



1) Prijunkite klaviatūra prie USB jungties, esančios galinėje ichroma™ II dalyje. Norint naudoti klaviatūrą specifinė nustatymo procedūra nėra reikalinga.



#### 11.4. WIFI įrenginys

ichroma™ II galite prijungti prie LIS naudodami WIFI įrenginį.

	Ši funkcija bus prieinama netolimoje ateityje.
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#### 11.5. Bluetooth įrenginys

ichroma™ II suteikia Bluetooth funkciją.

	Ši funkcija bus prieinama netolimoje ateityje.
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#### 11.6. SD kortelė

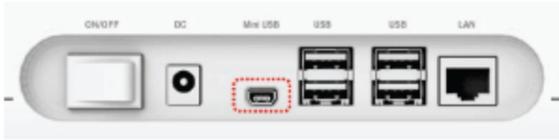
Naudodami SD kortelę galite atnaujinti ichroma™ II programinę įrangą. Daugiau informacijos rasite 10.3.6.5 skyrelyje Atnaujinimas.

#### 11.7. ichroma™ II AK jungties laidas (USB OTG laidas)

ichroma™ II suteikia funkciją spausdinimui ir atnaujinimui naudojant AK jungtį.



- 1) Prijunkite laidą prie USB OTG jungties, esančios galinėje ichroma™ II dalyje.
- 2) Prijunkite laidą prie USB jungties, esančios AK.



- 3) Paspauskite „Setup > Communication > PC“. Tada ichroma™ II parodys toliau pateiktą ekraną.



- 4) Norėdami prijungti ichroma™ II prie AK paspauskite mygtuką „ON“.

	<p>Norėdami prijungti ichroma™ II prie AK reikalinga specifinė programinė įranga. Prašome susisiekti su platintoju regione arba Boditech Med Inc. techninės pagalbos komanda detalesnei informacijai gauti.</p> <p>Norint atspausdinti testo rezultatus naudojant AK jungtį, reikalinga specifinė programinė įranga. Prašome susisiekti su platintoju regione arba Boditech Med Inc. techninės pagalbos komanda detalesnei informacijai gauti.</p>
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## 11.8. AA baterija

ichroma™ gali naudoti AA tipo baterijas vietoje AC adapterio. Norint įdiegti/įstatyti baterijas žiūrėkite 8 skyrių Galios tiekimas.

	<p>Baterijų naudojimas galimas tik trumpalaikiam prietaiso naudojimui. Normalaus naudojimo su baterijomis užtikrinti neįmanoma. Mes rekomenduojame saugiam ir stabiliam prietaiso veikimui naudoti AC adapterį ir galios laidą. Naudojant baterijas galima atlikti 30 multi testų arba 2 atskirus testus.</p> <p>Vienu metu galima naudoti ir AC adapterį ir baterijas. Tačiau mes rekomenduojame išimti baterijas, kai prietaisas veikia naudodamas AC adapterį.</p>
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Daugiau informacijos apie priedus gausite susisiekę su platintoju regione arba Boditech Med Inc. techninių pardavimų komanda.

## 12. Trikčių šalinimas

Požymiai	Galimos priežastys	Rekomenduojami taisymo veiksmai
Nieko nevyksta; ichroma™ II nerodo jokių funkcionavimo ženklų.	Bloga jungtis tarp galios adapterio ir galios laido.	Atjunkite galios laidą/adapterį ir vėl tinkamai sujunkite.
	Galios tiekimo sutrikimas.	Prašome naudoti Boditech Med Inc. tiekiamą AC adapterį
	Galios jungiklis išjungtas.	Ijunkite galios jungiklį.
	AC adapterio gedimas.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
LCD neįsijungia arba veikia netinkamai.	Išorinis šokas.	Patikrinkit ar apie ichroma™ II nėra elektromagnetinį lauką skleidžiančių prietaisų. Prašome įdiegti ichroma™ II toliau nuo tokių prietaisų. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
	Galios tiekimo sutrikimas.	Žr. „Niekas nevyksta“ problemą. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
ichroma™ II nerodo testo rezultatų po testo atlikimo.	ichroma™ atlieka testo rezultatų skaičiavimą.	Palaukite, kol ichroma™ II parodys testo rezultatus.
	Vidinės komunikacijos gedimas.	Pakartotinai paleiskite ichroma™ II. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Kasetės laikiklis neveikia.	Pašalinė medžiaga.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
	Programinės įrangos gedimas.	Pakartotinai paleiskite ichroma™ II. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.

Požymiai	Galimos priežastys	Rekomenduojami taisymo veiksmai
ichroma™ II veikimo metu generuojamas triukšmas.	Pašalinė medžiaga.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
	Programinės įrangos gedimas. 15 t.s.	Pakartotinai paleiskite ichroma™ II. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Pranešimas: Operation temperture is out of range. Do you want to proceed the test?	Aplinkos temperatūra viršija rekomenduojamas ribas (15-35°C).	Testą testuoti galima, tačiau testo rezultatai gali būti netikslūs dėl aplinkos temperatūros ribų viršijimo (15-35°C). Darbinė aplinkos temperatūra turi būti 15-35°C.
Pranešimas: It is impossible to proceed the test due to system error.	Sistemos klaida.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Pranešimas: ichroma™ II is working. Please wait.	Kasetės laikiklis juda.	Palaukite, kol kasetės laikiklis sustos.
Pranešimas: Insert test cartridge.	Pranešimas pasirodo, kai mygtukas „Next“ paspaudžiamas neįdėjus testo kasetės Single Test režime.	Įdėkite testo kasetę ir paspauskite mygtuką „Next“.
Pranešimas: Register or insert ID chip.	Jeigu ID lustas nebuvo užregistruotas arba registruotas elementas tiriamas be ID lusto.	Pirmiausia įdėkite arba registruokite ID lustą. Kai kurie elementai negali būti registruoti. Patikrinkite elementus dar kartą.
Pranešimas: Please check test cartridge.	Sistemos tikrinimo kasetės naudojimo atveju multi, single ir control material tyrimo režime.	Negalima naudoti sistemos tikrinimo kasetės multi, single arba control test režime. Pabandykite testą atlikti dar kartą su tinkama testo kasete.
Pranešimas: Check system check ID chip.	Pranešimas pasirodo, kai mygtukas „Next“ paspaudžiamas be sistemos tikrinimo ID lusto. Jeigu įdėtas kitas ID lustas.	Norint testuoti sistemos tikrinimą įdėkite sistemos tikrinimo ID lustą. Įdėkite sistemos tikrinimo ID lustą ir pabandykite atlikti sistemos tikrinimo procedūrą dar kartą.
Pranešimas: Check LOT number of system check cartridge and ID chip.	Sistemos tikrinimo kasetės ir ID lusto partijos numeriai nesutampa.	Patikrinkite partijos numerius ir pabandykite dar kartą.
Pranešimas: System check cartridge is expired. Do you want to proceed system check test?	Netinkamai nustatyta data ir laikas. Sistemos tikrinimo kasetės galiojimo laikas pasibaigęs.	Prašome patikrinti ichroma™ II datą ir laiką. Jeigu sistemos tikrinimo kasetės galiojimo laikas pasibaigęs, sistemos tikrinimo procedūrą testuoti galima, tačiau tai gali sugeneruoti neteisingus sistemos tikrinimo rezultatus.

Požymiai	Galimos priežastys	Rekomenduojami taisymo veiksmai
Pranešimas: Select name of control.	Pasirodo, jeigu kontrolės medžiagos testas pradedamas nepasirinkus kontrolės pavadinimo.	Įveskite kontrolės pavadinimą ir pabandykite dar kartą.
Pranešimas: It is impossible to print. Check printer.	Spausdintuve nėra popieriaus. Spausdintuvo gedimas.	Tinkamai įdėkite spausdintuvo popieriaus. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Pranešimas: It is impossible to search items which are not including patient ID.	Pasirodo, jeigu vartotojas bando ieškoti elementų, kurie neturi paciento ID.	Jeigu testo rezultatų informacija neturi paciento ID, ieškoti testo rezultatų pagal paciento ID neįmanoma. Prašome patikrinti ar paciento ID įtrauktas į testo rezultatų informaciją.
Pranešimas: There is no selected data.	Pasirodo, jeigu paspaudžiate mygtukus „Print“ arba „Delete“ nepasirinkdami duomenų.	Prašome pasirinkti duomenis, kuriuos norite atspausdinti arba ištrinti, ir pabandykite dar kartą.
Pranešimas: Input user ID with more than 2 characters at least.	Pasirodo, jeigu įvestą vartotojo ID sudaro tik 1 simbolis.	Prašome įvesti ID dar kartą naudojant daugiau nei 2 simbolius.
Pranešimas: Input password with more than 2 characters at least.	Pasirodo, jeigu įvestą slaptažodį sudaro tik 1 simbolis.	Prašome įvesti slaptažodį dar kartą naudojant daugiau nei 2 simbolius.
Pranešimas: Incorrect password. Check your password and try again.	Pasirodo, jeigu įvestas slaptažodis nesutampa su patvirtinamuoju slaptažodžius vartoto ID registravimo metu.	Prašome patikrinti įvestą slaptažodį ir pabandyti dar kartą.
Pranešimas: This ID is already registered.	Pasirodo, jeigu įvestas ID jau yra užregistruotas/egzistuoja vartotojo ID registravimo metu.	Prašome patikrinti vartotojo ID ir pabandyti dar kartą.
Pranešimas: ichroma™ II can register maximum 100 users.	Registruotų vartotojų ID kiekis viršija 100 naujo vartotojo ID registracijos metu.	Prašome ištrinti nereikalingus vartotojo ID ir pabandyti dar kartą.
Pranešimas: Input user ID.	Pasirodo, jeigu paspaudžiamas mygtukas „OK“ neįvedant vartotojo ID.	Įveskite vartotojo ID ir pabandykite dar kartą.
Pranešimas: Input password.	Pasirodo, jeigu paspaudžiamas mygtukas „OK“ neįvedant slaptažodžio.	Įveskite slaptažodį ir pabandykite dar kartą.

### 13. Klaidų kodai

Klaidos kodas	Galimos priežastys	Rekomenduojamos priemonės
Error 21-24	Elektrinis ar mechaninis gedimas	Išjunkite galios tiekimą ir skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Error 25-31	Techninė testo kasetėje.	Paimkite naują testo kasetę ir pakartokite tyrimą.
Error S1, Error S2	Optinis gedimas	Išjunkite galios tiekimą ir skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Value Error 1-10	Naudojamas netinkamas mėginys arba buferis.	Paimkite naują testo kasetę, naują mėginį ir pakartokite tyrimą.
Caution Error	Techninė problema testo kasetėje.	Paimkite naują testo kasetę ir pakartokite tyrimą.
Barcode Error	Problema identifikuojant testo kasetės brūkšninį kodą.	Patikrinkite testo kasetės brūkšninį kodą dėl sugadinimo arba užteršimo pašalinėmis medžiagomis. Įdėkite testo kasetę į kasetės laikiklį. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Password error	Netinkamas slaptažodis.	Patikrinkite vartotojo ID ir slaptažodį ir pabandykite dar kartą.
ID chip cartridge Mismatch	ID lustas ir testo kasetė nesutampa.	Sutikrinkite ID lustą ir testo kasetę. Pabandykite testą atlikti dar kartą.
ID chip cartridge Lot Number Mismatch	ID lusto ir testo kasetės partijos numeris nesutampa.	Sutikrinkite ID lusto ir testo kasetės partijos numerį. Pabandykite testą atlikti dar kartą.
Invalid Item	ID lusto problema.	Pakeiskite ID lustą ir pabandykite atlikti veiksmą su nauju ID lustu. Jeigu problema išlieka, skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
SW & Test batch not compatible	Testo elementas neįrauktas į programinę įrangą.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.

<b>Klaidos kodas</b>	<b>Galimos priežastys</b>	<b>Rekomenduojamos priemonės</b>
Optics part Error!	Optinis gedimas savitikros metu.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Moving part Error!	Judančios dalies gedimas savitikros metu.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Storage disk Error!	Vidinės atminties prietaiso gedimas savitikros metu.	Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Temperature sensor Error!	Temperatūros daviklio gedimas savitikros metu.	Testą tęsti galima, tačiau testo rezultatai gali būti netikslūs dėl aplinkos temperatūros ribų viršijimo (15-35 <sup>0</sup> C). Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Printer initializing Error!	Įmontuoto spausdintuvo gedimas savitikros metu.	Testą tęsti galima, tačiau testo rezultatai nebus atspausdinti. Skambinkite atstovui regione arba Boditech Med. Inc. techninės pagalbos komandai.
Inccoret Temperature!	Aplinkos temperatūra viršija nustatytas darbinės temperatūros ribas savitikros metu.	Testą tęsti galima, tačiau testo rezultatai gali būti netikslūs dėl aplinkos temperatūros ribų viršijimo (15-35 <sup>0</sup> C). Darbinė aplinkos temperatūra turi būti 15-35 <sup>0</sup> C).

## 14. Garantija

ichroma™ II praėjo griežtą kokybės užtikrinimo ir tyrimo procedūras.

Boditech Med Inc. išreikšta ir taikoma garantijos yra sąlygojamos visiško gamintojo publikuotų instrukcijų, skirtų Boditech Med Inc. produktams, laikymosi.

Jokiais atvejais Boditech Med Inc. neturi būti laikoma dėl netiesioginių arba pasekminių sugadinimų.

Siekiant gauti garantinį aptarnavimą pirkėjas turi grąžinti sugedusį ichromat™ II prietaisą arba bet kokį komponentą kartu su pirkimo įrodymų Boditech Med Inc. arba gamintojo įgaliotam artimiausiam serviso agentui.

### Garantijos informacija

Garantiniu laikotarpiu (12 mėnesių nuo įsigijimo dienos) spontaniškai neveikiantis arba turintis defektą ichroma™ II arba jo komponentai bus taisomi nemokamai arba pirkėjui kompensuojami nuostoliai pagal pirkėjo apsaugos taisykles ir reglamentus.

Pirkėjas privalės apmokėti ichroma™ II remontą garantiniu laikotarpiu esant toliau nurodytiems atvejams:

- Netinkamas arba neteisingas naudojimas
- Pirkėjo tyčinis produkto gadinimas
- Nepatvirtintas remontas arba bet kokių dalių keitimas ar modifikavimas
- Prarasta garantijos kortelė arba tyčinis informacijos garantinėje kortelėje modifikavimas
- Pažeidimai ar defektai atsirandantys dėl gaisro, taršos, žemės drebėjimo ar kitų gamtos stichijų

Užklausoms po pardavimo prašome kreiptis į Boditech Med Inc. arba įgaliota regioninį platintoją.

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## Garantijos kortelė

Dėkojame, kad įsigijote ichroma™ II.

Prašome užpildyti reikalingą informaciją ir nusiųsti šios garantijos kortelės kopiją per 30 dienų nuo įsigijimo datos anksčiau nurodytu adresu.

<b>Produkto pavadinimas</b>	ichroma™ II
Serijinis numeris	
Pagaminimo data	
Garantijos trukmė	12 mėnesiai nuo įsigijimo datos
Įsigijimo data	Metai _____ Mėnuo _____ Diena _____
Gamintojas	Boditech Med Inc.
Įsigijimo vieta	

## Respect for life



### **Boditech Med Inc.**

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바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 (200-883)



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21 t.s. Instrukcija anglų kalba

# 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.

*For technical assistance, contact:*

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**Revision 00**

**Date of last revision : January 7, 2016**



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 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 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 fining 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, 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 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
	<b>LASER Radiation</b> Do not stare into beam.
	<b>Potential Biohazard</b>

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

**2) Optional**

<p>① Built-in Printer</p> 	<p>② Barcode scanner</p> 	<p>③ Keyboard</p> 
<p>④ USB OTG Cable</p> 	<p>⑤ WIFI Dongle</p> 	<p>⑥ Bluetooth Dongle</p> 
<p>⑦ SD Card</p> 	<p>⑧ AA battery</p> 	

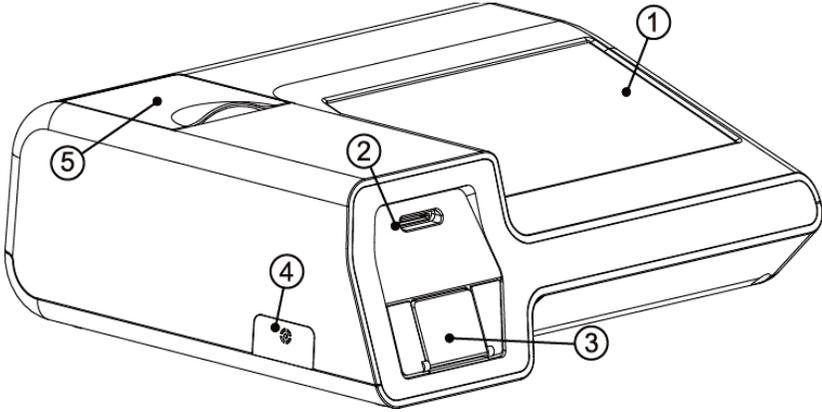
## 6. Technical specifications

Item	Specification
Product name	ichroma™ II
Principle	Fluorescent 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, 1.8A 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(optional)
Saving test results	Patient test : 1,000 results System check test results : 500 results Control materials test results : 1,000 results
Saving ID chip information	500 ID chips (maximum 5 LOTs per item)

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

## 7. Functional and operational elements

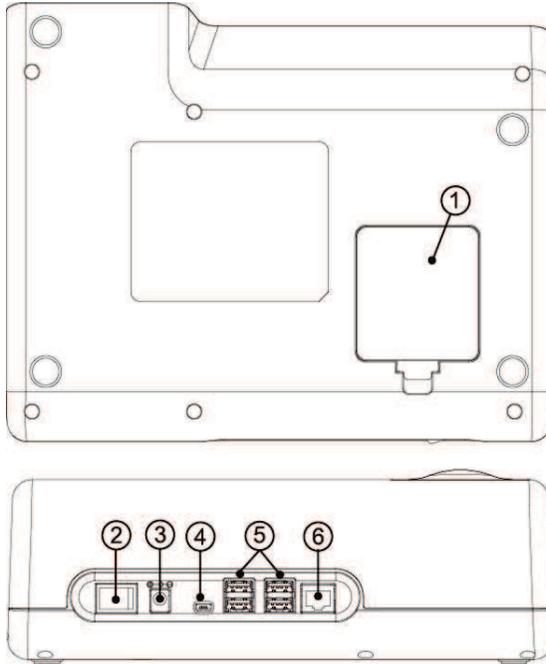
### Front side view of ichroma™ II



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 (optional)	Print test results out.

	<p>Built-in thermal printer is optional item. Basic contents does not include built-in thermal printer.</p> <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**



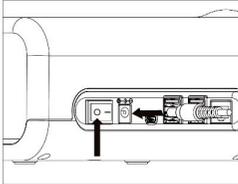
No.	Part name	Function
①	Battery cover	When the battery cover is opened, you can install/set batteries and SD card.
②	Power switch	Main power switch
③	Power port	Connection port for AC adaptor
④	USB OTG port	Connection port for PC connection and communication
⑤	USB port	Connection port for barcode scanner,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

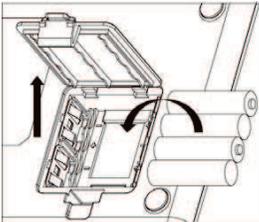


2) Connect power cord to external power outlet.

### ● 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. 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. Use of a printer can cause power down due to excessive power consumption.</p>
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1) Open the battery cover in the bottom of the ichroma™ II. Please check the direction of batteries and insert them with correct direction.

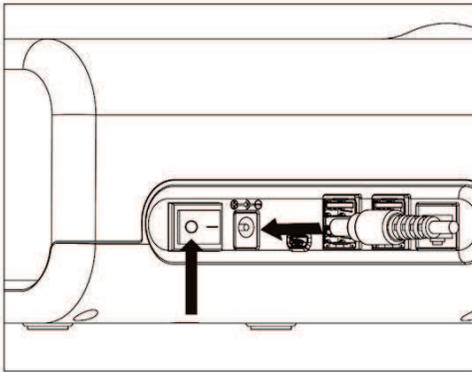


2) Close the battery cover and put the ichroma™ II on right position.

## 9. Installation

	Refer to Section 3 and Section 8 prior to installation.
--	---

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.

	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.
--	---

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 !	 <b>Turn off:</b> Turn the device off and call to manufacturer or authorized regional distributor. <b>Ignore:</b> You can proceed the next step but it is impossible to test items.
Moving parts Error !	
Storage disk Error !	
Temperature sensor Error !	 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. <b>Turn off:</b> Turn the device off and call to manufacturer or authorized regional distributor. <b>Ignore:</b> You can proceed the next step and test items.
Printer initializing Error !	 It is possible to test items but printing test result out is impossible. Please call to manufacturer or authorized regional distributor. <b>Turn off:</b> Turn the device off and call to manufacturer or authorized regional distributor. <b>Ignore:</b> You can proceed the next step and test items.
Incorrect Temperature !	 Please set environment temperature as 15 - 35°C. <b>Turn off:</b> Turn the device off and wait for environment temperature reaches to the operation temperature. <b>Ignore:</b> You can proceed the next step and test items.

	Self-testing items are as follows. 1. Driving part and printer (all in one thermal printer is adopted) 2. Optics 3. Disk 4. Temperature (environment temperature)
	Do not disassemble the ichroma™ II when some errors relevant to self-testing items are occurred.
	If you turn the device off during self-testing process, it can cause malfunction of the device.
	If the test results show "Not available" for driving part, optics or disk, call to manufacturer or authorized regional distributor. If temperature is out of range of operation temperature(15 - 35°C), please set environment temperature as 15 - 35°C.

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

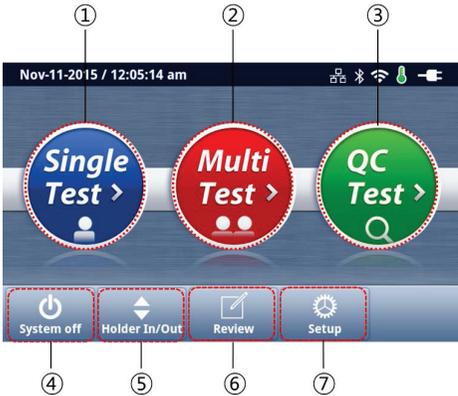


	The actual contents of the display could differ, depending on the specification and customer requirements.
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## 10. ichroma™ II operation

### 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

Nov-03-2015 / 8:10:45 am



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

### 10.2. System check

QC Test > System Check



System check is performed to confirm the ichroma™ II works properly.

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).



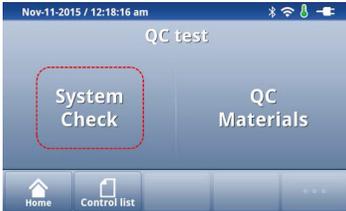
If there are foreign materials on the nitrocellulose membrane of a system check cartridge, this will cause erroneous system check result.

Do not load any test samples into the sample well of a system check cartridge.

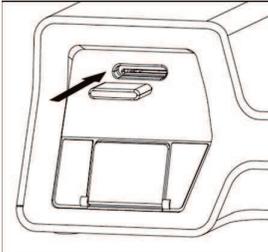
Do not touch the nitrocellulose membrane of a system check cartridge by hands.  
Do not damage the nitrocellulose membrane of a system check cartridge.

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

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

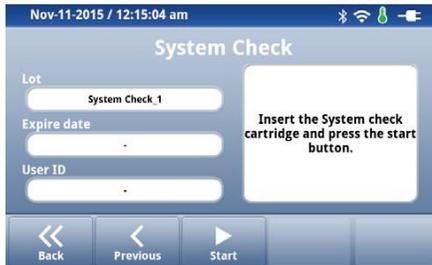
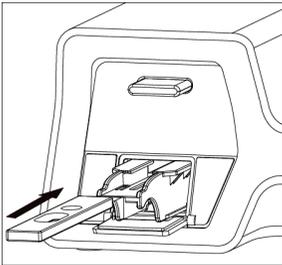


4) Insert a system check ID chip into the ID chip port and tap the "Next" button on the LCD.

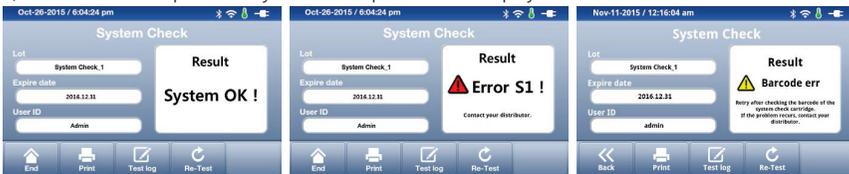


	<p>Wrong direction or excessive force during inserting ID chip will cause malfunctions of the ichroma™ II.</p>
	<p>You must insert system check ID chip to proceed system check process. Be careful loss of system check ID chip.</p> <p>If you lose system check ID chip, call Boditech Med Inc.'s Technical 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
<b>System OK !</b>	The system is normal.	There is no need to make counter measure. You can use the system normally.
<b>Error S1 !</b>	<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><b>Error S2 !</b></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><b>Barcode Error !</b></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><b>Mismatch Error !</b></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. (Optional)

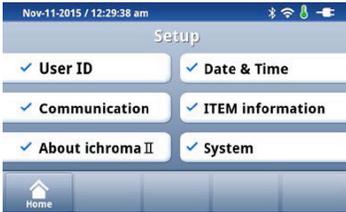
8) Please pack a system check cartridge and system check ID chip in the original pouch and seal it. Then store it at room temperature.

	<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.



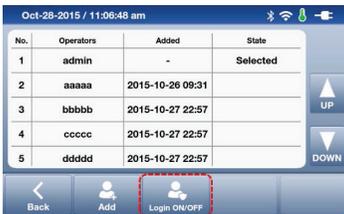
#### 10.3.1. User ID

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.

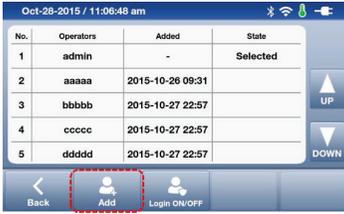


Item	Discription
Do you want to use Login function?	When you tap the "Ok" button, Login function is available.
Do you want to quit Login function?	When you tap the "OK" button, Login function is not available.

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



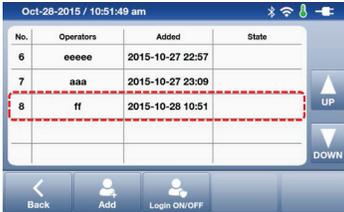
② Input new user ID, password and tap the "OK" button to complete registration of new user.



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.

### 3) Changing password비밀번호 변경

① Tap user ID what you want to change password.



② Tap "Change Password" button.



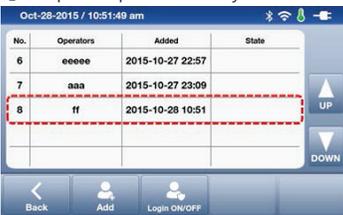
③ Input the current password, new password and new password for confirmation to change password. Then tap "OK" button.



#### 4) Select/change user

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

- ① Tap the operator what you want to change.



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



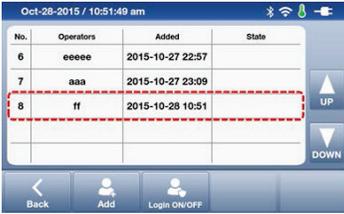
- ③ Input password and tap "OK" button to change user.



#### 5) Delete user

This function is for deletion the registered users.

- ① Tap a user what 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.



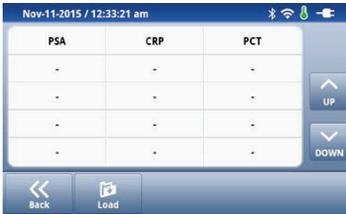
### 10.3.2. ITEM Information

Setup > ITEM information

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

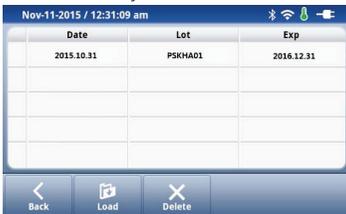
#### 1) ITEM registration

Insert ID chip what 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.

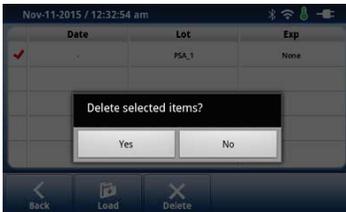


#### 2) ITEM management

- 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 what 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.



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.

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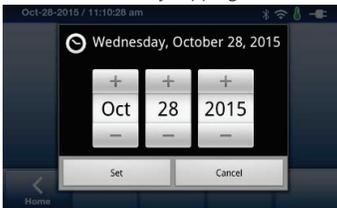
### 10.3.3. Date & Time

This function is for setting date and time.



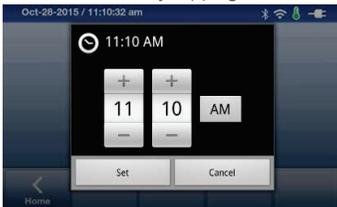
#### 1) Set date

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



#### 2) Set time

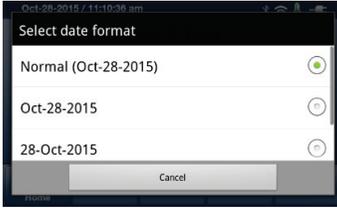
You can set time by tapping "+" or "-" button. To finish setting time, tap "Set" button.



#### 3) Time format

You can select 3 kinds of time 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>WIFI, Bluetooth, Ethernet functions will be prepared in near future. 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.
- 2) Alarm volume: You can set alarm volume by 4 steps.



	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.

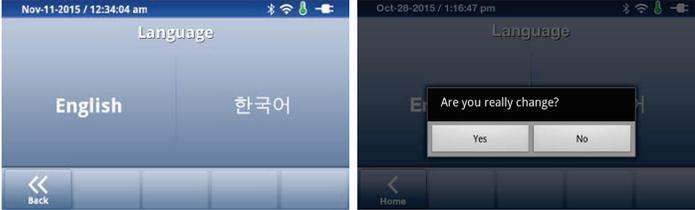


	This function is only available for built-in printer is selected.
--	---

### 10.3.6.4. Language

Setup > System > Language

To change language, tap language what 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.

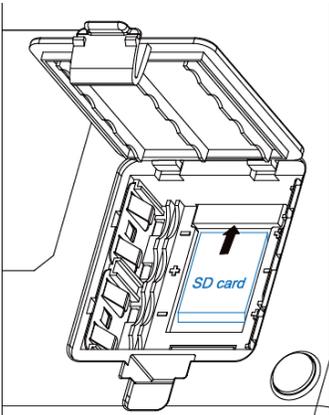


Do not turn ichroma™ II off during updating.  
Do not disconnect connection cable between ichroma™ II and PC during updating.  
Updating process will take few seconds or few minutes.

### 1) Application updating

Setup > System > Update > Application

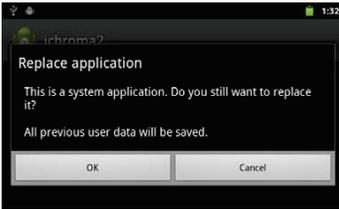
- ① Open the battery cover in the bottom of ichroma™ II.
- ② Insert a SD card which includes updating information into the SD card slot as following picture.



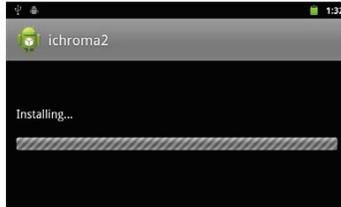
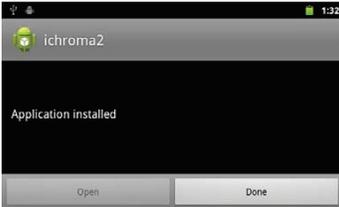
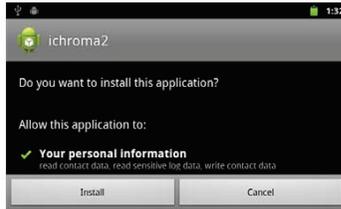
③ Tap "Application" in the "Update" screen.



④ Tap "OK" button.



⑤ Tap "Install" button.



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

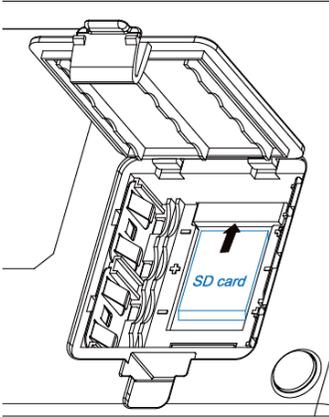
	If there is no SD card in the SD card slot or there is no updating information in a SD card, ichroma™ II will display a message for checking SD card.
--	---

## 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.

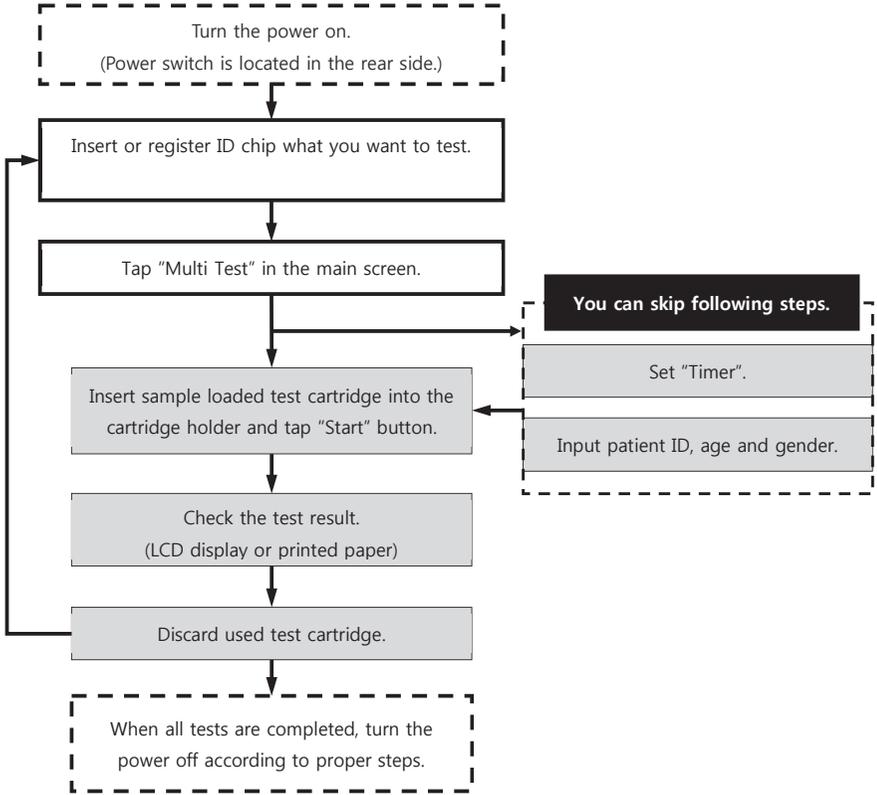
● **Firmware updating by using PC connection**



This function will be prepared in near future.

## 10.4. How to test

### 10.4.1. ichroma™ II Multi Test flowchart



### 10.4.2. Caution

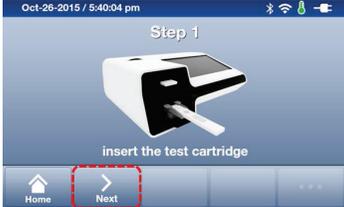
	<p>Test samples using in various test can be infectious. Therefore please use protective gloves, mask and so on during handling test samples.</p> <p>Used cartridges, pipette tips and samples should be discarded according to the relevant regional regulations with high temperature and high pressure sterile.</p>
 <b>Danger</b>	<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.

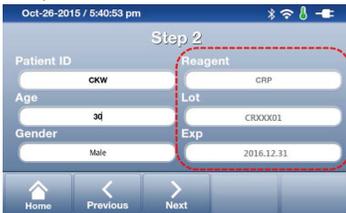
#### 10.4.3.1. Single Test

- 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, 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.
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### 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, age and gender. (You can skip this step.)
- 4) Insert sample loaded test cartridge into the cartridge holder and tap "Start" button immediately.



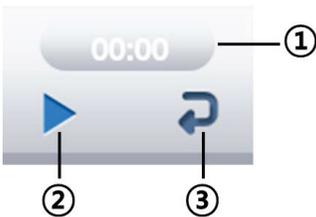
- 5) When tests are completed, names of items and test results are displayed and saved automatically.
- 6) You can delete displayed test result by selecting and tapping "Delete" button. And you can print test results what you want to.



7) Please discard used test cartridges.

● **How to set timer**

ichroma™ II provides "Multi Timer" function.



No.	명칭	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). <div style="text-align: center;"> </div>

		<p>To confirm setting timer, tap "Save" button. 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". 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. Before run test, please refer to relevant package insert for each test. 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. 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. If you do not want to use internal timer, you can skip this setting. You can skip inputting patient ID, age and gender. You can input patient ID by using barcode scanner. (Refer to clause 11.2.) 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.

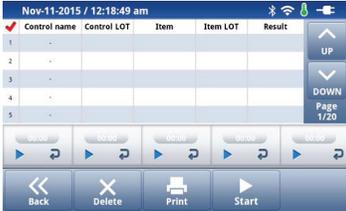
### 10.4.4.2. QC material test

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.

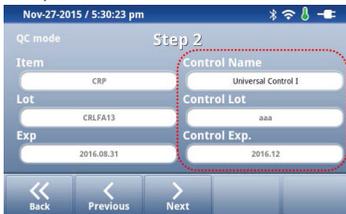
2) Open a cartridge pouch and insert a test cartridge into the cartridge holder and tap “Next” button.



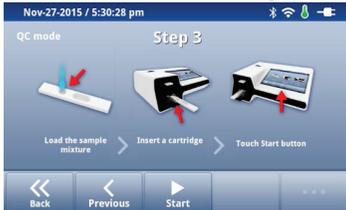
3) Check whether test item, LOT number and expiration date match the contents of screen. (Sometimes LOT number and expiration date may not be displayed according to LOT number of ichroma™ Item.)

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.