Confiscope F40

Revision No **(2022-03)**

User Manual

CE IVD

GenBody Inc.
CHANGE AND INNOVATION

CE

Manufacturer.

Date of manufacture:
To indicate the date of manufacture for this analyzer.

Serial number for this analyzer.

Consult instructions for use.

Caution, consult accompanying documents.

Do not use
if package is damaged

Be careful as there is a risk of infection if liquid is spilled inside the instrument.
Be careful as there is a biological cross-infection.

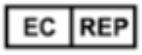
Symbol for "KEEP DRY".

To indicate that the product is fragile and you need to handle it with care.

Crossed out wheeled bin:
To discard it separately from other household waste.

Direct current

In vitro diagnostic
medical device



Authorized representative in the European Community

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1. Warnings and Precaution for Safety

1.1 Warnings and Precaution for Safety

1.1.1 For safe use of the instrument please be sure to read the User Manual thoroughly.

1.1.2 This user manual only contains exterior cleaning method and does not contain information about calibration, repairing or maintenance. In the event of a problem with the instrument, please contact your Dealer or GenBody Inc. for service.

1.1.3 Do not disassemble, repair or modify the instrument.

1.1.4 GenBody Inc. shall not be liable for any malfunction or damage to the product caused by improper operation not covered in this manual.

1.2 Precautions for Installation the Product

1.2.1 Do not install in an unsafe place(Indoor use).

1.2.2 Do not install the instrument near flammable materials or contaminated areas.

1.2.3 Do not install the instrument near moist or direct sunlight, near heating appliances, or near magnets

1.2.3 Use the AC-DC adapter provided by GenBody Inc.

1.2.4 Connect the power cord to a grounded outlet. Ungrounded outlets may cause damage to equipment or electrical shock

1.2.5 Install the location of the outlet in an easily accessible location. In the event of an issue, disconnect the plug to completely disconnect the power.

1.2.6 When moving the instrument, do not drop or shock the instrument.

1.3 Precautions before Use

1.3.1 This instrument is for In Vitro Diagnostics Only.

1.3.2 This instrument should be used only for analysis purposes of GenBody Inc. diagnostic kits.

1.3.3 This instrument should be used by medical professionals such as doctors and medical experimental scientists.

1.3.4 Read this manual and the kit manual thoroughly before using it.

1.3.5 Check the instrument regularly for damage or contaminants.

1.3.6 Use in a well-ventilated and dry place.

1.3.7 Ensure that the battery is sufficient before using it. If not, charge it in advance before using it.

1.4 Precautions during Use

1.4.1 Do not shock or move during analysis.

1.4.2 When putting the test cartridge, place it flat into the tray and then close the tray.

1.4.3 Touch the button analysis after the tray is closed.

1.4.4 Do not press the touch screen too hard or operate with wet hands.

1.4.5 It is recommended to use Shield LAN Cable.

1.5 Precautions for Storing and Managing the System after Use

1.5.1 Used cartridges should be treated in accordance with the Medical Waste Disposal Act.

1.5.2 Do not store the instrument in a place affected by temperature, humidity, or wind and so on.

1.5.3 Store the instrument on a flat surface and avoid shock or vibration.

1.5.4 Do not place any objects on the touch screen.

1.5.5 Operation Temperature at -10℃ ~ +50℃, <80% RH

1.5.6 Storage Temperature at -10℃ ~ +40℃, <80% RH

2. Product Introduction

2.1 Intended Use

This product is intended to be used for in vitro diagnostic medical instrument for human body specimen and the response level is analyzed numerically and the qualitative and quantitative data will be calculated.

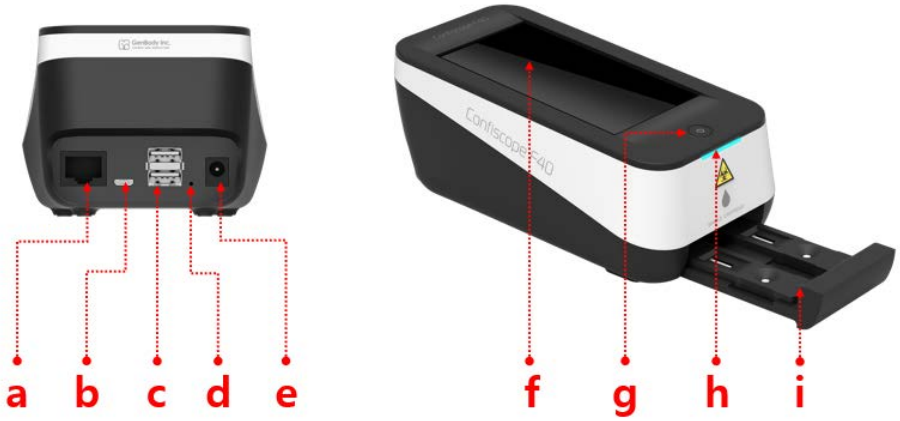
2.2 Principle of Analysis

Insert the sample and buffer solution into the cartridge and then open the tray and insert the cartridge into the instrument and press the start button. During the reaction time the instrument will be running the test and the optical module inside the instrument will acquire a reactive image area of the cassette. The color signal generated in the reaction area, including the test line, are converted to digital signal through various image processing and mathematical calculations. The converted digital signal will be displayed on the screen so that the user can judge or numerically confirmed the result.

2.3 Product Components

Confiscope F40 | Power Cord | AC/DC Adaptor | USB Memory (Cruzer Blade 16GB) | Quick Manual

2.4 Parts Description



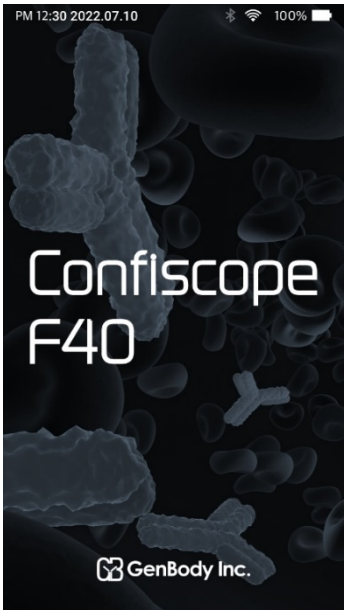
a. Ethernet port (RJ45)
b. USB port (C-type)
c. USB ports (2.0 A-type 2EA)
d. Reset switch
e. Power charging port
f. LCD display (touch screen)
g. Power button
h. Indicator LED
i. Test instrument tray

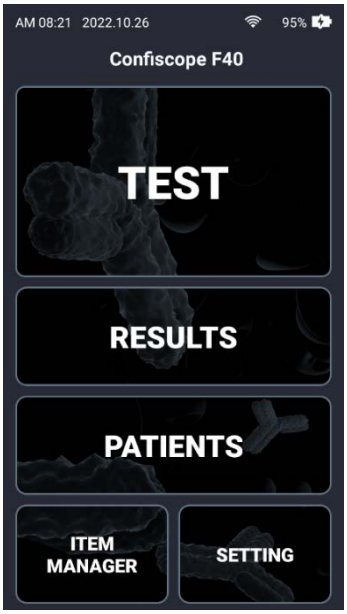
3. Installation and Start

3.1 Powering on the system

Press the power button on the lower front of the instrudment and then the instrument will illuminate red LED indicator and the instrument will start booting.

Test menu on the main screen is composed as follows:





Test Menu	Description
TEST	Initiate tests quickly, see results
RESULTS	Review and manage saved results
PATIENTS	Check patient list, enter and edit patient information Start the test after checking the patient's test history
ITEM MANAGER	Added new items and lot
SETTING	Enter user information Language setting Screen setting Date and time setting Test results backup and delete Reset Lot information Instrument information and update Network setting

3.2 Powering off the system

Press the power button for 2~3 seconds, press OK button if power off pop-up message appears on the screen to turn off the power completely.

If the instrument fails and the power off pop-up does not appear on the screen or the touch pad is not working, press and hold the power button for about 15 seconds or use the reset switch on the back of the instrument.

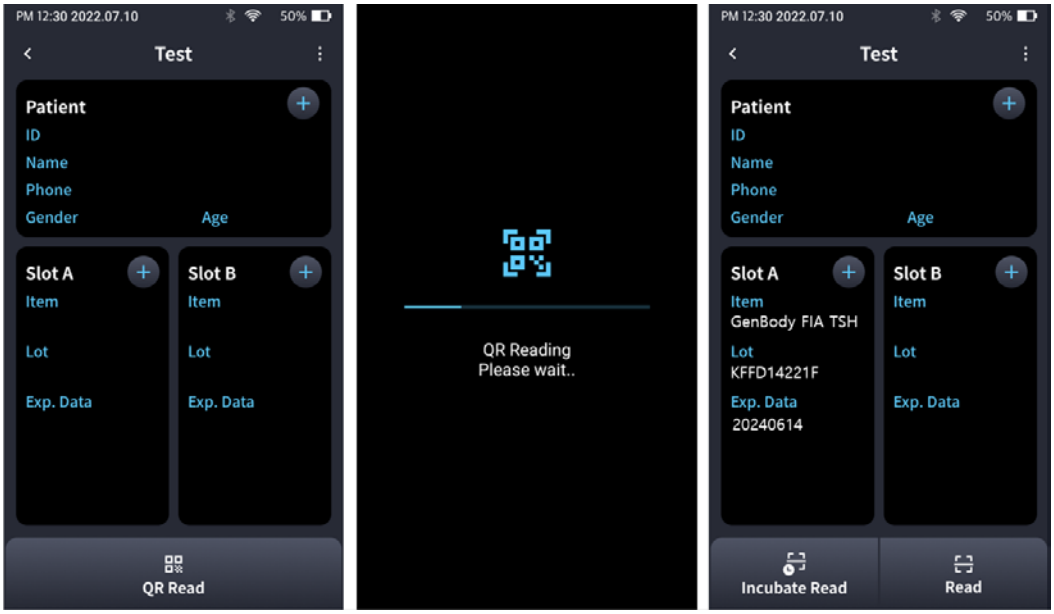
4. Test

4.1 Enter LOT Information(QR-Code)

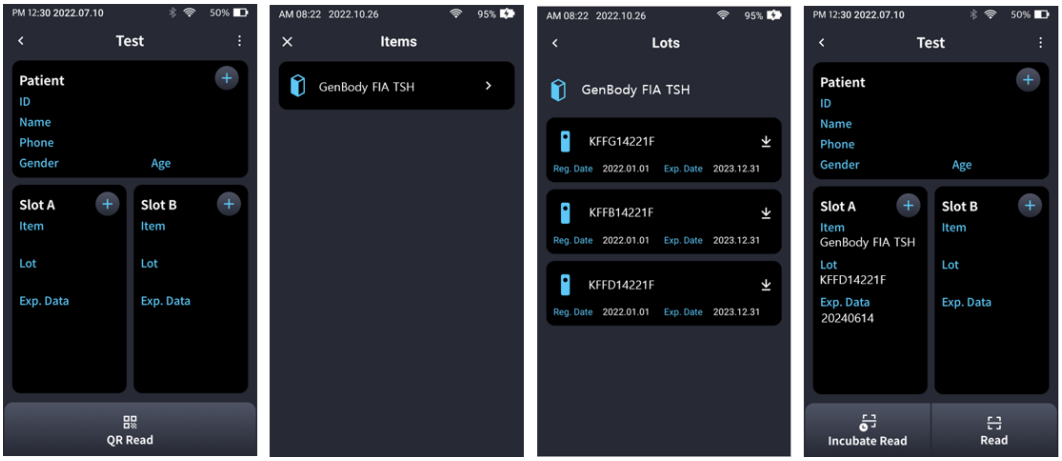
Touch the TEST button on the main screen to display the information screen required for testing.

Insert the unsampled cartridge into the tray and press the Read QR code button.

If the QR code is recognized normally, the item information is displayed in the center.



If the QR code cannot be recognized or a specific item needs to be selected, touch the select icon next to the item mark(+).



You can select only items, and LOTs stored on the instrument and proceed to the next step.

- If you need to enter patient information, register by touching the (+) button in the Patient input field.
- To apply new items, you can add through ITEM menu on main screen.
- To select an item through Select icon, change the manual item select function to enable

in the setting.

4.2 Incubation & Read

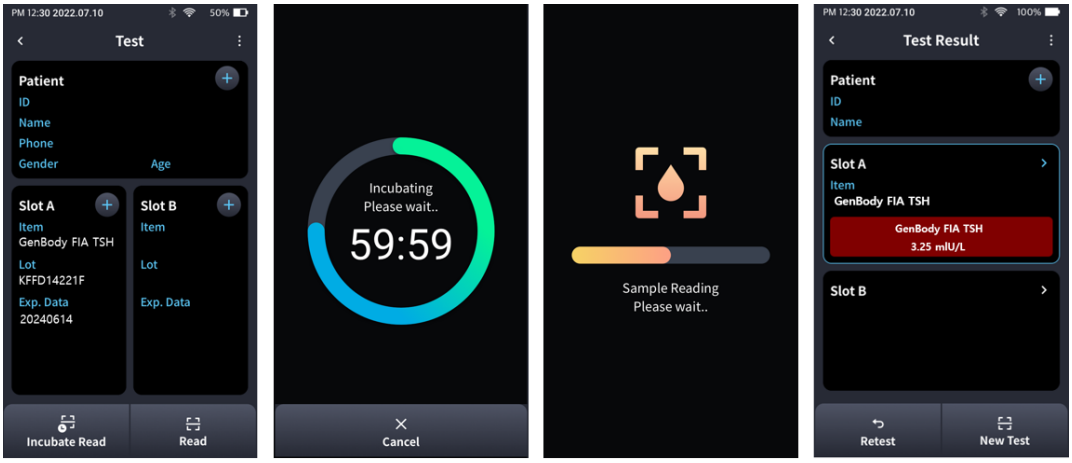
Insert the cartridge with the current QR information into the tray.

Inject the sample and touch the INCUBATE & READ button to start reading after the recommended incubation time for each item.

If you are inspecting two types of tests or items that use two cartridges, start the sample drip continuously because the incubation runs simultaneously.

If you want to cancel during Incubation, touch the Incubation & Read button one more time.

If a cassette different from the QR information currently displayed is inserted, the test will not proceed normally, so be sure to proceed with the Read QR code process.

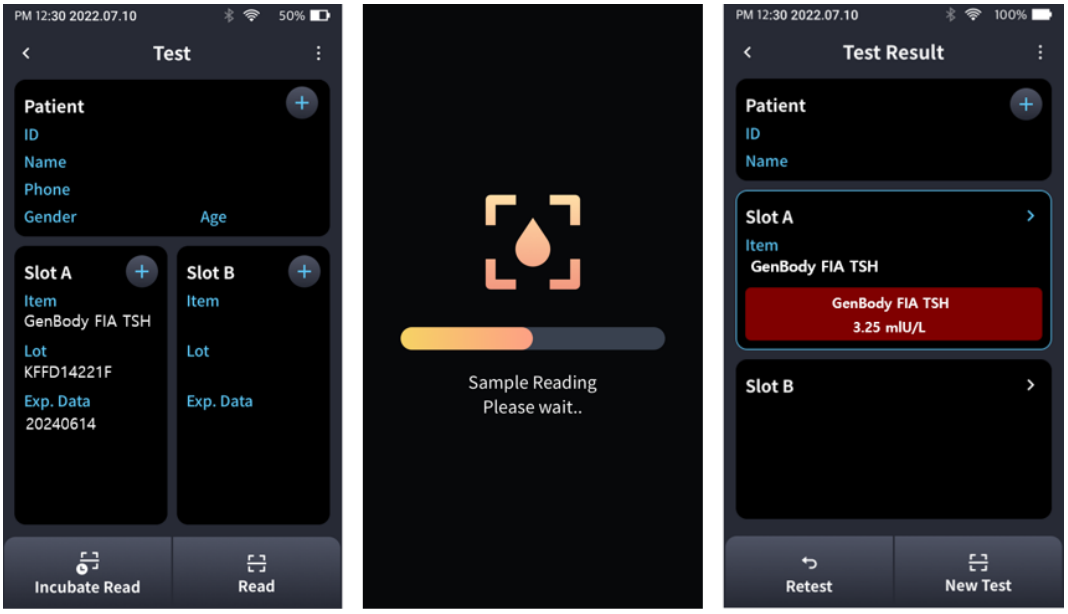


4.3 Read without Incubation

Prepare the cartridge with the current QR information.

Inject the sample, insert it with a stopwatch, etc. for an exact time, and insert it into the tray.

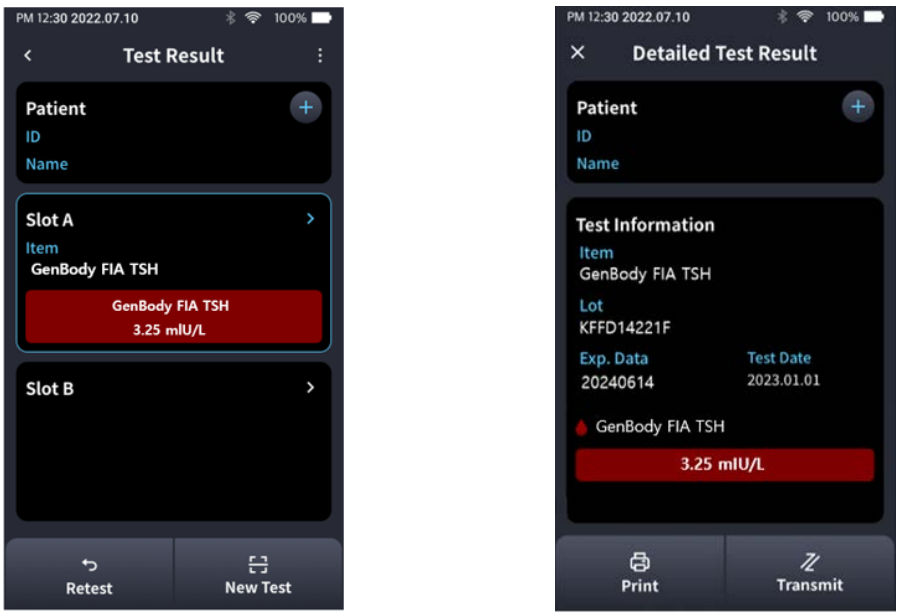
Touch the READ button to read the results immediately.



- In order to obtain accurate inspection results, be sure to observe the development (incubation) time specified in each item manual.

5. Test Result

Upon completion of test reading, the following results window will be appeared.
Please follow the instructions enclosed in each item kit box to read the test results.



Touch the screen of the results window for about 2 seconds to view the detailed results of the examination.

The examination results are automatically saved and the results can be sent to the server

by touching the TRANSMIT button at the bottom left of the screen. (option) Contact the manufacturer (GenBody Inc.) for server usage.

You can print the test results to a thermal printer. Printers can be purchased separately through the manufacturer. The printer supports Bluetooth transmission. With the printer connected normally, use the Print button at the bottom of the Detailed Result window.

- If the test result is Invalid, check the following:

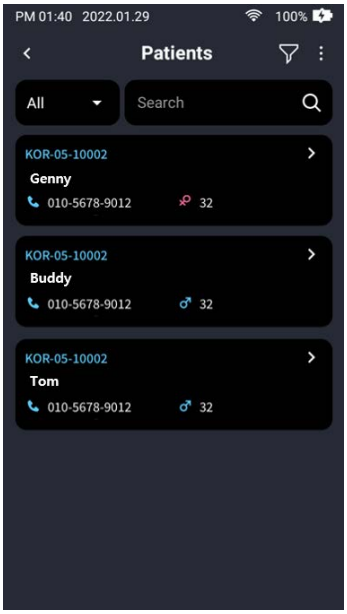
① If the control band is not colored due to contamination or damage to the product or sample: Discard the cartridge and re-examine with the new cartridge.
② If the QR code or selected item is incorrect: Press the Read QR code button to update the information on the newly installed cartridge and proceed with the re-examination.

Remove the inspected cartridges from the tray and discard them.

6. Test Patient

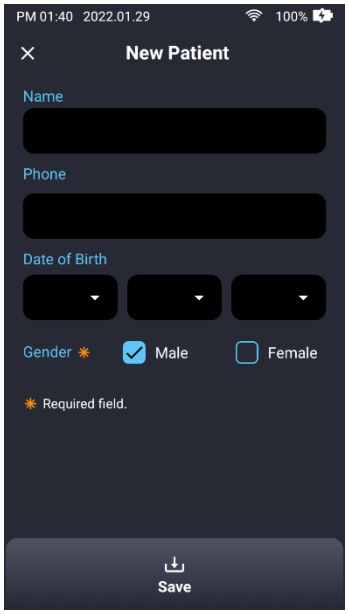
6.1 List of patients

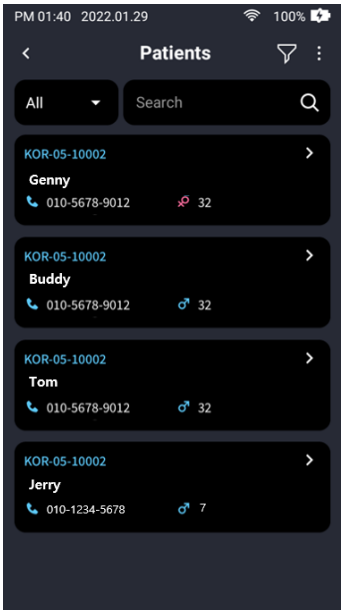
Touch Test Patient button on Main Menu.
You can search by patient ID, name, and phone number using the search bar at the top.



6.2 New patient registration

Touch the New button in the lower left corner of the Patient List screen.
After accurately entering the required items for each patient information, click the Save button to save.

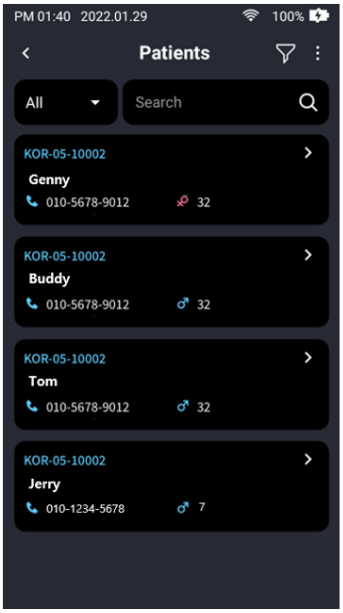


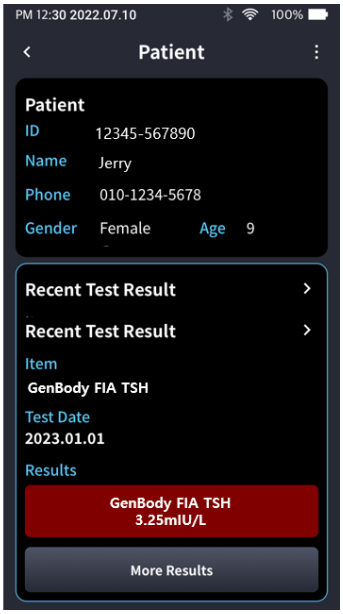


6.3 Checking patients testing record

On patient list screen, touch the patient you wish to search.

If you want to proceed with a new test after checking the existing test history, you can proceed with the additional test by pressing the Test button.





7. How to monitor test results

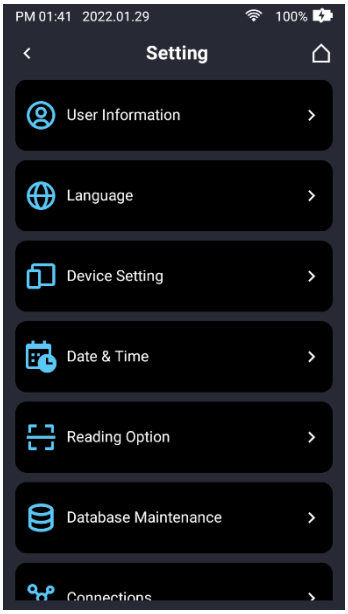
The RESULTS of the Main Menu allows you to manage the past test history.

If you have more than one examination history, it is sorted in the latest order and you can scroll through many results.

Touch each result for 1 to 2 seconds to switch to the Detailed Results window for detailed results.

8. Setting

If you touch the Setting button in the Main Menu, you can set the system environment as shown below.



9. Other Information

9.1 System Specification

System Specification	
Principle	Colorimetric assay Colloidal gold-based immunoassay
Operating System	Android 10.0

	Linux kernel: 4.19.111
Support Language	English,
USB Port	USB-A(2.0) 2 Port / Micro-USB 1 Port
Ethernet	10/100Mbps
WLAN 2.4 GHz	2412 ~ 2462 MHz
Bluetooth	2402 ~ 2480 MHz
Power Supply	Bluetooth : DC 7.2V Wi-Fi : DC 7.2V
Embedded Battery	Rechargeable Li-ion 7.2V 2600mAh
Display	5.0-inch color LCD (with Touch)
Light source	UV LED (365nm) 4ea : max 18.48W
Camera	4xCMOS (for measurement & reading QR)
Operating Condition	Temperature: -10 ~ 50°C Humidity: Under 80 % R.H
Shipping & Storage Condition	Temperature: -10 ~ 40°C Humidity: Under 80 % R.H
Altitude	up to 2000 m
Pollution degree	PD2
Dimension	17.5(L) x 9.8(W) x 7.7(H) Cm
Weight	Under 590g

9.2 System Characteristics

System Characteristics	
Operating Time	More than 250 continuous measurements
Charging Time	About 2 hours
Measurement	About 8 seconds (excluding incubation time)
One-time applicable test	Dual tests (automatic recognition)
Measurement mode	Incubate & read (or) No-Incubate & read
Data Capacity	Item capacity: Max 200 items Lot information capacity of each item: Max 100 Capacity of measurement data: Over 100K tests
Data Management	Transmission: Using Wi-Fi & Ethernet Backup: Download to USB memory stick (*.csv) - Data is still stored in device after backup Search: Patient and measurement data
Print	External Bluetooth printer (optional)
LIS/HIS	It can be implemented by requirement (HL7 protocol)

9.3 Product classification

- Confiscope F40 : Hunam
- Confiscope F40V : Animal
- Confiscope F40D : Metabolic syndrome

9.4 Product Service

GenBody Inc.

3-18, Eopseong 2-gil, Seobuk-gu, Cheonan, Chungcheongnam-do, Republic of Korea

TEL: +82-41-523-8993

Please contact your dealer for service.

[FCC]

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could avoid your authority to operate this equipment.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be collocated or operating in conjunction with any other antenna or transmitter unless authorized to do so by the FCC.

[ISED]

This device contains licence–exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licenceexempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be collocated or operating in conjunction with any other antenna or transmitter unless authorized to do so by the ISED Cet appareil est conforme aux limites d'exposition aux rayonnements de l'ISDE pour un environnement non contrôlé.

L'émetteur ne doit pas être colocalisé ni fonctionner conjointement avec à autre antenne ou autre émetteur, à moins d'y être autorise par l'ISDE.