SD BIOSENSOR User Manual for STANDARD F2400 Analyzer

Medical Device

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STANDARD™ F2400

Thank you for purchasing the STANDARD F2400 Analyzer.

This User manual contains all information about the Analyzer. Pease read this User manual carefully and familiarize yourself with the required preparations and test procedure before performing a first test.
Please read the instructions carefully which are included in each test device package before using the Analyzer.

If you have any questions about the analyzer, please contact your local distributor. You can also visit www.sdbiosensor.com for product demonstrations.

Again, thank you for purchasing the STANDARD F2400 Analyzer.

STANDARD™

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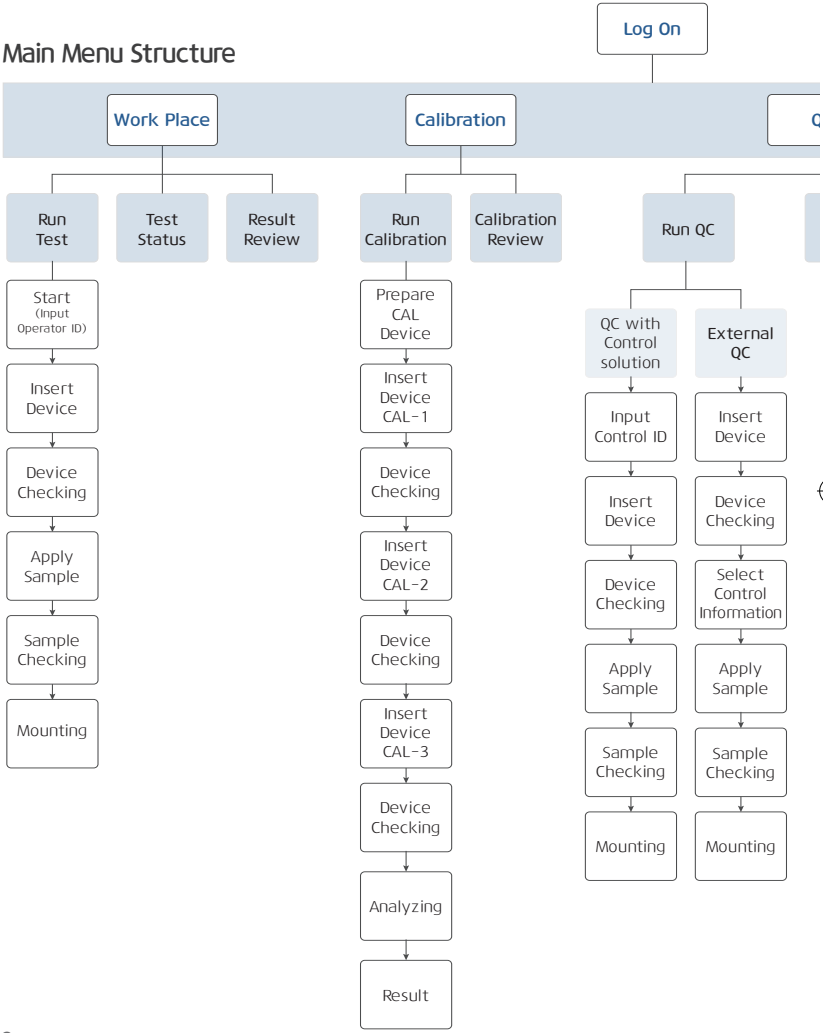
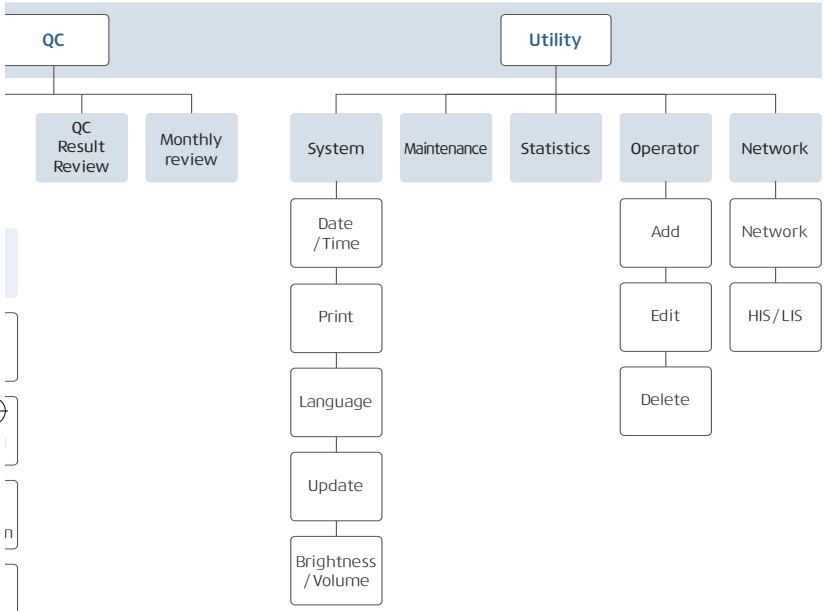
Main Menu Structure




QC
Utility
QC Result Review
Monthly review
System
Maintenance
Statistics
Operator
Network
Date / Time
Print
Language
Update
Brightness / Volume
Add
Edit
Delete
Network
HIS / LIS

Symbols and Abbreviation

The symbols and abbreviation presented below are indicated on the User Manual, labels and external package.

Symbols

Symbols	Description
	Manufacturer
	*In vitro* diagnostic medical device Intended to use outside the body
	Consult instructions for use
	Reference Number
	Date of Manufacture To indicate the date of manufacture
	Serial Number
	Note
	To indicates that the analyzer is fragile and you need to handle it with care
	Batch code Indicate the lot number of the system
	Crossed out wheeled bin Discard it separately from other household waste
	Fulfill the requirements of Directive 98/79/EC on in vitro diagnostic medical devices
	Indicate that you should keep the analyzer dry
	Caution Indicate a situation, which if not avoided could result in damage to the device or incorrect results

Abbreviations

Abbreviation	Description
Comm	Communication
LIS	Laboratory Information System
HIS	Hospital Information System
GUI	Graphic User Interface
S/W	Software
F/W	Firmware

Precautions

To reduce the risk of damage to Analyzer

- Use the Analyzer for *in vitro* diagnostics only.
- Keep the Analyzer in a flat and dry place. Avoid direct sunlight.
- Do not expose the analyzer to strong light. Otherwise, serious interference to the test results may occur.
- Do not move the Analyzer during the test.
- Do not drop the Analyzer. Otherwise, the Analyzer may be damaged.
- Do not attempt to disassemble the Analyzer.
- Do not immerse the Analyzer in water or cleaning solution.

To reduce the risk of inaccurate results

- This Analyzer should be used only by trained operators.
- If the error message occurs repeatedly, stop using the Analyzer.
- For accurate results, refer to the manual that comes with each test device.
- Do not use test devices which have expired.

To prevent electric shock

- Ensure the Analyzer is completely grounded. Do not connect the Analyzer to an ungrounded outlet.
- When using a power board, use a grounded power board.
- Make sure that all cables are connected to the Analyzer correctly and completely.
- There is a risk of electric shock if Analyzer is not grounded. Use the power cable provided by the SD Biosensor. It is recommended to use a power cable of 250V ~, 10A, 0.75mm2 (18 AWG).
- Do not share power supply with other instruments and/or devices.

To reduce the risk of biological hazards

- Discard the used specimens in accordance with federal, state and local requirements.
- Treat specimens as potentially biohazardous material.
- If you have no experience with collection and handling of specimens, appropriate education or guidance should be received.
- Nitrile or latex gloves are recommended when handling patient specimens.

Chapter 2. Overview

Intended Use

STANDARD F2400 Analyzer is an in vitro diagnostic medical device that measures quantitative or qualitative biomarkers of body fluids such as blood, urine, nasal discharge, etc., in a laboratory or POCT environment. The analyzer is indicated for monitoring and diagnosing from the body fluid parameter in clinical settings by healthcare professionals. In all cases, the Analyzer should be used with designated test devices produced by SD Biosensor, Inc.
For details regarding to specific tests, refer to the user manual included with each test device package.

Product overview

STANDARD F2400 Analyzer scans the 2D barcode of inserted test device. Based on the scanned result of the inserted test device, the analyzer determines the appropriate LED (UV, RGB) settings for the test device.
An antigen-antibody reaction takes a certain period of time after samples are dispensed.
Once a reaction is completed, fluorescence dye on the control line and test line will reflect the light from LED and this reflected value will be measured.
Then the measured value will be calculated based on the formula that is input to the 2D barcode.

Precautions before perform a test


Note

- Read and follow the instructions carefully in the user manual and Instructions for use of the test device and control. It is very important to follow the instructions in order to prevent an inaccurate result or improper treatment.
- Be sure to check with your distributor and SD Biosensor for the most up-to-date software and to update before use.
- Fatal consequences, such as fire or serious system damage, may occur when the system is installed at an inappropriate location, since the Analyzer cannot be replaced or removed from power supply.
- The Analyzer must be installed in such a way that easy access to power supply and power switch is ensured.

Specimens

The STANDARD F2400 Analyzer should be only used the specific test devices for the analyzer. Because specimens are quite different for each parameter, follow the instructions from the each test device instructions.

Safety Information

There is a potential risk of infection. Professional medical personnel should always wear gloves when handling patient samples with the STANDARD F2400 Analyzer and test device. It is recommended that you follow all other locally applicable health and safety regulations.

Operating Conditions

To operate the STANDARD F2400 Analyzer correctly, the following guidelines should be observed :

- The operating conditions of the Analyzer are: 0℃-50℃ / 32℉-122℉, 10%-93% RH.
- The operating temperature suitable for analyses differs in each test. For each test, refer to the instruction manual of the test device that you will use for analyses.
- To perform a test with the Analyzer, place the Analyzer on a flat surface.
- Do not use the Analyzer near strong electromagnetic radiation sources. Otherwise, strong electromagnetic fields may affect the function of the Analyzer adversely.
- If the Analyzer malfunctions suddenly, unplug the power cable from the outlet.

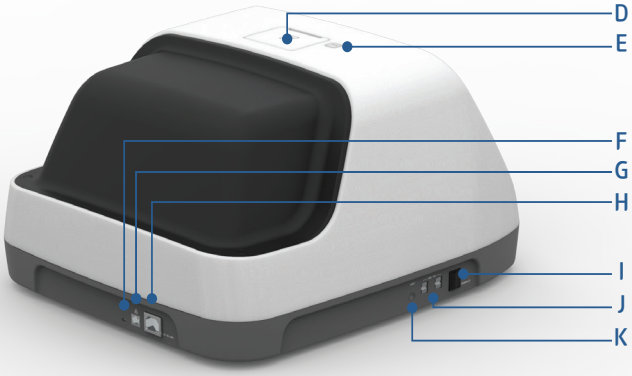
Note

It shall be lifted and carried by holding the bottom of an instrument frame zones.

Specification

Input Voltage	AC 100~240V, 50/60Hz
Display	10.1" Color TFT LCD (1024 X 600)
Display Control	Graphic User Interface
Power Consumption	Up to 84W
Number of Memories	5,000 (Run Test)
Real Time Clock	Including RTC Backup Battery
LIS / HIS	HL7 PCD 01 Profile Support
Dimension	510 X 566 X 297 mm
Inserts	User Manual
Bar Code Scanner (Option)	USB Barcode Scanner
Weight	20 kg

Appearance of STANDARD F2400 Analyzer



A. Color TFT LCD
Used for test screen display and interaction with graphical user interface

B. Inlet for insertion of test device
Used for insertion of test device into the Analyzer

C. Test device outlet
Used for discharge of test device that has completed the test

D. Printer cover
Used to cover and protect printer paper

E. Printer cover open button
Used to open printer cover

F. Mini USB
Used to upgrade firmware by connecting with PC

G. LAN
Used for communication using LAN Cable

H. AC power connection
Used for AC power cable connection

I. Power switch
Used to turn the Analyzer on/off

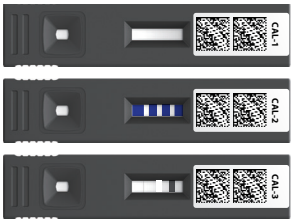
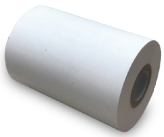
J. USB x 4
Used to connect the Analyzer to keyboard, barcode scanner and USB memory


Note

USB should be formatted as FAT32, so that the USB can be recognized by STANDARD F2400 Analyzer.

K. Additional device connection part
Only use for connecting specific device that is produced by SD Biosensor, Inc

Accessories of the STANDARD F2400 Analyzer

Accessories	STANDARD F Calibration Set	
	AC Power cable	
Optional	STANDARD F Test Device (Example : HbA1c, Influenza A/B)	
	Barcode scanner	
	Printer paper	

Chapter 3. Log On and Setting

Operation of Analyzer

Step 1. Connecting the power cable

1-1. Place the Analyzer in a proper environment where it can be plugged into outlet and barcode scanner (optional) can be positioned together.

1-2. Connect the power cable to the power connector on the back of the Analyzer and to the outlet.

1-3. Once the connection is complete, the analyzer is ready for use.

Step 2. Analyzer Log On

2-1. Press log on button.

2-2. The initial log on ID is admin and the password is 1111.

Step 3. Analyzer Setting

3-1. When the Analyzer is set up for the first time, user information must be registered.

3-2. For initial setup, select the Utility screen on the main screen. The details of the setting (Utility) menu are shown below.

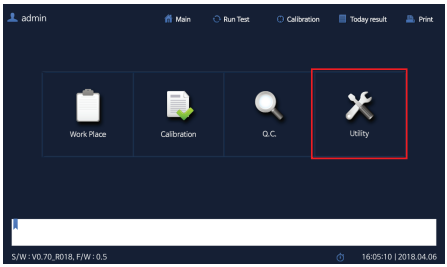
Step	Menu	Submenu
1	System	Date/Time
		Print
		Language
		Update
		Brightness/Volume
2	Operator	Add, Edit, Delete
3	Network	Network, HIS / LIS

Step 1: Log On Mode

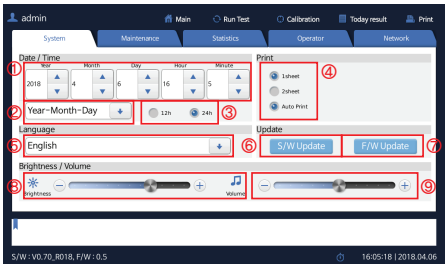
1. Enter the Operator ID and password on the Log On screen and press the Log On button. Operator ID is “admin” and password is “1111”.

Step 2: Setting Mode

1. Touch 'Utility' on the main menu screen to enter the setting mode.



2. Utility menu consists of submenus: System, Maintenance, Statistics, Operator, and Network. System submenu can be used to set the Date/Time, Language, Print, Brightness/Volume and proceed with the update.



System Menu

1) Date/Time Setting

① Press an Up(▲) or Down(▼) button to change the year, month, date, hour, and minute.

② The display type of year, month and date and be changed.
Change the date style setting.

Year-Month-Day ▼ - Year-Month-Day
Month-Day-Year ▼ - Month-Day-Year
Day-Month-Year ▼ - Day-Month-Year

③ Time unit is changeable between 12 hours (12h) and 24 hours (24h).

2) Print Setting

You can set the number of result sheet to 1 sheet or 2 sheets. Once press "Auto Print", the test result will be printed automatically after all.

3) Language Setting

Press a down arrow( ) to select the desired language from the drop-down list.

4) Update

① S/W Update

Items needed for S/W update

- STANDARD F2400 Analyzer
- Software update file
- USB(Not provided)
- Personal computer(Not provided)

How to update the software

a. Prepare a USB memory containing the F2400's new software file.
   ii. Format USB as FAT32 file system.
   iii. Copy the software file to USB memory.

b. Connect the USB(that F2400 Software is copied) to the USB port on the bottom left of the F2400 Analyzer.

c. If the USB is connected normally, "USB connected successfully" will be displayed.

d. Press the S/W Update button. Then, "S/W Update?" will pop up. Press " OK " to start the S/W update.

e. If the S/W Update is completed, "S/W Update OK" will be displayed on the screen. Press "OK" to reboot the analyzer.

f. Make sure that the latest S/W version is displayed in the lower left corner of the screen.

② F/W Update

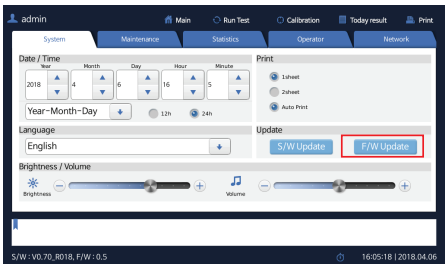
Items needed for F/W update

- STANDARD F2400 Analyzer
- Firmware update file
- Mini-5pin USB cable
- Personal computer(Not provided)

How to update the F/W

a. Connect your PC and device with a Mini USB cable. If the driver is not recognized on PC, install the CP2101 driver.

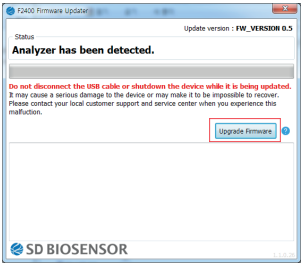
b. Press FW update (F/W Update)on the screen.



c. Press “OK”.

d. Run the PC program.

e. When the Update Firmware button is enabled, click the button.



f. Click“Update Firmware” on the PC and then press “OK” on the Analyzer.

g. When the update is completed on the PC, press the OK button

h. Press "OK"on the screen to complete FW Update.

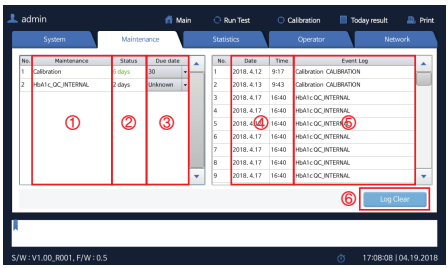
5) Brightness/Volume setting

① Use ⊖, ⊕ buttons or the slider to adjust screen brightness.

② Use ⊖, ⊕ buttons or the slider to adjust the volume.

Maintenance Menu

1) On the Maintenance tab, you can check the maintenance status and log of each item.



① Maintenance Area: Tested items are displayed.

② Status Area: QC scheduled date for tested item is displayed. The QC period can be set from due date in Area ③ above.

③ Due Date Area: You can set the period of test items. Press button to select "No QC(Off)" or set the due date by 15, 30, 45, 60, 90, 180 or 300 days.

④ Event Log Date & Time Area: Date and time of event log are displayed.

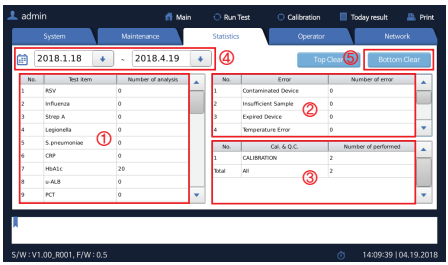
⑤ Event Log Area: History of all items tested by F2400 Analyzer is displayed in chronological order.

Caution

Log Clear Button: Delete the selected event log.

Statistics Menu

1) On the Statistics tab, you can check the number of tests, calibration, and QC tests for each item.



① The number of times that each test has been performed is displayed.
② The type and number of times of errors that occurred are displayed.
③ The number of times of calibrations and Q.C. for each test is displayed.
④ Period setting: Press ▾ button to set the period that you want to check.

Caution

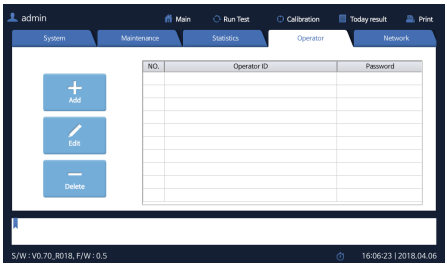
- Top Clear: Delete selecte.
- Bottom Clear: Delete selected Cal & QC Log.

Operator Menu

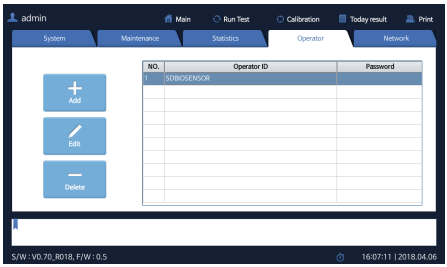
1) An Operator item can be registered, edited, and deleted.

- Password in Operator is the same as the password used for log-on.

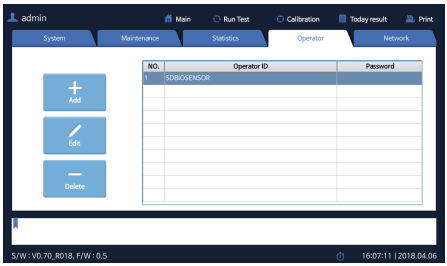
- To add an Operator ID, press "Add" .



· To modify the Operator ID, select the ID,, press “Edit”, type ID you wish to modify, and then press “OK”

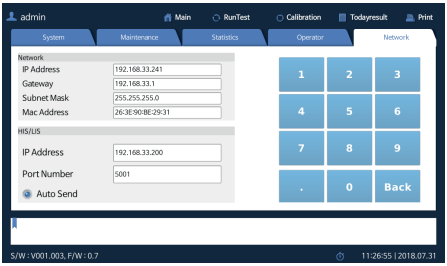


· To delete the Operator ID, select the ID, select the ID, press “Delete”, then press “ OK”



Network Menu

1) On the Network tab, you can set the HIS/LIS and Analyzer network. For the methods of setting, consult with your interface specialist.

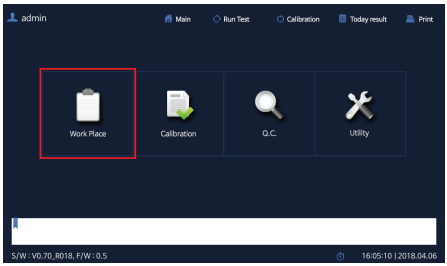


Chapter 4. Work Place

Performing a Test & Reviewing data

Before proceeding a test, check the following :
- Is the power cable connected to the Analyzer?
- Are the date and time settings of the Analyzer correct?
- Are all other settings correct?

1. Select the "Work Place" from the Main Menu.



2. The "Work Place" consists of 3 items: "Run Test", "Test Status", and "Result Review".

1) Run test Menu

"Run test" is a mode for testing the samples from patients.

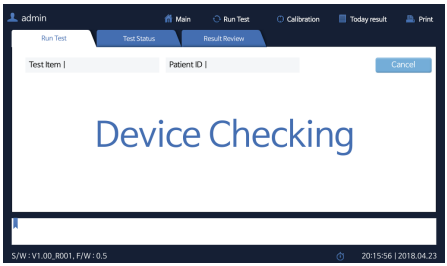
① After entering patient information in "Patient ID", press Run Test to move to the next step.

Patient ID can be entered by using the touch keyboard. You can also enter Patient ID by using a barcode scanner or by an external keyboard connected by USB.

** You can also press Run Test button to proceed with the test without enteringthe Patient ID.

② Insert the test device in the "Insert Device" step and the Analyzer will move to the next step automatically.

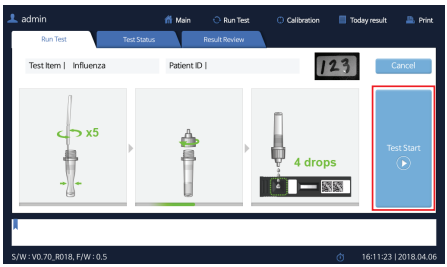
③ Analyzer checks the conditions of the inserted test device. If the test device has already been used, E-1 error pops up.



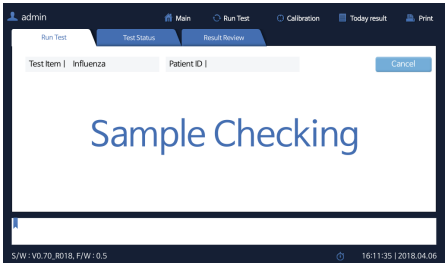
④ After confirming that the test device can be used with STANDARD F2400, the samples should be prepared according to the instruction for each test and applied to the sample well of the test device.

Caution

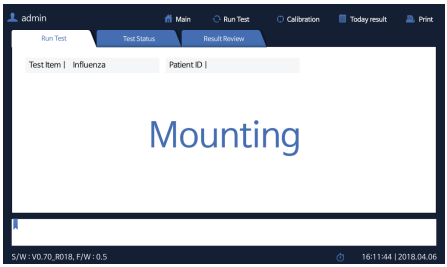
· Press the "Test Start" immediately after applying the sample to the test device.



⑤ Analyzer checks the applied sample's conditions and flow.



⑥ When the sample checking is completed, the test deviceis mounted inside the Analyzer.



⑦ When the mounting is completed, you can start a new test procedure.

2) Test Status Menu

"Test Status" menu shows the progress of test in the Analyzer.

Blue section is shown in the following cases:

- If the test is completed correctly.
- If the result of qualitative test is Negative
- If the result of quantitative test is within the normal range.

Red section is shown in the following cases:

- If the test is completed correctly.
- If the result of qualitative test is positive
- If the result of quantitative test is out of normal range

Black section is shown in the following cases:

- If the test result is Invalid

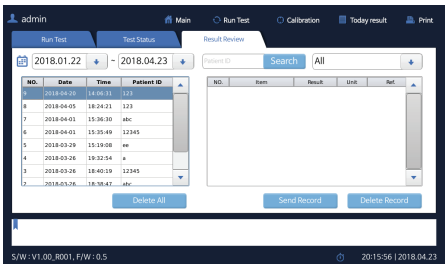
Green section is shown in the following cases:

- If the test is in progress

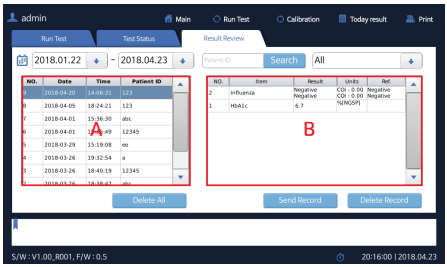
① If you select a completed item, you can check details of the test(test result, name label, procedural control, test date and time, Operator ID, Patient ID, manufacturing date of the test deivce, software version). In this window, you can print the test result by pressing on "Print". Press "OK" to close the window.

3) "Result Review" Menu

Result Review allows you to check the test results from "Run Test"



① Select All from the drop-down list on the right. And select a test from list shown in [Area A]. All of the test results belonging to the selected Patient ID will be shown in [Area B]. If you select a particular test from the drop-down list, you can see the tests in order from the most recent ones.

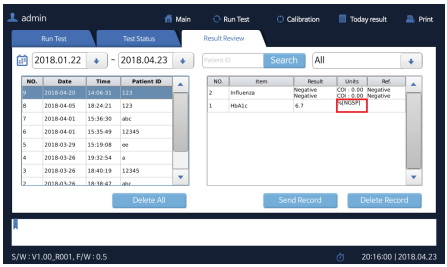


② If you select a test from the list in [Area B], you can see the test details.

· Test details window for qualitative test Example) Influenza A/B

· Test details window for quantitative test Example) HbA1c

For quantitative test, you can change the measurement unit by pressing the item under "Units" in the list on the right side[Area B]. (Available only when there are 2 or more types of measurement units.)



Chapter 05. Calibration

Calibration Set Test

Calibration Set Test is an essential function that ensures optimal performance of the Analyzer by checking the methods specified in the Manual.

Time for use of Calibration Set

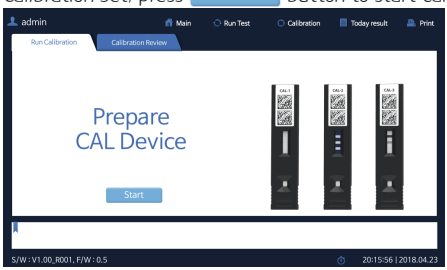
- Whenever the Analyzer is turned on
- When Analyzer is dropped
- When the result does not match the desired result
- When you want to check the performance of the Analyzer and test device

Caution

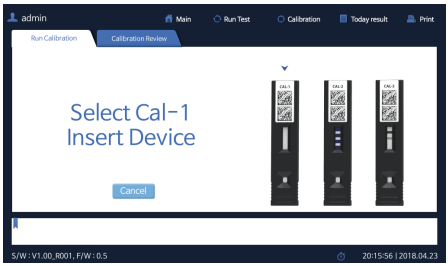
- Calibration Set test is independent from QC test and cannot replace QC test.

Calibration mode consists of "Run Calibration" and "Calibration Review".

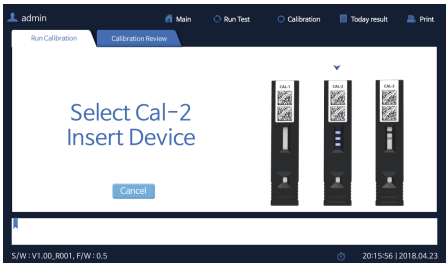
1. Run Calibration Menu
   Calibration can be performed in "Run Calibration". After preparation of Calibration Set, press Start button to start calibration.



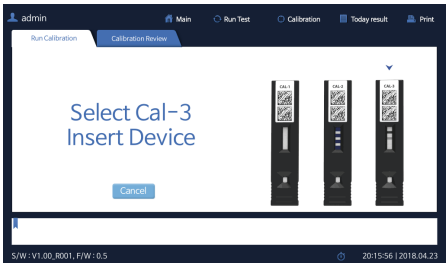
① Insert the Cal-1 Device into the test slot of the Analyzer.



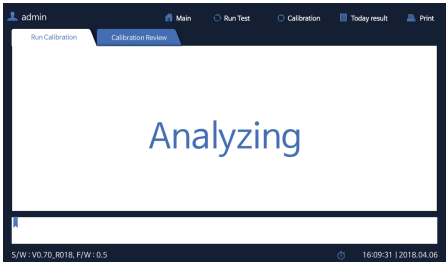
② After checking the Cal-1 Device, insert the Cal-2 Device into the test slot of the Analyzer.



③ After checking the Cal-2 Device, insert the Cal-3 Device into the test slot of the Analyzer.

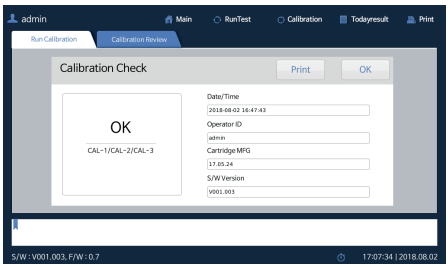


④ After inserting all the calibration devices, the analyzers performs the calibration analysis.

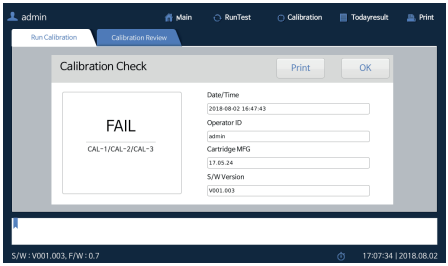


⑤ When the analysis is completed, you can check the result screen.

· Calibration check- OK screen

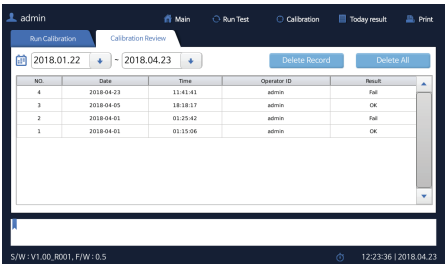


· Calibration check- FAIL screen



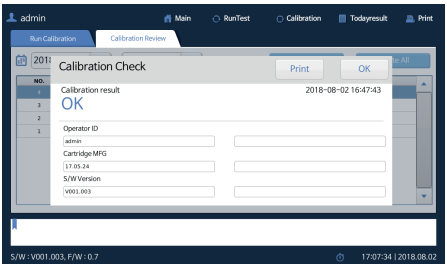
2. Calibration Review Menu

The result of calibration can be checked in "Calibration Review".

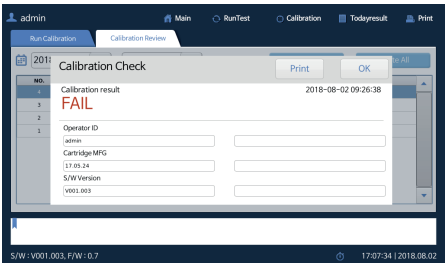


① You can check the details by selecting the Result from the list.

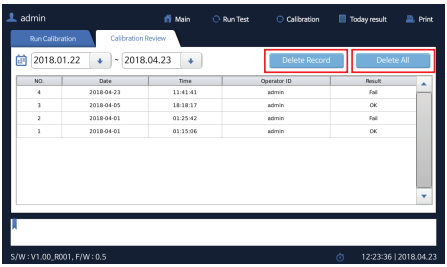
· Calibration Review - OK screen



· Calibration Review - FAIL Screen



② Select a list and press “Delete Record”(Delete Record) to clear the selected items. Press the “Delete All”(Delete All) to clear all results.



Chapter 6. Quality Control

Quality Control Test

To verify whether the Analyzer's system is functioning properly and whether the test procedure is correct, perform QC with one or more levels of quality control materials.

Time for use of Calibration Set

- When Analyzer is used for the first time
- When usinga tes device of newly opened package.
- When Analyzer is dropped
- When the result does not match the expected result
- When the result is lower or higher than expected even after repeated tests.
- When you want to check the performance of the Analyzer and test device

Before using the Control

- Check the expiration date of quality control material. Do not use after expiration or disposal date (3 months after the package of quality control material is opened), Consider the earlier date between those two.

QC Mode consists of "Run QC", "QC Result Review" and "Monthly Review".

1. Run QC Menu

   Run QC consists of "QC with Control Solution" and "External QC".

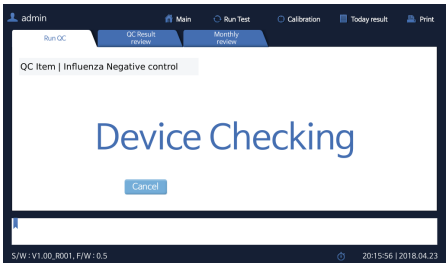
1) QC with Control solution

① Select "QC with Control solution" and the next screen will be shown.

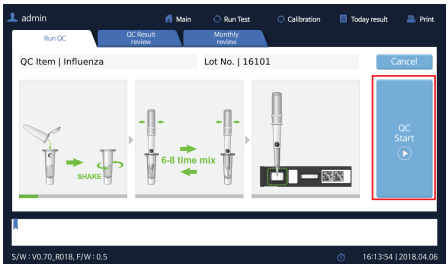
② Enter the information of quality control material (barcode number) and press OK to proceed to the next step.

③ Insert a test device that matches the quality control material information entered on the Insert Device screen.

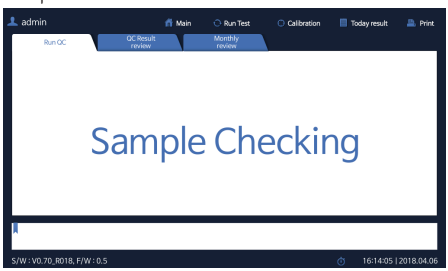
④ The Analyzer checks the conditions of inserted test device. If the test device has already been used, an E-1 error pops up.



⑤ When the verification of the test device is completed, apply the control to the sample well of the test device and immediately press "QC Start".



⑥ The F2400 Analyzer will check the conditions and flow of applied sample.



⑦ After the check is completed, the test device is mounted inside the Analyzer.

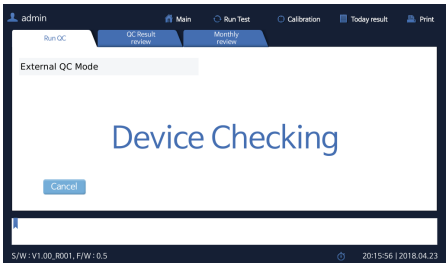
⑧ Once the mounting is complete, you can start a test procedure.

2) External QC

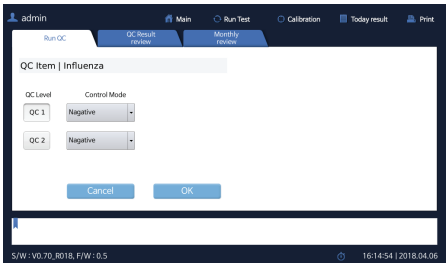
① Press "External QC" to move to the next screen.

② Insert the test device to test on the Insert Device screen.

③ Analyzer checks the conditions of inserted test device. If the test device has already been used, an E-1 error pops up.

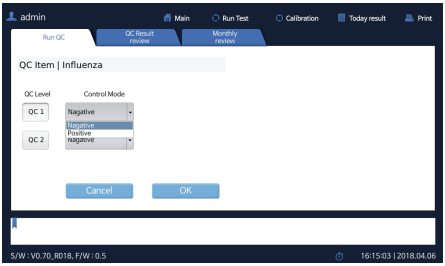


④ When the verification is completed, a screen for setting the range of quality control material appears.

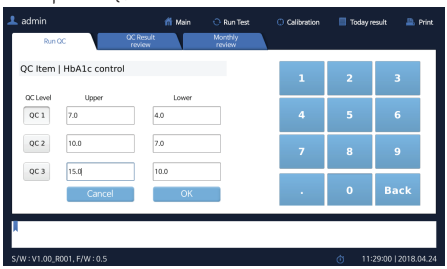


⑤ Set the information of the quality control material to be used and press "OK" to save the information.

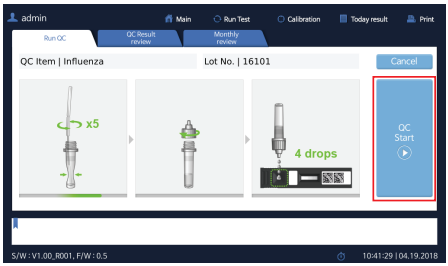
· Example of Qualitative test



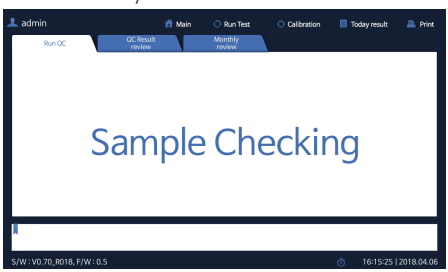
· Example of Quantitative test



⑥ After applying the prepared quality control material, press "QC Start" immediately.



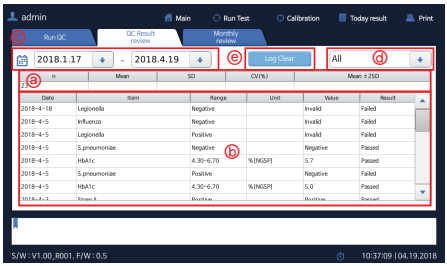
⑦ The F2400 Analyzer checks the conditions and flow of applied sample.



⑧ Once the verification is completed, the test device is mounted inside the Analyzer.

3) QC Result review Menu

① You can check the result of QC in "QC Result review".

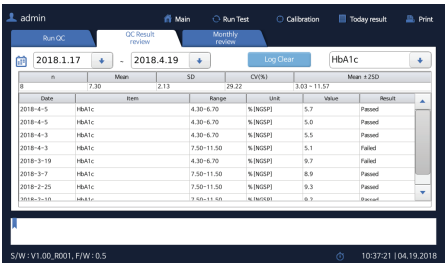


a. The number of times that QC was performed, average, standard deviation, coefficient of variation, and the result of ± 2SD are shown. For qualitative items, only the number of times is displayed. For the quantitative items, all values are displayed.

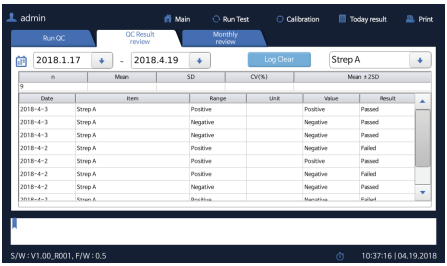
b. The QC history of selected test is displayed in the No. 4 drop-down list (d).

c. You can set the date for desired period.

d. If you select the test you want to view from the drop-down list, you can check the QC result of selected test.
Example) The results obtained when result retrieval period is set to 2018.1.17-2018.4.19 and then HbA1c is selected from the drop-down list

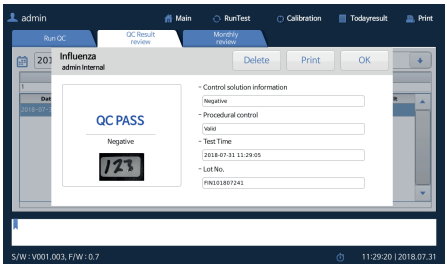


Example) The results obtained when result retrieval period is set to 2018.1.17-2018.4.19 and then Strep A is selected from the drop-down list



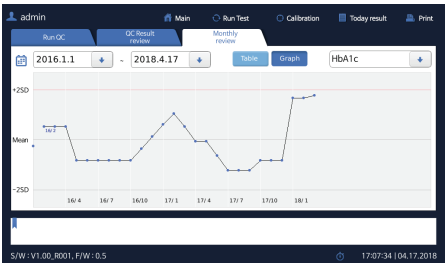
e. Deletes the entire QC result.

② If you select from the list, you can check the test details.



4) Monthly Review Menu

In "Monthly Review", you can check the monthly value of quantitative test.
If you select the period and press "Table", the QC results for that period are provided in the form of a list.
Here, you can check only the result of selected test by pressing "Select item" and selecting the desired item.
When a graph is selected, the Levey-Jennings control chart is provided.



Chapter 07. Cleaning & Maintenance

Cleaning of Analyzer

To prevent any malfunctioning of Analyzer, keep the test slot free from specimen moisture or dust. Clean the Analyzer with a lint-free cloth and suitable cleaning solution (example: mild soap, 70% ethanol or isopropyl alcohl). If the Analyzer is in a special environment (example: operating room), it is recommended to clean it with a mixture of 1-propanol, 2-propanol and glutaraldehyde (trade name: Bacillol plus).

- Do not use abrasive cleaners or liquid preservatives. Otherwise, the display screen may be damaged. Before cleaning, always turn off the Analyzer and disconnect the power cables.

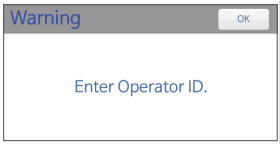
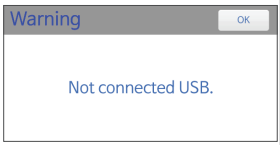
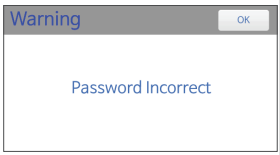
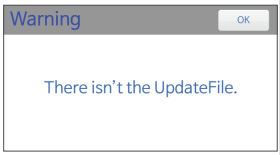
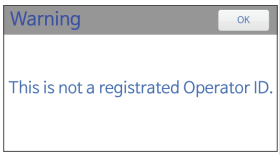
Maintenance and Transportation

Each time you turn on the Analyzer, the system in the Analyzer starts self verification to find any possible problem.

- Be careful not to contaminate the test device slot and internal parts of the Analyzer.
- The carrying case is designed to store the supplied components and to protect the Analyzer.
- The Analyzer must be stored and transported at -20°C ~ 50°C / -4°F ~ 122°F and 10%-93% RH.
- The F2400 Analyzer was designed to meet safety standards.
- Do not modify or repair the Analyzer.
- Do not repair the Analyzer yourself without the help of the supplier.

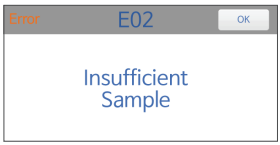
Chapter 08. Message & Troubleshooting

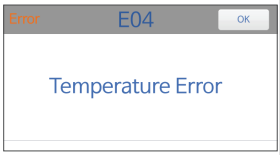
Warning Message

Display	Description of Warning
	**Warning: No user information entered** "OK" is pressed while no user information has been entered. **Solution** First, enter the user information and then press 'OK'.
	**Warning: USB not connected** USB is not connected to the Analyzer. **Solution** Make sure that USB is properly inserted into the Analyzer.
	**Warning: Password error** Incorrect administrator password entered. **Solution** Enter the correct password.
	**Warning: No Update File** Update file is not found in USB. **Solution** Check USB for update file. If you have confirmed that updated file is stored on the USB, Insert the USB and press 'OK'.
	**Warning: Unregistered user information** The entered user information is not registered in the Analyzer. **Solution** Add user information in setup mode.

 	**Warning: Incorrect IP address** Incorrect IP address entered. **Solution** Confirm the entered IP address, and enter the correct IP address.

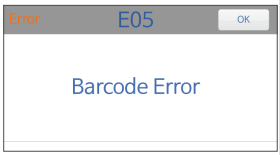
Error Message

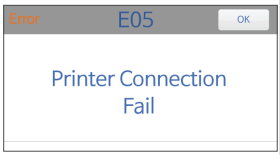
Display	Description of Warning
	**E01: Test device error** Inserted test device is contaminated or already used. **Solution** Discard the failed test device and retest with a new test device.
	**E02: Insufficient sample volume** Insufficient sample is applied. **Solution** Discard the failed test device, and test again by dropping sufficient volume of sample on new test device.
	**E03: Expired test error** A test device was used after expiration date. **Solution** Perform the test again with new test device that has not exceeded the expiration date.



E04: Temperature error
The ambient temperature deviates from the operating temperature range of the test device.

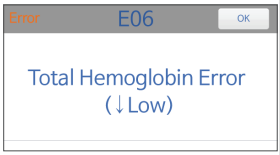
Solution
Move the Analyzer and test device into proper temperature range and perform the test. Do not artificially heat or cool the Analyzer.

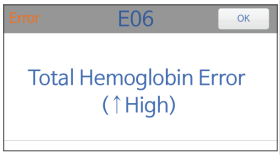




E05: Communication error
Communication between Analyzer and barcode or between Analyzer and printer has failed.

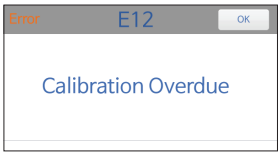
Solution
If the error persists after rebooting the Analyzer, consult the SD Biosensor.





E06: Total hemoglobin amount error
The total hemoglobin measured deviates from the range of 7-23 g/dL.

Solution
Test again with a new test device.
If the error persists after rebooting the Analyzer, contact the SD Biosensor.

	**E12: Calibration overdue error** Time limit for calibration has been exceeded. **Solution** If same error persists after calibrating, contact the SD Biosensor.
	**E13: Unsuitable test device error** Test device applied to Analyzer is not suitable. **Solution** Check if the analyzer is updated with the latest version of the software.
	**EEE: Analyzer internal error message** Analyzer has an internal error. **Solution** If the error persists after rebooting the Analyzer, contact the SD Biosensor.

ANNEX 01. Information for Professional Medical Personnel

Protection from Infection

Professional medical personnel must be careful to avoid infection caused by sample, etc. while performing diagnostic test with the STANDARD F2400 Analyzer.

- Wear medical gloves.
- When applying sample into the sample well of test device, be careful that the sample does not contaminate any part of analyzer.
- Observe the relevant guidelines and regulations of healthcare, sanity and safety.

Electromagnetic compatibility

The electrostatic discharge immunity test shall comply with the international standard IEC 61000-4-2. In addition, this Analyzer meets electromagnetic compatibility requirements in accordance with EN 61326 and there is no interference with other electronic equipment.

Disposal

Dispose of the STANDARD F2400 Analyzer in accordance with local regulations for disposal of electrical and electronic equipment. Waste Electrical Electronic Equipment (WEEE) regulation corresponds to the European Directive 2002/96/EC for reduction of wastes from the Analyzer. Before any disposal of STANDARD F2400 Analyzer, please contact the concerned authorities or staff.

MEMO

MEMO

REF F2400 IVD

Manufacturer

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