



IVD **R_x**only

SAMPINUTE™ Analyzer User Manual



Sampinute™ Analyzer (Immunoassay analyzer)

Sampinute™ Analyzer detects specific biomarker *via* immunoassay (MESIA; Magnetic Electrochemical Sandwich ImmunoAssay) from a small amount of test sample. Sampinute™ 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. For use under an Emergency Use Authorization (EUA) only.

SAMPINUTE



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1. Product Introduction

1-1. Intended Use

The Sampinute™ Analyzer is an instrument that performs immunoassay on test cartridges. It reads specific biomarkers within the test sample.

1-2. Principle

Sampinute™ Analyzer is an instrument based on an immunoassay technique called MESIA (Magnetic Electrochemical Sandwich Immunoassay). Sampinute™ 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 nanoprobe in the test cartridge to induce antibody-antigen reactions and remove unbound magnetic nanoprobe. The Sampinute™ Analyzer measures the concentration of any antigens or antibodies by detecting electrochemical signals from the reaction-completed magnetic nanoprobe. Sampinute™ 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.

Sampinute™ Analyzer is for use in IVDs.

Sampinute™ 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.

Aluminium tapes have been attached on the top of cartridges to help sustain the quality of the cartridges. Only remove these tapes upon usage.

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.

When discarding the analyzer, discard in a safe place in accordance with local, state and federal regulations or accreditation requirements.

For use under the Emergency Use Authorization (EUA) only

When used with the Sampinute™ COVID-19 Antigen MIA:

This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the requirements to perform moderate or high complexity tests.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

1-4. Components

The following are the components you should check upon opening the package of Sampinute™ 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.

Sampinute™ Analyzer, 1EA



















Check Cartridge, 1EA

User manual

Quick Reference 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		Prescription Use Only
	Date of Manufacture		Use by/Expiry date (for test cartridge)
	Batch code (for test cartridge)		Catalogue number (for test cartridge)
	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
	Do not reuse. (for test cartridge)		Please refer to user manual.
	Caution, please refer to accompanying documents		<i>In Vitro</i> Diagnostic Medical Device/ <i>In Vitro</i> diagnostic use
	Control		Contains sufficient for <n> tests.
	Waste electrical and electronic equipment (WEEE)		Important

2. Product Description

2-1. Sampinute™ Analyzer



(1) Screen

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

(2) Power Button

Button 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

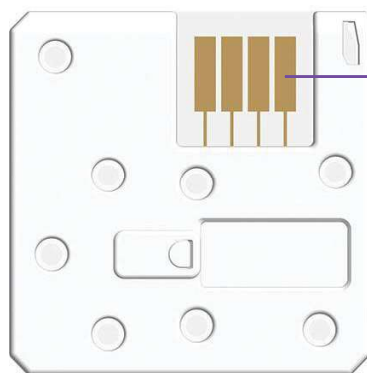
A switch to check cartridge insertion.

(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 Sampinute™ Analyzer

3. Screen Description

3-1. Home Screen



(1) Status bar

Indicates Sampinute™ Analyzer's network connection, battery level and time.

(2) Status indicating icon



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



is displayed when battery level is 15% or lower.



is displayed when temperature is either 15°C (59°F) or lower, or at least 30°C (86°F).



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) 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 QCtest

(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

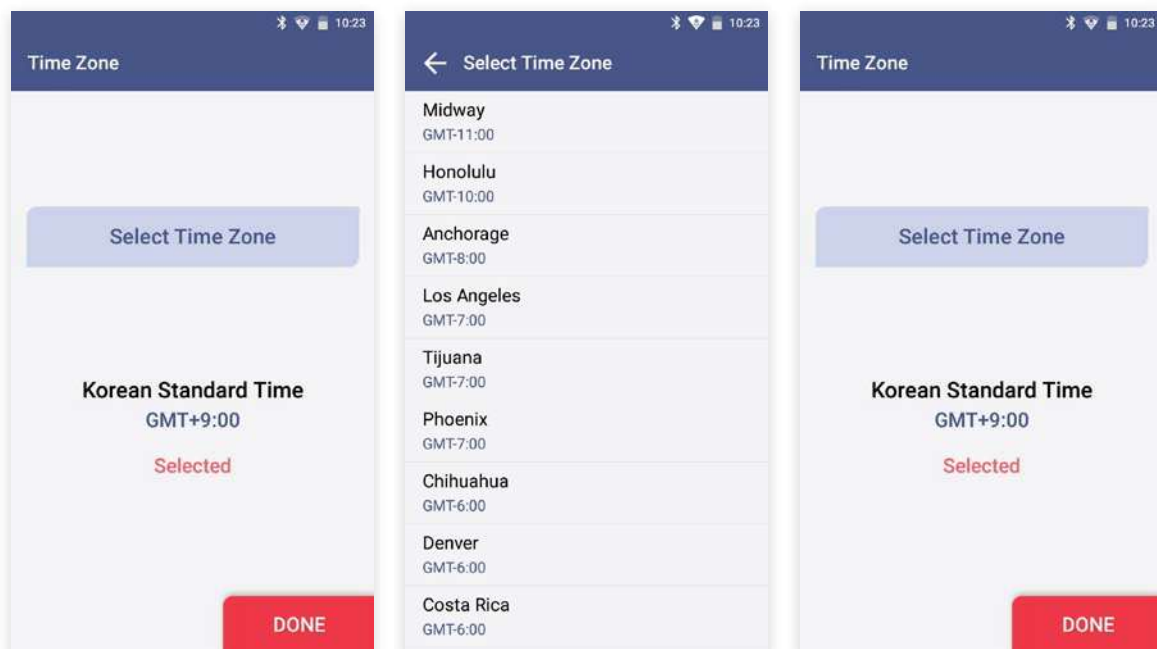
Touch the 'power' button to start.



STEP 3 Time Zone setting

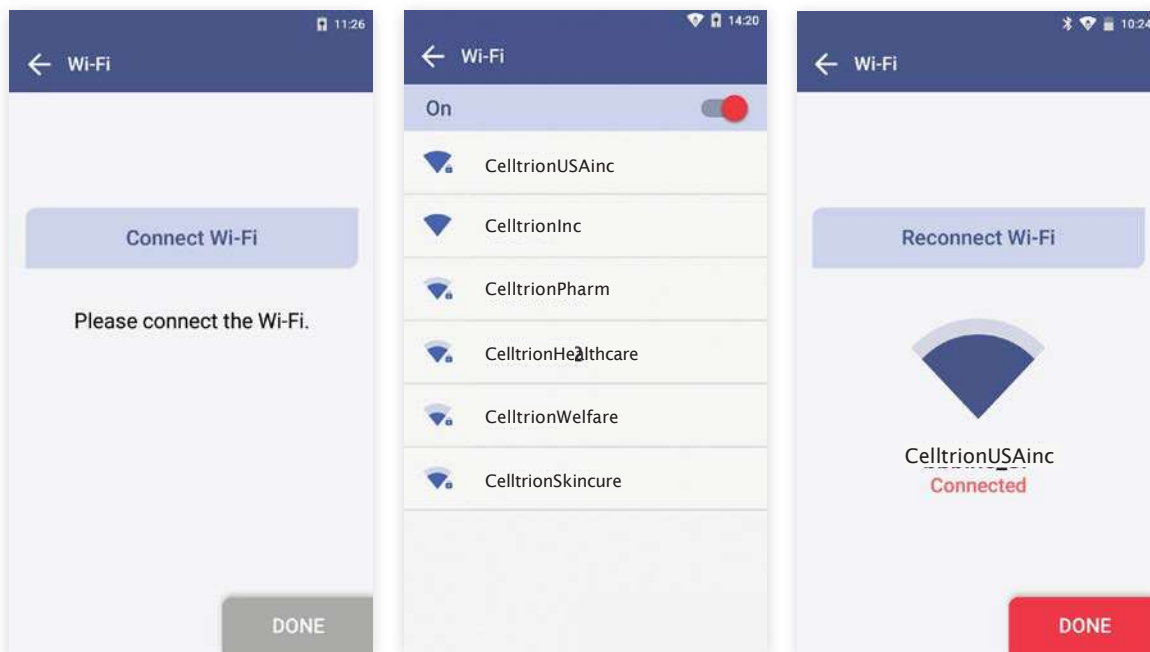
Touch the 'Select Time Zone' → Select the time zone where the user is located.





* 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

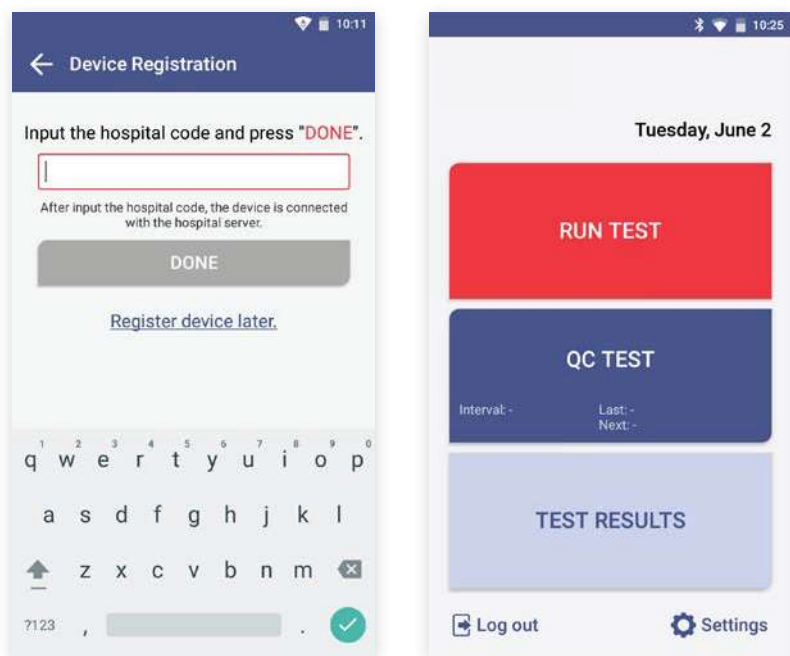
- A test can be run regardless of QC Test results.

QC Interval

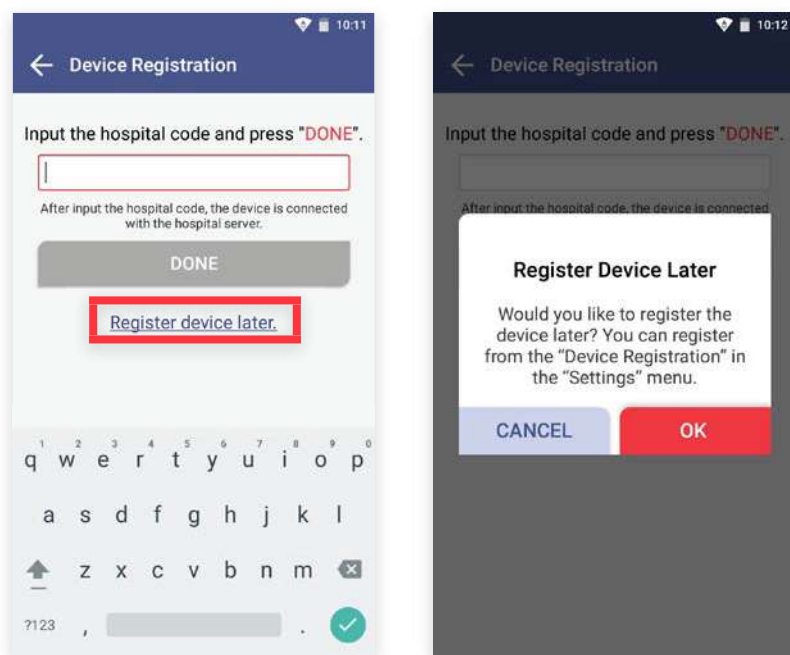
- On: A test can only be run upon completion and passing of the QC Test on the designated QC Test date
- Off: Disables QC Test interval
- Interval setting: Setup QC Test interval within 1 to 365 days

STEP 7 Device Registration

- Enter hospital code in the window.
- After entering hospital code, touch the 'DONE' button to connect to hospital server.
- Once connected to server, initial setup is completed and the home screen will be displayed.



- If there is no hospital code for device registration, touch the 'Register device later' button.
- Device registration is available later in ['Settings' → 'Device Registration'] (see Page 43).



Barcode Scanner Connection

- Connect the barcode scanner to the USB Port on the back of Sampinute™ Analyzer.
- Barcode scanner automatically starts operation when connected to the USB port.



*Barcode scanner has to be purchased separately.

Printer Connection

- Turn the printer on.
- USB Connection: The printer is automatically recognized once USB cable is connected.
- Bluetooth Connection: Please refer to [Function settings → Printer settings] (see Page 31).



*Printer is sold separately.

5. Running a Test

5-1. How to Perform RUN TEST

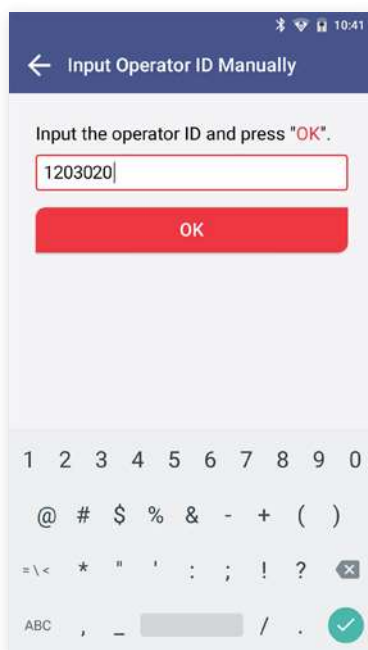
STEP 1 Touch the 'RUN TEST' button to start test



- Run the test at a temperature range of 15-30°C (59-86°F).
- If the temperature is out of range, the test cannot be run.
- When the battery level is 15% or lower, you cannot start the test.
- Fully charge the battery before running a test.

STEP 2 Scan the operator ID

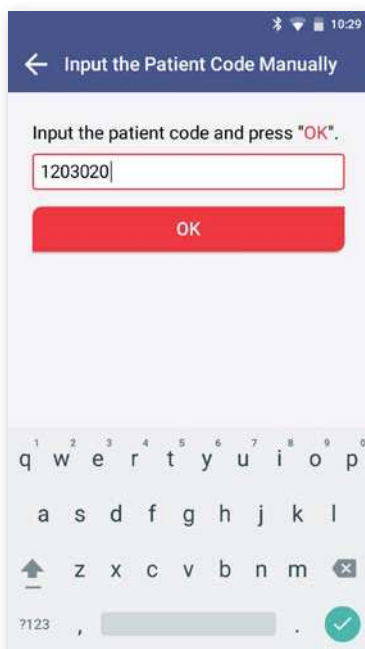
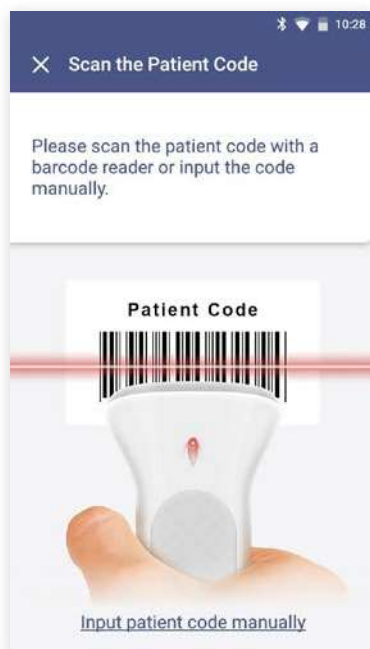
a. Scan the operator ID with the barcode scanner or manually enter the operator ID using the keypad. Touch the 'OK' button only if entered manually.



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

STEP 3 Scan the patient code

- Scan the patient code with a barcode scanner or manually enter the patient code using the keypad. Touch the 'OK' button only if entered manually.
- The operator ID and the patient code are displayed on the screen. The screen subsequently resumes to cartridge QR code scan.



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

STEP 4 Scan the QR code of the test cartridge

- Scan the QR code on the cartridge pouch with the barcode scanner.
- After scanning the QR code, the cartridge type and LOT will be displayed on the screen.



- The barcode scanner has to be purchased separately.
- If QR code recognition fails, scan a new cartridge pouch.
- Please check if the cartridge type of the cartridge is correct.

STEP 5 Test cartridge insertion

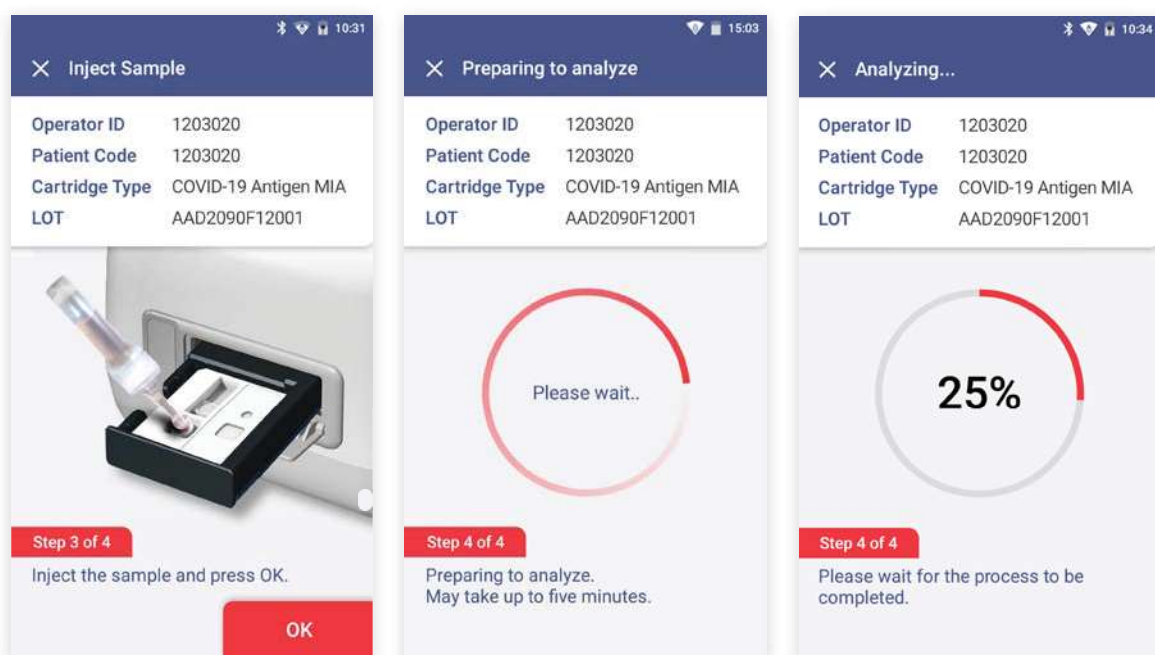
- Remove the aluminium tape attached on top of the cartridge.
- Insert the test cartridge to the tray according to the instructions on the screen.
- When the test cartridge is inserted in the correct position, the screen automatically proceeds to the sample injection stage.



- Make sure to check whether the correct operator and patient codes are entered before scanning the QR code.
- Ensure that the correct test cartridge is being used for the target analyte.
- Before inserting the cartridge, ensure that you are not using an already used one.
- When the error message, "**Please contact the system administrator**" is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

STEP 6 Test sample injection and starting test

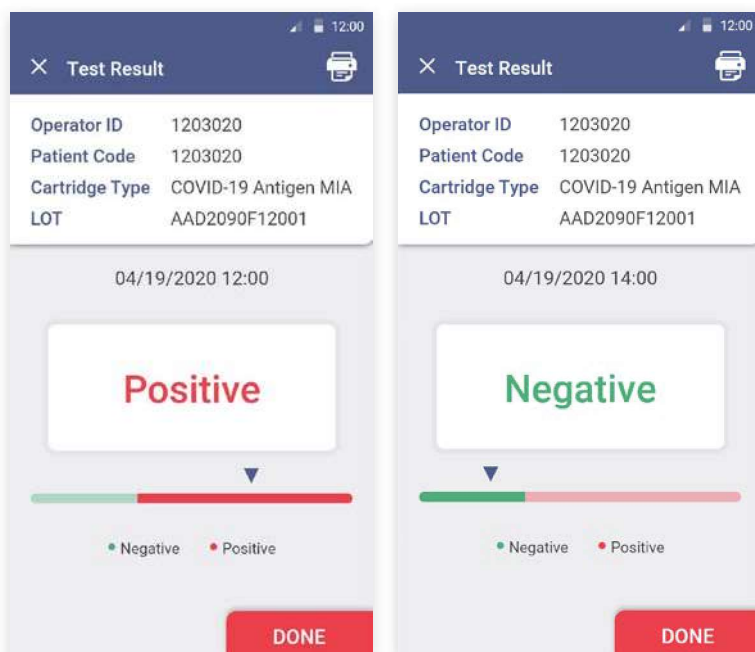
- Prepare a test sample.
- Before injecting the sample, check injection location of the test sample and whether a sufficient amount of test sample is prepared.
- Inject the test sample within 2 minutes after inserting a cartridge.
- Touch the 'OK' button.



- 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.

STEP 7 Check the result of the test

- When test is completed, the result of the test is displayed on the screen.
- Check the result and remove the cartridge from the tray.
- 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.

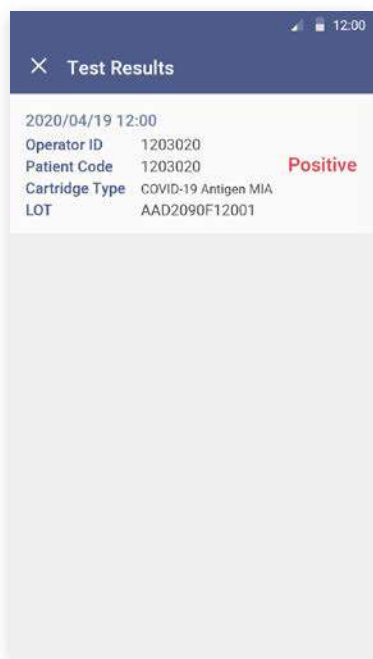
- Refer to the images below to eject the cartridge from the tray.
- Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.



5-2. Result Management

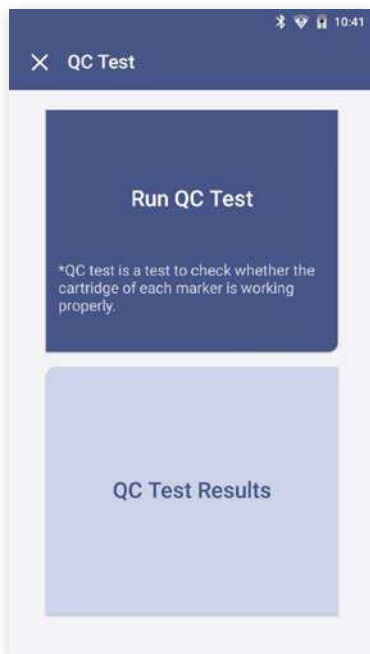
Check the results of the test.

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



6. Running a QC Test (Control Solution Test)

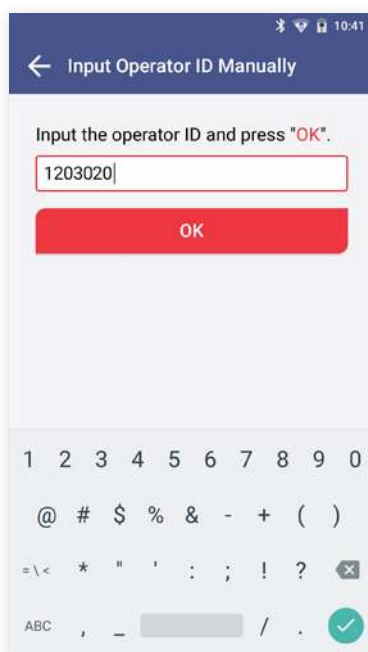
STEP 1 Touch the 'Run QC Test' button.



- Run the test at a temperature range of 15-30°C (59-86°F).
- If the temperature is out of range, the test cannot be run.
- When the battery level is 15% or lower, you cannot start the test.
- Fully charge the battery before running a test.

STEP 2 Scan the operator ID

Scan the operator ID with a barcode scanner or manually enter the operator ID using the keypad. Touch the 'OK' button only if entered manually.



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

STEP 3 Scan the test cartridge QR code

- Scan the QR code on the cartridge pouch with the barcode scanner.
- Upon scanning the QR code, test level, the cartridge type and LOT will be displayed on the screen.



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

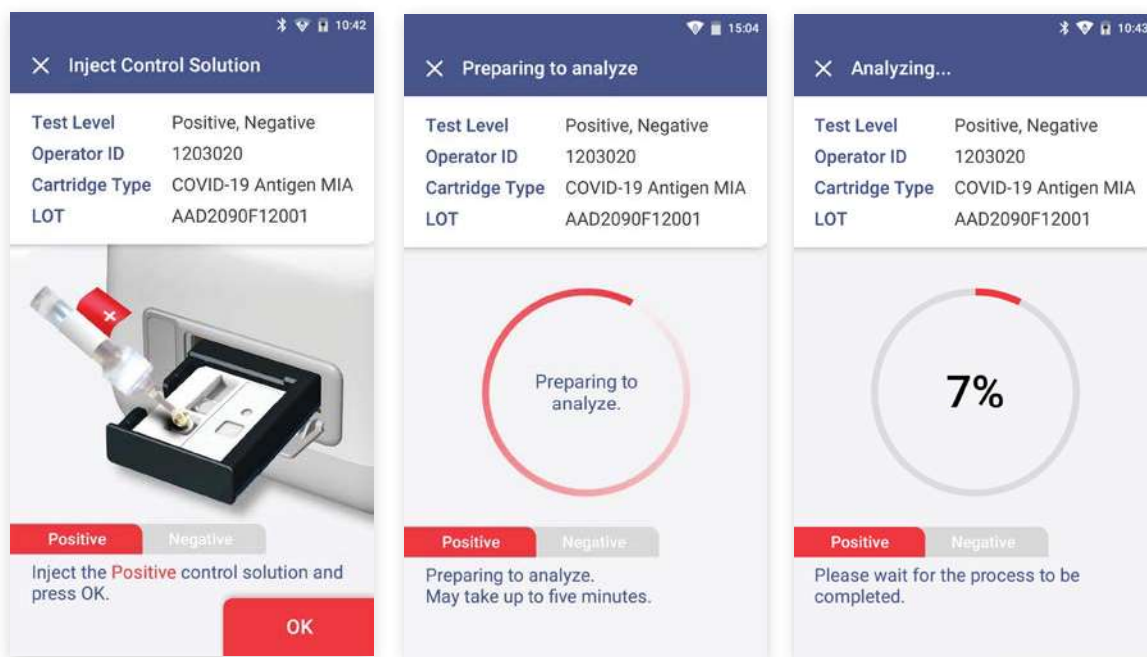
STEP 4 Insert the test cartridge



- Ensure the correct operator ID is entered.
- 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 target analyte.
- Before inserting a cartridge, ensure that you are not using a used one.
- Remove the aluminium tape attached on top of the cartridge.
- When the error message, **“Please contact the system administrator”** is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

STEP 5 Inject the positive control solution

- Prepare positive control solution of the same cartridge type as the inserted test cartridge.
- Add 2-3 drops of the positive control solution into the sample inlet of the test cartridge within 2 minutes.
- Touch the 'OK' button.



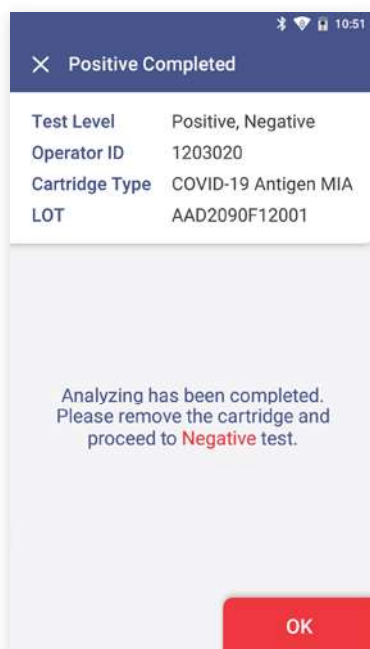
STEP 6 Discard the used cartridge

- Refer to the images below to eject the cartridge from the tray.
- Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.



STEP 7 Discard the used cartridge (continued)

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



STEP 8 Test cartridge QR code scan

- Scan the QR code on the cartridge pouch with the barcode scanner.
- After scanning the QR code, test level, the cartridge type and LOT will be 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 cartridge type is correct.

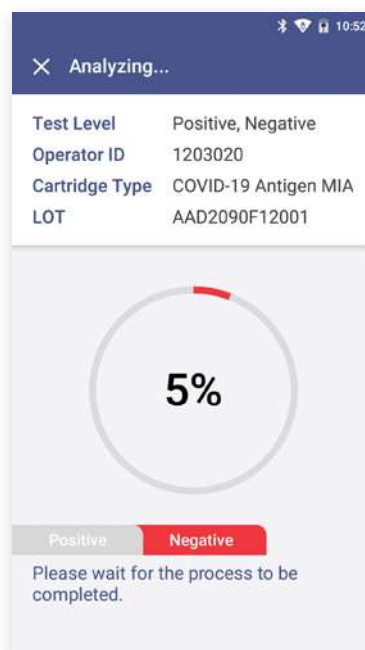
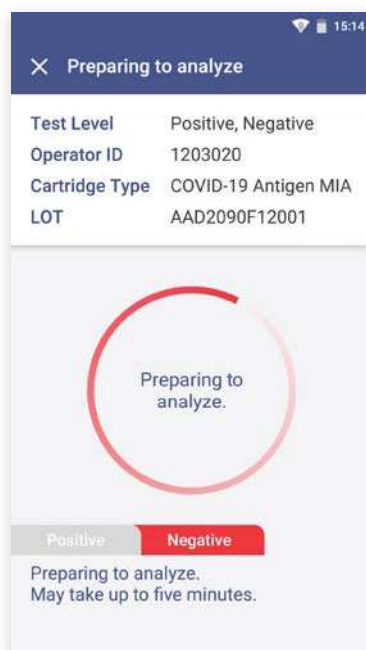
STEP 9 Insert the test cartridge



- Ensure that the correct operator ID is entered before inserting the 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 target analyte.
- Before inserting a cartridge, ensure that you are not using a used one.
- Remove the aluminium tape attached on top of the cartridge.
- When the error message, “**Please contact the system administrator**” is displayed after inserting the cartridge, stop the process and contact the administrator to resolve the issue.

STEP 10 Negative control solution injection

- Prepare negative control solution of the cartridge type as the inserted test cartridge.
- Add 2-3 drops of the negative control solution into the sample inlet within 2 minutes.
- Touch the ‘OK’ button.



STEP 11 Check the result of QC test

- When test is completed, the result of QC test is displayed on the screen.
- Check the result and remove the cartridge from the tray.
- Touch the 'DONE' button → Return to the home screen.



TEST RESULT: Pass - Successful operation of the test cartridge

TEST RESULT: Fail - Accuracy of the test cannot be verified, and the test needs to be conducted again or the administrator should be contacted.

STEP 12 Discard the used cartridge.

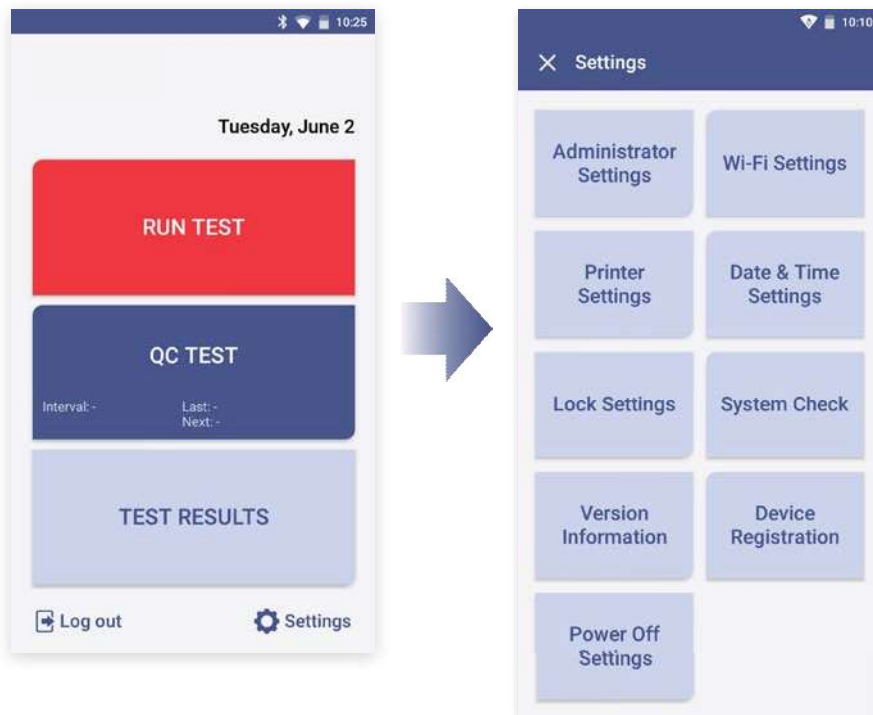
- Refer to the images below to eject the cartridge from the tray.
- Discard the Sampinute™ COVID-19 Antigen MIA test cartridge after use as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.



7. Function Settings

7-1. Setup Screen

Settings → Settings Menu



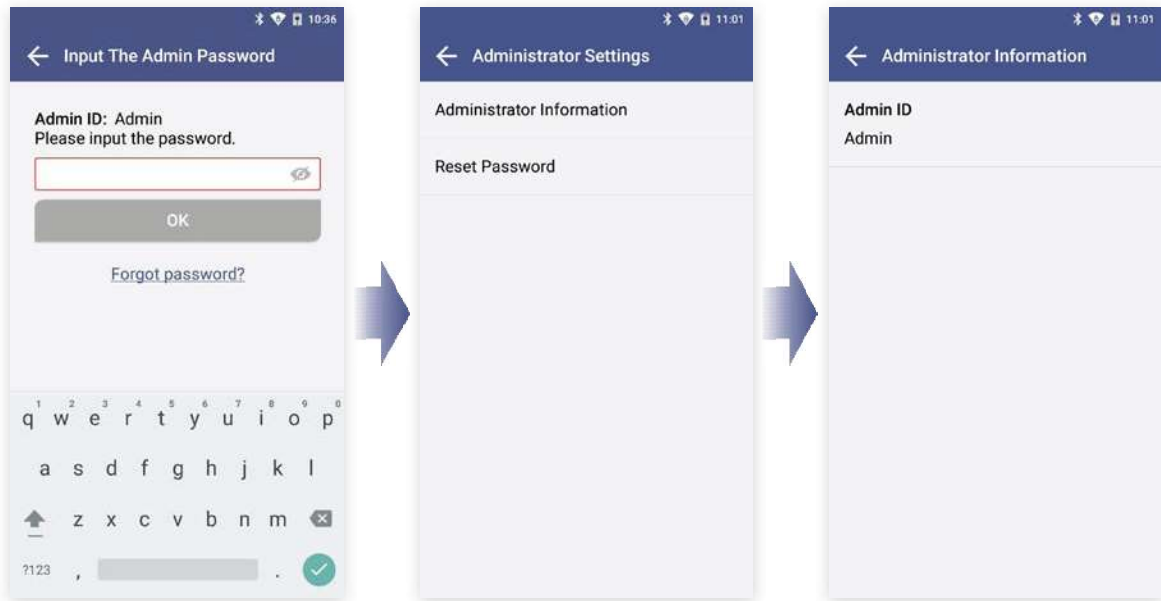
Settings menu

- 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

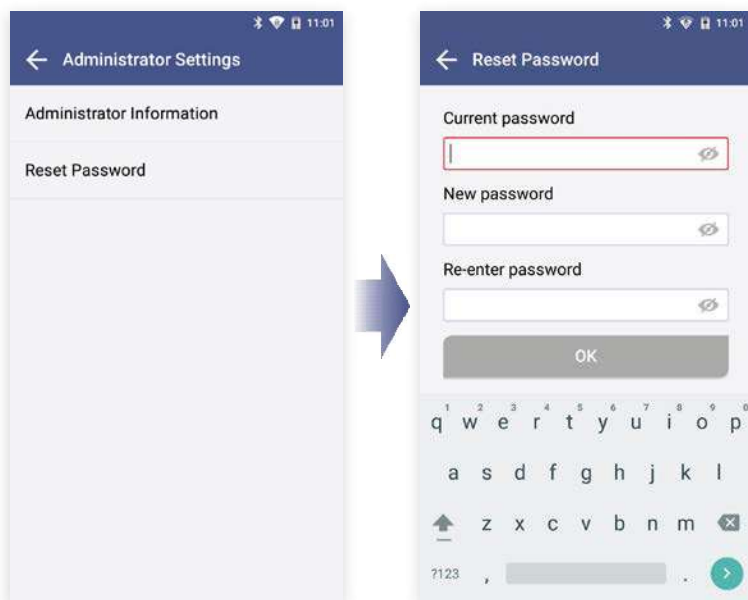
Administrator Information


- Enter admin password to proceed to administrator settings.
- Touch the 'Administrator Information' button to check the administrator information.



Change Administrator Password

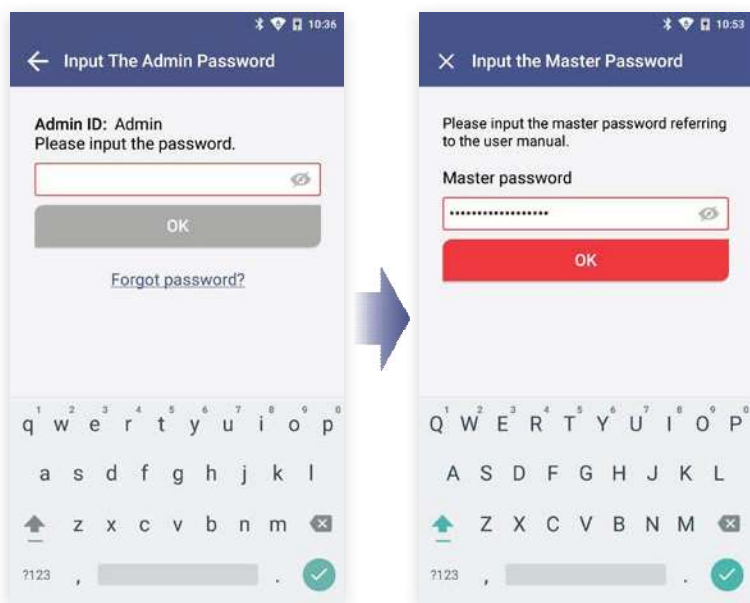
- Touch the 'Reset Password' button. → Enter the current password.
- Enter a new password in 'New password' and 'Re-enter password'. → Touch the 'OK' button.



- 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.

Forgot Password

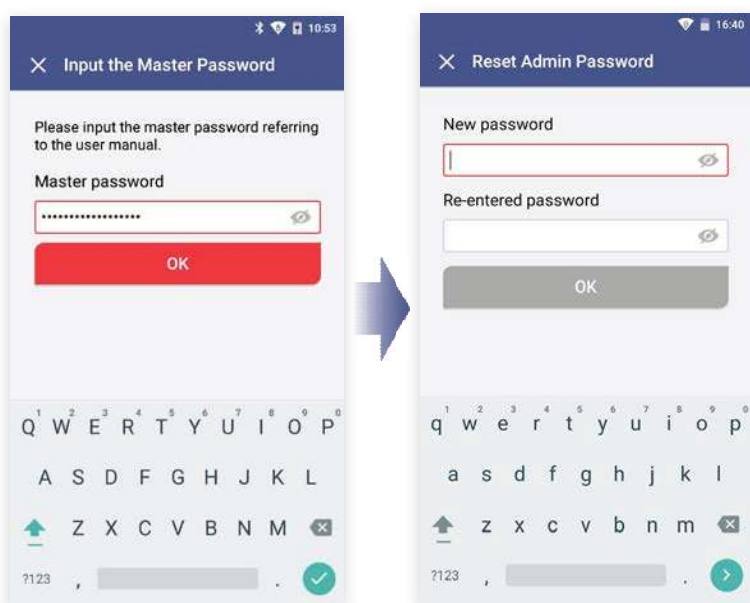
- If you forgot admin password, touch 'Forgot password?'.
- Master password input screen will be displayed.



Input the Master Password

Type the master password. → Enter the new admin password. → Touch the 'OK' button.

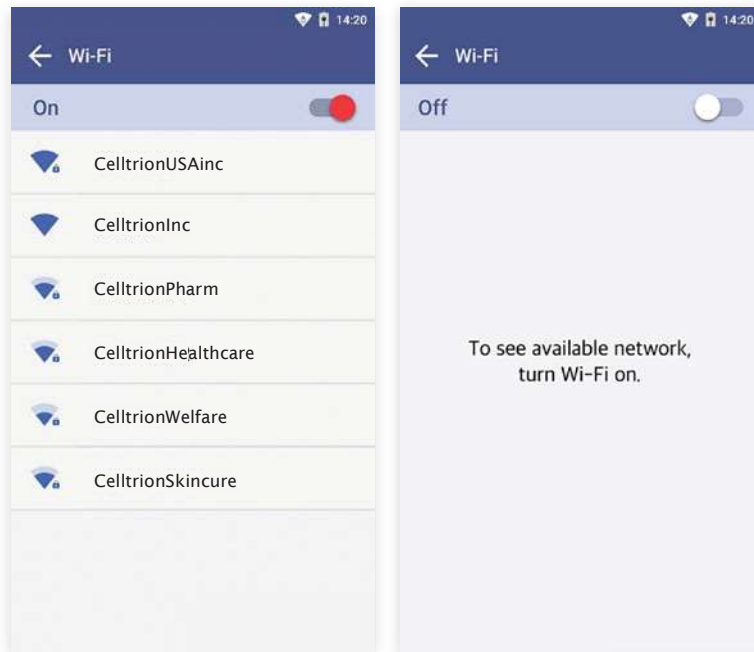
- Master password is the 'serial number of the device' + '0001'.
- Serial number is written in the label on the bottom of the device.



7-3. Wi-Fi Settings

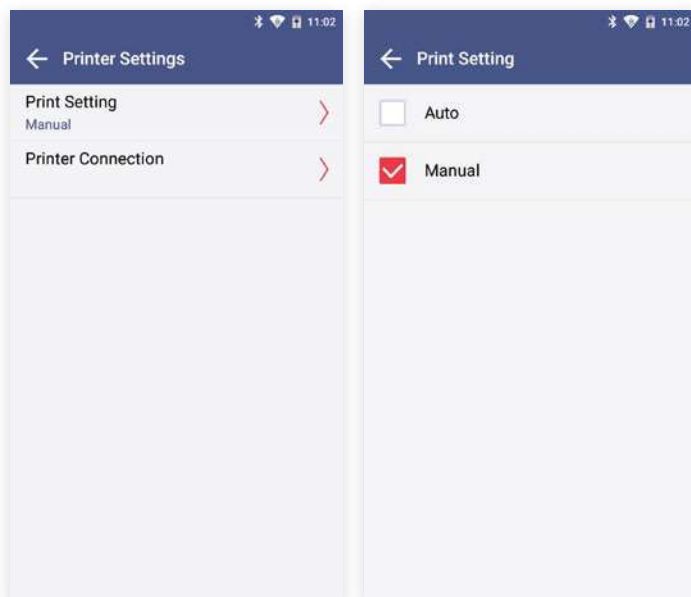
Turn Wi-Fi On or Off & Connect to a Wi-Fi.

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



7-4. Printer Settings

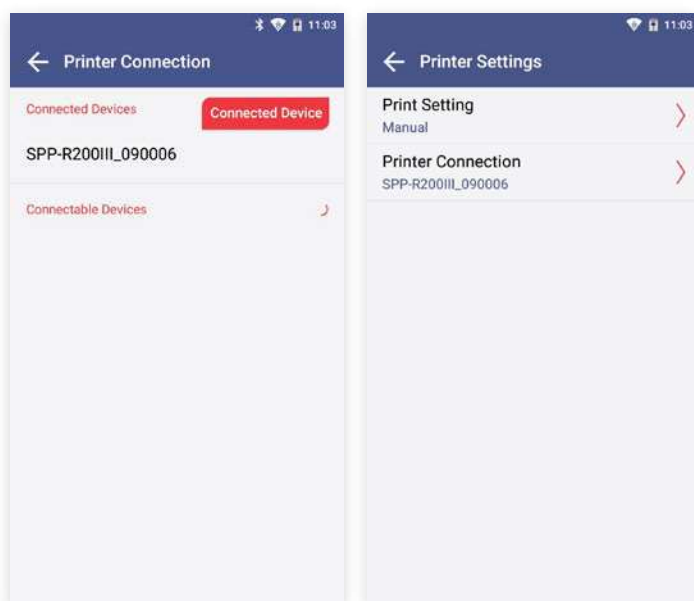
Print Setting



Select 'Auto' or 'Manual' button in Print Setting.

Printer Connection

- Find a printer model to link from the 'Connectable Devices' list.
 - Select the model.
 - The printer is connected and displayed in Connected Device.
 - 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.

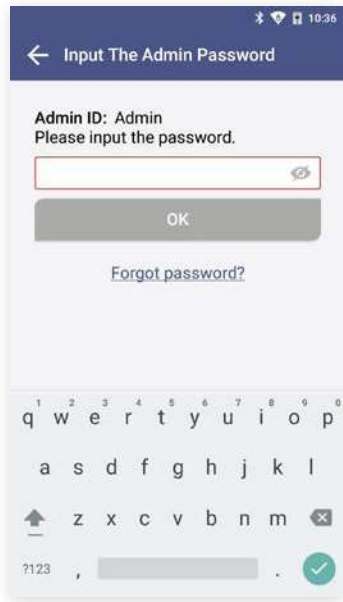


- If you try to connect with another printer *via* USB while Bluetooth has been connected prior, the Bluetooth will be unpaired and the device will be connected to the USB printer.
- Printing may be unavailable if you use a mobile printer incompatible with Sampinute™ Analyzer.
- Changing printer connection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

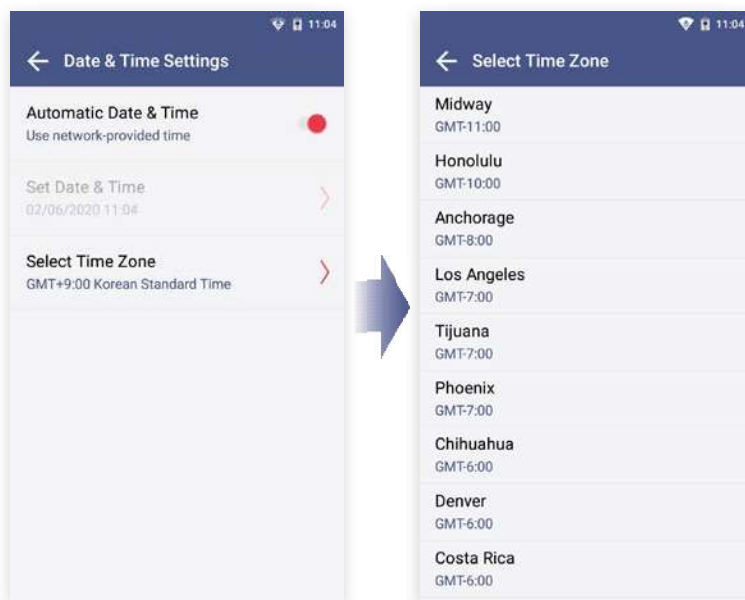
7-5. Date & Time Settings

Date & Time Settings

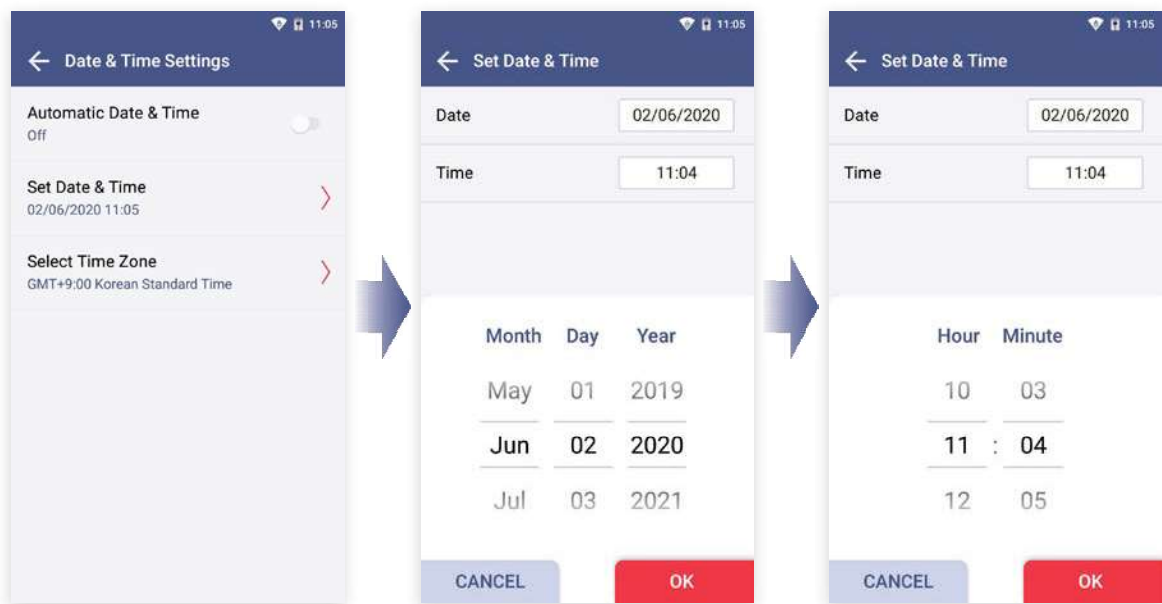
Enter the admin password to access 'Date & Time Settings'.



Touch 'Date & Time Settings'. → Touch 'Select Time Zone'. → Select the location.



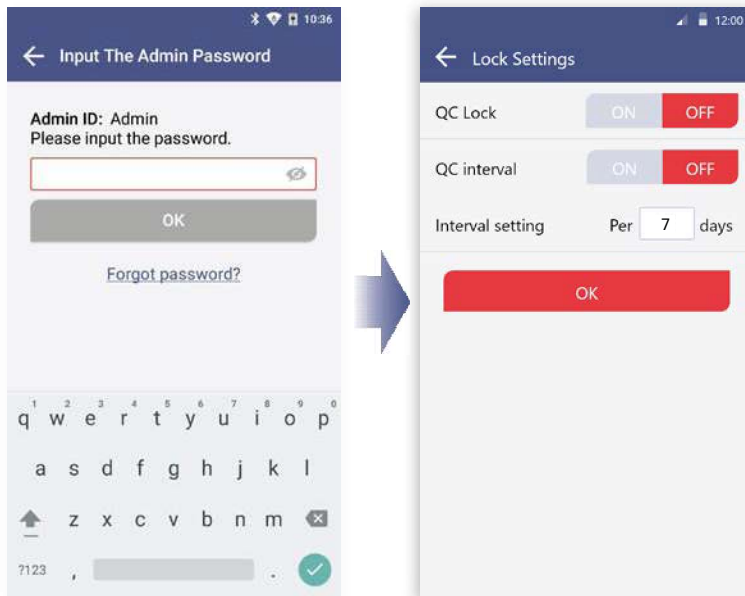
Adjust 'Set Date & Time'. → Touch the 'OK' button.



7-6. Lock Settings

STEP 1 Lock Settings

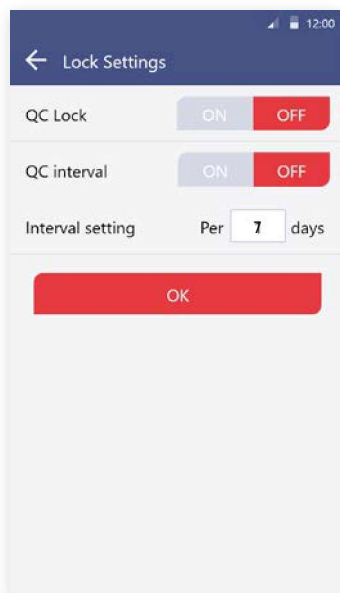
Enter the admin password to access Lock Settings.



STEP 2 Lock Settings 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.

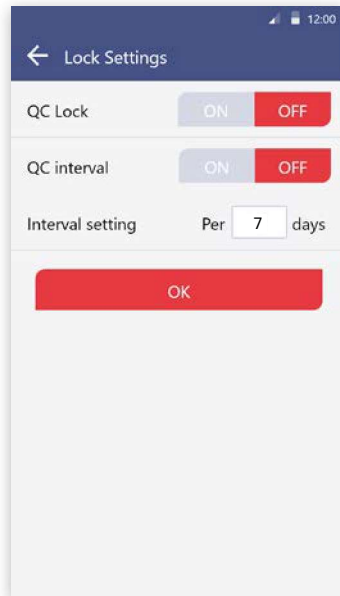


- When all settings of QC Lock are turned OFF, a test can be run even if QC Test result is 'fail'.
- The manufacturer is not responsible for the test results run under settings with all QC Lock Settings turned OFF.

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.

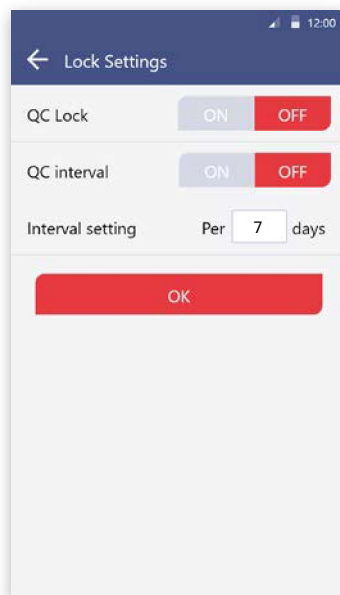


- You can set the intervals for QC test.
- When the interval is set up, it will be shown under Run QC Test on the home screen.

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

STEP 1 Touch the 'Run System Check' button



- Run the test at a temperature range of 15-30°C (59-86°F)
- If the temperature is out of range, the test cannot be run.
- When the battery level is 15% or lower, you cannot start the test.
- Fully charge the battery before running a test.

STEP 2 Scan the QR code of the check cartridge

- Scan QR code on a check cartridge with the barcode scanner.
- After scanning the QR code, the screen will display "Insert Check Cartridge."



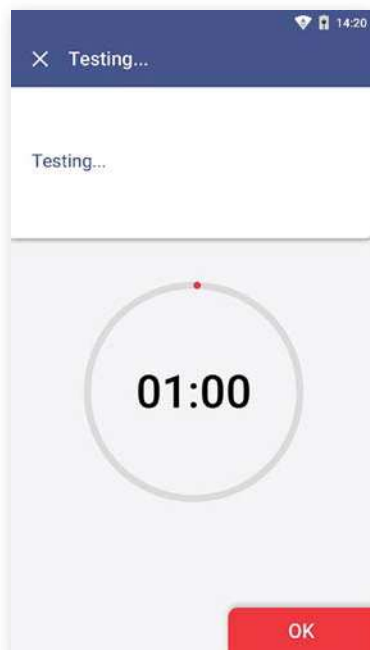
- Barcode scanner has to be purchased separately.
- If you do not scan QR code of the test cartridge, the test will not proceed.
- If QR code recognition continues to fail, please contact the administrator.

STEP 3 Insertion of check cartridge tray

- Insert a check cartridge to the tray according to instructions on the screen.
- Insert the check cartridge in the correct position.
- Touch the 'OK' button.



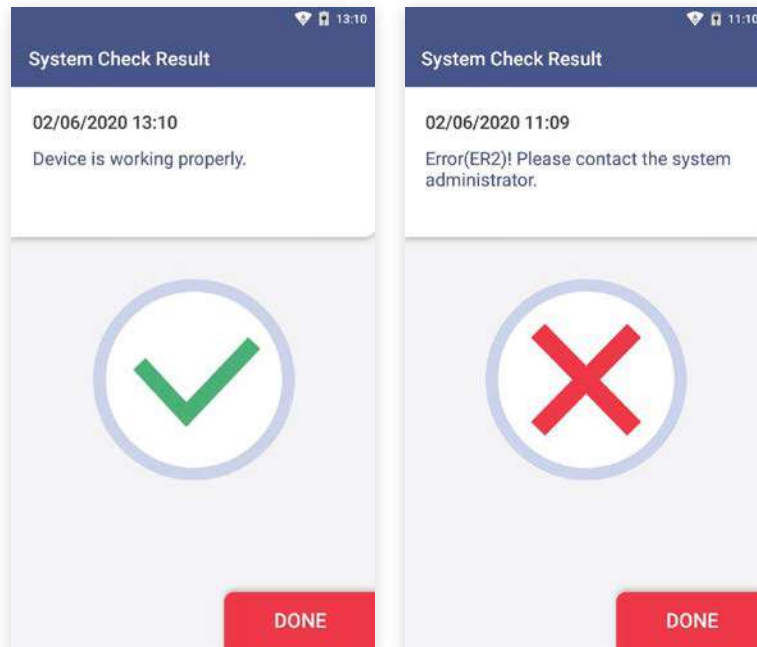
STEP 4 Start 'System Check'



- The system check takes about 1 minute.

STEP 5 Confirm the system check results

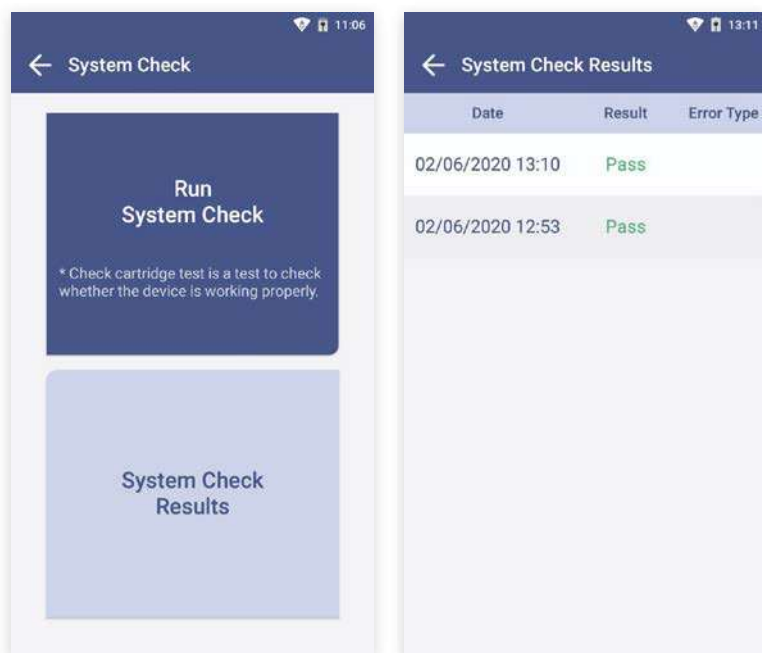
- The test results are displayed upon completion.
- After checking the results, remove the used cartridge from the tray.
- Touch the '**DONE**' button to move to the home screen.



- Pass: Indicates that the device is working properly and a V 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.

System Check → System Check Result

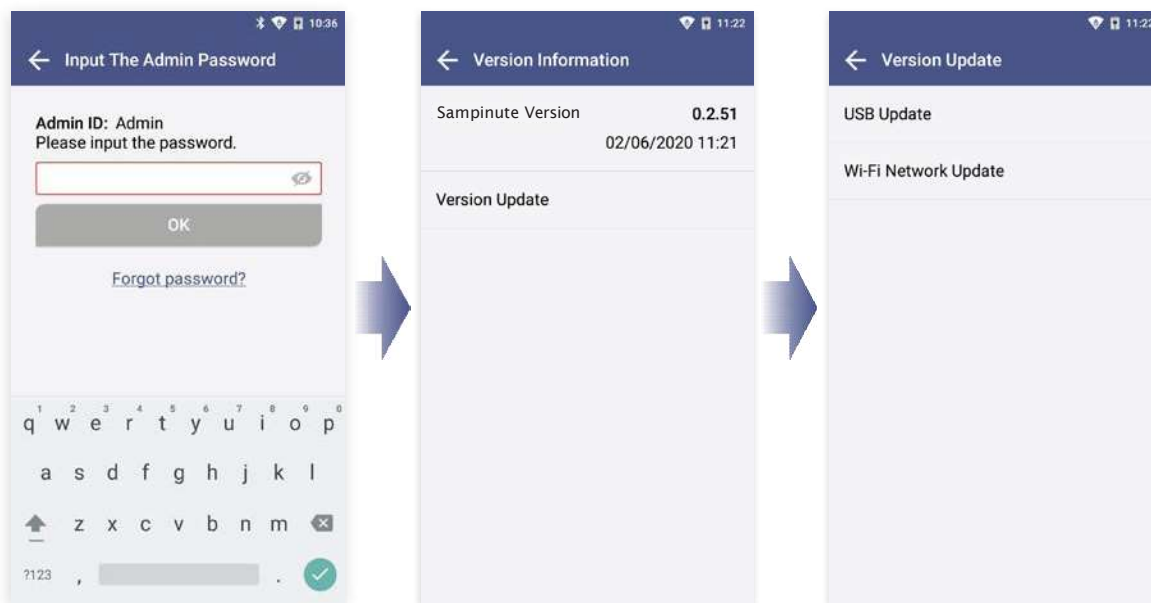
The System Check Results are displayed in order from the oldest to the newest.



8-2. Version Information and Update

STEP 1 Check the Version Information

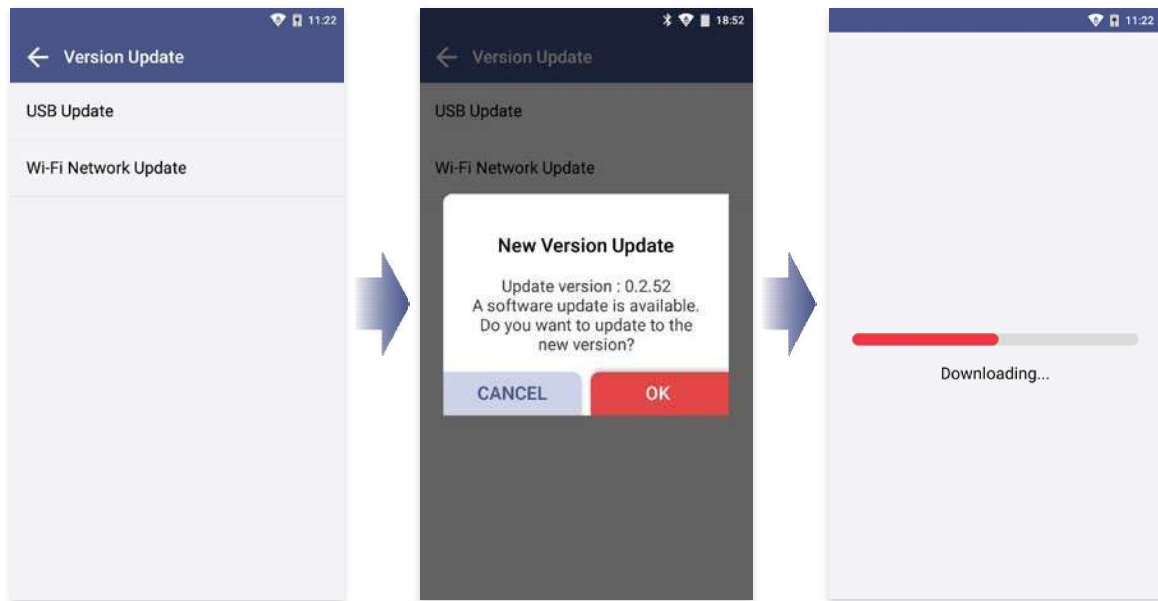
- Type the admin password and access device registration menu.
- Confirm the latest version



STEP 2 Update new version

Option 1. Software update by USB connection

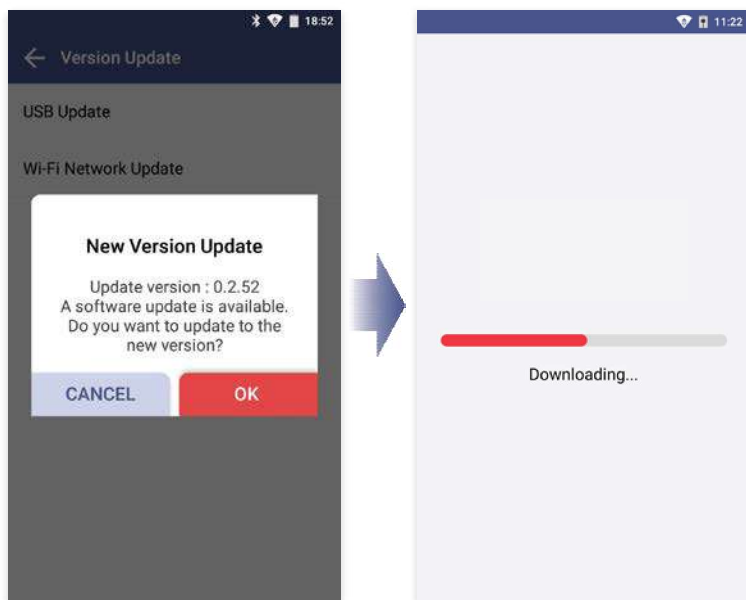
- Connect the USB containing the updated version to the USB port on the back of the analyzer.
- Select '**USB Update**'. (A message to update to new version will be displayed if the software needs to be updated.)
- Touch the '**OK**' button to update to the latest software.



- 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.

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.

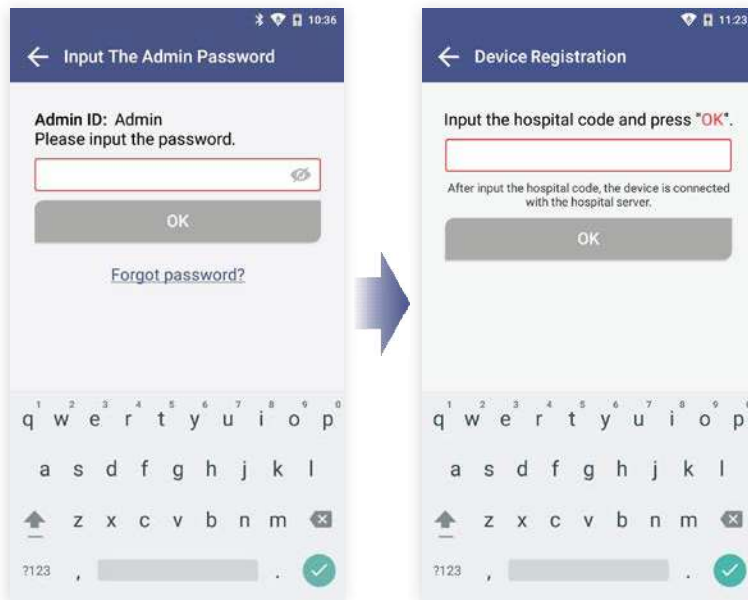


- The update starts when Sampinute™ Analyzer's battery level is 15% or higher.
- Unstable wireless network connectivity may cancel the update.
- If the update continuously fails, please contact the system administrator.

8-3. Device Registration

STEP 1 Settings → Device Registration

- Input the admin password to access device registration menu.
- Enter the hospital code on the device registration screen.
- Type the hospital code and touch the 'DONE' button. The device will try to access the hospital server.

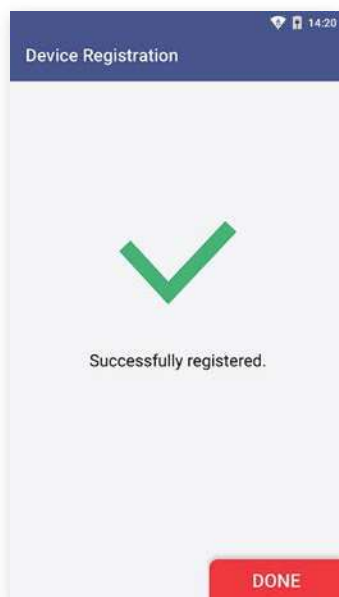


***If you have already registered the device during initial setup, you do not need to set it up again.**

STEP 2 Registration Completed

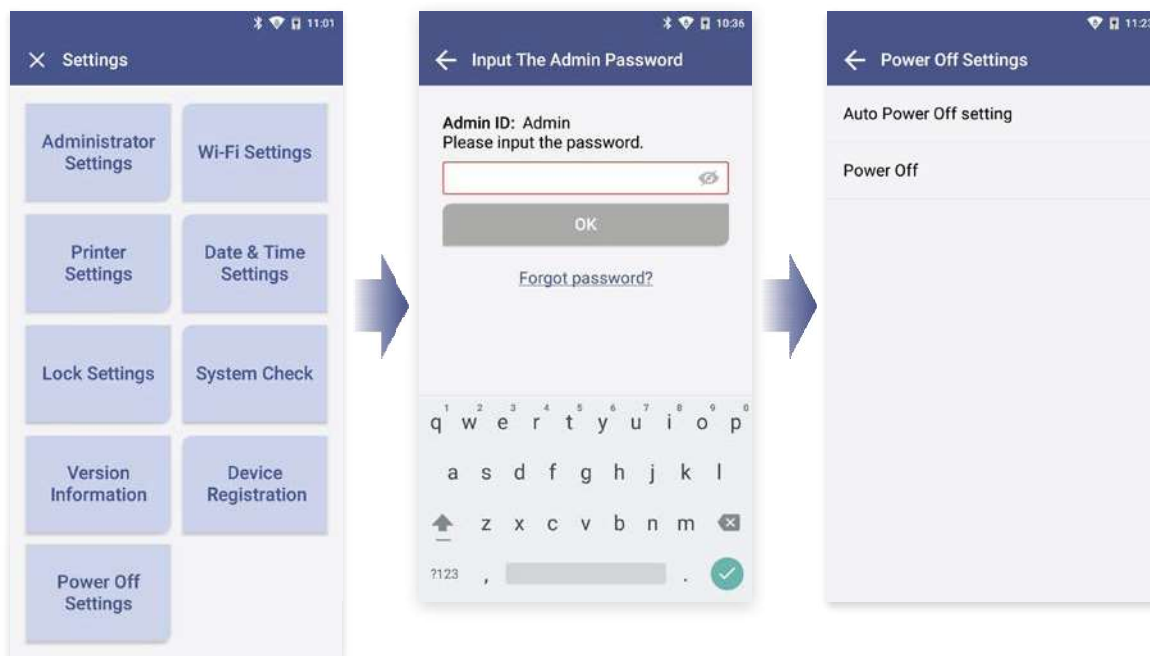
When registration is completed:

- The message 'Successfully registered' is displayed.
- Touch the 'DONE' button to proceed to settings screen.



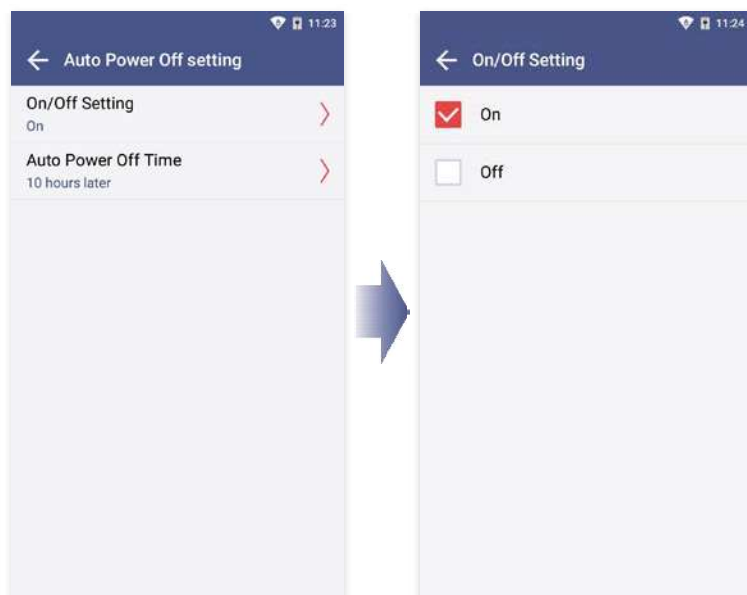
8-4. Auto Power Off Settings

- Select the 'Power Off Settings' button.
- Input the admin password.
- Select 'PowerOff'



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.

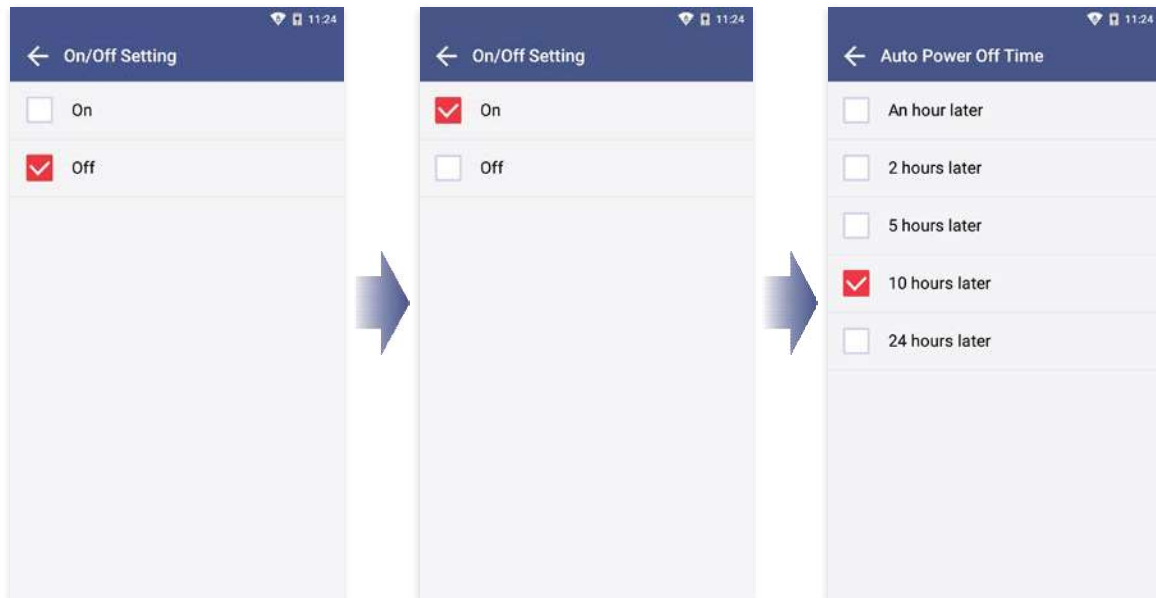


- Default auto power off time is 10 hours when the function is enabled 'On'.
- Auto power off time can be changed by selecting Auto Power off Time.

8-4. Auto Power Off Settings

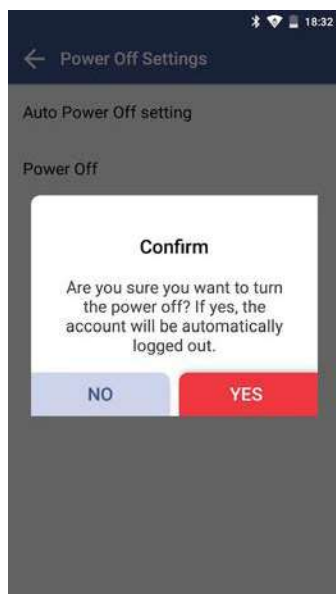
On/Off setting → **Select the 'On' button** → **Select the 'Auto power off time'**

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

- Select the 'Power off' button.
- Touch the 'YES' button to finally turn the power of the device off.



- It is recommended to turn Sampinute™ 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 Sampinute™ 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°C (14 - 113°F)
 - [Humidity] 10 - 80%
- Avoid storage places prone to tremors or that could cause falling.

9. Error Messages

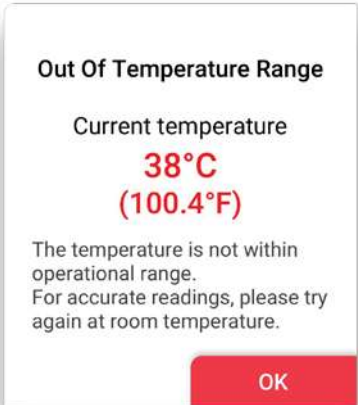


9-1. Notifications

Error Notifications	Descriptions and Solutions
Please input the admin password.	Admin password is not inputted. Displayed when touching the 'OK' button without having entered the admin password. Solution: Input the admin password and then touch the 'OK' button.
Please input the hospital code.	Hospital code is not inputted. Displayed when touching the 'DONE' button without having entered the hospital code. Solution: If a hospital code is required, contact the administrator. 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. Solution: If a hospital code is required, contact the administrator. Input registered hospital code. If the issue persists, contact the administrator.
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. Solution: Either try to connect again at a later time or connect to another network.
Unknown error. Please try again.	Wi-Fi communication error The alert pop up when Wi-Fi communication is failed. Solution: Try again. If the issue persists, then contact the administrator.
Please try again after connecting to a network.	No Wi-Fi connection Displayed when device requests server communication for Wi-Fi connection. Solution: Connect to a Wi-Fi.
Low battery. 14% of the battery level is remaining. The remaining battery must be 15% or higher to run the analyzer. Please connect the analyzer to a power source.	Low battery Displayed when touching the low-battery icon on the home screen. Solution: Connect to a power adapter.

Error Notifications	Descriptions and Solutions
Please perform the system check and the QC test prior to sample tests as instructed in the manual.	System check and QC test not performed Displayed when touching 'RUN TEST' without having performed system check and QC test. Solution: Perform system check and QC test if required.
The system check was failed. Please check the results again. Contact the system administrator.	Displayed when touching the system check warning  icon on the home screen under the condition that the system check was failed. Solution: Perform system check. [Settings screen → System Check →  System Check]
Either the QC test was failed or no tests have been performed within the set QC interval. Please check the results again.	Displayed when touching QC! icon on the home screen under the condition that either the QC test was failed or no analyses have been run within the set QC interval. Solution: Perform the QC test.
The temperature is not within operational range. (Current temperature: 38°C/100.4°F)	Inappropriate temperature Displayed when touching the temperature icon on the home screen which pops up when temperature is out of range for testing. Solution: Re-locate device in an environment of operational range (15-30°C / 59-86°F).
The admin account automatically logged out.	Administrator account logout Displayed when administrator account logs out before power off or reboot.
Please input the master password.	Master password has not been entered. Displayed when the 'OK' button is touched without master password input. Solution: Enter the master password.
Incorrect password. Please input the master password again.	Password input error Displayed when the correct password has not been entered. Solution: Enter the correct password.
The fan is activated due to increased internal temperature of the analyzer.	Fan activated Displayed when the fan is activated by the Celltrion Sampinute™ Analyzer's temperature sensor operation.
Invalid ID. Please check the ID again.	Wrong operator ID Displayed when wrong operator ID is entered. Solution: Enter the correct ID.

Error Notifications	Descriptions and Solutions
Please input the operator ID.	Operator ID has not been entered. Displayed when touching 'OK' without entering the operator ID. Solution: Enter the operator ID.
Please input the patient code.	Patient code has not been entered. Displayed when touching 'OK' without entering the patient code. Solution: Enter the patient 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. Solution: Insert the cartridge immediately upon request.
Please remove the cartridge	Cartridge is not removed. Displayed when cartridge is not removed upon request. Solution: Remove the cartridge.
Incorrect password. Please input the password correctly.	Current password mismatch. Displayed when you do not enter currently set password. Solution: Enter the 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. Solution: Ensure both passwords entered are the same.
Please input the new admin password.	New administrator password has not been entered. Displayed when a new administrator password has not been entered in the password settings screen. Solution: Enter new administrator password.
Please disconnect the device first and then try connecting the device.	Bluetooth disconnection Displayed when a new Bluetooth printer connection is requested while the analyzer is connected to a Bluetooth printer. Solution: Connect to the appropriate 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. Solution: Either disconnect the Bluetooth or the USB printer.

9-2. Error pop-ups

Error pop-ups	Descriptions and Solutions
 A white rectangular pop-up with a red border. The title is "Out Of Temperature Range". Below it, "Current temperature" is followed by "38°C (100.4°F)" in red. The body text says: "The temperature is not within operational range. For accurate readings, please try again at room temperature." There is a red "OK" button at the bottom right.	<p>Inappropriate temperature</p> <p>Case1. Pops up when the 'RUN TEST' button is touched on the home screen, or the 'RUN QC TEST' button is touched.</p> <p>Case2. Pops up when the temperature is out of test range after the 'RUN TEST' or "RUN QC TEST" button has been touched.</p> <p>Solution: Move the device to the recommended operating temperature (15-30°C, 59-86°F) and wait until device temperature decreases to below 30°C (86°F).</p>
 A white rectangular pop-up with a red border. It starts with a red warning triangle icon followed by the title "Battery Low!". The body text says: "Low battery. 14% of the battery level is remaining. The remaining battery must be 15% or higher to run the analyzer. Please connect the analyzer to a power source." There is a red "OK" button at the bottom right.	<p>Low battery</p> <p>Case1. Pops up when the 'RUN TEST' button is touched on the home screen, or the 'RUN QC TEST' button is touched at 14% battery level.</p> <p>Case2. Pops up when the battery level is 14% and the user touched Next to proceed to the next level of the QC test.</p> <p>Solution: Connect the analyzer to a power source.</p>
 A white rectangular pop-up with a red border. It starts with a red warning triangle icon followed by the title "QC Test Error!". The body text says: "The QC test was failed or has an error. Please test again or contact the system administrator." There is a red "OK" button at the bottom right.	<p>QC Test error</p> <p>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 the QC TEST result is 'Fail'.</p> <p>Solution: Conduct the test again. If the QC test is a fail, then contact the system administrator.</p>

Error pop-ups

Descriptions and Solutions



System Check Error!

The system check was failed or has an error.
Please test again or contact the system administrator.

OK

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'.

Solution: Conduct system check again. If the system check is a fail, then contact the system administrator.

Contact System Administrator

If you forgot your admin password, contact the system administrator.
- e-mail: support@bbbtech.com
- Tel: +82-070-4407-8808

OK

Contact the system administrator.

Pops up upon selecting 'Forgot password?'

Solution: Contact the system administrator.



Error!

Invalid QR code. Please scan the test cartridge QR code again.

OK

Invalid cartridge QR code

Pops up when an invalid QR code is scanned.

Solution: Scan a valid QR code.



Error!

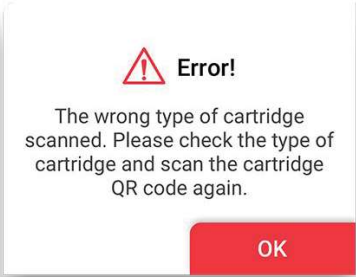
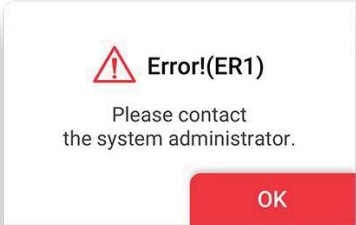
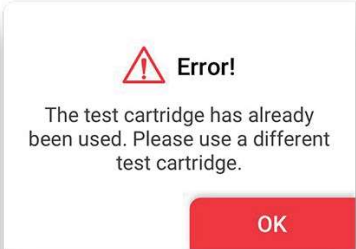

The test cartridge has been expired.
Please use a new test cartridge.

OK

Expired cartridge QR code

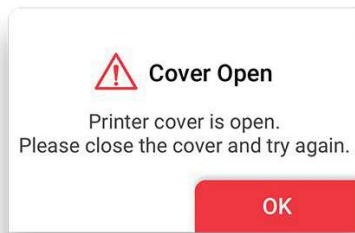
Pops up when expired cartridge QR code is scanned.

Solution: Scan a new cartridge of valid expiry date.

Error pop-ups	Descriptions and Solutions
 <p>Error!</p> <p>The wrong type of cartridge scanned. Please check the type of cartridge and scan the cartridge QR code again.</p> <p>OK</p>	<p>The QR code of the check cartridge is scanned.</p> <p>Pops up when the check cartridge's QR code is scanned instead of the test cartridge.</p> <p>Solution: Scan the QR code of a test cartridge.</p>
 <p>Error!(ER1)</p> <p>Please contact the system administrator.</p> <p>OK</p>	<p>Tray ejection failure</p> <p>Pops up within 10 seconds after tray ejection fails.</p> <p>Solution: Contact the system administrator.</p>
 <p>Error!</p> <p>The test cartridge has already been used. Please use a different test cartridge.</p> <p>OK</p>	<p>Pops up when a used cartridge is inserted.</p> <p>Solution: Remove used cartridge and insert a new cartridge.</p>
 <p>Insufficient Sample</p> <p>Please try again with enough volume (at least 50 μL). If failure persists for the third time, try again with a new cartridge.</p> <p>OK</p>	<p>Insufficient sample</p> <p>Pops up when a sample test fails due to errors associated with timeout, insufficient test sample injection, etc.</p> <p>Solution: Insert at least 50 μL of the sample again into the inlet. If failure persists for the third time, insert a new cartridge.</p>

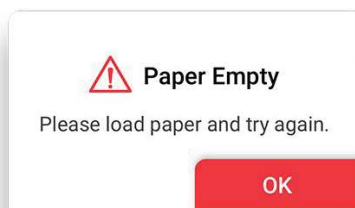
Error pop-ups

Descriptions and Solutions



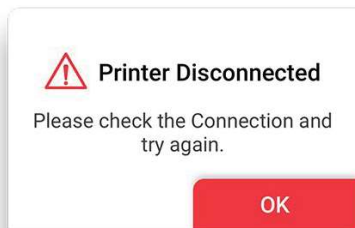
Pops up when the printer cover is open.

Solution: Close the printer cover.



Pops up when there is no paper left in the printer.

Solution: Re-fill printer with paper.



Printer disconnection

Pops up when the printer is not connected and the user touches the 'Print' button.

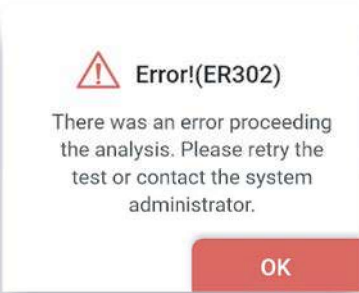
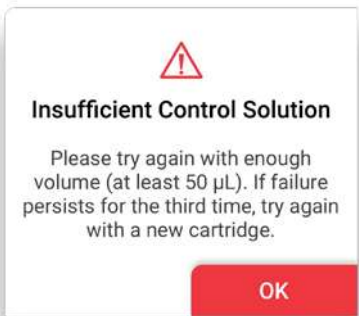
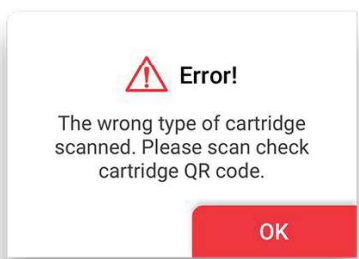
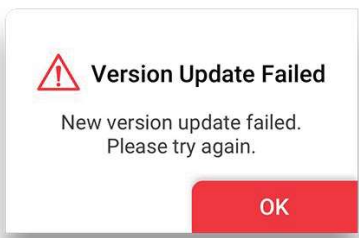
Solution: Ensure that the printer is connected.



Analysis failure

Pops up when analysis is failed.

Solution: Either try the analysis again or contact the administrator.

Error pop-ups	Descriptions and Solutions
 <p>Error!(ER302)</p> <p>There was an error proceeding the analysis. Please retry the test or contact the system administrator.</p> <p>OK</p>	<p>Analysis failure</p> <p>Pops up when analysis is failed.</p> <p>Solution: Either try the analysis again or contact the administrator.</p>
 <p>Insufficient Control Solution</p> <p>Please try again with enough volume (at least 50 μL). If failure persists for the third time, try again with a new cartridge.</p> <p>OK</p>	<p>Insufficient solution</p> <p>Pops up when a solution test fails due to either timeout, insufficient solution injection, or solution reading failure.</p> <p>Solution: Insert at least 50 μL of the control solution again into the inlet. If failure persists for the third time, insert a new cartridge.</p>
 <p>Error!</p> <p>The wrong type of cartridge scanned. Please scan check cartridge QR code.</p> <p>OK</p>	<p>The QR code of the test cartridge is scanned.</p> <p>Pops up when the QR code of the test cartridge is scanned during the System Check process.</p> <p>Solution: Scan the QR code of a check cartridge.</p>
 <p>Version Update Failed</p> <p>New version update failed. Please try again.</p> <p>OK</p>	<p>New version installation failure</p> <p>Pops up upon new version installation failure during software update.</p> <p>Solution: Re-try version update.</p>

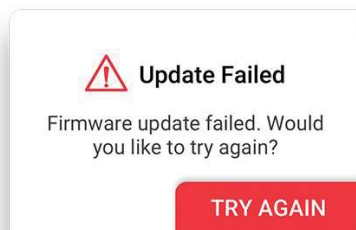
Error pop-ups

Descriptions and Solutions



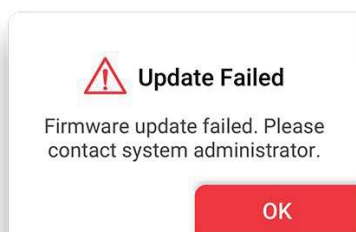
USB Device Connection Error
The alert pops up when USB is removed or disconnected during software update.

Solution: Connect the USB device and try again in 5 seconds.



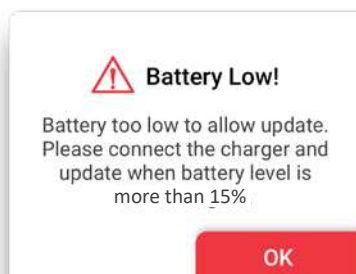
Pops up when the firmware update fails.

Solution: Try updating the firmware again.



Repetitive update failure
Pops up when the firmware update fails more than 3 times.

Solution: Contact the system administrator.



Low battery during software update
Pops up upon touching 'Update' when battery level is 14 % or lower.

Solution: Connect the device to a charger.

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 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
FCC ID	2AKGP-MB100

11. Product Warranty

Product Warranty

Manufacturer guarantees to the original Purchaser of Sampinute™ Analyzer that the Instrument is free from material defects in material and workmanship for a period of one (1) years from the date of the original purchase. This warranty does not guarantee the uninterrupted operation of the Instrument. Manufacturer's only liability and Purchaser's exclusive remedy under this warranty is that during the warranty period Manufacturer shall replace or repair, at no charge, and at the Manufacturer's sole discretion, any and all part of the Instrument proven to be defective. MANUFACTURER MAKES NO OTHER WARRANTIES AND EXPRESSLY EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR USE. IN NO EVENT SHALL Manufacturer or distributor BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES, INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF USE OR REVENUE, OR PROFITS IN CONNECTION WITH OR ARISING OUT OF MANUFACTURER'S PROVISION OF THE INSTRUMENT, OR PURCHASER'S USE OF THE INSTRUMENT.

Tampering with any portion of the Instrument, abusing the Instrument or using the Instrument in a manner inconsistent with its User Manual will void this warranty. This warranty does not apply to any component that is damaged by improper storage in environmental conditions outside the recommended range, accident, or that is subject to alteration, misuse, tampering or abuse. Purchaser must file a warranty claim in writing and within the applicable warranty period to the USA Distributor.

Please contact – Celltrion USA, Inc. Customer Service Center, Sampinute@celltrion.com

Distributor Information



Celltrion USA, Inc.

One Evertrust Plaza Suite 1207, Jersey City, New Jersey, 07302 USA

Phone: 201-499-1844

Email: Sampinute@celltrion.com | www.celltrion.com

Manufacturer Information



BBB Inc.

7F, 22, Teheran-ro 81-gil, Gangnam-gu, Seoul, Republic of Korea

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SAMPINUTE





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