BIO TECHNOLOGY

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hemochroma PLUS

Table of Contents

1. General Information 2
- **1.1 Precautions** 2
- **1.2 Main Menu Displays** 2
- **1.3 Labels and Symbols** 3
- **1.4 Safety Information** 4

2. Introduction 5
- **2.1 Intended Use** 5
- **2.2 Summary and Explanation of the Test** 5
- **2.3 Principles of the Procedure** 5
- **2.4 Quality control (QC)** 5
- **2.5 hemochroma PLUS ID Chip** 5

3. List of package contents and accessories 6
4. Functional and operational elements 8
5. System Display Icons 9
6. Initial Installation Procedure 10
7. System Display 11
8. Operation 12
9. Testing Procedure 15
10. MENU - Data Retrieval 17
11. MENU - Optical System Check 19
12. Set Time & Date 22
13. System Setup 23
14. Technical Specifications 25
15. Warning & Precautions 26
16. Service, Maintenance, and Disposal 28
- **16.1 Disposal** 28
- **16.2 Cleaning exterior of hemochroma PLUS Analyzer** 28
- **16.3 Cleaning inside of sample holder** 29
- **16.4 Disinfection of the instrument** 30
- **16.5 Use of Optical System Check** 30
- **16.6 Protection from Virus and Malware** 31

17. Trouble Shooting 32
18. Performance Characteristics 33
19. Results and Reference Ranges 34
20. Product Warranty 35
21. Contact Information 36

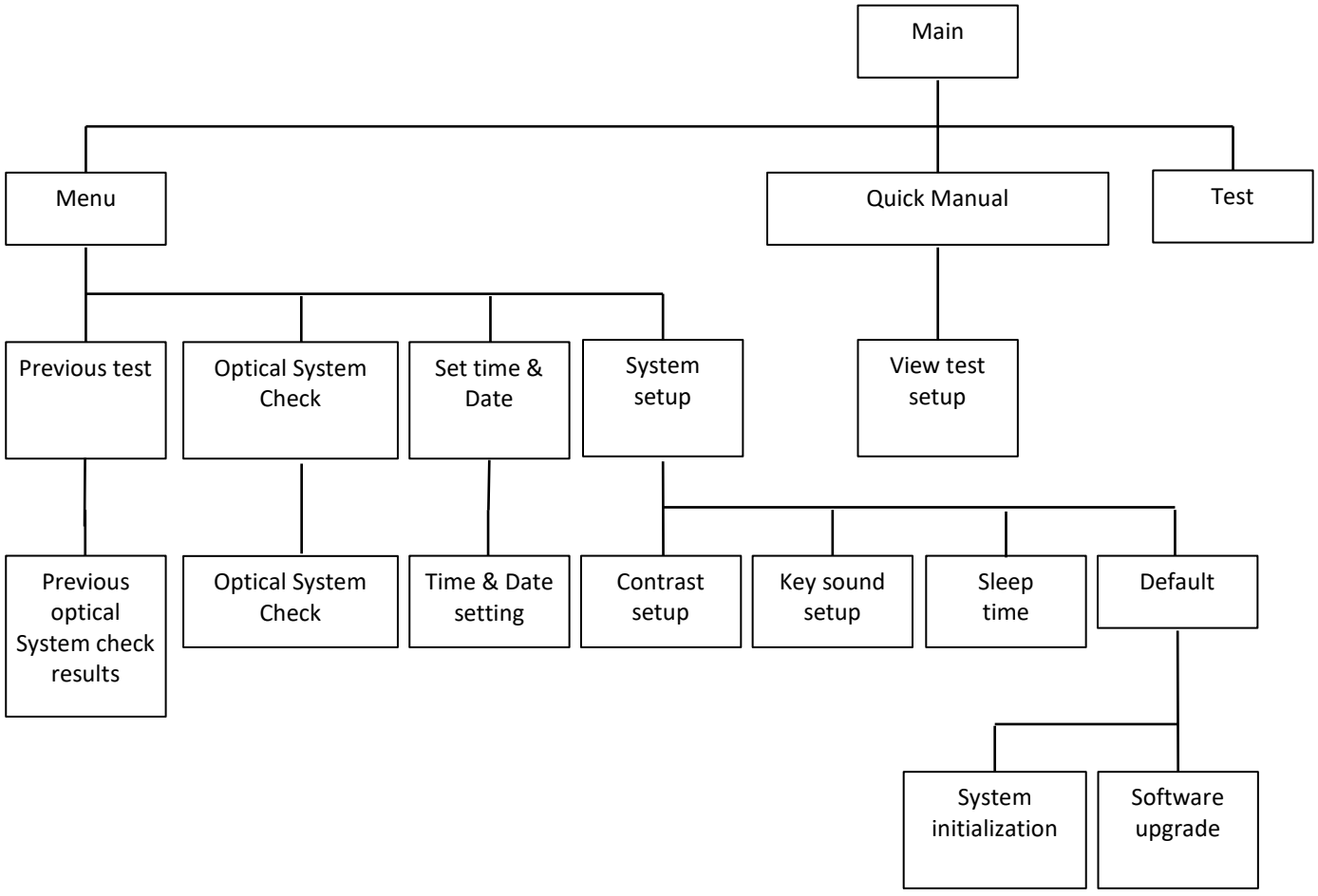
*Thank you for choosing **hemochroma PLUS System.***
Please read this manual thoroughly before you start testing.
This manual provides you with information required for the proper operation.

1. General Information

1.1 ⚠ Precautions

- Do not drop hemochroma PLUS Analyzer as it could damage the unit.
- Do not subject hemochroma PLUS Analyzer to mechanical shocks.
- The user should not make any decision on medical relevance of test results without first consulting the attending physician.
- Keep your hemochroma PLUS Analyzer free of dust, water or any other liquid. Do not expose it to direct sunlight.

1.2 Main Menu Displays



1.3 Labels and Symbols

Label	Description
IVD	*In vitro* diagnostic medical device
	Consult instructions for use
REF	Catalog Number
SN	Serial Number
	Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)
	Temperature limitation
	Date of manufacture
LOT	Batch code
	Contains sufficient for < n > tests
	Use by
	Do not reuse
	Caution and Warning Indicates a situation, which if not avoided could result in damage to the device or provide incorrect results.
	Warning Indicates a hazardous situation, which if not avoided, could result in injury such as electrical shock to the operator or a bystander.
Rx Only	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner
CLIA Waived	CLIA complexity for measurement of hemoglobin in whole blood is CLIA Waived

1.4 Safety Information

hemochroma PLUS Analyzer has been designed to provide safe operation and reliable test results when used in accordance with this User Manual. Users should follow the warnings and precautions included in this manual in order to avoid any incident that could potentially result in device damages or malfunctions.

Warning!

To reduce the risk of electric shock

- Do not immerse hemochroma PLUS Analyzer in water.
- Do not spill any liquid on hemochroma PLUS Analyzer.

Caution!

To reduce the risk of obtaining misleading or erroneous test results with hemochroma PLUS Analyzer:

- Use only fresh venipuncture or finger prick blood samples for testing.
- Do not operate hemochroma PLUS Analyzer near cellular or cordless telephones, microwave oven or other electrical/electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the hemochroma PLUS Analyzer.
- Do not disassemble hemochroma PLUS Analyzer.
- Do not insert anything other than a microcuvette provided by the manufacturer into the sample holder.
- hemochroma PLUS Analyzer can only be used with the microcuvette(s) supplied by Immunostics, Inc.

To reduce the risk of damage:

- Do not place any object on hemochroma PLUS Analyzer as it may adversely affect its performance or result in mechanical damage.

2. Introduction

2.1 Intended Use

The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K2-EDTA, K3-EDTA, sodium citrate, lithium heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities.

Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/L) and in patients ≥ 6 months old.

The hemochroma PLUS Controls are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS System in measuring the human hemoglobin concentration.

The hemochroma PLUS Microcuvettes are only used with hemochroma PLUS Analyzer. The hemochroma PLUS System is for in vitro diagnostic only.

The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.

2.2 Summary and Explanation of the Test

The hemochroma PLUS Analyzer is a battery powered, hand-held device to measure the concentration of total hemoglobin in blood in 3 seconds with 15µL of whole blood. Whole blood may be collected by fingerstick (capillary) or venipuncture and analyzed without pre-processing.

2.3 Principles of the Procedure

The hemochroma PLUS Analyzer uses hemochroma PLUS Microcuvettes with dual ports where the user applies samples either through capillary action or direct volume pipetting. The hemochroma PLUS Analyzer determines hemoglobin concentration in whole blood samples using a dual wavelength photo-absorption method and measures the degree of light absorption with a spectrophotometer.

The optical distance between the hemochroma PLUS Microcuvette walls is fixed and permits photometric determination of hemoglobin in undiluted blood samples. The computed end result is displayed on the LCD display.

2.4 Quality control (QC)

hemochroma PLUS Controls are available in 3 levels (Levels 1-low, 2-middle, and 3-high) are for the hemochroma PLUS Analyzer use only.

2.5 hemochroma PLUS ID Chip

The hemochroma PLUS ID Chip contains encoded memory with the calibration data/information for the lot-to-lot variation. With the ID Chip inserted in the designated port, the hemochroma PLUS Analyzer reads and utilizes the calibration data regarding the lot under consideration and applied appropriate correction to the conversion formula while computing the test result.

3. List of package contents and accessories

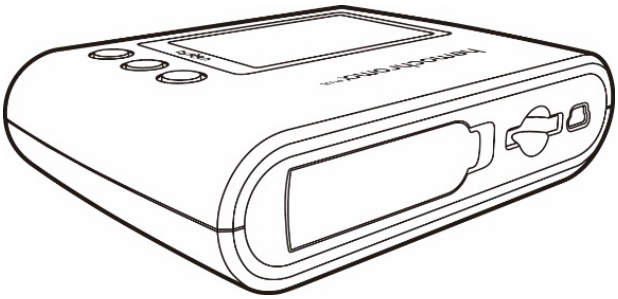
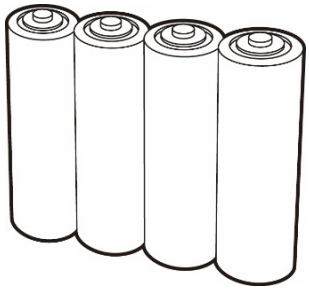
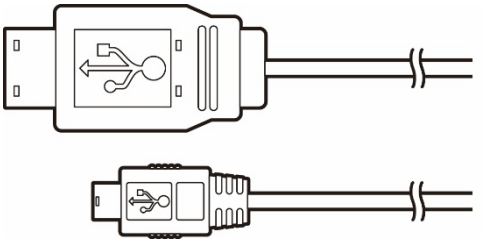
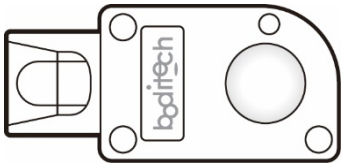
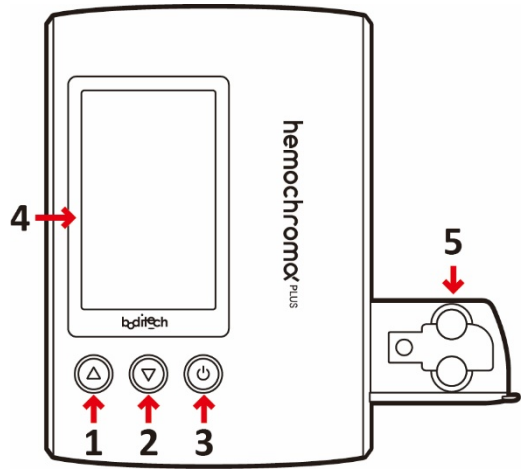
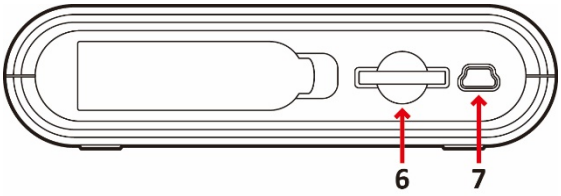
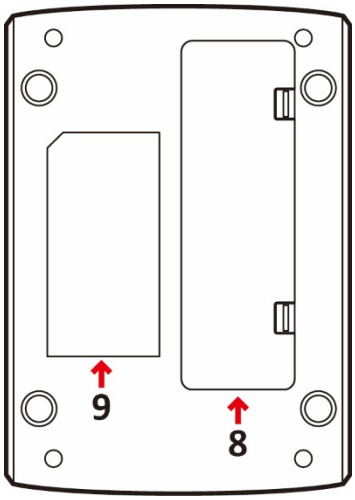
Figure	Description
	hemochroma PLUS Analyzer
	4 Batteries (Type AA or R6 1.5V)
	hemochroma PLUS Analyzer User Manual

Figure	**Description**
	USB serial cable (optional; supplied on demand)
	Microcuvette (not included, marketed separately) REF 100-202

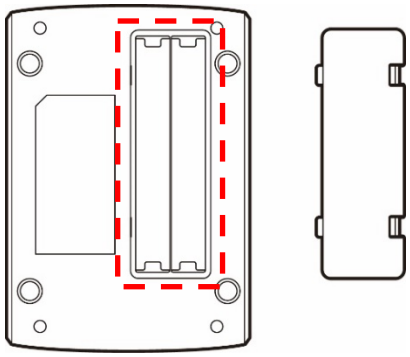
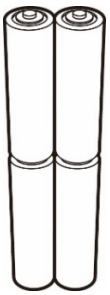
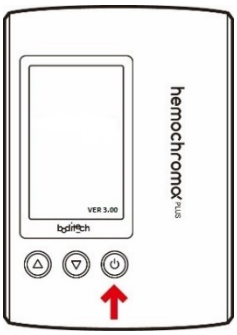
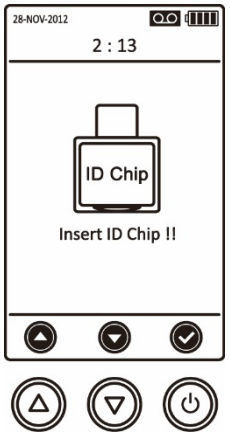
4. Functional and operational elements

Figure	Description
	① Up or Previous button ② Down or Next button ③ Power ON/OFF button or Select button ④ Display Screen ⑤ Sample holder
	⑥ Slot for ID chip ⑦ Connector Port for USB cable
	⑧ Battery Cover ⑨ Label

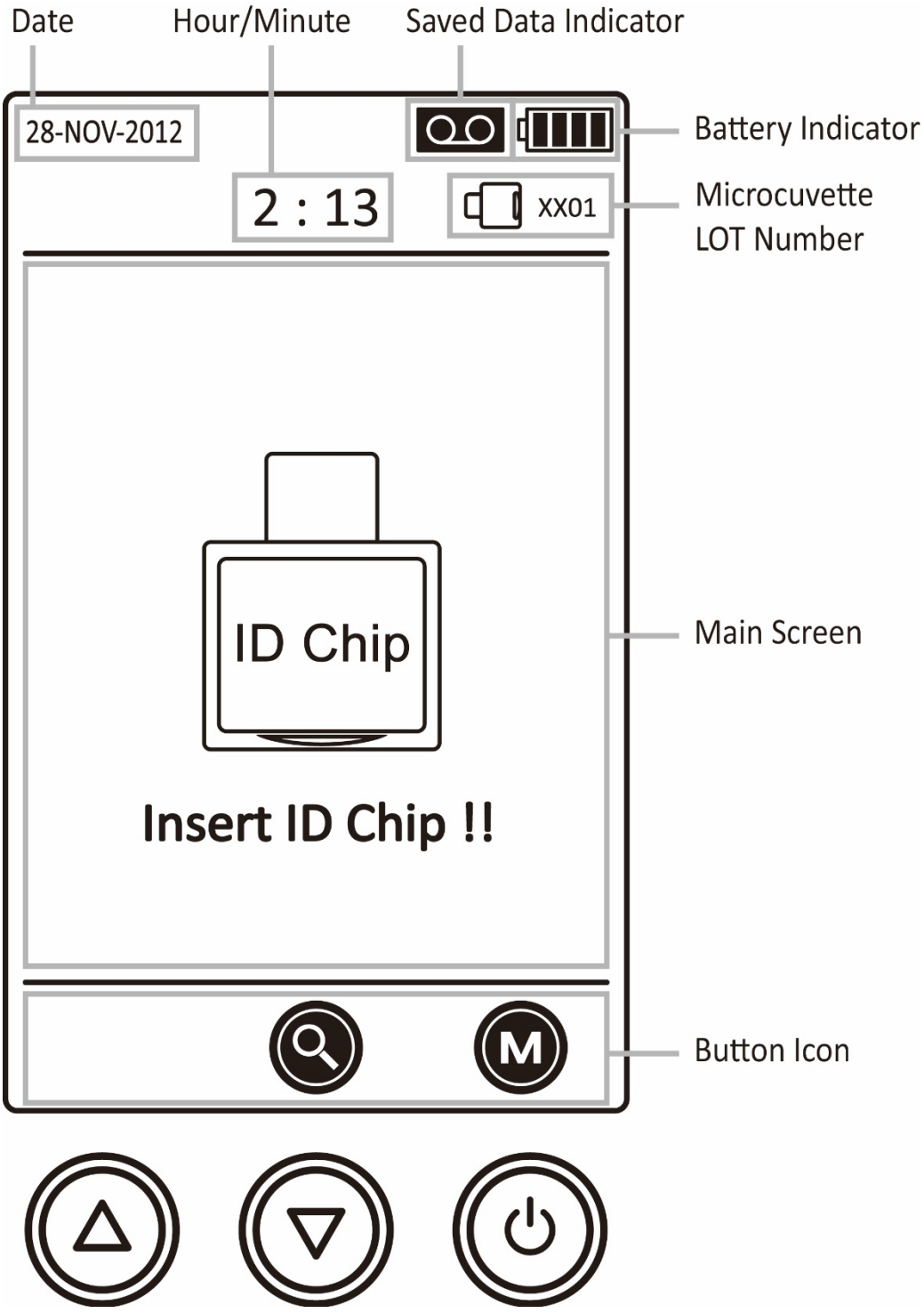
5. System Display Icons

ICON	Description
	Quick manual
	Menu display
	Down
	Up
	Previous
	Next
	Select or Enter
	Cancel
	Return to main
	Delete

6. Initial Installation Procedure

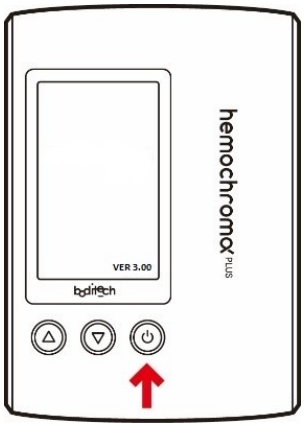
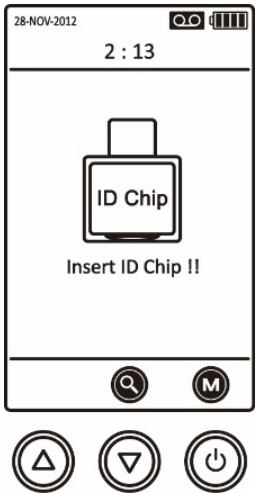
Figure	Description
	Remove the battery cover provided at the bottom and insert the four (4) type AA batteries.
	Position each battery in appropriate direction as shown inside the battery compartment.
	Press the power ON/OFF button until the software version appears at the bottom right corner of the display screen.
	hemochroma PLUS Analyzer is ready for operation when the display 'Insert ID Chip' appears on the screen.

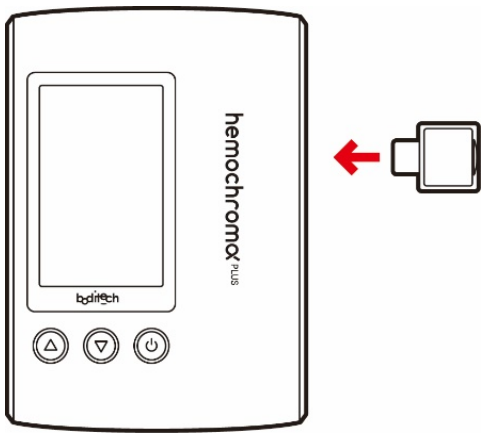
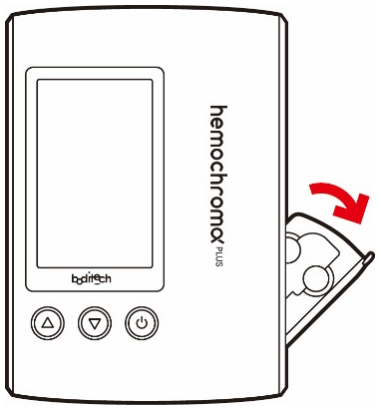
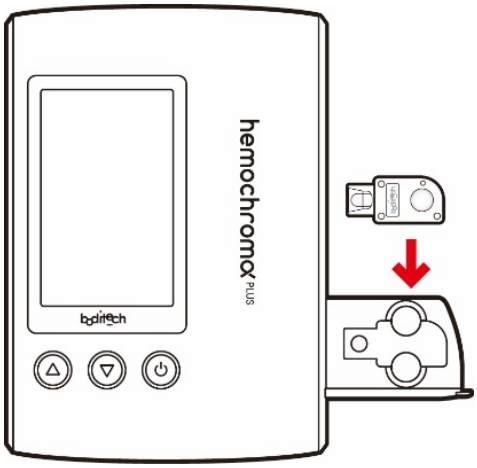
7. System Display

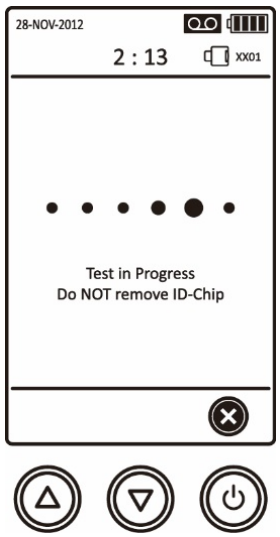
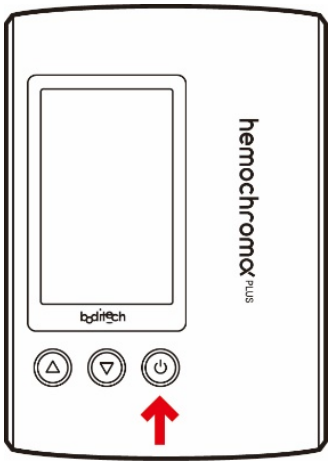


8. Operation

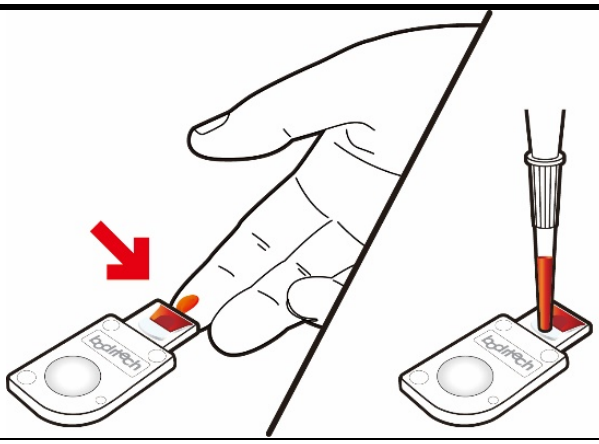
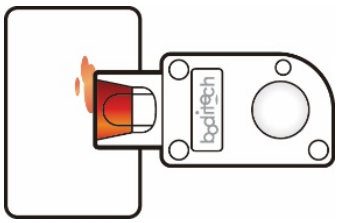
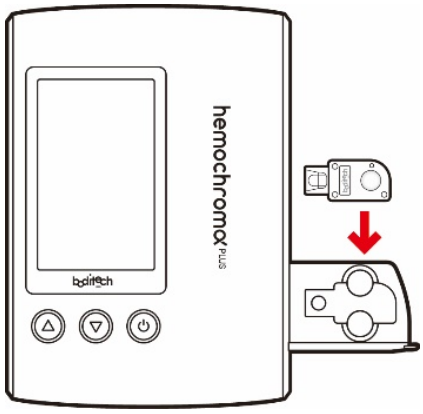
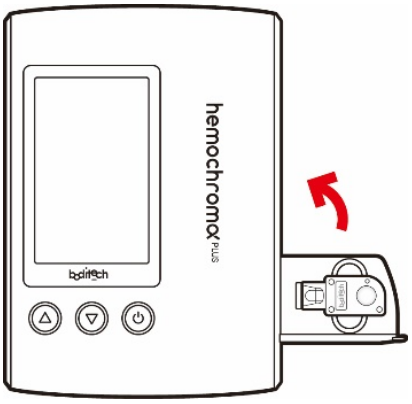
Follow the steps described in this section to run tests on clinical samples.

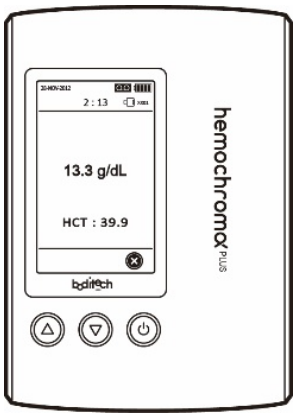
Figure	Description
	Switch the **Power** button 'On'. The screen is lit. The software version information is displayed momentarily.
	"SYSTEM OK" is displayed and the analyzer is ready to run tests.
	"Insert ID Chip !!" is displayed.

	Insert the 'ID Chip' in the ID chip slot of the analyzer. The ID Chip is provided in the microcuvette box.
	With a finger, open the microcuvette holder located on the right side.
	Insert a sample-loaded microcuvette in the holder and close the holder completely. A beep tone sounds and the test proceeds automatically. ⚠ Ensure that lot number of the microcuvette is exactly same as that of the ID chip. Lot number is printed on the microcuvette container and microcuvette box. ⚠ In case the test does not proceed, open the holder and close it again.

	During the test, “Test in Progress! DO NOT Remove ID Chip!” will be displayed.
	To turn the analyzer off, press and hold the ‘**Power’** button for 3 seconds until screen turns off.

9. Testing Procedure

Figure	Description
	**1. Collecting the sample** ➢ Draw finger-prick blood into a microcuvette by bringing the cuvette in contact with the blood drop or apply 15 µL of whole blood sample into the opening of the microcuvette using a micropipette. ⚠ **Follow the precautions described in 'Section 15: Warnings & Precautions'.**
	**2. Removing excess sample** ➢ Wipe off excess blood from the surface of the cuvette using a piece of soft gauze.
	**3. Inserting the Microcuvette** ➢ Open the microcuvette holder. ➢ Place the sample-loaded microcuvette in the holder. Ensure that the microcuvette is oriented in the direction imprinted on the holder.
	**4. Measurement** ➢ Close the holder completely and the analyzer runs the test automatically. ➢ If the test does not proceed automatically, open and close the holder again.

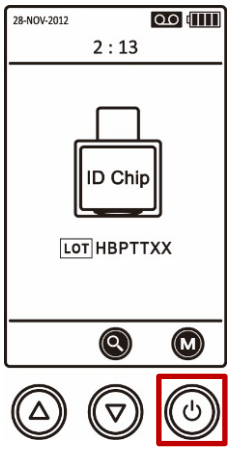
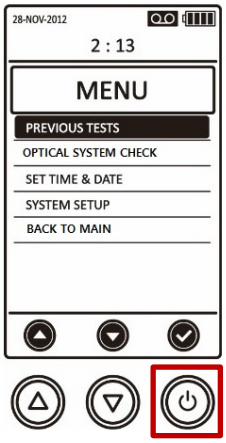
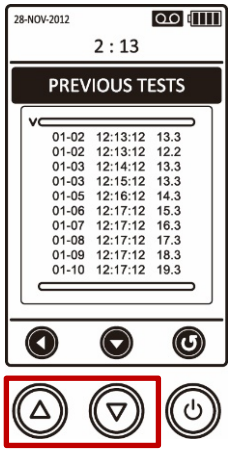


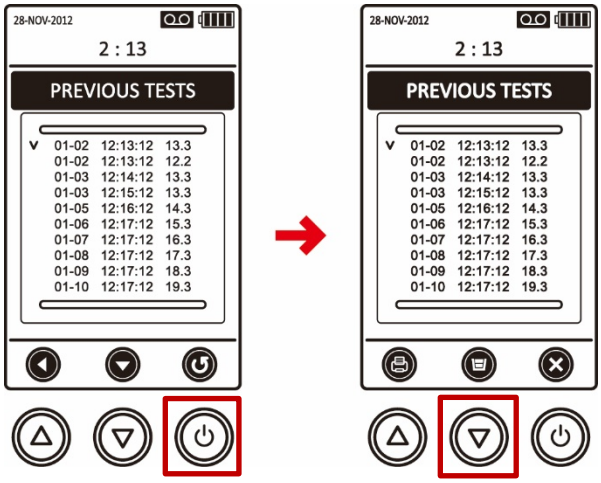
5. Reading the test result

- The test result will be displayed with a “beep” sound.
- The hemoglobin value will be displayed in g/dL. HCT is the calculated accordingly.
- (Estimation of hematocrit, as a function, is only for normal hemoglobin values from 12.0 to 18.0 g/dL (120 to 180 g/L) and in patients ≥ 6 months old.)
- The test result continues to be displayed as long as the microcuvette remains inside the analyzer.
- Removing the microcuvette erases the display and the test result is stored in the memory.
- Use ‘Data Retrieval’ feature to redisplay the result.

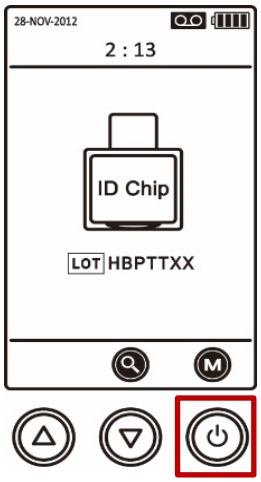
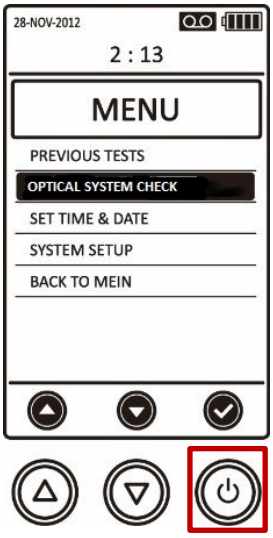
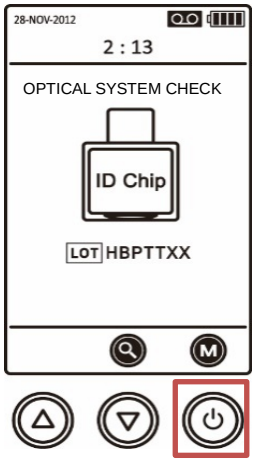
10. MENU – Data Retrieval

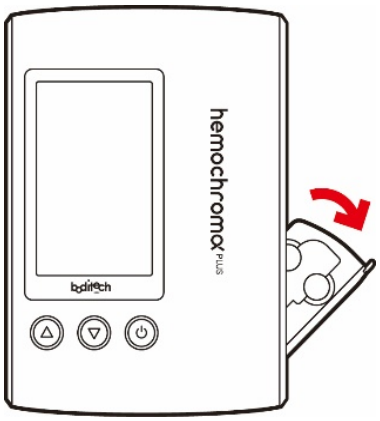
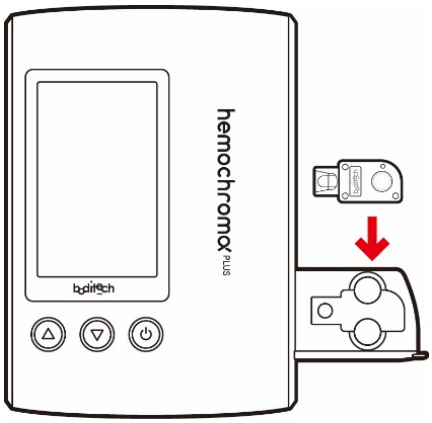
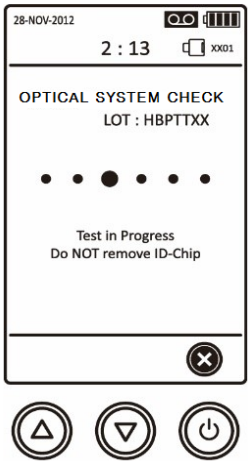
Results for up to 1,000 tests are automatically stored in the on-board memory. Any further test will erase the earliest-stored test result. User can access the stored data using the 'Data Retrieval' feature.

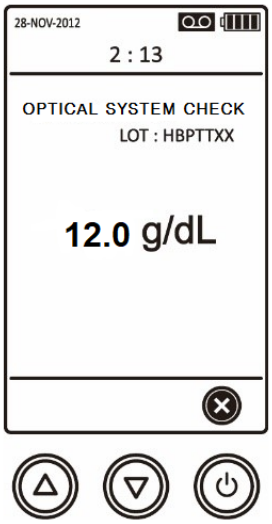
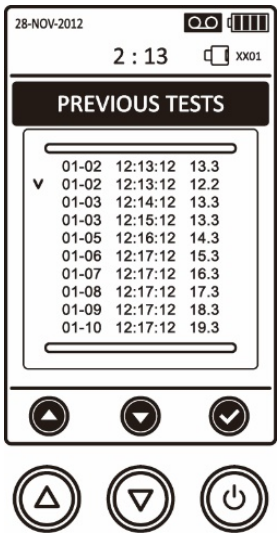
	Figure	Description
1		For data retrieval, activate the 'M' icon in the main menu by momentarily pressing the power button. This would open the submenu list as shown step 2.
2		"PREVIOUS TESTS" option would be highlighted. Activate the '**Select**' icon on the screen by momentarily pressing the power button.
3		Stored test results along with corresponding date and time of testing are displayed. Details of 10 stored test results are accommodated per screen display which is marked by hollow green bars at the top and the bottom. By pressing 'Up' or 'Down' button, the cursor can be moved across the 10 test results being displayed. Moving the cursor beyond the bottom green bar (by pressing the 'Down' button) would display the next set of 10 stored test results. Pressing the 'Up' button would display the immediately previous set of 10 stored test results.

4		**Deleting stored test results:** Set the cursor on the test result to be delete and activate the '**Select**' icon on the screen by momentarily pressing the power button. To delete/erase the selected test result permanently, activate the 'Delete' icon on the screen by pressing the 'Down' button. (Note: Stored test results displayed in yellow fonts denote the tests performed for Optical System Check.)
	To exit 'Data Retrieval' mode, move the cursor on the top green bar as shown in step 3 and press the 'power' button.	

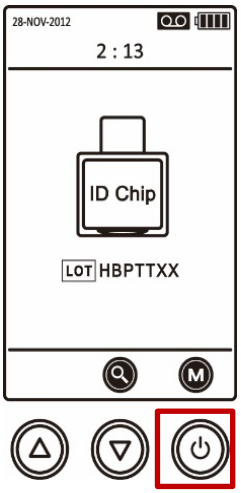
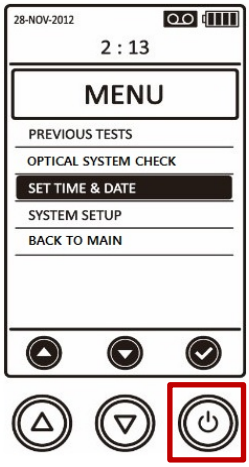
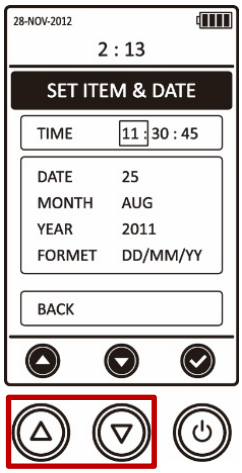
11. MENU – Optical System Check

	Figure	Description
1		Activate the 'M' icon in the main menu by momentarily pressing the power button. This would open the submenu list as shown step 2.
2		Press the 'Down' button to highlight the "Optical System Check" option. Activate the '**Select**' icon on the screen by momentarily pressing the power button.
3		Screen displays the "OPTICAL SYSTEM CHECK" menu. A set of 'Optical System Check Microcuvette & ID Chip' is provided (on demand) with hemochroma PLUS Analyzer. Insert the 'Optical System Check ID chip' in the ID chip slot. ⚠ Once the user performs 'Optical System Check' using a given set of 'Microcuvette & ID Chip', he/she does not need to insert the same 'Optical System Check ID Chip' again since the information of the Optical System Check ID Chip is stored in the system.

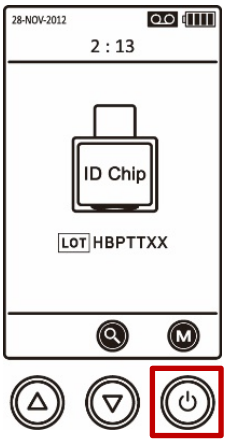
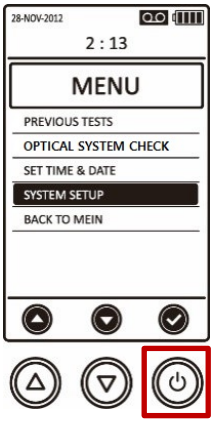
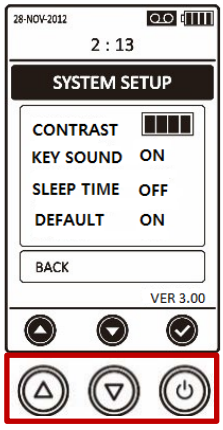
4		Open the microcuvette holder.
5		Insert the 'Optical System Check Microcuvette' in the holder and close the holder completely. Once the analyzer makes a short beep sound, the test proceeds automatically. ⚠ Ensure that lot number of the 'Optical System Check ID Chip' is exactly same as that of the 'Optical System Check ID Chip'. ⚠ In case the test does not proceed, open the holder and close it again.
6		Optical System Check proceeds as displayed on the screen. Do not open the holder while the test is in progress.

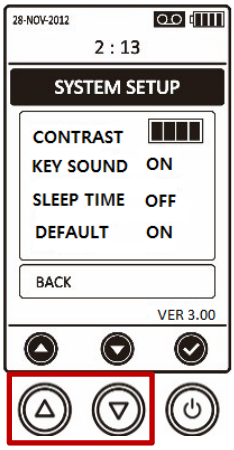
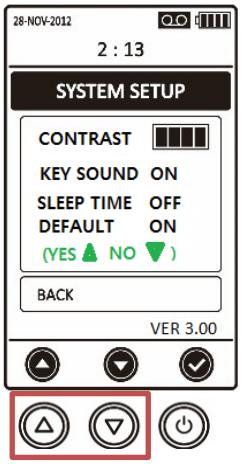
7		Result of Optical System Check is displayed on the screen and also stored in the memory.
8		Optical System Check result(s) is displayed in yellow font when retrieved.

12. Set Time & Date

	Figure	Description
1		Activate the 'M' icon in the main menu by momentarily pressing the power button. This would open the submenu list as shown in step 2.
2		Press the 'Down' button to highlight the "SET TIME & DATE" option. Activate the '**Select**' icon on the screen by momentarily pressing the power button.
3		Set the numerals for the time (Hour: Minute: Second), date and year by pressing the 'Up'/ or the 'Down'/ button. Month and date format can also be set in the same manner. After setting the desired value for a particular field, press the power button to move on to the next field in the order Hour → Minute → Second → Date → Month → Year → Date Format.
	After setting date and time, relevant information appears in yellow font. To exit the "SET TIME & DATE" mode, press the power button.	

13. System Setup

	Figure	Description
1		Activate the 'M' icon in the main menu by momentarily pressing the power button. This would open the submenu list as shown in step 2.
2		Press the 'Down' button to highlight the "SYSTEM SETUP" option. Activate the '**Select**' icon on the screen by momentarily pressing the power button.
3		**Adjusting contrast and key sound:** Adjust the CONTRAST and KEY SOUND (if necessary) by pressing the 'Up'/ or the 'Down'/ button. While setting system parameter, press the power button to move on to the next field in the following order: Contrast → Key Sound → Sleep Time → Default

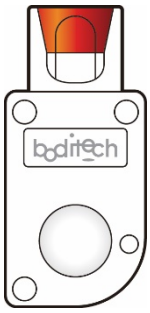
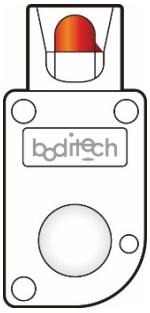
4		**Sleep time:** User can set a sleep time as “OFF” / 5 minutes / 2 hours using the ‘Up’/△ and the ‘Down’/▽ button.
5		**Setting ‘Default’:** Set the ‘Default’ as ‘Yes’ or ‘No’ pressing the ‘Up’/△ and the ‘Down’/▽ button respectively. When Microcuvette ID chip or optical system check ID chip is inserted, the system is set to DEFAULT. After this step, all saved data will be erased. The software will be upgraded automatically when an upgraded ID chip is inserted.
	After setting the system parameters, relevant information appears in yellow font. To exit the “SYSTEM SETUP” mode, press the power ⏻ button.	

14. Technical Specifications

Technical Specifications	
Range of Measurement	5.0 - 25.6 g/dL
Testing time (Turnaround time)	3 seconds
Sample volume	15 µL
Sample	Capillary or Venous Whole Blood
Dimension	106.5 x 151 x 38.5 mm (W x L x H) mm
Weight	(without batteries) 215 ± 3 g
Power	Internal batteries (type AA x 4)
Output	On-board display screen
Environmental Set-up	
Temperature	15 - 35 ℃
Humidity	Max. 75 %

15. ⚠ Warnings & Precautions

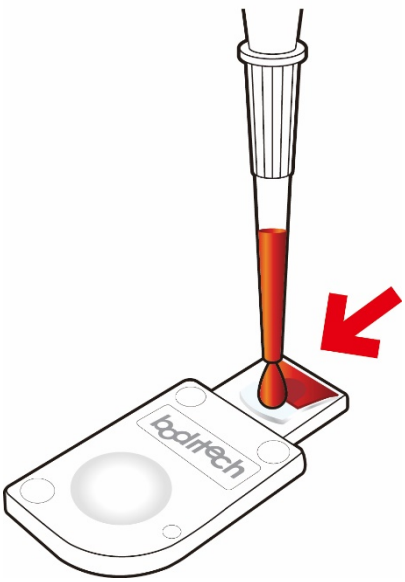
Precaution 1. Withdrawing blood sample into the microcuvette

Right	Wrong		
Sufficient	**Unacceptable bubbles**	**Insufficient**	**Insufficient**
			

When the blood sample is being drawn into the microcuvette, the following precautions should be considered.

1. Any size of bubbles in the optic window of the microcuvette is not acceptable.
2. Sufficient volume of blood should be filled in the microcuvette as shown above.

Precaution 2. Blood sample application onto the microcuvette using a pipette



Set the pipette volume at 15 µL and draw blood from a blood tube. (K_2-EDTA, K_3-EDTA, sodium citrate, lithium heparin, or sodium heparin)

Apply the sample to the top hole as shown.

For the best result, it is advised to place the pipette tip as shown in the drawing.

The excess sample, if any, should be removed, with a piece of gauze.

Right	Wrong
Properly prepared sample 	Improperly prepared sample 

16. Service, Maintenance and Disposal

If any service or maintenance is required, hemochroma PLUS Analyzer should be sent to Immunostics Inc. or its designated representatives. No maintenance other than periodic cleaning and disinfecting is required for the analyzer. Thorough cleaning of the analyzer can prevent the risks of spreading infectious microorganisms to the users.

16.1 **Disposal**

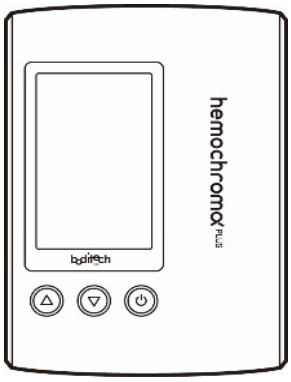
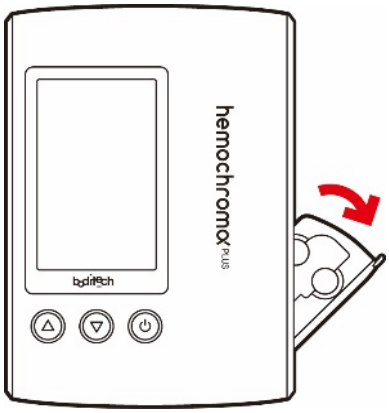
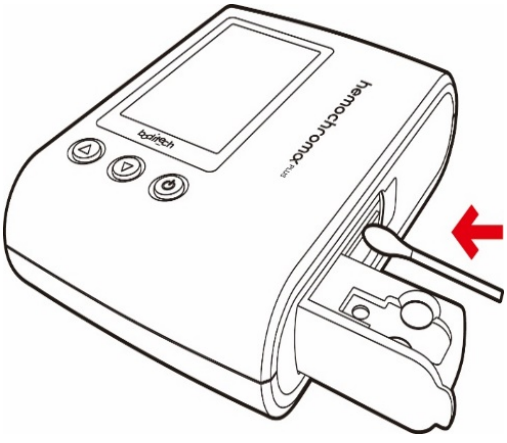
If, for any reason, hemochroma PLUS Analyzer should be disposed, the user is advised to observe applicable ordinances regarding the disposal of electrical equipment. Dispose used lancets or syringes in a sharps container and used microcuvettes should be disposed in a biohazard container. Dispose used batteries according to local environmental regulations.

16.2 **Cleaning exterior of hemochroma PLUS Analyzer**

Clean the exterior of the analyzer daily with a soft clean cloth slightly dampened with mild detergent or 70 % rubbing alcohol (wipes). Avoid applying excessive pressure when cleaning the surface. Also, do not directly pour detergent or rubbing alcohol on the hemochroma PLUS Analyzer.

The microcuvette holder should be cleaned daily or when there is visible dirt or dried blood with a cotton swab dampened with water or 70 % rubbing alcohol.

16.3 Cleaning inside of sample holder

	Figure	Description
1		➢ Turn the power off before cleaning.
2		➢ Open sample holder such in the picture.
3		➢ Use a cotton swab (dampened with 70 % alcohol) or mild neutral detergent to clean inside of the sample holder. ➢ Do not apply excessive alcohol or mild neutral detergent to a cotton swab. ➢ Do not use a sharp stuff or contaminated cotton swab. ➢ Please wait for to use at least 15 minutes after cleaning (Be sure the holder is completely dry before inserting the microcuvette in the holder).

16.4 **Disinfection of the instrument**

Micro-Kill Bleach Germicidal Bleach Wipes (EPA Reg. No: 37549-1) are recommended to use to disinfect the instrument. The instrument does not need to be wiped with the bleach wipes necessarily after every test, but it should be used daily (when blood collection is finished for the day) or when the patient is known to have *C.diff*, MRSA, Hepatitis viruses, and etc. Both the surface and the holder should be wiped thoroughly.

16.5 **Use of Optical System Check**

Optical System Check kit contains an Optical System Check Microcuvette and an Optical System Check ID Chip.

Optical System Check ensures and verifies the performance of hemochroma PLUS Analyzer. Optical System Check is recommended to be used when:

- A new analyzer is taken out of the box.
- A new lot of hemochroma PLUS Microcuvettes is open.
- It is to be operated in a different environment than usual.
- The analyzer has not been used more than a week.
- The test results do not match patients' symptoms.
- For training purposes.

The acceptance value is written inside the Optical System Check box (i.e. 12±0.3 g/dL).

- The analyzer is expected to give any results from 11.7 to 12.3 g/dL.
- If the readings are outside the given range, check if the Optical System Check Microcuvette is contaminated. If any dirt is detected, then gently wipe it with a soft piece of cloth. If the result is still outside the range, please use a new optical system check kit. If the readings continue to be the outside the expected range, please halt any further testing and contact your distributor.

For further information, please refer to the hemochroma PLUS Optical System Check Package Insert.

16.6 **Protection from Virus and Malware:**

hemochroma PLUS Analyzer is an embedded system. The user cannot make changes to the software. The software is specific for the hemochroma PLUS Analyzer. The operating system was written using ANSI C programming language and manages the basic functions of the hemochroma PLUS Analyzer hardware, including peripherals. The Analyzer does not have wireless capabilities; therefore, data cannot be transmitted to a computer.

The hemochroma PLUS Analyzer is thoroughly protected from external threats such as external viruses and malwares, which ensures integrity of devices software from point of origin to destination.

17. Trouble Shooting

Error Messages	Description of the Problem	Solutions
hemochroma PLUS Analyzer does not turn on.	Batteries are low.	Replace all 4 batteries.
	Batteries are installed incorrectly or there are no batteries in the analyzer.	Check if batteries are inserted correctly in accordance with (+) and (-) markings inside the battery compartment.
Insert ID Chip!!	1. No ID Chip	Insert an ID Chip.
	2. Defective ID Chip	Replace with a new ID Chip.
Check Microcuvette	There is no Microcuvette or sample blood	Repeat the test and confirm if there is correct sample volume loaded in the Microcuvette.
Results < 5.0 g/dL	Hgb concentration is lower than 5.0 g/dL.	Repeat the test and confirm if there is correct sample volume loaded in the Microcuvette.
Warning! Holder is open. Close holder!	Holder is open.	Close the holder to resume test.
Optical failure	Photo sensor intensity is low.	Check the holder and remove the used Microcuvette and restart the analyzer.
	Light source and/or the photo-sensor is contaminated or malfunctioning.	Contact Technical Service.

18. Performance Characteristics

- A total of 480 test results generated from the precision study conducted at three intended use sites over 20 operating days showed that % CV was less than 3.0 %.
- An interference study with the potential interfering endogenous and exogenous substances (listed in the table below) showed there was no interference.

Exogenous Substances	Test Concentration	Endogenous Substances	Test Concentration
Acetaminophen	1324 µmol/L	**Bilirubin (conj.)**	342 µmol/L
Ammonium Ferric citrate	300 mg/L	**Cholesterol**	13 µmol/L
Ascorbic Acid	342 µmol/L	**Creatinine**	442 µmol/L
Ferrous Sulfate	222 mg/L	**Protein (Total)**	120 g/L
Ferrous Fumarate	300 mg/L	**Triglycerides**	37 mmol/L
Folic Acid	7.5 mg/L	**Urea**	42.9 mmol/L
Ibuprofen	2425 µmol/L	**Uric acid**	1.4 mmol/L
Iron Dextran	2838 mg/L		
Salicylic Acid	4.34 mmol/L		
Tetracycline	34 µmol/L		
Vitamin B12	1000 pg/mL		

19. Results and Reference Ranges

The saved results can be accessed through the main menu under the “Previous Test” tab.

The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.

The following hemoglobin values are considered normal:

■ Expected values: [1, 2]

Group	Cited Reference Range
2-6 months	9.5-13.5 g/dL
7 months-2 years	10.5-14.0 g/dL
3-6 years	11.5-14.5 g/dL
7-12 years	11.5-15.5 g/dL
13-18 years Male	13.0-16.0 g/dL
13-18 years Female	12.0-16.0 g/dL
Adult Male	14.0-18.0 g/dL
Adult Female	12.0-16.0 g/dL

1. Billett, HH. Hemoglobin and Hematocrit. Clinical Methods: The History, Physical, and Laboratory Examinations. Boston: Butterworths, 3rd edition, 1990: chapter 151.
2. Andropoulos, Dean B., and George A. Gregory. Gregory’s Pediatric Anesthesia. 5th ed., Wiley-Blackwell, 2012.

* Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establishes its own normal range. The hemochroma PLUS System was not evaluated in patients < 6 months of age.

■ The reportable range of the hemochroma PLUS Analyzer is **5.0 - 25.6** g/dL.

20. Product Warranty

This product has passed strict quality assurance and testing procedures. Immunostics, Inc. expressed and implied warranties are conditional upon full observance of manufacturer's published directions.

Under no circumstances whatsoever shall either Boditech Med Inc. or Immunostics, Inc. be held liable for any indirect or consequential damages due to this product.

[Warranty Information]

Defective products or spontaneously malfunctioning products will be repaired at no charge or compensated in accordance with the consumer protection rules and regulations.

This warranty does not provide protection against any failure of, defect in or damage to the product caused by any situations beyond normal exposure conditions, including but not limited to the following:

- Improper use or misuse.
- Consumer's intentional abuse or neglect of the products.
- Unauthorized repairs or parts replacement.
- Changes in contents.
- Damages or defects due to pollution, earthquake, lightening, fire, tornado, flood, or any other natural disasters.

Product Name	hemochroma PLUS Analyzer
Serial No.	
Date of Manufacture	
Warranty Period	24 months from the date of purchase
Date of Purchase	Mo Day Year
Distributed by	Immunostics, Inc.
Purchase Location	

21. Contact Information

For technical assistance, call or E-mail: Immunostics Inc. Technical Service at

Tel: (732) 918-0770 / Toll Free: (800) 722-7505

E-mail: technical@immunostics.com

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Fax: (732) 918-0618 / E-Mail: sales@immunostics.com

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