



iCHROMA II



The information contained herein is subject to change without prior notice.

Boditech Med Inc. shall not be liable for any technical and editorial errors or omissions contained herein.

Additionally, any malfunction in elements including the optical sensor assembly, the system board and the drive train should be consulted with and serviced by Boditech Med Inc. Any unauthorized operations on elements not suggested in this document will void the existing warranty.

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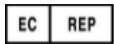
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The actual contents of the display could differ, depending on the specification and customer requirements.

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1. Intended Use

ichroma™ II is a semi-auto portable fluorescence and Europium nanoparticle 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 ichroma™ Immunoassay Tests manufactured by Boditech Med Incorporated.

ichroma™ II is to be used only in conjunction with various ichroma™ Immunoassay Tests and meant only for in vitro diagnostic purpose.

ichroma™ II can be used for screening, monitoring and/or routine physical examination in centralized laboratories of hospitals, physicians' clinics.

2. Introduction

ichroma™ II is a semi-auto portable fluorescence and Europium nanoparticle 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 ichroma™ Immunoassay Tests manufactured by Boditech Med Incorporated. ichroma™ II is easy to use. When collected samples are loaded to a test cartridge, ichroma™ II measures intensity of fluorescent signal. ichroma™ II converts this intensity of fluorescent signal to quantitative value and displays this value as a test result.

3. Safety Information

● Safety information prior to use

- 1) Please read this manual before use.
- 2) This equipment is in vitro diagnostic medical device. Please use it with correct intended use.
- 3) ichroma™ II is only compatible with ichroma™ test cartridges manufactured by Boditech Med Inc. In case of use of other test cartridges, it may cause malfunction of ichroma™ II or incorrect test results.
- 4) When initial purchase and installation, please set exact/correct date and time. Incorrect setting may cause various errors regarding expiration date.
- 5) To prevent infection or contamination, please use protective gloves, mask and so on during handling test samples.
- 6) All tests should be done at flat and stable place. Do not move and force mechanical stress in ichroma™ II during tests.
- 7) ichroma™ II should be used in clean place.
- 8) Please use ichroma™ II indoor only.

- 9) Operation temperature is 15-35°C (59 - 95°F) and humidity is maximum 70%. If ichroma™ II is stored at some place with out of operation environment, please leave it operation environment at least 30 minutes.
- 10) If the cartridge holder or holder cover are contaminated by some reagent, dust or foreign materials, please clean them and use ichroma™ II.
- 11) External stresses such as mechanical, chemical and electric stresses can cause malfunction of ichroma™ II or incorrect test results. Do not stress ichroma™ II in any case.

● **Warnings and cautions**

- 1) ichroma™ II is only for in vitro diagnostic use with ichroma™ test cartridges.
- 2) In case of finding malfunctions in ichroma™ II, turn the power off immediately and contact regional distributor or Boditech Med Inc.'s technical support.
- 3) Install ichroma™ II at flat surface.
- 4) Excessive force during inserting a test cartridge into the cartridge holder, or pushing switches or buttons may cause malfunction or error in ichroma™ II.
- 5) Be careful in handling test samples to prevent infection.
- 6) Do not install ichroma™ II at high temperature and humidity place.
- 7) Avoid exposure of ichroma™ II to dust, salinity, water or any other liquid and direct sunlight.
- 8) Please use your ichroma™ II gently. Avoid throwing, shaking, or dropping it, which may damage its internal components.
- 9) Do not store ichroma™ II in chemicals storage or gassing area.
- 10) Remove power cable if ichroma™ II is not used for a long time.
- 11) Do not allow ichroma™ II to come in contact with liquid in any manner.
- 12) Do not place anything on top of ichroma™ II even when it is lying idle.
- 13) Read this manual carefully before use. Violation of instruction for installing and operating ichroma™ II may cause electric, mechanical or bio-hazardous risks.
- 14) We do not become responsible for any unauthorized opening or servicing of ichroma™ II. When you find malfunctions in ichroma™ II, please contact regional distributor or Boditech Med Inc.'s technical support team.
- 15) The user of ichroma™ II in conjunction with the ichroma™ 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.
- 16) ichroma™ II should be operated by trained medical technologist or medical personnel such as nurse or physicians.

17) If you have any inquiry regarding ichroma™ II operation, please contact regional distributor or Boditech Med Inc.'s technical support team.



● **Storage after using & management**

- 1) Please insert cartridge holder by tapping "in/out" button after using ichroma™ II to prevent contamination by dust or foreign materials.
- 2) When you turn the power off, please follow proper steps described in this manual. If not, it may cause malfunction in ichroma™ II.
- 3) Do not open or alter ichroma™ II by intention.
- 4) Store ichroma™ II at liquid free place.
- 5) Store ichroma™ II at slope/vibration/mechanical shock free place.
- 6) Do not store ichroma™ II in chemicals storage or gassing area.
- 7) Avoid direct sunlight during storage.
- 8) In case of ichroma™ II exterior is contaminated by foreign materials, please wipe them out using soft and dry cloth or tissue.

● **Symbols**

Various symbols are used in this manual as follow.

Symbol	Description
	Manufacturer
	Consult instructions for use
	For <i>in vitro</i> diagnostic use
	This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices
	Attention! Read instructions before use
	Separate collection for electrical and electronic equipment
	Bio Hazard
	USB Memory
	Temperature limitation
	Serial Number
	LASER Radiation Do not stare into beam.
	Potential Biohazard

	<p>This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions with the device, which are not otherwise found on the label. The symbol "Caution" is still sometimes used to have the meaning of "Attention, see instruction for use".</p>
	<p>Indicates a hazardous situation, which if not avoided, could result in injury to the operator or a bystander (e.g. electrical shock or UV exposure).</p>

4. Principle




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

5. Package contents

ichroma™ II and its accessories are provided in a single box. For proper operation of the system, user must be familiar with the technical term and use of each item. User must ensure that following items are included the commercial package. If any item(s) were to be missing, please contact your sales distributor or Boditech Med Inc.'s customer care representative(refer to Section 14. Warranty).

1) Basic contents

<p>① ichroma™ II</p> 	<p>② AC adaptor & power cable</p> 
<p>③ Operation manual</p> 	<p>④ System check cartridge set</p> 

2) Optional

<p>① Barcode scanner</p> 	<p>② Keyboard</p> 	<p>③ USB OTG Cable</p> 
<p>④ WIFI Dongle</p> 	<p>⑤ Bluetooth Dongle</p> 	<p>⑥ SD Card</p> 
<p>⑦ AA battery</p> 		

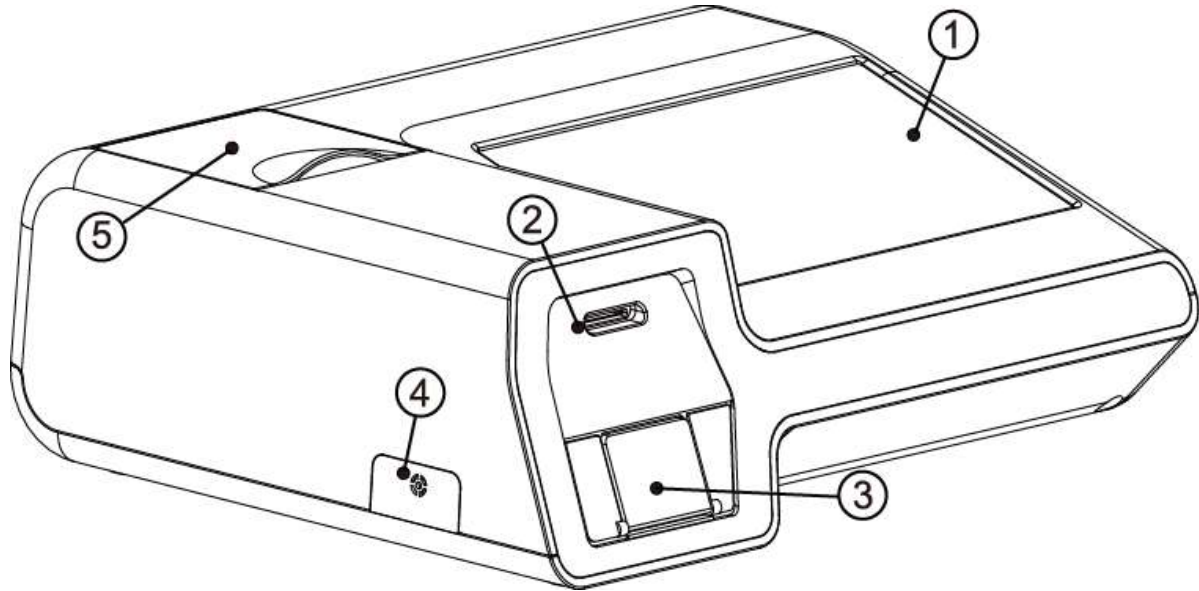
6. Technical specifications

Item	Specification
Product name	ichroma™ II
Principle	Fluorescence and Europium Nanoparticle Immunoassay
Dimensions	276mm (W) X 220mm (L) X 91mm (H)
Weight	1.3kg
Power	DC 12V/5A AC/DC Adaptor Input: 100-240V ~ 50/60Hz, 1.5A Output: DC 12V/5A Battery : DC 1.5V X 4ea
Display	7 inch touch color LCD
Motor	Stepper Linear Actuators(5V, 0.34A)
Communication ports	USB 4 ports, LAN Port, USB OTG port
Operation temperature / humidity	Temperature 15-35°C Humidity 10~70% (Non-condensing)
Storage temperature / humidity	Temperature -20 ~ 50°C Humidity < 90% (Non-condensing)
Output	LCD, Built-in Printer
Saving test results	Patient test : 1,000 results System check test results : 500 results Control materials test results : 1,000 results

ichroma™ II meets the EMC guideline as per EN 61326-2-6.

7. Functional and operational elements

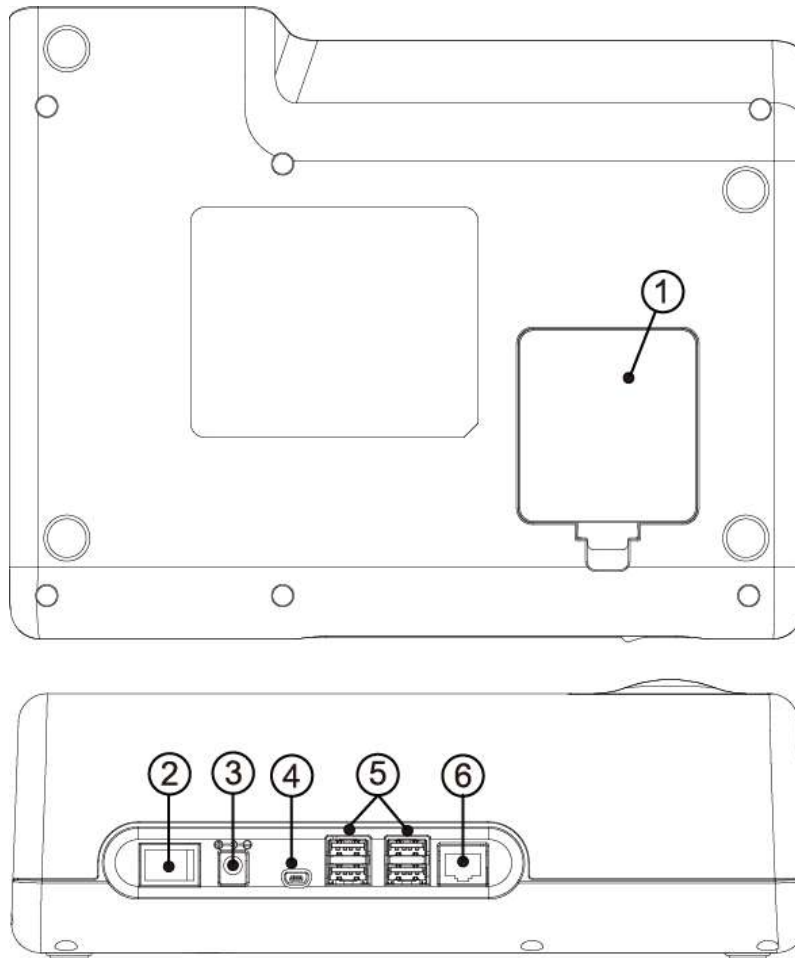
Front side view of ichroma™ II



No.	Part name	Function
①	7 inch touch LCD	You can input various needed information for testing by touchpad of LCD. LCD displays various important information such as various status, test results and so on.
②	ID chip slot	Slot for ID chip insertion.
③	Holder & holder cover	Inserting test cartridge for proceeding tests. Holder cover is for light / dust / foreign materials prevention.
④	Temperature sensor	It measures room temperature around ichroma™ II.
⑤	All in one thermal printer	Print test results out.

	<p>For detailed information regarding optional items, please contact regional distributor or Boditech Med Inc.'s technical sales team.</p>
	<p>Temperature sensor measures room temperature. Do not change temperature by intentional heating or cooling.</p> <p>Do not install ichroma™ II in area which has big temperature variation..</p>

Bottom and rear side view of ichroma™ II



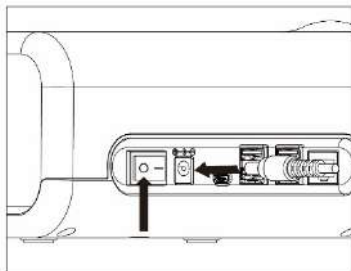
No.	Part name	Function
①	Battery cover	When the battery cover is opened, you can install/set batteries and SD card.
②	Power switch	Main power switch
③	Power port	Connection port for AC adaptor
④	USB OTG port	Connection port for PC connection and communication
⑤	USB port	Connection port for barcode scanner, keyboard, WIFI Dongle, Bluetooth Dongle and USB memory stick
⑥	LAN port	Connection port for Ethernet connection

8. Power supplement

	<p>Power rating for ichroma™ II is AC 110-120V or 220-240V, 50 ~ 60Hz.</p> <p>To protect electric hazard such as electric shock and fire, please use AC adaptor and power cable provided by Boditech Med Inc. only and check power rating before use.</p> <p>If you can't confirm power rating, please consult with your facility management officer.</p> <p>When using batteries, please check the type of batteries (AA type) and install them with correct direction.</p>
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● Use of AC adaptor

1) Please check the power switch is off "(O)" and connect AC adaptor to the power port.

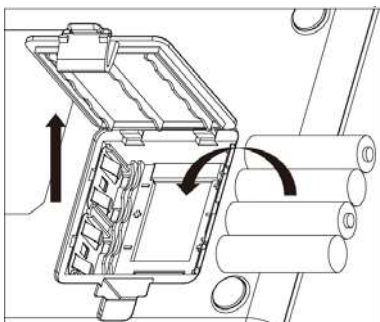


2) Connect power cord to external power outlet.

● Use of batteries

	<p>Use of batteries is only available in case of a blackout for instant operation. It is impossible for normal use with batteries for a long time. We suggest to use AC adaptor and power cable for stable and safe operation. It is possible 30 multi tests or 2 single tests when batteries are used.</p> <p>It is possible to use AC adaptor and batteries simultaneously.</p> <p>But we suggest to remove batteries when AC adaptor is used.</p>
	<p>Please do not use a printer when ichroma™ II is operating with batteries.</p> <p>Use of a printer can cause power down due to excessive power consumption.</p>

1) Open the battery cover in the bottom of the ichroma™ II. Please check the direction of batteries and insert them with correct direction.

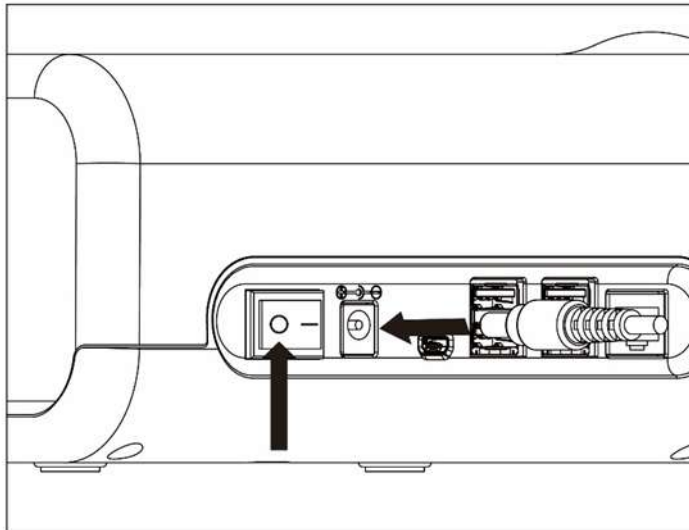


2) Close the battery cover and put the ichroma™ II on right position.

9. Installation

	<p>Refer to Section 3 and Section 8 prior to installation.</p>
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1) Connect a power cord and AC adaptor provided by Boditech Med Inc. to the power port of rear side of ichroma™ II. Then turn the power switch on.



2) ichroma™ II displays the product logo and loading screen serially. When loading, it takes few seconds. Please wait.

	<p>If loading screen lasts more than 5 minutes, please turn ichroma™ II off and turn it on again. If same problem is occurred, please call Boditech Med Inc.'s technical service or authorized regional distributor.</p>
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3) When loading is completed, ichroma™ II will proceed the self-testing and display the self-testing results.




Test result	Description
OK !	System of ichroma™ II is normal.
Not available !	There are some problems in the relevant parts or environmental temperature is out of suggested condition.

4) Example of errors




Error	Counter measures
Optics parts Error !	 <p>Turn off: Turn the device off and call to manufacturer or authorized regional distributor.</p> <p>Ignore: You can proceed the next step but it is impossible to test items.</p>
Moving parts Error !	
Storage disk Error !	
Temperature sensor Error !	 <p>It is possible to test items but test results may not be accurate because temperature is out of suggested condition. Please call to manufacturer or authorized regional distributor.</p> <p>Turn off: Turn the device off and call to manufacturer or authorized regional distributor.</p> <p>Ignore: You can proceed the next step and test items.</p>
Printer initializing Error !	 <p>It is possible to test items but printing test result out is impossible. Please call to manufacturer or authorized regional distributor.</p> <p>Turn off: Turn the device off and call to manufacturer or authorized regional distributor.</p> <p>Ignore: You can proceed the next step and test items.</p>
Temperature out of recommended range. Proceed?	 <p>Please set environment temperature as 15 - 35°C.</p> <p>Turn off: Turn the device off and wait for environment temperature reaches to the operation temperature.</p> <p>Ignore: You can proceed the next step and test items.</p>

	<p>Self-testing items are as follows.</p> <ol style="list-style-type: none"> 1. Driving part and printer (all in one thermal printer is adopted) 2. Optics 3. Disk 4. Temperature (environment temperature)
	<p>Do not disassemble the ichroma™ II when some errors relevant to self-testing items are occurred.</p>
	<p>If you turn the device off during self-testing process, it can cause malfunction of the device.</p>
	<p>If the test results show "Not available" for driving part, optics or disk, call to manufacturer or authorized regional distributor.</p> <p>If temperature is out of range of operation temperature(15 - 35°C), please set environment temperature as 15 - 35°C.</p>

5) When self-testing is completed successfully, the ichroma™ II will display the main screen.

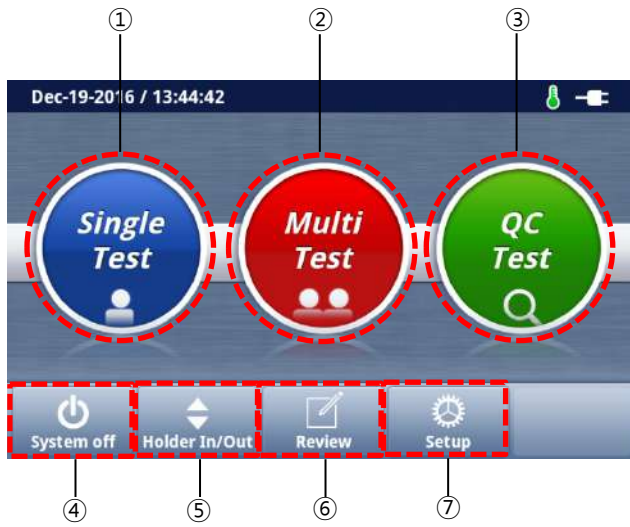


	<p>The actual contents of the display could differ, depending on the specification and customer requirements.</p>
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10. ichroma™ II operation

10.1. Main screen

Single Test, Multi Test, QC test, Review and Setup menu is shown in the main screen as follow.



- **Function for each button**

No.	Button	Function
①	Single Test	Move to Single Test mode.
②	Multi Test	Move to Multi Test mode.
③	QC Test	Move to QC Test mode.
④	System Off	Turn the device off or restart.
⑤	Holder In/Out	Insert or eject the cartridge holder.
⑥	Review	Move to Review mode.
⑦	Setup	Move to Setup mode.


● 2) Description of each icon



Icon	Name	Description
	Battery	Displaying battery status when the ichroma™ II is operating with batteries.
	AC adaptor	This icon will be displayed when AC adaptor is connected.
	Temperature range	Green : Environment temperature is in the range of 15 - 35°C. Red : Environment temperature is out of the range of 15 - 35°C.
	WIFI	This icon will be displayed when WIFI is connected.
	Bluetooth	This icon will be displayed when Bluetooth is connected.
	Ethernet	This icon will be displayed when Ethernet is connected.


10.2. System check

QC Test > System Check

	<p>System check is performed to confirm the ichroma™ II works properly.</p>
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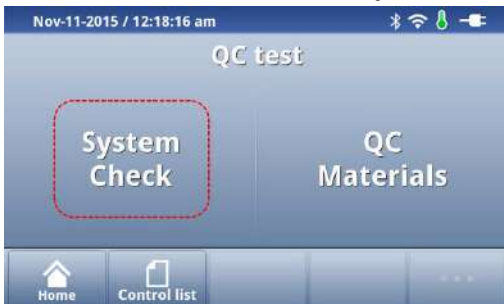
1) Open the system check cartridge pouch which is packed with the ichroma™ II and check the contents as follow(System check cartridge and system check ID chip).



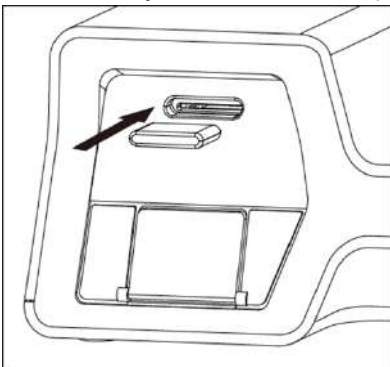
	<p>If there are foreign materials on the nitrocellulose membrane of a system check cartridge, this will cause erroneous system check result. Do not load any test samples into the sample well of a system check cartridge.</p>
	<p>Do not touch the nitrocellulose membrane of a system check cartridge by hands. Do not damage the nitrocellulose membrane of a system check cartridge.</p>

2) Tap the "QC Test" on the main screen.

3) Then the ichroma™ II will eject the cartridge holder automatically.

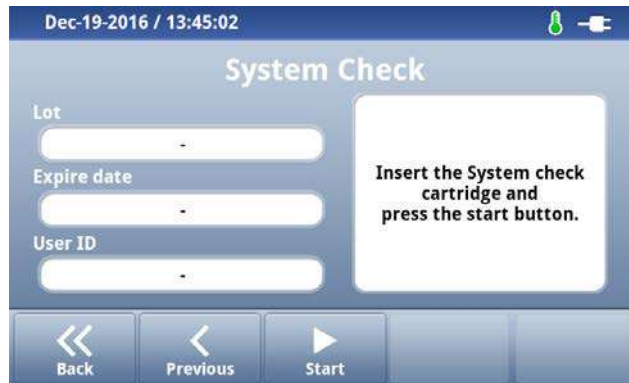
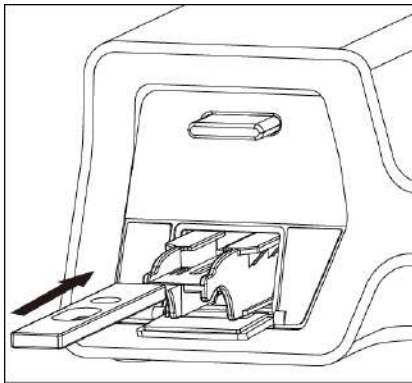


4) Insert a system check ID chip into the ID chip port and tap the "Next" button on the LCD.



	<p>Wrong direction or excessive force during inserting ID chip will cause malfunctions of the ichroma™ II.</p>
	<p>You must insert system check ID chip to proceed system check process. Be careful loss of system check ID chip.</p> <p>If you lose system check ID chip, call Boditech Med Inc’s Technical service or authorized regional representative.</p>
	<p>User ID displayed in LCD means that the relevant user logs in the ichroma™ II.</p> <p>If log in function is not used, the ichroma™ II will displays user ID as “-”.</p>




5) Insert a system check cartridge with correct direction and tap the “Start” button.



6) The ichroma™ II performs system check process and displays the result.




Test result	Description	Counter measure
System OK !	The system is normal.	There is no need to make counter measure. You can use the system normally.
Error S1 !	<div style="text-align: center;"> </div> <p>There are some problems in system check cartridge or optics.</p>	<p>Check there are foreign materials or damages in a system cartridge and try again system check process.</p> <p>Call Boditech Med Inc’s Technical service or authorized regional representative if same problems exist.</p>

<p>Error S2 !</p>	 <p>There are some problems in system check cartridge or optics.</p>	<p>Check there are foreign materials or damages in a system cartridge and try again system check process. Call Boditech Med Inc.'s Technical service or authorized regional representative if same problems exist.</p>
<p>Barcode Error !</p>	 <p>It is impossible to identify a bar code on a system check cartridge.</p>	<p>Insert a system check cartridge in the cartridge holder correctly. Check there are foreign materials or damages on a bar code of a system cartridge and try again system check process. Call Boditech Med Inc.'s Technical service or authorized regional representative if same problems exist.</p>
<p>Mismatch Error !</p>	 <p>Lot numbers of a system check cartridge and system check ID chip do not match.</p>	<p>Check and match Lot numbers of a system check cartridge and system check ID chip and try again system check process. Call Boditech Med Inc.'s Technical service or authorized regional representative if same problems exist.</p>

7) You can print the test result out by tapping "Print" button.

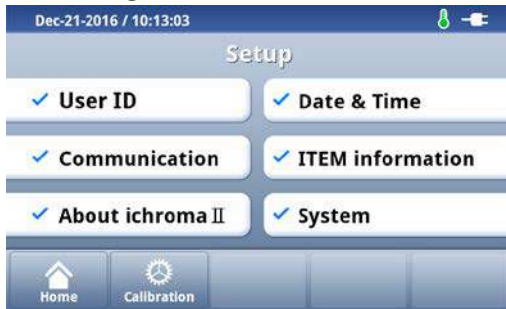
8) Please pack a system check cartridge and system check ID chip in the original pouch and seal it. Then store it at room temperature.

	<p>Sometimes LOT number and expiration date may not be displayed according to LOT number of system check cartridge.</p>
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10.3. Setup

Tap the "Setup" button then the the ichroma™ II will display setup screen as follow.

The setting condition is saved and not changed though power is off.



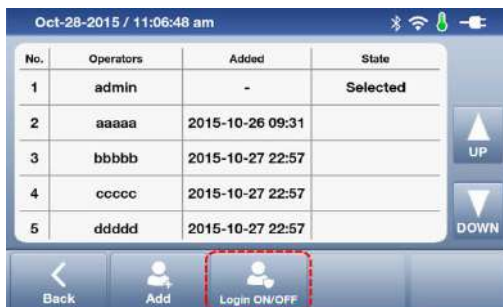
10.3.1. User ID

Setup > User ID


Setup for using of login function, registration of user ID, change of user information and etc. is available in this mode.

1) Setting Login function (This setting is only available when admin is logged in.)

① Tap the "Login ON/OFF" button to set this function.

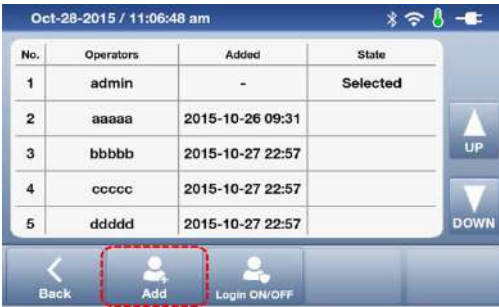


Item	Discription
Do you want to use Login function?	When you tap the "Ok" button, Login function is available.
Do you want to quit Login function?	When you tap the "OK" button, Login function is not available.

	<p>To set login function, log in with admin account. (The ichroma™ II is set with 'Login OFF' by default when releasing.) <How to log in admin account.></p> <ol style="list-style-type: none"> 1) Tap the "Setup > User ID" 2) Tap the "Admin". 3) Tap the "Select User" and input password. (The initial password is "0000".) 4) Tap the "OK" for login and the ichroma™ II will display "Add" and "Login ON/Off" button in the bottom of screen.
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2) Registration of new User ID (This setting is only available when admin is logged in.)

① Tap the "Add" button.



② Input new user ID, password and tap the "OK" button to complete registration of new user.



	<p>When "Login" function is live, the ichroma™ II requires User ID and password to log in. Be careful spelling of user ID and password. User ID and password should be more than 2 characters.</p>
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3) Changing password

① Tap user ID that you want to change password.



② Tap "Change Password" button.



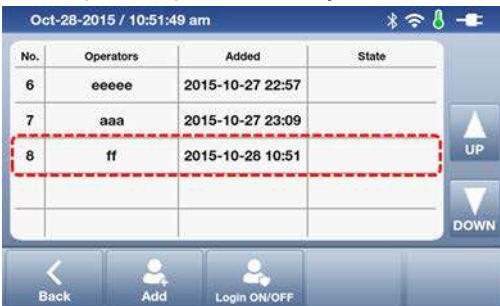
- ③ Input the current password, new password and new password for confirmation to change password. Then tap "OK" button.



4) Select/change user

You can change user without logout procedure from the current user.

- ① Tap the operator that you want to change.



- ② Tap "Select User" button. Then ichroma™ II will display "User change menu" pop-up window.



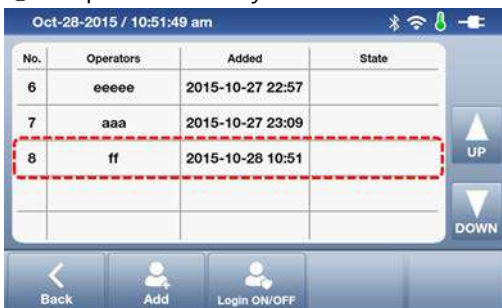
- ③ Input password and tap "OK" button to change user.



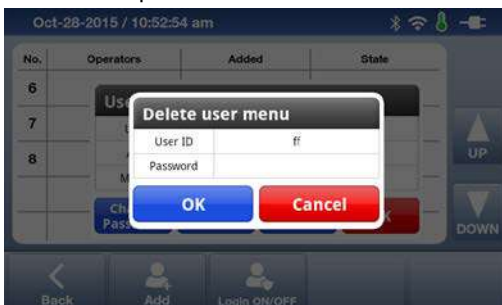
5) Delete user

This function is for deletion the registered users.

- ① Tap a user that you want to delete.



- ② Tap "Delete" button. Then ichroma™ II will display "Delete user menu" pop-up window. Input password and tap "OK" button to delete the selected user.



6) Logout

- ① In case of "Login" function is used, you can find "Logout" button in the right bottom of main menu.



- ② If you want to logout, tap "Logout" and "OK" button by turns. Then ichroma™ II will display "Login menu" pop-up window for new user.



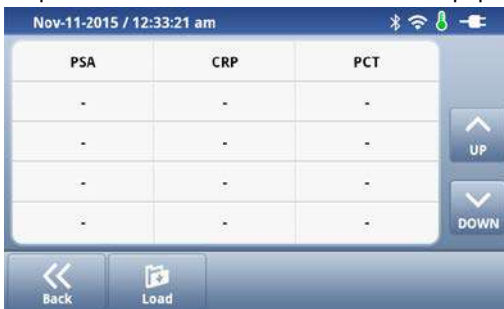
10.3.2. ITEM Information

Setup > ITEM information

This is for registration and management of ID chip information for each test item.

1) ITEM registration

Insert ID chip that you want to register and tap "Load" button. Then ichroma™ II will display the name of ID chip which is inserted into the ID chip port.

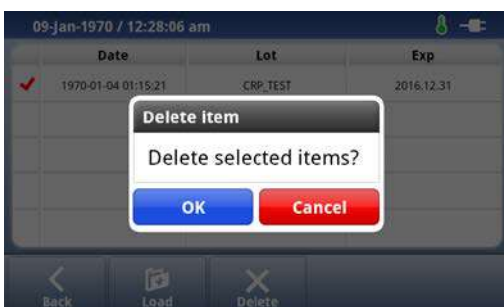


2) ITEM management

- ① To check the registration date, LOT number and expiration date of the relevant item, tap the name of item what you want to check.



- ② To delete the registered LOT, select the LOT that you want to delete and tap "Delete" button. Then ichroma™ II will display "Delete selected items?" pop-up window. To confirm the deletion, tap "Yes" button.



This function will be presented in near future.

Maximum 5 LOTs of ID chip per each item can be saved.

In case of 5 LOTs are registered, if user try to register a new LOT on same item, the oldest LOT will be deleted automatically and a new LOT will be registered.

If user register the same LOT on same item, the latest information will be registered.

Once an item is registered, there is no need to insert ID chip when you test the same item.
 If you proceed test without registration of item, that item will be registered automatically.
 There can be some limitation according to LOT number of ichroma™ Item.

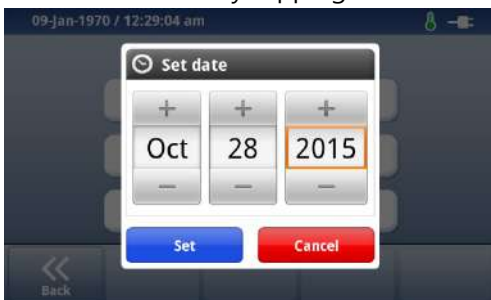
10.3.3. Date & Time

This function is for setting date and time.



1) Set date

You can set date by tapping "+" or "-" button. To finish setting date, tap "Set" button.



2) Set time

You can set time by tapping "+" or "-" button. To finish setting time, tap "Set" button.



3) Date format

You can select 3 kinds of date format.

- ① Month-Day-Year
- ② Day-Month-Year
- ③ Year-Month-Day



	<p>Please set the correct and exact date and time. If incorrect date is set, ichroma™ II can't calculate or check an expiration date of test cartridge correctly.</p>
--	---

10.3.4. Communication

Setup > Communication

This is for connect PC, Ethernet, WIFI and Bluetooth function.

Tap function what you want to connect.



1) PC



Connect PC with ichroma™ II using USB OTG cable and tap "ON" button.

	<p><u>WIFI, Bluetooth, Ethernet functions will be prepared in near future.</u> USB OTG cable, WIFI dongle and Bluetooth dongle are optional items. If connection is not possible, please contact authorized regional distributor or Boditech Med Inc's technical service.</p>
--	--

10.3.5. About ichroma™ II

Setup > About ichroma™ II


In this menu, you can check firmware version, memory, IP address and self-testing results of ichroma™ II. In addition this menu provides factory setting function.



1) Factory setting

Tap "Initialize" button and tap "Yes" button to proceed factory setting.



	<p>When you run factory setting, all saved data will be deleted and deleted data can't be restored. Be careful for running factory setting.</p>
	<p>Self-testing result which is displayed in this menu is the latest test result. Temperature in the self-testing result is current temperature.</p>

10.3.6. System

Setup > system

This menu is for setting display, sound, language, printer and update.




10.3.6.1. Display

Setup > System > Display

1) Brightness: ichroma™ II provides 5 steps of brightness.

2) Sleep mode: You select for using set sleep mode by tapping "ON" or "OFF" button. When you use sleep mode, you can set time for sleep mode.




	Time for sleep mode is 10, 20, 30, 60 and 120 minute.
---	---

10.3.6.2. Sound

Setup > System > Sound

1) Alarm on/off: You can set alarm by tapping On/Off button.



	ichroma™ II sounds alarm when test is completed, timer is over and error is occurred.
---	---

10.3.6.3. Printer

Setup > System > Printer

1) ON: When printer is on, ichroma™ II will prints out the test result when test is completed.

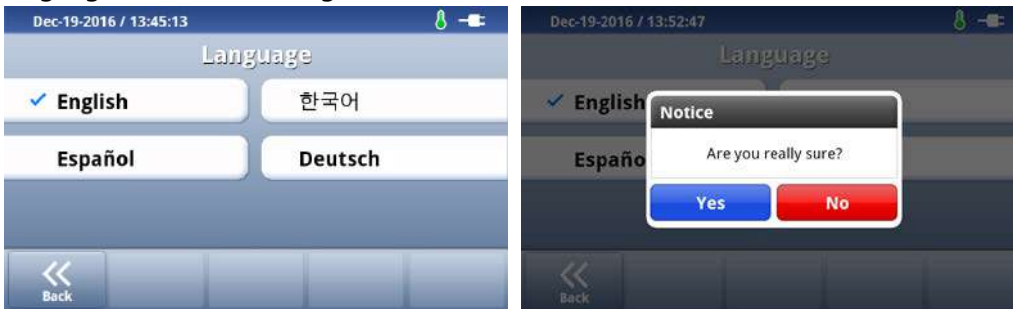
2) OFF: When printer is off, ichroma™ II does not print out the test result when test is completed. You can print out the previous test result for Multi test or Single test.



10.3.6.4. Language

Setup > System > Language

To change language, tap language that you want to change and tap "Yes" button. If you tap "No" button, language will not be changed.



	Supported language will be changed according to customer's requests.
--	--

10.3.6.5. Update

Setup > System > Update

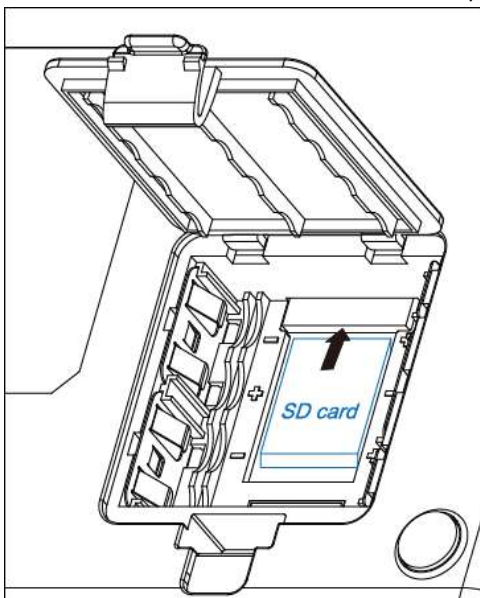
ichroma™ II provides updating function for application and firmware.

	<p>Do not turn ichroma™ II off during updating.</p> <p>Do not disconnect connection cable between ichroma™ II and PC during updating.</p> <p>Updating process will take few seconds or few minutes.</p>
--	---

1) Application updating

Setup > System > Update > Application

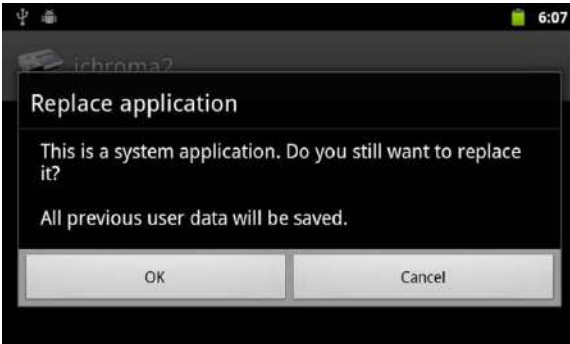
- ① Open the battery cover in the bottom of ichroma™ II.
- ② Insert a SD card which includes updating information into the SD card slot as following picture.



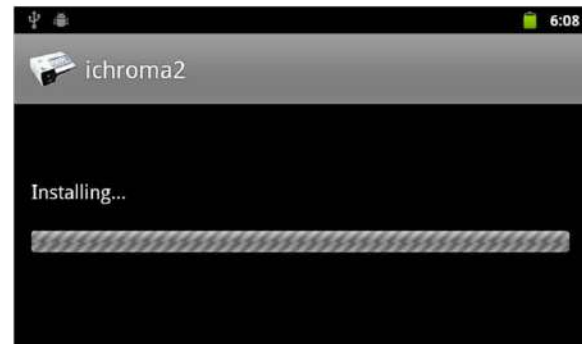
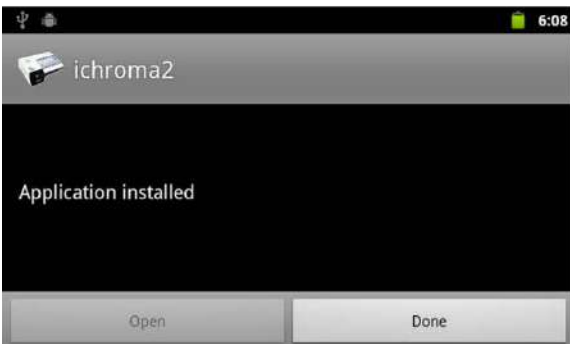
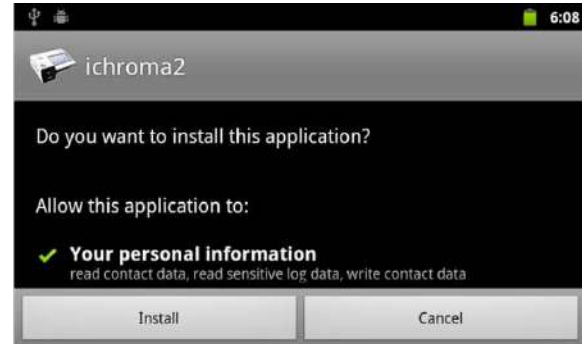
③ Tap "Application" in the "Update" screen.



④ Tap "OK" button.



⑤ Tap "Install" button.



⑥ When updating is completed, tap "Done" button. Then ichroma™ II will restart automatically.

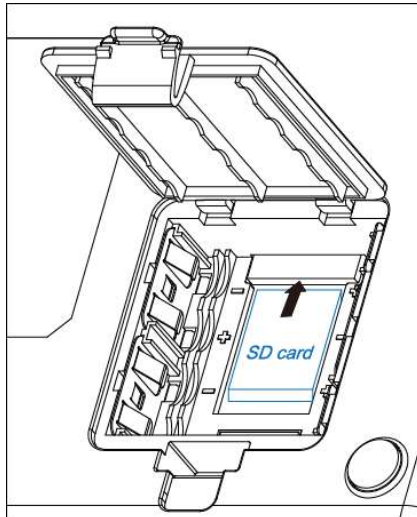
	If there is no SD card in the SD card slot or there is no updating information in a SD card, ichroma™ II will display a message for checking SD card.
	It is impossible to downgrade the application.

2) Firmware updating

Setup > System > Update > Firmware

● Firmware updating using SD Card

- ① Open the battery cover in the bottom of ichroma™ II.
- ② Insert a SD card which includes updating information into the SD card slot as following picture.



- ③ Tap "Firmware" in the "Update" screen.



- ④ Tap "OK" button to proceed firmware updating.



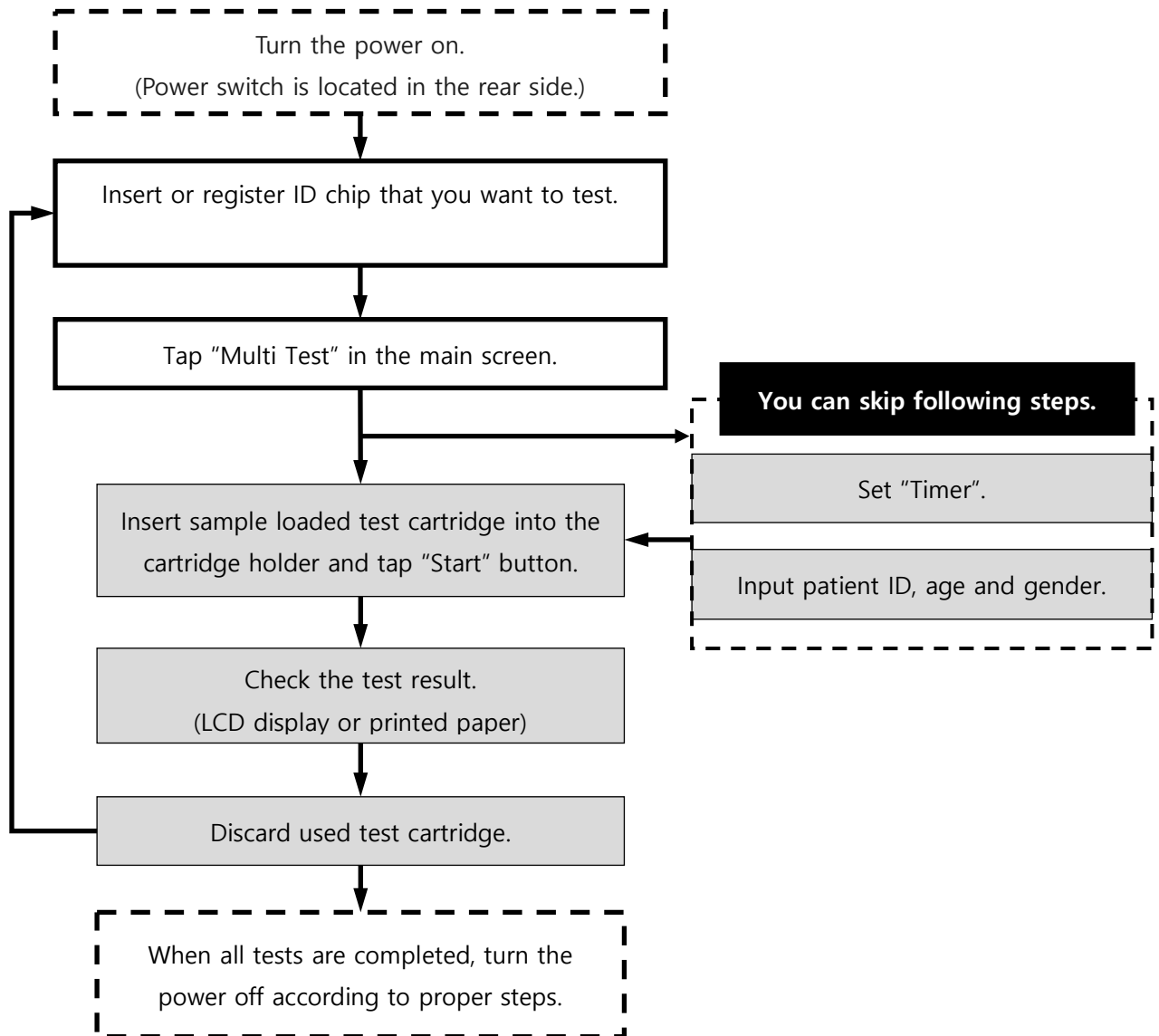
- ⑤ When updating is completed, ichroma™ II will restart automatically.






During firmware updating, ichroma™ II can generate continuous beep sound. When firmware updating is finished, ichroma™ II will stop beep sound automatically.

10.4. How to test

10.4.1. ichroma™ II Multi Test flowchart



10.4.2. Caution

	<p>Test samples using in various test can be infectious. Therefore please use protective gloves, mask and so on during handling test samples.</p> <p>Used cartridges, pipette tips and samples should be discarded according to the relevant regional regulations with high temperature and high pressure sterile.</p>
 Danger	<p>Do not handle ichroma™ II with wet hands.</p> <p>If you find/feel some smoke or burning smells, turn the power off immediately.</p> <p>Do not move ichroma™ II to other place during test.</p>
	<p>Do not stare inside of ichroma™ II during test.</p>

10.4.3. Run Test

ichroma™ II provides "Multi Test" and "Single Test" functions.

10.4.3.1. Single Test

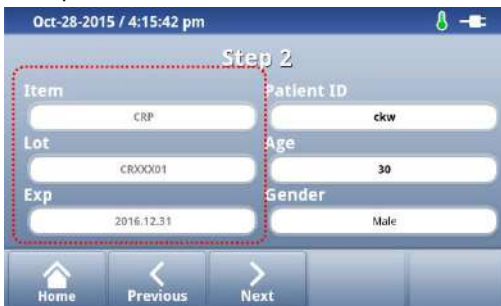
- 1) Tap "Single Test" in the main screen then ichroma™ II will display following screen.
- 2) Open a test cartridge and insert a test cartridge into the cartridge holder and tap "Next" button.




- 3) Check whether test item, LOT number and expiration date match the contents of screen. (Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ Item.)

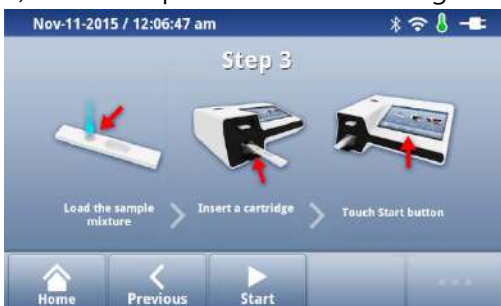
- 4) Input patient ID(maximum 15 characters), age and gender. (You can skip this step.)

- 5) Tap "Next" button. Then ichroma™ II will display test procedure.



	<p>Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ Item.</p>
---	--

- 6) Insert sample loaded test cartridge into the cartridge holder and tap "Start" button immediately.



7) ichroma™ II displays reaction time. When reaction is completed, ichroma™ II starts the test automatically.



8) When the test is completed, ichroma™ II displays the test result in LCD and saves it in the internal memory. You can print the test result out by tapping "Print" button.



9) If you tap "OK" or "Print" button, ichroma™ II goes back to "Single Test" screen.

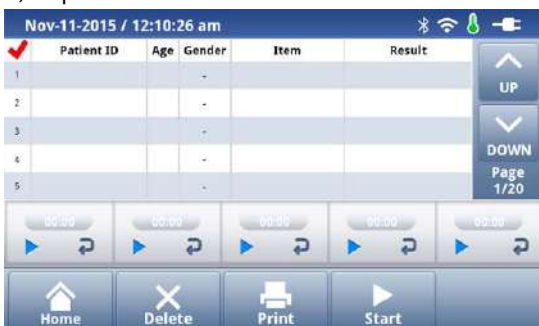
10) Please discard used test cartridge.



Used cartridges, pipette tips and samples should be discarded according to the relevant regional regulations with high temperature and high pressure sterile.

10.4.3.2. Multi Test

1) Tap "Multi Test" in the main screen then ichroma™ II will display following screen.



2) Set "Timer".

3) Input patient ID(maximum 15 characters), age and gender. (You can skip this step.)

4) Insert sample loaded test cartridge into the cartridge holder and tap "Start" button immediately.



5) When tests are completed, names of items and test results are displayed and saved automatically.

6) You can delete displayed test result by selecting and tapping "Delete" button. And you can print test results that you want to.






7) Please discard used test cartridges.


● **How to set timer**

ichroma™ II provides "Multi Timer" function.



No.	Name	Function
①	Time icon	When you tap "Time icon", ichroma™ II displays "Set Timer(Min.)" pop-up window. By tapping "+" and "-" button, you can set timer(maximum 60 minutes). 

		<p>To confirm setting timer, tap "Save" button.</p> <p>If you tap "Save All" button, all timers are saved with setting time.</p> <p>When time is over, ichroma™ II sounds alarm and time display will be changed with red color.</p>  <p>To finish alarm sound, tap reset button.</p>
②	Start button	<p>After setting time, tap "Start button" to start timer. Then "Start button" is changed to "Pause button".</p>  <p>To pause timer, tap "Pause button". Then "Pause button" is changed to "Start button".</p> <p>To resume timer, tap "Start button".</p>
③	Reset icon	<p>If you tap "Reset button" when timer is over or time is in pause status, "Time icon" will be changed to the initial setting time.</p>

	<p>All tests should be done in clean and stable place.</p> <p>Before run test, please refer to relevant package insert for each test.</p> <p>Excessive force during inserting a test cartridge into the cartridge holder may cause malfunction or error in ichroma™ II.</p>
	<p>Please register test item before running test.</p> <p>All test cartridges are disposable. Please discard used cartridges according to the relevant and proper regional regulations.</p>
	<p>When ichroma™ II works on "Multi test" mode, ichroma™ II can run 100 tests continuously.</p> <p>If you do not want to use internal timer, you can skip this setting.</p> <p>You can skip inputting patient ID, age and gender.</p> <p>You can input patient ID by using barcode scanner. (Refer to clause 11.2.)</p> <p>If built-in printer is not selected, "Print" button is not displayed in LCD. In this case, you can print the test results out by connecting PC. (Refer to clause 10.6.)</p>

10.4.4. QC test

10.4.4.1. System check test

Refer to section 10.2.

10.4.4.2. QC material test

QC Test > QC Materials

ichroma™ II provides "Multi Test" and "Single Test" during QC material test.

A. Multi Test

1) Tap "QC Test > QC Materials > Multi test". Then ichroma™ II will display following screen.



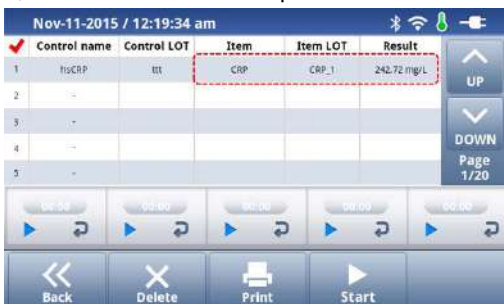
2) Select control name by tapping red rectangle area. If there is no registered control, please register control first. (Refer to clause 10.4.4.3.)

3) When you select registered control, LOT number of selected control is displayed automatically.

4) Load control to a test cartridge and insert it into the cartridge holder and tap "Start" button immediately.



5) When tests are completed, names of items and test results are displayed and saved automatically.



6) You can delete displayed test result by selecting and tapping "Delete" button. And you can print test results what you want to. Please discard used test cartridge.

A. Single Test

1) Tap "QC Test > QC Materials > Single Test". Then ichroma™ II will display following screen.

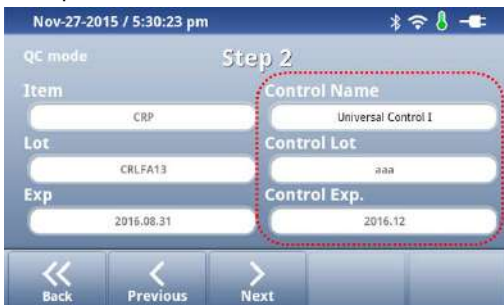
2) Open a cartridge pouch and insert a test cartridge into the cartridge holder and tap "Next" button.



3) Check whether test item, LOT number and expiration date match the contents of screen. (Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ Item.)

4) Select control name. (LOT number of selected control is displayed automatically.)

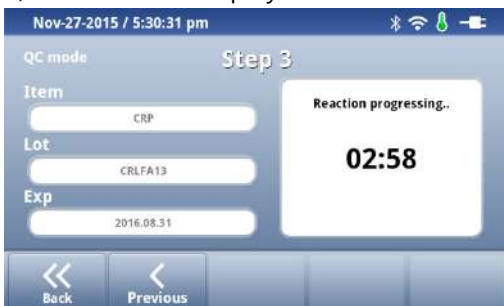
5) Tap "Next" button. Then ichroma™ II will display test procedure.



6) Load control to a test cartridge and insert it into the cartridge holder and tap "Start" button immediately.



7) ichroma™ II displays reaction time. When reaction is completed, ichroma™ II starts the test automatically.



8) When the test is completed, ichroma™ II displays the test result in LCD and saves it in the internal memory. You can print the test result out by tapping "Print" button.



9. If you tap "OK" or "Print" button, ichroma™ II goes back to "Single Test" screen.

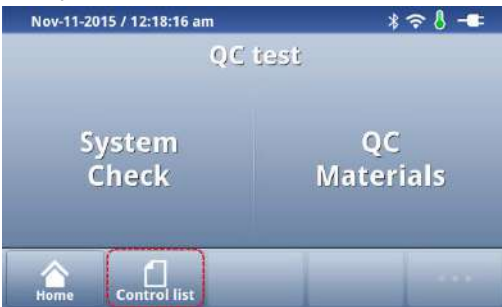
10. Please discard used test cartridge.

	Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ Item.
--	---

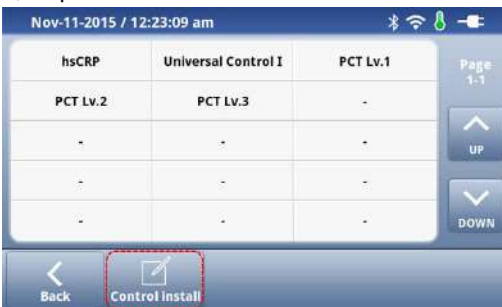
10.4.4.3. Registration of Control Materials

QC Test > Control List

1) Tap "Control List" button.



2) Tap "Control Install" button.



3) Tap "Control Name" then ichroma™ II displays list of controls which are provided by Boditech Med Inc. Select one of them for registration. Also you can input control name by using barcode scanner.



4) Tap "Control Lot" and "Control Exp." and input relevant information which are printed on the label of control. Then tap "Next" button. In case of inputting control name by using barcode scanner, LOT number and expiration date are inputted automatically.



5) Input item name(name of test), mean value and low/high limit. You can input this information by using barcode scanner also.



6) In case of you want to register more than 1 test item, please tap "Add Item".

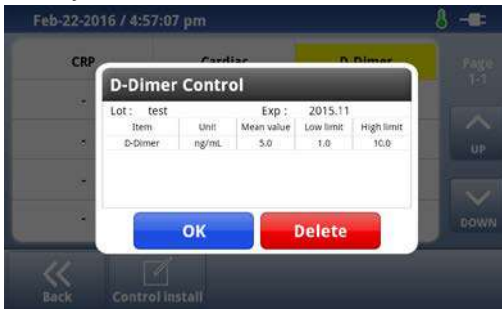


7) Input relevant information and tap "Save" button for completing registration. After tapping "Save" button, you can find registered controls in LCD screen.



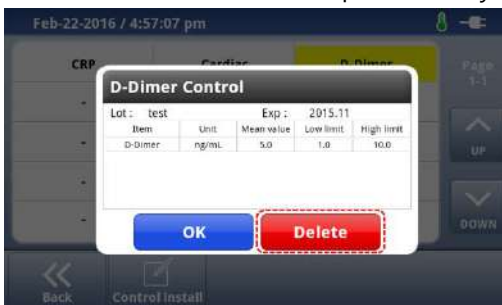
- **Checking information of registered control materials**

To check information of registered control materials, tap registered control name what you want to check. Then you can check name of item, unit, LOT number, expiration date, mean value and low/high limit value.



- **Delete information of registered control materials**

Tap control name that you want to delete and tap "Delete" button. To confirm deletion, tap "OK" button. This information will be deleted permanently.



	<p>You can input control information by manual input or using barcode scanner.</p>
	<p>When you input control information by manual input, please input exact and correct information for LOT number and expiration date. Incorrect information may cause erroneous results.</p>
	<p>Barcode scanner is an optional item. If you want to purchase it, please contact regional distributor or Boditech Med Inc.'s Sales department.</p>
	<p>If user register the same control material on same item, the latest information will be registered.</p>

10.5. Review data

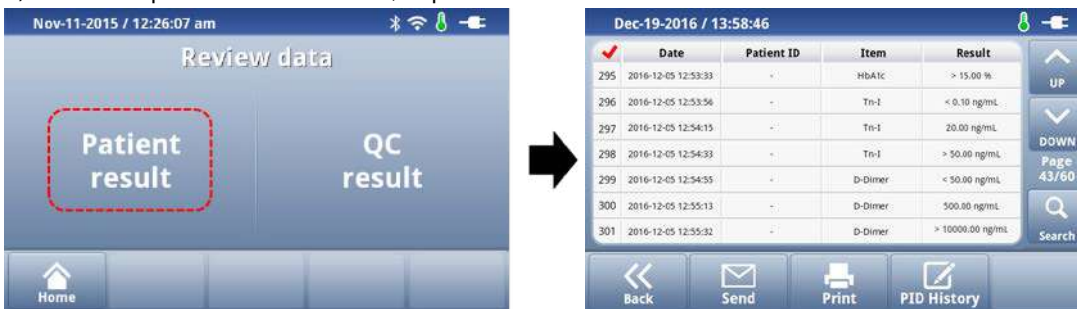
10.5.1. Patient test result

Review > Patient result

1) Tap "Review" button.



2) To check previous test results, tap "Patient result".









3) For more information, tap a test result that you want to check.



Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ Item.

● Button description

Button	Function / Description
	Go back to the previous screen.
	Print selected test results out. (Only available when built-in printer is selected.)
	Send selected test results to connected PC, LIS, WIFI or Bluetooth.

	<p>When you tap this button after selecting one patient ID, all test results for selected patient ID are displayed. If there is no patient ID, this function is not available.</p>
	<p>You can search test results by inputting test date, name of item and patient ID.</p>
	<p>Go to the next page.</p>
	<p>Go back to the previous page.</p>
	<p>Selecting or deselecting listed test results. When this is marked on, it means that item is selected.</p>
	<p>ichroma™ II can save up to 1,000 test results in its internal memory. Further test results are saved automatically and oldest test results will be deleted.</p>

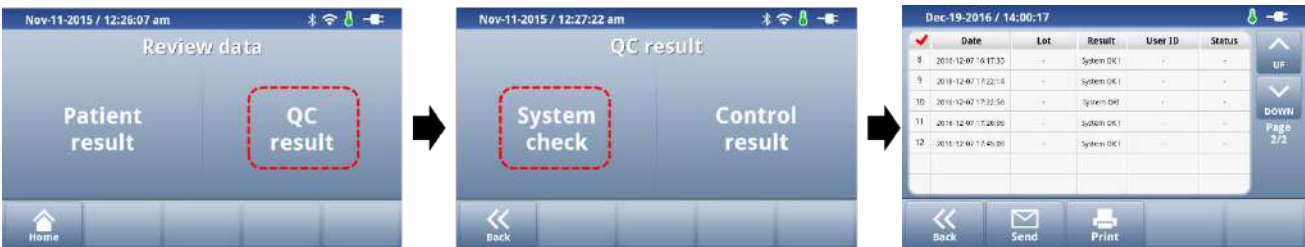
10.5.2. QC test result

10.5.2.1. System check test result

Review > QC result > System Check



Tap "System check" and check the system check test results.



	<p>Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ system check cartridge.</p>
--	--

● **Button description**

Button	Function / Description
	Go back to the previous screen.
	Print selected test results out.
	Send selected test results to connected PC, LIS, WIFI or Bluetooth.
	Go to the next page.
	Go back to the previous page.
	Selecting or deselecting listed test results. When this is marked on, it means that item is selected.

10.5.2.2. QC material test result

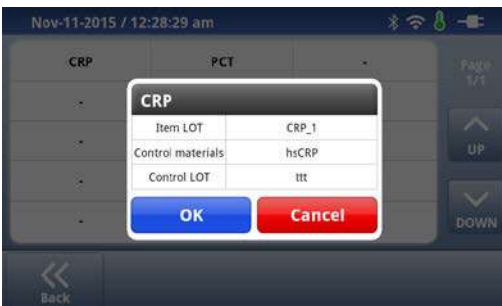
Review > QC result > Control Sample

ichroma™ II provides functions for checking and monitoring QC test result. Through these functions, we can provide proper quality control method.

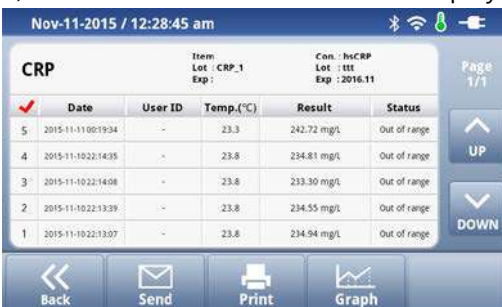
1) Tap name of item.



2) Select LOT number of test Item, Control Name and Control LOT and tap "OK" button.



3) Information of selected item is displayed.



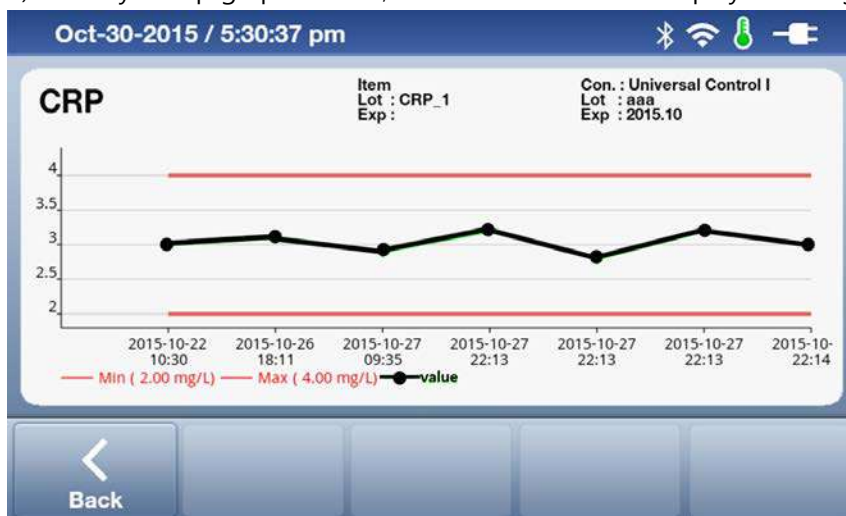
	<p>Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ item.</p>
--	--

● **Button description**

Button	Function / Description
	Go back to the previous screen.
	Print selected test results out.

	Send selected test results to connected PC, LIS, WIFI or Bluetooth.
	Test results are displayed with graph type.
	Go to the next page.
	Go back to the previous page.
	Selecting or deselecting listed test results. When this is marked on, it means that item is selected.

4) When you tap graph button, listed test results are displayed with graph type as follow.



	ichroma™ II provides efficient quality control method by displaying and analyzing QC test result as graph type.
--	---

10.6. Print test result

ichroma™ II can print test result out by using built-in printer or PC connection.

10.6.1. Print test results out by using built-in printer

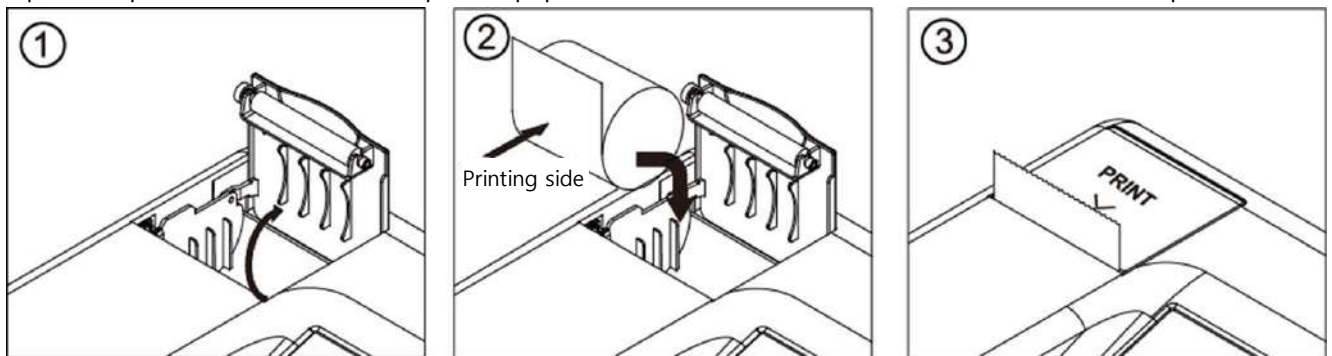
- 1) In case of built-in printer is installed, you can print test result out immediately after test is completed.
- 2) To set built-in printer, please refer to clause 10.3.6. System.

Run Test result(example)	QC Test result(example)	System Check result(example)
<p>[CRP Test]</p> <p>Date : 2015-10-29 Time : 08:54:36 User ID : admin ITEM LOT : CRXXX01 ITEM Exp. : 2016.12.31</p> <p>Patient ID : aaa Age : 30 Gender : Male</p> <p>Result : 2.65 mg/L Reference Value :</p>	<p>[PSA QC Test]</p> <p>Date : 2015-10-29 Time : 08:54:36 User ID : admin ITEM LOT : PSXXX01 ITEM Exp. : 2016.12.31</p> <p>Control : Universal Control I Control LOT : UCIXXX03 Control Exp. : 2015.12</p> <p>Result : 2.65 ng/mL Low Limit : High Limit :</p>	<p>[System Check Test]</p> <p>Date : 2015-10-29 Time : 08:54:36 User ID : admin ITEM LOT : ITEM Exp. :</p> <p>Result : System OK ! Or Result : Not Available ! Error code</p>

	<p>Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ item.</p>
--	--

● **Changing printer paper**

Open the printer cover and insert printer paper with correct direction as follow. Then close the printer cover.



	<p>When the printer cover is closed, built-in printer ejects printer paper a little for initialization.</p>
	<p>Be careful excessive force when opening or closing the printer cover for preventing malfunction of built-in printer.</p>

10.6.2. Print test results out by PC connection

ichroma™ II can print test results out by PC connection.



To print test results out by PC connection, the specific software provided by Boditech Med Inc. is needed.

This function will be presented in near future.

11. Optional

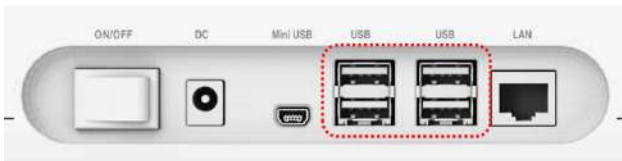
11.1. Barcode scanner

Barcode scanner is used for inputting user ID, patient ID or information of QC materials(controls).



How to use

- 1) Connect barcode scanner to USB port which is located on the rear side of ichroma™ II.
To use barcode scanner, specific setting procedure for using barcode scanner is not needed.



11.2. Keyboard

You can use keyboard instead of touchpad in LCD display.



How to use

- 1) Connect keyboard to USB port which is located on the rear side of ichroma™ II.
To use keyboard, specific setting procedure for using keyboard is not needed.



11.3. WIFI Dongle

ichroma™ II provides wireless internet connection using WIFI dongle.

	This function will be presented in near future.
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11.4. Bluetooth Dongle

ichroma™ II provides Bluetooth function.

	This function will be presented in near future.
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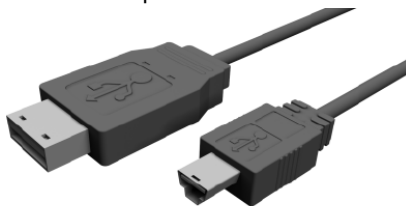
11.5. SD Card

You can update software of ichroma™ II using SD Card.

Please refer to clause "10.3.6.5 update".

11.6. ichroma™ II PC Connector Cable (USB OTG Cable)

ichroma™ II provides functions for printing by PC connection.



How to use

- 1) Connect connection cable to USB OTG port which is located on the rear side of ichroma™ II.
- 2) Connect connection cable to USB port of PC.



3) Tap "Setup > Communication > PC". Then ichroma™ II displays following screen.



4) To connect ichroma™ II to PC, tap "ON" button.

	<p>To connect ichroma™ II to PC, the specific software is needed. Please contact regional distributor or Boditech Med Inc.'s technical support team for detailed information.</p> <p>To print test results out by PC connection, the specific software provided by Boditech Med Inc. is needed. Please contact regional distributor or Boditech Med Inc.'s technical support team for detailed information.</p>
--	---

11.7. AA battery

ichroma™ II can use AA type batteries instead of AC adaptor.

To install/set batteries, please refer to section "8. Power supplement".

	<p>Use of batteries is only available in case of a blackout for instant operation. It is impossible for normal use with batteries for a long time. We suggest to use AC adaptor and power cable for stable and safe operation. It is possible 30 multi tests or 2 single tests when batteries are used.</p> <p>It is possible to use AC adaptor and batteries simultaneously. But we suggest to remove batteries when AC adaptor is used.</p>
	<p>For detailed information regarding optional items, please contact regional distributor or Boditech Med Inc.'s technical sales team.</p>

12. Troubleshooting

Symptoms	Problem causes	Recommended remedial/corrective measures
Nothing happens; ichroma™ II does not show any sign of functioning	Poor connection between the power adapter and the power cable.	Remove the power cable / adaptor and reconnect firmly.
	Power failure	Please use AC adaptor provided by Boditech Med Inc.
	Power switch is off.	Please turn the power switch on.
	AC adaptor failure	Contact regional distributor or Boditech Med Inc.'s technical support team.
LCD is not on or does not work properly.	External shock	Check there are some electromagnetic field emitting devices around ichroma™ II. Please install ichroma™ II apart from that kinds of devices. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical support team.
	Power failure	Refer to "Nothing happens" descriptions. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical support team.
ichroma™ II does not display test result after completing the test.	ichroma™ II in under calculating test result.	Please wait until ichroma™ II displays the test result.
	Internal communication failure	Restart ichroma™ II. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical support team.
The cartridge holder does not work.	Foreign material	Contact regional distributor or Boditech Med Inc.'s technical support team.
	Software failure	Restart ichroma™ II. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical

		support team.
Some noise generate while ichroma™ II is working.	Foreign material	Contact regional distributor or Boditech Med Inc.'s technical support team.
	Software failure	Restart ichroma™ II. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical support team.
Operation temperature is out of range. Do you want to proceed the test?	Environment temperature is out of operation temperature range(15-35°C).	It is possible to proceed test. But test result may not correct due to operation temperature is out of suggested condition(15-35°C). Please set environment temperature as 15-35°C.
It is impossible to proceed the test due to system error.	System error	Contact regional distributor or Boditech Med Inc.'s technical support team.
ichroma™ II is working. Please wait.	The cartridge holder is moving.	Please wait until the cartridge holder stops.
Insert test cartridge.	In case of tapping "Next" button without inserting test cartridge in single test mode.	Please insert test cartridge and tap "Next" button.
Register or insert ID chip.	In case of ID chip is not registered or not registered item is tested without ID chip.	Please insert or register ID chip first. Some items are can't be registered. Please check items again.
Please check test cartridge.	In case of use of system check cartridge in multi, single and control materials test mode.	It is impossible to use system check cartridge in multi, single and control test mode. Try the test again with proper test cartridge.
Check system check ID chip.	In case of tapping "Next" button without system check ID chip. In case of other ID chip is inserted.	To proceed system check, you should insert system check ID chip. Please insert system check ID chip and try system check procedure again.
Check LOT number of system check cartridge and ID chip.	LOT number of system check cartridge and ID chip do not match.	Please check LOT number and try again.
System check cartridge is expired. Do you want to proceed system	Incorrect set of date and time.	Please check date and time in ichroma™ II.

check test?	System check cartridge is expired.	In case of expiration date of system check cartridge is over, it is possible to proceed system check procedure. But it may cause incorrect system check test result.
Select name of control.	In case of control materials test is started without selecting name of control.	Please input name of control and try again.
It is impossible to print. Check printer.	There is no printer paper. Printer failure	Please install/insert printer paper with correct direction. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical support team.
It is impossible to search items which are not including patient ID.	In case of user tries to search items which are not including patient ID.	If test result information does not include patient ID, it is impossible to search test result by patient ID. Please check patient ID is included in the test result information.
There is no selected data.	In case of tapping "Print" or "Delete" button without selecting data.	Please select data what you want to print or delete and try again.
Input user ID with more than 2 characters at least.	In case of inputted user ID with only 1 character.	Please input ID again with more than 2 characters.
Input password with more than 2 characters at least.	In case of inputted password with only 1 character during user ID registration.	Please input password with more than 2 characters.
Incorrect password Check your password and try again.	In case of inputted password and confirmation password do not match during user ID registration.	Please check inputted password and try again.
This ID is already registered.	In case of inputted user ID is already registered/exist during user ID registration.	Please check user ID and try again.
ichroma™ II can register maximum 100 users.	The number of registered user ID exceed 100 during user ID registration.	Please delete user ID and try again.
Input user ID.	In case of tapping "OK" button without inputting user ID.	Please input user ID and try again.
Input password.	In case of tapping "OK" button without inputting password	Please input password and try again.

13. Error code

Error code	Probable causes	Recommended Remedial / Corrective measures
Error 25 - 31	Technical problems in test cartridge	Try again the test with new test cartridge.
Error S1, Error S2	Optical failure	Turn the power off and contact regional distributor or Boditech Med Inc.'s technical support team.
Value Error 1 - 10	Improper sample or buffer is used.	Try again the test with new test cartridge and test sample.
Caution Error	Technical problems in test cartridge	Try again the test with new test cartridge.
Barcode Error	Problem in identification of barcode on test cartridge	Check barcode on test cartridge is damaged or contaminated by foreign materials.. Insert test cartridge into the cartridge holder to the end. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical support team.
Mismatch error	ID chip and test cartridge do not match.	Match ID chip and test cartridge. Then try again the test.
Password error	Incorrect password	Try again after checking user ID and password.
ID chip cartridge Lot Number Mismatch	LOT number of ID chip and test cartridge do not match.	Match LOT number of ID chip and test cartridge. Then try again the test.
Invalid Item	ID chip problem	Change ID chip and try again with new ID chip. If problems are not solved, contact regional distributor or Boditech Med Inc.'s technical support team.
SW & Test batch not compatible	Test item is not included in software.	Contact regional distributor or Boditech Med Inc.'s technical support team.
Optics part Error !	Optical failure during self-testing procedure	Contact regional distributor or Boditech Med Inc.'s technical support team.

Moving part Error !	Moving part failure during self-testing procedure	Contact regional distributor or Boditech Med Inc.'s technical support team.
Storage disk Error !	Internal storage failure during self-testing procedure	Contact regional distributor or Boditech Med Inc.'s technical support team.
Temperature sensor Error !	Temperature sensor failure during self-testing procedure	It is possible to proceed test. But test result may not correct due to operation temperature is out of suggested condition(15-35°C). Contact regional distributor or Boditech Med Inc.'s technical support team.
Printer initializing Error !	Built-in printer failure during self-testing procedure	It is possible to proceed test. But it is impossible to print the test result out. Contact regional distributor or Boditech Med Inc.'s technical support team.
Temperature out of recommended range. Proceed?	Environment temperature is out of operation temperature range during self-testing procedure	It is possible to proceed test. But test result may not correct due to operation temperature is out of suggested condition(15-35°C). Please set environment temperature as 15-35°C.

14. Warranty

ichroma™ II has passed strict quality assurance and testing procedures.

Boditech Med Inc.'s expressed and implied warranties are conditional upon full observance of Boditech Med Inc.'s published directions with respect to the use of Boditech Med Inc.'s products.

Under no circumstances whatsoever shall Boditech Med Inc. be held liable for any indirect or consequential damages.

To avail the warranty service, the consumer must return the defective ichroma™ II unit or any component thereof; along with proof of purchase to Boditech Med Inc. or its nearest Authorized Service Agent.

Warranty Information

During the warranty period (24 months from the date of purchase), defective or spontaneously malfunctioning ichroma™ II or its component(s) will be repaired free of cost or may be compensated for in accordance with consumer protection rules and regulations.

The consumer may be charged for repair of ichroma™ II even during the warranty period in following cases:

- Improper use or misuse
- Consumer's intentional mishandling, abuse or neglect of the product(s)
- Unauthorized repair / replacement of or alteration in any component
- Missing of warranty card or intentional modification of information in warranty card
- Damages or defects due to fire, pollution, earthquake or other natural disasters.

For after-sales inquiry, please contact:

Boditech Med Incorporated

43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do 24398

REPUBLIC OF KOREA.

Phone No.: +82 33 243 1400 / Fax No.: +82 33 243 9373

E-mail: support@boditech.co.kr / Website: www.boditech.co.kr

Warranty card

Thank you for purchasing ichroma™ II.

Please fill the required information and send a copy of this warranty card within 30 days of date of purchase to the above address.

Product Name	ichroma™ II
Serial No.	
Date of Manufacture	
Warranty Period	24 months from the date of purchase
Date of Purchase	Year _____ Month _____ Day _____
Manufacturer	Boditech Med Inc.
Purchase Location	

Respect for life



Boditech Med Inc.

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