Confiscope F20

Revision No(2019-05)

User Manual

FC CE IVD

GenBody Inc.
CHANGE AND INNOVATION

APPENDIX

EXPLANATION OF LABEL SYMBOLS

CE

FC

Manufacturer.

Symbol for "KEEP DRY".

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

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

Serial number for this analyzer.

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

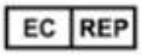
Consult instructions for use.

Direct current

Caution, consult accompanying documents.

In vitro diagnostic medical device

Do not use
if package is damaged



Authorized representative in the European Community

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.

APPENDIX

The FCC/IC Compliance Statement

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.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The IC Compliance Statement

This device contains licence-exempt transmitter(s)/receiver that comply with Innovation, Science and Economic Development Canada's licence-exempt 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.

Cet appareil contient des emetteurs / recepteurs exempts de licence qui sont conformes aux RSS exempts de licence d'Innovation, Sciences et Developpement economique Canada.

Son fonctionnement est soumis aux deux conditions suivantes:

(1) Cet appareil ne doit pas provoquer d'interferences.

(2) Cet appareil doit accepter toute interference, y compris les interferences qui peuvent provoquer un fonctionnement indesirable de l'appareil.

Confiscope F20 is used for human diagnosis.
Confiscope F20V is used for veterinary diagnosis.

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1. Warnings and Precaution for Safety

1.1 Warnings and Precaution for Safety

1.1.1 For safety purposes, please ensure to read user manual thoroughly before using this device.

1.1.2 In this user manual, no calibration of the product, repair or maintenance stated. In the event of technical issues, please contact the authorized dealer or GenBody Inc. for service.

1.1.3 Do not disassemble, repair or modify the machine without any permission.

1.1.4 GenBody is not responsible for malfunctions and damage to the product caused by irregular operation that is not mentioned in this manual.

1.2 Precautions for Installation the Product

1.2.1 Do not install in an unsafe place.

1.2.2 Do not install near inflammable objects or contaminated places.

1.2.3 Do not install in areas where moisture is high or exposed to direct sunlight, near heaters or near magnetic objects.

1.2.3 Make sure to use provided AC-DC adapter.

1.2.4 Plug the power cable to the grounded power outlet. Plugging to the ungrounded power outlet may cause device failure as well as electric shock.

1.2.5 Install the outlet in an easily accessible location. In event of technical issues, please disconnect the plug completely to turn off the power.

1.2.6 Do not drop or shock the product when moving.

1.2.7 Be careful as there is a biological risk of cross-infection.

1.3 Precautions before Use

1.3.1 This analyzer is designated to be used for in vitro diagnosis only.

1.3.2 Read this user manual and reagents manual thoroughly before use.

1.3.3 Please ensure to check the machine regularly for damage or contamination.

1.3.4 Use in well-ventilated and dry areas.

1.3.5 Check the battery percentage before use. If it's insufficient, please charge the battery in advance.

1.4 Precautions during Use

1.4.1 Do not shock or move when analyzing.

1.4.2 Keep the machine level during analysis.

1.4.3 When installing the testing cartridge into the tray, make sure the cartridge is fully placed on the surface of the tray.

1.4.4 Press the operating button after the tray is completely closed.

1.4.5 Do not operate the machine with too much force or with wet hands.

1.5 Precautions for Storing and Managing the System after Use

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

1.5.2 Do not store the machine in areas where can be affected by temperature, humidity, wind and so on.

1.5.3 Store the product on a flat surface and do not allow it to be affected by impact or vibration.

1.5.4 Usage Temperature: +10℃ ~ +30℃, <70% RH

1.5.5 Storage Temperature: -10℃ ~ +40℃, <70% RH

2. Product Introduction

2.1 Intended Use

This instrument is an in vitro diagnostic medical device for human body. The collected sample is reacted with the reagent and the reaction level is numerically analyzed and the qualitative data is calculated.

2.2 Principle of Analysis

Insert the sample and buffer solution to be tested into the cartridge, open the tray, insert it into the instrument, and press the start button. The instrument is testing during the reaction time and the optical module inside the analyzer acquires a reactive area image of the cartridge. Fluorescence signals generated in the reaction zone, including test lines, are converted to digital signals through several image processing and mathematical calculations. The converted digital signal is displayed to the user so that it can be judged or numerically confirmed.

2.3 Product Components

2.4 Parts Description

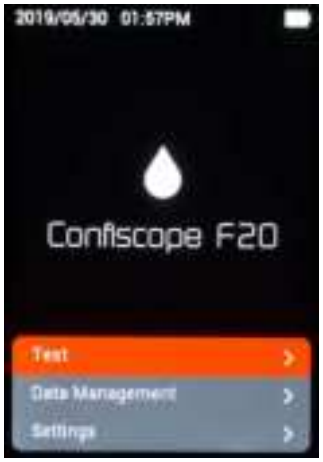
a. RFID Sensor
b. LCD display
c. Down Button
d. Up Button
e. Select / Back Button
f. Tray
g. Power Button
h. USB ports (2.0 A-type) ; use for administrator
i. Battery charging port (micro-USB)
j. Forced power off switch

3. Installation and Start

3.1 Powering on the system

Press the power button on the right side of the machine for 2-3 seconds to boot.

The screen during booting and the main screen after completion are as follows:



The menu configuration of the machine is as follows:

Main Menu	1st Sub Menu	2nd Sub Menu
Test	RFID Tag	1. Select Item 2. Select Lot
Data Management	Test Records	
	USB Backup	
	Delete	
Settings	General Settings	Brightness
		Date & Time
		Key Sound
		Battery Alarm
		Incubation Time
		Equipment Reset
		Sleep Timer
	Calibration Setup	
	Device & Update	

3.2 Powering off the system

Press the power button for 2-3 seconds to turn off.

If the power button fails due to an error in the machine, you can turn off the device by pressing Forced Power off switch located on the right side of the device.

4. Test

4.1 Start the Test

Use the button at the bottom of the screen to select Test in the main menu.

If user place the RFID tag of the kit you want to test or inspect close to the rear of the device as shown below, the information will be read and entered into the machine.

- Products without RFID tags cannot be analyzed.
- Please ensure that the RFID tag is attached to the product to be tested.
- If RFID tags attached to the product are damaged, accurate recognition may not be possible.

Once RFID is recognized normally, it automatically navigates to the test window and verify the item information you want to check is correct.

If an item with a history of previous examination has the same lot, you can select the item and Lot directly without scanning the RFID tag.

- Press the select button on the RFID Tags screen.

- At the Select Item screen, navigate to the item to be inspected by using the upper and lower buttons and select it.

- When the Select Lot screen appears, you can replace RFID tags by moving to the same lot as the kit you want to inspect.

Latest Lot information shows at the top of the display. It can save up to 20 items and old items will be deleted automatically.

4.2 Reading

Once the item information that needs to be inspected is matched on the test screen, remove the cartridge from the sealed aluminum pouch. The tray will be opened once pressed inwards and then insert the cartridge. The analysis starts automatically when the prepared samples and reagents are injected into the cartridge and the tray is closed immediately.


- Press the analysis button if analysis does not start even when the tray is closed

- Do not open the tray until the results are appeared. If you like to cancel the test, press the select button long.

- Please be careful not to overflow reagent when filling the cartridge outside the tray.

4.3 Test Result

When the analysis is complete, the result screen appears with a beep sound as shown below.

If the test result is invalid, check the following:

① The cartridge used in the Confiscope F20 is for one time use only. And if reused, the result will appear as Invalid. Occasionally a positive/negative result may appear on the reused strip, however, this is not a valid result.

② If the control band is not illuminated due to contamination, damage to the product or sample, Invalid status may appear and discard the cartridge and re-examine it with a new cartridge.

③ If the band in the cartridge is not illuminated due to the use of the wrong sample, Invalid status may appear and refer to the cartridge's manual for re-examination.

The test results are automatically saved and can be printed if an external printer is connected.

- External printer is not included in the product. Please contact the manufacturer.

Remove the inspected cartridge from the tray and discard it in accordance with the medical waste disposal act.

5. Data Management

Select Data Management from the main menu to view and manage past examination results.

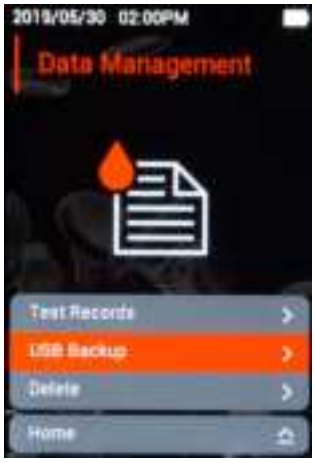
5.1 Test Records

If you have more than one exam history, it is arranged in the latest order and many results can be viewed using the up/down buttons.

Selecting each result using the up/down buttons will switch to the Detailed Results window to view and print or delete the detailed results.

5.2 USB Backup

Up to 1,000 results are automatically saved and can affect the machine if memory is exceeded. A warning screen appears when storage is short, however, consistent backups and deletions are highly recommended.



Once user has selected Data Management, USB Backup from the main menu, the following screen appears: Connect the USB memory to the right side of the machine, navigate to the time period for which user want to back up, and press the Select button.

- Make sure you have enough USB memory space and do not disconnect it during backup.

- Some manufacturers or models' USB memory cannot be recognized. Please ensure that the backup is successfully done before you delete the data.

- USB is recommended in FAT32 format.
- Backed up files are saved as text files.
- Data backup using USB memory should be performed by the administrator.

5.3 Delete

Deleting Data is to free up the storage space. Once you have selected Data Management, delete from the main menu, the following screen appears: navigate to the time period you want to delete and press the Select button. Deleted data cannot be retrieved. Please check before you proceed.

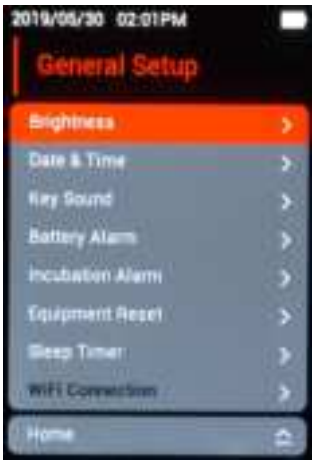
6. Settings

User can set preferences and system check and updates. If you select Settings on the main menu, a screen for selecting General Setup, Calibration Setup, Device & Update will appear.

Settings	Description
General Setup	Brightness Date & Time Key Sound Battery Alarm Incubation Alarm Equipment Reset Sleep Timer
Calibration Setup	Calibration Setup
Device & Update	Serial Number of device and version check Update

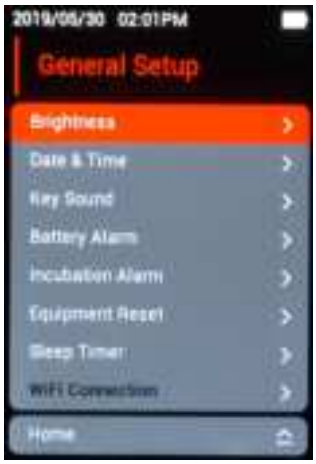
6.1 General Setup

User can change and apply the settings by entering General Setup.



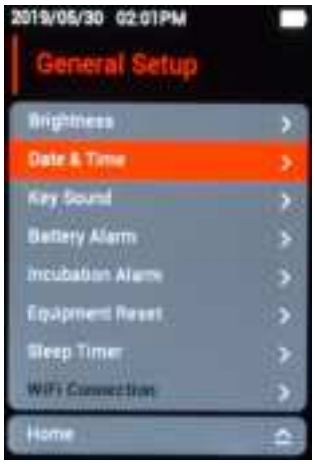
6.1.1 Brightness

User can adjust or change the brightness of the screen by Up / Down button
Use the Up / Down button or press the Deselect button to adjust the screen. Press and hold the Select button to return to the General Settings screen.



6.1.2 Date & Time

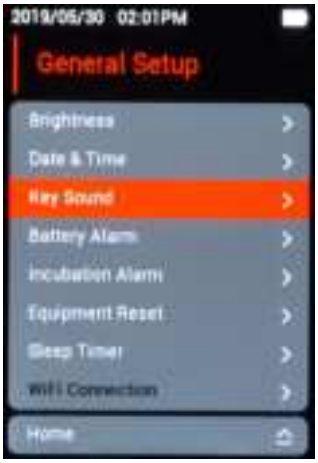
Press the Select button to move to the section where you want to change. Press the Up / Down button to adjust the current date and time and press the Select button to temporarily save the changes. Press and hold the select button to return to the General Setup screen and the saved date & time will be applied.



- If the test is performed with unadjusted date and time, it will be reflected to test result and test record. Please do check the current time and date periodically because the results and lot history management may fail due to the wrong implementation of time and date.

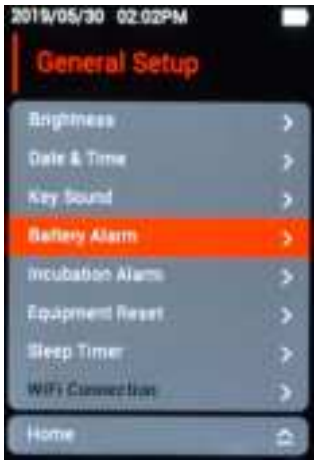
6.1.3 Key Sound

Use the up/down buttons to enter to Key Sound setting and press the select button to adjust the loudness of button effect sound. Press and hold the Select button to return to the General Settings screen.



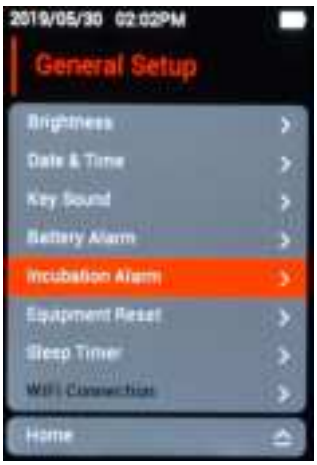
6.1.4 Battery Alarm

By entering to Battery Alarm setting, user can adjust the strength of the low battery sounds effect by using the up/down buttons. Press and hold the Select button to return to the General Settings screen.



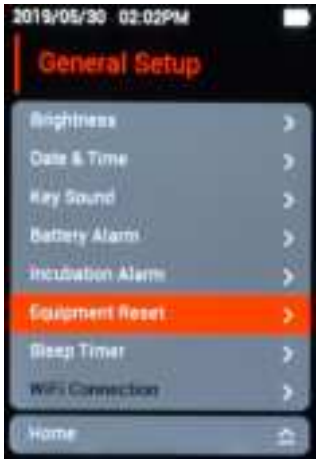
6.1.5 Incubation Alarm

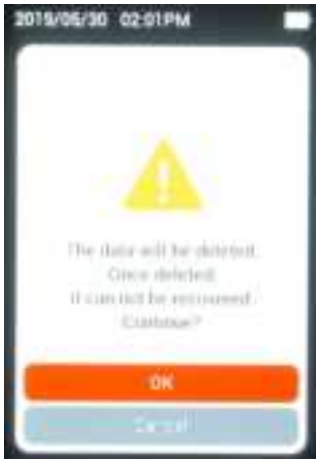
By entering the Incubation Alarm setting, user can adjust the loudness of incubation complete sound effect by pressing the up/down buttons. Press and hold the Select button to return to the General Settings screen.



6.1.6 Equipment Reset

If the user resets the instrument, all test records and Lot information will be initialized. Be sure to back up the data's and proceed the reset with the kit's RFID tag secured.





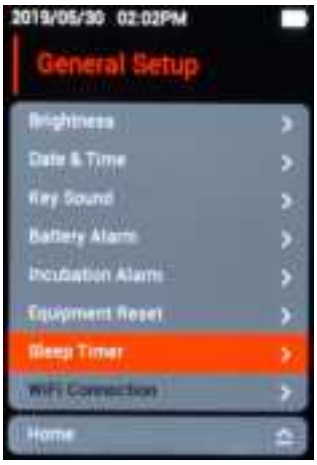
- The data cannot restore once the initialization has been made.

- Press and hold the power button for 2 to 3 seconds to turn the unit back on after initializing is complete.

6.1.7 Sleep Timer

User can adjust or disable the device's sleep mode entry time by pressing the up/down buttons by entering Sleep Timer setting. Press and hold the Select

button to return to the General Settings screen.



Press and hold the power button for 2 to 3 seconds to turn the unit back on from the sleep mode.

6.2 Device & Update

User can check the system information of the device and proceed the update. If you want to update to the latest version, download the file from PC and copy the downloaded file to the USB drive and connect the USB to the USB port located on the side of the device. Press the Update button and press OK for an update.

The update starts with a beep sound, and when the update is it is completed, it will beep again and power off. After rebooting, you can check for updated versions on the Device & Update screen.

- Update will not proceed if the battery power is low. Please connect the charger.

- Do not turn off the power or remove the USB drive during an update.

- Contact your manufacturer for the latest version of Firmware.

7. Cleaning

   Calibration and maintenance of equipment other than cleaning is only carried out by the manufacturer. Use a soft cloth and 70% ethanol to remove contaminants from the machine surface and tray except for LCD. In order to clean LCD, please use a lens cleaner.

- Make sure to turn off the power and use the liquid to prevent the solution from infiltrating into the inside.

- Validation of the device's performance is possible by the user, but calibration is only possible by the manufacturer and service center.

8. Trouble shooting

Problem	Suggested Solution
In the event of no power	1. If the battery is completely discharged, charge for about 30 minutes and try again. 2. If the circuit is broken by the unprovided adapters, please contact the manufacturer for assistance. ** This machine does not support fast charging function.
In the event of frozen screen while in use	1. Shut off the power and reboot using Forced Power off switch on the side of the machine. 2. Please contact the manufacturer when the power neither cannot be shut off nor reboot the machine.
In the event of RFID tags reading failure.	1. Check if RFID tags attached to item boxes are broken. 2. Please contact the manufacturer if it recurs even after reboot.
In the event of Invalid	1. Check if the test was carried out correctly according to

result	the user manual. 2. Ensure that the injected sample solution is well deployed. 3. Select an item that has already been entered to check if the item matches Lot information during analysis.
In the event of USB drive reading failure	1. USB drive only supports FAT 32 format. Low-quality USB drive can be difficult to detect or may damage the machine.

9. Other Information

9.1 System Specification

System Specification	
Principle	Analysis immunofluorescence assay (fluorescence based rapid test)
Operating System	Embedded Firmware (non-OS)
Support Language	English
USB Port	USB-A(2.0) 1 Port / Micro-USB 1 Port
RFID Module	13.558Mhz, for Reading Lot Information * Tested temperature is from -20℃ to 50℃
Adaptor In/Out, Rating	Input : 100~240V, ~50/60Hz, 0.5A Max / Output : 5V/2.0A Rating : 5V/0.5A
Embedded Battery	Rechargeable Li-ion 5200mAh
Display	3.5 inch color LCD (without Touch)
Light source	UV LED(365nm)
Camera Module	2M CMOS (for Measurement)
Optic Filter	Band Pass Filter (λc : 615nm, over 90% Transmission)
Printer	External Portable Thermal Printer (with Battery)
Operating Condition	Temperature: 10 ~ 30°C Humidity: Max. 70% non condensing
Shipping and storage Condition	Temperature: -10 ~ 40°C Humidity: Max. 70% non condensing
Dimension	17.2(L) x 7.3(W) x 5.7(H) cm
Weight	Under 330g

9.2 System Characteristics

System Characteristics	
Operating Time	More than 500 continuous measurements when battery is fully charged.
Stand-by time (Power Off)	More than 30 days when battery is fully charged
Charging Time	About 7 hours when battery is fully discharged
Measurement Time	About 15 seconds
Measurement Mode	Only Incubation Mode - Qualitative analysis are available for 2 or 3 bands. - Incubation time is automatically set up by RFID Tag.
Item Quantity	Max 10
Lot Information Quantity of each item	Max 20 - When 20 lot information data are saved, 1st stored information is automatically deleted
Capacity of measurement data	Max 1000 test - When 950 tests are saved, backup warning is displayed.
Data Search	Search is only available through “Data Management Tool(PC)”
Data Transmission	Data transmission is available through “Data Management Tool(PC)”
Data Backup	Measurement data is not deleted even after backup. - Additional Backup SW function is supported by "Data Management Tool (PC)".
Print	Print is available by "Data Management Tool (PC)” or External Thermal Printer. It cannot be printed directly from the device.
LIS/HIS	It can be implemented by requirement (HL7 protocol) - It is supported by "Data Management Tool (PC)” only.

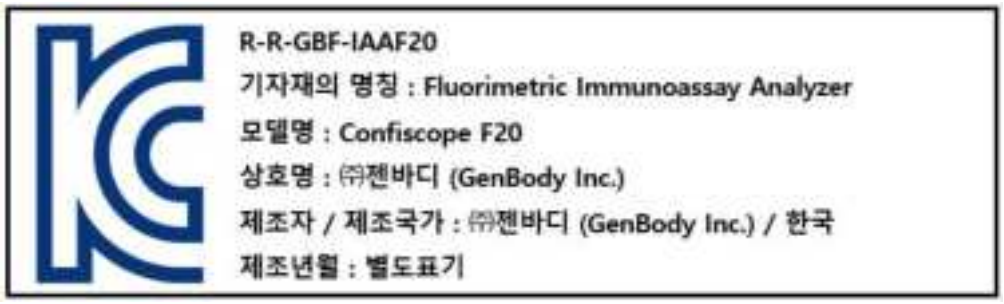
10.3 Product Service

GenBody Inc.

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

TEL: +82-41-523-8993

Please contact your dealer for service.



Confiscope F20

REF FQGBH201

GenBody Inc.
CHANGE AND INNOVATION

Manufactured and sold by-
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31077, Republic of Korea
Tel.82-41-523-8990, (International) 82-41-523-8993, Fax.82-41-523-8991 http://www.genbody.co.kr

EC REP MT Promedt Consulting GmbH Altenhofstr. 80
D-66386 St.Ingbert, Germany, Tel +49 6894-5810 20