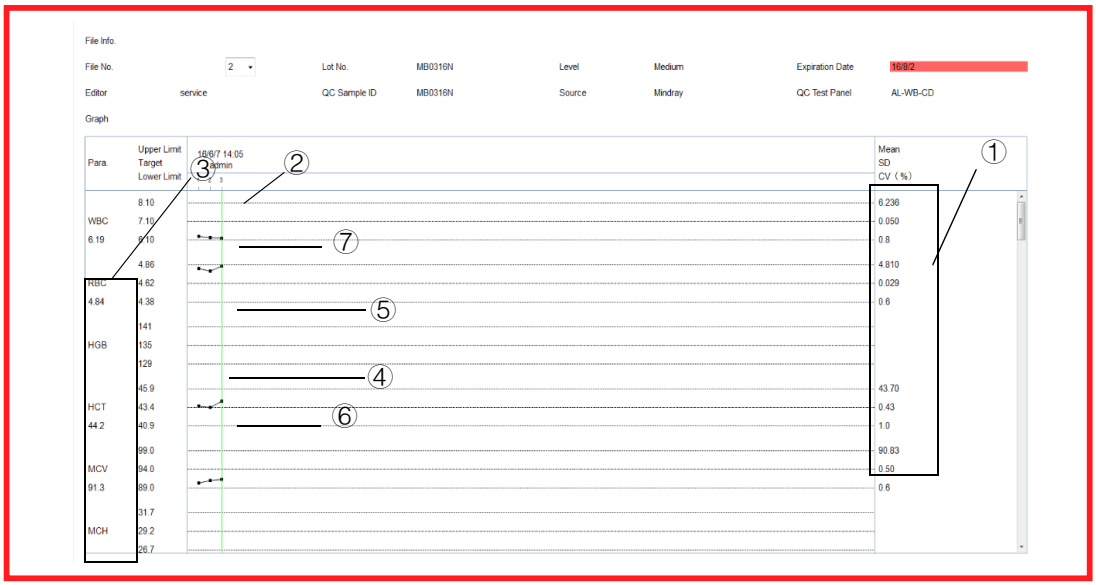


Figure 4-1 L-J QC Graph

Automatiškai apskaičiuojami visų rodiklių vidurkiai, standartiniai nokrupiai, variacios koficientai, autoamtiškai įrašomos į atmintį rodiklių kokybės kreivės.

1 C results of each parameter in the current graph.

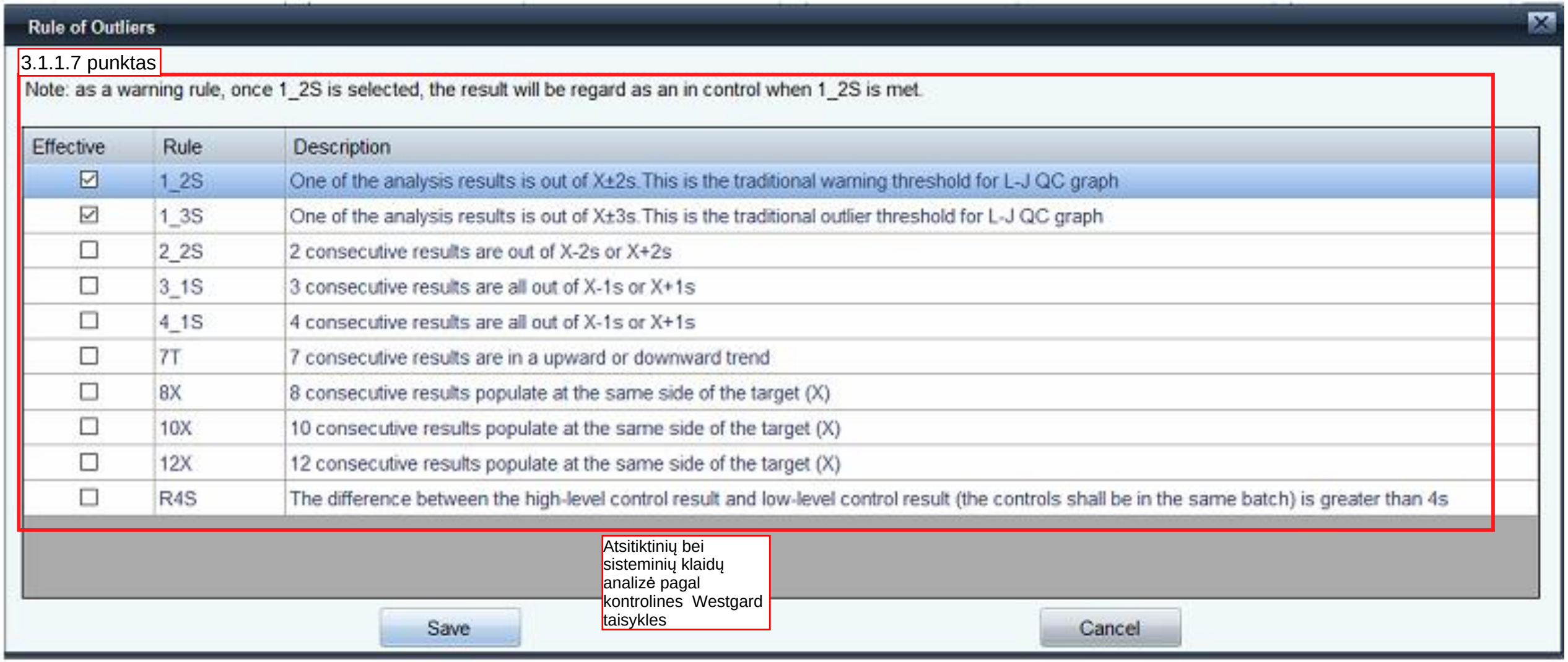
2 QC points on the green line.

3 lysis and obtained the QC points 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 the QC points of the same analysis, all of which are displayed on the line when you select one of them.


Rule of Outliers
3.1.1.7 punktas
Note: as a warning rule, once 1_2S is selected, the result will be regard as an in control when 1_2S is met.
Effective
Rule
Description
1_2S
One of the analysis results is out of X±2s.This is the traditional warning threshold for L-J QC graph
1_3S
One of the analysis results is out of X±3s.This is the traditional outlier threshold for L-J QC graph
2_2S
2 consecutive results are out of X-2s or X+2s
3_1S
3 consecutive results are all out of X-1s or X+1s
4_1S
4 consecutive results are all out of X-1s or X+1s
7T
7 consecutive results are in a upward or downward trend
8X
8 consecutive results populate at the same side of the target (X)
10X
10 consecutive results populate at the same side of the target (X)
12X
12 consecutive results populate at the same side of the target (X)
R4S
The difference between the high-level control result and low-level control result (the controls shall be in the same batch) is greater than 4s
Atsitiktinių bei sisteminių klaidų analizė pagal kontrolines Westgard taisykles
Save
Cancel

5 Operation Principles

4.1 Measurement of the Optical Channel

3.1.1.2 punktas

5.1.1 Laser Flow Cytometry

WBC diferencijavimas-
Lazerio tėkmės citometrija

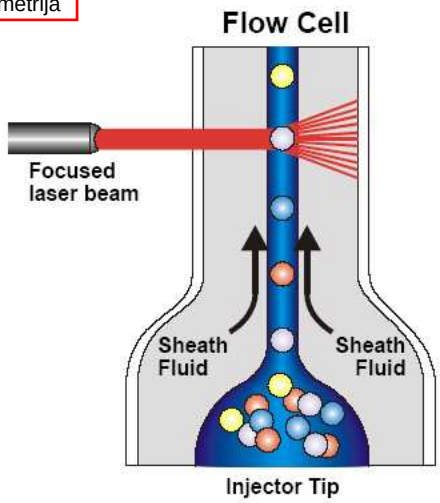


Figure 5-1 WBC measurement

The blood sample reacted with certain amount of lyse and fluorescent dye is injected into the conical flow cell filled with diluent by the sample probe. Surrounded with sheath fluid (diluent), the blood cells pass through the center of the flow cell in a single column. When the blood cells suspended in the diluent pass through the flow cell, they are exposed to a laser beam. The intensity of the light scatter reflects the blood cell size and intracellular granularity. The low-angle forward scatter reflects cell size, the high-angle side scatter reflects intracellular granularity, and the intensity of fluorescent signal reflects the contents of RNA and DNA in the cells. The light signals are collected and converted into electrical pulses. Each blood cell will generate electrical pulse in the directions of low-angle, high-angle and fluorescent light scatter. Pulse data collected can be used to draw a 3-dimensional distribution (scattergram), with the low-angle FS, high angle SS and fluorescence FL as the axes. The scattergram reflects cell size, intracellular granularity and contents of RNA/DNA. The blood cells are differentiated according to their different clinical characteristics.

6.3.12 Setting up the Probe Cleanser Maintenance Time (Menu > "Setup"> "Maintenance") (administrators)

3.1.1.12 punktas

Administrators may set up the start time for daily Probe Cleanser maintenance on the "Maintenance" setup screen.

Administratorius gali nustatyti kasdieninės Probe Cleanser procedūros pradžios laiką "Maintenance" nustatymų ekrane.

1. Tap Menu - "Setup" - "Maintenance" to enter the "Maintenance" setup screen.
2. Set up the start time for daily Probe Cleanser maintenance as needed.

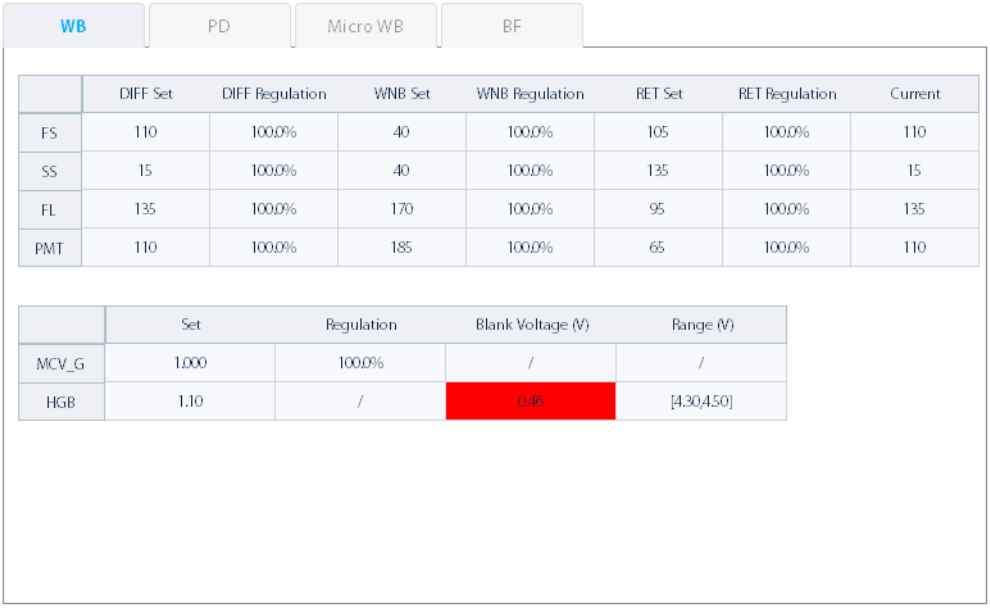
NOTE

- **The allowed range is 0:00 to 23:59. Make sure you enter the valid time and in the required format.**

6.3.13 Setting up HGB Gains (Menu > "Setup" > "Gain Setup") (administrators)

When the analyzer reports the HGB blank voltage abnormal error, and you cannot remove the error by pressing the "Remove Error" button, adjust the HGB gains to correct the HGB blank voltage.

1. Tap Menu - "Setup" - "Gain Setup" - "WB" to enter the WB "Gain Setup" screen.



	DIFF Set	DIFF Regulation	WNB Set	WNB Regulation	RET Set	RET Regulation	Current
FS	110	100.0%	40	100.0%	105	100.0%	110
SS	15	100.0%	40	100.0%	135	100.0%	15
FL	135	100.0%	170	100.0%	95	100.0%	135
PMT	110	100.0%	185	100.0%	65	100.0%	110

	Set	Regulation	Blank Voltage (V)	Range (V)
MCV_G	1.000	100.0%	/	/
HGB	1.10	/	0.46	[4.30,4.50]

2. Adjust the HGB default gain in the HGB "Default" text box, until the HGB blank voltage is in the range of [4.30,4.50].

NOTE

- **When you modify the HGB default gain, the HGB blank voltage will change accordingly.**

3. If necessary, repeat above procedure to adjust the HGB voltages for other modes.

1 Introduction to labXpert Software

1.1 A Brief Introduction to labXpert Software

NOTE

- **For more information about the labXpert software, refer to the Instruction for Use of the labXpert software.**

3.1.1.1 punktas

Mindray's Laboratory Data Management Software (or the labXpert software) is used to managing, processing and analyzing the test data from the hematology analyzer.

Mindray laboratorijos duomenų tvarkymo programa (arba labXpert programa) naudojama valdymui, apdorojimui ir analizavimui testų duomenims iš hematologinio anaizatoriaus

well as set up and edit QC files, and review QC results. You can also set up for the re-exam rules and analyzer's communication with LIS/HIS systems.

The labXpert software consists of two parts: the operation end and the data management end.

The operation end supports following tasks:

- To create and edit tube worklist and tube rack orders;
- To view operation messages;
- To update invalid sample IDs.

The data management end supports following tasks:

- To view, edit and process sample information and results;
- To set up QC files;
- To set up expert tips and validation rules;
- To set up system settings;
- To view statistical information and logs.

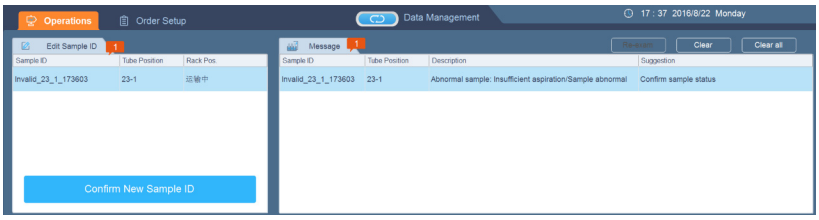


Figure 1-1 labXpert operation end

6 Overview of the Validation Rules

6.1 References

NOTE

- **Inappropriate rule definition may lead to incorrect sample categorization. It is highly recommended that users carefully read the references below and those suggested by your laboratory, and make the rule configuration appropriate and reasonable.**

The International Consensus Group for Hematology Review: Suggested Criteria for Action Following Automated CBC and WBC Differential Analysis; P. W. BARNES, S. L. MCFADDEN, S. J. MACHIN, E. SIMSON; Lab Hematol. 2005;11:83-90.

2.3.4 punktas

6.2 Auto Validation Rules Automatinio validavimo taisyklės

Users at Administrator's level can set up auto validation rules based on the actual needs of the laboratory. The software outputs data summary based on the validation rules set up by the users. labXpert software.

6.2.1 Introduction to the Auto Validation Rules Screen

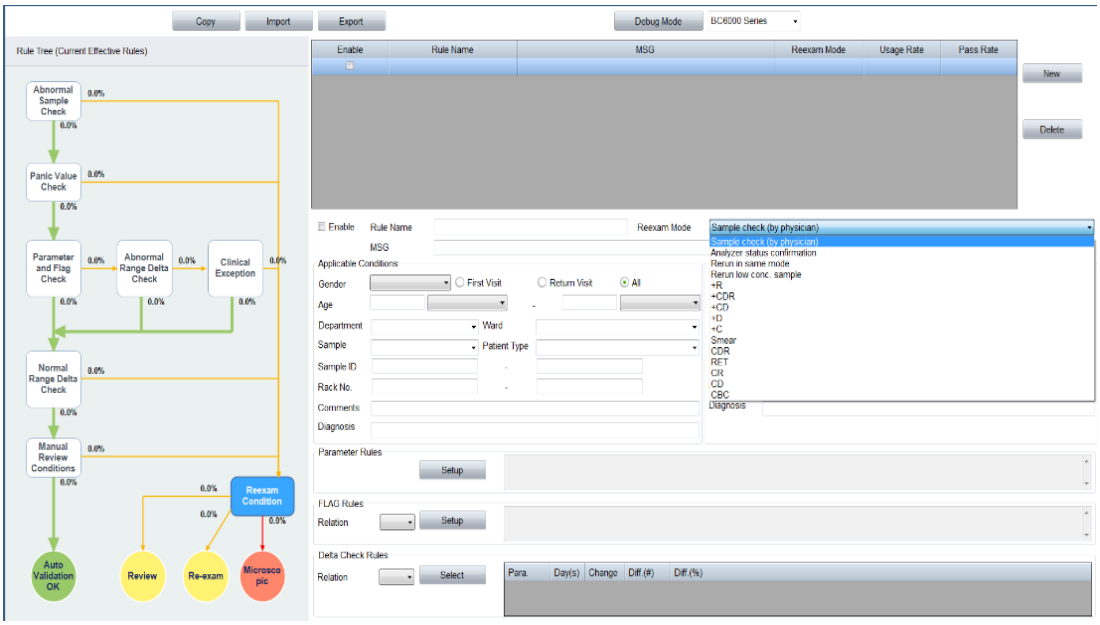


Figure 6-1 Auto validation screen

1	Function button area	• Click "**Import**" to import the auto validation rules from a PC disk. • Click "**Export**" to export the auto validation rules set on the software to a PC disk. • Click "**Debug Mode**" to test the current auto validation rules.
2.	Rules tree	The rules tree displays current auto validation rules

NOTE

- **Users at operator's level can only review the unit system and the parameter units.**
- **Tap "Default" to restore the default units for all parameters.**

Setting up parameter reference range (administrators)

The "Reference Range Setup" screen provides 5 factory reference groups for your selection. In addition, you can set up to 10 custom reference groups. Users at administrator's level may select and customize reference ranges and reference groups.

1. Tap Menu" - "Setup" - "Reference Range Setup" to enter the "Reference Range Setup" screen.

2.4.4 punktas
Analizatoriuje pateikiamos 5 gamintojo rekomenduojamos normų reikšmės, taikomos suaugusiems ir vaikams

2. Tap the "Screen Cal." button in the middle of the screen.
3. Tap the black plus sign at the upper left corner of the screen as instructed by the screen display to start the calibration.

   √ When the calibration completes, the screen displays "Calibration succeeded."

12.9 Reviewing and Exporting Logs

2.2.7 punktas

The "Log" screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer. "Log" ekrane įrašyta visa veiksmų istorija

The analyzer can save logs of the recent two years. If number of logs exceeds the upper limit, the latest log will overwrite the oldest one. You can browse and print logs, but cannot delete them.

Administrators and operators have different authorities:

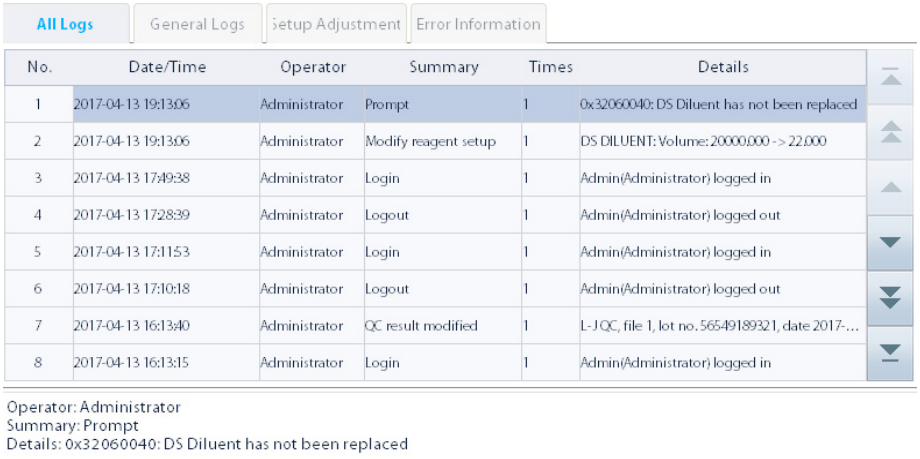
Table 12-6 Logs

	Administrator's level	Operator's level
All Logs	Review both types of logs	Review the logs for analyzer startup and shutdown, user logging in and logging out (only for his/her own account)
General Logs	Review all operation-related logs under both administrator and common user access levels.	Review the logs for analyzer startup and shutdown, user logging in and logging out (only for his/her own account)
Parameter Adjustment	Review all setting adjustment logs under both administrator and common user access levels.	Cannot review
Troubleshooting message	Review error information and troubleshooting information of the analyzer.	Cannot review

12.9.1 Reviewing the Logs

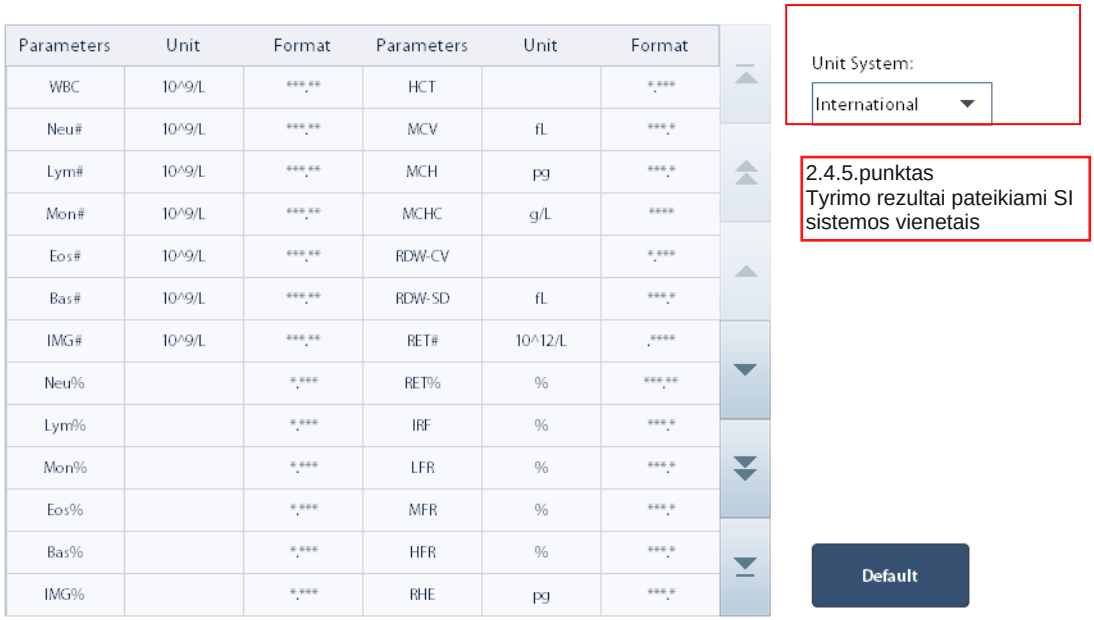
Follow below instructions:

1. Tap Menu - "Service" - "Log" to enter the "Log" screen.



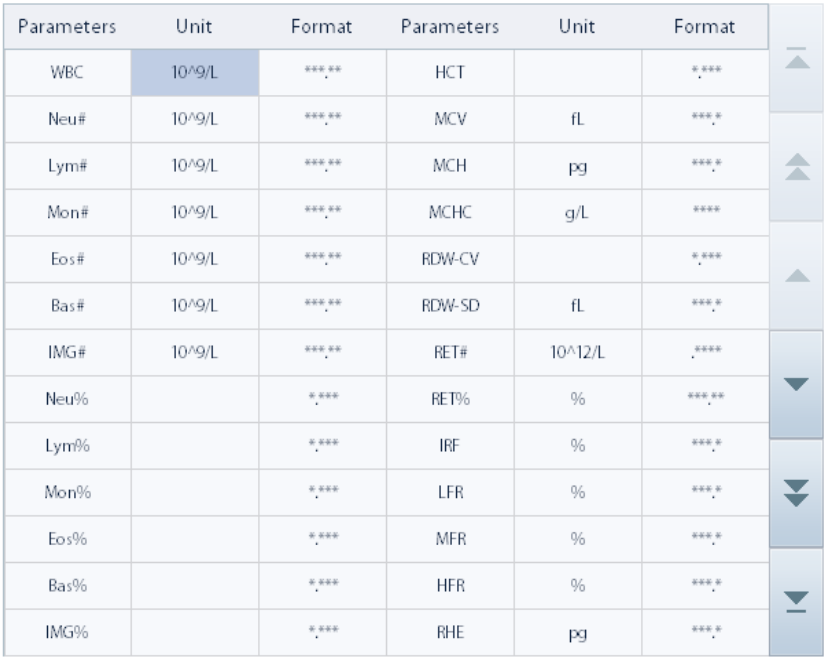
2. Tap the desired log type to review.
3. (Optional) Review the logs at specified date range.
   1. Tap the "Go to" button.

1. Tap Menu - "Setup" - "Para. Setup"- "Parameter Unit Setup" to enter the "Parameter Unit Setup" screen.



2. (Optional) If necessary, select the unit system from the "Unit System" pull-down list.

3. Tap the "Unit" cell of the parameter of which you want to change the unit.



3.1.1.11 punktas

❶	Touch screen	The touch screen displays all alphanumeric and graphic data. You can use it to operate your analyzer		
❷	Status indicator Būsenos indikatorius	The indicator tells you about the status of the instrument including ready, running, error, standby and on/ off, etc. Indikatorius nurodo instrumento būseną, įskaitant ar jis yra pasiruošęs, dirba, klaida, laukimo rėžime, įjungtas/ išjungtas ir tt.	Ready: indicator stays in green	Pasiruošęs: indikatorius lieka žalias
			Running: indicator flickers in green	Dirba: indikatorius mirksi žaliai
			Error: indicator lights in red	Klaida: indikatorius šviečia raudonai
			Sleep: indicator lights in orange	Miego rėžimas: indikatorius šviečia oranžine spalva
			Off: indicator off	Išjungtas: indikatorius išjungtas
❸	[Aspirate] key	The [Aspirate] key is behind the sample probe. Press the key to start open-vial analysis or add diluent		
❹	Sample probe	The sample probe aspirates samples and adds diluent		
❺	Autoloader	The autoloader is in the front of the analyzer. You can use it to load tubes automatically.		
❻	Fluorescent dye compartment	Open the fluorescent dye compartment to replace the fluorescent dyes		
❼	[Run] key	When running samples under autoloading mode, press the [Run] key to start analysis		
❽	Mode switch key	Press the mode switch key to quickly switch between the autoloading mode and the open-sampling mode		