Real-time Gene Amplificator

Software User Manual

Model: isoQuarkF2
S/W : isoQuark

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CE IVD

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1. Product description

IsoQuark SW from **RevoSketch Inc.** controls all the functionality of the **real-time gene amplification device(isoQuarkF2)** and monitors PCR processes in real time

Working principle

- This product is a device that can check the amplification and accumulation of genes at isothermal temperatures in real-time. The body consists of a thermal block, an optical module, and a stage for moving the optical module. The heat block amplifies the gene while maintaining the sample at a specific temperature, and the optical module excites and detects the fluorescent material associated with the gene.
- This product consists of a main body, software that controls the main body to show changes in the amount of fluorescence in real-time, a USB cable, and an adapter.

1.1. *Main features*

Real-time gene amplification Device for Isothermal PCR
isoQuark S/W can monitor the PCR amplification process of isoQuarkF2 equipment in real-time.

User-friendly interface
With one start button, the instrument starts up and can see the final result. You can select and view the desired graph with a simple input while the equipment is running.

2. Software installation

2.1.   Installation SW Environment

– Recommended specifications

Operation System	Android 10
CPU	Octa-core or higher
RAM(memory)	RAM 4GB or more
Storage	64GB Free Space
USB	2.0 High speed or more
Display	2560x1600

–Minimum specification

Operation System	Android 9.0 pie
CPU	Quad-core
RAM(memory)	RAM 2GB or more
Storage	32GB Free Space
USB	2.0 High Speed
Display	1280x800

2.2.   Installation method

The software can be downloaded from the website below.

Home page: www.revosketch.com

Installation file: isoQuark app_version number.apk

1) Save the installation file (**isoQuark app_version number.apk**) to the Internal Storage Download folder.
2) Proceed installation with the file (**isoQuark app_version number.apk**).
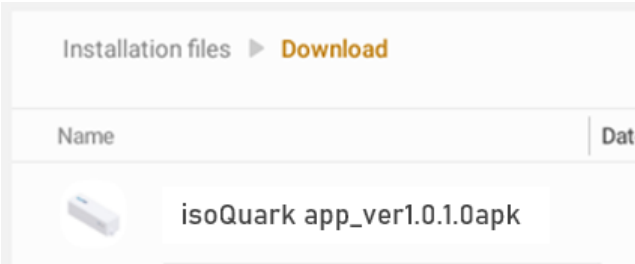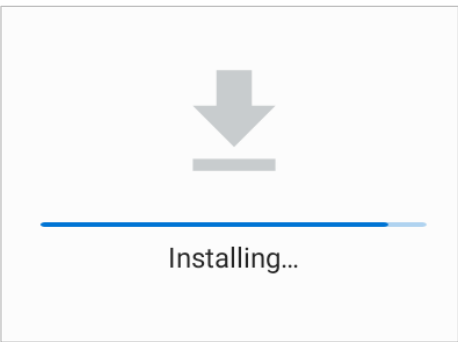
Figure 2.1.1 S/W Installation file
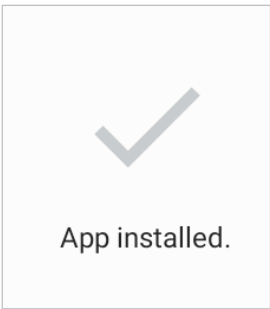

Figure 2.1.2 Installing S/W

Figure 2.1.3 Installation of S/W completed.

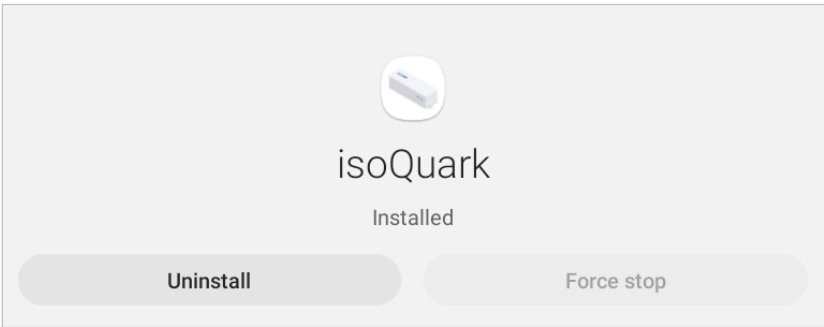3) If installation fails, delete the app and reinstall.

Figure 2.1.4 Delete S/W

3. How to run the software.

3.1. Run and Close the Software

1) Running the SW

(1) Run the isoQuark app
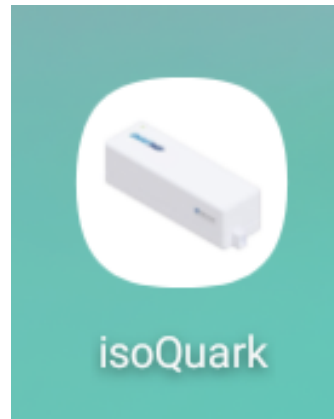

Figure 3.1.1 isoQuark Icon

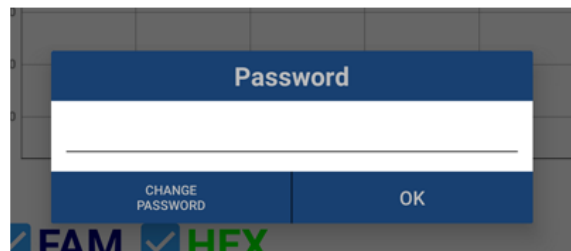(2) Input the initial password. A password is required every time when running SW. The initial password is set to "*admin*"

Figure 3.1.2 Password Input

(3) Change the initial password before using the device for the first time

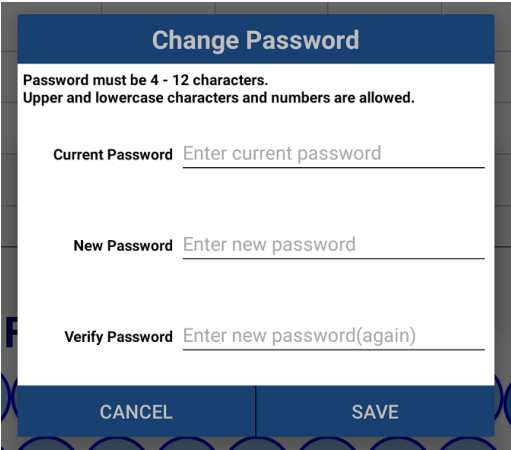   * SW re-installation will be required in case the password is lost

Figure 3.1.3 Password change

(4) After changing the password, click the "SAVE" button to save it. Be careful not to expose your password to outsiders.
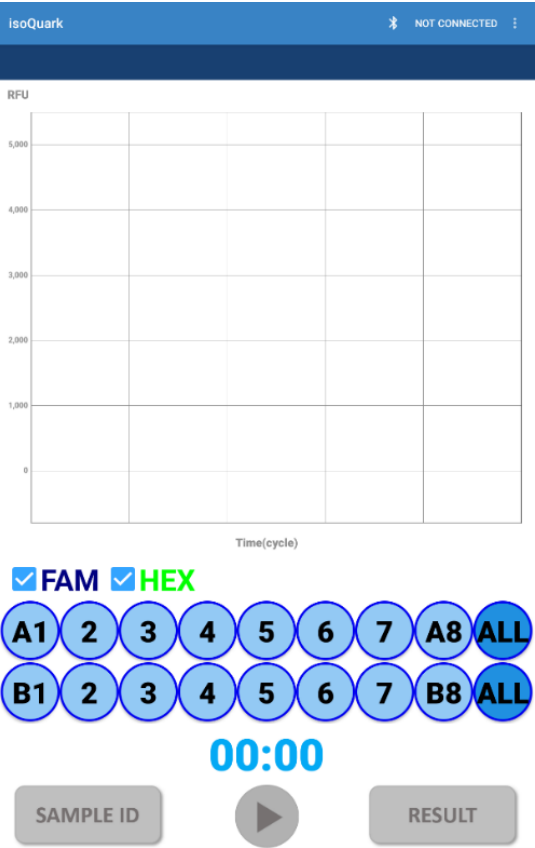
(5) Initial screen

Figure 3.1.4 Initial screen

2) Close a Software

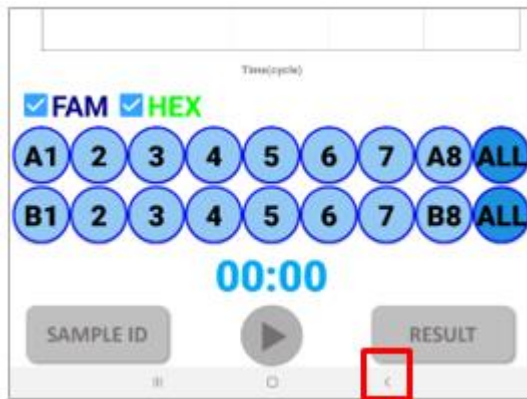Press the Back button [<] at the bottom of the screen to exit.

Figure 3.1.5 Exit button

3.2. *Connecting to the device*

isoQuark S/W can be connected to isoQuarkF2 via USB or Bluetooth

1) USB connection

(1) Connect USB cable to USB port at the back side of device. isoQuark SW automatically connects with the device and display connecting message at top side.

Figure 3.2.1 USB connection complete

(2) If it is not connected as "NOT CONNECTED," check the USB connection status and the isoQuark device's power, shut down the isoQuark S/W, and restart.
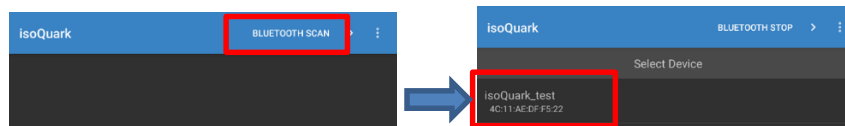

Figure 3.2.2 No USB connection

2) Bluetooth connection

(1) With the power turned on, touch the Bluetooth icon on the application screen.

Figure 3.2.3 Bluetooth icon

(2) Touch the BLUETOOTH SCAN button on the screen to search for isoQuark products. If the device is not found, power on isoQuark again and try to search.

Figure 3.2.4 Bluetooth Scan, Scan result

(3) Touch the searched isoQuark name to move to the main screen and complete the connection. Please check the CONNECTED message above the screen

Figure 3.2.5 Connection Check

3.3. *Home screen*

1) Screen Configuration

The home screen is the start screen when running the program, and equipment connection, real-time amplification graph. This screen shows the control of the equipment, the status of the equipment, etc.
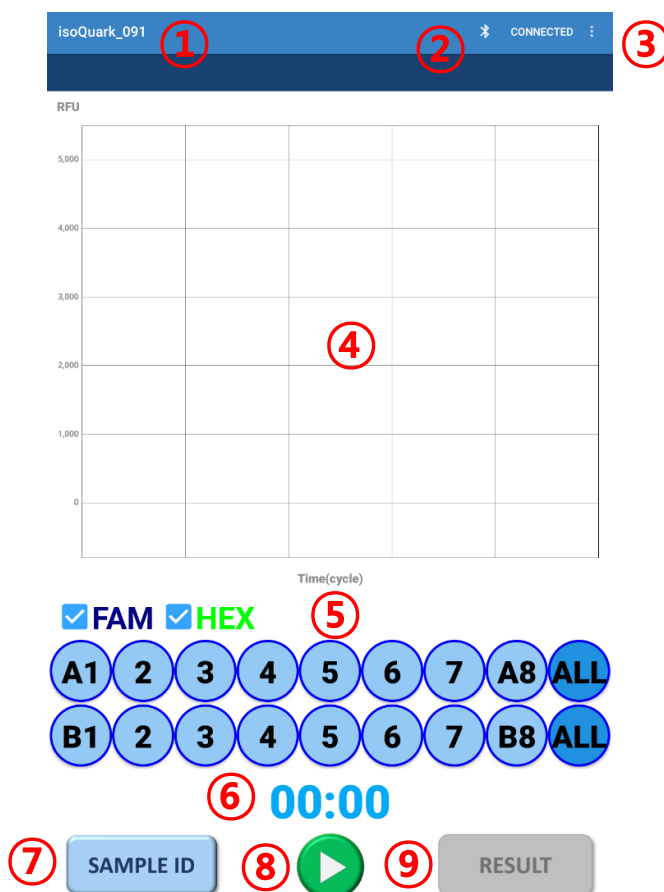

Figure 3.3.1 Home screen configuration

- ① Connected equipment name
- ② Status of connection
- ③ Menu - save, load, device name change, temperature change, version check
- ④ Real-time PCR amplification graph
- ⑤ Graph selection button for 16 wells (A1~A8, B1~B8) channel 1(FAM), 2 (HEX)
- ⑥ Display the elapsed time.
- ⑦ It opens a window to assign the name to 16 wells.
- ⑧ PCR start/stop button
- ⑨ PCR result screen

2) Real time PCR Graph

(1) Well (A1~A8, B1~B8) 16 of channel 1(FAM) and channel 2(HEX) can be selected and viewed.

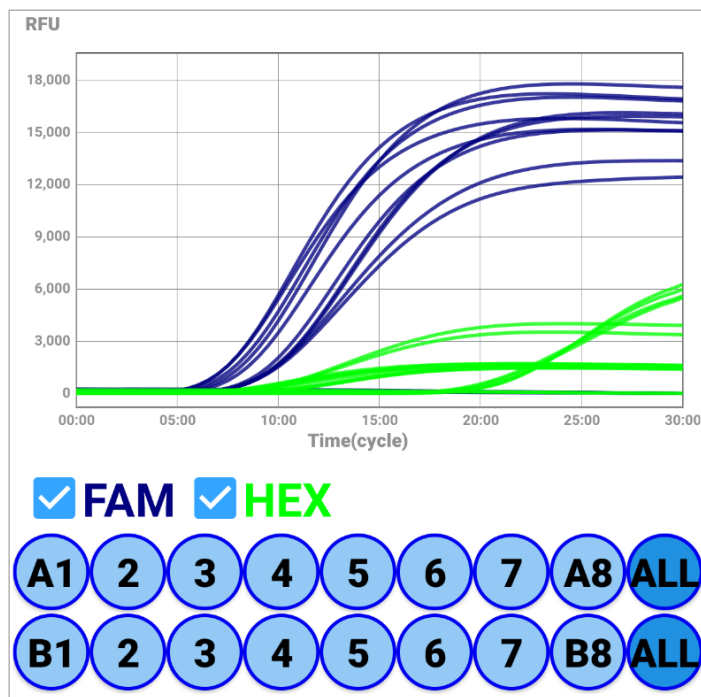(2) X axis : Elapsed time, Y axis : RFU(Reference Fluorescence Unit)

Figure 3.3.2 Real-time amplification graph

3.4. *Start and Stop PCR*

1) Insert the PCR tube into the device and click the Start button at the bottom of the screen to start the PCR.

Figure 3.4.1 Start bottom

2) Click the RESEARCH MODE button in Select the assay and set the test time. The default time is 30 minutes.
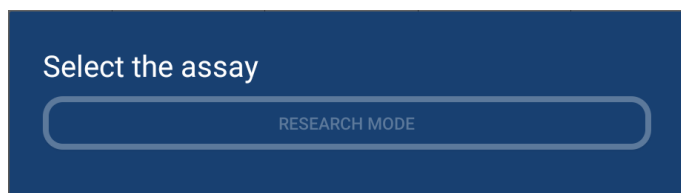
Figure 3.4.2 Select the assay

Setting	
Time : 30 minutes	
CANCEL	OK

Figure 3.4.3 Test time setting

3) Confirm the PCR

Start

Are you sure want to start the scan?

CANCEL   OK

Figure 3.4.4 Start confirmation

4) Heating will start to meet the target temperature for 2 min., and optical module start to scan fluorescence change of PCR.

Heating... 01:55

Figure 3.4.5 Heating Counting Pop-up

5) Measured Fluorescence will be updated in real-time and displays FAM in Blue, HEX in Green. PCR graph of each well can be selectively displayed on the graph by selecting wells below the graph chart
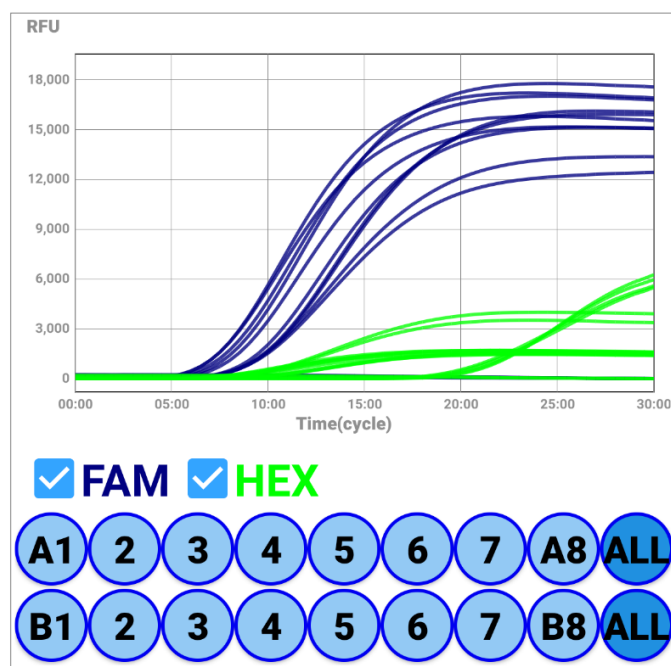
Figure 3.4.6 Real time PCR graph

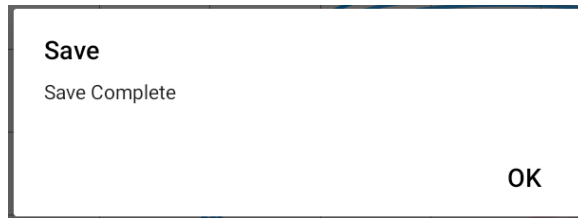6) After 20 minutes (Based on 40 cycle), PCR is terminated, and the results are automatically saved.

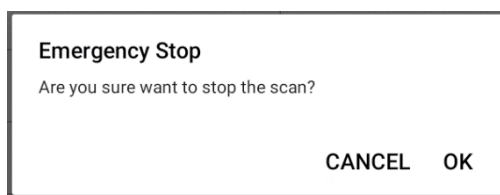**Figure 3.4.7 Automatically save after exiting PCR**

7) **Emergency stop**
(1) If malfunction of device or error in PCR experiment occurs, PCR can be stopped at any time with STOP button

Figure 3.4.8 Emergency Stop Button
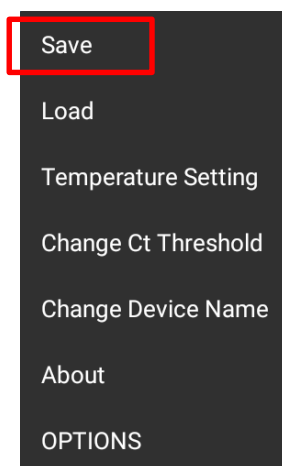
(2) Confirm before stopping the PCR

Figure 3.4.9 Emergency Stop Confirmation Message

3.5. *Save and Load PCR results*

1) Save PCR Result

Results are automatically saved with PCR shutdown, and you can also save manually by clicking the Save menu.

(1) Go to "Menu → Save" then, last PCR result will be saved
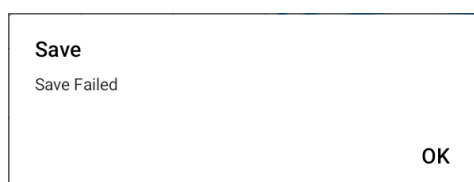

Figure 3.5.1 Save Menu

(2) "Save complete" message will be shown after saving last result.
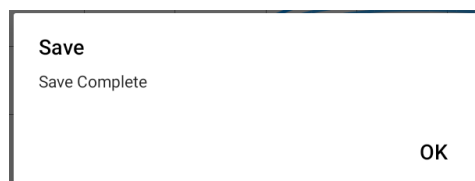
Figure 3.5.2 Save successful message

(3) Otherwise, "Save failed" message will be shown when it's failed. In this case, please save it again.

Figure 3.5.3 Failed to save message

2) Storage Location

Internal Memory> Documents> isothermal PCR> Under "Year_Month" folder

It is saved as "equipment name_year_month_day_hour_minute_second".
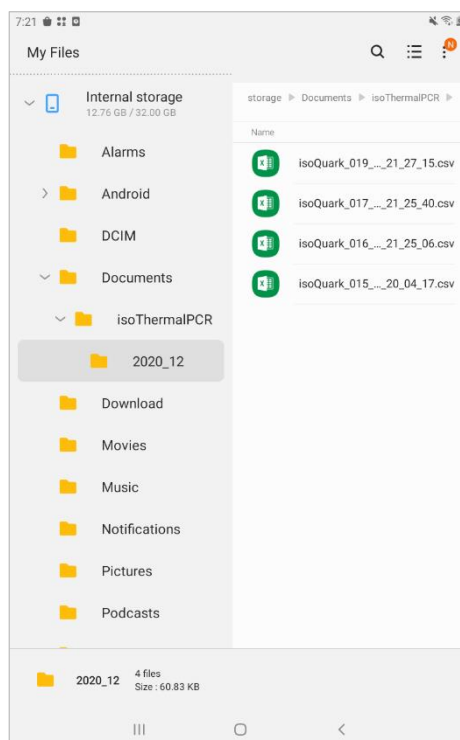
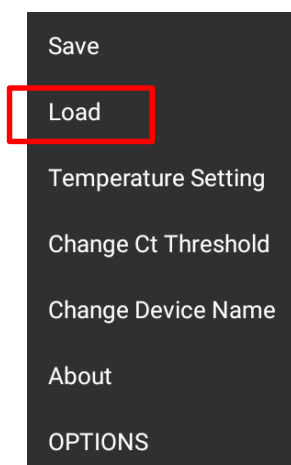**Figure 3.5.4 Storage Location**

3) Load PCR result

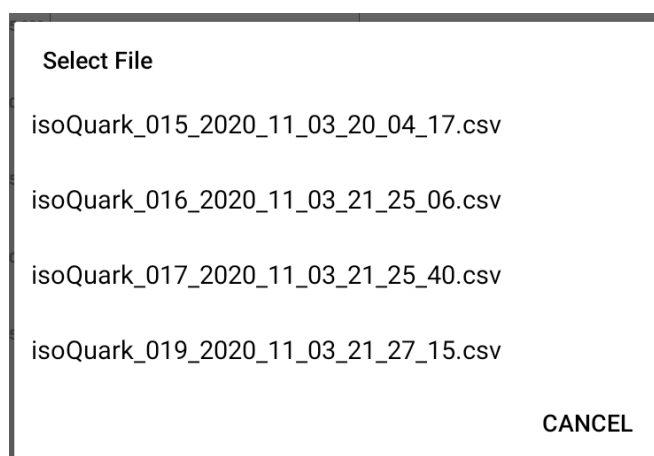You can load previously saved results.

(1) Go to "Menu → Load"

Figure 3.5.5 Load Menu

(2) In the pop-up window that appears, select the desired year_month folder.

Figure 3.5.6 Select folder

(3) Select and load a file of the desired date and time.

Figure 3.5.7 Select file

3.6. *Review PCR Result*

After completing the test, you can click the result button to check the result.
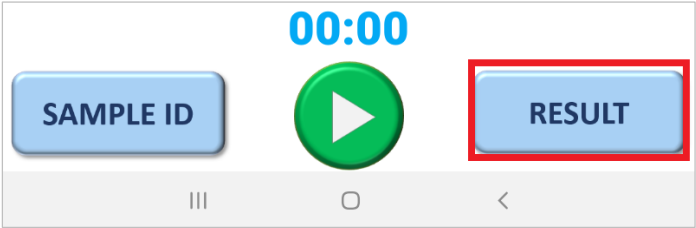
1) Select "RESULT" button

Figure 3.6.1 Result button
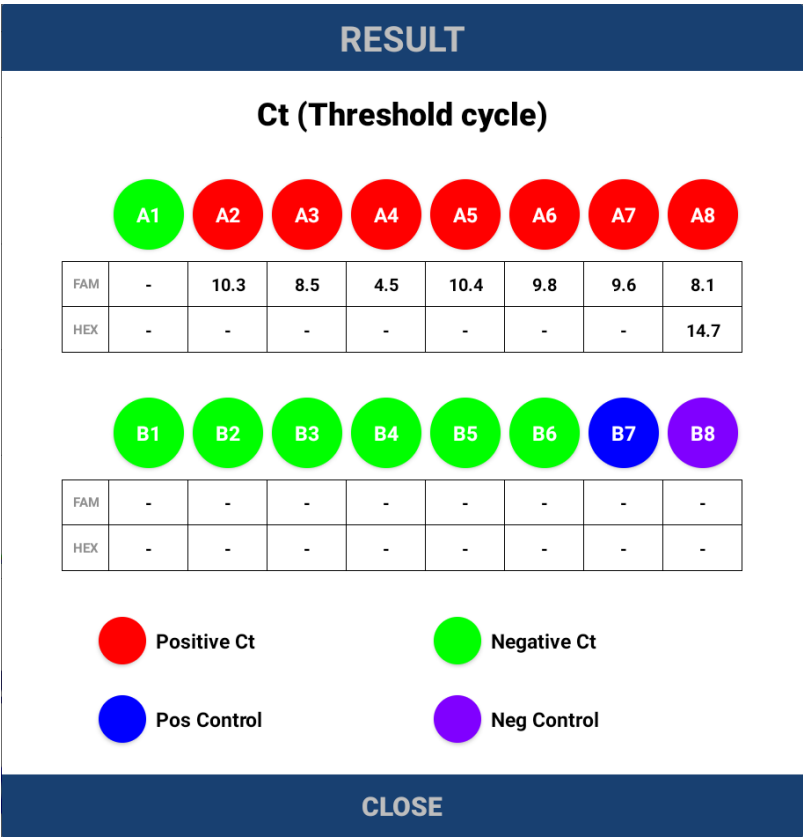
2) You can check the CT values of FAM and HEX for 16 wells.
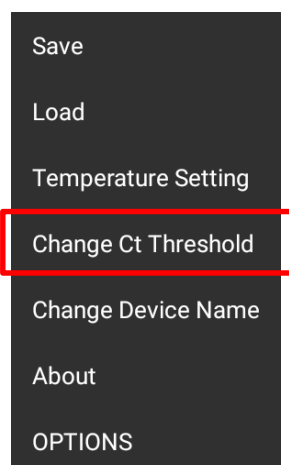

Figure 3.6.2 Results screen

3.7. *CT Threshold Change*

1) Go to "Menu → Change Ct Threshold"

Figure 3.7.1 CT Threshold Change

2) Change the FAM and HEX values and touch the CHANGE button to change the Threshold setting.

3) The range that can be set is 500 ~ 30000, and if you press the DEFAULT button, FAM 500 and HEX 500 are input.

Figure 3.7.2 CT Threshold Setting.

Figure 3.7.3 CT Threshold change completed

3.8. *PCR Temperature Setting*

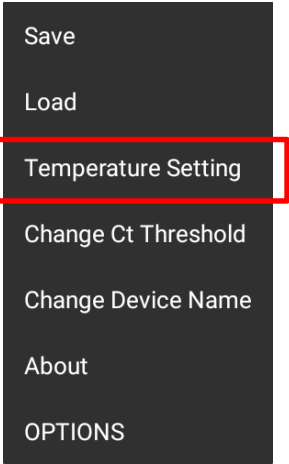Menu for changing PCR temperature.

1) Go to "Menu →Temperature Setting"

Figure 3.8.1 Temperature change menu

2) In the Temperature menu, enter the heating block temperature (40 ℃ ~ 70 ℃) and hottop temperature (80 ℃ ~ 100 ℃) and click the ″CHANGE″ button.

Figure 3.8.2 Temperature input window

3) When the temperature setting change is completed, a confirmation message is output as shown in the image below.
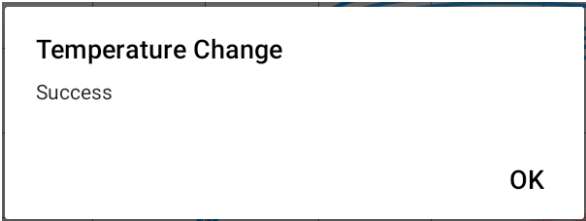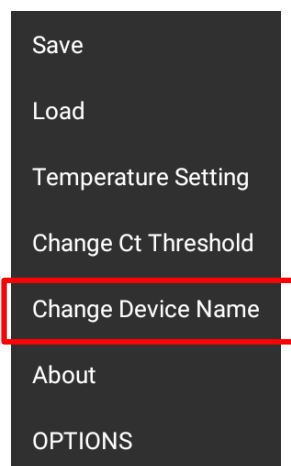

Figure 3.8.3 Temperature change confirmation message
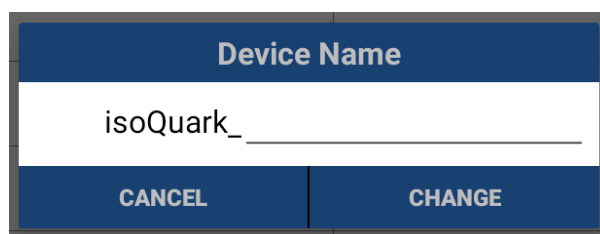
3.9. *Edit the name of the Equipment*

Device name can be easily changed for configuration when using multiple devices.

1) Go to   "Menu → Change Device Name"

Figure 3.9.1 Device name change menu

2) Enter the last three digits and press the CHANGE button to change the device name.
   Ex) isoQuark_000, isoQuark_abc

Figure 3.9.2 Device name change menu

3) When the finish edit the name, please restart the device.

3.10. *cDNA Synthesis*

Before starting the scan, can set the cDNA Synthesis function to preheat the sample to a certain temperature.
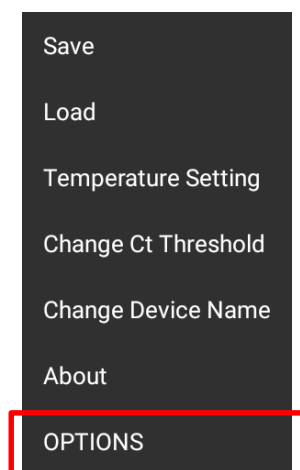
1) Connect to isoQuarkF2 device.
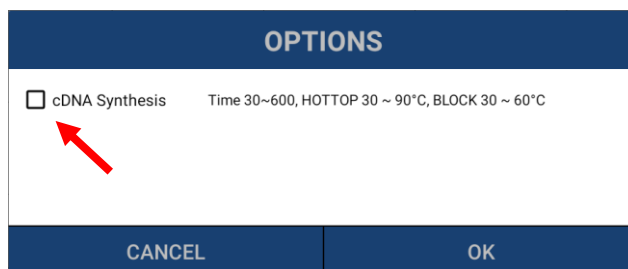
그림 **3.10.1 OPTIONS**

2) Go to "Menu → OPTIONS"

그림 **3.10.2 cDNA Synthesis screen**

3) Selecting the check box activates the cDNA Synthesis function. If you don't want to use it, please release the check box.
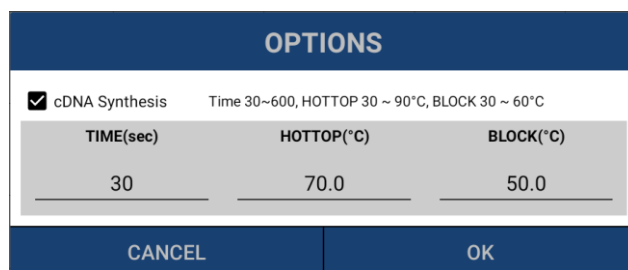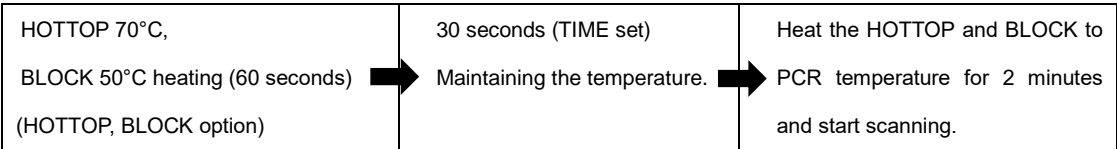

그림 **3.10.3 cDNA Synthesis set screen**

4) When the cDNA Synthesis function is activated, TIME, HOTTOP, and BLOCK can be set.
   (1) TIME   : The time when the cDNA Synthesis function operates.
   (2) HOTTOP   : HOTTOP temperature set in cDNA Synthesis step.
   (3) BLOCK   : BLOCK temperature set in cDNA Synthesis step.

5) Please press "OK" and save it. cDNA Synthesis settings are stored on isoQuarkF2 devices, so cDNA Synthesis settings are maintained even when the isoQuarkF2 device is rebooted.

6) When scanning is started with the cDNA Synthesis option activated, the BLOCK and

HOTTOP are heated for a time set at the temperature set by the cDNA Synthesis option.

7) At the end of the cDNA Synthesis step, heat the HOTTOP and BLOCK to the set temperature (See 3.8. PCR Temperature Setting) for 2 minutes before the scan begins.

※ Example of cDNA Synthesis

After activating cDNA Synthesis and setting TIME 30, HOTTOP 70, and BLOCK 50, scan start.

HOTTOP 70°C, BLOCK 50°C heating (60 seconds) (HOTTOP, BLOCK option)	30 seconds (TIME set) Maintaining the temperature.	Heat the HOTTOP and BLOCK to PCR temperature for 2 minutes and start scanning.

3.11. *Set up the Sample ID*

Give ID and select positive control and negative control for 16 wells. And you can enter a memo about the inspection.
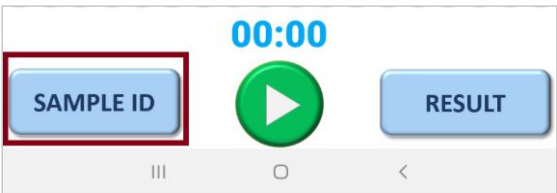
1) Select the "SAMPLE ID" button.

Figure 3.11.1 SAMPLE ID button

2) Select the positive control, negative control, and edit each sample IDs. After editing sample ID, please click the accept button at bottom of the window.

Figure 3.11.2 SAMPLE ID window

3) An edit completion message is displayed.

Sample ID Edit
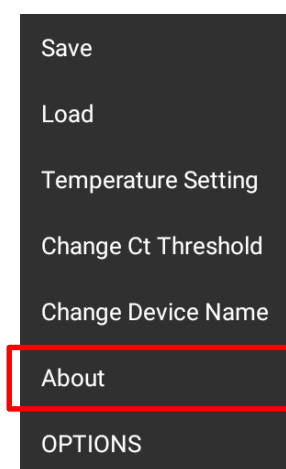Edit Complete
OK
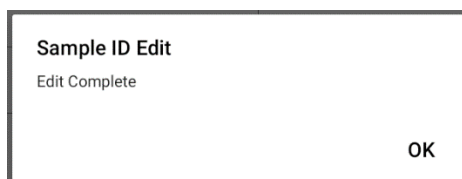
Figure 3.11.3 conformation message

3.12. *SW version*

Go to "Menu → About", version of SW will be displayed

Save

Load

Temperature Setting

Change Ct Threshold

Change Device Name

About

OPTIONS

Figure 3.12.1 About

About
App Ver. 1.0.1.0
CLOSE

Figure 3.12.2 check the SW version

4. Warning messages

4.1. Temperature problem

1) When the equipment temperature is abnormal, a warning message window appears.

2) The Abnormal temperature message also appears when the heater block is removed.

3) If you get an abnormal temperature message, the test is invalid.

4) When temperature problems consistently, contact the service center.

Temperature

The temperature is abnormal.

OK
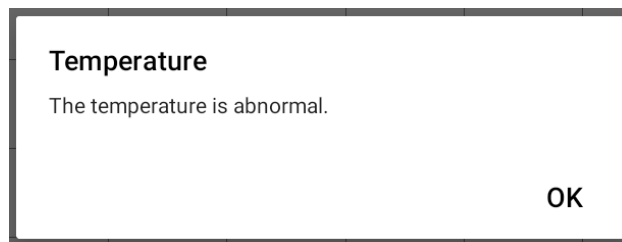
Figure 4.1.1 Warning messages of temperature

4.2. Connection problem

1) When the disconnection with the device, "NOT CONNECTED" is displayed on the top.

2) Please check the power to the device, and the USB cable is properly connected.

3) If the connection is still not successful, please restart the device.

4) Please check and activate Bluetooth function on your control device

5) When connection problem is not cleared, contact the service center.

isoQuark_004   NOT CONNECTED ⋮

Figure 4.2.1 Not connected state

5. Management and storage

5.1. Precautions after using

1) If the sample is not removed, there is a risk of contamination inside the device. After use, separate the heating block and remove the sample.
2) If you open the heating block for a long time, dust can accumulate and interfere with the analysis. After use, make sure to keep the heater block in the device.

5.2. Precautions for cleaning

1) Make sure to turn off the power before cleaning the product.
2) Do not pour liquid into the product or drop the product.
3) If the sample falls on the device and is contaminated, stop the experiment and clean it quickly.

5.3. How to storage device after using

1) Make sure to keep the device after use with the power off.
2) Please store or use it avoid direct sunlight or near heat sources.
3) Please store or use it in a well-ventilated environment.
4) Avoid storage in places where there is a risk of falling or where vibration or mechanical impact may occur.
5) Avoid near chemicals or where gas is generated.
6) Storage and transportation environment of the device.

   Temperature: -10℃ ~ 65℃.

   Humidity: 15 ~ 95%.

6. Symbols

Symbol	Description
▲▲▲	Manufacturer
� symbol	Date of Manufacture
SN	Serial number
LOT	Lot Number/ Batch Code
IVD	In Vitro Diagnostic Medical Device
EC | REP	Authorized representative in the European Community / European Union
UDI	Unique Device Identifier Indicates a carrier that contains Unique Device Identifier information
|	Equipment Power ON
◯	Equipment Power OFF
⚠	Warning, Consult Accompany Documents General mandatory action manual General prohibition indication Caution
📖i	User Manual Reference

	Do not dispose of this product as unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of waste electrical and electronic equipment (WEEE).
	Universal serial bus (USB) port
	Bluetooth Connection
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Keep Dry
	Fragile
	This side up
	Non-ionizing electromagnetic radiation
	For Professional Use Only
	CE Mark

7. Technical support

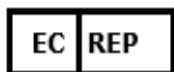When you have some questions during the install or use, please contact the local distributor and us.

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