# Veri-Q PinoView

# MIC-C100

## User Manual

**06.2021**

RUO

**For research use only**

Cat No. 9T210

MiCo BioMed

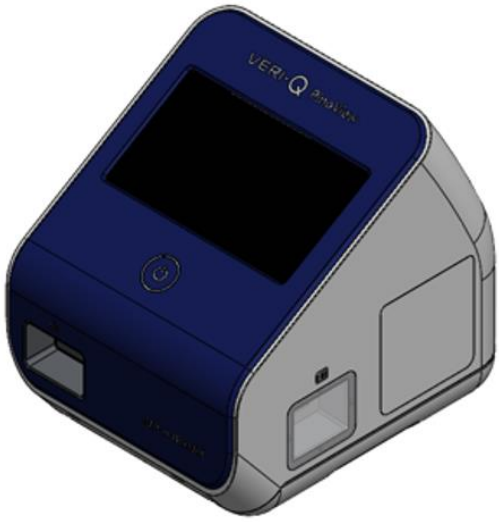
# User Instruction

Common name : Colorimetric Immunoassay Device

Model name : MIC-C100

Brand name : Veri-Q PinoView

The users must thoroughly read and understand this manual prior to using this device. This manual must be placed in the designated area for appropriate use whenever necessary.



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# Table of Contents

# 1 Before Starting

## 1.1 How to use this manual

This Manual is made for researchers and laboratory staff who are responsible for installing and maintaining the **Veri-Q PinoView, MIC-C100**.

## 1.2 General Requirements for Installation

This guide assumes that you:
Have basic techniques for handling Cartridge sample.
Have basic skills of data storage, copying, and pasting in device.

## 1.3 How to Obtain More Information

To obtain more information about the MIC-C100, please visit our website at http://micobiomed.com/ or send E-mail to salesbio@micobiomed.com

## 1.4 How to Reach Customer Support

For prompt customer support, please call us at +82-70-5227-6000.
Technical support is also available on our website at http://micobiomed.com/

## 1.5 Precautions against Transferring or Copying Content of This Document

# 2 Cautions and Instructions for MIC-C100

## 2.1 Intended Use

The device used to optically measure the concentration of a specific component using immune substances that react with components of body fluids.
The Instrument is intended for research use only (RUO) and not for clinical use.

## 2.2 General Instruction

The personnel specialized and trained in genetic analysis should use the MIC-C100 System. The user should thoroughly understand the manual before operating this device. The safety of device and personnel may be threatened in the event the user fails to follow the instructions in this manual. The user must read and follow the warnings mentioned under the following signs.

| | |
|---|---|
|  | Warning, Caution, Risk of Danger – May cause physical injury and damage on the device if the guideline or procedure is not observed. |
|  | Waste - Separate collection for electrical and electronic equipment waste |

### 2.2.1 Warning and Prevention

 WARNING

The MIC-C100 System is an electronic device. It may cause electronic shock and injury if the manual is not followed when using the device. The manufacturer is not responsible for any issues and problems caused by the failure of observing the manual.

**1)** Follow the general safety regulations applied to this electronic device.
**2)** Do not access the internal device while the device is turned on.
**3)** Do not move the device while device is being operated.
**4)** The power cable must be separated during cleaning and maintenance.
**5)** Do not use the device near the moist environment.
**6)** Do not touch the power cable or device with wet hands.
**7)** Do not randomly disassemble or remodel the device. It may cause fire, electric shock and breakdown which are not covered by A/S.
**8)** Service should be provided by qualified personnel only.
**9)** Do not overload the power outlet. It may cause fire and electric shock.
**10)** Do not install the device on the unstable or slope location. If device is wet, immediately unplug the cable.

**11)** The device should not be used other purposes. It may cause failure and damage on the product.

**12)** The components provided by manufacturer should be used only. It may cause the malfunction and damage of product.

**13)** Separate the power cable and contact the manufacturer if applicable to one of the followings.

- If power cord or plug is damaged,
- If device is exposed to water or liquid,

**14)** Do not place the goods above the device.

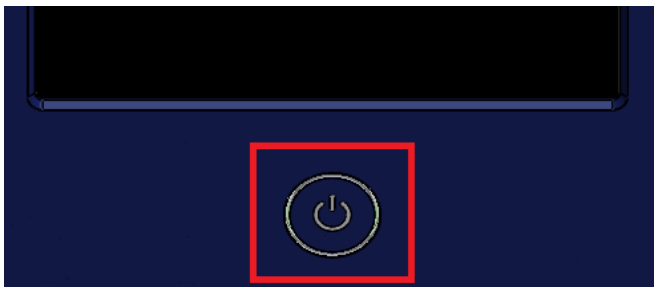
**15)** In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

**16)** The electromagnetic environment should be evaluated prior to operation of the device.

**17)** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

**Immediately unplug the power cable in the emergency situation.**

**Or Press and hold the power button to turn it off.**



**<u>WARNING</u> – Chemical Safety**

Refer to the MSDS prior to handling chemical substances and follow all instructions.
The wastes produced while using the device may cause damage, disease or death. Refer to the MSDS and local regulations for handling, saving and disposal of wastes.

**<u>WARNING</u> – Chemical Waste Disposal**

Please wear the appropriate protective guards such as goggles, lab coat, glove, etc. when disposing of the reagent and chip. The wastes should be saved, transported and disposed in accordance with regional, local or national regulations.

**Caution – LED Safety**

The user may be exposed to LED if they fail to observe the instructions.

### 2.2.2 Transport and Delivery

MIC-C100 System is packed in a paper box and is shipped in a box.
The case includes MIC-C100 System and its components. The product components and specification, installation and use are later explained in detail. However, the warranty does not cover any faults caused by transportation and delivery though valid warranty period.

**1) Condition during transportation**

| | |
|---|---|
| **Temperatures allowed** | Room Temperature (RT) |
| **Relative humidity** | 20% to 90%, no condensation |

**2) Shipping methods**

The device should always be transported or delivered in a case.

### 2.2.3 Operating Environments and Installation

The user is exposed to risks in the event that instructions are not properly followed when installing the device. Please follow the directions carefully.

**1)** This device is a precise optical device; therefore, the device should be installed and kept out of direct sunlight.
**2)** Check the power connection. The device is operable by both 200V/110V. It is recommended to use automatic voltage regulator (AVR) or AVR-combined UPS (Uninterrupted power supply) for a stable use.
**3)** Use the grounded power only. The user can be physically injured due to falling without grounding, and the product cannot be used in a stable condition.
**4)** Do not use a loose-fitting power plug. The plug can overheat, become damaged, and lead to electric shock.
**5)** Wipe down the dust on the power plug and surely plug it not to shake it. Unstable connection causes fire.

**6)** Do not use multiple devices on a single outlet at a time. It may cause fire due to an overloaded outlet.

**7)** The system body should be installed at least 10cm away from the wall side and at least 20cm away from other product. If the device is installed adjacent to the wall, it can lead to failure.

**8)** Do not place products or goods near the device, it may interrupt the operation. It also may cause errors in operating the door.

**9)** The device should be installed out of dust. Dust can cause the malfunction or failure of a device.

**10)** The installation place should avoid the flames such as electric heating apparatus. It causes fire.

**11)** The device should not be installed in a wet or humid place. It causes electric shock, fire and failure.

**12)** Do NOT install the device within the place of inflammable or corrosive gas. If exposed to gas, do not modify the power plug but open the window for ventilation. Flames cause explosion and fire.

**13)** Do not randomly disassemble or remodel the device. It causes fire, electric shock or failure and cannot be covered by A/S.

- Operating Condition
  - Temperature: 15 to 40°C
  - Humidity: 20~80 %
  - Max. 80% at 40°C, no condensation
  - Min. 20% at 15 to 40°C
- LED Module
  - Please see the product specification on page 11

### 2.2.4 Consumables

Cartridges inserted into this equipment are disposable. Do not use the chip more than 1 times. It may bring unreliable results.

### 2.2.5 Warnings and Cautions for Use and Management of Device

The MIC-C100 System does not require cleaning on a regular basis.

**1)** Maintenance

The MIC-C100 System does not require special maintenance.

**2)** Warnings and Cautions for Use and Management

- Do not use the device for the other purposes. It may cause failure in product or physical injury in personnel.
- Debris should not be found in the cartridge area. It may cause failure in product or physical injury in personnel, and accurate experimental data cannot be obtained.
- Do not place papers, decking made of synthetic resin under the device. It may cause fire.
- Do not cover product by paper or plastic while device is being operated. It may cause fire and failure.
- The user may be exposed to LED if randomly disassembling the device. If exposed to eyes, the user may become injured.
- The inside of this product has areas subject to high temperature, which may cause burns. Do not touch the Thermal block.
- Do not charge the coin battery, as there is risk of explosion if the battery is replaced by an incorrect type.

**WARNING** Unplug the power cable while cleaning.

**WARNING** Do not pour liquid into chip door.

**Environmental conditions for transport and storage.**

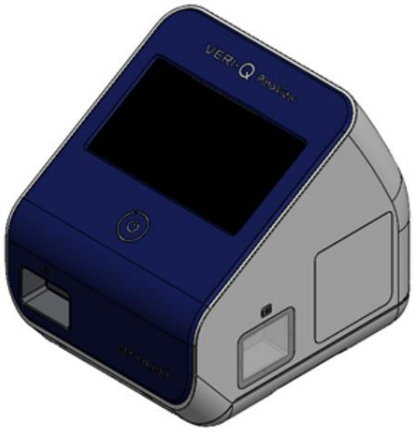
| | Operating | Storage | Transport |
|---|---|---|---|
| Ambient Temperature(℃) | 15 to 40 | RT | RT |
| Relative Humidity(%) | 20 to 80 | 20 to 90 | 20 to 90 |
| Air Pressure(kPa) | 70 to 100 | 70 to 100 | 70 to 100 |

# 3 Product Composition and Specification

## 3.1 Product Composition and Specification

The warranty service is available for a year from the date of purchase at no extra cost. The warranty does not cover the failure caused by user's careless handling. Any defaults or failure caused after warranty period will be covered in charge. Check if followings are contained in the product package.

### 3.1.1 Product Composition



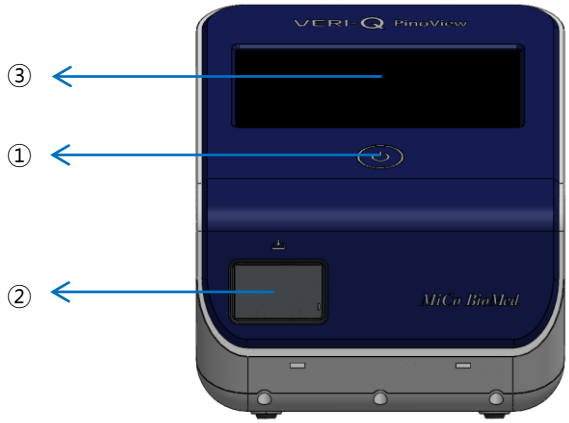
| *Component* | *Quantity* |
|---|---|
| MIC-C100 Instrument | 1 |
| AC adapter<br>- Model designation : KPL-040F-VI<br>- Manufacturer : CHANNEL WELL TECHNOLOGY<br>- Input : 100-240V, 1.7A, ~50/60Hz<br>- Output : 12Vdc, 3.33A | 1 |
| Main power cable | 1 |
| Warranties | 1 |

### 3.1.2 Product Specification

| | |
|---|---|
| **Common name** | Colorimetric Immunoassay Device |
| **Brand name** | Veri-Q PinoView |
| **Model name** | MIC-C100 |
| **Software (SWVCI-00)** | Main Processor_1.00 Ver. |
| **Firmware (FWVCI-00)** | Control Processor_1.00 Ver. |
| **Input Rating** | 12V dc |
| **Input Current** | 3.33A |
| **Detection** | CMOS |
| **Ports** | USB |
| **Weight** | Approx. 3Kg |
| **Dimension (W x D x H)** | 205 x 240 x 225 mm |
| **LED** | White LED |
| **Battery** | Coin battery (ML1220) |

### 3.1.3 Structure and Name

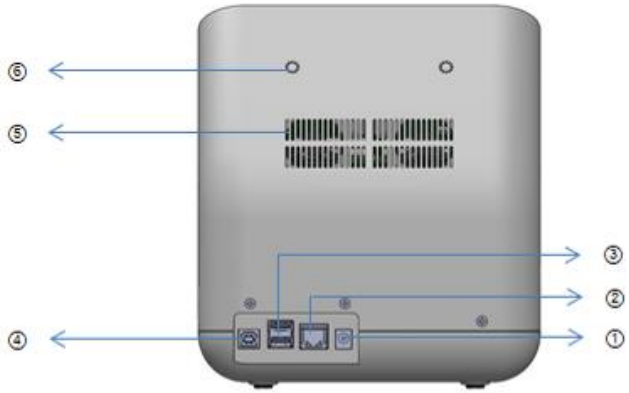
#### 1) Front View




| No. | Name | Description |
|---|---|---|
| ① | Power Switch | Device Power On Switch |
| ② | Door | Entrance/exit for insertion of Tray |
| ③ | Touch Screen | User interface screen for device operation |

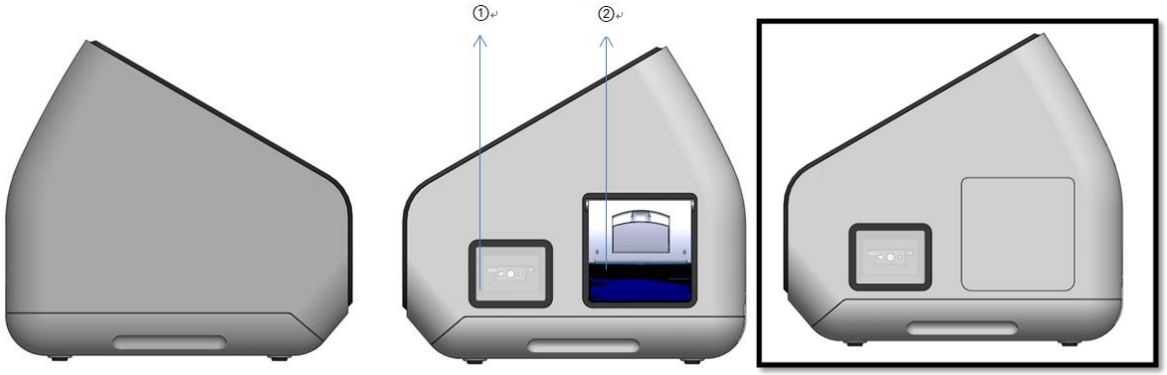
#### 2) Top View

### 3) Rear View




| No. | Name | Description |
|---|---|---|
| ① | Power Connector | Connect power adaptor and main body |
| ② | LAN Connector | Port for updates |
| ③ | USB Connector(Flash Memory) | Flash memory insertion connector for data storage |
| ④ | USB Connector(Update) | Port for updates |
| ⑤ | Vent Hole | Ventilation hole for heat radiation |
| ⑥ | Speaker Hole | Speaker Hole for Buzzer |

### 4) Side View




**(By default, no printer is used.)**

| No. | Name | Description |
|---|---|---|
| ① | External Bar code | Barcode Reader |
| ② | Thermal Printer (Optional) | Output operated results in thermal printing paper |
| ③ | Internal Bar code (Optional) | Barcode Reader |

**5) 5 color models**


Black


Gray

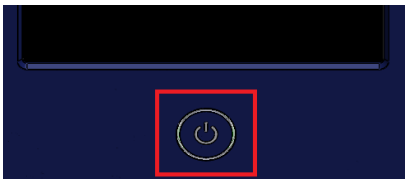

Navy


Gray navy


Purl navy

### 3.1.4 Installation

#### 1) Device Connection

| | |
|---|---|
|   | Connect the adapter to the power port. |
|   | Connect the AC inlet of AC adapter to the power cable. |
|  | Connect the power outlet. |
|  | Press and hold the power button to turn it on. |

**2) Instructions for Installation**

The product needs to be installed according to the manual. Incorrect location of installation may cause damage to the device.

- The product should be installed and kept out of direct sunlight.
- Unplug the cable and turn off the power during the installation to prevent damage to device
- Be careful not to get damaged by statics.
- Installation Location
  - The backside should be installed at least 10cm away from the wall.
  - The side or wall side should be installed at least 20cm away from other product or good.

**3) Installation**

The **MIC-C100 System is a standalone device** that can be operated without a computer.

Please contact the customer support center at MiCo BioMed for other inquiries.

## 3.2 Operation

Device Operation and Experimental Preparation

If device is installed, check for the proper operation of the device and prepare for experiment.

### 3.2.1 System booting & initial screen

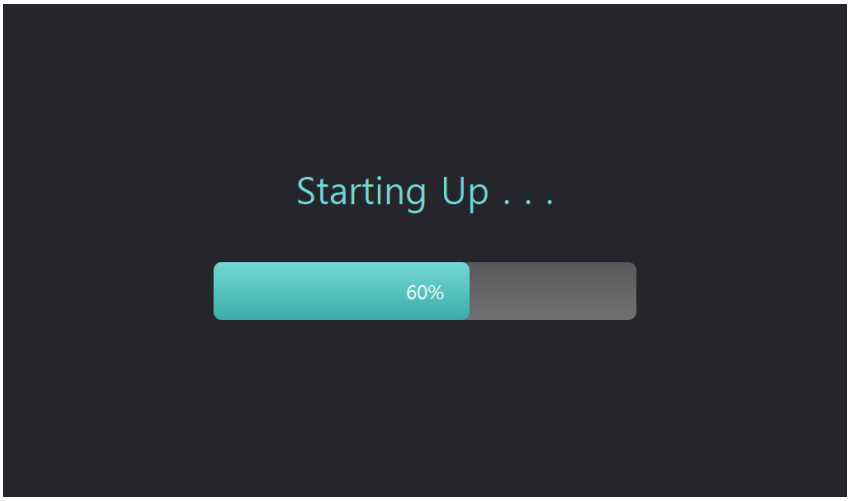
Press power button for 5sec in the middle of equipment. After power-up led will turn on and initial screen will be displayed like [Fig. 2].


[Fig. 1] Equipment

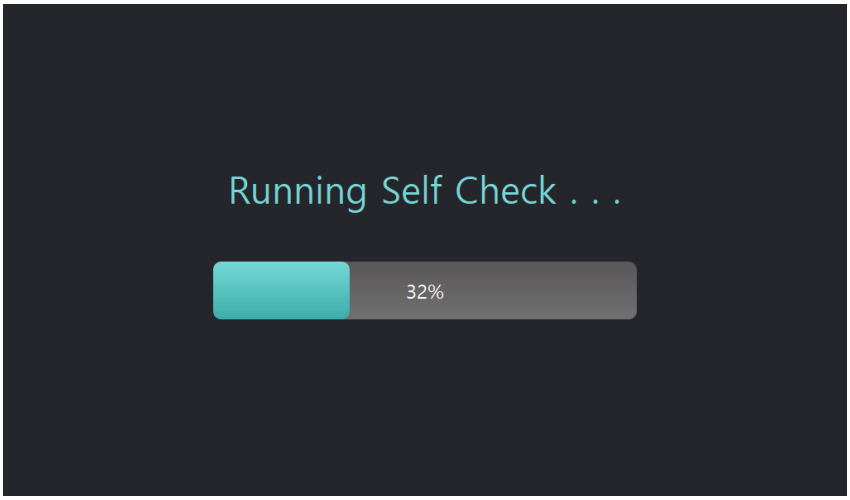

[Fig. 2] Logo image after equipment power-up

### 3.2.2 Starting Up & Self Check

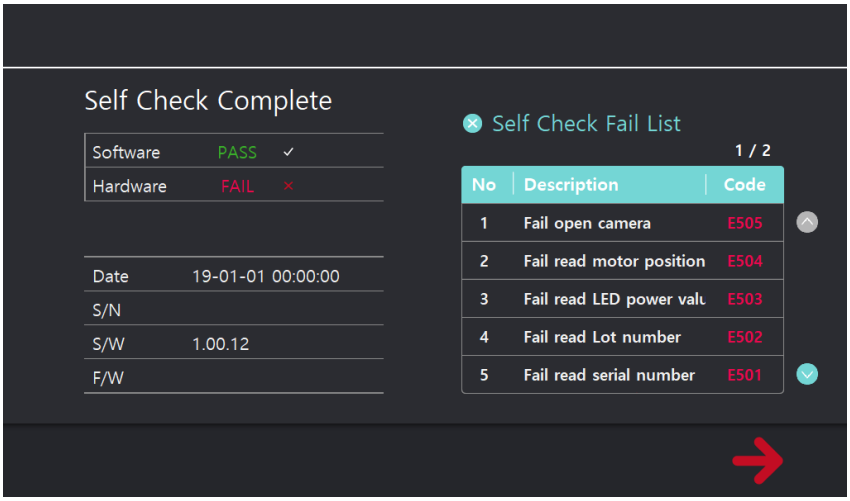
After logo image, Starting Up & Self Check will be done and its results also be displayed. User can log in by touching arrow image at the right bottom corner.




[Fig. 3] Starting Up screen

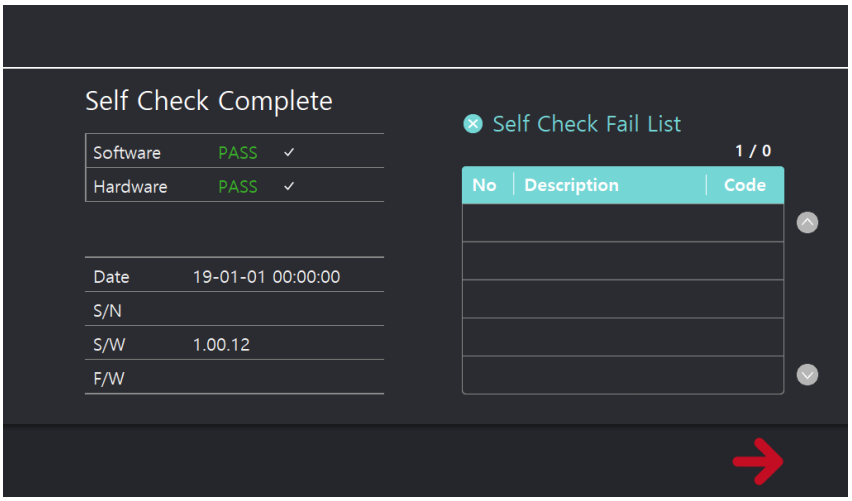



[Fig. 4] Self Check screen




[Fig. 5] Self Check - Fail screen

After Self Check, If some functional problems exist, their list will be displayed.
(Screen will be changed for log in, if user touches the arrow image at the right bottom corner)

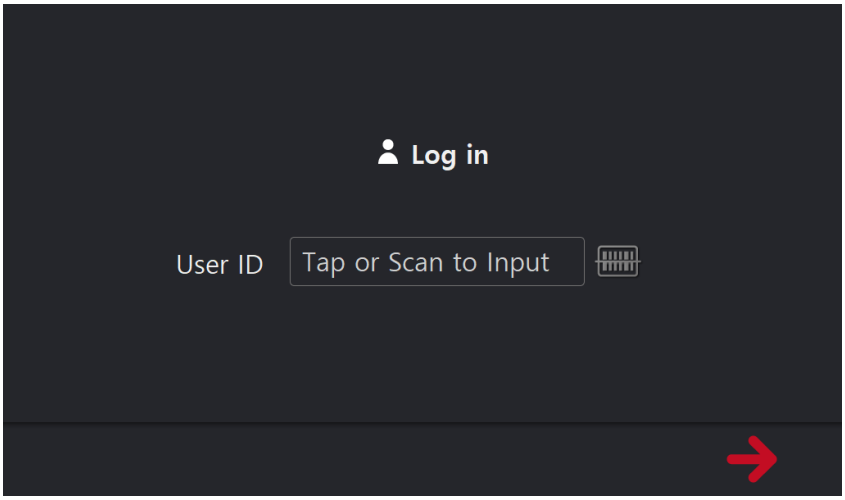



[Fig. 6] Self Check - Pass screen

After Self Check, If no problem exists, PASS messages will be displayed.
(Screen will be changed for log in, if user touches the arrow image at the right bottom corner)

### 3.2.3 Log in screen

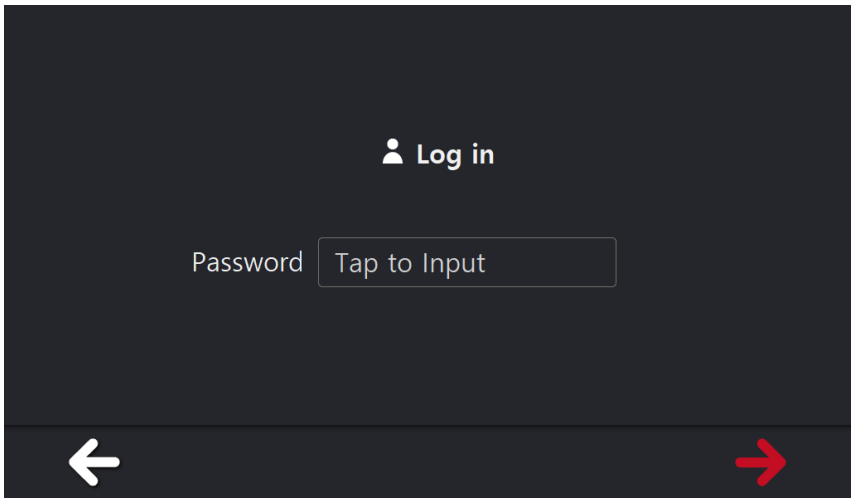
User can input user ID & password in the log in screen.




[Fig. 7] Log in – User ID screen

Touch the 'Tap to Input' to input ID and touch the arrow image to input password, then screen will be changed like [Fig. 8]

* User can log in by touching text box and input operator ID or press barcode button for ID scanning.

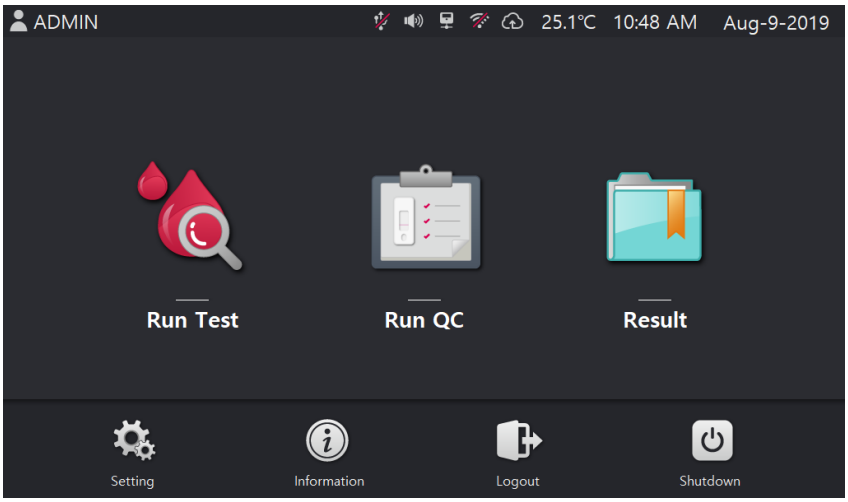



[Fig. 8] Log in – Password screen

Touch the 'Tap to Input' to input password.

Touch the arrow image at the right bottom for home scree or at the left bottom for ID input.

### 3.2.4 Home screen




[Fig. 9] Home screen

Display current user ID

Display USB connection

Display equipment sound ON/OFF state

Display networld connection

Display wi-fi connection

Display cloud ON/OFF state

25.1℃ Display equipment's internal temperatur

10:48 AM Aug-9-2019 Display set up date and time

Image for test menu

Image for QC menu

Image for QC and test results menu

Image for set-up menu. User can set up equipment's password, operator, sound volme, language, print, S/W update, equipment's operation time, date/time, QC menu, scanner configuration, patients information, administrator, network connection and PC connection

Image for equipment's information

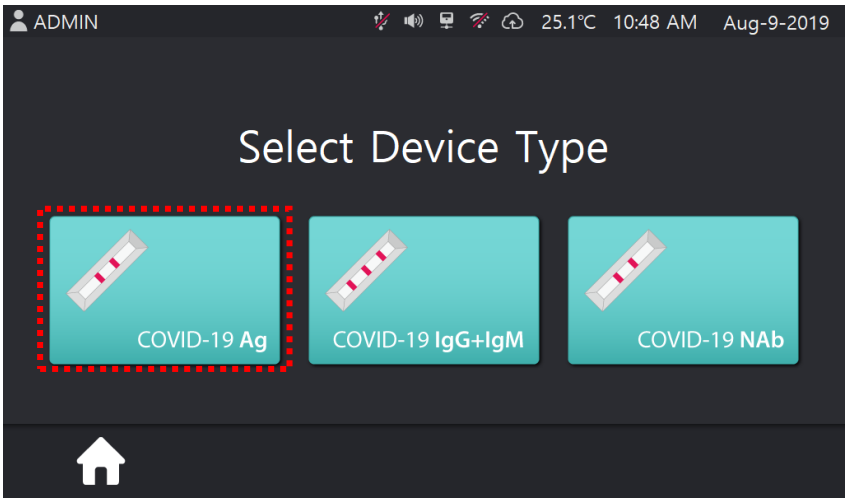
Image for log out

Image for power-down

### 3.2.5 Run Test – COVID-19 Ag

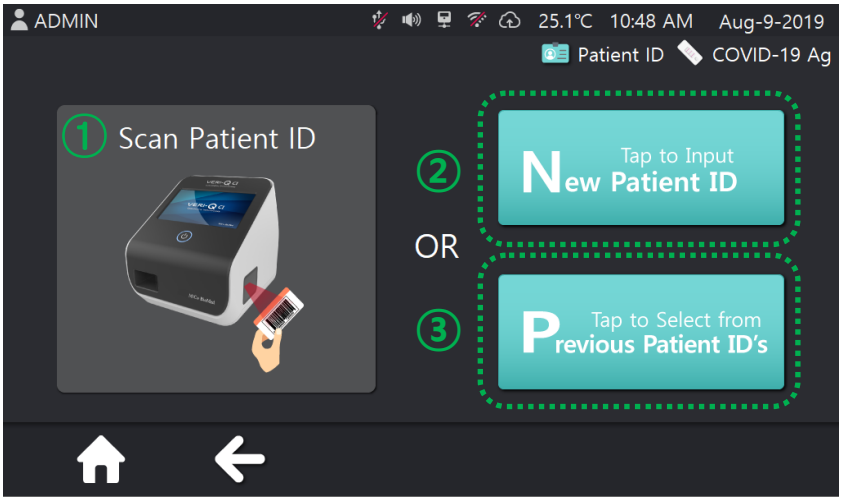
If user selects **[Run Test]** menu in home screen, the screen will be changed like below [Fig. 10]
* In case of barcode mode, this **[Select Device Type]** step will be skipped.

User can select one of **[COVID-19 Ag]**, **[COVID-19 IgG/IgM]** & **[COVID-19 NAb]** in this screen.




[Fig. 10] Screen after selection of Run Test

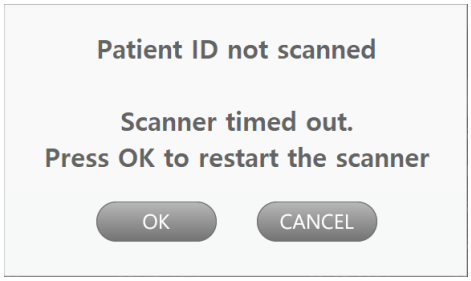
If **[COVID-19 Ag]** selected, screen is changed like [Fig. 11] which shows patient's ID scan menu. Through these menus, user can input new patient ID or select existing patient's ID for test




[Fig. 11] Scan Patient ID screen

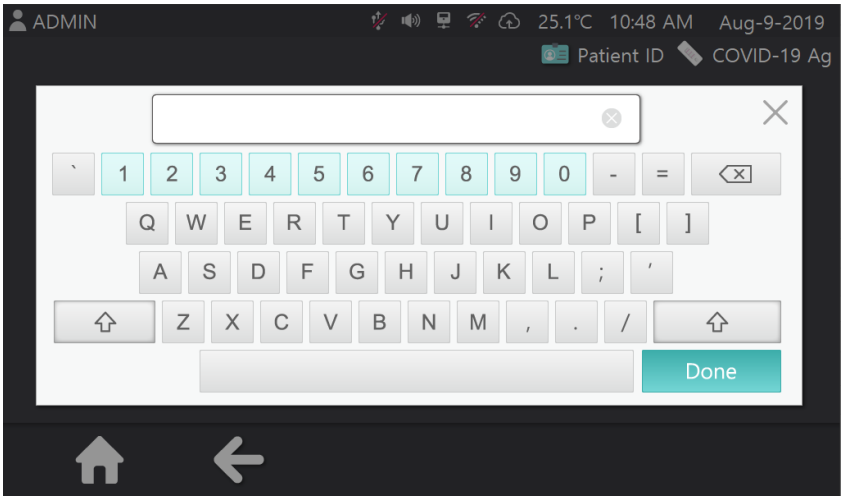
① By using barcode reader at the right side of equipment, user can scan patient's ID directly. Like above figure, attach the barcode to reader.

* If user didn't scan barcode in the limited time, the warning message is popped up like below [Fig.11]



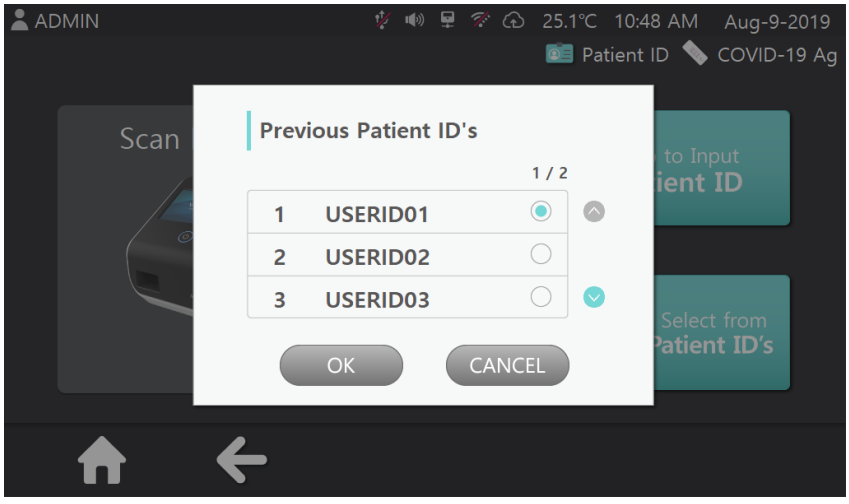

[Fig. 12] pop up message for barcode scanning failure

② To input new patient's ID, press **[Tap to Input New Patient ID]** button. The screen will be changed like [Fig. 13], then attach barcode to barcode reader at the right side of equipment. Equipment will aware the barcode.

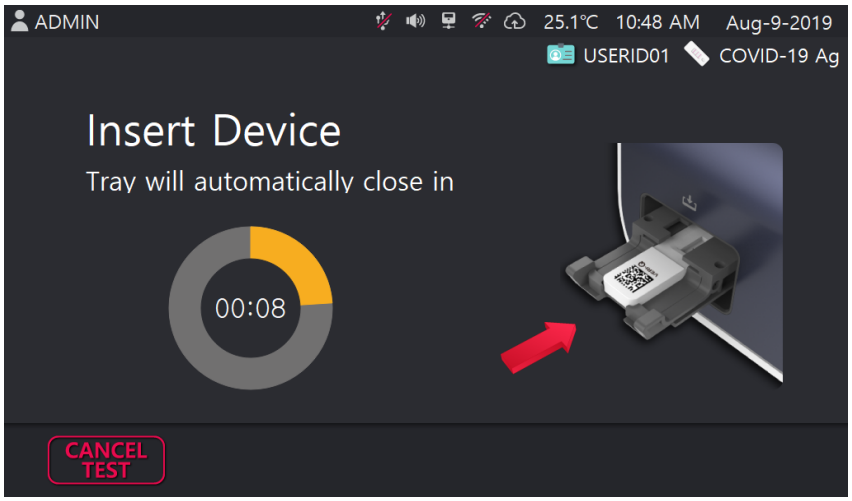



[Fig. 13] The pop up image when user press [Tap to Input New Patient ID] button

③ Press **[Tap to Select from Previous Patient ID's]** button, then select existing patient's ID and press **[OK]** button (See [Fig. 13]).



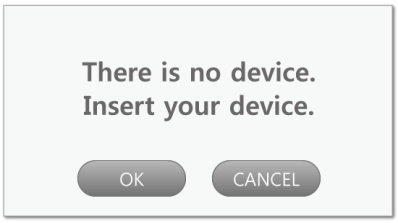

[Fig. 14] The pop up image when user press [Tap to Select From Previous Patient ID's]




[Fig. 15] scan device screen

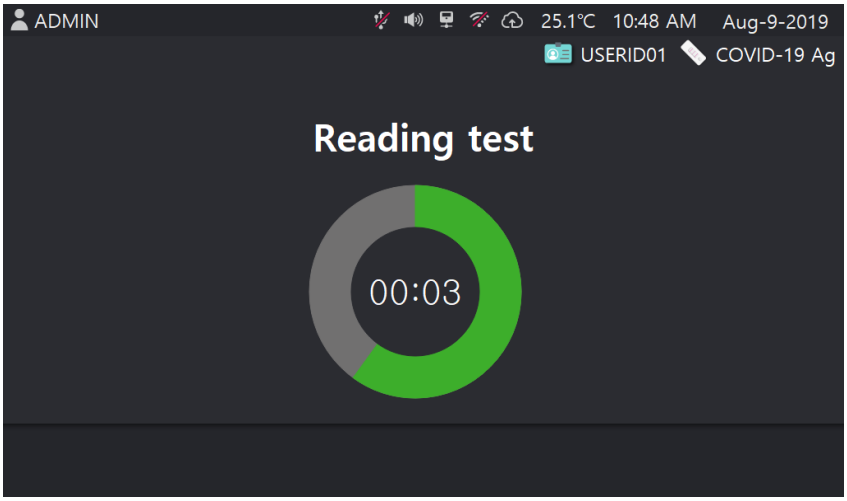
Like [Fig. 15], insert device into equipment. Device's inlet should be located inside, thus inserted first. Then, equipment will aware device.

*If user do not insert device in limited time, the warning message will be popped up like [Fig. 16]



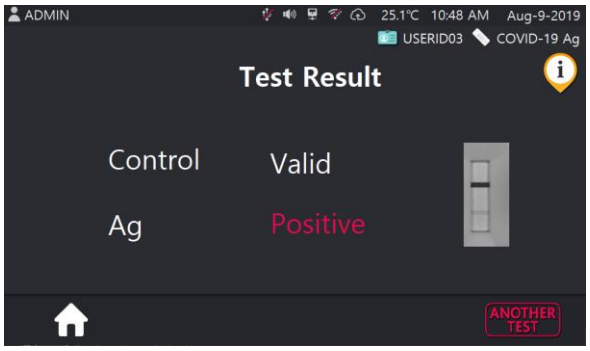

[Fig. 16] pop up message for device scanning failure

If user presses "OK" button, equipment will scan the device again. However presses "Cancel" button, screen will be changed for home screen like [Fig. 9]. If device scanning is done successfully, test will be done and screen will be changed like [Fig. 17]

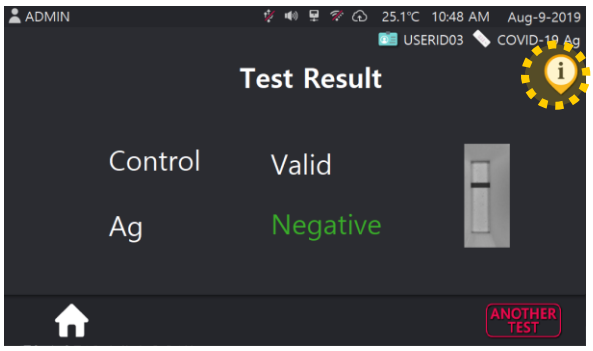



[Fig. 17] Reading test screen

The test is being done for 8 seconds, and then results will be displayed like [Fig.18] / [Fig. 19].

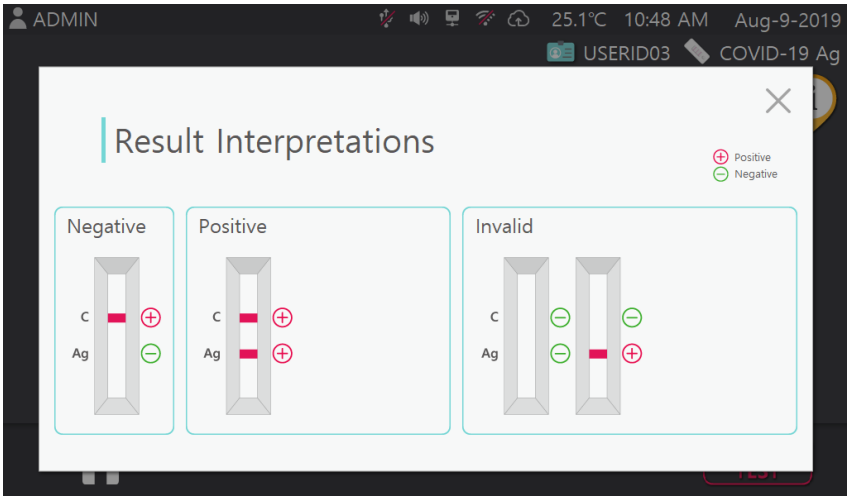



[Fig. 18] Result – Positive screen




[Fig. 19] Result Negative screen

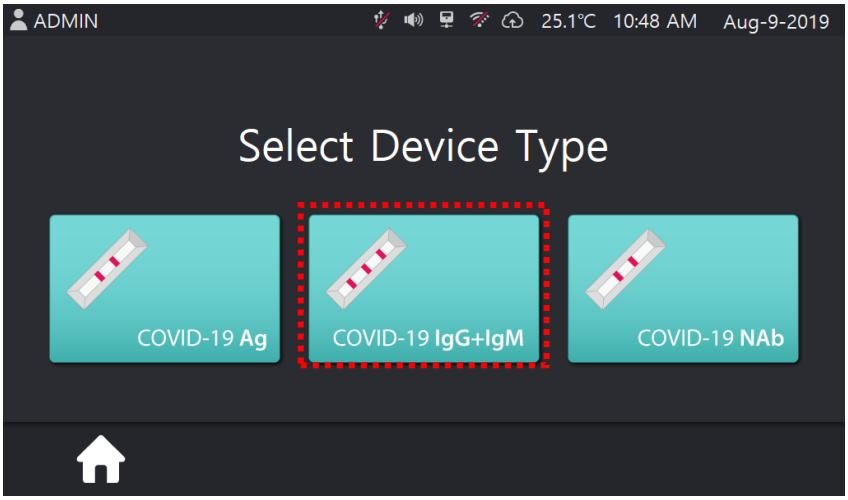
[Fig.19] by pressing  icon, user can check the result and see the interpretations (see [Fig. 20]).




[Fig. 20] Result Interpretations screen

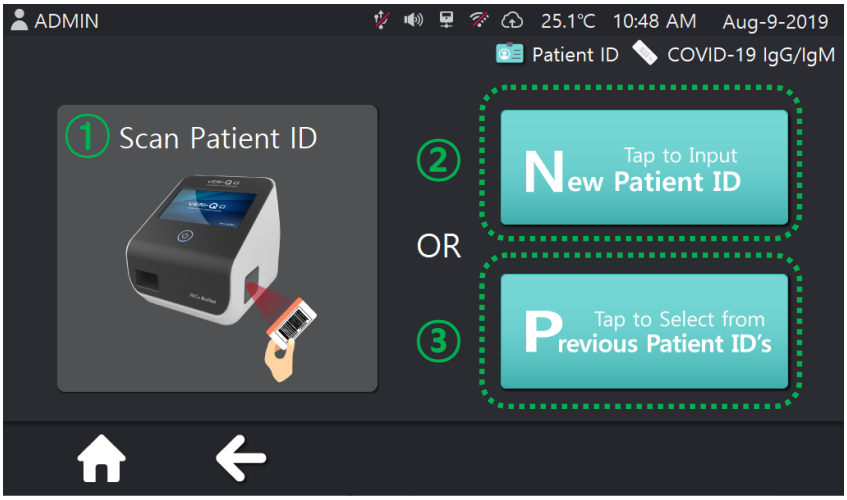
### 3.2.6 Run Test – COVID-19 IgG/IgM

If user selects **[Run Test]** menu in home screen, the screen will be changed like below [Fig. 21]
* In case of barcode mode, skip this **[Select Device Type]** step
User can select one of **[COVID-19 Ag]**, **[COVID-19 IgG/IgM]** & **[COVID-19 NAb]** in this screen.



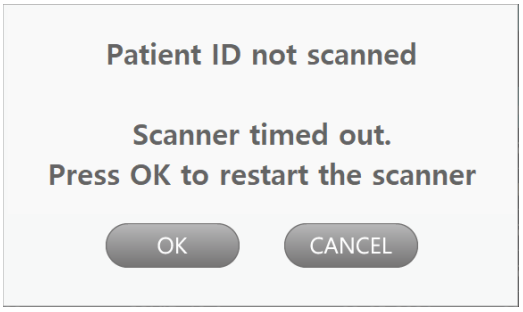

[Fig. 21] Screen after selection of Run Test

If user selects **[COVID-19 IgG/IgM]**, screen will be changed for patient's ID scan like [Fig. 22]
User can scan or input new patient's ID, also user can select existing patient's ID from list to proceed test.



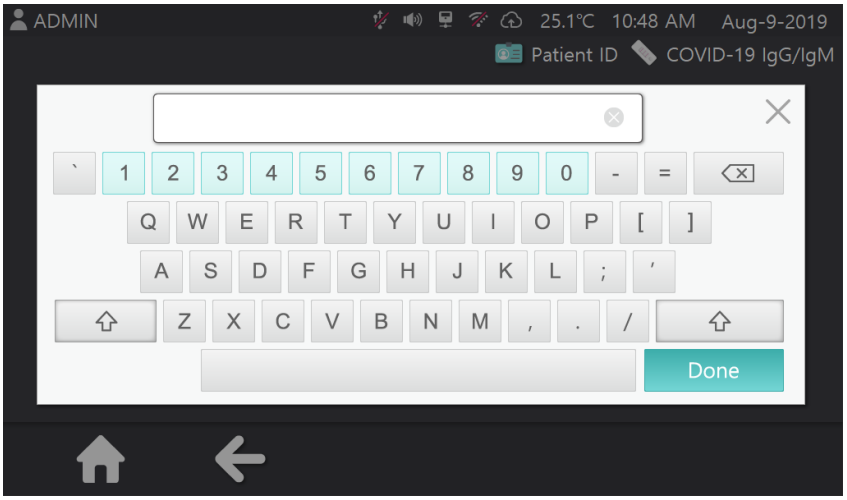

[Fig. 22] Scan Patient ID screen

① By using barcode reader at the right side of equipment, user can scan patient's ID directly. Like above figure, attach the barcode to reader.
* If user didn't scan barcode in the limited time, the warning message is popped up like below [Fig.23]



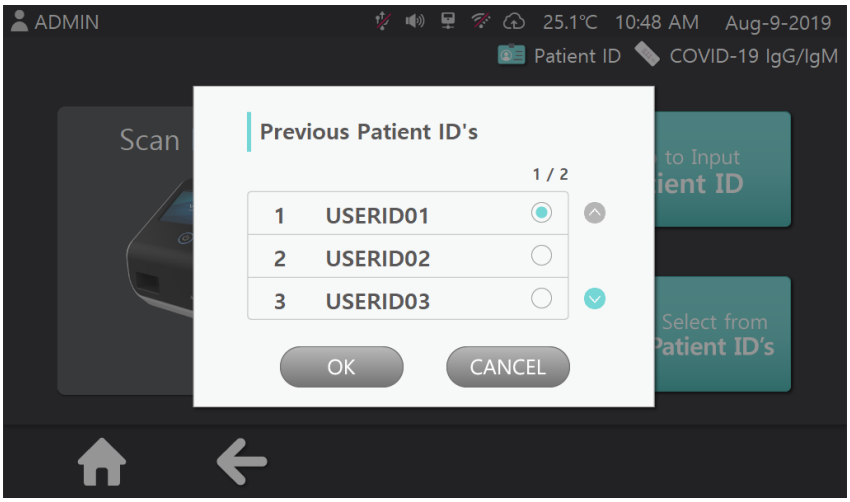

[Fig. 23] pop up message for barcode scanning failure

② To input new patient's ID, press **[Tap to Input New Patient ID]** button. The screen will be changed like [Fig. 24], then type patient's ID.

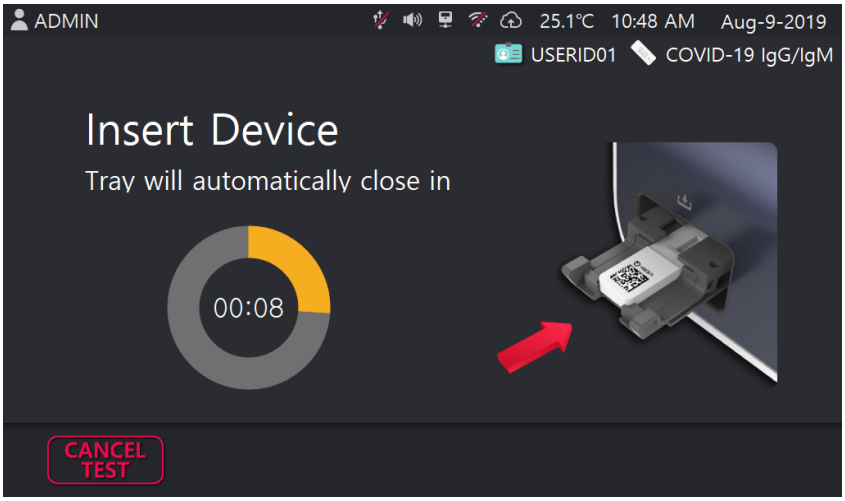



[Fig. 24] The pop up image when user press [Tap to Input New Patient ID] button

③ Press **[Tap to Select from Previous Patient ID's]** button, then select existing patient's ID and press **[OK]** button (See [Fig. 25]).



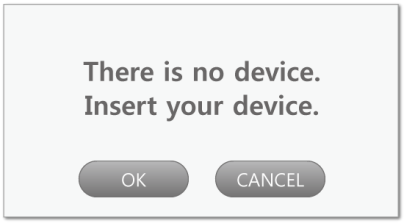

[Fig. 25] The pop up image when user press [Tap to Select From Previous Patient ID's]




[Fig. 26] scan device screen

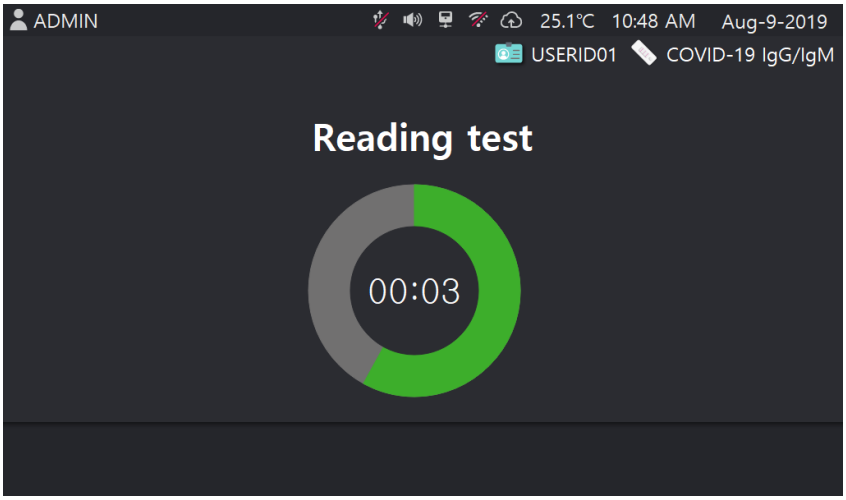
Like [Fig. 26], insert device into equipment. Device's inlet should be located inside, thus inserted first. Then, equipment will aware device.

*If user do not insert device in limited time, the warning message will be popped up like [Fig. 27]



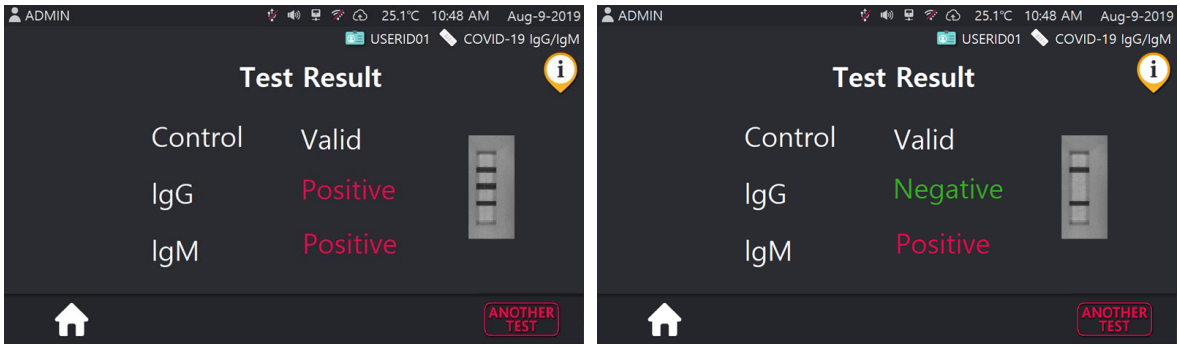

[Fig. 27] pop up message for device scanning failure

If user presses "OK" button, equipment will scan the device again. However presses "Cancel" button, screen will be changed for home screen like [Fig. 9]. If device scanning is done successfully, test will be done and screen will be changed like [Fig. 28]




[Fig. 28] Reading test screen

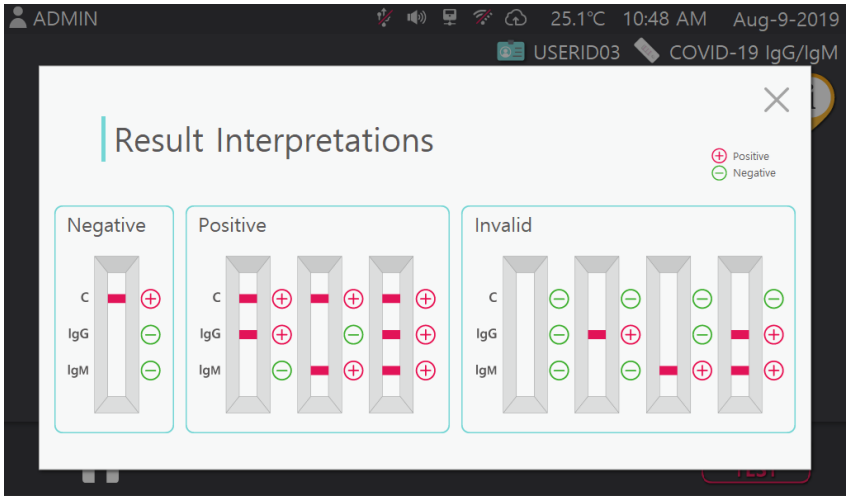
The test is being done for 8 seconds, and then results will be displayed like [Fig.29] / [Fig. 30].




[Fig. 29] Result – Positive screen


[Fig. 30] Result - Negative screen

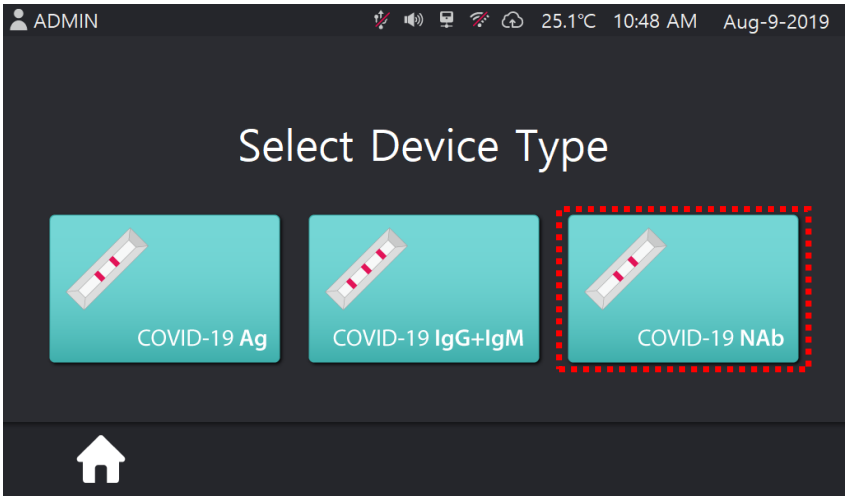
[Fig.30] By pressing icon, user can check the result and see the interpretations (See [Fig. 31]).




[Fig. 31] Result Interpretations screen

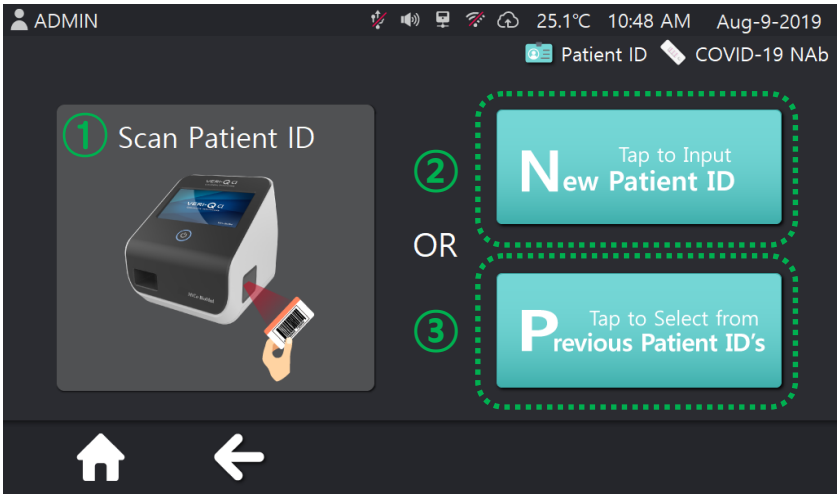
### 3.2.7 Run Test – COVID-19 NAb

If user selects **[Run Test]** menu in home screen, the screen will be changed like below [Fig. 32]
* In case of barcode mode, skip this **[Select Device Type]** step
In this screen, user can select one of **[COVID-19 Ag]**, **[COVID-19 IgG/IgM]** & **[COVID-19 NAb]**




[Fig. 32] Screen after selection of Run Test

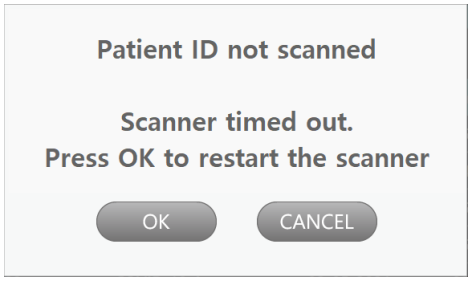
If **[COVID-19 NAb]** selected, screen is changed like [Fig. 33] which shows patient's ID scan menu. Through these menus, user can input new patient ID or select existing patient's ID for test




[Fig. 33] Scan Patient ID screen

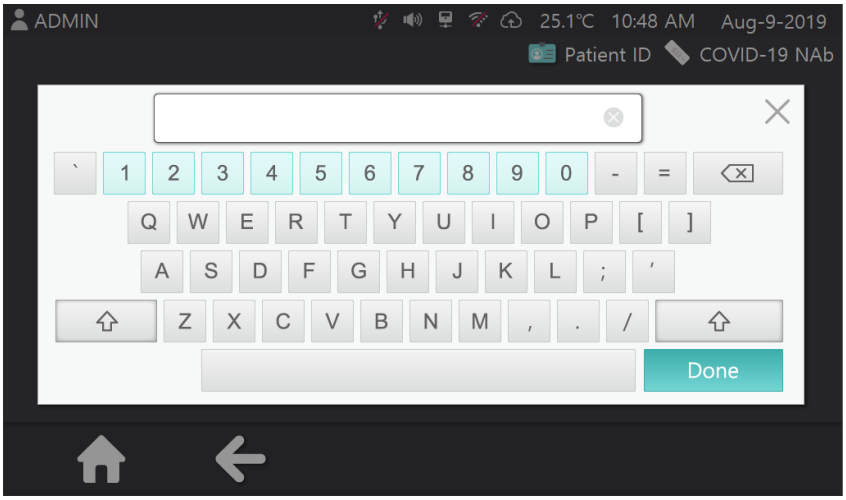
① By using barcode reader at the right side of equipment, user can scan patient's ID directly. Like above figure, attach the barcode to reader.

* If user didn't scan barcode in the limited time, the warning message is popped up like below [Fig.33]



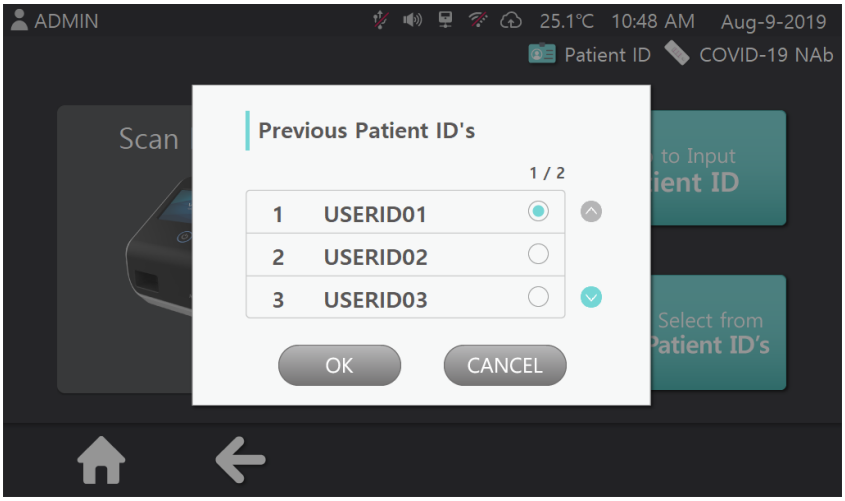

[Fig. 34] pop up message for barcode scanning failure

② To input new patient's ID, press **[Tap to Input New Patient ID]** button. The screen will be changed like [Fig. 35], then attach barcode to barcode reader at the right side of equipment. Equipment will aware the barcode.

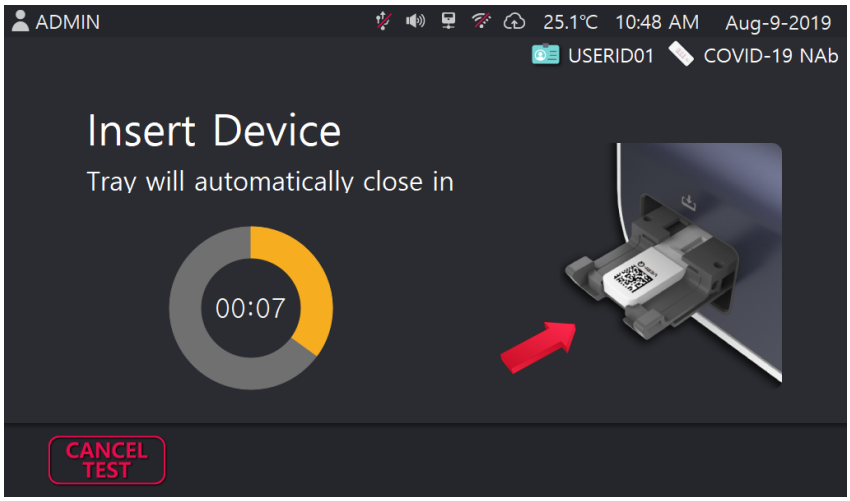



[Fig. 35] The pop up image when user press [Tap to Input New Patient ID] button

③ Press **[Tap to Select from Previous Patient ID's]** button, then select existing patient's ID and press **[OK]** button (See [Fig. 36]).



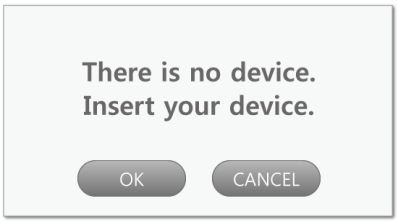

[Fig. 36] The pop up image when user press [Tap to Select From Previous Patient ID's]




[Fig. 37] scan device screen

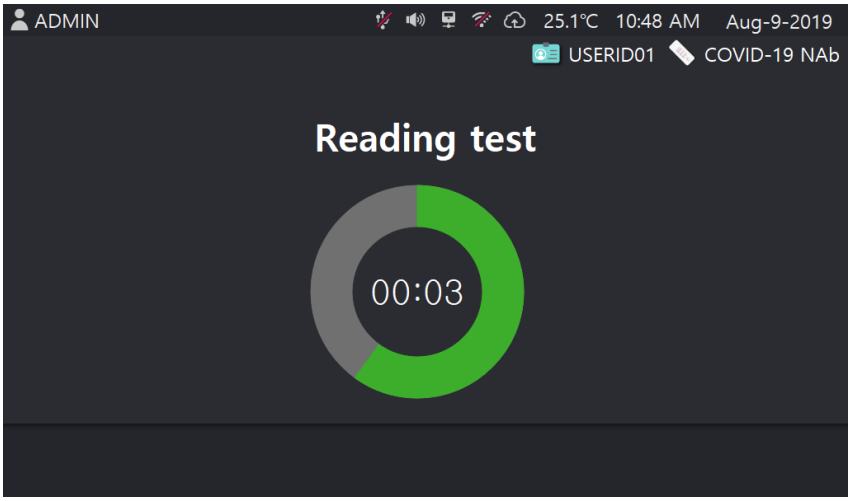
Like [Fig. 37], insert device into equipment. Device's inlet should be located inside, thus inserted first. Then, equipment will aware device.

*If user do not insert device in limited time, the warning message will be popped up like [Fig. 38]



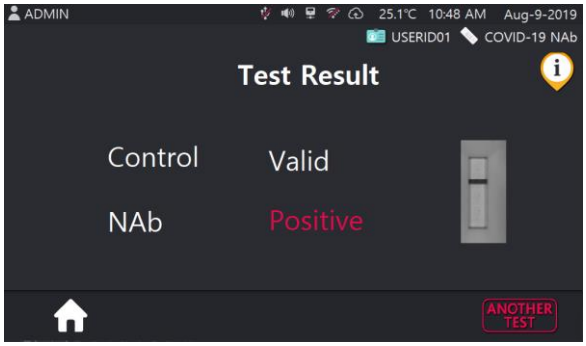

[Fig. 38] pop up message for device scanning failure

If user presses "OK" button, equipment will scan the device again. However presses "Cancel" button, screen will be changed for home screen like [Fig. 9]. If device scanning is done successfully, test will be done and screen will be changed like [Fig. 39]




[Fig. 39] Reading test screen

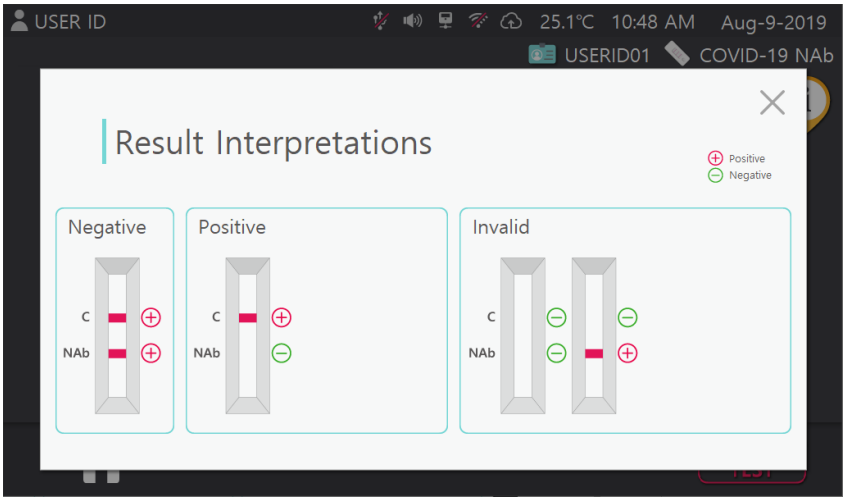
The test is being done for 8 seconds, and then results will be displayed like [Fig. 40] / [Fig. 41].




[Fig. 40] Result – Positive screen

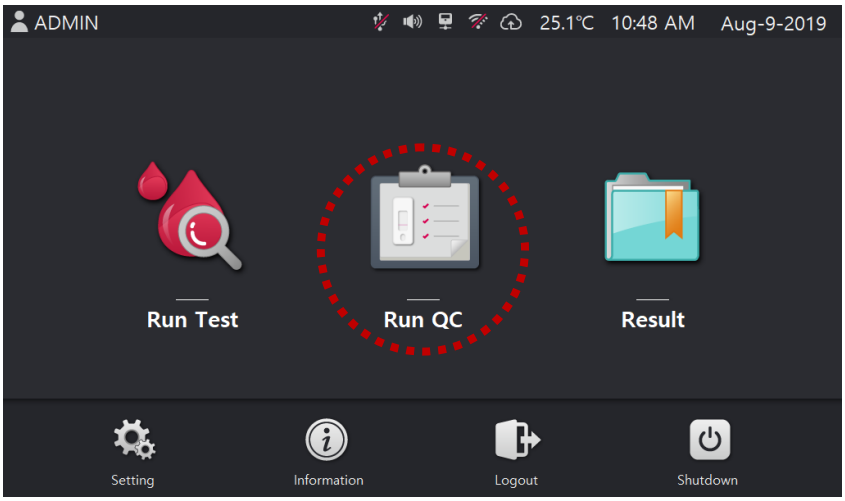

[Fig. 41] Result Negative screen

[Fig. 41] By pressing  icon, user can check the result and see the interpretations (see [Fig. 42]).



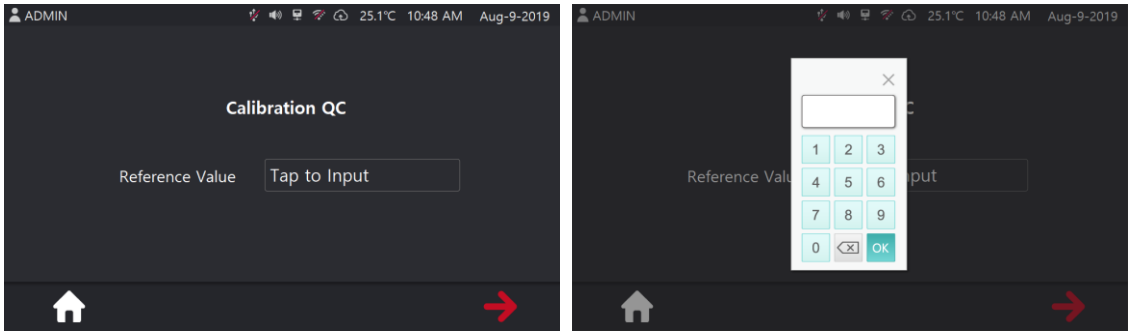

[Fig. 42] Result Interpretations screen

### 3.2.8 Run QC – Reference Device(High)



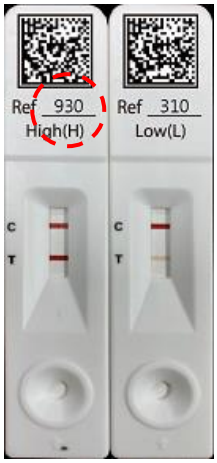

[Fig. 43] Home screen

In home screen (see [Fig. 43]), if user selects **[Run QC]** menu, screen is changed like [Fig. 44] Touch the "Tap to Input" to input reference value, then keypad will be popped up.

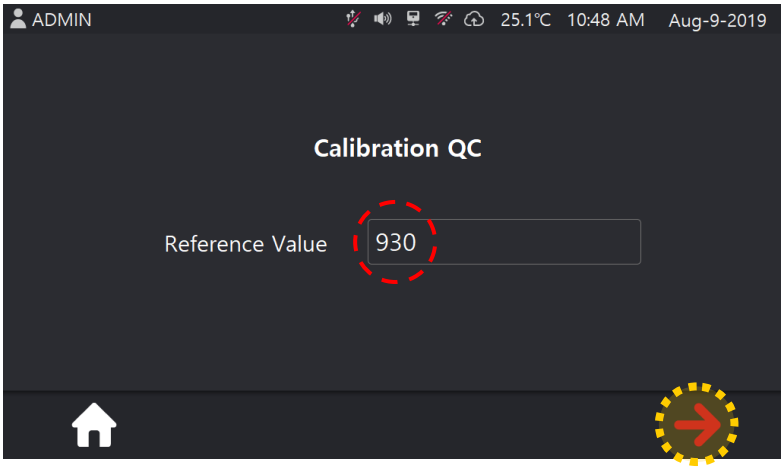



[Fig. 44] Clibaration QC screen

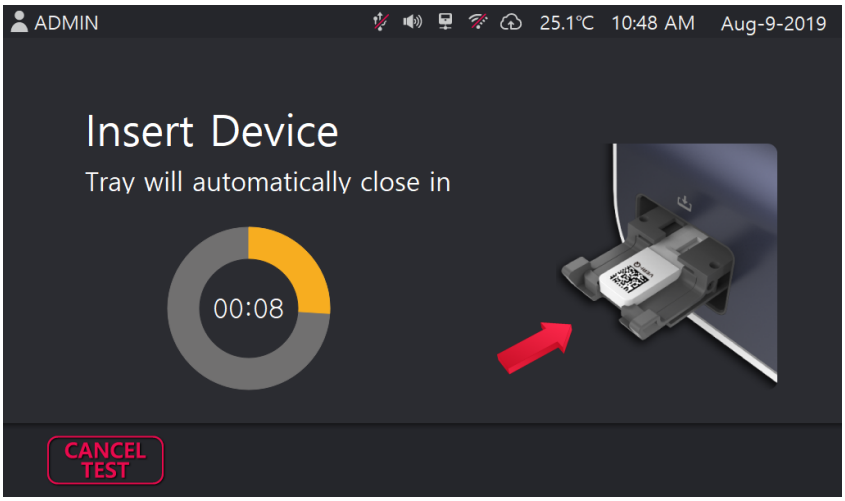
Input QC Ref value of Device(High)(see [Fig. 45]), then touch the arrow image at the right bottom.




[Fig. 45] QC Reference Device



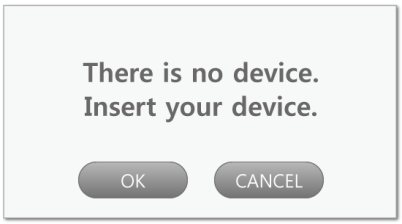

[Fig. 46] Input QC Reference value




[Fig. 47] Insert Device screen

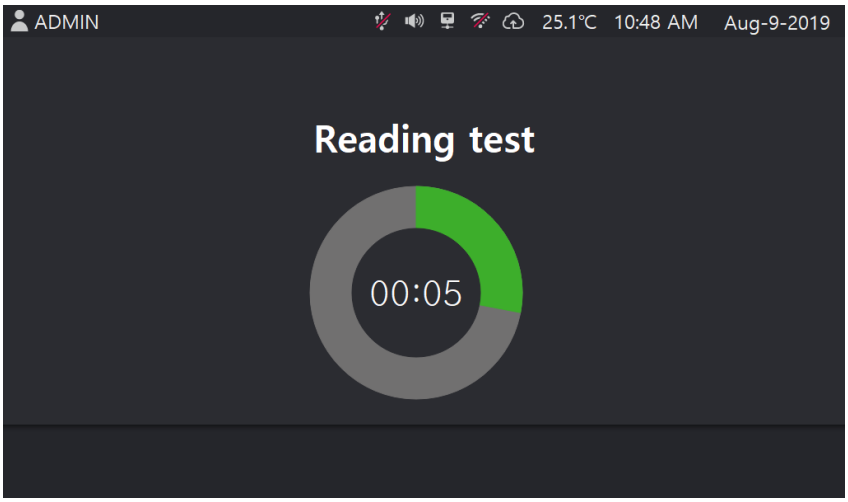
[Fig. 47] Insert QC Reference Device (High) into equipment. Device's inlet should be located inside, thus inserted first. Then equipment reads device.

* If user do not insert device in the limited time, warning message will be popped up like [Fig. 48]




[Fig. 48] pop up message for warning

If user selects "OK" button, equipment reads device again. On the other hand, selects "CANCEL" button, screen is changed for home screen. And if equipment successes to read device, it starts test.




[Fig. 49] Reading test screen

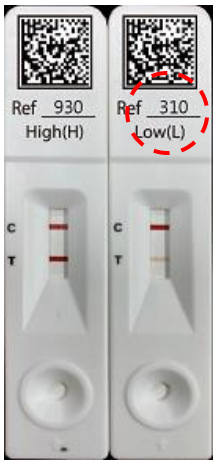
[Fig. 49] After 5 seconds, QC result (PASS or FAIL) will be displayed (see [Fig. 50], [Fig.51]).


[Fig. 50] QC Result – PASS

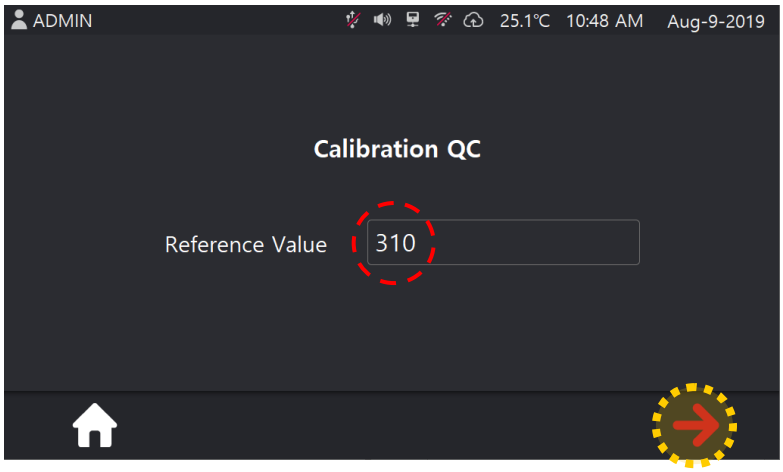

[Fig. 51] QC Result – FAIL

### 3.2.9 Run QC – Reference Device(Low)

After check of QC result of Reference Device(High), select **[RUN QC]** menu in the home screen.

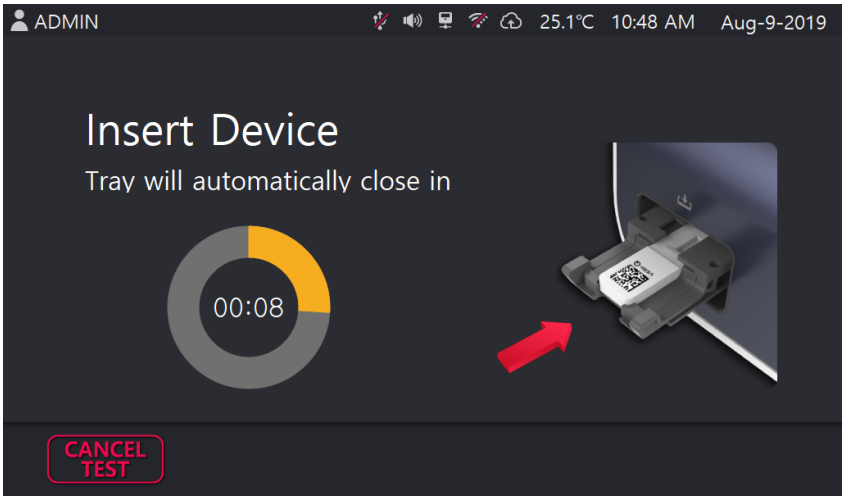



[Fig. 52] QC Reference Device




[Fig. 53] Input QC Reference Value

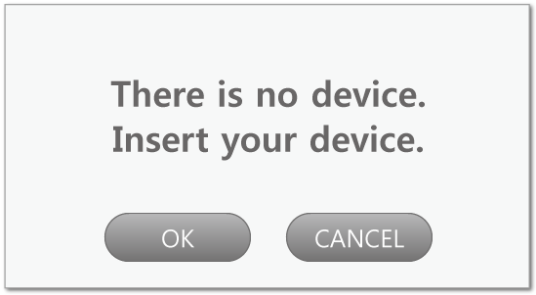
Input QC Ref value of Device(Low)(see [Fig. 52]), then touch the arrow image at the right bottom.




[Fig. 54] Insert Device screen

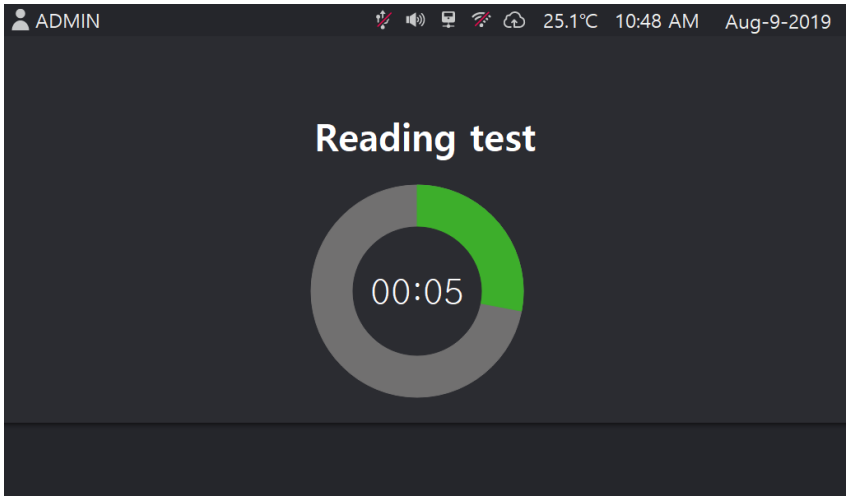
[Fig. 54] Insert QC Reference Device (Low) into equipment. Device's inlet should be located inside, thus inserted first. Then equipment reads device.

* If user do not insert device in the limited time, warning message will be popped up like [Fig. 55]




[Fig. 55] pop up message for device scanning failure

If user selects "OK" button, equipment reads device again. On the other hand, selects "CANCEL" button, screen is changed for home screen. And if equipment successes to read device, it starts test (see [Fig. 56]).




[Fig. 56] Reading test screen

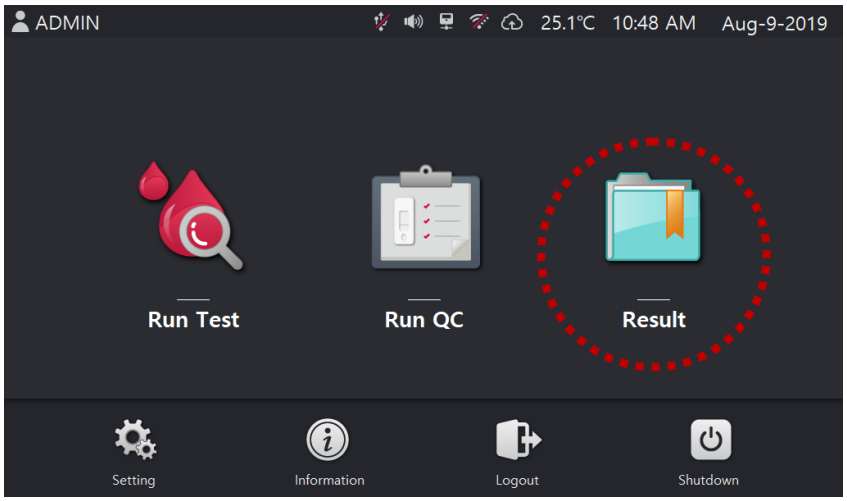
After 5 seconds, QC result (PASS or FAIL) will be displayed (see [Fig. 57], [Fig.58]).


[Fig. 57] QC Result – PASS


[Fig. 58] QC Result – FAIL

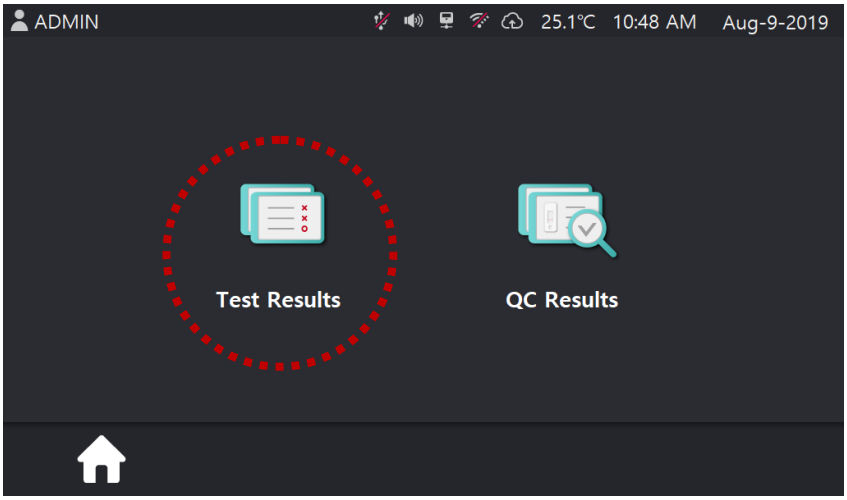
### 3.2.10 Result – Test Result

[Fig. 59] In home scree, if user selects **[Result]**, screen is changed like [Fig. 60]



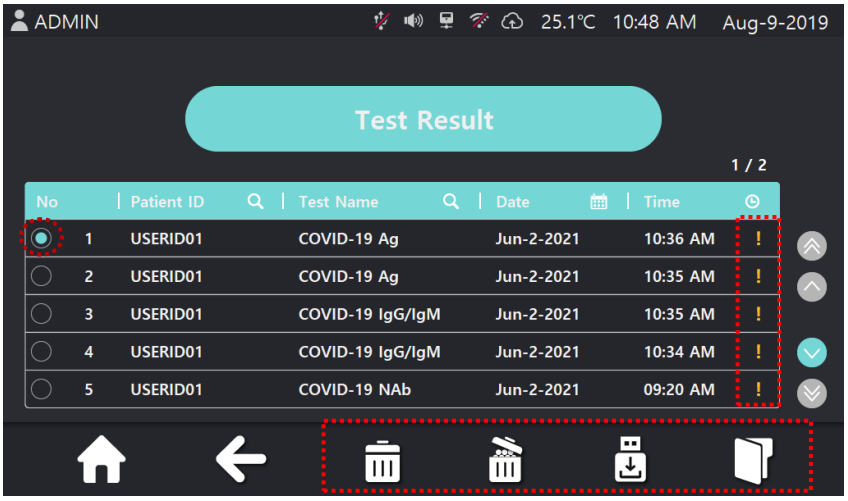

[Fig. 59] Home screen

In this screen, user can review **[Test Result]** and **[QC Result].**




[Fig. 60] Screen after selection of [Result]

If user selects **[Test Results]** menu in the screen of [Fig. 60], screen is changed and user can review test results like [Fig. 61].




[Fig. 61] Test Result screen

Item selection

Transmission to USB

Removal of selected item

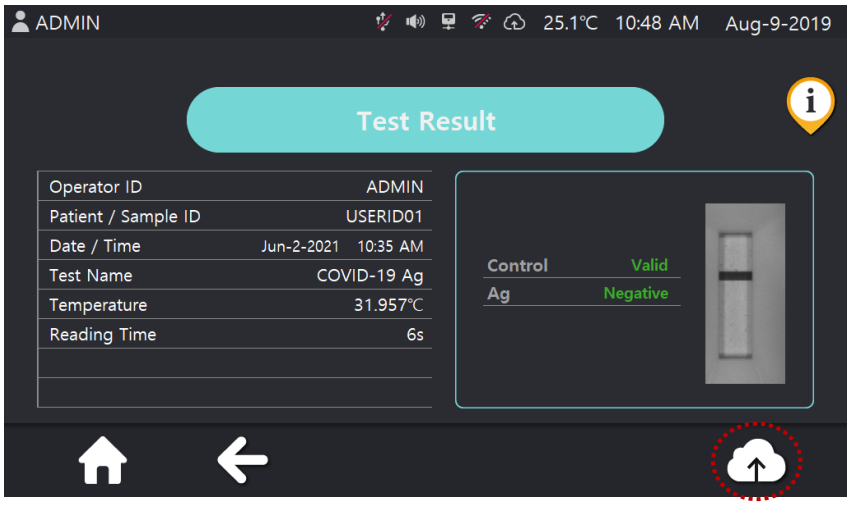
File opening

Removal of all items

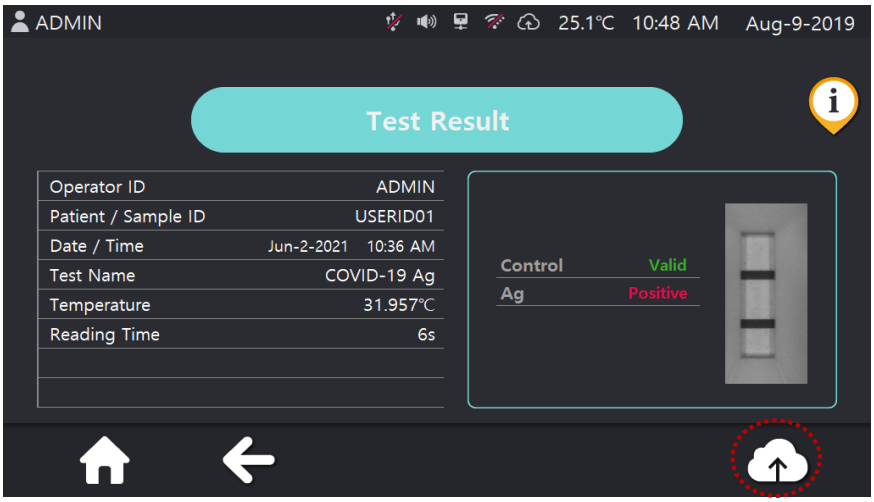
Status of upload to cloud

In the screen of [Fig. 61], user can check detailed result by selecting patient ID and touching button.

In case of fail to upload the results after Run Test or Run QC, image will be shown on right end of each item. (see [Fig. 61]) In the screen of [Fig. 62] [Fig. 63], user can upload the results to the cloud server manually using upload button on right bottom side.

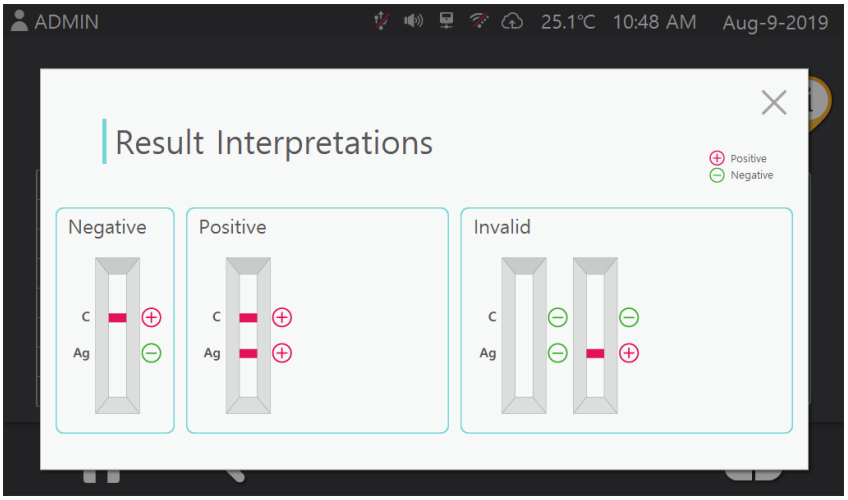



[Fig. 62] TEST Data Result(Negative)

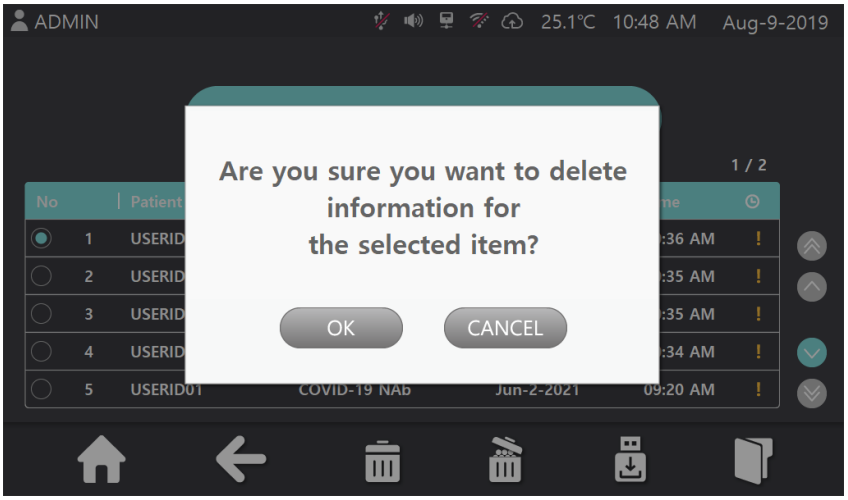



[Fig. 63] TEST Data Result(Positive)

By touching icon, user can see the result interpretation like [Fig. 64]

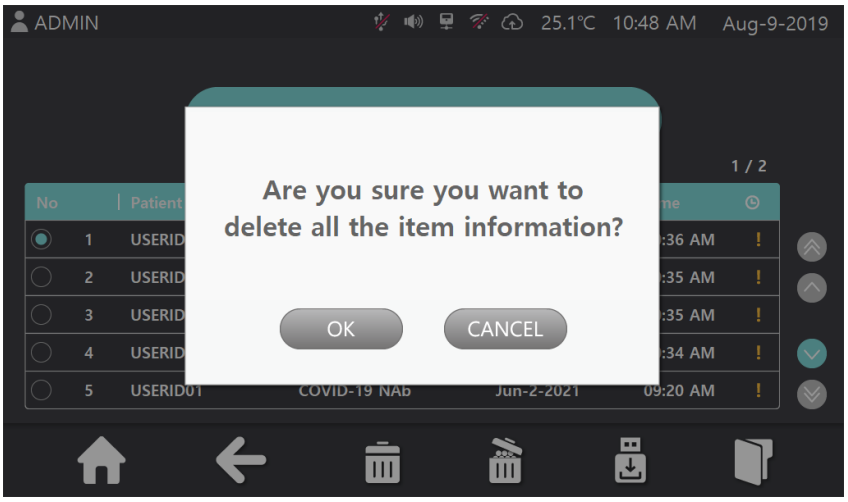



[Fig. 64] Result Interpretations screen



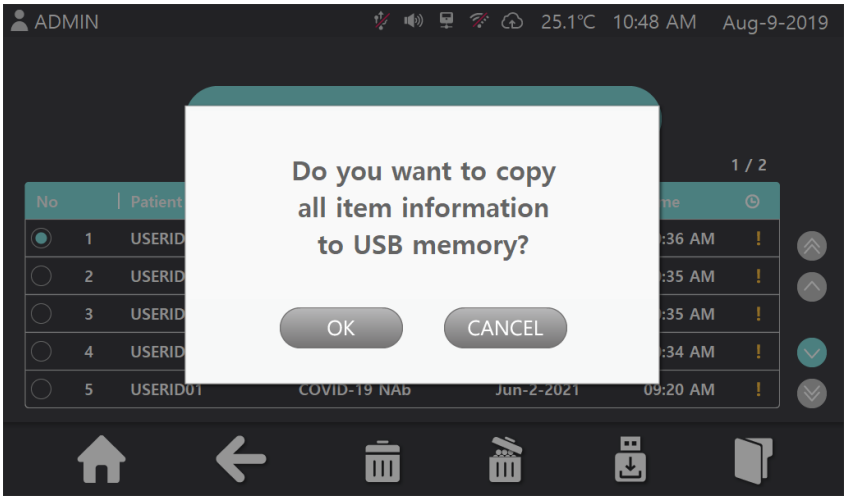

[Fig. 65] pop up image for removal of selected item

In the screen of [Fig. 61], user can remove an item by selecting patient ID and touching  image. Then, Image will be popped up like [Fig. 65]. The item will be removed if user select "OK" button.




[Fig. 66] pop up image for removal of all items

In the screen of [Fig. 61], if user selects  image, the warning message will be popped up like [Fig. 66]. And when user selects "OK" button, every item will be removed in the list.

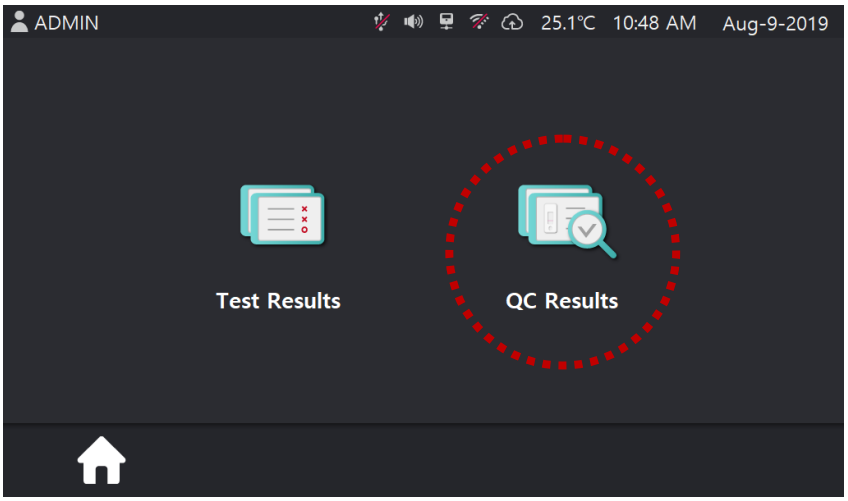



[Fig. 67] pop up image for transmission to USB

In the screen of [Fig. 61], if user selects  image, the message will be popped up like [Fig. 67]. And if user selects "OK" button, every item will be transmitted to USB in the list.

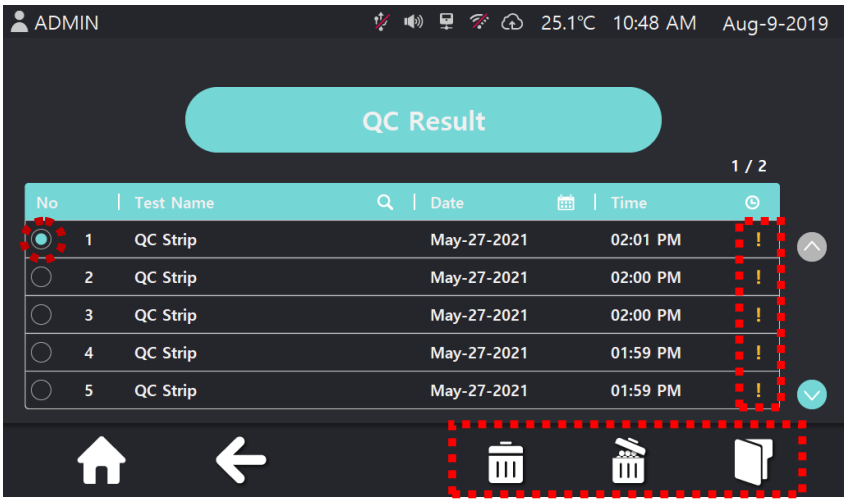
### 3.2.11 Result – QC Result

In home scree, if user selects **[Result]**, screen is changed like [Fig. 68]




[Fig. 68] Screen after selection of [Result]

If user selects **[QC Result]** menu in the screen of [Fig. 68], screen is changed and user can review QC results like [Fig. 69].




[Fig. 69] QC Result screen

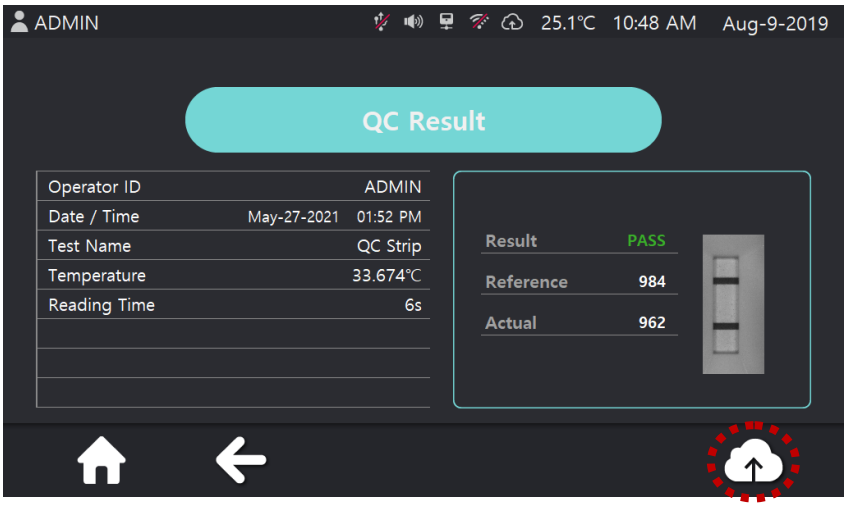
Item selection

File opening

Removal of selected item

Status of upload to cloud

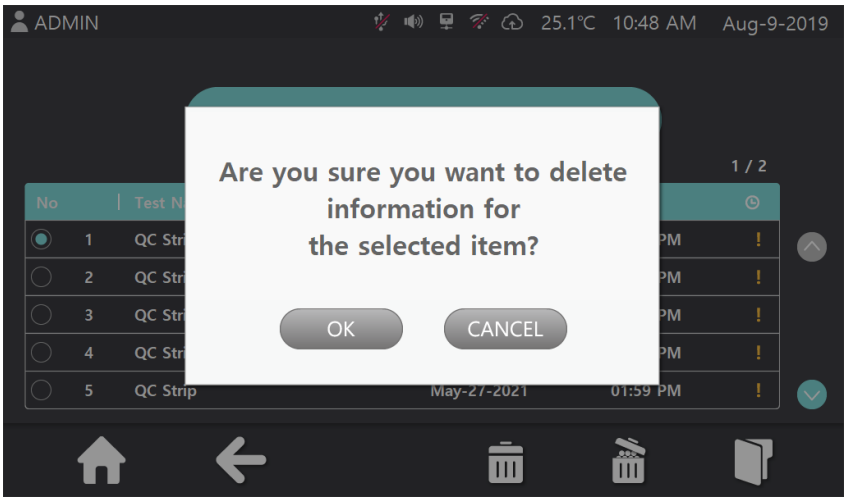
Removal of all items




[Fig. 70] QC result screen

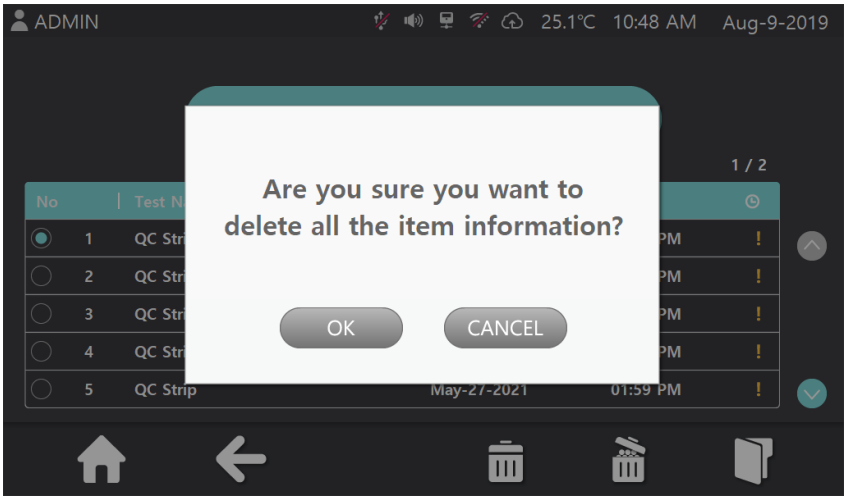
In the screen of [Fig. 69], by selecting test name and touching button, user can review detailed QC result.

In case of fail to upload the results after Run QC, image will be shown on right end of each item. (see [Fig. 69]) In the screen of [Fig. 70], user can upload the results to the cloud server manually using upload button on right bottom side.




[Fig. 71] pop up image for removal of selected item

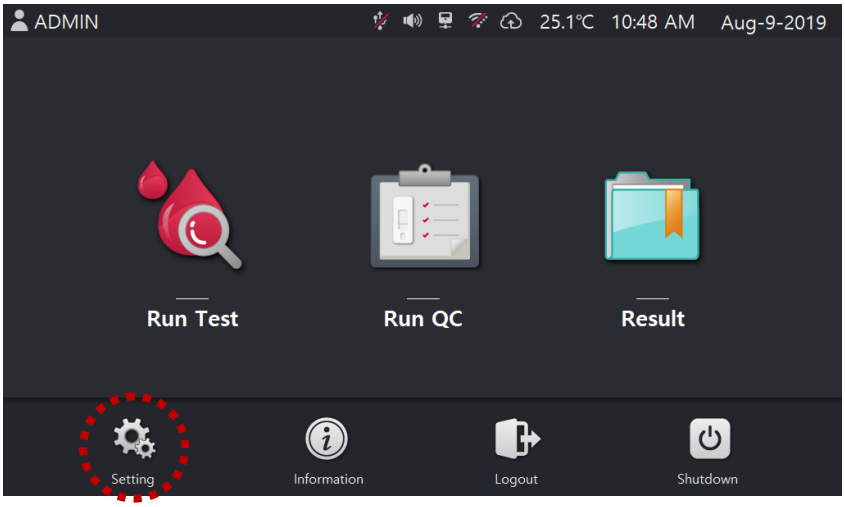
In the screen of [Fig. 69], user can remove an item by selecting test name and touching image. Then, Image will be popped up like [Fig. 71]. The item will be removed if user select "OK" button.




[Fig. 72] pop up image for removal of all items

In the screen of [Fig. 69], if user selects  image, the warning message will be popped up like [Fig. 72]. And if user selects "OK" button, every item will be removed in the list.

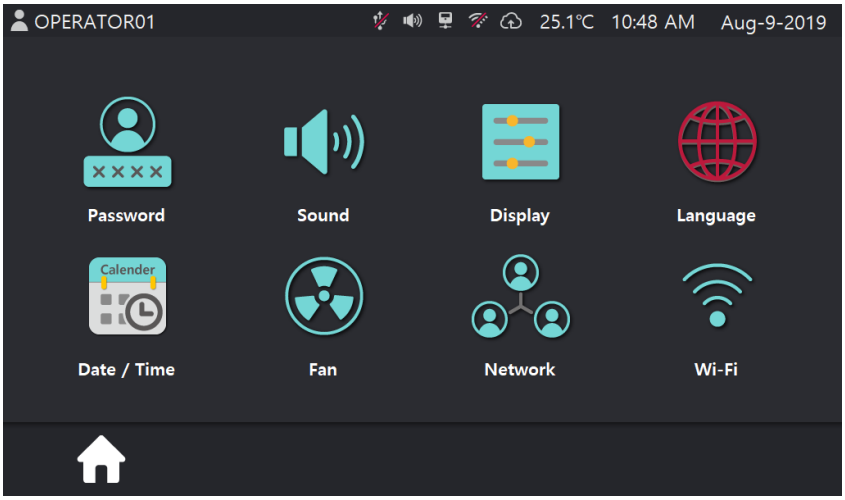
### 3.2.12 Setting



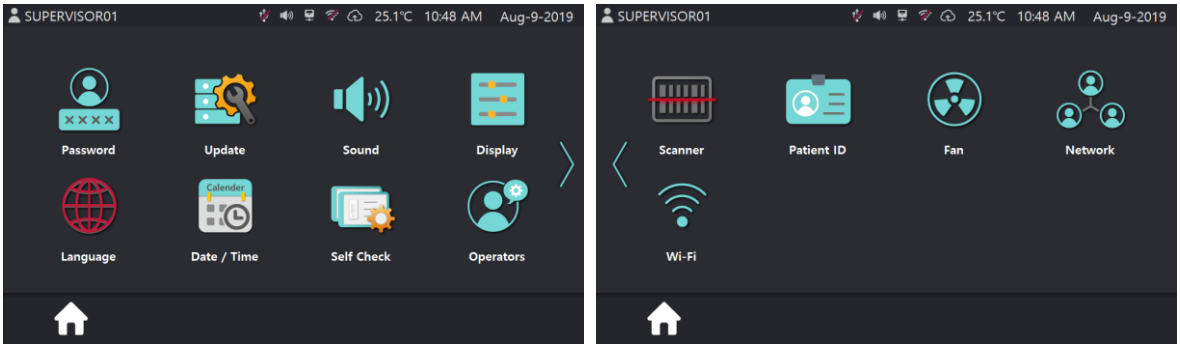

[Fig. 73] Home screen

In the screen of [Fig.73], if user selects **[Setting]** button, setting screen will be displayed and it will be show the items differently depends on login authority.

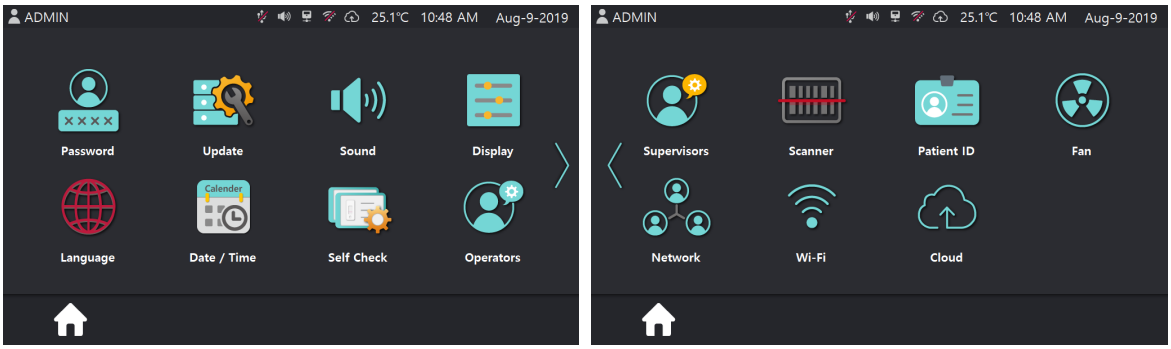
It has 3 authority and the screen for each permission is like below [Fig. 74], [Fig. 75] & [Fig 76]




[Fig. 74] Setting page (In case of operator login)

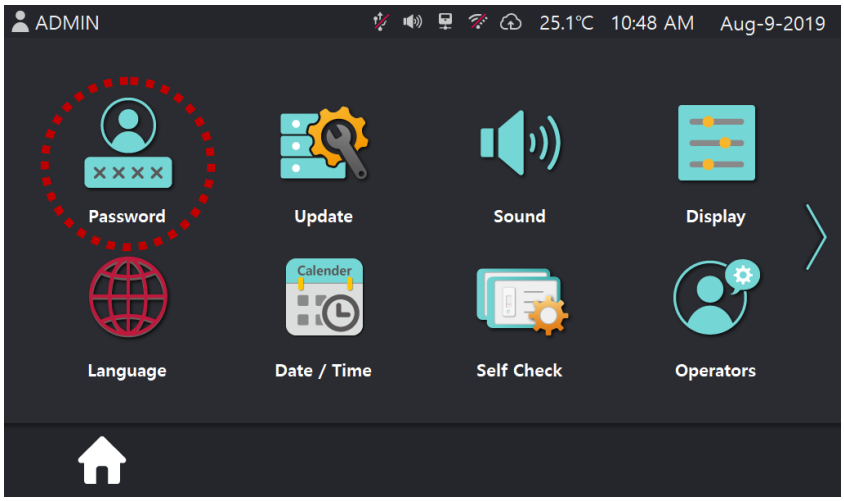



[Fig. 75] Setting pages (In case of supervisor login)



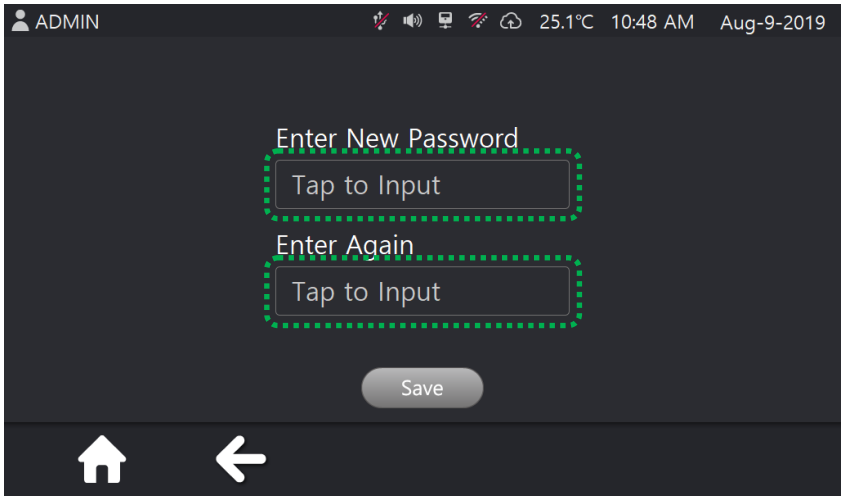

[Fig. 76] Setting pages (In case of admin login)

**1)** Setting – Password




[Fig. 77] Setting page 1

To change password, press the **[Password]** button in [Fig.77], then screen is changed and user can change password.

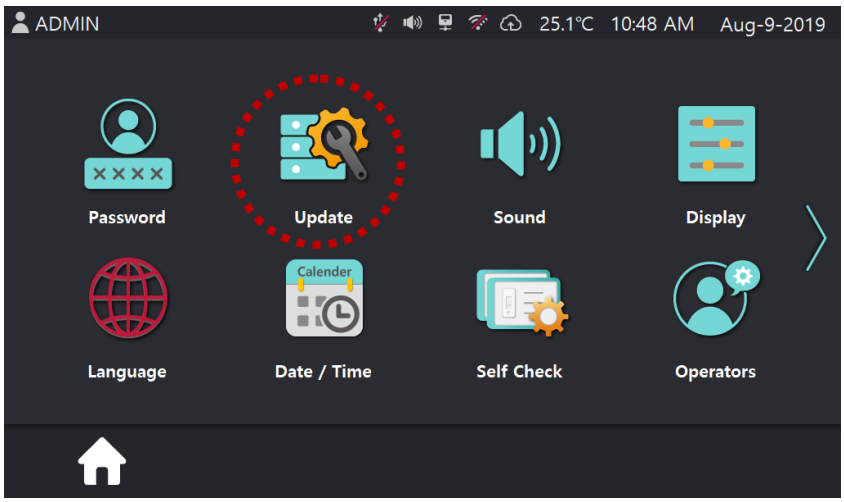



[Fig. 78] New Password screen

Select text box and use keyboard in [Fig. 78] to input password, then press **[Save]** button to save.

[Fig. 79] Keyboard

**2)** Setting – Update

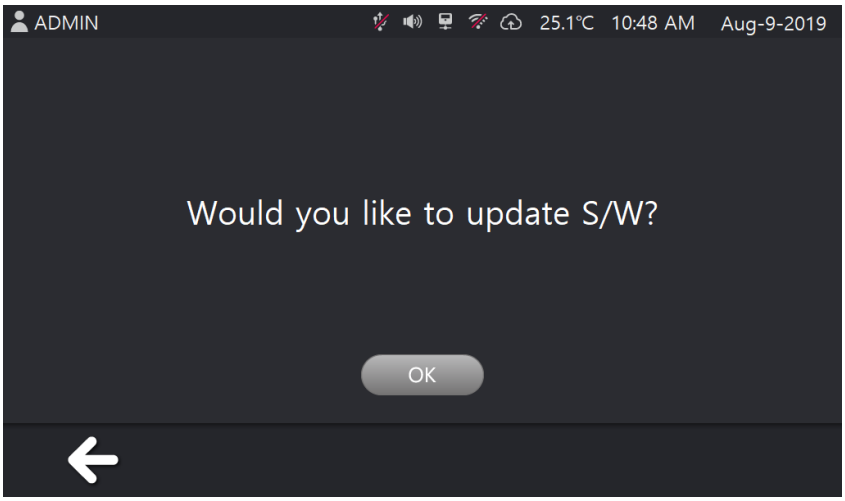



[Fig. 80] Setting page 1

In the setting page 1, user can upgrade software and firmware by touching **[Update]** button. If do so, screen is changed like [Fig. 81]. And there is two menu for **[S/W Update]** and **[F/W Update]**

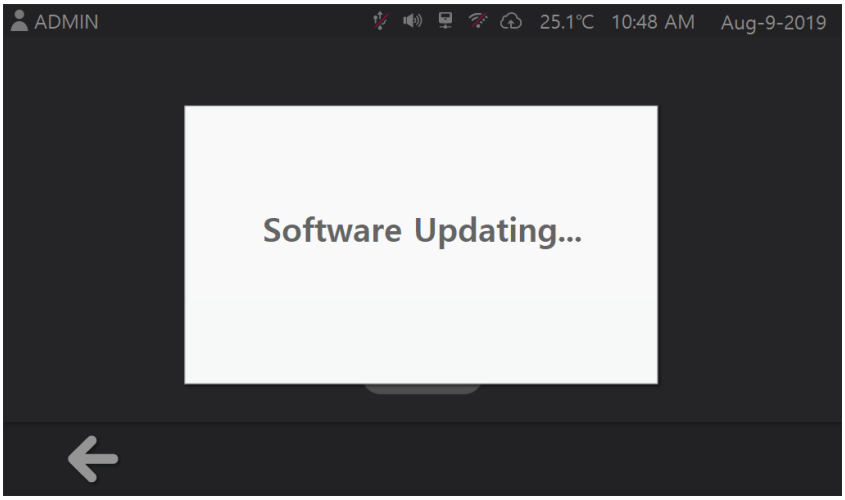

[Fig. 81] Update page

① If selects **[S/W Update]** button, screen is changed and asks that user wants to update software.

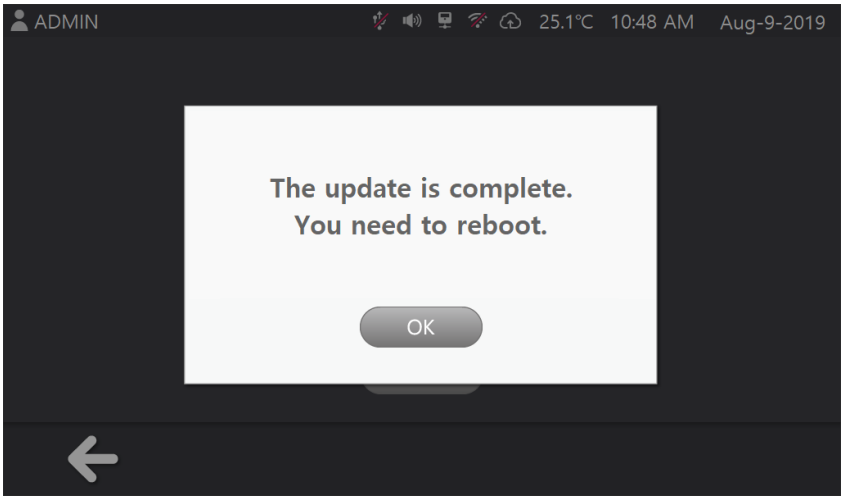



[Fig. 82] S/W Update confirmation screen

Software will be updated when user selects **[OK]** button.



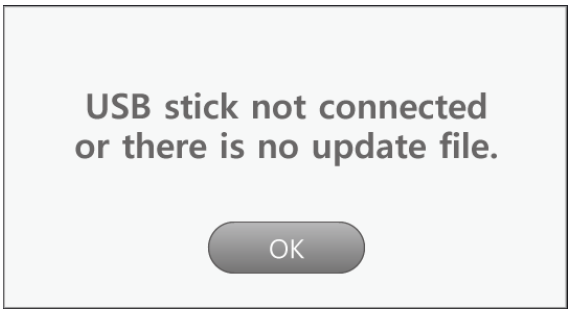

[Fig. 83] S/W Updating screen




[Fig. 84] S/W Update complete screen

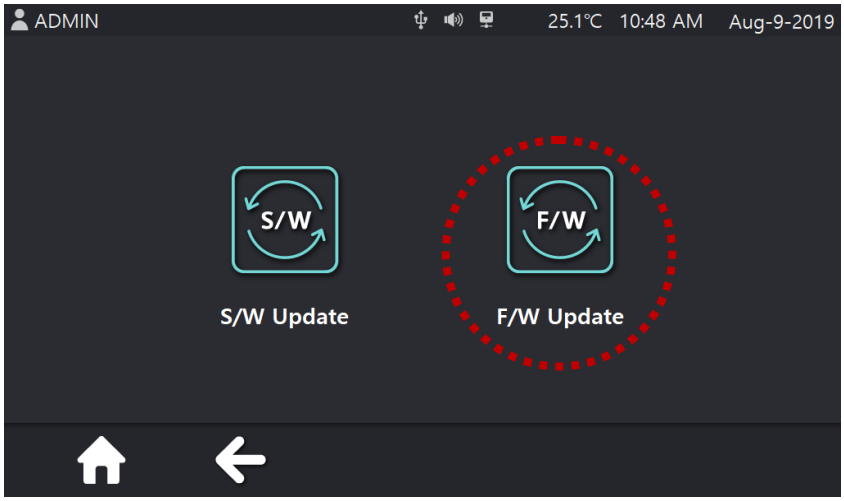
If software update is done, pop up image will be displayed. And equipment will be turned off when user touches [OK] button.

* If there is no file for update or USB stick is not connected, warning message will be popped up like [Fig. 85]




[Fig. 85] S/W Update Pop-up

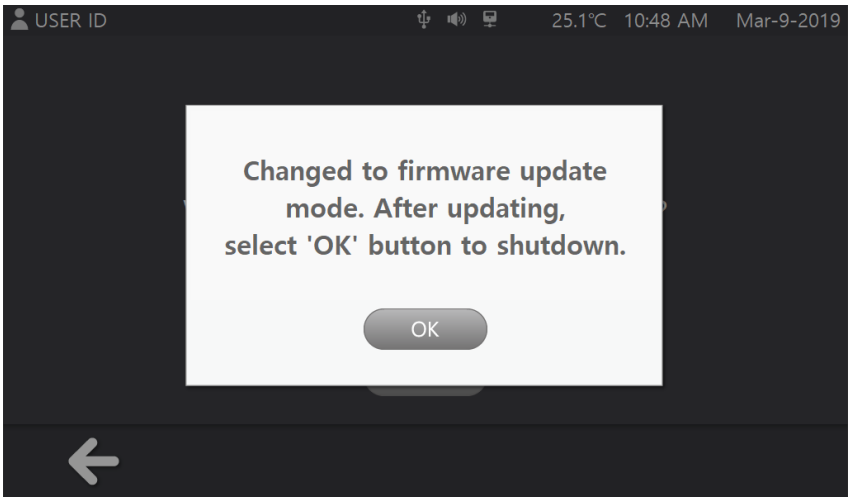
② To update F/W, user should connect PC and equipment by using USB A to B cable.




[Fig. 86] Update page

Select [F/W Update] button in the update page, then message will be popped up like [Fig. 87]. And update sequence will be being done.

*Before complete F/W update, do not press [OK] button. Unless updated will be canceled and equipment will be shut down. Press [OK] button only after F/W update is completed.




[Fig. 87] Update page

F/W update will be done through the PC program named "Flash Loader Demonstrator".


[Fig. 88] Device Manager

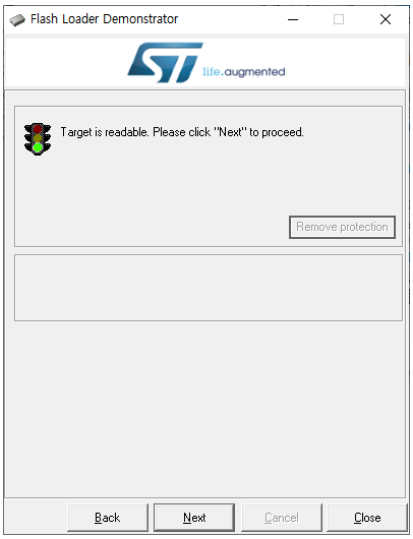
Before update, check the connected USB port in the PC. It should be the same as [Fig. 76].

*The connected port number may be different.


[Fig. 89] Flash Loader Demonstrator Program

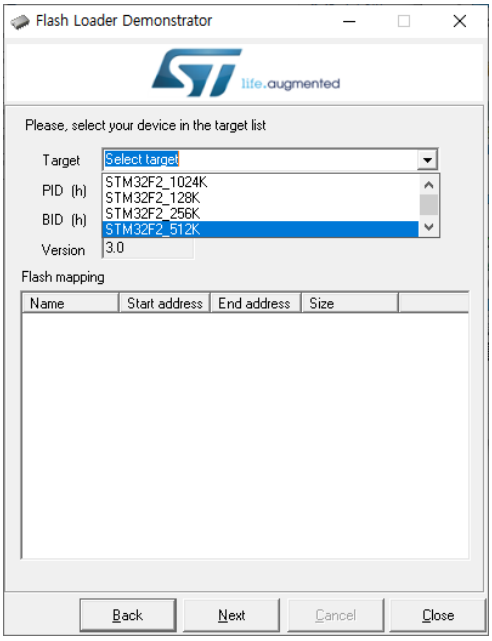
Execute "Flash Loader Demonstrator" and select Port Name as "COM3", then press [Next].

*Port Name must be the same as port number.



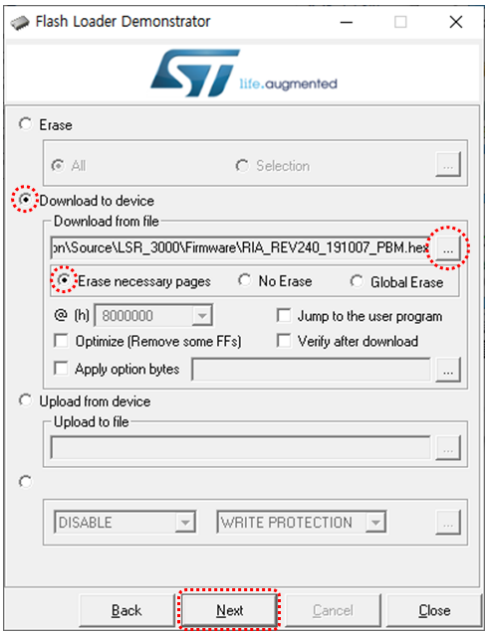

[Fig. 90] Flash Loader Demonstrator Program

Press [Next].




[Fig. 91] Flash Loader Demonstrator Program

Select target as [STM32F2_512K], then press [Next].

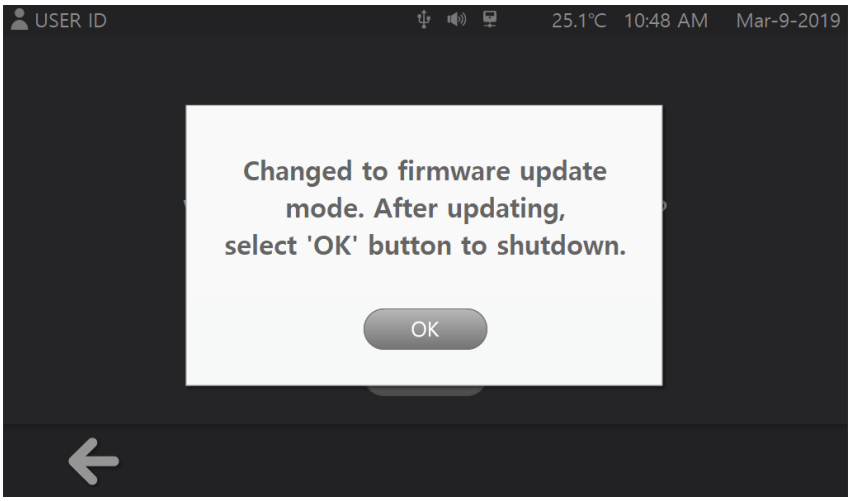



[Fig. 92] Flash Loader Demonstrator Program

Select [Download to Device], then click [...] box – Select file named as [oooooooo.hex] – Select [Erase necessary pages] – Press [Next].

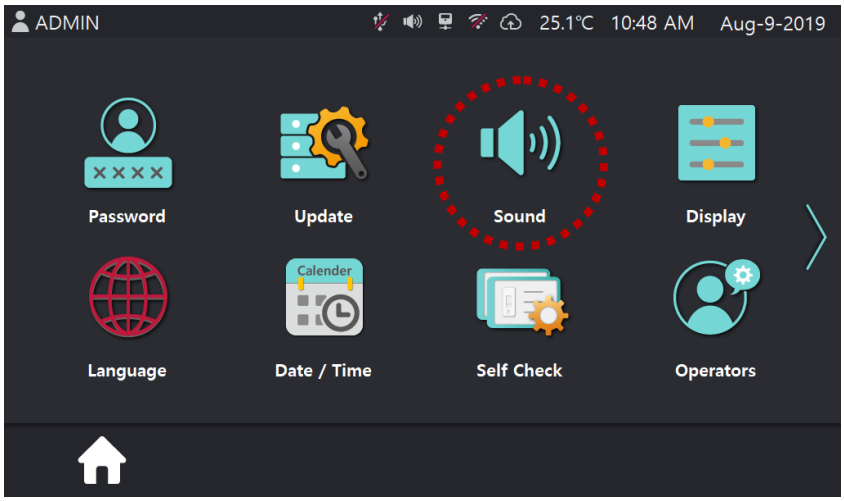

[Fig. 93] Flash Loader Demonstrator Program

If Update is completed, image will be changed like [Fig. 93]. Press [Close] button and touch the [OK] button of update page.




[Fig. 94] Update page

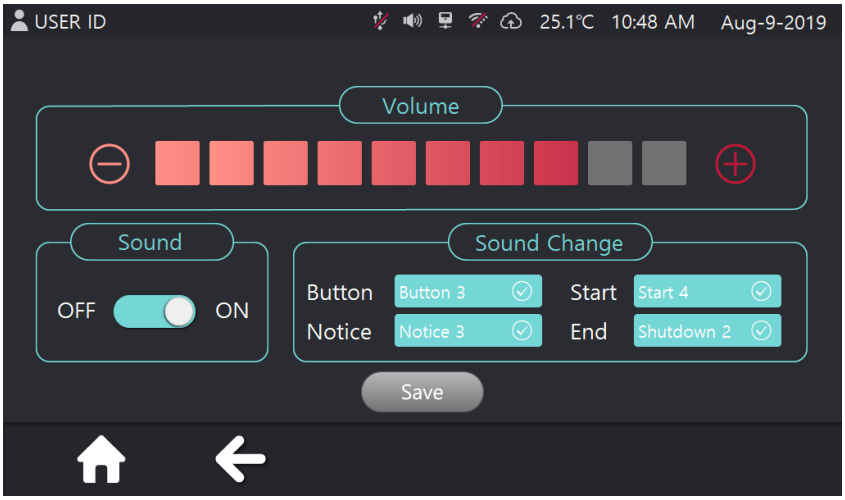
### 3) Setting – Sound




[Fig. 95] Setting page 1

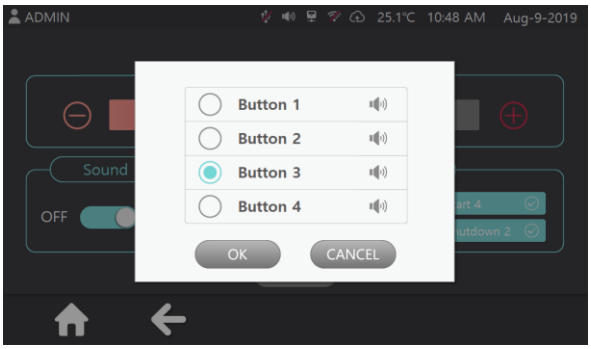
In the Setting page 1, select **[Sound]** button, then screen is changed like [Fig. 96].

By using ⊖ and ⊕ buttons, user can control sound volume. And turn on or off the sound through **[ON/OFF]** button.

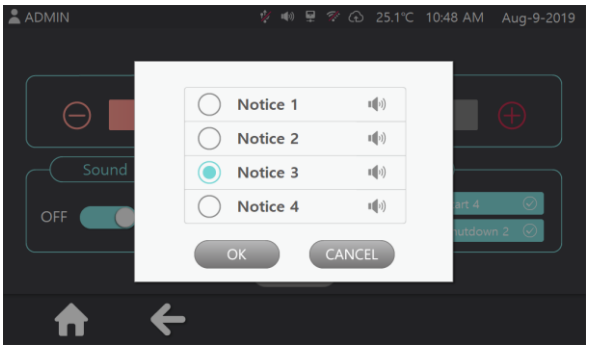



[Fig. 96] Sound Setting page

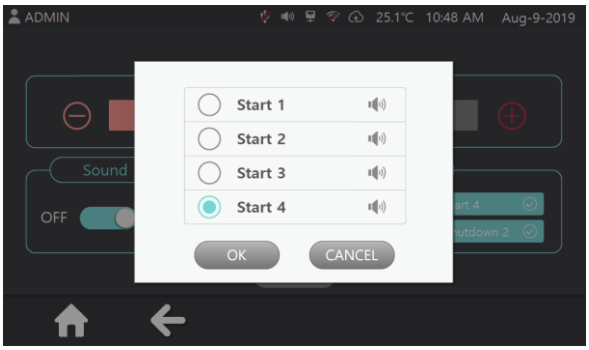
[Button], [Notice], [Start] and [End] buttons have their own pop up image like below.



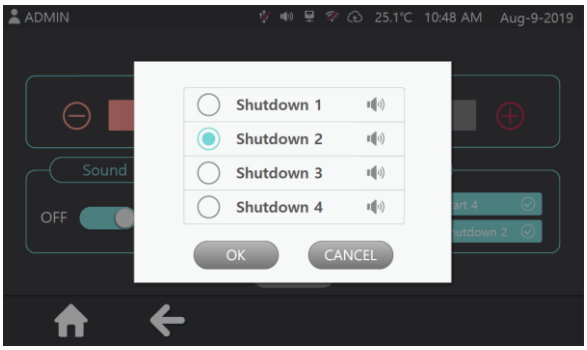

[Fig. 97] Button sound




[Fig. 98] Notice sound



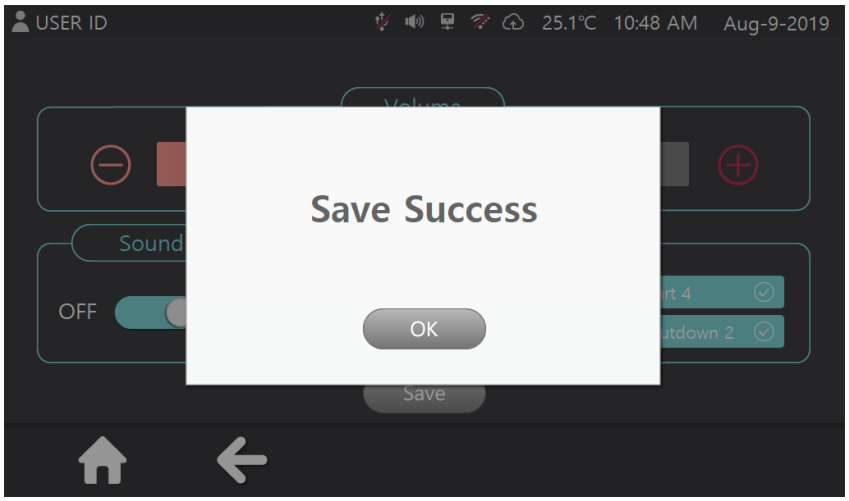

[Fig. 99] Start sound




[Fig. 100] End sound

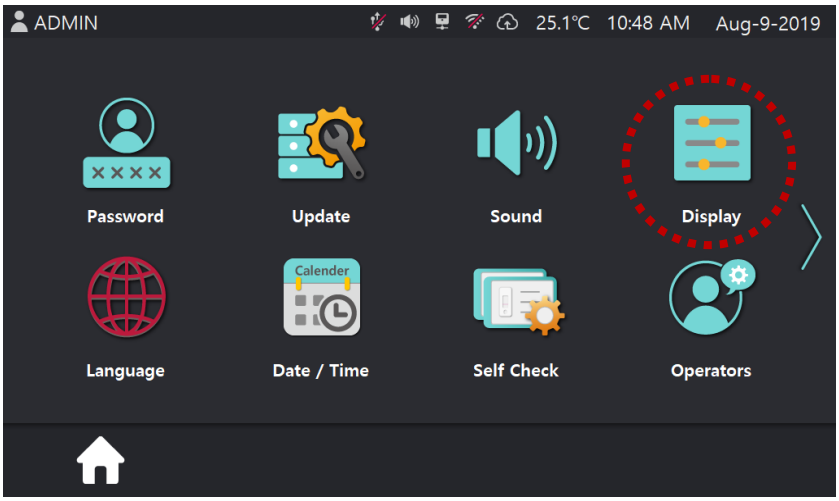
[Fig. 97] ~ [Fig. 100], User can check sound through button and select it by using button.

The configuration will be saved if user press **[OK]** button, then message will be popped up like [Fig. 101]



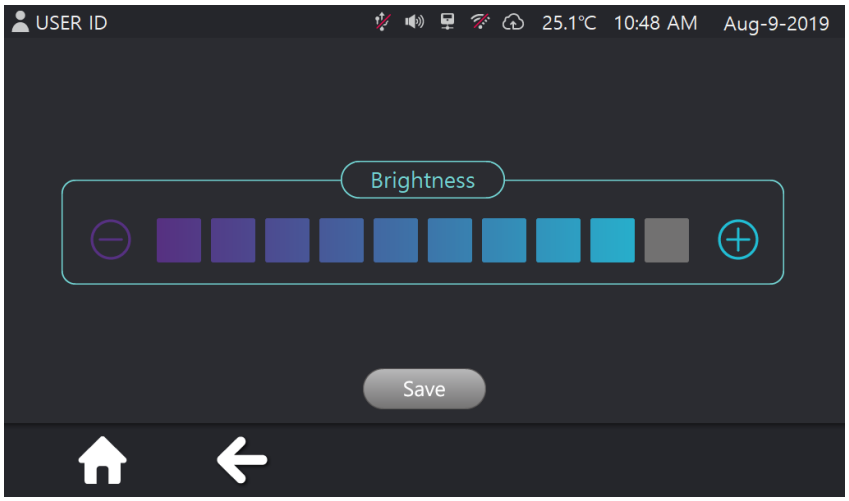

[Fig. 101] Save Success Popup page

**4)** Setting – Display




[Fig. 102] Setting page 1

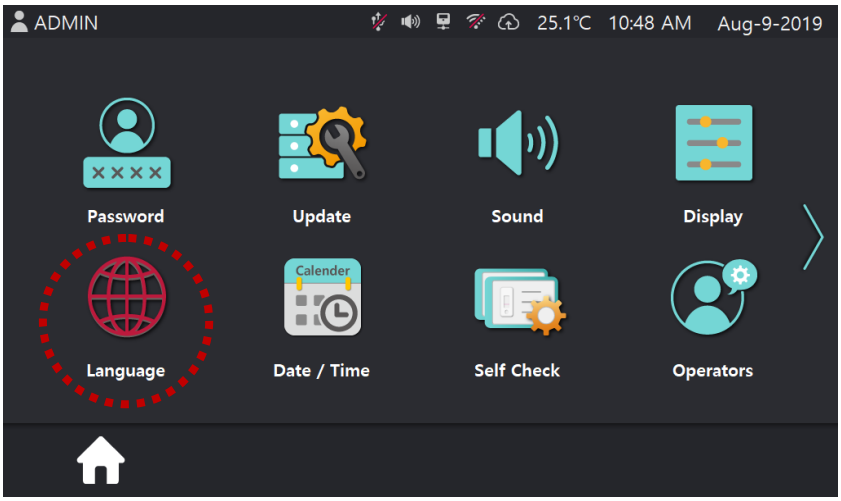
In the Setting page 1, select **[Display]** button, then screen is changed like [Fig. 102]. By using ⊖ and ⊕ buttons, user can control screen brightness.




[Fig. 103] Brightness setting page

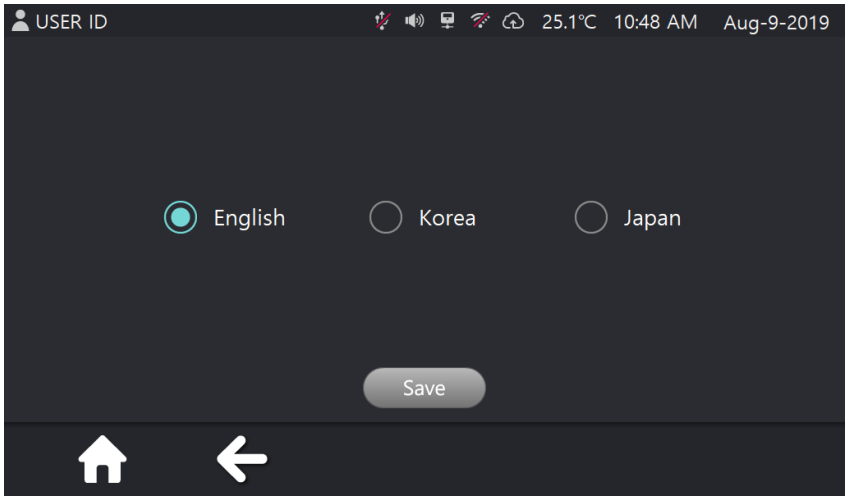
By pressing **[Save]** button, user can save configured brightness and message will be popped up.

**5)** Setting – Language



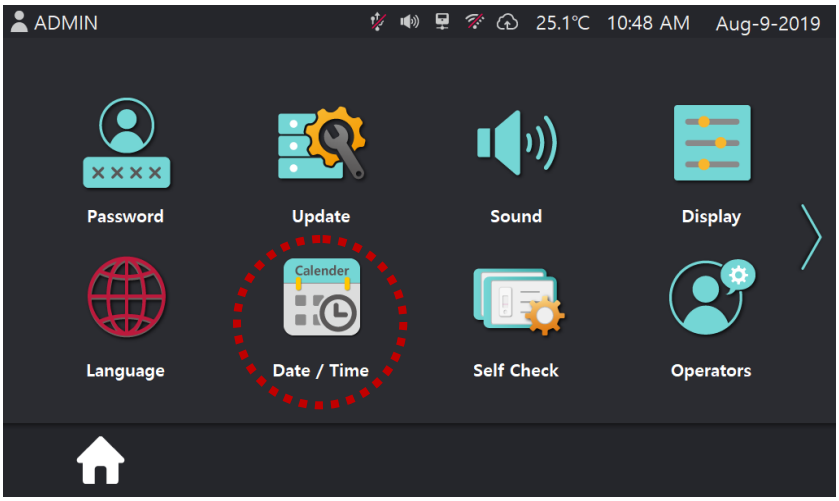

[Fig. 105] Setting page 1

In the Setting page 1, select **[Language]** button, then screen is changed like [Fig. 106]. Select language and press **[Save]** button to save configuration.



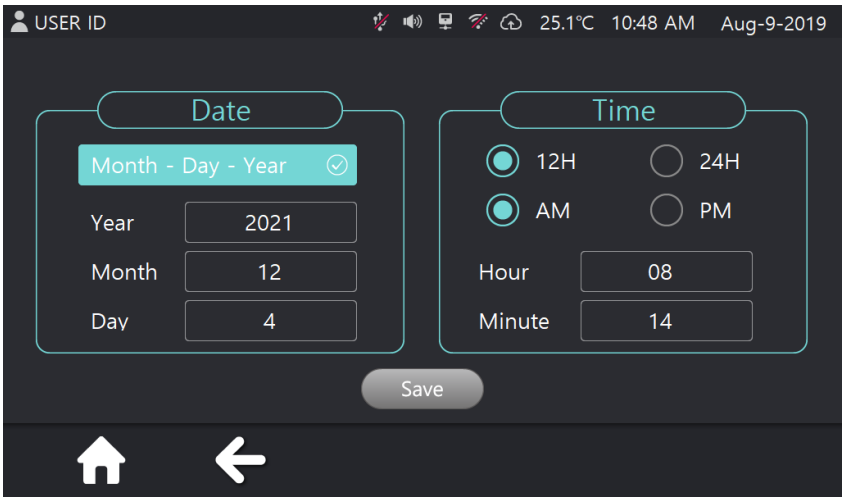

[Fig. 106] Language setting page

### 6) Setting – Date / Time




[Fig. 107] Setting page 1

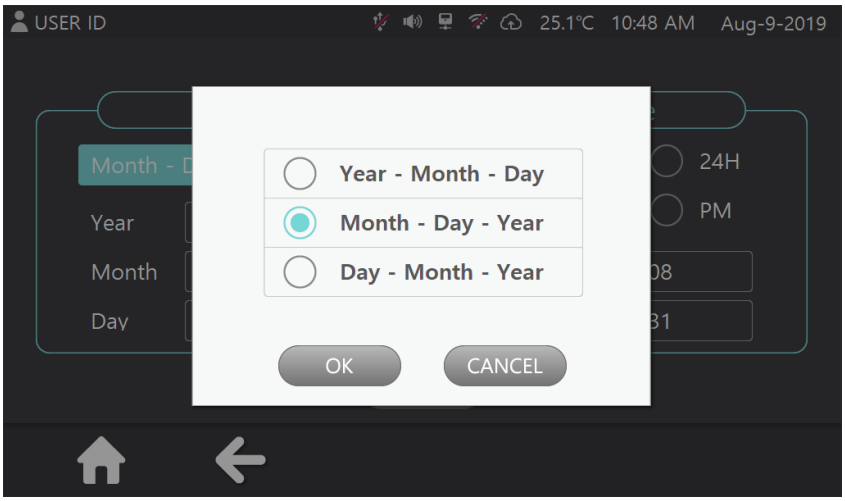
In the Setting page 1, select **[Date/Time]** button, then screen is changed like [Fig. 108].



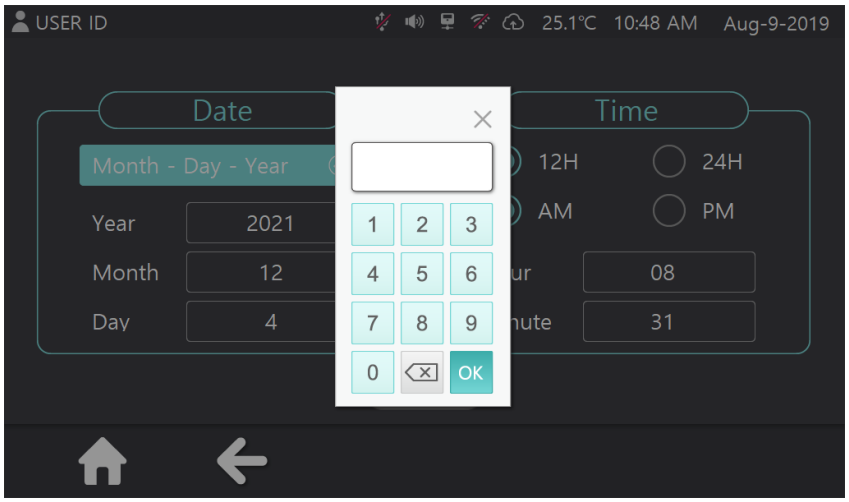

[Fig. 108] Date/Time Setting page

Select **[Year-Month-Day]** button and displaying type, then press **[OK]** button (See [Fig. 109]).

User can change data and time by touching related image. Keypad image like [Fig. 110] will be displayed. After that press **[Save]** button to save configuration.

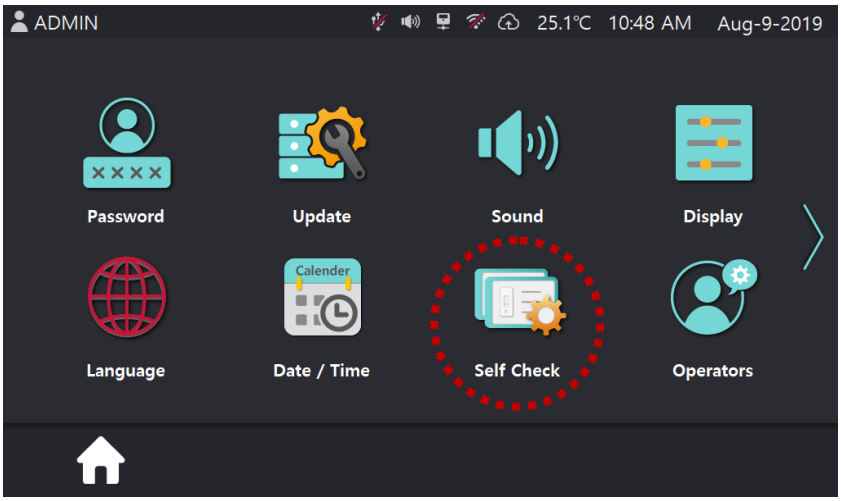



[Fig. 109] Date/Time pop up image



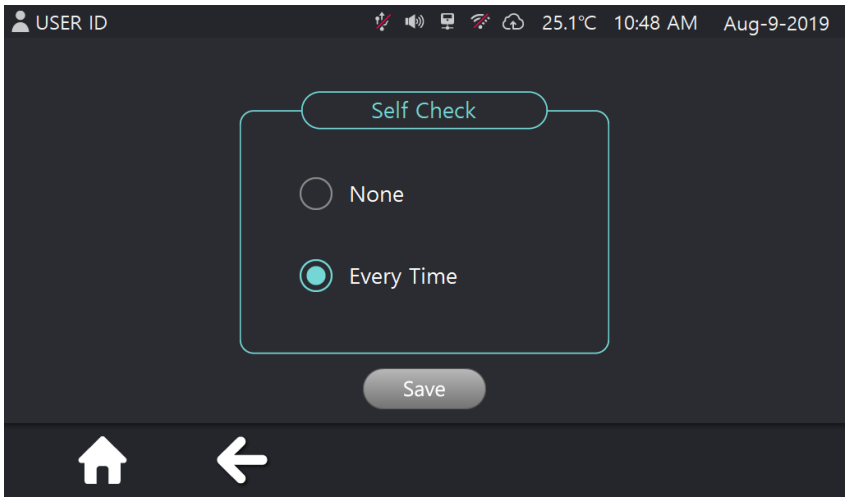

[Fig. 110] Date/Time input keypad

**7)** Setting – Self Check



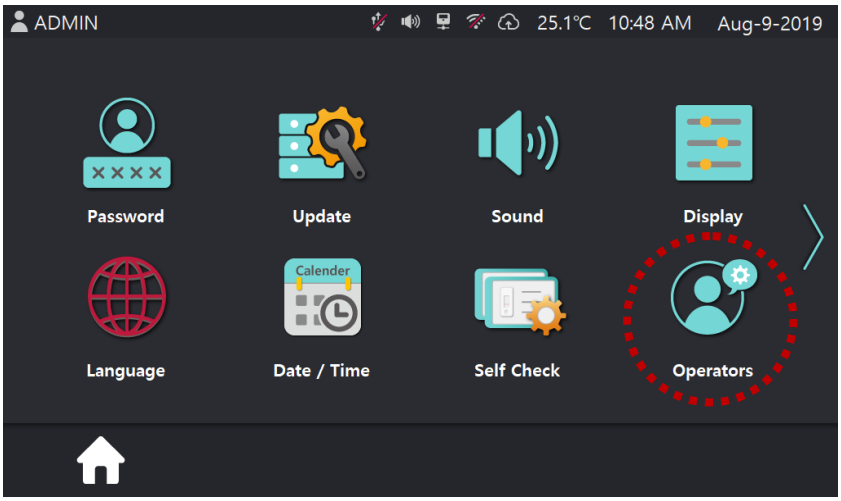

[Fig. 111] Setting page 1

In the Setting page 1, select **[Self Check]** button, then screen is changed like [Fig. 111]. User can configure to use self-check function. Configuration will be saved when user press **[Save]** button.




[Fig. 112] Self Check screen

### 8) Setting – Operators

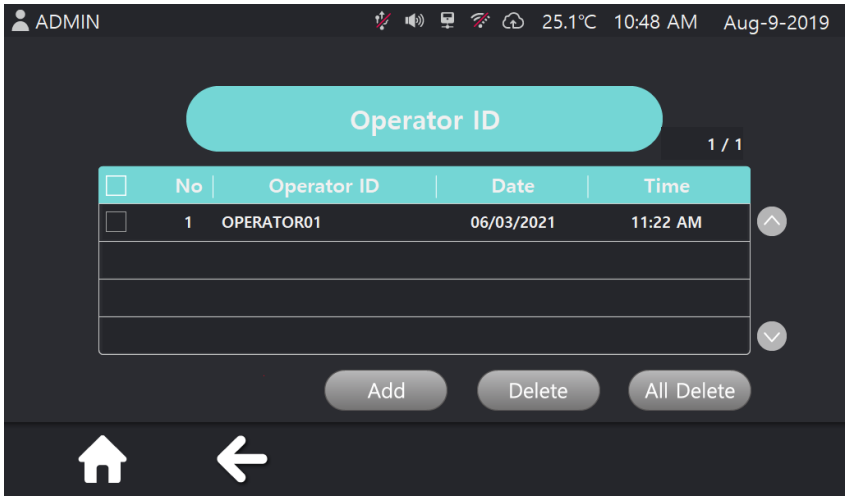



[Fig. 113] Setting page 1

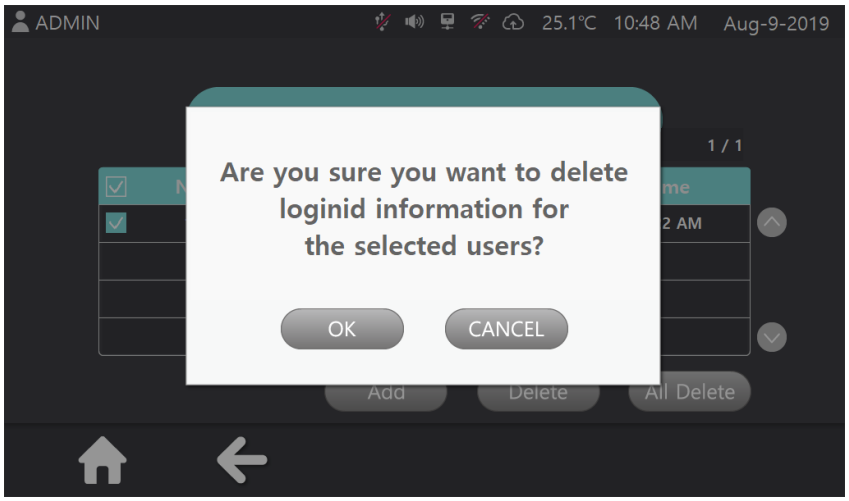
In the Setting page 1, select **[Operator]** button, then screen is changed like [Fig. 113]. In here user can manage operator information.

① If user select operator ID and press **[Delete]**, selected the operator information will be deleted.
* When user press **[Delete]** button, message will be popped up like [Fig. 115].

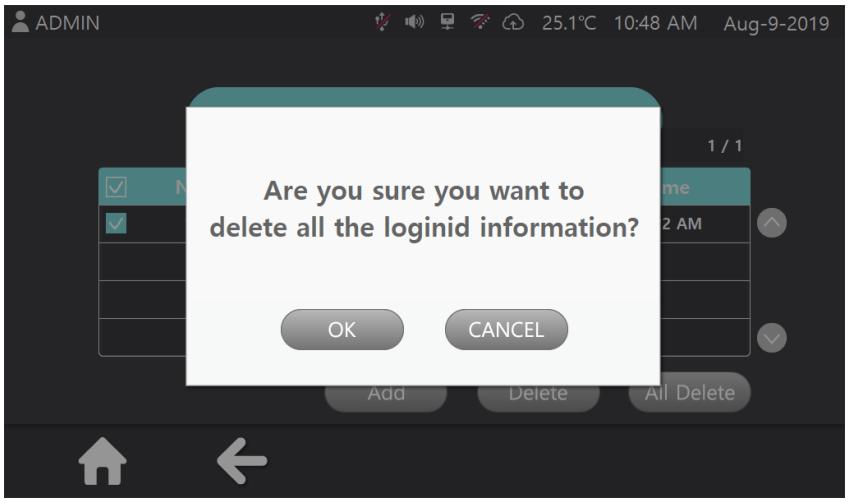
② If user select **[All Delete]** button, every information will be deleted.
* When user press **[All Delete]** button, message will be popped up like [Fig. 116].




[Fig. 114] Operator setting page

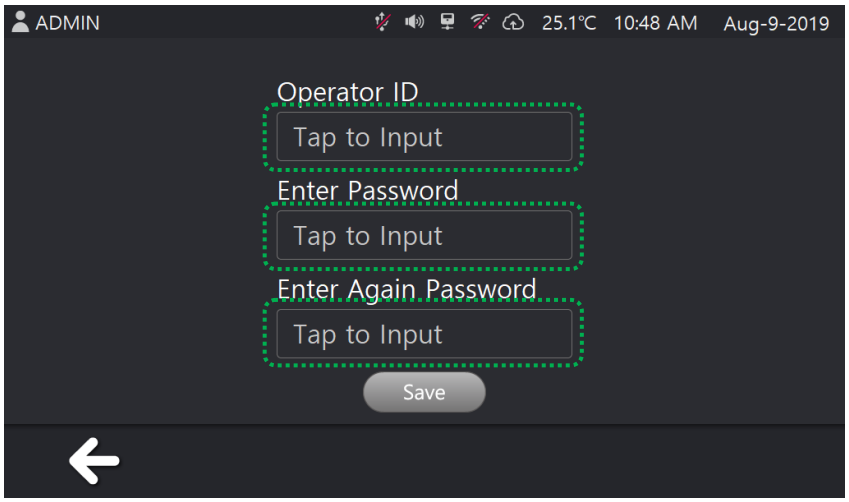



[Fig. 115] Pop up message for delete




[Fig. 116] Message for all delete

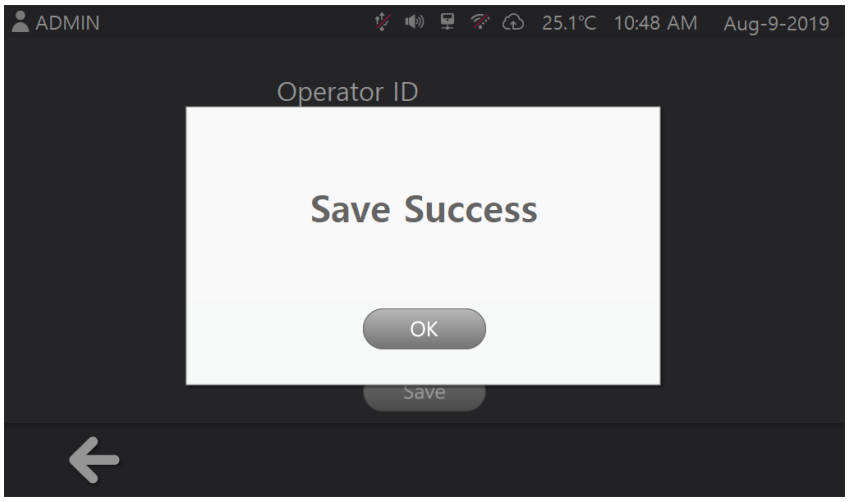
③ If user select **[Add]** button, screen is changed like [Fig. 117].



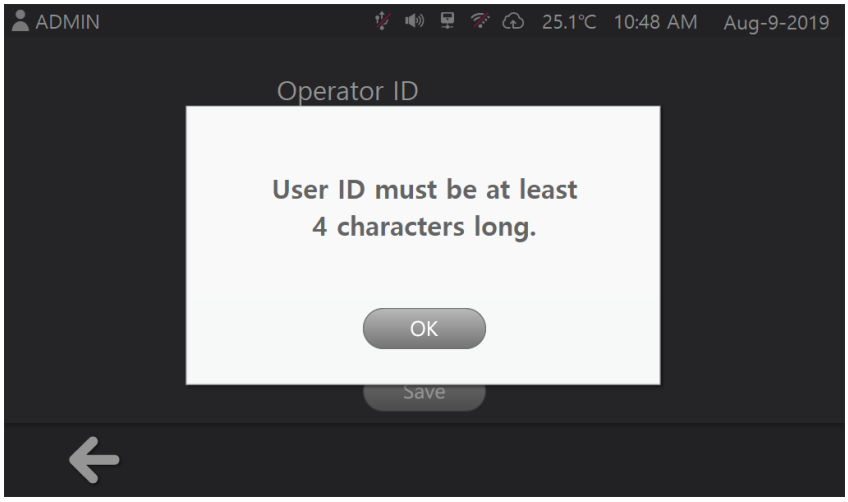

[Fig. 117] Operator add page

When select text box, Keyboard image will be displayed and user can input Operator ID and password.

The information will be saved by touching **[Save]** button and message will be popped up like [Fig. 118].
* If user do not input any information and touch **[Save]** button, then warning message will be popped up like [Fig. 119].




[Fig. 118] Save Success message

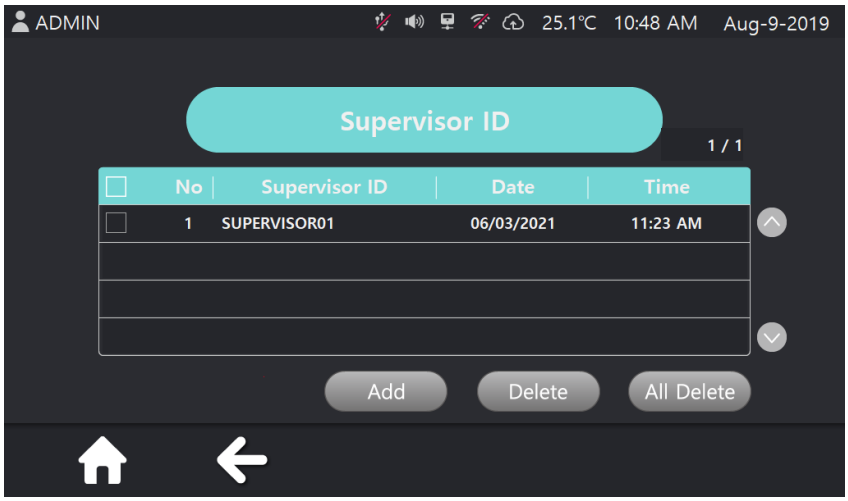



[Fig. 119] User ID input error message

### 9) Setting – Supervisors


[Fig. 109] Setting page 2

In the Setting page 2, select **[Supervisor]** button, then screen is changed like [Fig. 110].



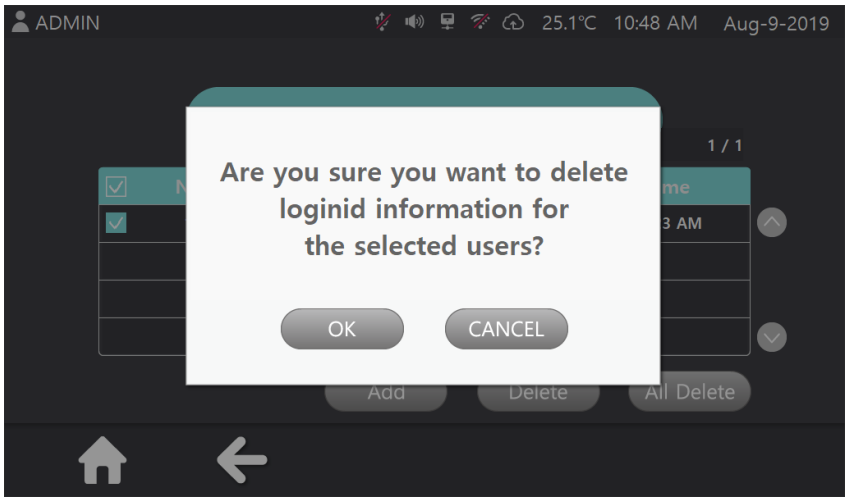

[Fig. 110] Supervisors setting page

① If user select supervisor ID and press **[Delete]**, selected the operator information will be deleted.

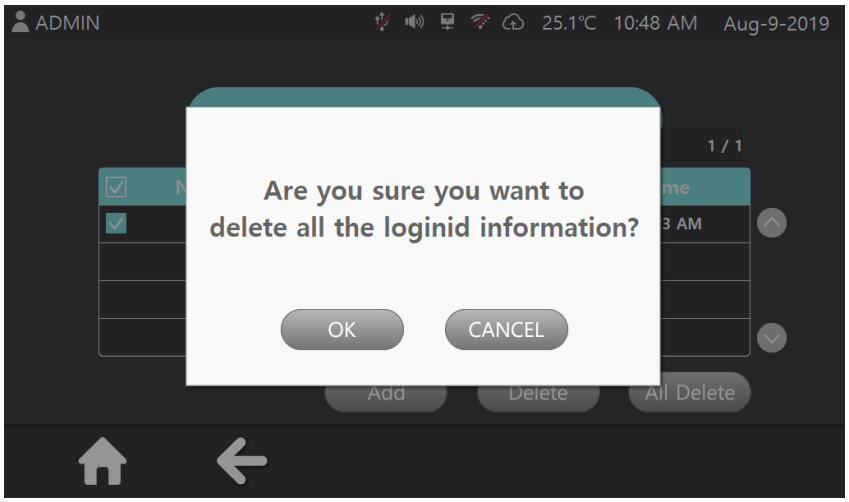
* When user press **[Delete]** button, message will be popped up like [Fig. 111].

② If user select **[All Delete]** button, every information will be deleted.

* When user press **[All Delete]** button, message will be popped up like [Fig. 112].

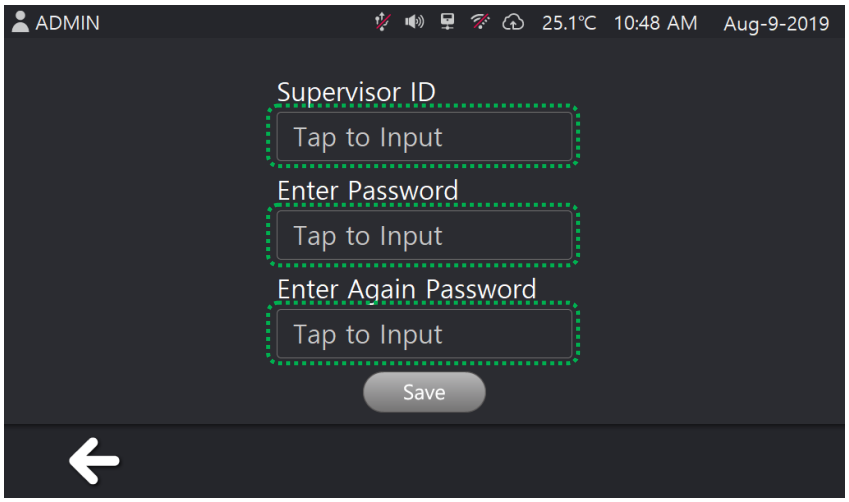



[Fig. 111] Pop up message for delete




[Fig. 112] Message for all delete

③ If user select **[Add]** button, screen is changed like [Fig. 113].



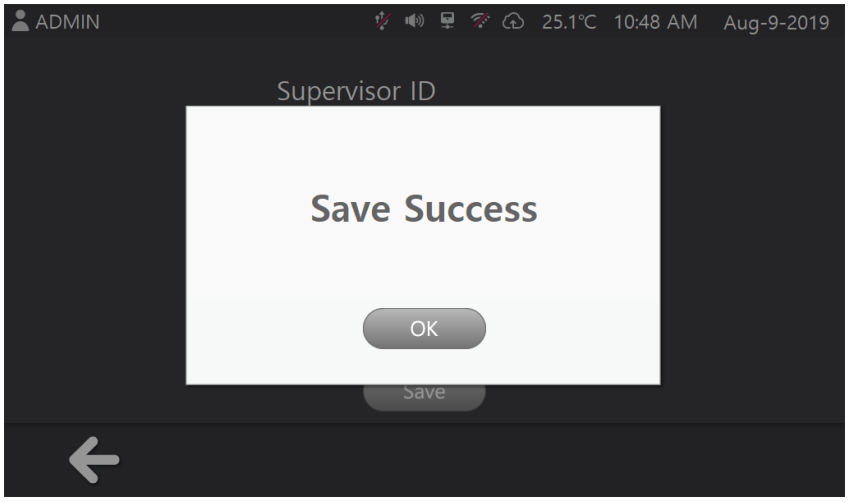

[Fig. 113] Operator add page

When select text box, Keyboard image will be displayed and user can input supervisor ID and password.

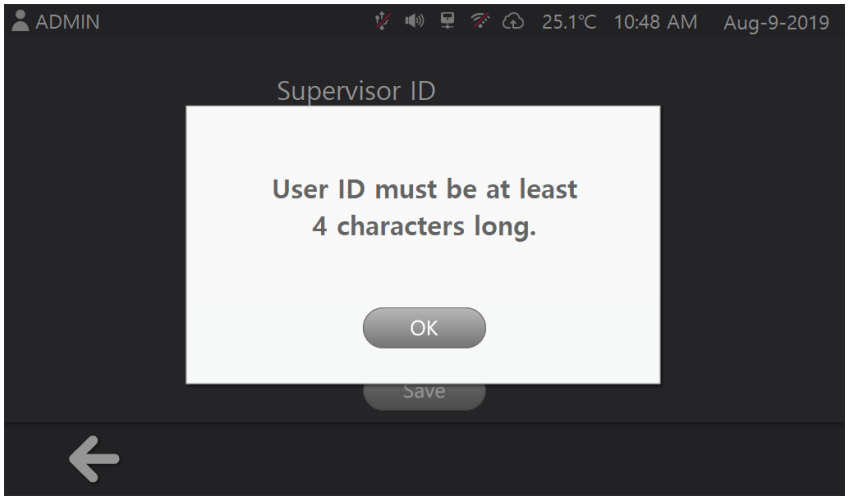
[Fig. 114] Keyboard

The information will be saved by touching **[Save]** button and message will be popped up like [Fig. 115].

* If user do not input any information and touch **[Save]** button, then warning message will be popped up like [Fig. 116].

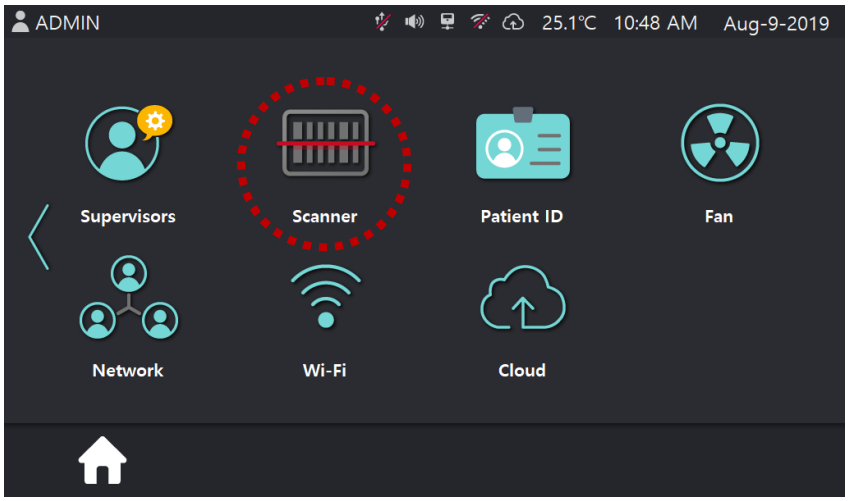



[Fig. 115] Save Success message



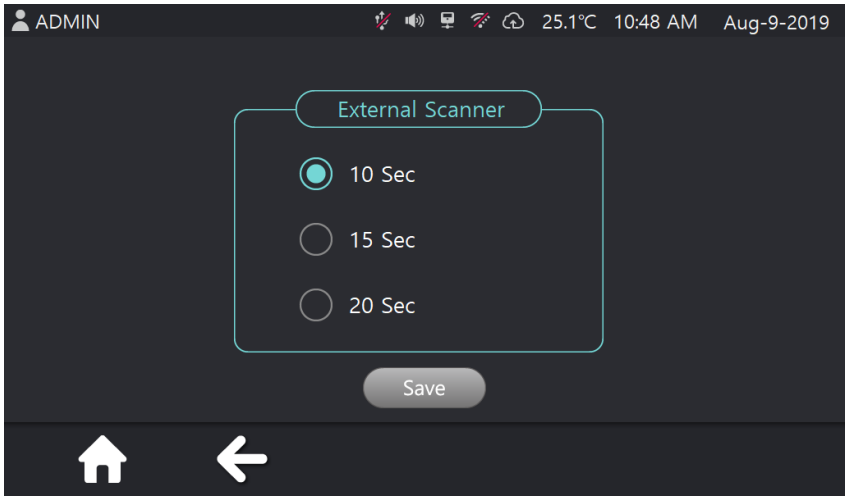

[Fig. 116] User ID input error message

**10)** Setting – Scanner




[Fig. 117] Setting page 2

In the Setting page 2, select [Scanner] button, then screen is changed like [Fig. 118]. Select reading time for external scanner, then press [Save] button.

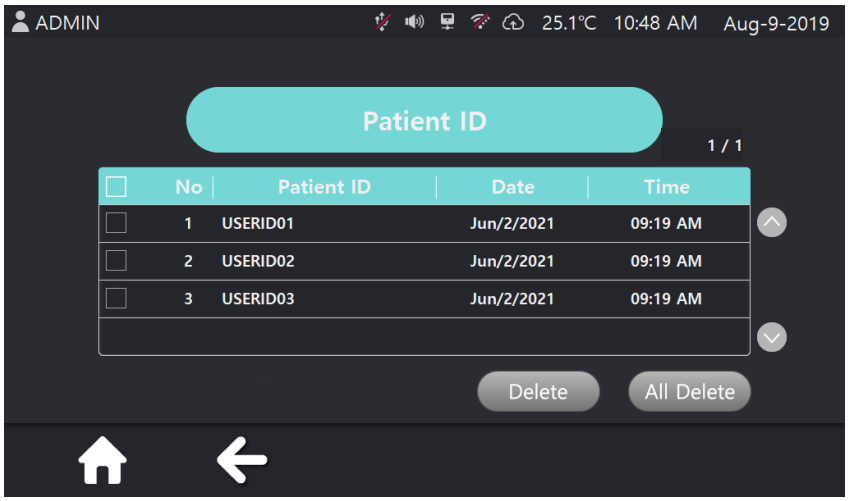



[Fig. 118] Scanner setting page

**11)** Setting – Patient ID


[Fig. 119] Setting page 2

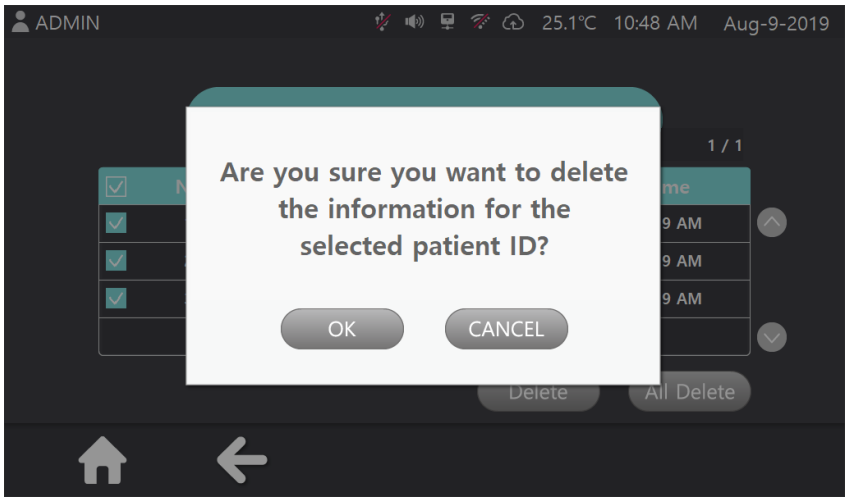
In the Setting page 2, select **[Patient ID]** button, then screen is changed like [Fig. 120].




[Fig. 120] Patient ID Setting page

① If user select patient ID and press **[Delete]**, selected the operator information will be deleted.

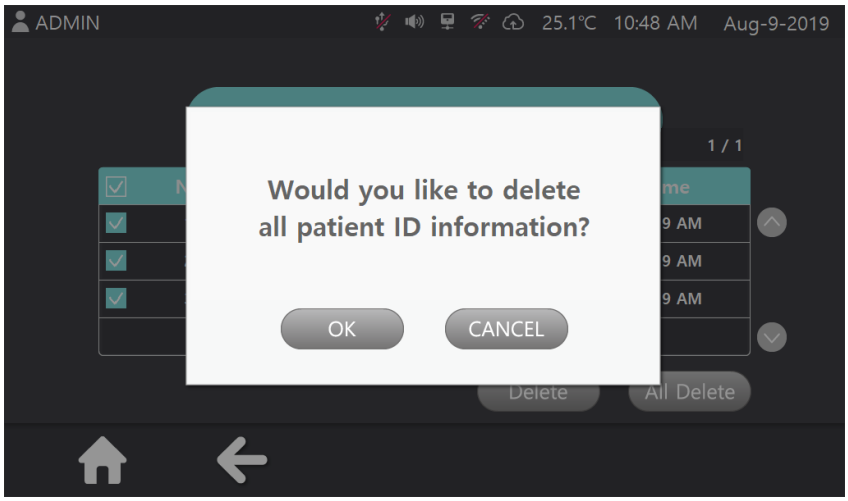
* When user press **[Delete]** button, message will be popped up like [Fig. 121].




[Fig. 121] Pop up message for delete

② If user select **[All Delete]** button, every information will be deleted.

* When user press **[All Delete]** button, message will be popped up like [Fig. 122].

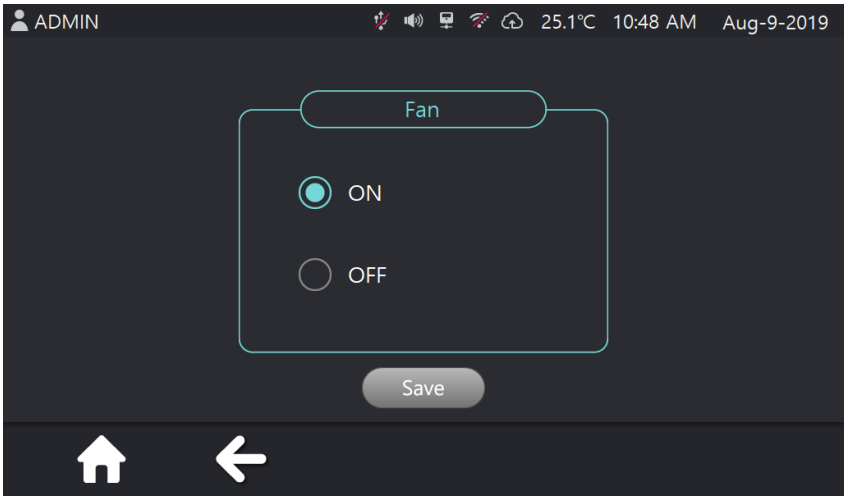



[Fig. 122] Message for all delete

**12)** Setting – Fan


[Fig. 123] Setting page 2

In the Setting page 2, select **[Fan]** button, then screen is changed like [Fig. 124]. Select internal fan operation, then press **[Save]** button.

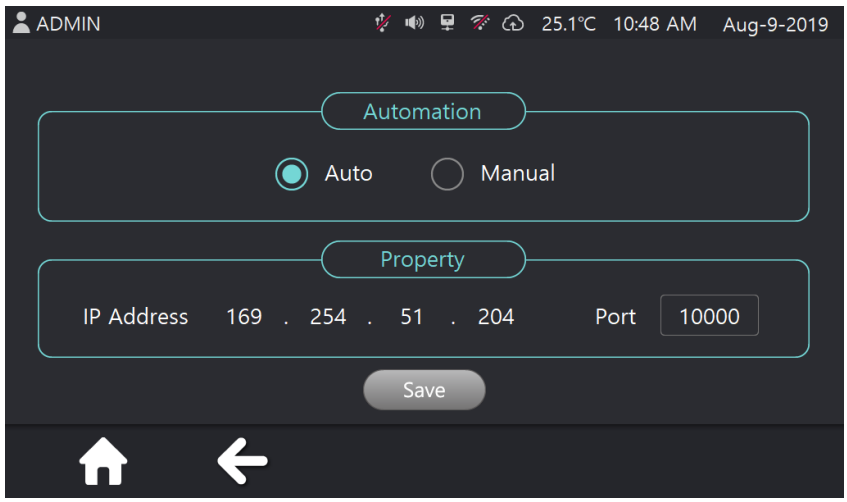



[Fig. 124] Fan operation setting page

**13)** Setting – Network


[Fig. 125] Setting page 2

In the Setting page 2, select **[Network]** button, then screen is changed like [Fig. 125]. Set the network settings, then press **[Save]** button.



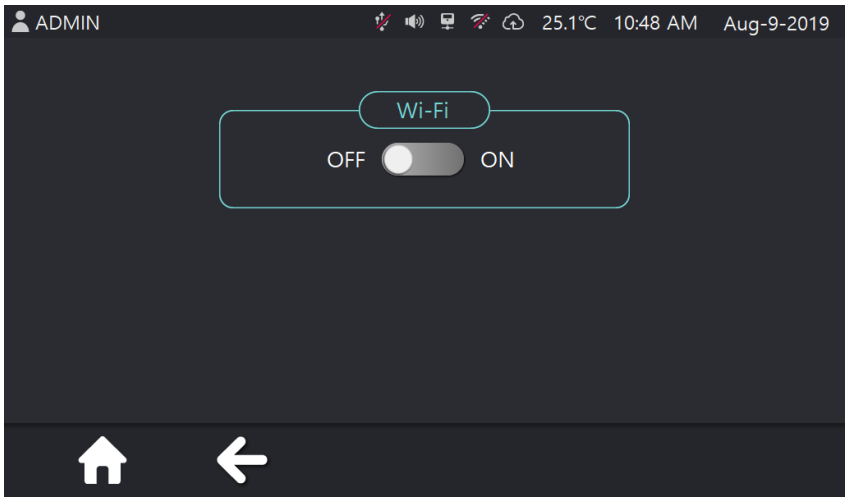

[Fig. 126] Network setting page

**14)** Setting – Wi-Fi

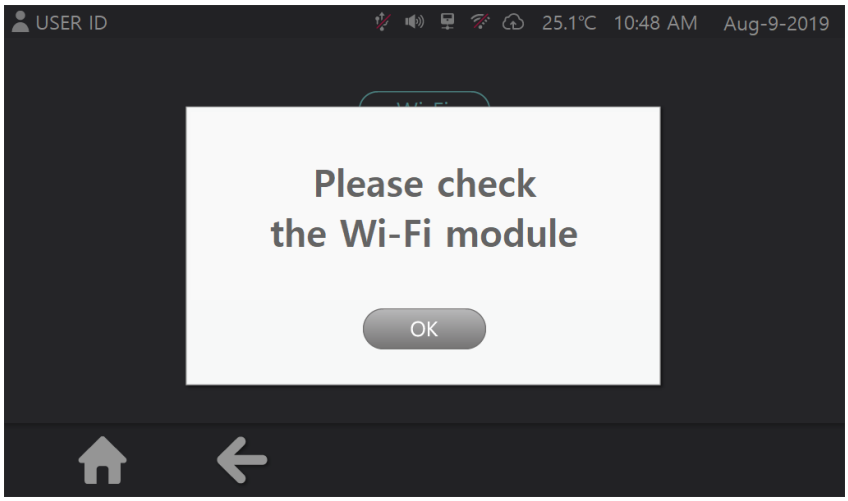

[Fig. 127] Setting page 2

In the Setting page 2, select **[Wi-Fi]** button, then screen is changed like [Fig. 128]

* If the Wi-Fi module is not connected to the device, error message will be popped up. (See [Fig 129])

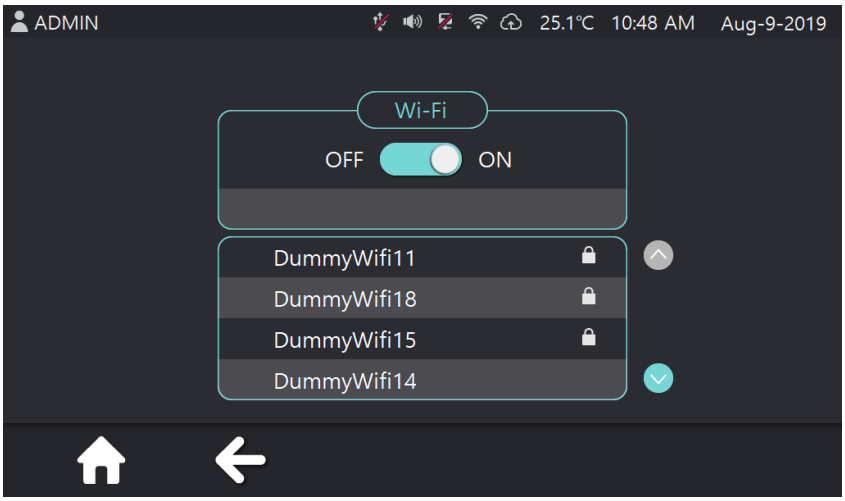



[Fig. 128] Wi-Fi setting page



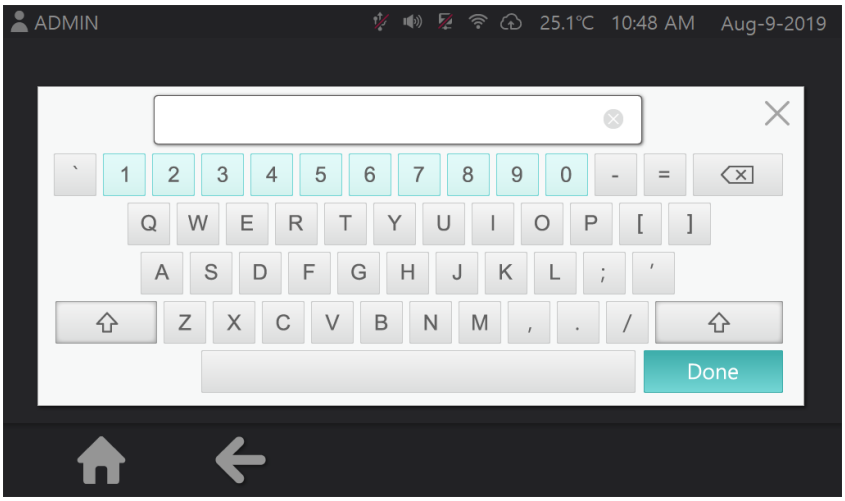

[Fig. 129] No Wi-Fi module

In normal case, show Wi-Fi list on screen. Wi-Fi list on screen when user change the Wi-Fi switch to ON. (See [Fig. 130])



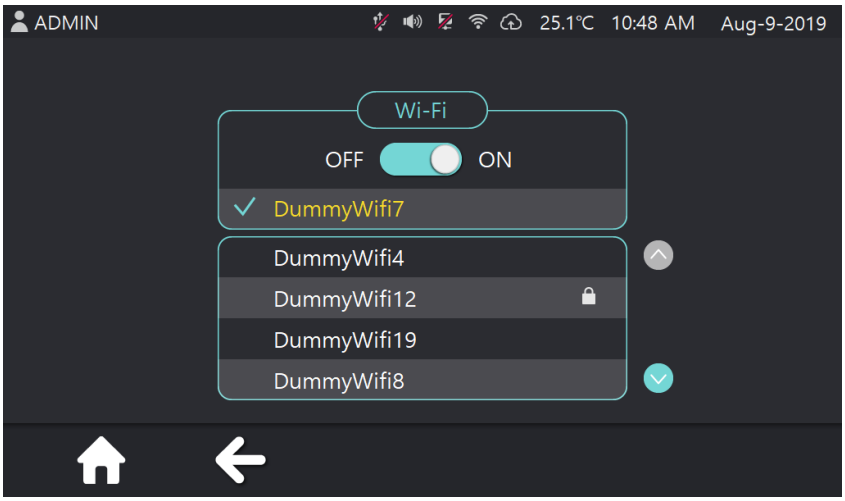

[Fig. 130] Wi-Fi ON

If user select the encrypted Wi-Fi, keyboard will be displayed and user can input the password. (See [Fig. 131])



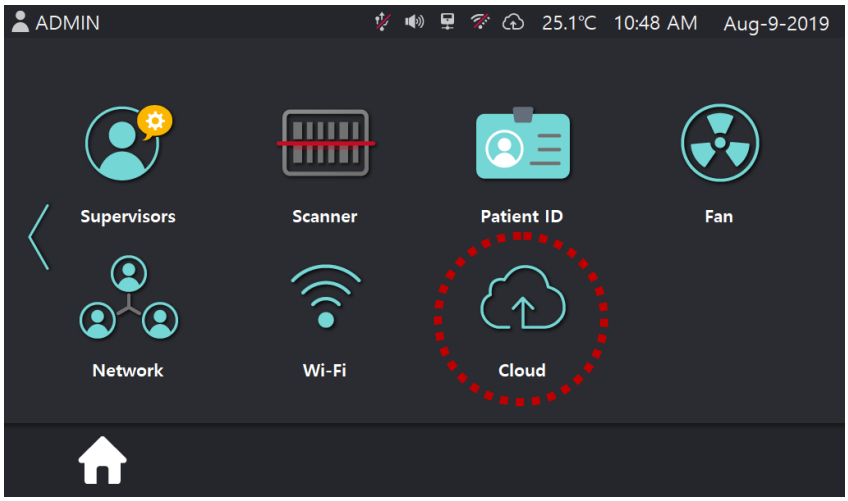

[Fig. 130] Input password

Display the connected Wi-Fi name on Wi-Fi ON/OFF window when completed the Wi-Fi connection. (See [Fig. 131])



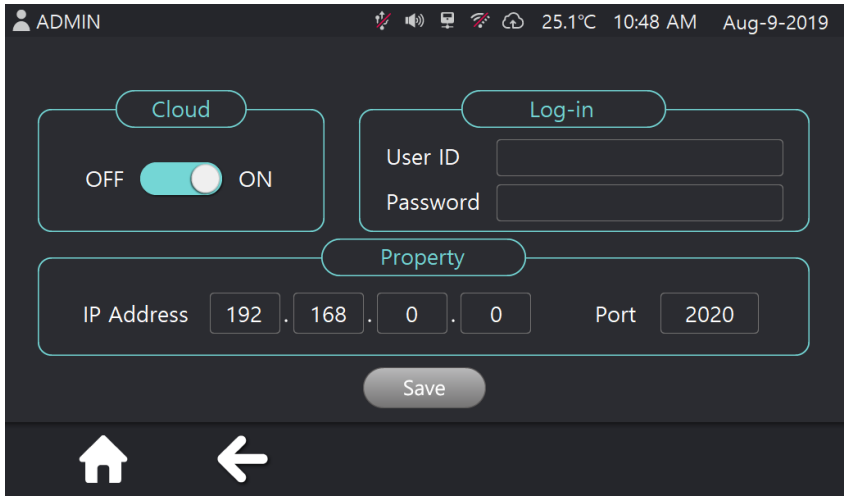

[Fig. 131] Connecting Wi-Fi

**15)** Setting - Cloud



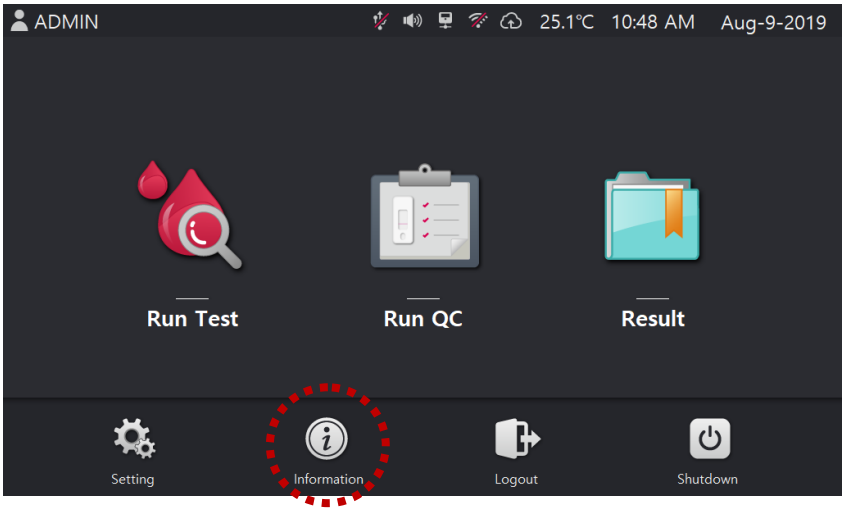

[Fig. 131] Connecting Wi-Fi

In the Setting page 2, select **[Cloud]** button, then screen is changed like [Fig. 132] Change the cloud information, then press [Save] button.



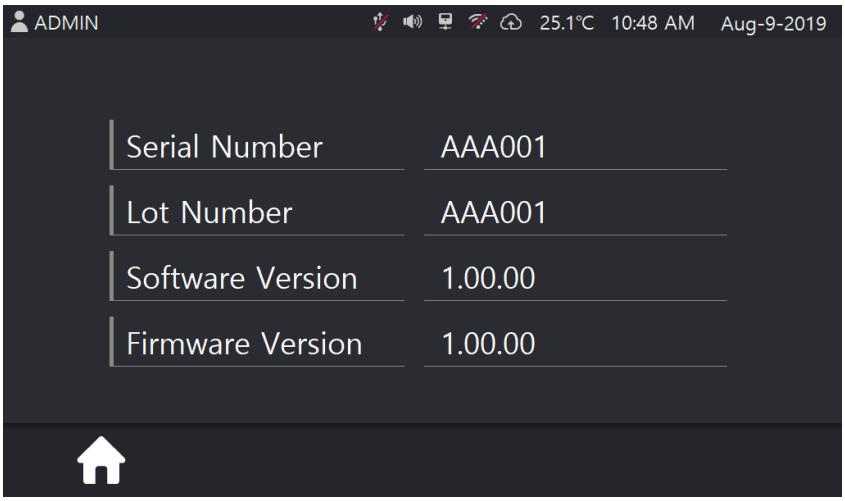

[Fig. 131] Connecting Wi-Fi

### 3.2.13 Information



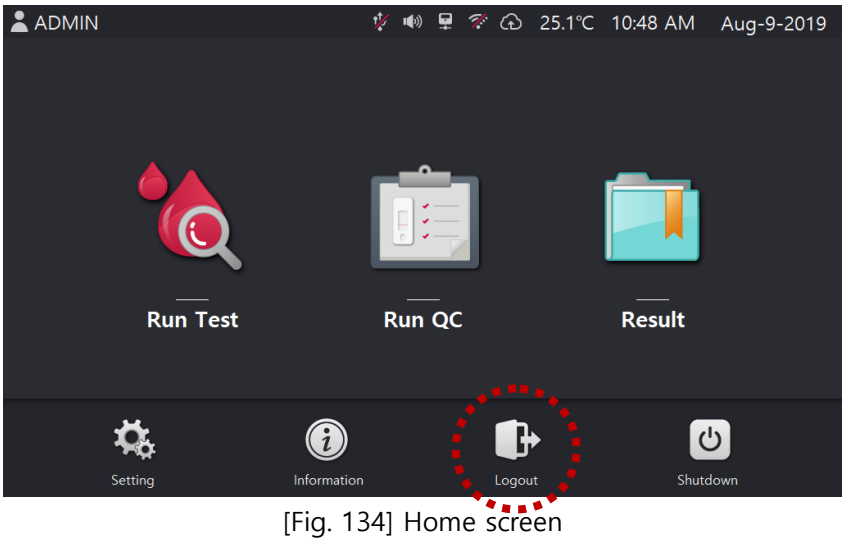

[Fig. 132] Home screen

In home screen, select **[information]** button, then screen is changed like [Fig. 133] and user can check equipment information.




[Fig. 133] Information page

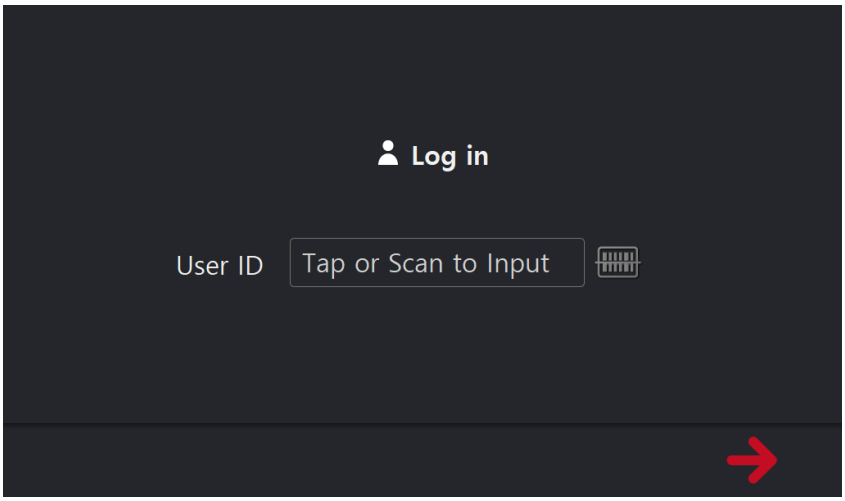
### 3.2.14 Logout




[Fig. 134] Home screen

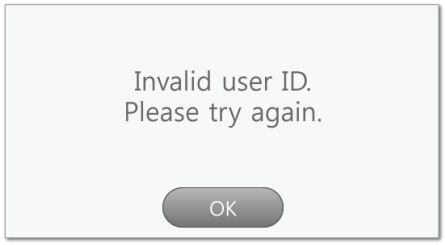
In home screen, select **[Logout]** button, then screen is changed like [Fig. 135] and equipment's state is changed to logout status.

User can log in by touching text box and input operator ID or press barcode button for ID scanning.



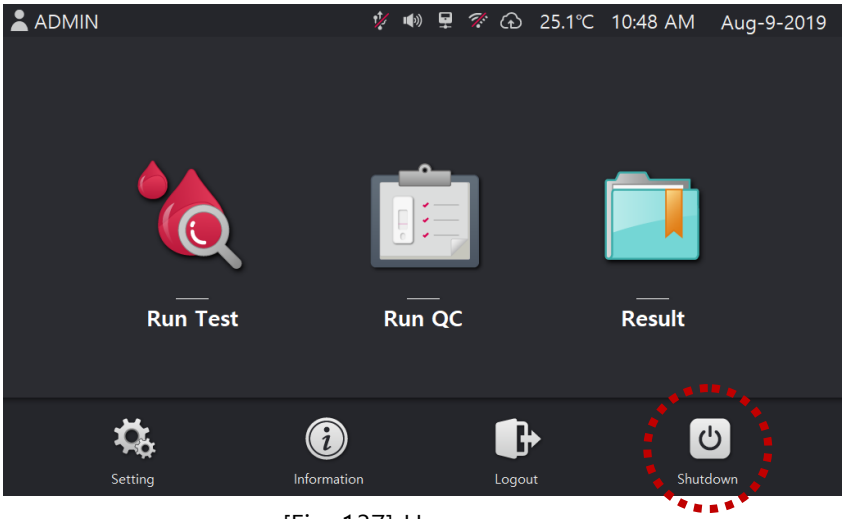

[Fig. 135] Log-in page after Logout button press

If input wrong or unregistered ID, error message will be popped up like [Fig. 129]



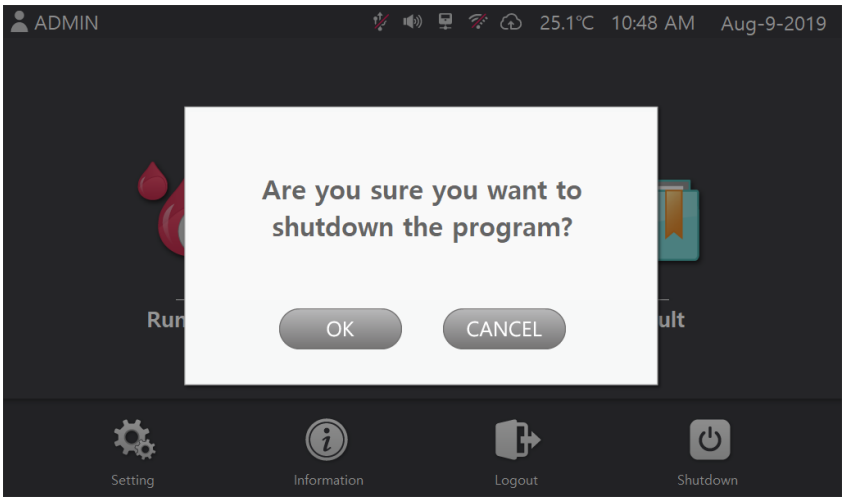

[Fig. 136] Login error popup screen

### 3.2.15 Shutdown



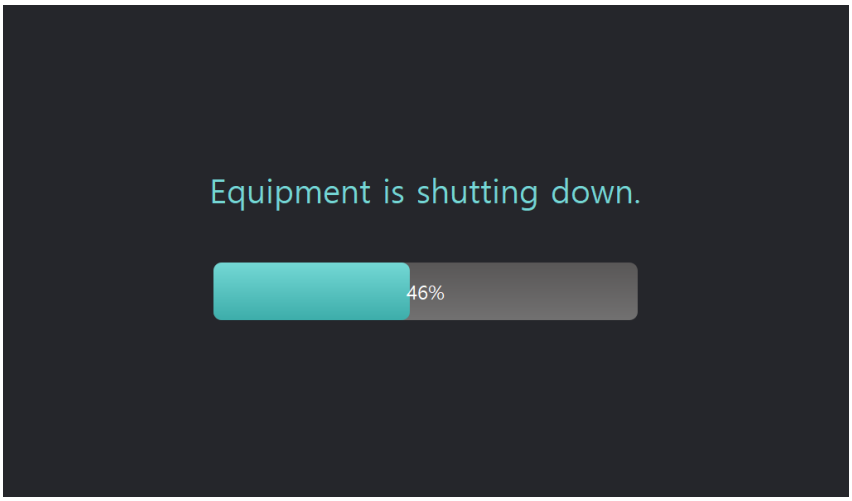

[Fig. 137] Home screen

In home screen, select **[Shutdown]** button, then confirmation message will be popped up like [Fig. 138].




[Fig. 138] Shutdown confirmation pop up message

If user press **[OK]** button, screen will be changed like [Fig. 132] and equipment will be turned off.



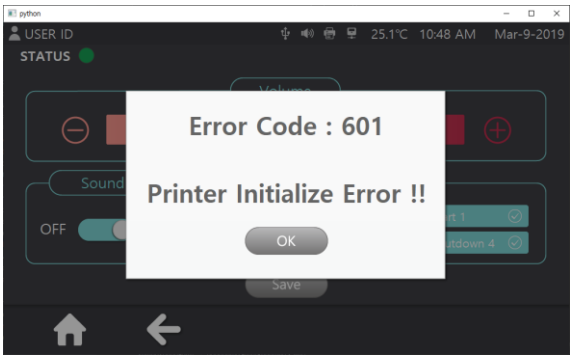

[Fig. 139] Shutdown progress screen

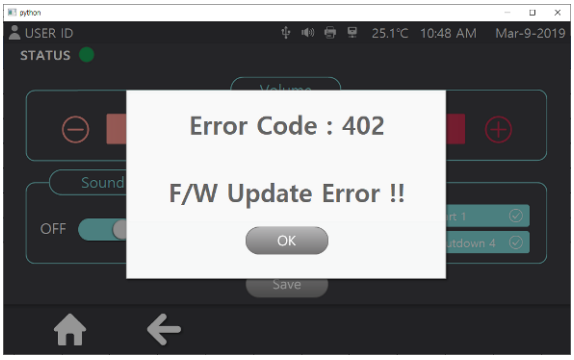
### 3.3 Guideline for Functional Inspection and Calibration

MIC-C100 Systems is capable of measuring the optical data for each channel. Calibrate the optical part in order to measure the florescence.

# 4 Troubleshooting

## 4.1 Error Massege




### 4.1.1 Identifying the cause of malfunctions

Common malfunctions can be judged by the color of the "Status LED."

| Error Code | Contents |
|---|---|
| **100** | Strip insertion error |
| **101** | Strip reverse insert Error |
| **200** | Internal barcode image save failed Error |
| **201** | Device not registered Error |
| **202** | Internal barcode cannot be recognized Error |
| **203** | External barcode cannot be recognized Error |
| **204** | ID card not recognized Error |
| **300** | Motor Communication Error |
| **400** | F/W Communication Error |
| **401** | F/W Version Check Error |
| **402** | F/W Update Error |
| **403** | S/W Update - Version Check Error |
| **600** | Camera Initialize Error(Camera Off) |
| **601** | Printer Initialize Error |

### 4.1.2 User correctable malfunction

When the Error Code is 100 or 101, check the strip and restart operation. When the Error Code is 202, 203 or 204, retry same operation. When the Error Code is 300, 400, 600 or 601, restarting the device, and see if the status normal.

If the same error occurs again after retry, service inquiry through the Manufacturer or Distributor is necessary.

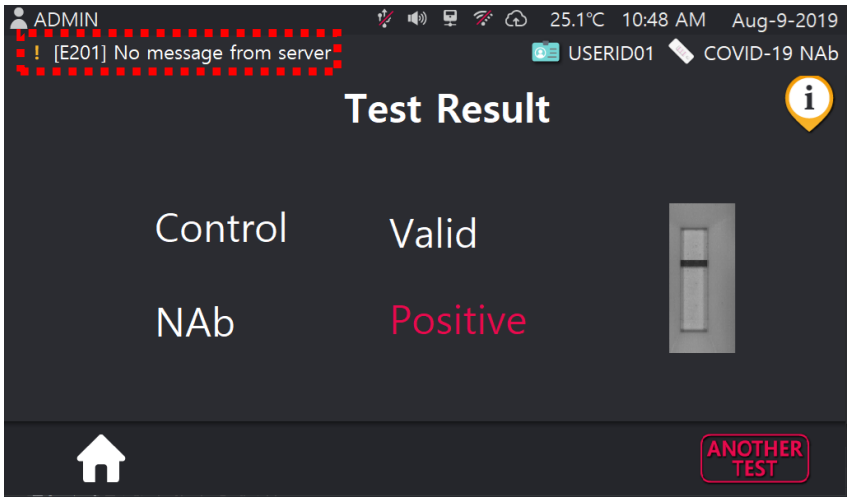
### 4.1.3 Malfunction that requires service inquiry

Other problems that cannot be resolved by the user require a service inquiry through the Manufacturer or Distributor.

### 4.1.4 When the performance of the in vitro device changes

Equipment upgrades and service can be made through service inquiries to the Manufacturer or Distributor.

## 4.2 Cloud Error Massege




### 4.2.1 Identifying the cause of malfunctions

Common malfunctions can be judged by the error message.

| Error Code | Contents |
|---|---|
| **E000** | Unknown |
| **E001** | Disabled cloud mode |
| **E002** | Invalid connection |
| **E010** | Invalid user ID |
| **E011** | Invalid Password |
| **E012** | Invalid log-in information |
| **E100** | Invalid server IP or port |
| **E101** | Network in unreachable |
| **E111** | Connection refused |
| **E201** | No message from server |

### 4.2.2 User correctable malfunction

In case of the Error Code is E001, check the cloud mode status in cloud setting screen. In case the Error Code is E002, E101 or E111, check the connection of Ethernet or Wi-Fi. In case the Error Code is E010, E011, E012 or E100, check the information in cloud setting screen. In case of the Error Code is E201, check the server status.

If Error Code is E000 or the same error occurs again after retry, service inquiry through the Manufacturer or Distributor is necessary.

## 4.3 Maintenance

### 4.3.1 Cleaning

MIC-C100 does not need regular cleaning.

If you want to clean the device, follow these guidelines.

**1)** Make sure to turn off the MIC-C100.

**2)** Gently wipe the LCD surface with a soft cloth.

**3)** Gently wipe the MIC-C100 surface with a soft cloth that is slightly dampened with one of these cleaning solutions;

- Super sani-cloth
- 70% isopropyl alcohol
- Mild dishwashing liquid mixed with water

**4)** Make sure to squeeze off excess liquid from the cloth before you wipe the MIC-C100 surface

**5)** If you need to clean inside or serious contamination occurs, contact manufacturer or distributor.

### 4.3.2 Warning

**1)** Do not pour liquid into the MIC-C100.

**2)** Do not spray any cleaning solution directly onto MIC-C100.

**3)** Do not put the MIC-C100 beside water or liquid.

**4)** Do not disassemble.

**5)** Do not clean inside.

### 4.3.3 Maintenance

If you need calibration, contact manufacturer or distributor.

And if there is a change in the performance characteristics of device, please make an inquiry to the manufacturer or dealer.

# 5 WARRANTY POLICY

Unless a separate, written agreement subsists, our instruments are secured against visible and invisible defects, manufacturing and material default for a period of one year from the date of shipment.

This warranty does not cover transport or handling damage, misuse of instrument or normal wear and tear. Any intervention by the user without the prior written approval of the supplier will also void this warranty.

Consumables are the responsibility of the purchaser. All repair work carried out under warranty is chargeable unless covered specifically by the original warranty and carried out within the country or countries specified therein. Purchasers should be aware that where parts are subject to import restrictions, repair times may be extended. Deviations in material color and finish, which cannot technically be avoided, will not constitute sufficient reason for a claim. All instruments are individually tested before leaving the factory.

Returns of faulty goods can only be accepted after approval of the warranty claim by the supplier. Instruments can only be accepted in their original packaging.

Instruments should be returned promptly on being found defective. Acceptance of a return does not automatically constitute acceptance of a claim.

When a complaint is accepted, the supplier's responsibility is limited to repair or replacement of the product or relevant spare parts. In any event, the purchaser is not entitled to suspend payment or to arbitrarily deduct a discount on the amount due without the written consent of the supplier. Our decision on all matters relating to complaints shall be final. Any instrument which has been replaced shall become our property.

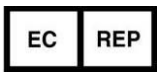
This guarantee is in addition to statutory or other rights of the purchaser.

# 6 RETURN POLICY

Our Goal is to provide the highest quality instrument at the lowest possible cost to the customer. Due to this, we can only accept returns for instrument that have been inadvertently misrepresented. Returns must be preauthorized before sending back. Please contact us within 7 days of receiving your instrument if you feel that you qualify for a return. The returned instrument must be in as shipped condition to be eligible for a refund.

# 7 Clarification of the Symbols

The packaging, the identification plate of the instrument, and the manual may contain the following symbols or abbreviations:

| Symbol | Explanation |
|---|---|
|   | For research use only |
|  | Consult instructions for use |
|  | Waste Electrical and Electronic Equipment |
|  | Caution |
|  | European conformity |
|  | Caution - LED |
|  | Manufacturer |
|   | EC Representative |
|   | Serial number |
|   | Catalogue number |
|  | Fragile; handle with care |

# 8 Disposal of Used Electrical & Electronic Equipment

The meaning of the symbol on the product, its accessory or packaging indicates that this product shall not be treated as household waste. Please, dispose of this equipment at your applicable collection point for the recycling of electrical & electronic equipment waste. In the European Union and Other European countries there are separate collection systems for used electrical and electronic products. By ensuring the correct disposal of this product, you will help prevent potentially hazardous to the environment and to human health, which could otherwise be caused by unsuitable waste handling of this product. The recycling of materials will help conserve natural resources. Therefore please do not dispose of your old electrical and electronic equipment with your household waste. For more detailed information about recycling of this product, please contact your local city office, your household waste disposal service or the shop where you purchased the product.

# 9 EMC Test Results

This equipment complies with IEC 61326-1:2012, IEC 61326-2-6:2012 Class A requirements and the emissions of the energy used are low and not likely to cause interference in nearby electronic equipment.
The equipment is tested for immunity to electrostatic discharge at test level 2kV, 4kV, 8kV of air discharge.
The equipment is tested for immunity to radio frequency interference at the frequency 80 MHz to 1.0 GHz and test levels 3V/m.
The equipment is tested for immunity to radio frequency interference at the frequency 1.0 GHz to 2.0 GHz and test levels 3V/m.
The equipment is tested for immunity to radio frequency interference at the frequency 2.0 GHz to 2.7 GHz and test levels 1V/m.

**The system fulfills the EU safety test & EMC test requirements (IEC 61010-1:2010, IEC 61326-1:2012). This instrument complies with IEC 61010-1("Safety requirements for electrical equipment for measurement, control and laboratory use; General requirement") and was in perfect safety conditions when it left the factory. Installation, use and maintenance of the MIC-C100 is the full responsibility of the user.**

# 10 Purchase of Reagents and Consumables

## 10.1 Consumables

The Cartridge must use only products Specified by MICOBIOMED.
Please contact your representative for purchase detail information.
(http://micobiomed.com/ +82-70-5227-6000)

## 10.2 Reagents

Only Kits optimized for MIC-C100 equipment Specified by MICOBIOMED should be used.
Please contact your representative for purchase detail information.
(http://micobiomed.com/ +82-70-5227-6000)

# 11 Maintenance Checklist

## 11.1 Daily checklist

| Checklist | Pass | Fail |
|---|---|---|
| The equipment is in the designated location. | □ | □ |
| No foreign objects can be found around the equipment. | □ | □ |
| The device is not exposed to direct sunlight. | □ | □ |
| There are no installations that can cause dust, heat, and fluid inflow into the equipment. | □ | □ |
| The power cord and adapter connector are plugged securely. | □ | □ |
| The door is closed. | □ | □ |
| There is no object on the equipment that can cause LCD damage. | □ | □ |

※ For any failed items, contact the equipment manager.

## 11.2 Monthly checklist

| Checklist | Pass | Fail |
|---|---|---|
| Normal operation has been checked by turning on the power switch with the power cable plugged in. | □ | □ |
| The LCD and touch screen operate without problems. | □ | □ |

※ For any failed items, contact the manufacturer.

## 11.3 Quarterly checklist

| Checklist | Pass | Fail |
|---|---|---|
| The operation status has been checked by operating the functions. | □ | □ |
| Check data after Run | □ | □ |

※ For any failed items, contact the manufacturer.

## 11.4 Annual checklist

| Checklist | Pass | Fail |
|---|---|---|
| The quarterly checklist has been completed. | □ | □ |

※ For any failed items, contact the manufacturer.

Date of Preparation : June. 2021