IVD CE

MARK-B™ 1 analyzer User Manual

MARK-B™ 1 analyzer (Immunoassay analyzer) *Model: MB-100

MARK-B™ 1 analyzer detects specific biomarkers *via* immunoassay (MESIA; Magnetic Electrochemical Sandwich ImmunoAssay) from a small amount of test sample (e.g. whole blood). MARK-B™ 1 analyzer is intended to be used as an *in vitro* diagnostic medical device. Please read this user manual thoroughly for correct use and keep it for future reference.

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Table of Content

1. Product Introduction · · · · · 4
   - 1-1. Intended Use · · · · · 4
   - 1-2. Principle · · · · · 4
   - 1-3. Precautions & Warnings · · · · · 4
   - 1-4. Components · · · · · 5
   - 1-5. Symbol Guide · · · · · 5

1. Product Description · · · · · 7
   - 2-1. MARK-B™ 1 analyzer · · · · · 7
   - 2-2. Check Cartridge · · · · · 8

2. Screen Description · · · · · 9
   - 3-1. Home Screen · · · · · 9

1. Initial Setup · · · · · 10
2. Running a Test · · · · · 15
   - 5-1. How to perform RUN TEST · · · · · 15
   - 5-2. Result Management · · · · · 20

3. Running a QC Test (Control Solution Test) · · · · · 21
4. Function Setting · · · · · 27
   - 7-1. Setup Screen · · · · · 27
   - 7-2. Administrator Settings · · · · · 28
   - 7-3. Wi-Fi Settings · · · · · 30
   - 7-4. Printer Settings · · · · · 31
   - 7-5. Date & Time Settings · · · · · 32
   - 7-6. Lock Settings · · · · · 34

1. Maintenance · · · · · 36
   - 8-1. System Check · · · · · 36
   - 8-2. Version Information and Update · · · · · 40
   - 8-3 Device Registration · · · · · 43
   - 8-4. Auto Power Off Settings · · · · · 45
   - 8-5. Cleaning · · · · · 46
   - 8-6. Storage Requirements · · · · · 46

1. Error Messages · · · · · 47
   - 10-1. Notifications · · · · · 47
   - 10-2. Error pop-ups · · · · · 51

1. Technical Information · · · · · 57
2. Product Warranty · · · · · 58

1. Product Introduction

1-1. Intended Use

The MARK-B™ 1 analyzer is an instrument that performs immunoassay on test cartridges. It reads specific biomarkers within the test sample.

1-2. Principle

MARK-B™ 1 analyzer is an instrument based on an immunoassay technique called MESIA (Magnetic Electrochemical Sandwich Immunoassay). MARK-B™ 1 analyzer can be used to analyze a single or multiple analyte(s) by detecting electrochemical signals on the test cartridge, which is for a one-time *in vitro* diagnostic (IVD). The magnets within the device form magnetic fields, which facilitate the interaction of nanoprobes in the test cartridge to induce antibody-antigen reactions and remove unbound magnetic nanoprobes. The MARK-B™ 1 analyzer measures the concentration of any antigens or antibodies by detecting electrochemical signals from the reaction-completed magnetic nanoprobes. MARK-B™ 1 analyzer transmits the test data to the designated server *via* Wi-Fi.

1-3. Precautions & Warnings

Please read this user manual thoroughly for appropriate use.
MARK-B™ 1 analyzer is for use in IVDs.
MARK-B™ 1 analyzer and test cartridges are indicated for use in clinical laboratories.
Check that all components are present in the package.
Read this user manual before operating the analyzer.
The analyzer needs AC power connection to operate for an extended period of time and charge.
Please ensure your power supply is compatible with the analyzer's power specifications.
Increasing the inner temperature activates the cooling fan inside the air vent.
Establish a free distance of at least 10 cm (4 inches) from the face of the air vent when installing the device.
Keep the air vent free from inflow of foreign substances.
Accidental entry of metals into the analyzer may cause breakdown or electric shock.
Please refer to product-specific package inserts included in each test kit for more information.
Turn off the power and remove the adapter if you do not expect to use the analyzer for an extended period of time.
Do not use or store the product in a location exposed to open flames.
Do not expose or store the product in a location subject to high temperature and high humidity.
Prevent water and dust from entering the device.
Do not apply excessive force, drop or step on the product.
Avoid dropping the device while moving it.
Do not assemble or modify the analyzer.
The analyzer is not water-resistant. Do not wash it with water or touch it with wet hands.
Do not use the product to diagnose specific illnesses and conduct screening tests, such as neonatal screening.
Use the analyzer only to assist medical decision-making.
Keep this product out of the reach of children.
In order to comply with radio frequency (RF) exposuer limits, antennas should be located at a minimum of 20cm or more from the body all persons.

When discarding the analyzer, discard in a safe place in accordance with the WEEE Directive (2002/96/EC).

1. Product Introduction

1-4. Components

The following are the components you should check upon opening the package of MARK-B™ 1 analyzer.

Please check that all components are included in the box.

Please contact the purchase location if any of the following components are not included or damaged.

- ✔ MARK-B™ 1 analyzer, 1EA
- ✔ User manual
- ✔ Quick guide

1-5. Symbol Guide

Please refer to the following symbols that can be found on the external package, package descriptions, enclosed papers, etc.

Manufacturer	EC REP — Authorized Representative in European community
Date of Manufacture	Use by/Expiry date (for test cartridge)
LOT — Batch code (for test cartridge)	REF — Catalogue number (for test cartridge)
SN — Serial number (for analyzer)	To indicate the temperature limitation in which the transport package has to be kept and handled
To indicate the humidity limitation in which the transport package has to be kept and handled	Biological risks

1. Product Introduction

Do not reuse.
(for test cartridge)

Please refer to
user manual.

Caution, please refer to accompanying documents

In Vitro Diagnostic Medical Device/In Vitro diagnostic use

Control

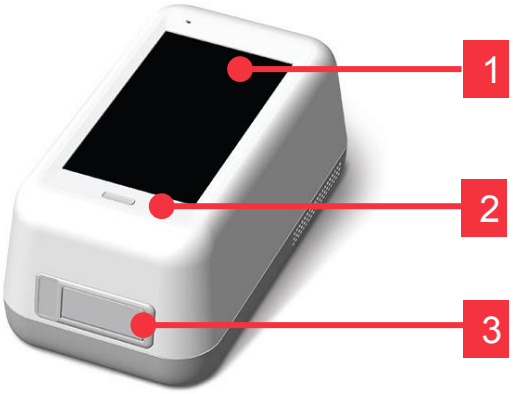
Contains sufficient for <n> tests.

Waste electrical and electronic equipment (WEEE)

Important

2. Product Description

2-1. MARK-B™ 1 analyzer



1 Screen
Interface that the user can touch to operate the analyzer and check the results.

2 Power button
Buttons to turn the device on or off.

3 Tray (closed)
A component to insert the test cartridge.
Opening and closing of the tray are controlled by the software.

4 Air vent
A component to control temperature inside the analyzer.

5 Power supply connector
An adapter connection port to supply power to the device.

6 USB port
A USB-A port for barcode scanner and mobile printer.

7 Electrode connector for test cartridge
A connector for cartridge reading.

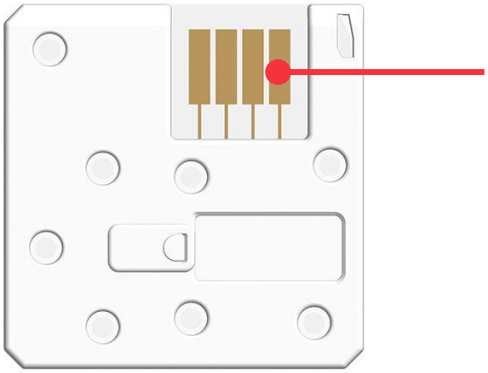
8 Cartridge recognition switch
A switch to check cartridge insertion.

9 Tray (open)
The tray is open with the cartridge inserted.
(Component as closed status shown in 3.)

2-2. Check Cartridge

The check cartridge is used to evaluate instrumental and electronic operations of the analyzer.

An alignment sensor is embedded in the check cartridge to check the alignment of magnets at the top and bottom of the analyzer.

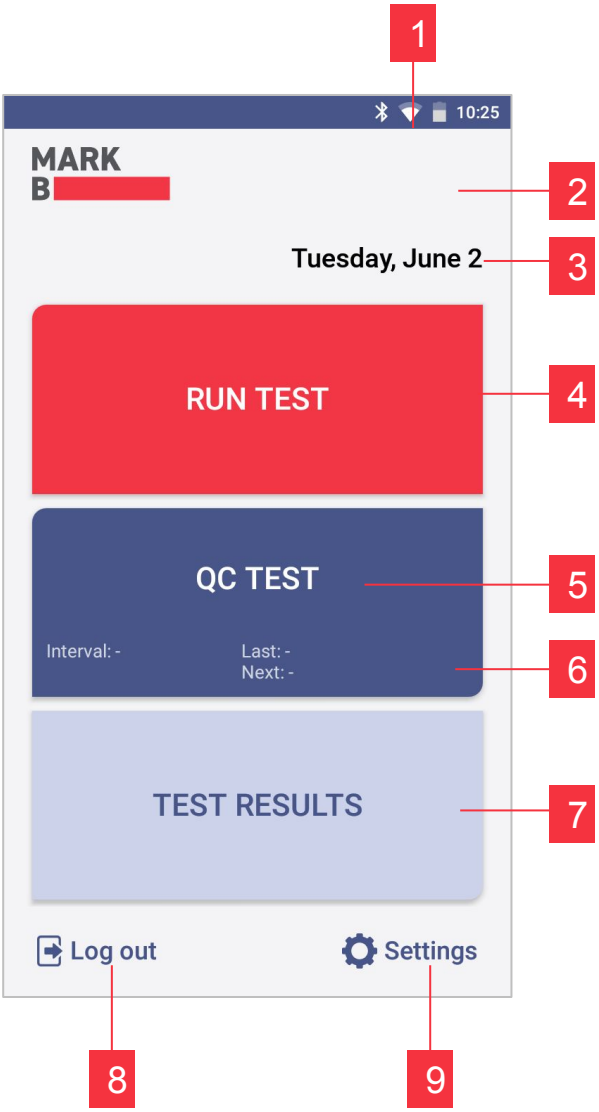


Cartridge contact pad

Contact pad for the operation check of MARK-B™ 1 analyzer

3. Screen Description

3-1. Home Screen



1 Status bar

Indicates MARK-B™ 1 analyzer's network connection, battery level and time.

2 Status indicating icon

QC! is displayed when QC test result shows "fail" or the QC test is not carried out.

15 is displayed when battery level is 15% or lower.

is displayed when temperature is either 15℃ or lower, or at least 30℃.

Check Cartridge is displayed when the first System Check is not performed, or System Check result is Fail.

3 Time

Displays day, date and month.

4 Run test

Touch the button to start the test.

5 Run QC Test

Touch the button to run the QC test.

6 QC Test interval and test information

Check QC Test intervals and recent/next test schedule of the QC test

7 Test results

Check all test results.

8 Admin login / logout

Login to / logout of the admin account.

9 Settings

Change settings.

Check device information and update it.

4. Initial Setup

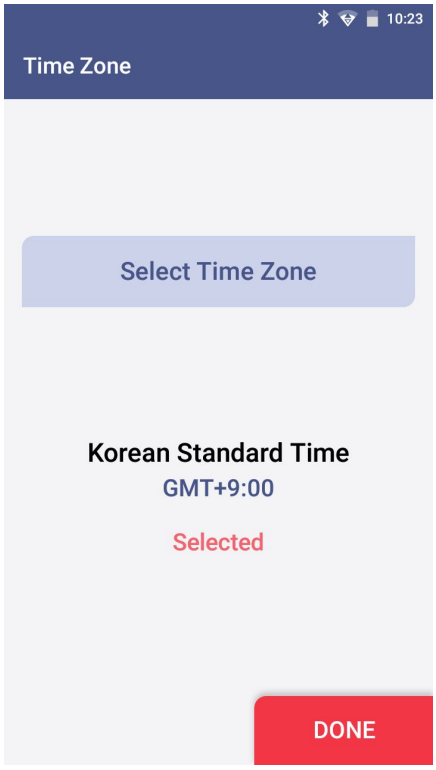
STEP 1. Connect the power adapter.

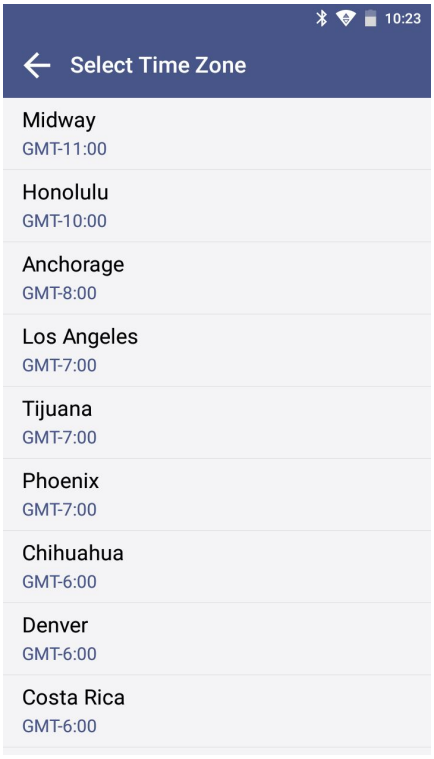
STEP 2. Touch the '**power**' button to start.

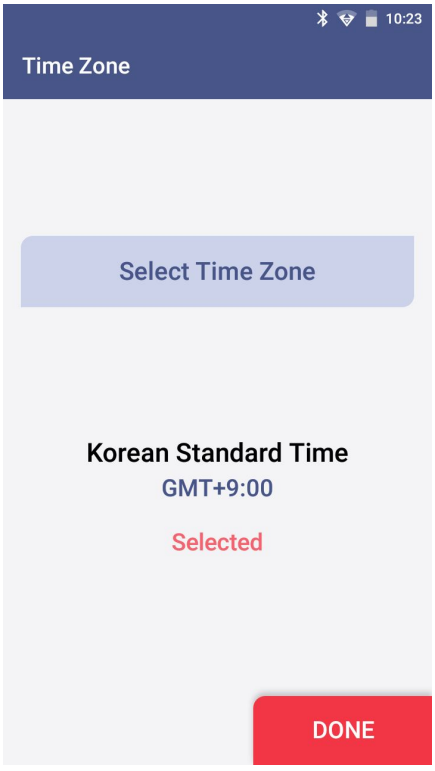
STEP 3. Time Zone setting

Touch the '**Select Time Zone**' → Select the time zone where the user is located.

→ When setting is completed, touch the '**DONE**' button.

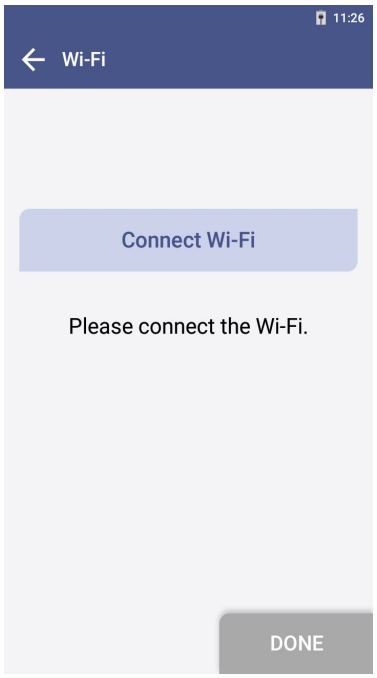


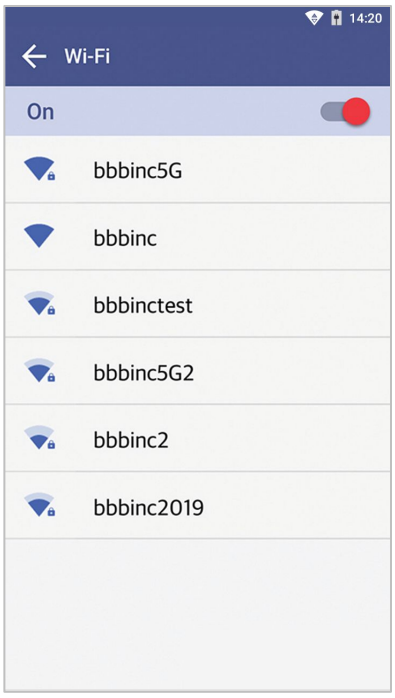


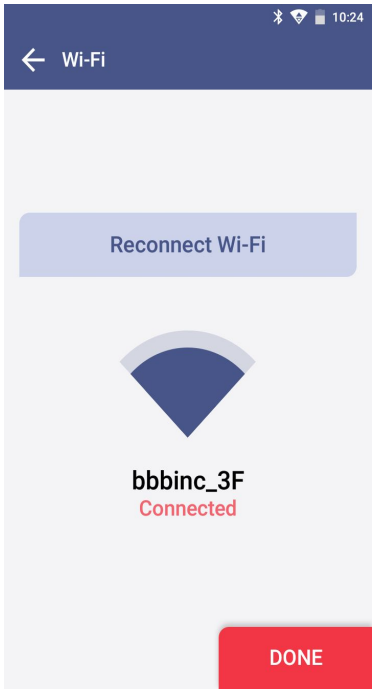


STEP 4. Wireless network (Wi-Fi) setting

Connect Wi-Fi → Select the Wi-Fi to connect to. → When connected, the ‘**DONE’** button is activated.→ Touch the ‘**DONE’** button.



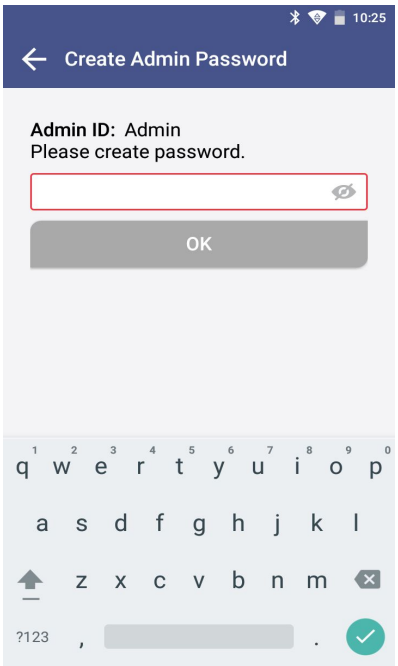




Icon	Connection Status	Description
	Connected	Wi-Fi is connected and active.
	Requesting connection	Please wait as the Wi-Fi signal is being acquired. In the case of no response, touch ‘**Reconnect Wi-Fi’** to try again.
	Connection Failure	Wi-Fi connection has failed. Check wireless connection status or select other Wi-Fi.
	Network not connected	The icon indicates that Wi-Fi is not connected. Select the ‘**Reconnect Wi-Fi’** to connect in-range accessible Wi-Fi.

STEP 5. Create Admin Password

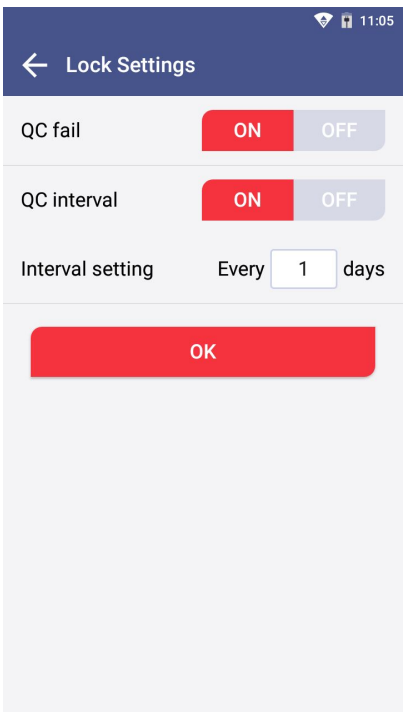
Enter admin password → Touch the **'OK'** button



- Administrator ID is automatically set as 'Admin'.
- Please set your own admin password.
- Password is case-sensitive and must be a combination of letters and numbers.
- Your password cannot contain spaces and must be less than 45 characters long.
- Touch the eye-shaped icon to check entered password.

STEP 6. Lock Setting

Establish QC Test settings according to each item → Touch the '**OK**' button



QC Lock On

- In the case of when QC Test result shows **'FAIL',** the test is unavailable until the result shows **'PASS'.**
- Conduct QC test regularly as scheduled, otherwise test cannot be run.

QC Lock OFF

- A test can be run regardless of QC Test results.

QC interval

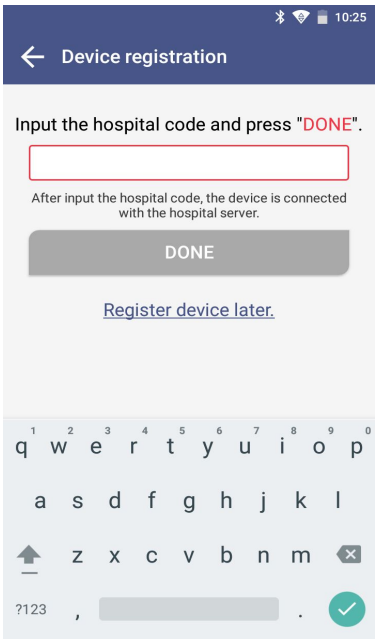
- On : A test can only be run upon completion and passing of the QC Test on the designated QC Test date
- OFF : Disables QC Test interval
- Interval setting : Set up QC Test interval within 1 to 365 days

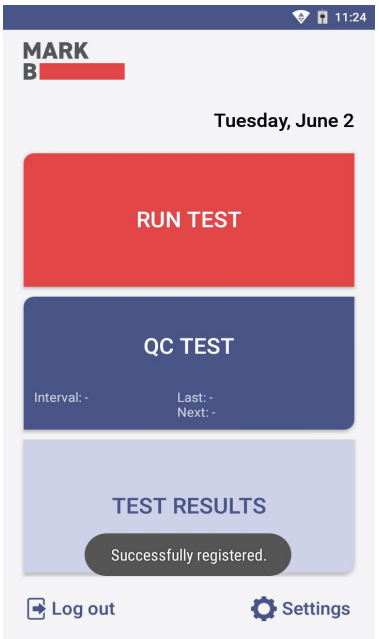
STEP 7. Device registration

a. Enter hospital code in the window.

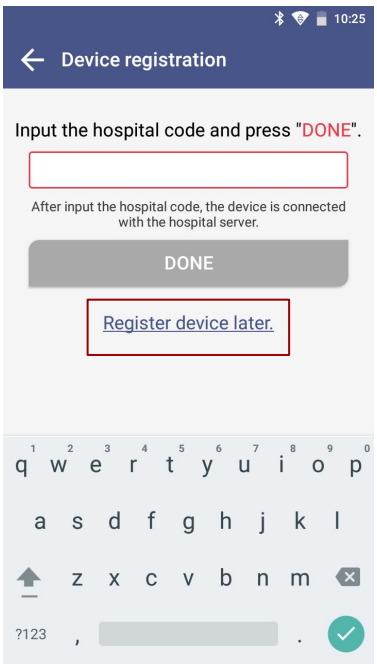
b. After entering hospital code, touch the ‘**DONE**’ button to connect to hospital server.

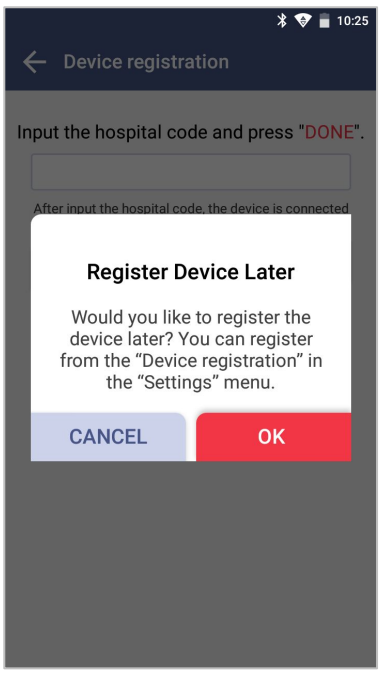
c. Once connected to server, initial setup is completed and the home screen will be displayed.





- If there is no hospital for device registration, touch the ‘**Register device later**’ button.
- Device registration is available later in **[‘Settings’ → ‘Device registration’] (see Page 44)**.





Barcode Scanner Connection

a. Connect the barcode scanner to the USB Port on the back of MARK-B™ 1 analyzer.

b. Barcode scanner automatically starts operation when connected to the USB port.

Barcode scanner is sold separately.

Printer Connection

a. Turn the printer on.

b. USB Connection

The printer is automatically recognized once USB cable is connected.

c. Bluetooth Connection

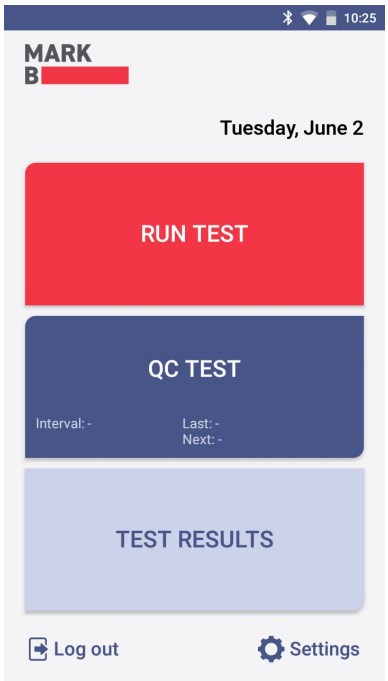
Please refer to **[Function settings → Printer setting]** on Page 32 of this manual.

Printer is sold separately.

5. Running a Test

5-1. How to Perform RUN TEST

STEP 1. Touch the 'RUN TEST' button to start test

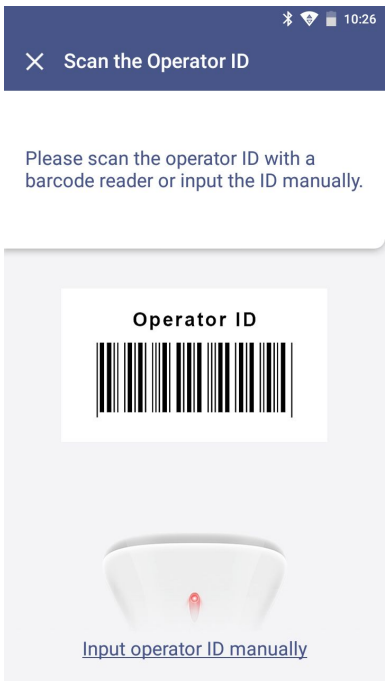


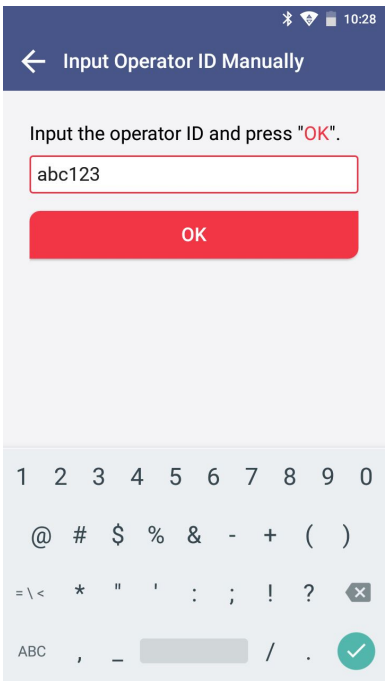
- Operating temperature(Device without a cartridge) is -10 ~ 45°C (14 ~ 113°F).
- Run test within the specified range of temperature.
- If the temperature is out of range, the test cannot be run.
- When the battery level becomes 15% or lower, the test cannot be run.
- Fully charge the battery before running a test.

STEP 2. Operator code scan

a. Scan the code with a barcode scanner or type it using the keypad.

b. Touch the '**OK' button**.





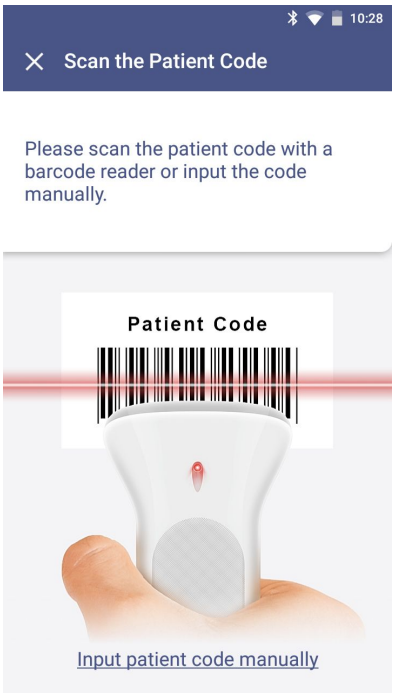
If you do not have a barcode scanner, touch the **'Input operator ID manually'** to enter the code using the keypad.

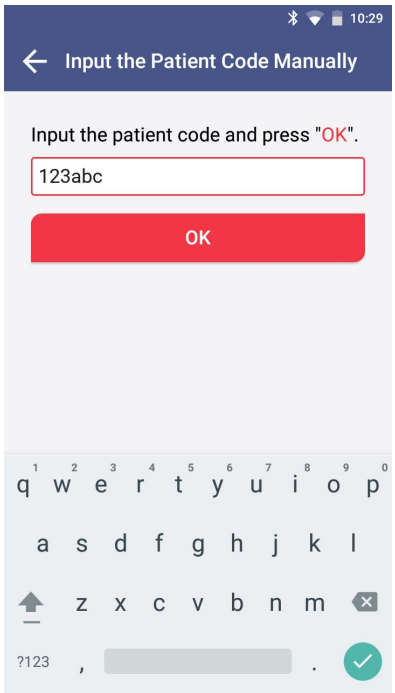
5-1. How to Perform RUN TEST

STEP 3. Patient code scan

a. Scan the patient code with a barcode scanner.

b. When the code is inputted, proceed to the cartridge insertion.





If you do not have a barcode scanner, touch the **'Input patient code manually'** to enter the code using the keypad.

STEP 4. Cartridge QR code scan

a. Scan the QR code on the cartridge pouch with a barcode scanner.

b. After scanning the QR code, cartridge type and LOT code are displayed on the screen.

- Barcode scanner is sold separately.
- If QR code recognition fails, scan a new cartridge pouch.
- Please check if the test marker is correct.

5-1. How to Perform RUN TEST

STEP 5. Test cartridge insertion

a. Insert a test cartridge to the tray according to the instructions on the screen.

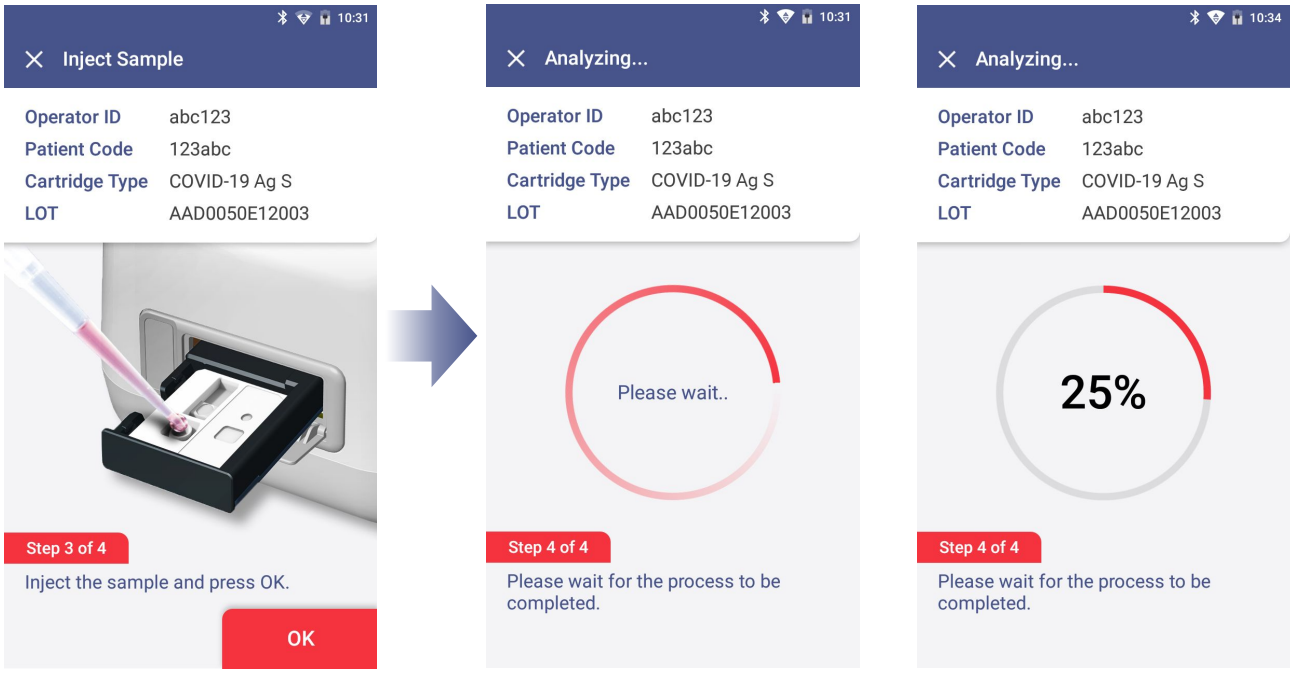
b. When the cartridge is inserted in the correct position, the screen automatically instructs to inject test sample.

- Ensure the correct operator and test sample code are entered before inserting a cartridge.
- Ensure the QR code of the cartridge to be inserted is scanned.
- Double check whether you are using the correct test cartridge for the marker.
- Before inserting a cartridge, ensure that you are not using an already used one.
- When **'Please contact the system administrator'** message is displayed after inserting a cartridge, stop using it and contact the administrator.

- If the tray does not move out, the device displays 'Contact System Administrator'**.** In that case, follow the instructions and contact the administrator.

5-1. How to Perform RUN TEST

STEP 6. Test sample injection and starting test



a. Prepare a test sample.

b. Before injecting the sample, check injection location of the test sample and whether a sufficient amount of test sample is prepared.

c. Inject the test sample within 2 minutes after inserting a cartridge.

d. After injection of the test sample is completed, touch the **'OK'** button.

- When the analysis starts, please wait until analysis reaches '100%'.
- If the tray is not inserted into analyzer within 2 minutes after injected sample, start over with a new cartridge.
- If an error occurs in waiting mode, inject more of the sample into the cartridge inserted.
- When an error occurs in analyzing mode, start over with a new cartridge.
- Refer to the test cartridge package insert for details on how to draw test samples.

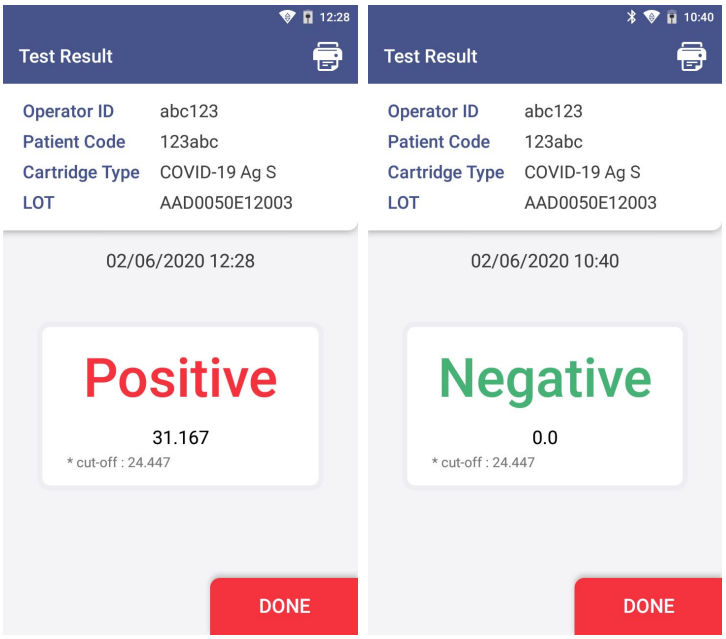
5-1. How to Perform RUN TEST

STEP 7. Check the result of the test.

a. When test is completed, the result of the test is displayed on the same screen.

b. Check the result and remove the cartridge from the tray.

c. Touch the '**DONE**' button → Return to the home screen.



TEST RESULT: Positive or Negative
- Normal operation of test cartridge

If the warning sign is displayed as shown:

*" * warning: unexpected signal detected.",*

a retest is recommended.

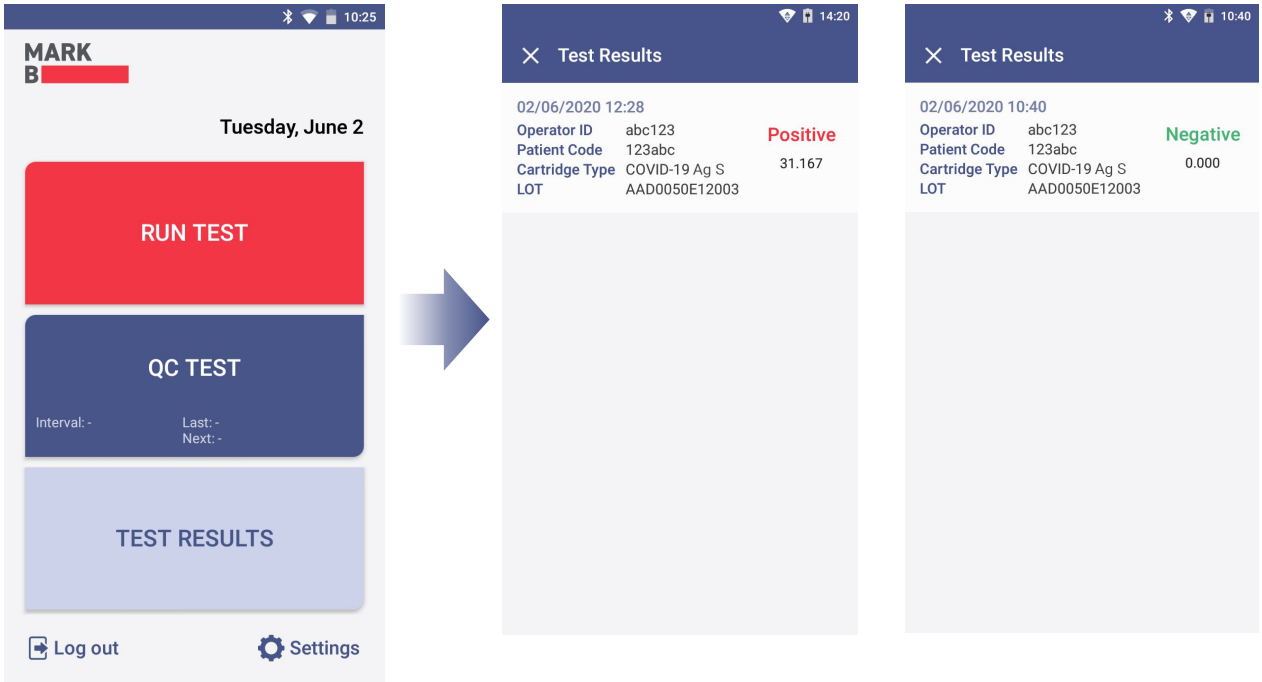
STEP 8. Discard the used cartridge.

Refer to the images below to eject the cartridge from the tray.
Discard used cartridge in a safe place under relevant laws and regulations.

5-2. Result Management

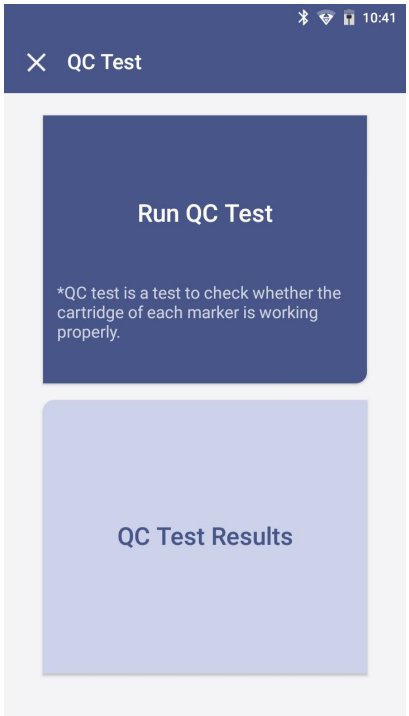
Check the results of the test.

- The results can be checked by touching the **'TEST RESULTS'** button on the home screen.



6. Running a QC Test (Control Solution Test)

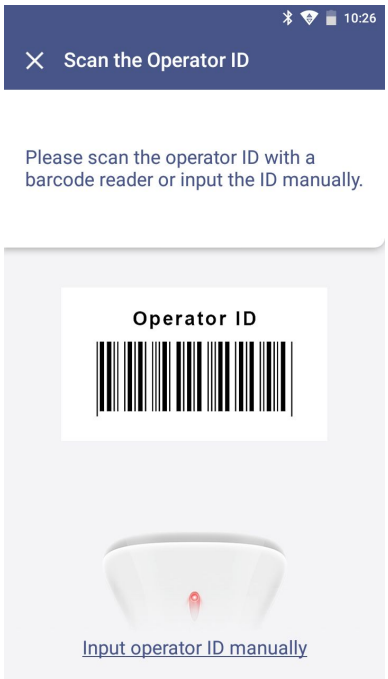
STEP 1. Touch the ‘Run QC Test’ button.

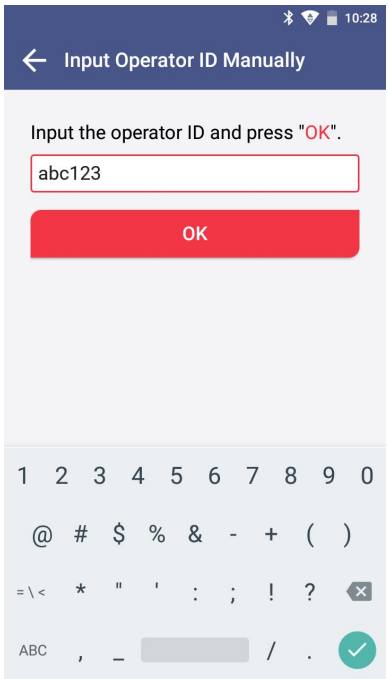


STEP 2. Operator code scan

a. Scan the code with a barcode scanner or type it using the keypad.

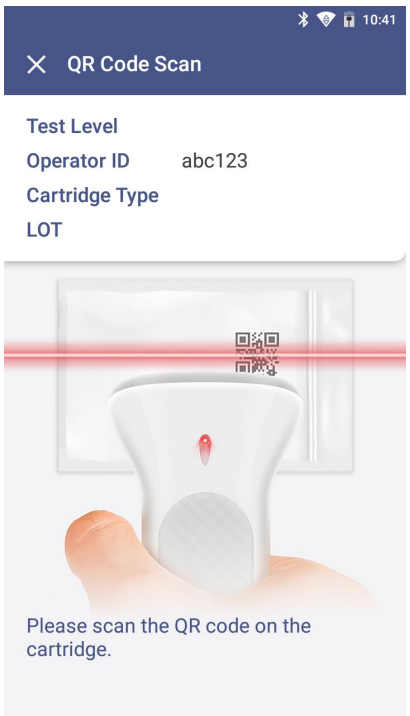
b. Touch the ‘**OK**’ button.





If you do not have a barcode scanner, touch ‘Input operator ID manually’ to enter the code using the keypad.

STEP 3. Test cartridge QR code scan

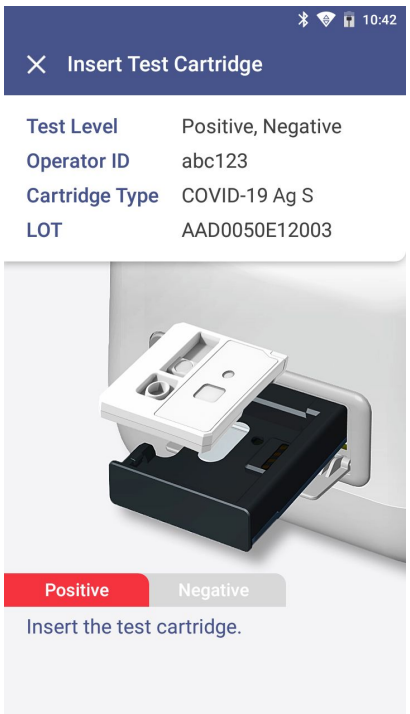


a. Scan the QR code on the cartridge pouch with a barcode scanner.

b. After scanning the QR code, test level, cartridge type and LOT code are displayed on the screen.

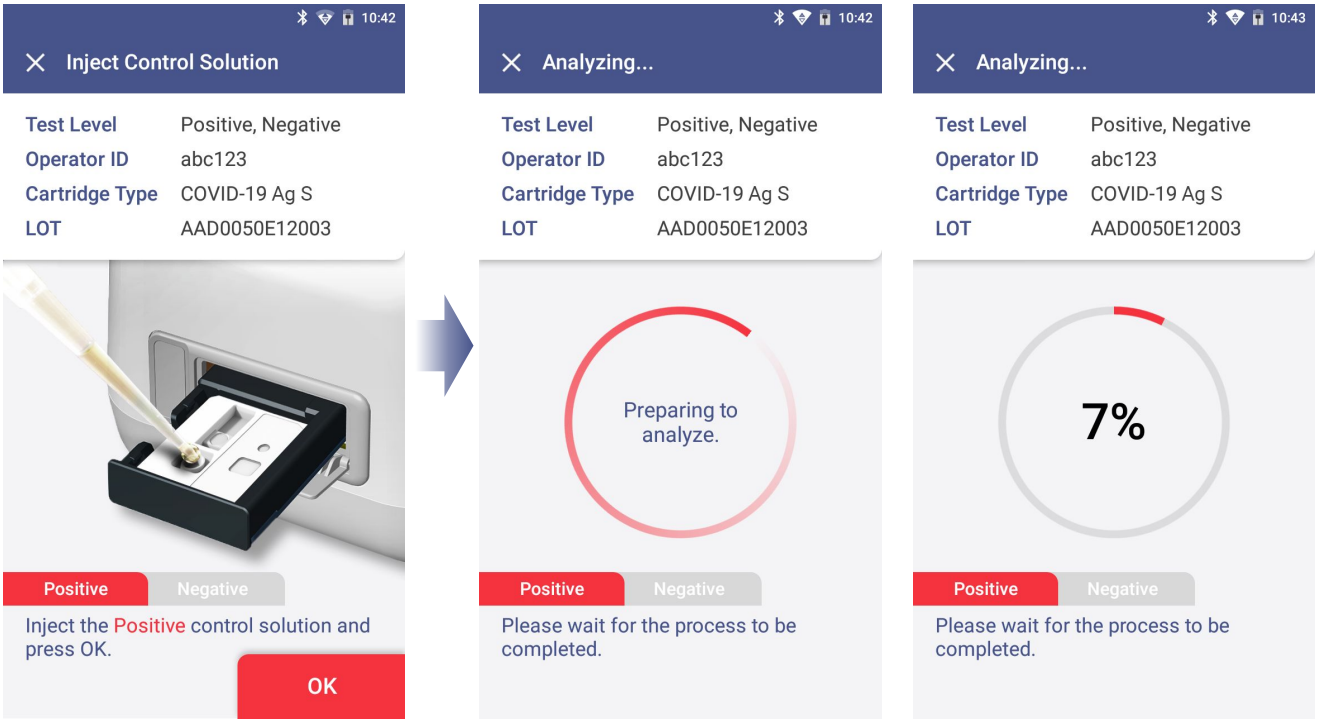
- Barcode scanner has to be purchased separately.
- If QR code recognition fails, scan a new cartridge pouch.
- Please check if the test marker is correct.

STEP 4. Test cartridge insertion



- Ensure the correct operator and test sample code are entered before inserting a cartridge.
- Ensure that you scanned the QR code of the cartridge to be inserted.
- Double check whether you are using the test cartridge for the correct marker.
- Before inserting a cartridge, ensure that you are not using a used one.
- When ‘Contact System Administrator’ message is displayed after inserting a cartridge, stop using it and contact the administrator.

STEP 5. Positive control solution injection



a. Prepare positive control solution of the same marker as the inserted test cartridge.

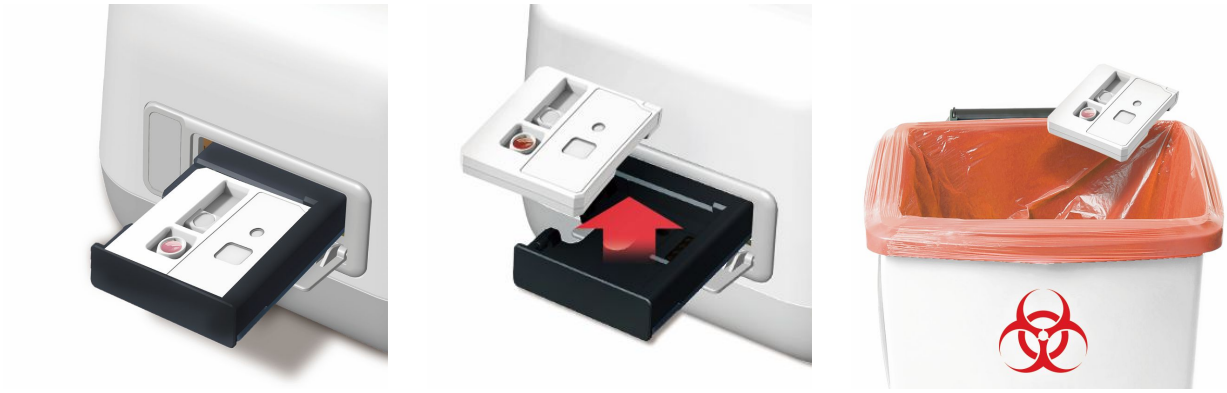
b. Draw control solution to inject it into the cartridge within 2 minutes.

c. Touch the **'OK'** button.

STEP 6. Discard the used cartridge.

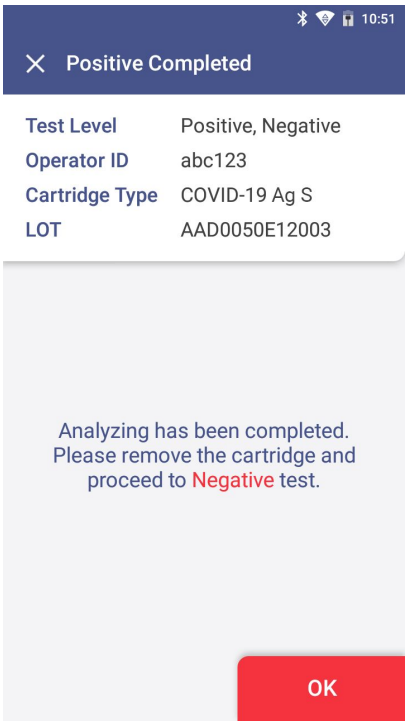
a. Refer to the images below to eject the cartridge from the tray.
Discard used cartridge in a safe place under relevant laws and regulations.

b. Touch the **'OK'** button.

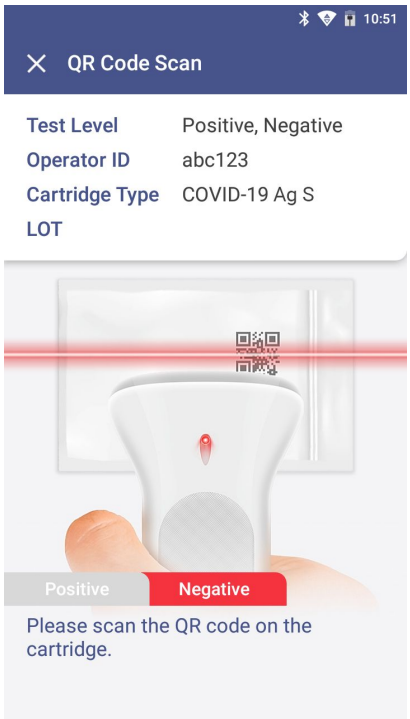


STEP 6. Discard the used cartridge. **(continued)**

b. When touching the '**OK**' button, the screen will proceed to the **'QR Code Scan'** screen.



STEP 7. Test cartridge QR code scan



a. Scan the QR code on the cartridge pouch with a barcode scanner.

b. After scanning the QR code, cartridge type and LOT code are displayed on the screen.

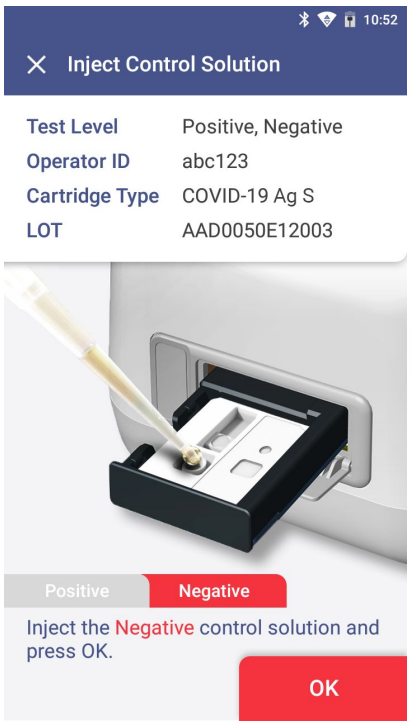
- Barcode scanner has to be purchased separately.
- If QR code recognition fails, scan a new cartridge pouch.
- Please check if the test marker is correct.

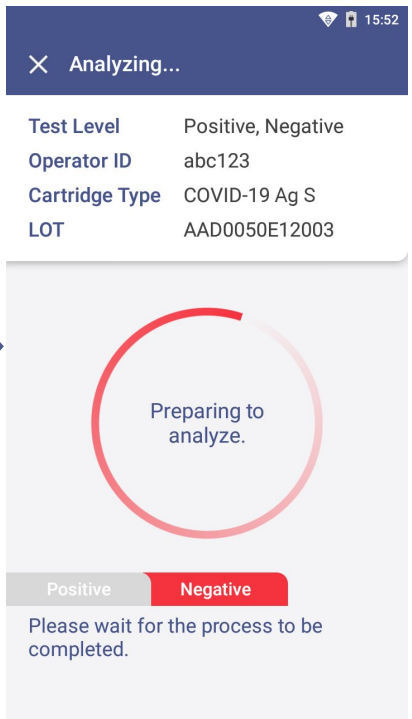
6. Running a QC Test (Control Solution Test)

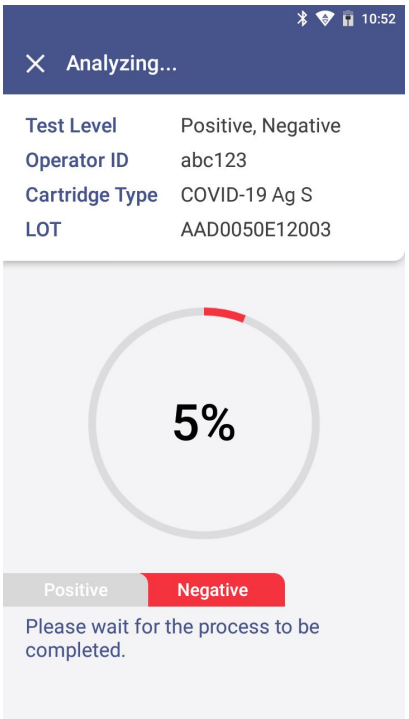
STEP 8. Test cartridge insertion

- Ensure the correct operator and test sample code are entered before inserting a cartridge.
- Check that you scanned the QR code of the cartridge to be inserted.
- Double check whether you are using the test cartridge for the correct marker.
- Before inserting a cartridge, ensure that you are not using a used one.
- When '**Please contact the system administrator**' message is displayed after inserting a cartridge, stop using it and contact the administrator.

STEP 9. Negative control solution injection





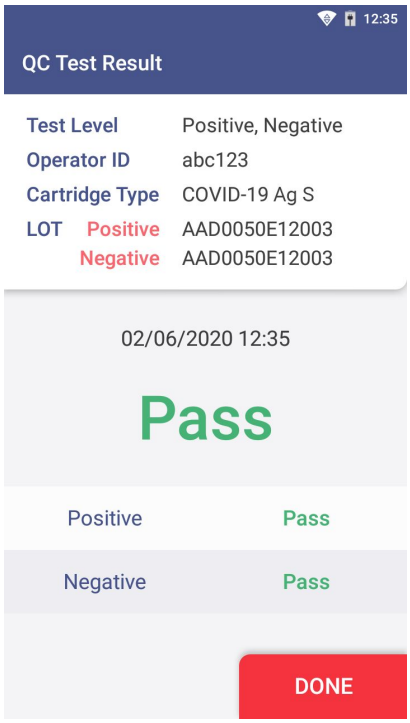


a. Prepare negative control solution of the same marker as the inserted test cartridge.

b. Draw control solution to inject it into the cartridge within 2 minutes.

c. Touch the **'OK'** button.

STEP 10. Check the result of QC Test



a. When test is completed, result of QC test is displayed on the same screen.

b. Check the result and remove the cartridge from the tray.

c. Touch the '**DONE**' button → Return to the home screen.

TEST RESULT: Pass

Normal operation of test cartridge

TEST RESULT: Fail

Accuracy of the actual test is not verified.

Conduct the test again or contact the administrator.

STEP 11. Discard the used cartridge.

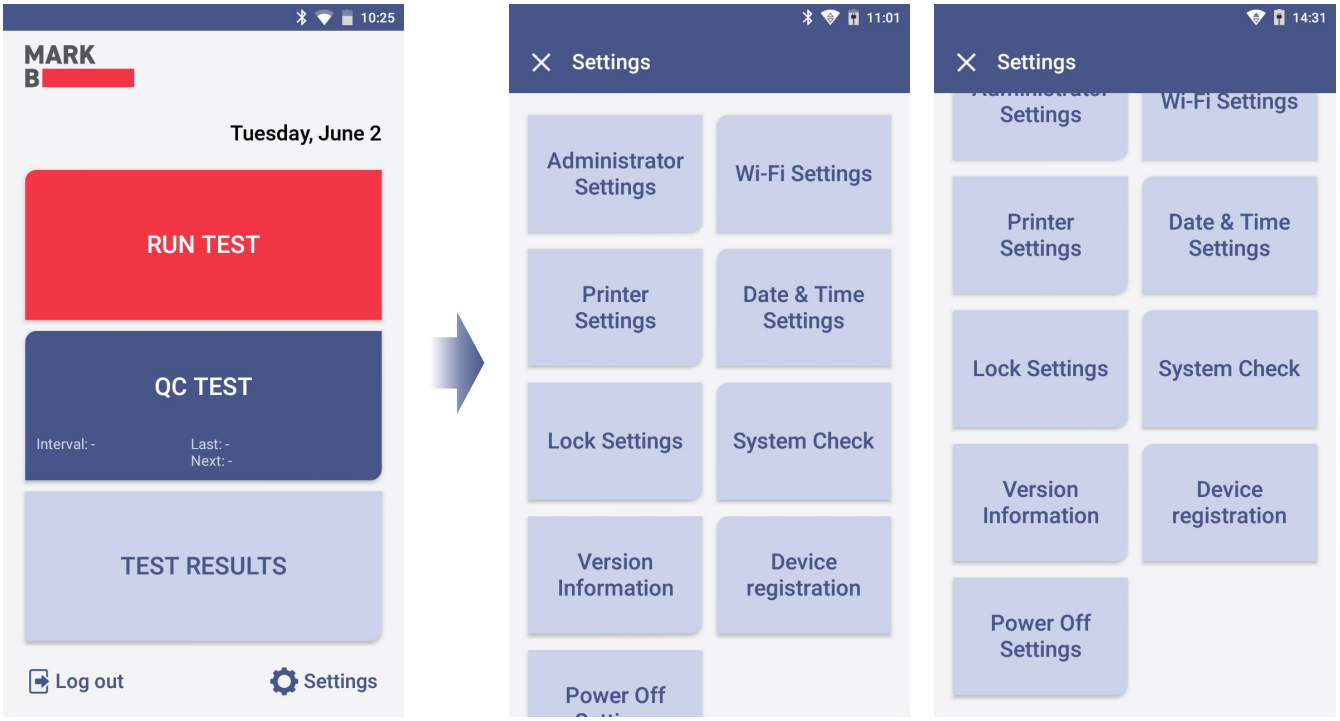
a. Refer to the images below to eject the cartridge from the tray.
Discard used cartridge in a safe place under relevant laws and regulations.

b. Touch the '**DONE**' button.

7. Function Settings

7-1. Setup Screen

Settings → Settings Menu



<u>Setting menu</u>

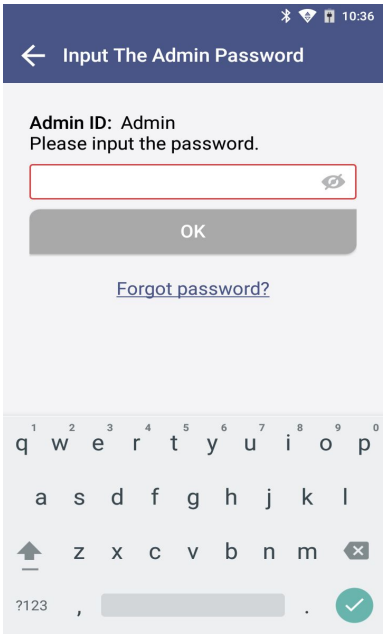
- Administrator Settings
- Wi-Fi Settings
- Printer Settings
- Date & Time Settings
- Lock Settings
- System Check
- Version Information
- Device Registration
- Power Off Settings

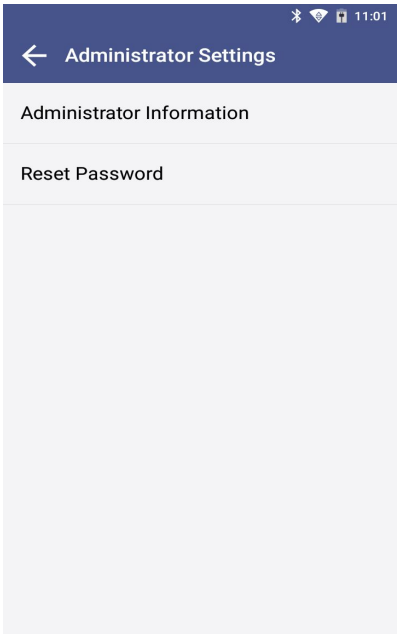
7-2. Administrator Settings

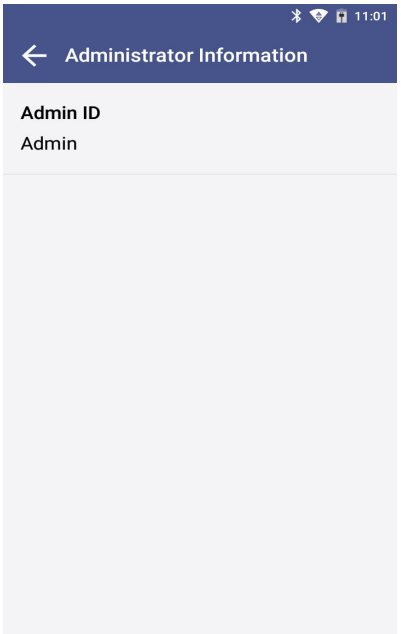
Administrator Information

a.Enter admin password to proceed to administrator settings.

b.Touch the **'Administrator Information'** button to check the administrator information.



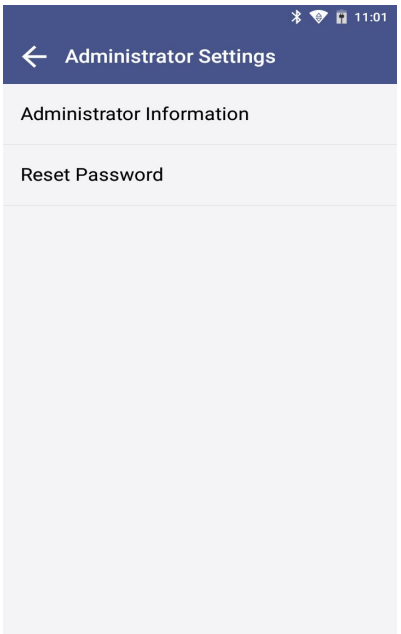


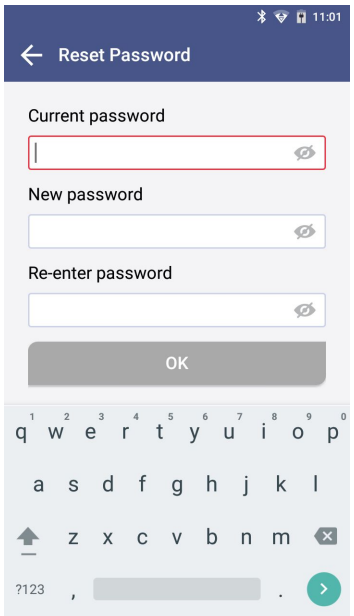


Change Administrator Password

a. Touch the '**Reset Password**' button. → Enter the current password.

b. Enter a new password in 'New password' and **'Re-enter password'**. → Touch the **'OK'** button.





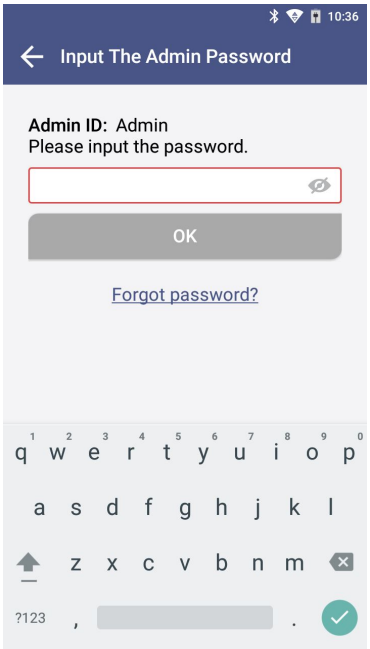
- Password is case-sensitive and must be a combination of letters and numbers.
- Your password cannot contain spaces and must be less than 45 characters long.
- Touch the eye-shaped icon to check entered password.

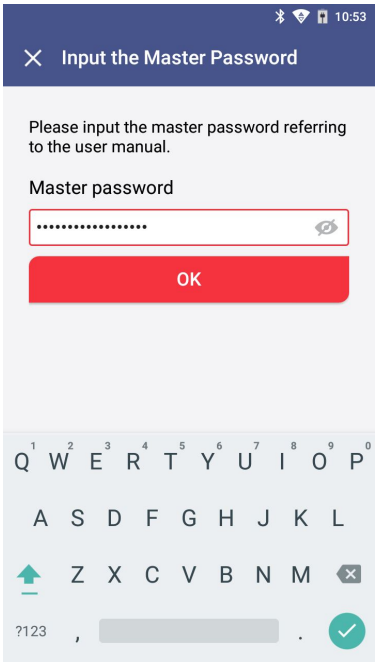
7-2. Administrator Settings

Forgot Password

a. If you forgot admin password, touch ‘Forgot password?’.

b. Master password input screen will be displayed.

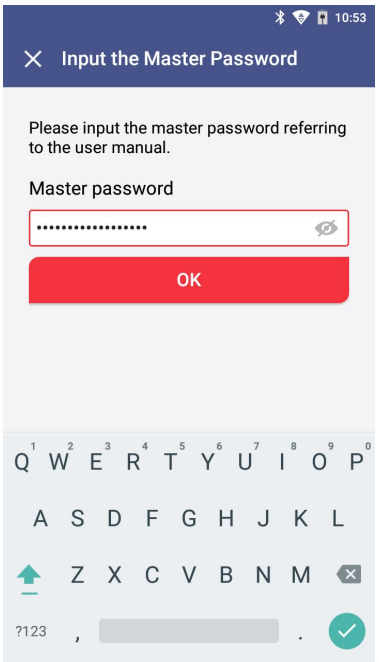


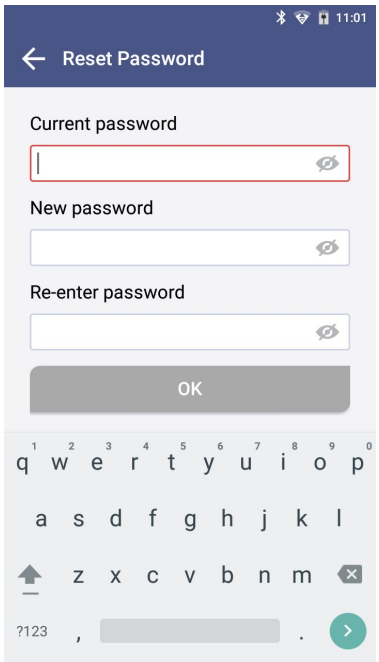


Input the Master Password

Type the master password. → Enter the new admin password. → Touch the **‘OK’** button.

- Master password is the ‘serial number of the device’ + ‘0001’.
- Serial number is written in the label on the bottom of the device.

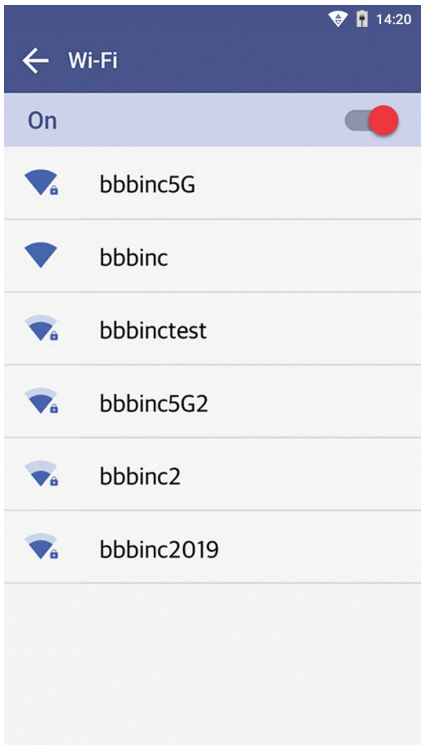


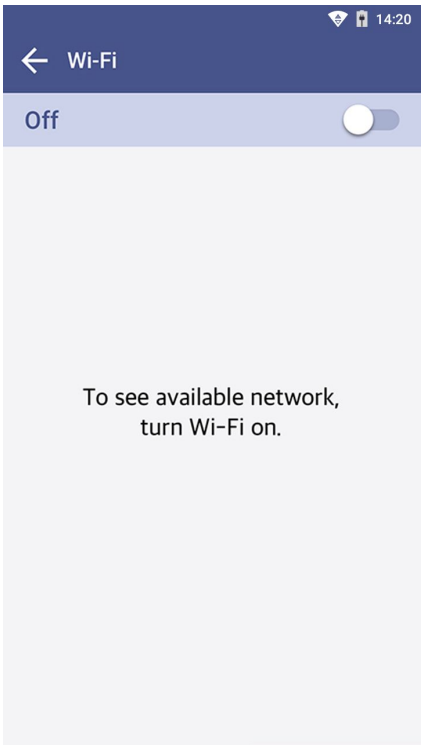


7-3. Wi-Fi Settings

Turn Wi-Fi On or Off & Connect to a Wi-Fi.

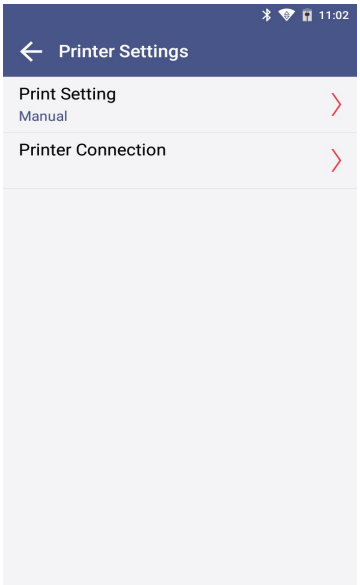
[Wi-Fi Setting → On/Off] : Turn Wi-Fi network on or off.
Select **'On'** : Select Wi-Fi to connect to.

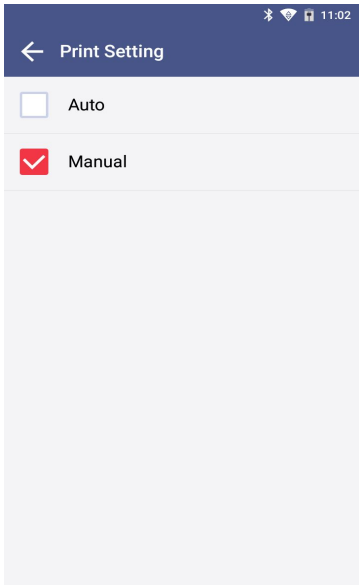




7.4. Printer Settings

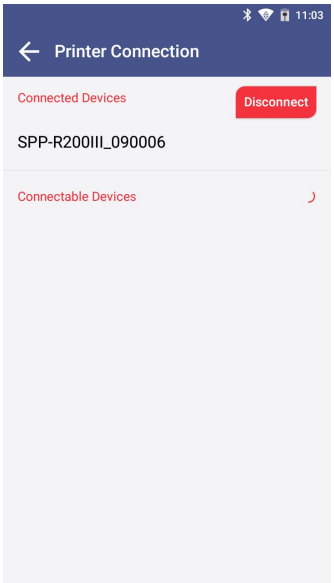
Print Setting

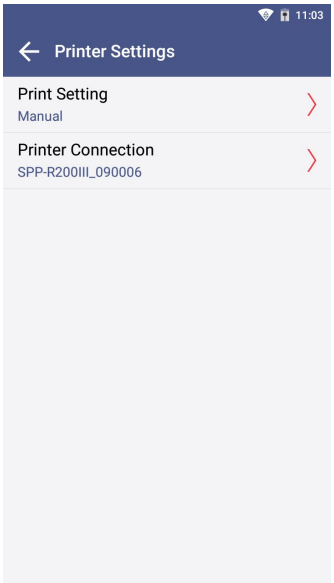




Select ‘Auto’ or ‘Manual’ button in Print Setting.

Printer Connection





a. Find a printer model to link from the ‘Connectable Devices’ list.
b. Select the model.
c. The printer is connected and displayed in Connected Device.
c. To disconnect, touch the ‘Disconnect’ button.

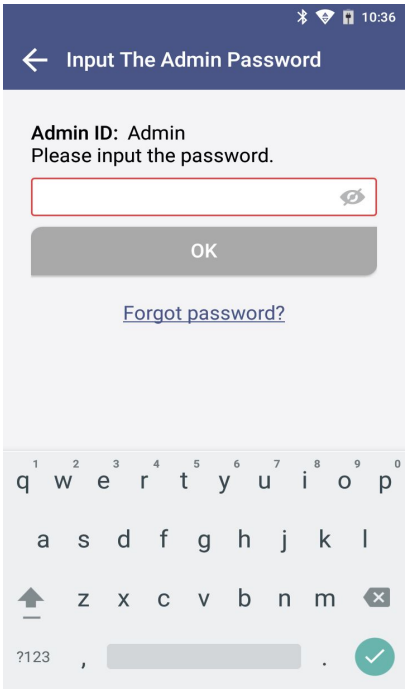
- Printer is automatically linked when you connect USB port.
- To find a printer’s model number, remove the battery of printer. Then, check the product label.

- If you try to connect with another printer *via* USB while Bluetooth has been connected prior, the Bluetooth will be unpaired and the device will be connected to the USB printer.
- Printing may be unavailable if you use a mobile printer incompatible with MARK-B™ 1 analyzer.
- Changing printer connection mode may cause a delay for two seconds.
  Please wait until the message ‘Please wait’ disappears.

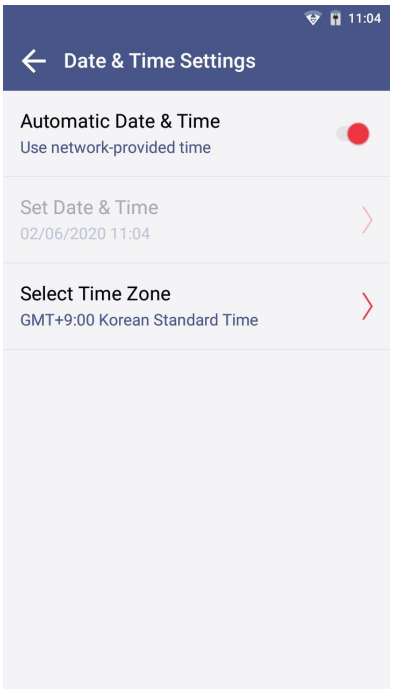
7-5. Date & Time Settings

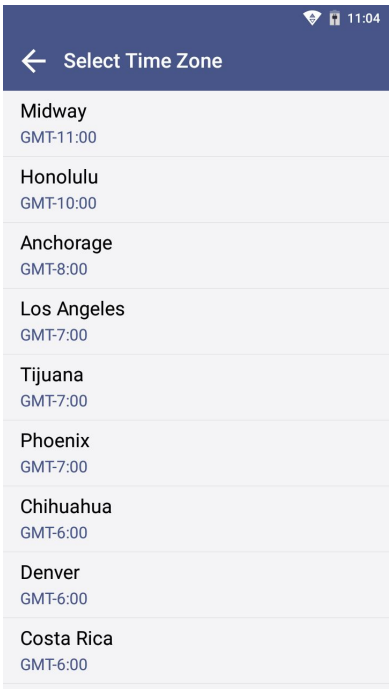
STEP 1. Date & Time Settings

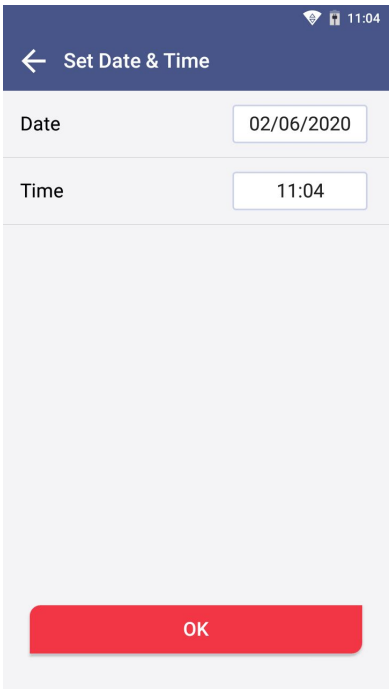
Enter the admin password to access ‘Date & Time Settings’.



- Touch ‘Date & Time Settings’. → Touch ‘Select Time Zone’. → Select the location.

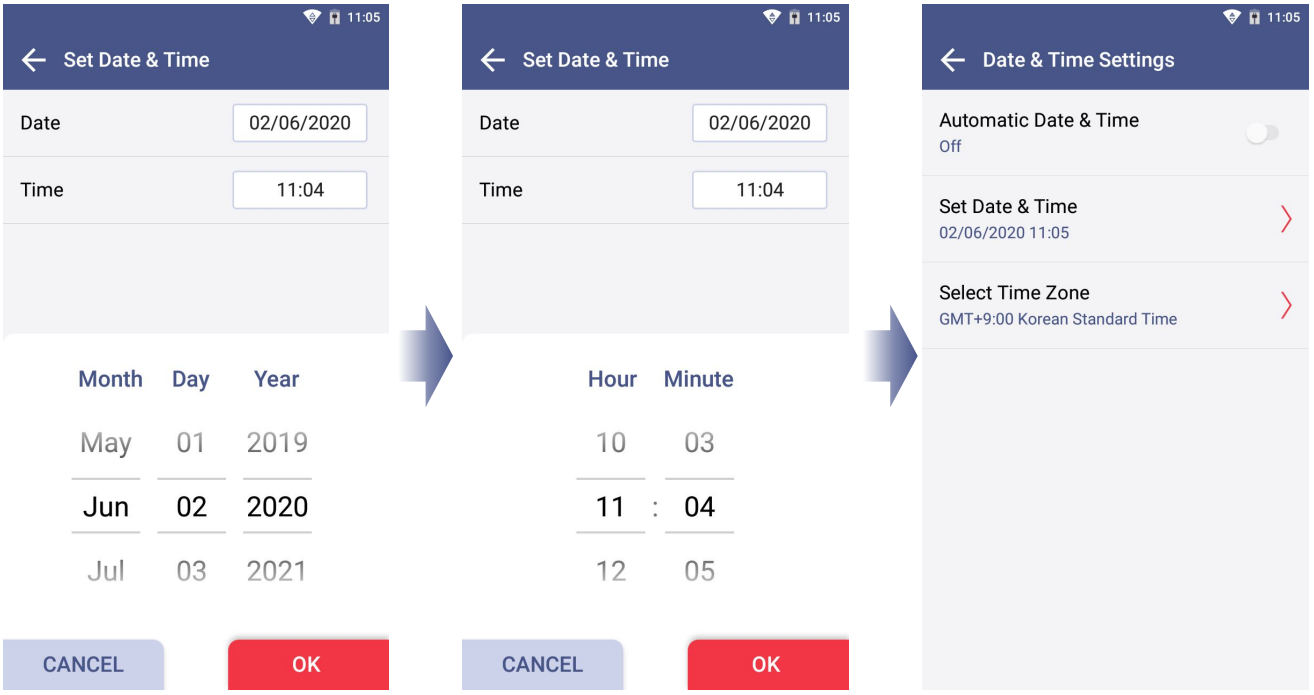






7-5. Date & Time Settings

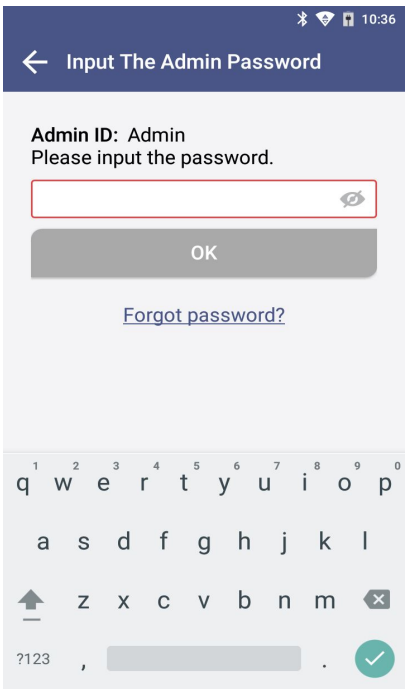
- Adjust ‘Set Date & Time’. → Touch the ‘OK’ button.

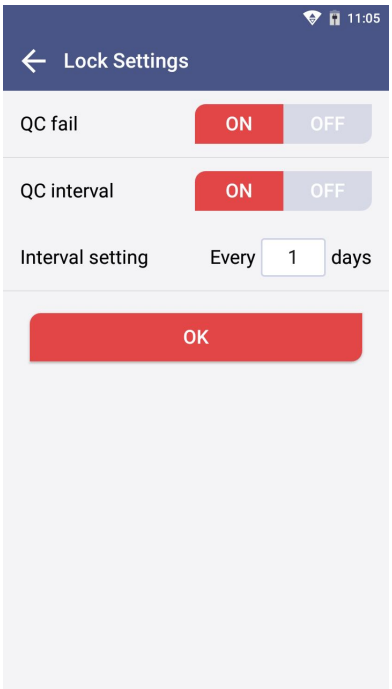


7-6. Lock Settings

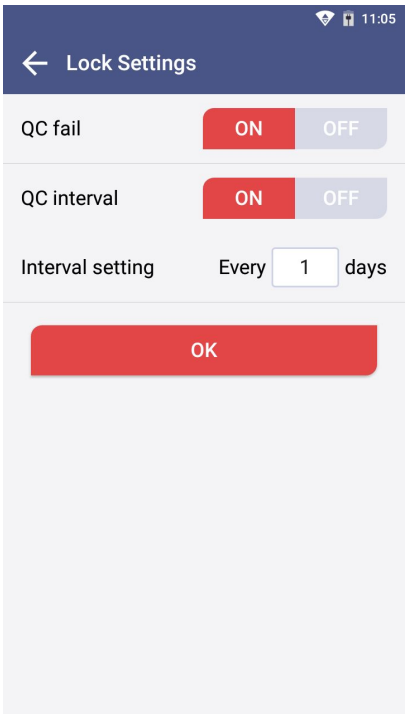
STEP 1. Lock Settings

Enter the admin password to access Lock Settings.





STEP 2. Lock Settings and QC Test



[ON] The QC Test result must be a ‘PASS’ to be able to run a test.

[OFF] A test can be run regardless of QC Test result.

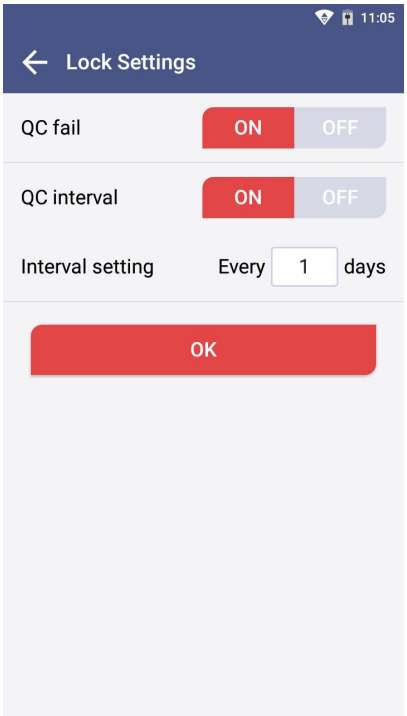
☑ QC Lock is to lock or unlock the RUN TEST.

⚠

- When all settings of QC Lock are turned OFF, a test can be run even if QC Test result is ‘fail’.
- BBB is not responsible for the test results run under settings with all QC Lock Settings turned OFF.

7-6. Lock Settings

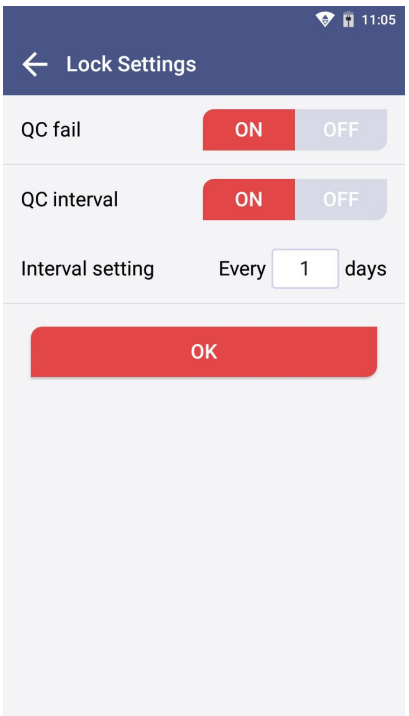
STEP 3. QC Test interval setting



[ON] A sample test is available after conducting QC test at the intervals you set up.
[OFF] You can continue QC test without setting up intervals.

- You can set the intervals for QC test.
- When the interval is set up, it will be shown under Run QC Test on the home screen.

STEP 4. Date interval setting



a. Touch the input box and then select using the numeric keypad shown on the screen.
b. Enter a number between 1 and 365 to set up QC Test intervals.

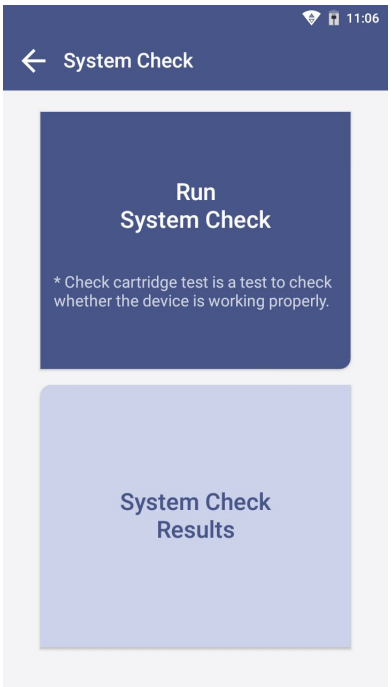
- Please input only numbers for the date interval setting.

8. Maintenance

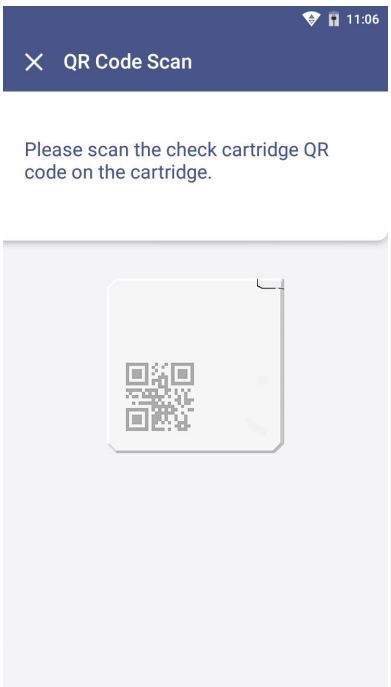
8-1. System Check

System Check : The purpose of the check cartridge test is to verify proper operation of MARK-B™ 1 analyzer.

STEP 1. Touch the '**Run System Check**' button



STEP 2. Scan QR code of the check cartridge



a. Scan QR code on a check cartridge with a barcode scanner.
b. After scanning the QR code, the screen proceeds to 'Insert Check Cartridge'.

- Barcode scanner has to be purchased separately.
- If you scan QR code of the test cartridge, the test will not proceed.
- If QR code recognition continues to fail, please contact the administrator.

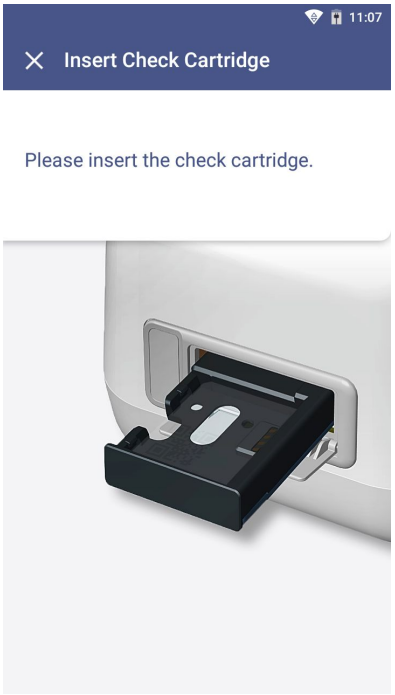
8-1. System Check

STEP 3. Insertion of check cartridge tray

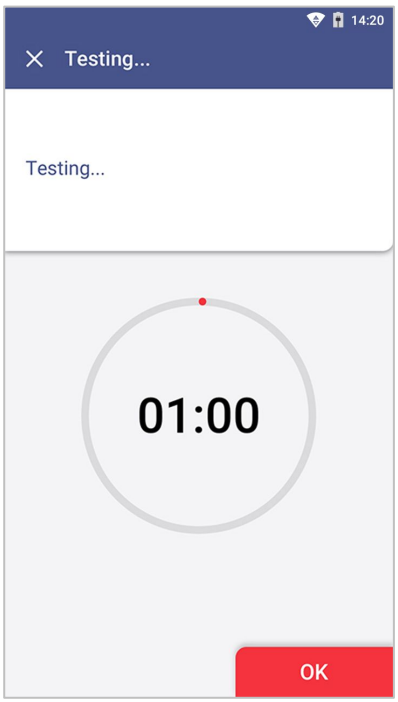
a. Insert a check cartridge to the tray according to instructions on the screen.

b. Insert the check cartridge in the correct position.

c. Touch the **'OK'** button.



STEP 4. Start **'System Check'**

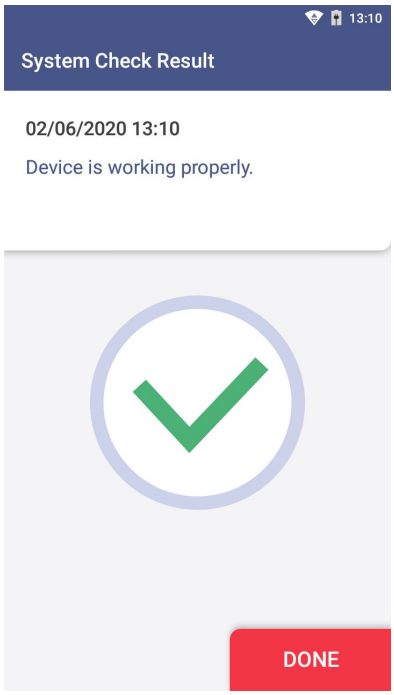


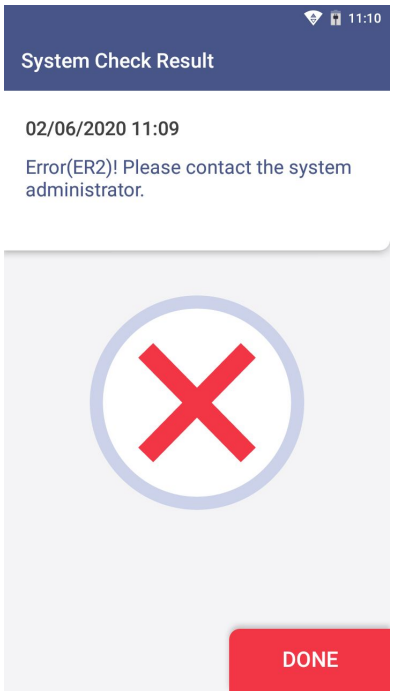
☑ A check cartridge test takes about 1 minute.

8-1. System Check

STEP 5. Confirm the check cartridge test results

a. The test results are displayed upon completion.
b. After checking the results, remove the used cartridge from the tray.
c. Touch the **'DONE'** button to move to the home screen.





Pass : A message that the device is working properly and a ✓ mark is displayed on the screen.

Fail : An error message and an X mark is displayed on the screen.

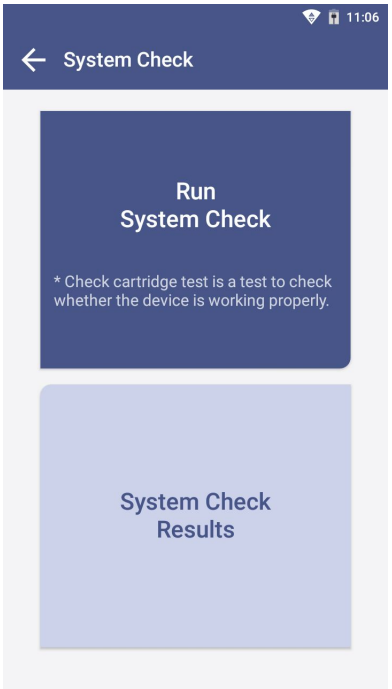
Try out the test again or contact the administrator.

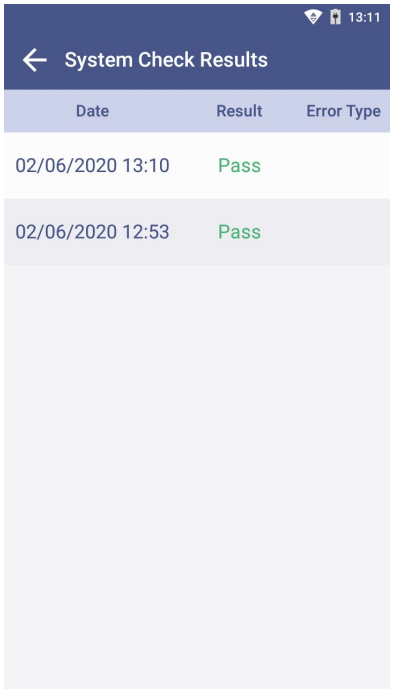
If the test fails under **[QC Test Settings → QC Lock ON],** a test cannot be run.

8-1. System Check

System Check → System Check Result

The System Check Result is displayed in order from latest to earliest.



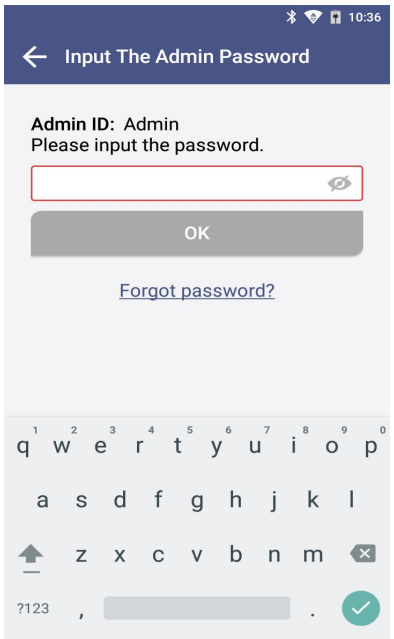


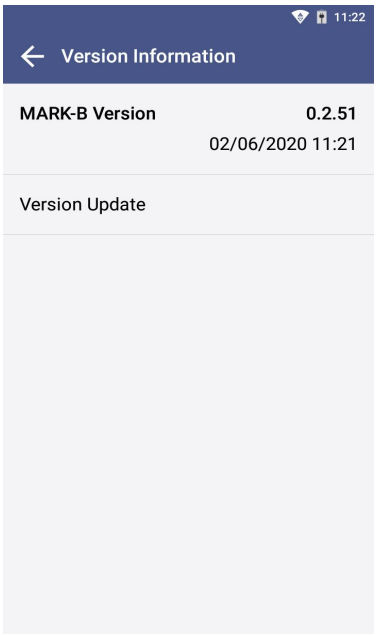
8-2. View Version Information and Update

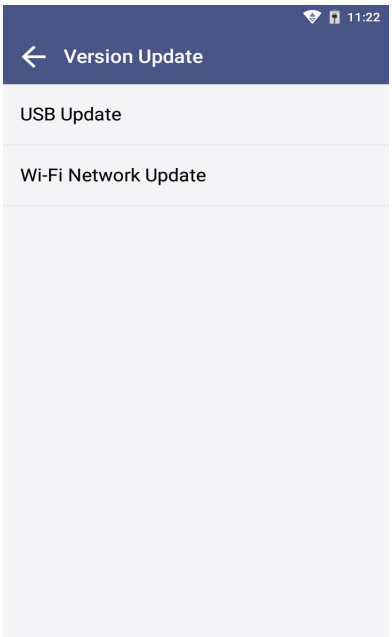
STEP 1. Check the Version Information

a. Type the admin password and access device registration menu.

b. Confirm the latest version.







8-2. Version Information and Update

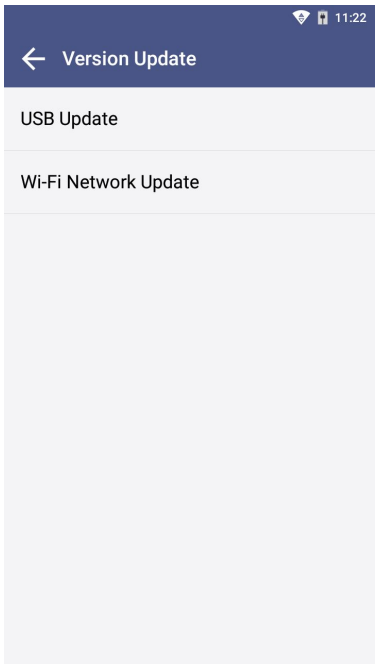
STEP 2. Update new version

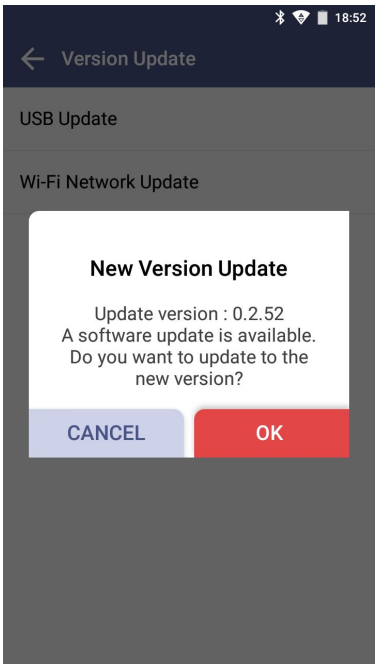
Option 1. Software update by USB connection

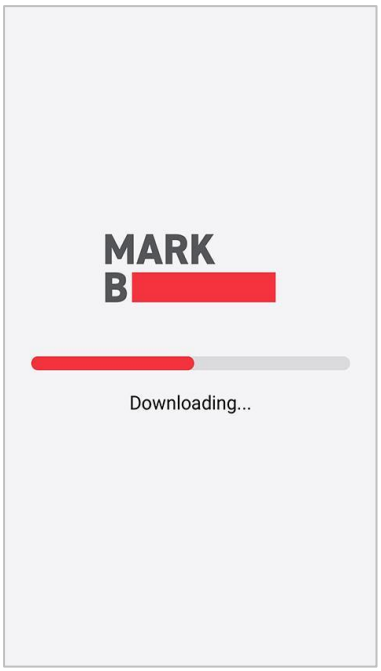
a. Connect the USB containing the updated version to the USB port on the back of the analyzer.

b. Select ‘USB Update’. (A message to update to new version will be displayed if the software needs to be updated.)

c. Touch the ‘OK’ button to update to the latest software.







- USB connection → The above message pops up. → Check the pop-up box. → Touch OK.
- Allow USB drive connection for successful update.
- The update starts when the analyzer’s battery level is 15% or higher.
- Removing the USB before finishing the update may cancel the update.
- If the update continuously fails, please contact the system administrator.

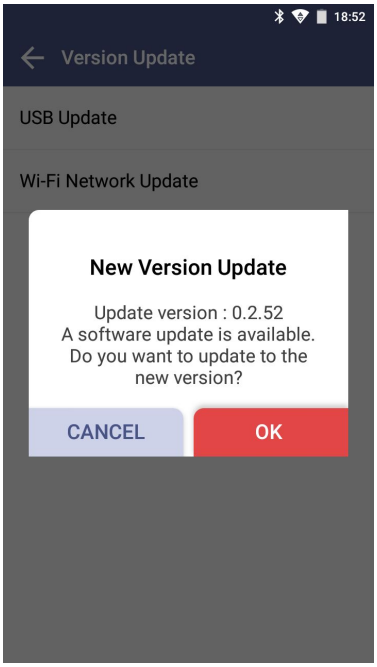
8-2. Version Information and Update

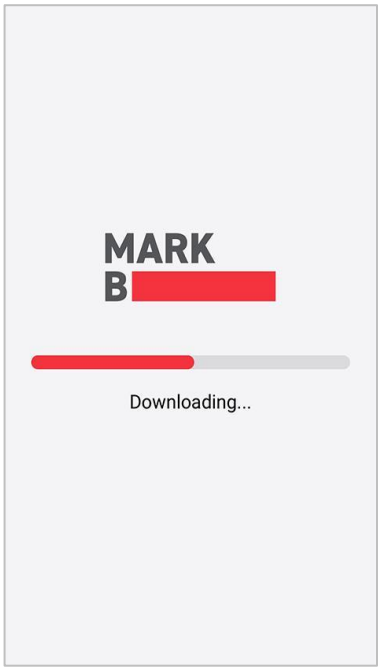
STEP 2. Update new version

Option 2.Wireless update of software

a. Select ‘WI-FI Network update’. (A message to update to new version will be displayed if the software needs to be updated.)

b. Touch the ‘OK’ button to update to the latest software.





- The update starts when MARK-B™ 1 analyzer’s battery level is 15% or higher.
- Unstable wireless network connectivity may cancel the update.
- If the update continuously fails, please contact the system administrator.

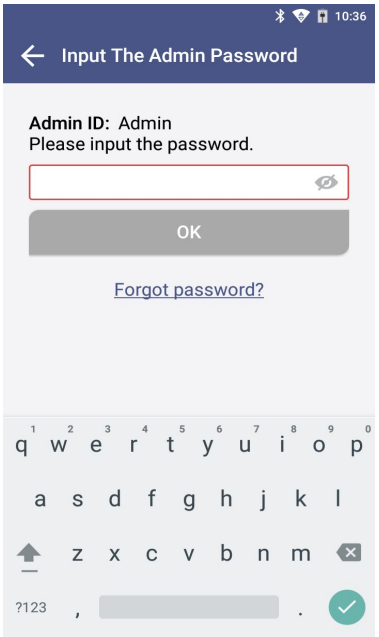
8-3. Device Registration

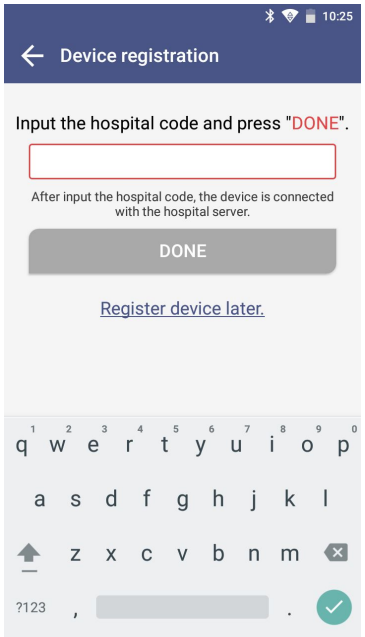
STEP 1. Settings → Device Registration

a. Input the admin password to access device registration menu.

b. Enter the hospital code on the device registration screen.

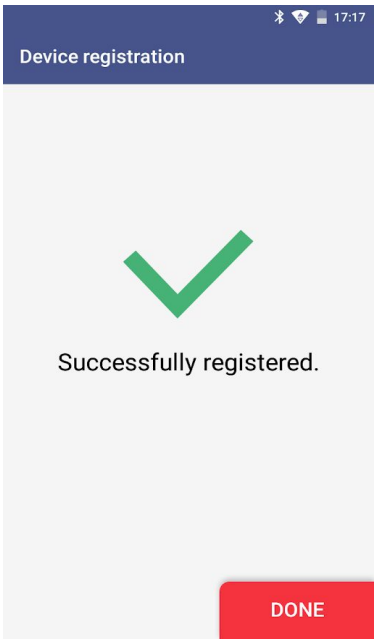
c. Type the hospital code and touch the ‘**DONE’** button. The device will try to access the hospital server.





If you have already registered the device during initial setup, you do not need to set it up again.

STEP 2. Registration Completed



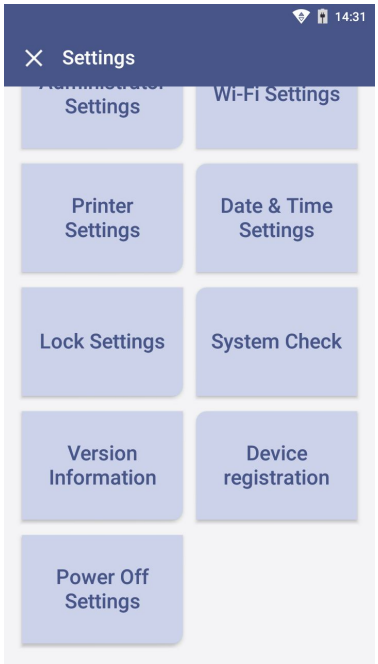
When registration is completed:

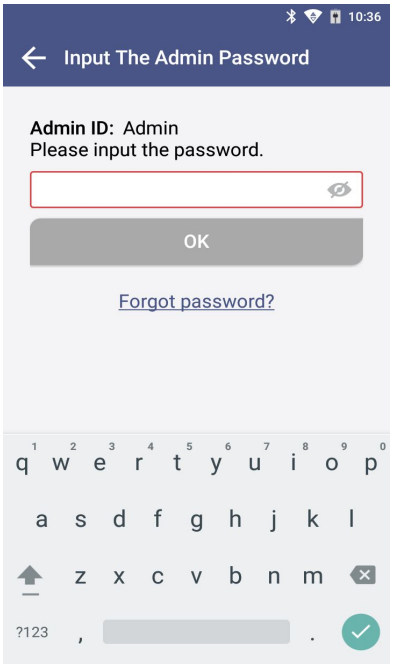
a. The message ‘Successfully Registered’ is displayed.

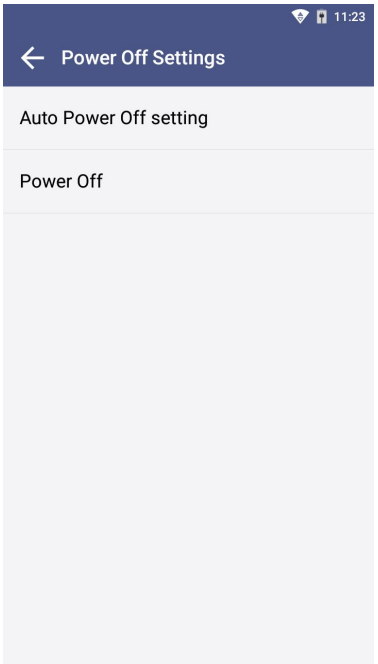
b. Touch the ‘**DONE’** button to proceed to settings screen.

8-4. Auto Power Off Settings

a. Select the ‘Power Off Settings’ button.
b. Input the admin password.
c. Select ‘Power Off’

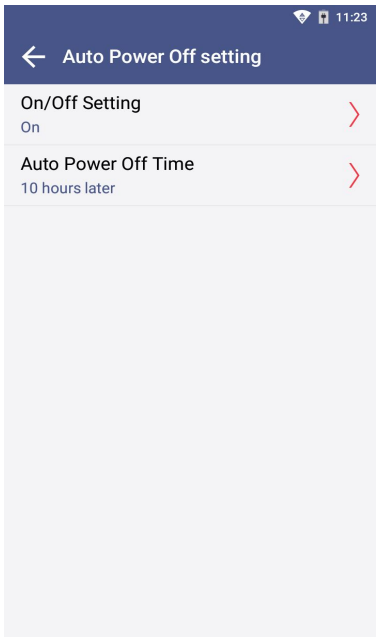


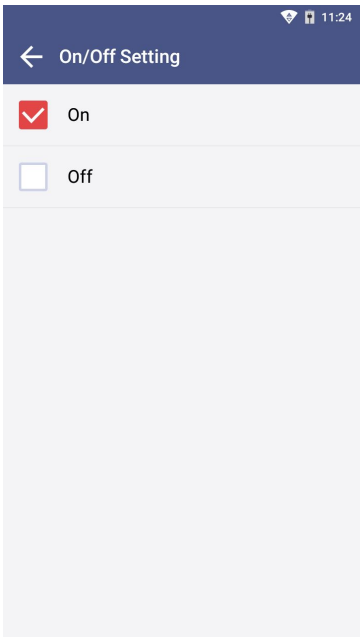




Option 1. On/Off Setting of Auto Power Off

Select on or off by touching **[Auto Power Off Settings → On/Off]** to enable or disable the function.

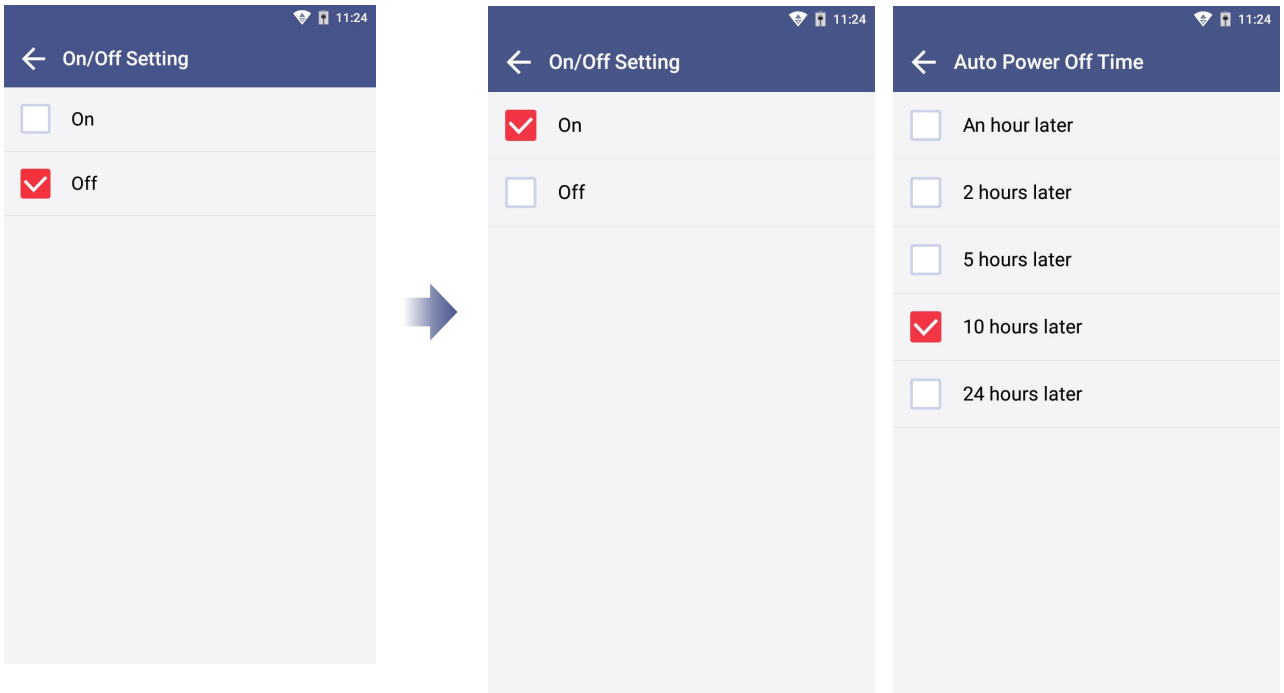




- Default auto power off time is 10 hours when the function is enabled ‘On’.
- Auto power off time can be changed by selecting **Auto Power off Time**.

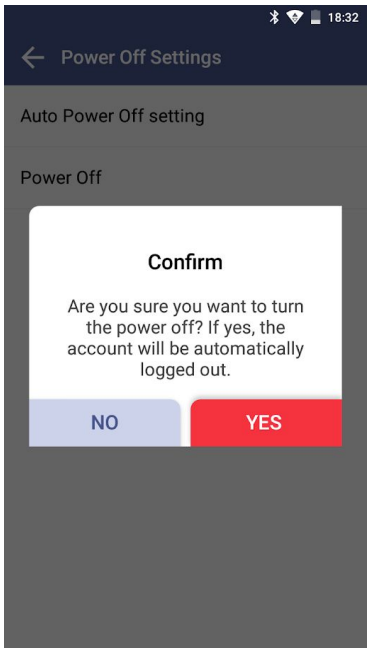
8-4. Auto Power Off Settings

On/Off setting → Select the **'On'** button →Select the '**Auto power off time'**
After selecting the duration time for the screen to be displayed, the device will be automatically turned off after that duration time.



Option 2. Power Off

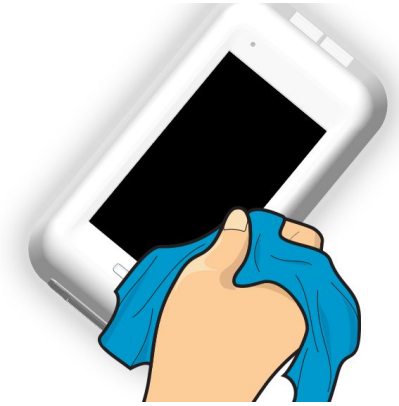
a. Select the 'Power off' button.
b. Touch the '**YES**' button to finally turn the power of the device off.



- It is recommended to turn MARK-B™ 1 analyzer off, if the instrument is not used for a long period of time.
- If you turn off the analyzer for a long time, time settings of the device may be initialized. Time is automatically set up, once the instrument is connected to Wi-Fi.

8-5. Cleaning

Clean the analyzer periodically with a soft and dry cloth.



Clean the analyzer periodically with a soft and dry cloth. Do not use highly corrosive cleaning solution or chemicals,
or a cleaning tissue contains chemical substances that may damage the device.

Make sure to turn off when cleaning the device.

Test Tray Cleaning

The blood, moisture or dust that enters the tray may lead to failure of the MARK-B™ 1 analyzer. Wipe the tray carefully with an alcohol-moistened swab if needed.

- Make sure to turn off the device when cleaning the tray.
- Avoid contact with electrode when cleaning as it is a sensitive part.

8-6. Storage Requirements

- Protect the device from dust and do not expose it to direct sunlight.
- Recommended temperature and humidity for storage condition are as follows:
  [Temperature] -10 ~ 45℃ (14 - 113℉)
  [Humidity] 10 ~ 80%
- Avoid storage places prone to tremors or that could cause falling.

9. Error Messages

9-1. Notifications

Notifications	Description and Measure
Please input the admin password.	Admin password is not inputted. Displayed when touching the '**DONE**' button without entering the admin password. ▶️Input the admin password and then touch the '**DONE**' button.
Please input the hospital code.	Hospital code is not inputted. Displayed when touching the '**DONE**' button without entering the hospital code. ▶️Input the hospital code and then touch the '**DONE**' button.
Unregistered hospital code. Please contact administrator.	Unregistered hospital code Displayed when unregistered hospital code is entered.
Failed to connect to network. Please try again.	No response from server Displayed when device registration fails due to lost network connection or other errors which make server communication unavailable.
Unknown error. Please try again.	Server Error The alert pop-up when server communication is failed.
Please try again after connecting to a network.	No Wi-Fi Connection Displayed when device requests server communication for Wi-Fi connection.
Low battery. 15% of battery is remaining. The remaining battery must be more than 15% to run the analyzer. Please connect the analyzer to the power source.	Low battery Displayed when touching the low-battery icon on the home screen.

9. Error Messages

9-1. Notifications

Notifications	Description and Measure
The system check was failed or has an error. Please check the results again. Contact the system administrator.	System Check is not performed. Displayed when system check is not performed. **[Setting screen → System Check → Run System Check]**
The QC was failed or has an error. Please check the results again.	QC not performed. Displayed when touching QC! icon on the home screen in the case of when the QC Test has not been performed.
The temperature is not within operational range. (Current temperature: 38℃ / (100.4℉)	Inappropriate temperature Displayed when touching temperature icon on the home screen which pops up when temperature is out of range for test.
The admin account automatically logged out.	Administrator account logout Displayed when administrator account logs out before power off or reboot.
Please log in first.	Attempted access in a logged off state Displayed when the setting menu requires administrator account login.
Please input the master password.	Master password is not inputted Displayed when the '**DONE**' button is touched without master password input.
Incorrect password. Please input the master password again.	Password input error Displayed when wrong password is inputted.

9. Error Messages

9-1. Notifications

Notifications	Description and Measure
The fan is activated due to increased internal temperature of the analyzer.	Fan activated Displayed when the fan is activated by MARK-B™ 1 analyzer's temperature sensor operation.
Invalid ID. Please check the ID again.	Wrong operator code Displayed when wrong operator code is entered.
Please input the operator ID.	Operator code is not inputted. Displayed when touching DONE without entering the operator code.
Please input the test sample code.	Test sample code is not inputted. Displayed when touching DONE without entering the test sample code.
Please insert test cartridge in the tray.	Tray ejection failure Displayed when a cartridge is not inserted in the tray within the specified time period.
Please remove the cartridge.	Cartridge is removed. Displayed when cartridge is removed.

9. Error Messages

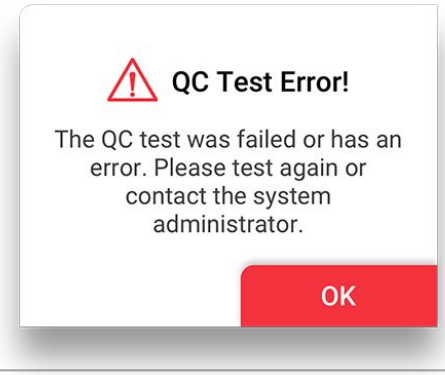
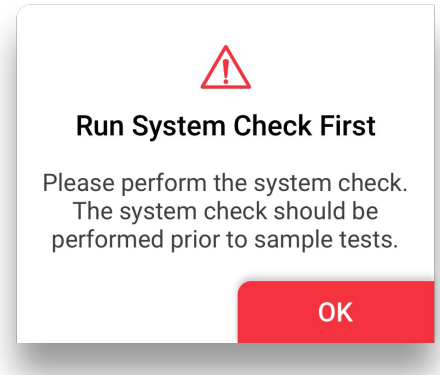
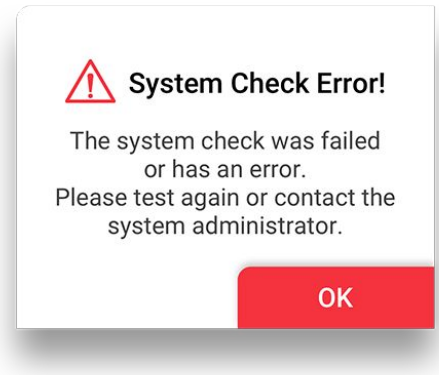
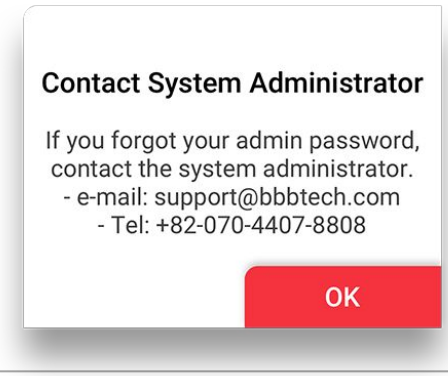
9-1. Notifications

Notifications	Description and Measure
Incorrect password. Please input the password correctly.	Current password mismatch Displayed when you do not enter currently set password.
The new password and re-entered password do not match. Please input the passwords again.	New password mismatch Displayed on the **Change Administrator Password** screen when newly entered password does not match with the one typed in the new password **confirm** box.
Please input the new admin password.	New administrator password is not inputted. Displayed when new administrator password is not inputted in the password setting screen.
Please disconnect the device first and then try connecting the device.	Bluetooth disconnection Displayed when new bluetooth printer connection is requested while the analyzer is connected to a bluetooth printer.
Please remove the USB port first and then try connecting the device.	USB disconnection Displayed when a bluetooth printer connection is requested while the analyzer is connected to a USB mobile printer.
Unregistered hospital code. Please contact administrator.	Unregistered hospital codes Displayed when unregistered hospital code is inputted.

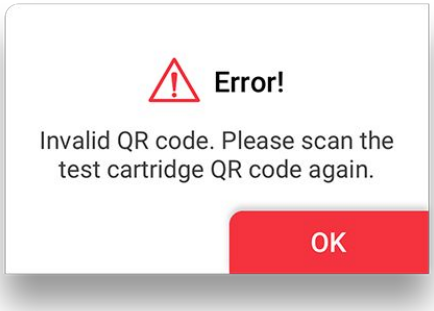
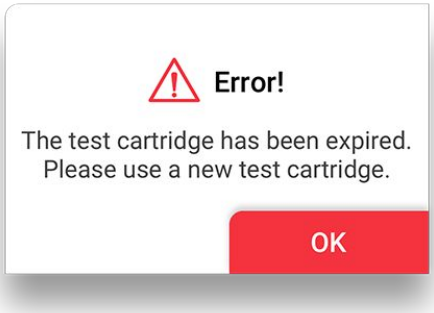
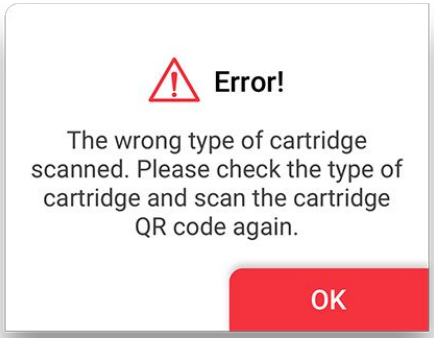
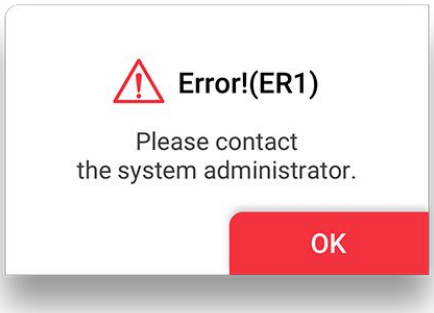
9-2. Error pop-ups

Error Pop-ups	Description and Measure
Out Of Temperature Range Current temperature **38°C** **(100.4°F)** The temperature is not within operational range. For accurate readings, please try again at room temperature. OK	Inappropriate temperature <u>Case1.</u> Pops up when the '**RUN TEST'** button is touched on the home screen, or the '**RUN QC TEST'** button is touched. <u>Case2.</u> Pops up when the temperature is out of test range.
Battery Low! Low battery. 15% of battery is remaining. The remaining battery must be more than 15% to run the analyzer. Please connect the analyzer to the power source. OK	Low battery <u>Case1.</u> Pops up when the '**RUN TEST'** button is touched on the home screen, or the '**RUN QC TEST'** button is touched. <u>Case2.</u> Pops up when the battery level is 15% or lower and the user touched **Next** to proceed to the next level of QC test.
Run QC Test First Please perform the QC test. The QC test should be performed prior to sample tests. OK	QC test has not been performed. Pops up when the '**RUN TEST'** button on the home screen is touched under the condition that QC TEST has not been performed.

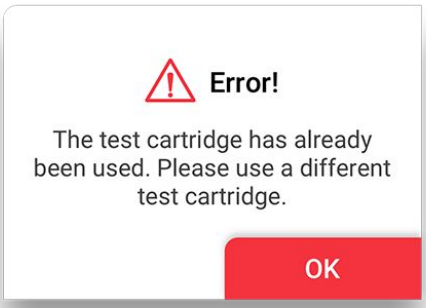
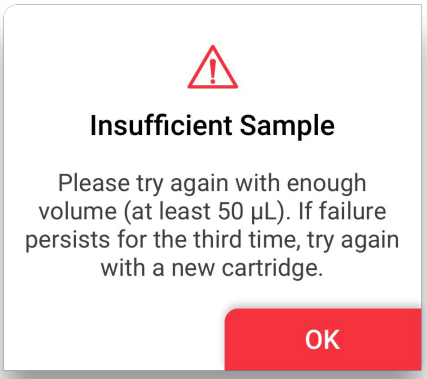
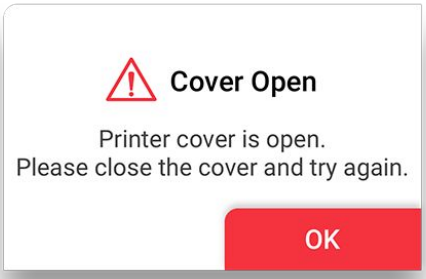
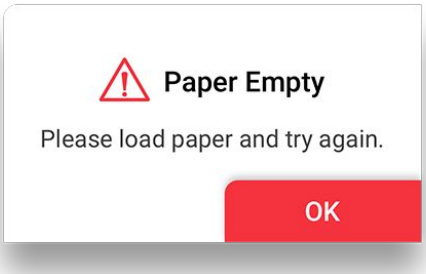
9-2. Error pop-ups

Error Pop-ups	Description and Measure
	QC Test error Pops up when the '**RUN TEST'** button is touched on the home screen under the condition that QC lock settings are turned '**ON'**, and/or QC TEST result is **'Fail'.**
	A check cartridge test has not been performed. Pops up when the '**RUN TEST'** button is touched on the home screen under the condition that the system check has not been performed.
	System Check Error Pops up when the '**RUN TEST'** button is touched on the home screen under the condition that the system check result is **'Fail'**.
	Contact the system administrator. Pops up upon selecting 'Forgot password?'.

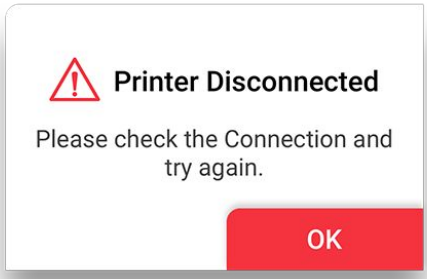
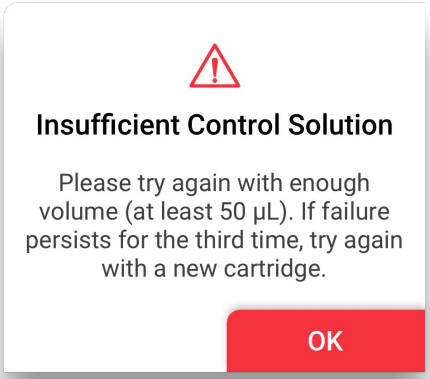
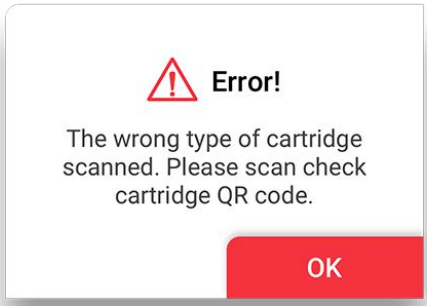
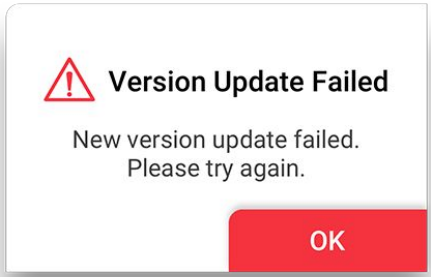
9-2. Error pop-ups

Error Pop-ups	Description and Measure
	Invalid cartridge QR code Pops up when an invalid QR code is scanned.
	Expired cartridge QR code Pops up when expired cartridge QR code is scanned.
	QR code of check cartridge is scanned. Pops up when the check cartridge's QR code is scanned instead of the test cartridge.
	Tray ejection failure Pops up within 10 seconds after tray ejection fails.

9-2. Error pop-ups

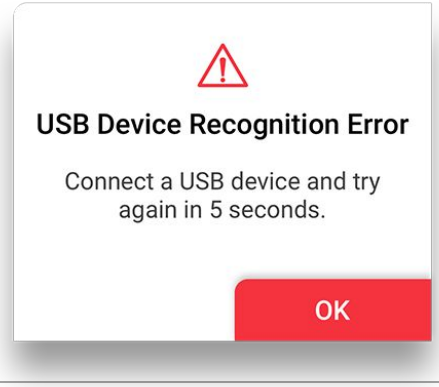
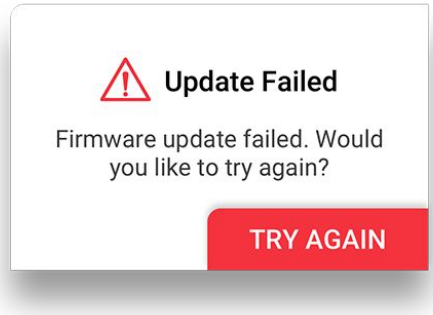
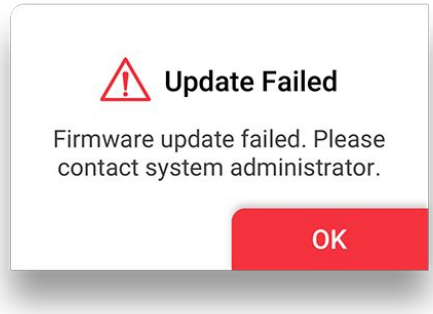
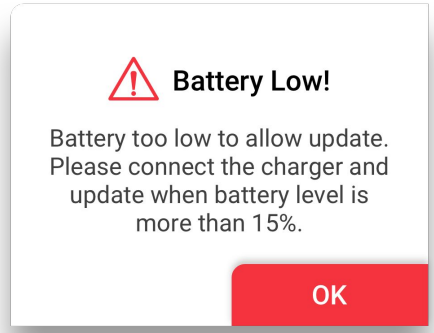
Error Pop-ups	Description and Measure
	Pops up when used cartridge is inserted.
	Failure of plasma separation or test sample test Pops up when test sample test fails due to errors in sample separation including timeout, insufficient test sample injection, etc.
	Pops up when the printer cover is open.
	Pops up when there is no paper left in the printer.

9-2. Error pop-ups

Error Pop-ups	Description and Measure
	Printer disconnection Pops up when the printer is not connected and the user touched the '**Print'** button.
	Solution separation error or insufficient solution Pops up when solution separation fails due to either timeout, insufficient solution injection, or solution reading failure.
	QR code of test cartridge is scanned. Pops up when the QR code of test cartridge is scanned during System Check process.
	New version installation failure Pops up upon new version installation failure during software update.

9. Error Messages

9-2. Error pop-ups

Error Pop-ups	Description and Measure
	USB Device Connection Error The alert pops up when USB is removed or disconnected during software update.
	Pops up when firmware update failed.
	Repetitive update failure Pops up when firmware update failed more than 3 times.
	Low battery during software update Pops up upon touching ‘Update’ when battery level is 15% or lower.

10. Technical Information

Model Name	MB-100
CPU	MT8163B (Quad core)
Display type	5.5” HD display, Touch screen
Memory capacity	8GB ROM / 1GB RAM
Battery	Main battery : 2,700mAh 3.8V Sub battery : 2,500mAh 14.4V (3.7V 18650 4cell)
Power	rating : 12VDC, 1.5A plug interface : 5.5mm * 2.5mm
Dimension/weight	114 x 206 x 86mm / 1,300g
OS	Android 7.0
LOT code reading	QR Code
Operating temperature (Device without a cartridge)	-10 ~ 45°C (14 ~ 113°F)
Storage environment	-10 ~ 45°C (14 ~ 113°F), less than 80% of relative humidity
Wi-Fi	2.4GHz (IEEE 802.11/b/g/n)
Bluetooth	4.0
USB port	USB A
Software version	v1.0.0
Firmware version	MBMP100

11. Product Warranty

Product Warranty

BBB Inc. offers product warranty in accordance with “Regulations on Consumer Dispute Resolution” as follows.
Within the warranty period, if the product fails due to manufacturing defect(s) or spontaneous failure, it will be replaced without any charges.

Warranty Period : One year from the purchase date

Manufacturer Information

BBB Inc.

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

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

FCC Information to User

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

• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is con-nected.
• Consult the dealer or an experienced radio/TV technician for help.

Caution

Modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

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