

IMMUNOFLUOROMETER EQUIPMENT

ichroma™ Reader

Operation Manual



IMMUNOFLUOROMETER EQUIPMENT

Thank you for your decision to use **ichromα™ Products**

Please read this manual thoroughly before you start testing with
ichromα™ Reader.

This manual provides all the information required for operating
the **ichromα™ Reader.**

Carefully follow the instructions given in this manual.

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1. Important Information

Intended Use:

ichrom α TM Reader is a portable fluorescence scanning instrument for measuring the concentration of designated analytes in the human blood, urine and other specimens; duly processed and tested in accordance with various ichrom α TM Immunoassay Tests manufactured by Boditech Med Incorporated.

ichrom α TM Reader is to be used only in conjunction with various ichrom α TM Immunoassay Tests and meant only for in vitro diagnostic purpose.

ichrom α TM Reader can be used for screening, monitoring and/or routine physical examination in centralized laboratories of hospitals, physicians' clinics as well as for self-testing by the patients.










Please note:

- The user of ichrom α TM Reader in conjunction with the ichrom α TM Immunoassay Test should not arrive at any conclusion and/or should not take any decision of medical/therapeutic importance after knowing the test result without first consulting his/her physician.
- Unless otherwise explicitly stated in the package insert; use only fresh blood, urine or other human specimen for testing with ichrom α TM Immunoassay Test in conjunction with the ichrom α TM Reader.
- ichrom α TM Reader is compatible only with various ichrom α TM Immunoassay Tests manufactured by Boditech Med Incorporated. Use of ichrom α TM Reader in conjunction with immunoassay test devices of other marketed brands may yield misleading results.
- In order to obtain accurate results, the ichrom α TM Immunoassay Tests should be performed and scanned/read on the ichrom α TM Reader in an environment having temperature 15~35°C (59~95°F) and maximum relative humidity 70%.
- The test set up should be exposed to the ambient temperature for at least 30 minutes until just prior to performing the test actually.
- Avoid exposure of ichrom α TM Reader to dust, water or any other liquid and direct














sunlight. Similarly refrain from throwing, shaking, dropping or mishandling the ichromα™ Reader, which may damage its internal parts.

- Do not operate your ichromα™ Reader in close proximity of cellular or cordless telephones and electrical or electronic equipment like microwave oven that are sources of electromagnetic radiation, as these may interfere with normal functioning of the ichromα™ Reader.
- Don't disassemble your ichromα™ Reader in any case.

Following list explains various symbols, which the user will find in this ichromα™ Reader operation manual, ichromα™ product labels and packaging and the package inserts.

	For in vitro diagnostic use
	This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices
	Caution! Risk of electric shock
	Attention! Read instructions before use
	LASER Hazard
	Manufacturer
	Direct Current
	Separate collection for electrical and electronic equipment
	Bio Hazard

2. Safety Information

 Caution	<p>The user must ensure that ichromα™ Reader functions safely and it is in proper working condition before being used.</p> <p>Be sure to read thoroughly and follow all instructions, warning and cautions before using ichromα™ Reader.</p>
 Caution	<p>ichromα™ Reader is based on a high voltage circuit. Never attempt to remove or open any part of the ichromα™ Reader casing.</p>
 Caution	<p>Use of damaged or improperly adjusted ichromα™ Reader or improper use of ichromα™ Reader could result in personal injury.</p>
 Caution	<p>Never attempt to look into the laser aperture.</p> <p>Never attempt to use mirror or other devices to observe the laser beam or the lens.</p>
 DANGER	<p>Being electrical equipment, misuse or unwarranted use of ichromα™ Reader may cause electrocution, burns, fire and other hazards.</p> <p>Use only the power adapter provided with ichromα™ Reader.</p>
 DANGER	<p>Do not allow ichromα™ Reader to come in contact with liquid in any manner.</p> <p>If ichromα™ Reader becomes wet, unplug it before touching it.</p>
 Important	<p>Ensure that the voltage setting of ichromα™ Reader matches the power supply voltage.</p>
 Important	<p>Use ichromα™ Reader only for its intended use described in this manual.</p>
 Important	<p>Do not use ichromα™ Reader with such accessories which are not recommended and/or supplied by Boditech Med Incorporated.</p>
 Important	<p>Do not use ichromα™ Reader if it is not working properly, or if it has suffered any damage.</p>
 Important	<p>Do not place anything on top of ichromα™ Reader even when it is lying idle.</p>
 Important	<p>Unless otherwise instructed specifically, do not insert anything into any opening, socket or holder provided in the ichromα™ Reader. Similarly do not put anything in any hose or attach anything to any coupling of the ichromα™ Reader.</p>
 Important	<p>Do not use ichromα™ Reader in outdoor settings.</p>

3. Principle

ichromα™ Reader is a fluorescence scanning instrument to be used in conjunction with various ichromα™ Immunoassay Tests which are based on antigen-antibody reaction and fluorescence technology.

ichromα™ Reader uses a semiconductor diode laser as the excitation light source for illuminating the test cartridge membrane (pre-loaded with the clinical specimen duly processed as per the standard test procedure prescribed by Boditech Med Inc.) thereby triggering fluorescence from the fluorochrome molecules present on the membrane.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluoresced light. Intensity of the fluorescence is scanned and converted into an electric signal which is proportional to the intensity of fluorescence produced on the test cartridge membrane.

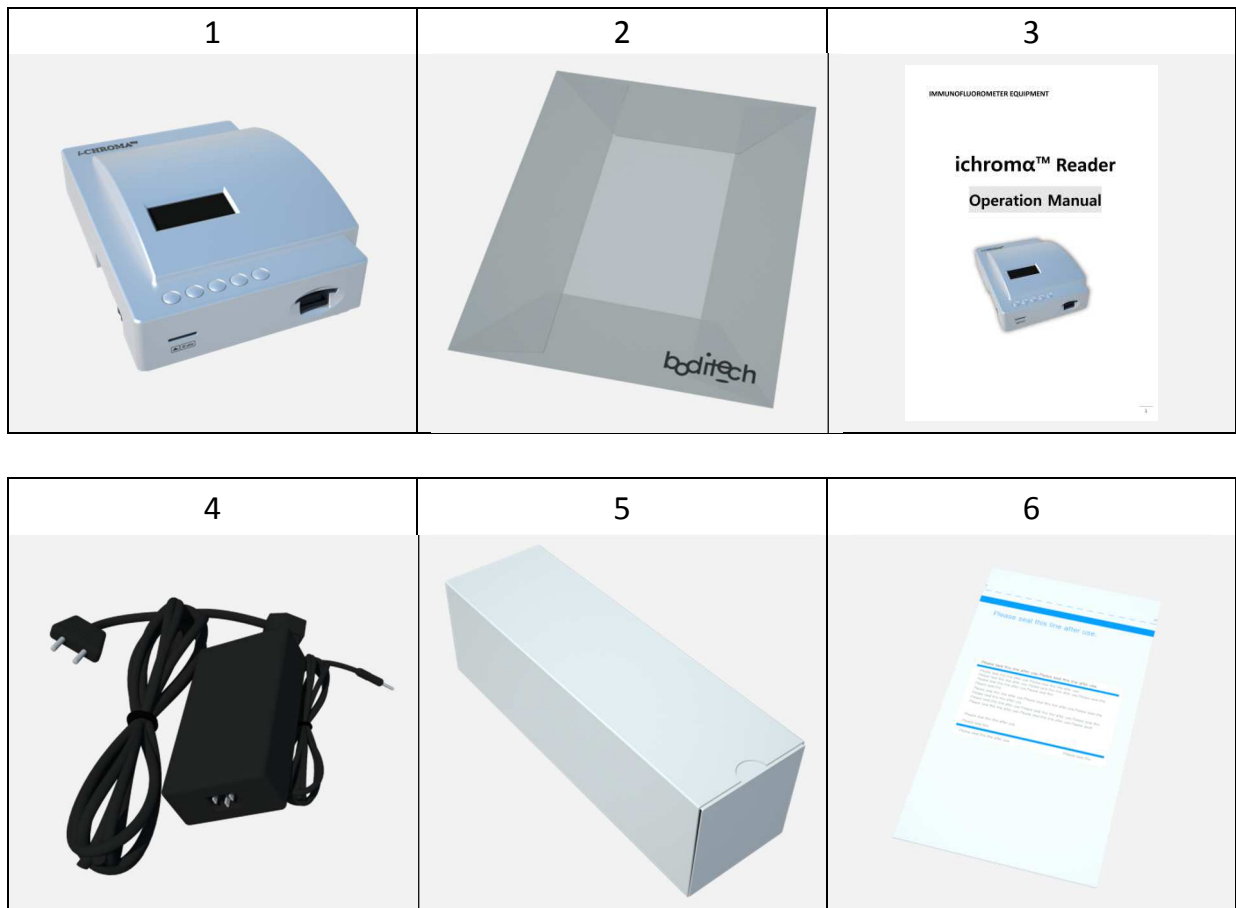
The on-board microprocessor computes concentration of the analyte in the clinical specimen based on a pre-programmed calibration. The computed and converted result is displayed on the display screen of the ichromα™ Reader.

4. Package Contents

ichromα™ Reader consists of several items included in the system. For proper operation of the system, the user must know the technical name and use of each item.

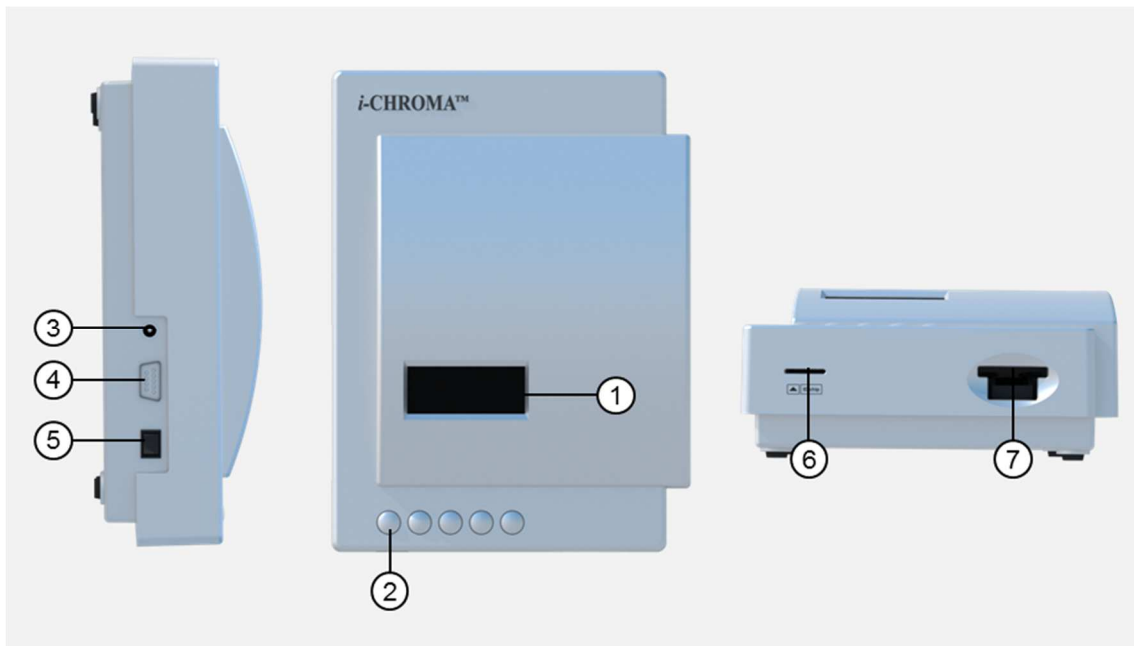
The user must ensure that following items are part of the commercial package. If any item is missing, please contact your sales distributor or Boditech Med Inc.'s customer representative at +82 (33) 243-1400 in Korea

1. ichromα™ Reader
2. Cover
3. Operation Manual
4. Power Cable and Connection Cable
5. Power Cable and Connection Cable Box
6. System Check Chip Set

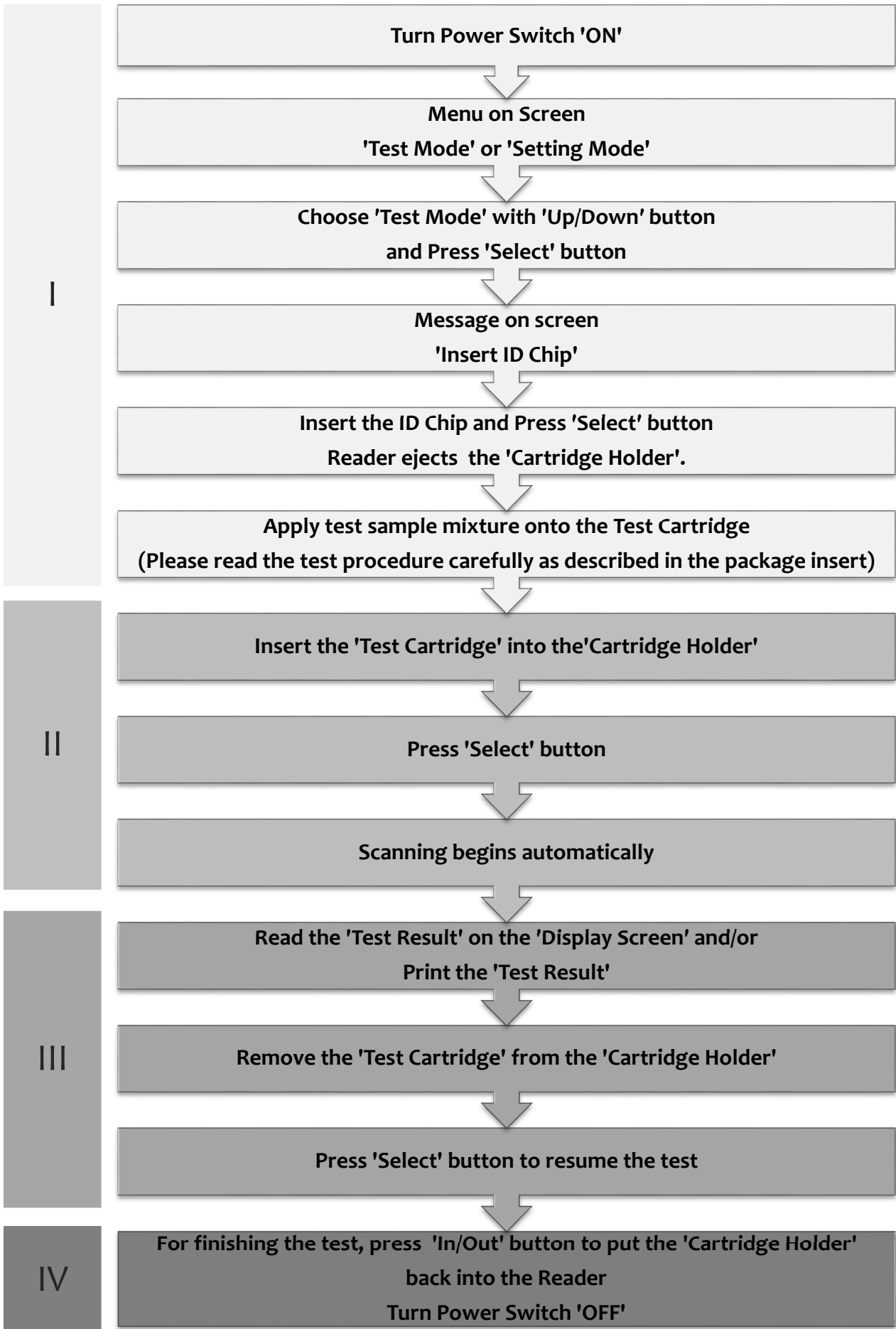


5. Functional and Operational Elements

- | | | |
|---|---------------------|---|
| ① | LCD Window | Displays test result, date, error messages etc. |
| ② | Function Keys | Used to select Menu, Return , Up and Down functions and In/Out of Test Cartridge Holder |
| ③ | Power Jack | Connects to the power cord |
| ④ | Serial Port | Connects to the printer |
| ⑤ | Power Switch | Power On/Off |
| ⑥ | ID Chip Port | For inserting the ID Chip |
| ⑦ | Test Cartridge Port | Accommodate the cartridge holder meant for inserting the Test Cartridge |



6. Low Chart for Test Model



7. Technical Specifications

Physical Description

- Dimensions 250 mm (L) x 185 mm (W) x 80 mm (H)
- Weight 1.2 Kg
- Power supply 100-240 V AC
- Data output On-board Screen / Printer

Permissible Environmental Conditions

- Temperature 15 ~ 35 °C
- Humidity Maximum 70 %
- Location Dry, clean, flat and horizontal surface in an in-door setting away from direct sunlight, mechanical vibration and magnetic field

Permissible Environmental Conditions



- Light source Laser Diode, 2.5 mW, 637 nm
- Detector Silicon Photo Diode

Physical Description

- Drive motor 12V
- Interface RS-232 Serial Port (For Printer)
- Printer Thermal
- Display LCD (16 x 4 Charaters)
- Key Pad 5 Function Keys

*** This device meets the EMC guideline as per EN 61326-2-6:2006.

8. Initial Installation Procedure

 <p>Important</p>	Before using the ichromα™ Reader, make sure you have read the warning and cautions described previously in the 'Safety Information' section 2 of this manual.
 <p>Important</p>	Ensure that the voltage setting matches the power supply voltage.

Power requirements

ichromα™ Reader will work on household power line i.e. 110-120 V or 220-240 V AC with 50 ~ 60Hz. If you are uncertain of your power line, consult your utility manager.

Location

ichromα™ Reader should be placed on a dry, clean, flat, and horizontal surface in an in-door setting away from direct sunlight, mechanical vibration and any source of electromagnetic radiation (power transformers for example).

To set-up ichromα™ Reader for the first time, remove the contents from the package. Inspect the contents for any physical damage and/or missing component(s).

Installation

1. Connect the power cord to the ichromα™ Reader. (Figure 1)



Figure 1: Connect the Power Cord

2. Plug-in the power cord into an external power outlet.
3. Turn 'On' the power switch provided on the left side of ichromα™ Reader. (Figure 2)



Figure 2: Turn Power Switch 'On'

4. ichromα™ Reader will execute a series of self-checking routine. Upon successful completion, the screen will initially display the following:
(Actual content of the display text may differ depending on the specification and customer requirements.)



5. ichromα™ Reader is now ready for use.

9. Operation






The operation of ichromα™ Reader is based on five primary functions; each of which can be represented and/or controlled by a specific corresponding key in the key pad provided on the front panel of the ichromα™ Reader.

The software programmed in the ichromα™ Reader has been designed in a concise and user-friendly manner so as to be used in a point-of-care setting.


Each of these five primary functions of ichromα™ Reader is described in the following section.

Function Keys

The term 'cursor' used in the successive description stands for the '*' notation.

Key	Description of the function
 In/Out	This function moves the 'Cartridge Holder' in and out of the main body of ichromα™ Reader. This key is also used to end the test run. At the end of the test run, the cartridge holder stays protruded outside the main body of the ichromα™ Reader. This key retracts the holder back into the main body.
 Select	This function selects and executes the command denoted by the position of the cursor.
 Reset	This function reverts the screen to the previous mode.
 Up	This function moves the cursor upwards the line of commands on the display window.
 Down	This function moves the cursor downwards the line of commands on the display window.

10. Procedure for System Check

 <p>Important</p>	The 'System Check' is performed to ascertain whether the ichromα™ Reader is functioning properly.
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Following steps describe the recommended system check procedure for ichromα™ Reader using the 'System Check Device' which consists of a 'System Check Cartridge' and a 'System Check ID Chip'.



ichromα™ Reader 'System Check Cartridge' and 'System Check ID Chip'

On-Screen Displays and Applicable Steps

- 1 When you turn the power switch 'On', you will see "MENU" on Screen after "Self-Test Mode".



Please Wait
Self Test Mode
Ver : X.XX

- 2 Choose 'Test Mode' by moving the cursor with 'Up' or 'Down' key.
Press 'Select' key to proceed.



MENU 22C
13:13:00
* Test Mode
Setting Mode

- 3 Note the message 'Insert ID Chip' displayed on the screen.



Insert
ID Chip

- 4 Insert the 'System Check ID Chip' in the 'ID Chip Port'.



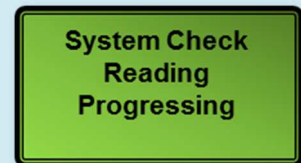
- The message 'Insert Control Cartridge' will be displayed on the screen.
- 5 Prepare the 'System Check Cartridge' which is a specially made test cartridge for the purpose of 'System Check'.



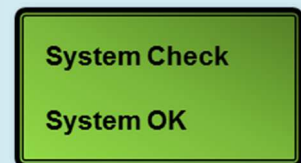
- 6 Insert the 'System Check Cartridge' into the 'Cartridge Holder' Press the 'Select' key.



- 7 The Chromα™ Reader will scan the 'System Check Cartridge' automatically.




- The 'System Check' test result will be displayed on the screen. You can print it also.
- 8 Press the 'Reset' key twice. Screen will return to the 'MENU' mode. Now you can perform another test.



If you receive 'Error S1 or S2', contact your local Boditech Med Inc. sales representative.






11. Procedure for Test Mode

 <p>Important</p>	<p>The actual display may differ from the ones shown below, depending on the factory configuration of the Reader.</p> <p>If the scanning process is interrupted abruptly or an error message is displayed on the screen, you will hear an alarm sound. (Refer to the section 15 'Troubleshooting'.)</p>
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Following steps describe the operational part of ichromα™ Reader for performing a test using the specific 'ichromα™ Test Cartridge'.

Before performing any ichromα™ Test, please read the respective package insert carefully for other details of the test procedure.

On-Screen Displays and Applicable Steps

<p>1 When you turn the power switch 'On', you will see "MENU" on-Screen after "Self-Test Mode".</p>	
<p>2 Choose 'Test Mode' by moving the cursor with 'Up' or 'Down' key. Press 'Select' key to proceed.</p>	
<p>3 Note the message 'Insert ID Chip' displayed on the screen.</p>	
<p>4 Insert the 'Test Cartridge of ID Chip' in the 'ID Chip Port'.</p>	
<p>5 The message 'Insert XXXXXX Cartridge' will be displayed on the screen. Prepare the 'Test Cartridge' as per the details described in the procedure of the test being performed. (Please refer the package insert of the 'ichromα™ Test'.)</p>	

- 6 Insert the sample-loaded 'Test Cartridge' into the 'Cartridge Holder'.
Press the 'Select' key.



- 7 ichromα™ Reader will scan the inserted test cartridge automatically after 3 min for immune reaction.

hsCRP Test
Reaction
Progressing
03 : 00



Reaction times vary depending on the each Test Cartridge.
Please read the insert of the Test Cartridge.

- 8 ichromα™ Reader will scan the Test Cartridge automatically.

hsCRP Test
Reading
Progressing

- 9 The test result will be displayed on the screen.
You can also print the test result (optional).

hsCRP Test
0.0 mg/L

- 10 Press 'Reset' key twice. Screen will return to the 'MENU' mode.
Now you can perform another test.

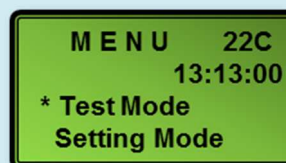
M E N U 22C
13:13:00
* Test Mode
Setting Mode

 Important	Please read the package insert carefully before performing the ichromα™ Test.
 Important	Before performing any ichromα™ Test, ensure that the name of the test as well as the lot number mentioned on the 'ID Chip' should match with that of the 'ichromα™ Test Cartridge'.
 Important	'ID Chip' having a lot number mismatching with that of the 'ichromα™ Test Cartridge' may yield misleading test results.
 Important	After the ichromα™ Test is successfully performed; the tested cartridge should be disposed of in accordance with local regulations regarding the disposal of bio-hazardous materials.

12. Procedure for Setting Mode

Procedure for Setting Time

Select '**Setting Mode**' and then select '**Time Set**' by moving the cursor with '**Up**' or '**Down**' key.
Press '**Select**' key to proceed.



M E N U 22C
13:13:00
* Test Mode
Setting Mode

Press '**Select**' key to move to the next step after you select a specific mode.



Recall Result
* Time Set
Calibration
Reaction Time

'**Time Set**' mode is for setting the date/time when you activate the instrument for the first time or reuse the instrument after not using it for more than a month.
After pressing '**Reset**' key, you can set the year with '**Up**' and/or '**Down**' key(s).



MENU → SELECT
SET → RESET
day. month. year
hour : min

Use '**Select**' key to move from day → month → year → time while setting day/month/year/time with '**Up**' or '**Down**' key.

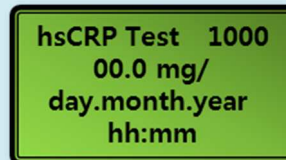
Press '**Reset**' key to go back to '**Menu**' mode when you finish setting date/time.



PRE → RESET
NEXT → SELECT
day. month. year
hour : min

Procedure for Recalling Previous Results

'**Recall Result**' mode is used to recall or retrieve stored/previous test results.
You can recall and print up to 100 stored test results. (The Counter start is 1000)
You can search the test result(s) date-wise and/or time-wise with '**Up**' or '**Down**' key.



hsCRP Test 1000
00.0 mg/
day. month. year
hh:mm

For printing the test result(s), press '**Select**' key.

Select '**One**' mode for a single result or '**All**' mode for the entire stored data with '**Up**' or '**Down**' key and then press '**Select**' key.

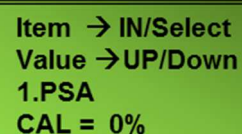


Print Data
*One
All
Erase

Procedure for Calibration

'**Calibration**' mode is used to change/adjust calibration of the tests.

You can change/adjust the calibration factor and thereby the test results with '**Up**' or '**Down**' key after changing the test with '**In/Out**' or '**Select**' key.



Item → IN/Select
Value → UP/Down
1.PSA
CAL = 0%

For previous screen, press '**Reset**' key.

Procedure for Reaction Time

'**Reaction Time**' mode is used to program/set the reaction time of the ichromα™ test.

'**Multi**' mode programs/sets the reaction time of all ichromα™ tests to a default value of 0 minute.

If you select '**Multi**' mode and want to perform any ichromα™ test e.g. ichromα™ PSA, then proceed as follows:

- 1) Read the ichromα™ PSA package insert carefully.
- 2) Process the test sample with the detection buffer and apply the processed test sample into the 'sample well' of the ichromα™ PSA test cartridge as per the recommended procedure.
- 3) Keep the sample-loaded test cartridge for 15 minutes which is the reaction time of the ichromα™ PSA test
- 4) After 15 minutes, insert the sample-loaded test cartridge in the 'cartridge holder' of ichromα™ Reader.
- 5) ichromα™ Reader scans the test cartridge and displays the test result immediately.



<Choose One>
* Multi
Single
Individual

'**Single**' mode programs/sets the reaction time of each ichromα™ test differently as fixed by Boditech Med Inc. because reaction time is different for various ichromα™ tests.

If you select 'Single' mode and want to perform any ichromα™ test e.g. ichromα™ PSA, then proceed as follows:



<Choose One>
Multi
* Single
Individual

- 1) Read the ichromα™ PSA package insert carefully.
- 2) Process the test sample with the detection buffer and apply the processed test sample into the 'sample well' of the ichromα™ PSA test cartridge as per the recommended procedure.
- 3) Insert the sample-loaded test cartridge in the 'cartridge holder' of ichromα™ Reader immediately.

ichromα™ Reader will automatically scan the test cartridge and display the test result after 15 minutes which is the reaction time of the ichromα™ PSA test.

'Individual' mode combines the features of 'Multi' mode and 'single' mode. 'Individual' mode is ideal for better time management in relation to the work load.

If you select 'Individual' mode, you can perform some ichromα™ tests on the basis of 'Multi' mode and some ichromα™ tests on the basis of 'Single' mode.

Suppose your laboratory mostly performs ichromα™ PSA and ichromα™ CRP tests on daily basis.

If you operate the ichromα™ Reader in 'Multi' mode, you have to ensure that the test cartridge(s) is inserted in the ichromα™ Reader after specific reaction time is over. You will have to be very careful while performing the ichromα™ CRP test which has the reaction time of just 3 minutes.

If you operate the ichromα™ Reader in 'Single' mode, you will be able to perform only 4 ichromα™ PSA tests per hour because the reaction time of ichromα™ PSA test is 15 minutes.

Hence 'Individual' mode is recommended in such cases. In 'Individual' mode, set the reaction times of ichromα™ CRP and ichromα™ PSA tests to 3 and 0 minutes respectively.'

If you operate the ichromα™ Reader in 'Individual' mode,



you will not have to note the time while performing the ichromα™ CRP test because you will perform the ichromα™ CRP test in a manner similar to 'Single' mode.

Moreover, you will be able to perform more than 4 ichromα™ PSA tests per hour because you will perform the ichromα™ PSA test in a manner similar to 'Multi' mode.

In 'Individual' mode, you can set the reaction time with 'Up' or 'Down' key after changing the test with 'In' or 'Select' key.

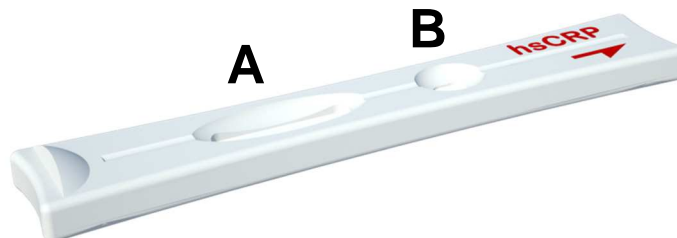
For previous screen, press 'Reset' key.



Reaction time varies depending on the ichromα™ test performed. Please read the package insert of the specific test. Please read the package insert of the ichromα™ test under consideration for confirming the reaction time.

13. ichroma™ Test Cartridge Handling Precautions

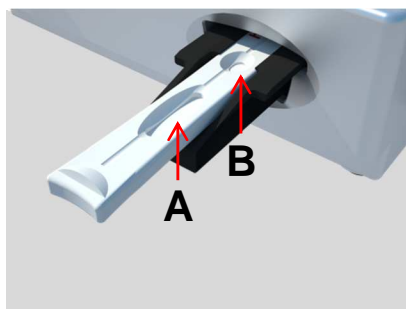
The processed specimen/sample should be loaded into the 'Sample Well' (denoted by 'B' in the figure below) of the 'ichroma™ Test Cartridge'.




The sample-loaded 'Test Cartridge' should be inserted into the 'Cartridge Holder' in the direction pointed by the 'Arrow' specially marked on the test cartridge so that the 'Sample Well' is oriented towards the ichroma™ Reader.

For inserting the sample-loaded 'Test Cartridge', push it gently; using your thumb or the index finger, all the way into the 'Cartridge Holder' until it comes to a stop. Use of excessive force for this purpose may result in mechanical failure of the system.

The tested cartridge should be treated as a potential bio-hazard and be disposed off in accordance with local regulations regarding the disposal of bio-hazardous materials.




 <p>Important</p>	For reducing the chances of bio-hazards, high temperature autoclaving of the tested ichroma™ test cartridges followed by their incineration is recommended.
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14. Maintenance, Servicing and Disposal

No maintenance other than proper replacement and periodic cleaning is required for the ichromα™ Reader normally. Occasional cleansing of the exterior with a soft and dry cloth is sufficient. However, if any service or maintenance were to be required, ichromα™ Reader should be sent to Boditech Med Inc.

Power Supply

 Important	Ensure that the voltage setting of ichromα™ Reader matches the power supply voltage.
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Use only the AC/DC power adapter provided with the ichromα™ Reader. In case the power adapter needs replacement, you should contact Boditech Med Inc. or its authorized representative. Boditech Med Inc. provides CE certified Class 2 power adapters, rated at +12V 3-5A.

Return Procedure

Should your ichromα™ Reader malfunction, first call Boditech Med Inc. on (+82) 33-243-1400 for consultation. If it is decided that the unit be returned to Boditech Med Inc., a return authorization number will be issued. Boditech Med Inc. will then send a replacement for the ichromα™ Reader. The user is expected to utilize the packaging supplies accompanying the replacement to ship the malfunctioning unit. Verify the return authorization number on the package and send the malfunctioning unit to Boditech Med Inc. upon receiving the replacement for ichromα™ Reader.


Transportation and Storage

The original shipping container/box should be used to ship or transport ichromα™ Reader. The same container/box is also recommended for storing ichromα™ Reader over an extended period of non-use.

 Caution	When transporting or storing ichromα™ Reader, keep it dry in an upright position and protect it from mechanical shocks.
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Disposal

If the ichrom α TM Reader is to be disposed of for any reason, the user is advised to observe standing applicable ordinances regarding the disposal of class B electrical equipment.

 <p>Important</p>	<p>At the end of its useful life, the ichromαTM Reader could be sent back to Boditech Med Inc. for recycling or proper disposal.</p> <p>Alternatively it should be disposed of in accordance with the local regulations.</p>
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15. Troubleshooting

Though the ichromα™ Reader in conjunction with the ichromα™ Tests has been designed to be a perfectly working system, it may encounter some operational problems occasionally. The symptoms, probable causes and recommended remedial/corrective measures for these problems have been listed in the table below.

Symptoms	Probable Causes	Recommended Remedial/Corrective Measures
Noting happens; ichromα™ Reader does not show any sign of functioning	Power failure	Check if the wall outlet is alive.
	Poor connection between the power adapter and the power cable.	Remove the power cable (connecting the SMPS to the ichromα™ Reader) and reconnect firmly.
	Main switch is 'Off'.	Turn the main switch 'On'.
	Faulty power adapter	Call Boditech Med Inc.'s Technical Services.
'Test Run' over but no result returned	Excessive computational load	Wait till the computation is finished.
	Computational abnormality	Turn the power 'Off' and turn it 'On' again.
'Cartridge Holder' does not protrude out as and when required.	Mechanical failure (Buzzing noise)	Call Boditech Med Inc.'s Technical Services.
	Software Abnormality	Turn the power 'Off' and turn it 'On' afresh.
Clicking noise while the 'Cartridge Holder' protrudes out	Normal mechanical setting	User's action is not required.
'Screen Display' does not function properly.	Electrostatic shock	Ground the surface of ichromα™ Reader to the electric ground terminal. Remove any source of electric charge. Reset the system.
	Electrical circuit failure	Call Boditech Med Inc.'s Technical Services.

Symptoms	Probable Causes	Recommended Remedial/Corrective Measures
Error 21-24 Turn Off the Power	Internal electrical or mechanical fault	Call Boditech Med Inc.'s Technical Services.
Error 25-29 Press Reset	Technical problem with the 'ichromα™ Test Cartridge'	Test again using a new 'ichromα™ Test Cartridge'
Error S1 or S2 Press Reset	Optical failure	Call Boditech Med Inc.'s Technical Services.
Value Error 1-10 Press Reset	Unusual sample or improper storage of reagents	Test again using a fresh sample and a new 'ichromα™ Test Cartridge'
Caution! Error Press Reset	Technical problem with the 'ichromα™ Test Cartridge'	Repeat the test using a new 'ichromα™ Test Cartridge'
Caution! Barcode Error Press Reset	Test Cartridge alignment is off.	Remove the 'ichromα™ Test Cartridge' and try again.
Caution! Lot Number Error Press Reset		Repeat the test using a new 'ichromα™ Test Cartridge'.
Caution! Lot Number Error Press Reset		Call Boditech Med Inc.'s Technical Services.
Caution! ID Chip Lot Number Mismatch	'Lot Number' of the 'ichromα™ Test Cartridge' does not match with that of the 'ID Chip'	Check the Lot number of the 'ichromα™ Test Cartridge' as well as that of the 'ID Chip'
Caution! ID Chip Cartridge Mismatch	'ichromα™ Test Cartridge' does not match with the 'ID Chip' inserted in the 'ID Chip Port'.	Check whether 'ichromα™ Test Cartridge' and the 'ID Chip' are matching with each other.
Insert ID Chip	No 'ID Chip' inserted in the 'ID Chip Port'.	Insert a proper 'ID Chip' in the 'ID Chip Port'.
Hb Low	Hemoglobin concentration of the sample is below 5.0 g/dL	Test the sample again. Ensure that a correct volume of the detection buffer is applied.
Hb High	Hemoglobin concentration of the sample is above 25.0 g/dL. The volume of detector is too small	Test the sample again. Ensure that a correct volume of the detection buffer is applied.

16. Warning, Precautions and Limitations

Do not disassemble your ichromα™ Reader. If you have any questions, please contact our local distributor or authorized representative.

Please use your ichromα™ Reader gently. Avoid throwing, shaking, or dropping it, which may damage its internal components.

Keep your ichromα™ Reader free of dust. Occasionally clean or wipe the exterior of the ichromα™ Reader with a soft cloth slightly dampened with water.

Do not use industrial solvents for cleaning the ichromα™ Reader.

Do not wash the ichromα™ Reader or pour any liquid over it.

Handle your ichromα™ Reader with care and avoid exposing it to direct sunlight and/or extreme temperatures.

Do not expose your ichromα™ Reader to an environment having high humidity, such as bathroom, kitchen etc.

Store and transport the ichromα™ Reader in dry conditions having temperatures 15~35°C (59~95°F).

It is recommended to use the carrying case whenever required.

Expose the test system to ambient temperature for at least 30 minutes until just prior to performing the test actually.

17. Warranty

This product has passed strict quality assurance and testing procedures. Boditech Med Inc.'s expressed and implied warranties are conditioned upon full observance of manufacturer's published direction with respect to the use of Boditech Med Inc.'s products.

To obtain warranty service you must return the defective meter or meter part along with proof of purchase to your nearest Boditech Med Inc.'s Authorized Warranty Station.

Warranty Information

- 1 Defective products or spontaneously malfunctioning products will be repaired at no charge or compensated in accordance with consumer protection rules and regulations.
- 2 Products will be repaired with charge during the warranty period in following cases;
 - 2.1 Improper use or misuse
 - 2.2 Consumer's intentional abuse or neglect of the products
 - 2.3 Unauthorized repair or parts replacement
 - 2.4 Lots product warranty or changes in contents
 - 2.5 Damages or defects due to fire, pollution, earthquake or other natural disasters.

Product or AS inquiries

Thank you for purchasing our product.

Please complete and mail this warranty card within 30 days of purchase of your ichromα™ Reader.

Product Name	
Serial No.	
Date of Manufacture	
Warranty Period	12 months from the date of purchase
Date of Purchase	year _____ month _____ day _____
Manufacturer	Boditech Med Inc.
Purchase Location	

18. Statement of Conformity

Boditech Med Inc., declares that the ichrom α TM Reader meet the CE Mark Requirements according to Annex III, IV, VII of the *in-vitro* diagnostic medical devices Directive 98/79/EC following standards:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purpose
EN 980:2008 Symbols for use in the labelling of medical devices
EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-5:2011 In vitro diagnostic medical devices- Part 5-In vitro diagnostic instruments for selftesting
EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing
EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
IEC 61010-1 : 2002 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101:2002 Safety requirements for electrical Equipment for measurement, control and laboratory use: particular requirements for in vitro diagnostic (IVD) medical equipment.
EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 62304:2006 Medical device software- Software life cycle processes

19. Contact Information

Boditech Med Inc.'s expressed and implied warranties are conditioned upon full observance of manufacturer's published direction with respect to the use of Boditech Med's products. **Under no circumstances whatsoever shall Boditech Med Inc. be held liable for any indirect or consequential damages.**

For Technical Assistance call

Boditech Med Inc.'s Technical Services at

Tel: +82 (33) 243-1400, E-mail: support@boditech.co.kr



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Revision 16

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The actual contents of the display could differ, depending on the specification and customer requirements.