


SD BIOSENSOR

USER MANUAL FOR STANDARD F200 ANALYZER

Manufactured by  SD BIOSENSOR

 **Head office** C-4th&5th, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

 **Manufacturing site** 74, Osongsangmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

 +82-31-300-0400

 +82-31-300-0499

 sales@sdbiosensor.com

 www.sdbiosensor.com



STANDARD™ F200



Thank you for your purchase of the STANDARD F200 Analyzer

This user manual contains all the information needed to use the analyzer and keep it ready to operate. Please read this user manual carefully before using the analyzer. Familiarize yourself with the required preparations and the measurement procedure before performing the first measurement. Please read the instructions which are included in each test device package before you try testing.

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

Thank you again for choosing the STANDARD F200 Analyzer.

STANDARD™

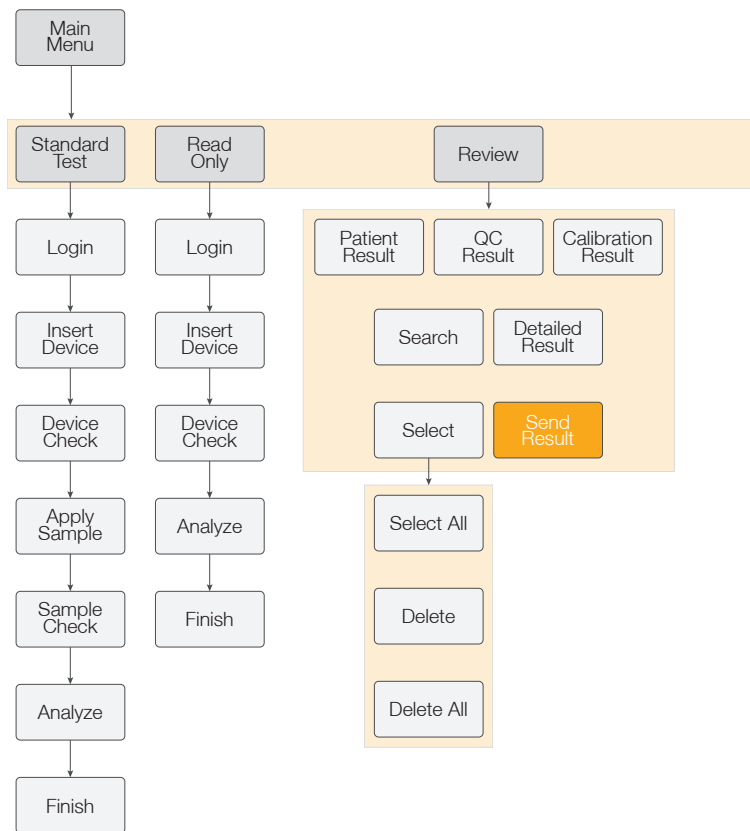
TABLE OF CONTENTS

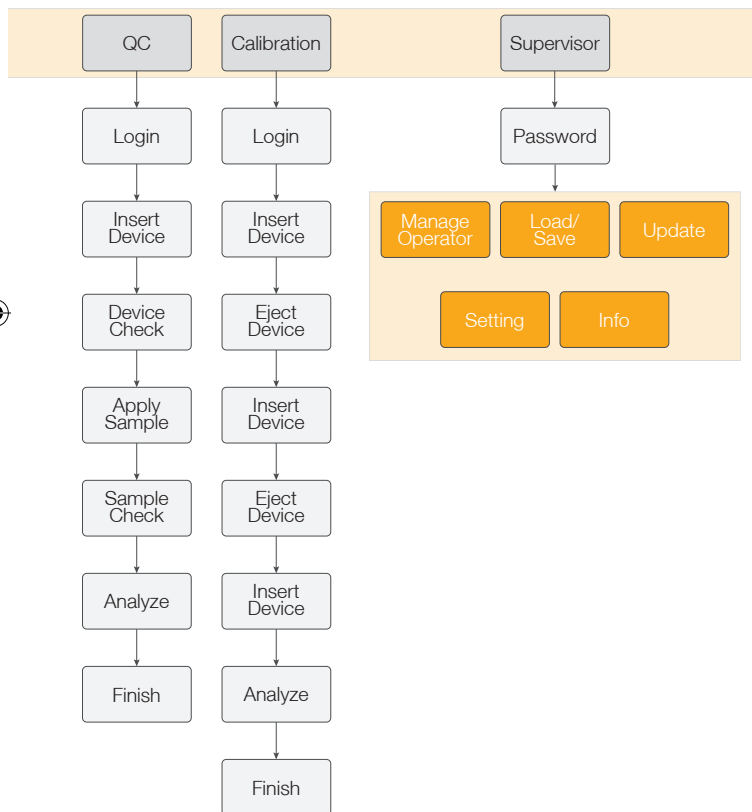
CHAPTER 01. General Information	6
Main Menu Structure.....	6
Symbol and Abbreviation	10
Brief Precautions and Limitations	12
CHAPTER 02. Introduction	13
Intended Use.....	13
Product Description.....	13
Before You Start Testing.....	13
Specifications.....	15
CHAPTER 03. Setting and Performing	18
Operating the Analyzer	18
Performing a Measurement.....	37
CHAPTER 04. Using the Analyzer Memory and Data Transfer	44
Displaying Stored Measured Values	44
Send Results.....	45
CHAPTER 05. Quality Control	47
Control Test	47
How to Run the Quality Control	47
CHAPTER 06. Calibration Set.....	51
Calibration Set Test.....	51
How to Run the Calibration Set Test	51
CHAPTER 07. Cleaning and Maintenance	54
Cleaning the Analyzer	54
Maintenance and Transportation	54

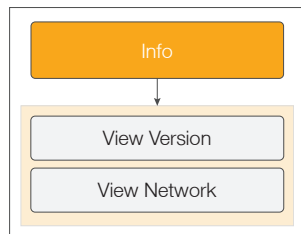
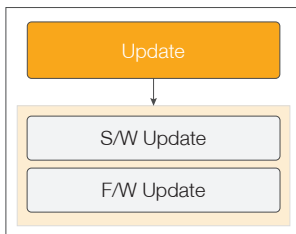
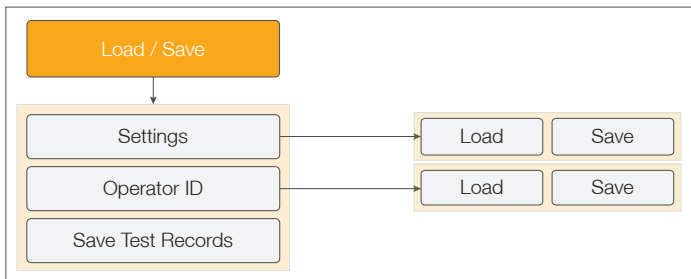
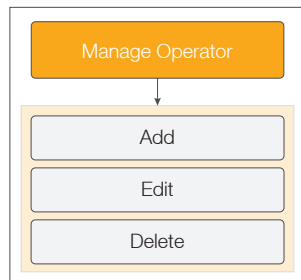
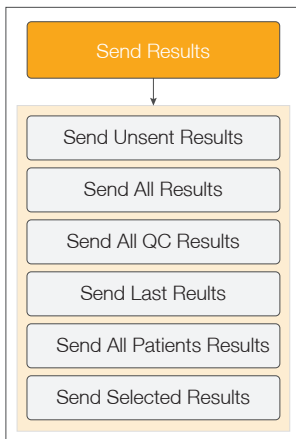
CHAPTER 08. Screen Messages and Troubleshooting	55
Warning Messages	55
Error Messages	57
 ANNEX 01. Information for Healthcare Professionals.....	60
Protection against Infections	60
Electromagnetic Compatibility	60
 ANNEX 02. Reference.....	61

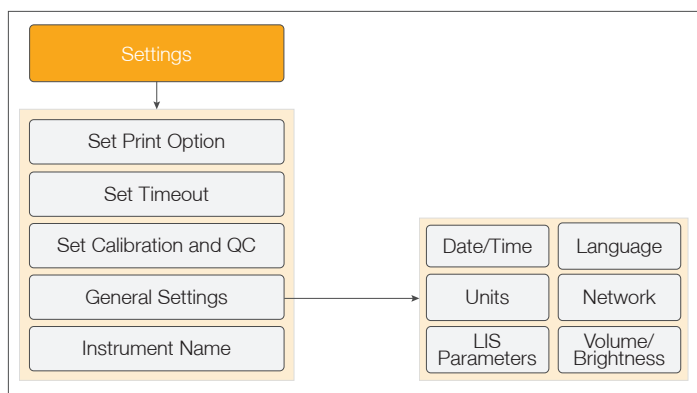
CHAPTER 01. General Information

Main Menu Structure






















Symbol and Abbreviation

The symbols and abbreviations may appear on the packaging, on the labels, and in the instructions for the STANDARD F200 Analyzer.

Symbol

Symbol	Description
	Manufacturer
	<i>In vitro</i> 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 for the system
	Crossed out wheeled bin Discard it separately from other household waste
	Fulfill the requirements of Directive 98/79/EC on <i>in vitro</i> 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

Abbreviation

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

Brief Precautions and Limitations



Caution

To reduce the risk of analyzer damage

- For *in vitro* diagnostic use.
- Keep the STANDARD F200 Analyzer on a flat and dry surface and avoid direct sunlight when operating.
- The analyzer has internal correction for normal levels of ambient light, but highly intense light falling into the analyzer may cause serious interference for the result, so it must be avoided.
- Never move the analyzer while a test is in progress.
- Do not drop the analyzer as it could damage the unit.
- Do not attempt to disassemble the analyzer.
- Do not immerse the analyzer in water or cleaning solutions.

To reduce the risk of incorrect results

- The analyzer should be used by trained operators.
- Do not use if the analyzer is displaying an error message that cannot be corrected.
- To obtain accurate result, refer to the instructions included in each test device package for test storage and system operating conditions.
- Using test devices that are expired can cause the results to be inaccurate.



Potential
Biohazard!

To reduce the risk of biohazard

- Dispose of used specimens in accordance with federal, state and local requirements.
- Treat specimens as potentially biohazardous material.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
- Use of nitrile, latex, or other gloves is recommended when handling patient specimens.

CHAPTER 02. Introduction

Intended Use

The STANDARD F200 Analyzer works for measuring quantitative or qualitative biomarker with body fluid such as blood, urine, nasal mucus, and so on based *in vitro* diagnostic assays in laboratory and point-of-care settings. The analyzer is indicated for monitoring and diagnosing from the body fluid parameter in clinical settings by healthcare professionals. The analyzer should be used with the specified test device which produced by SD BIOSENSOR, Inc. Refer to assay-specific package insert for details on specific tests.

Product Description

The STANDARD F200 Analyzer can read the lot of the specific test devices in use by checking their 2D barcodes. While the test device is inserted into the STANDARD F200 Analyzer, the application well of the test device would be illuminated by UV or RGB LED (light-emitting diode) with scanning. Before performing the measurement, the type of the light reflected determines the way the test device is reflected. When the specimen is applied, the specimen would act an enzymatic reaction with forming dye and the amount of formed dye would be proportional to the concentration of specimen. The intensity of visual color or fluorescence can be measured by illuminating with motor and LED, and detected by reflectance photometry. The measured value takes into account the signal strength of the light, measured blank value previously and the reads information including 2D barcode data. Finally, the test result would display on its screen and be stored in the memory of the analyzer simultaneously.

Before You Start Testing



Note

Read and follow the instructions carefully in the user's manual and Instructions for use of the test device and control. It is very important to follow the instructions in order to prevent an incorrect result or improper treatment.

Before use, please check the latest version of software from your distributor and head office. Then update and start measuring.

Samples

The STANDARD F200 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. We recommend that healthcare professionals using the STANDARD F200 Analyzer to perform measurements for more than one patient use gloves and follow all other locally applicable health and safety regulations.

Operating Conditions

To ensure proper function of the STANDARD F200 Analyzer, observe the following guidelines.

- Operate the analyzer only within temperature 0-50°C and humidity 10-93%.
- In order to perform a measurement, place the analyzer on a flat surface.
- Strong electromagnetic fields may impair the function of the analyzer. Do not use the analyzer close to sources of strong electromagnetic radiation.
- The analyzer's air vents must be free for air (Do not cover the air vents).
- If the analyzer cause a sudden malfunction, unplug the adaptor from the outlet.

Specifications

Power Supply	Input: DC 12V/5A Max
Rating Power Supply	DC 12 V
Display	7" Color TFT LCD (800x480)
Display Controls	Graphic User Interface
Power Consumption	Max 60W
Over Voltage Category	II
Pollution Degree	II
Memory	3000
RTC	RTC Backup Battery Included
LIS/HIS	HL7 PCD-01 Profile Support
Size	200 x 240 x 205 mm
Labeling	Manual

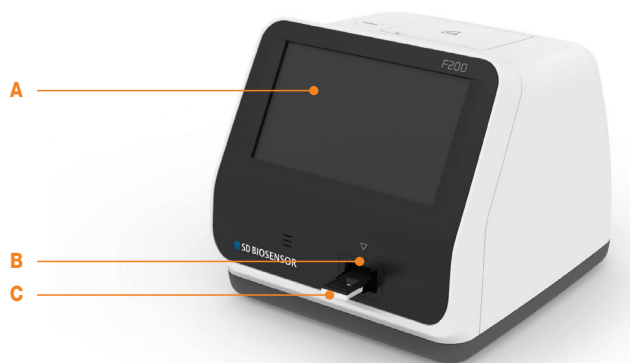
Contents

- STANDARD F200 Analyzer
- STANDARD F Calibration Set

Materials required but not provided

- STANDARD F Test Device
- 12V/5A AC/DC Power adaptor
- USB Barcode scanner

Overview of STANDARD F200 Analyzer



A. Color TFT LCD

Use for displaying test screen and interacting with the graphic user interface

B. Test Slot

Part for inserting a test device to analyzer

C. Test Device

Use for proceeding the test by inserting the specified test device

D. Printer Cover

Use for covering and protecting the printer sheet

E. Printer Cover Button

Use for opening the printer cover

F. DC Jack Port

Use for connecting power supply adaptor 12V/5A to its compartment

G. Power Switch

Use for turning on/off the analyzer

H. USB x 4

Use for connecting with keyboard, barcode scanner and USB memory



Note

When using USB memory or USB storage device, the USB file system should be formatted to the FAT32 so that the STANDARD F200 Analyzer recognizes the USB.

I. LAN

Use for communicating through the local area network

J. Mini USB

Use for upgrading the F/W upgrade by PC connection

K. Additional Device Port

Use for connecting with specific device manufactured by SD BIOSENSOR, Inc.

Accessories of the STANDARD F200 Analyzer

Accessory	STANDARD F Calibration Set	F CAL-1, F CAL-2, F CAL-3
Optional	STANDARD F Test Device	Specific test device manufactured by SD Biosensor, Inc.
	Barcode scanner	USB Barcode scanner
	Printer Paper	-
	AC/DC Power Adaptor	Input: AC 100~240 V, 50/60 Hz (Voltage tolerance $\pm 10\%$) Output: DC 12V/5A

CHAPTER 03. Setting and Performing

Operating the Analyzer

STEP 1. Connect AC/DC adaptor jack

- 1-1. Place the analyzer on the bench top within reach of an electrical outlet. The unit is portable and can be moved to a suitable location for testing. Ensure counter top is stable, flat and dry. Also check the bench provides adequate space for the analyzer and barcode scanner.
- 1-2. Plug the DC power cord into the power port in the back of the analyzer. Plug the AC/DC adaptor power cord into the cord and an available electrical outlet.
- 1-3. Once the connection is complete, the analyzer is ready for use.

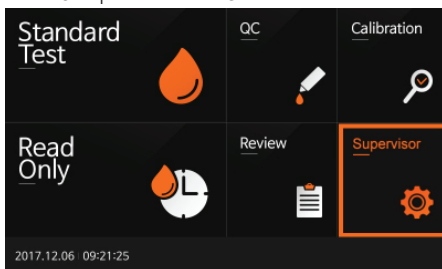
STEP 2. Set the analyzer

- 2-1 When setting on the analyzer for the first time, operator ID should be registered. **Initial supervisor password is 0000.**
- 2-2 It is recommended to acknowledge following table given on the supervisor menu.

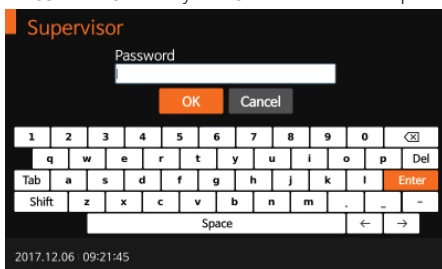
Stage	Menu	Sub Menu	
1	Manage Operator	Add / Edit / Delete	
2	Load/Save	Settings / Operator ID / Save test records	
3	Update	F/W update / S/W update	
4	Settings	Print option	Printed sheet 1/Printed sheet 2/Auto-printing
		Time out	Automatic turn-off time /Insert test device time
		Calibration & QC	Time period
		General	Date / Time / Language / Units / Network/LIS / Volume / Brightness ※ LIS/HIS can be set only when LIS / HIS server and connection is ready.
		Instrument name	Instrument name/Facility name
5	Info	View version / View network	

1st step: Entering set mode

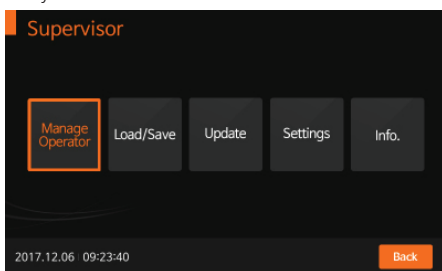
1. First, touch the 'Supervisor' on the screen in the main menu to enter the set mode and proceed the test.



2. Input the password and press the 'OK' for entry. **Initial password is 0000.** Press the 'Cancel' if you want to return to the previous setting.

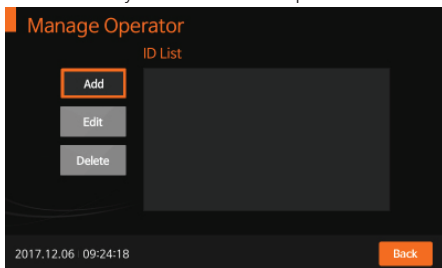


3. The supervisor menu allows operator to access additional functionality and security options depending on work environment and the location of the analyzer.

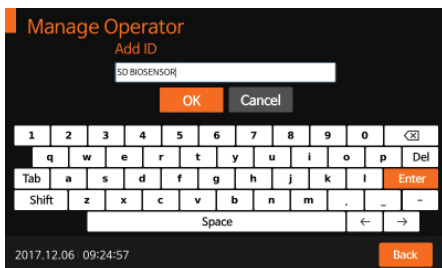


2nd step: Supervisor>Manage operator

1. Select the 'Manage Operator' on the screen to add, edit or delete operator ID. Press the 'Back' if you want to return to previous setting.
2. To add operator ID, press 'Add'. Also, use the touch panel keyboard or USB connected keyboard to add the operator ID.



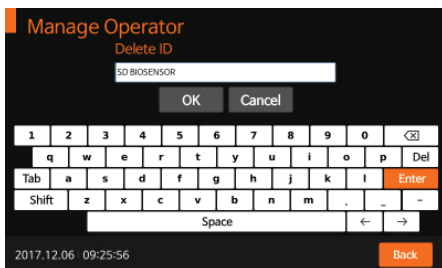
3. After adding the operator ID is completed, the analyzer will register it. Press 'OK' to confirm.



4. To edit the a name of the operator currently registered in the analyzer, select the operator ID you want to edit and press 'Edit'. After editing, Press 'OK' to confirm.



5. To delete the name of the operator currently registered in the analyzer, select the operator ID you want to delete and press 'Delete'. After deleting, Press 'OK' to confirm.



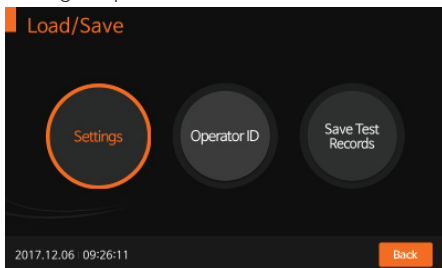
3rd step: Supervisor > Load/Save



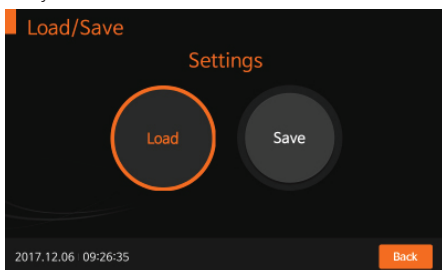
Note

The software including GUI can be updated by USB memory, and the firmware can be updated by mini USB with PC connection. The USB can be connected at any time with the analyzer's power on.

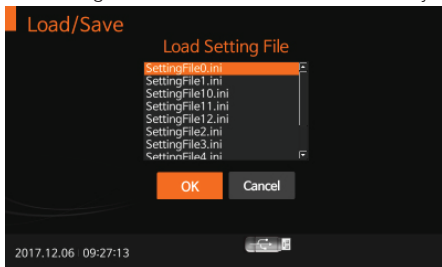
1. To load or save the analyzer's setting, enter the 'Load/Save' menu and press 'Settings' to proceed.



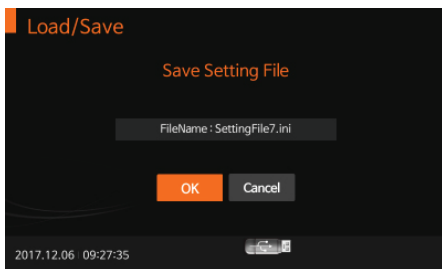
2. To load appropriate analyzer's data according to test type, press 'Load'. This can be done by inserting the USB with the data that can be loaded into the analyzer.



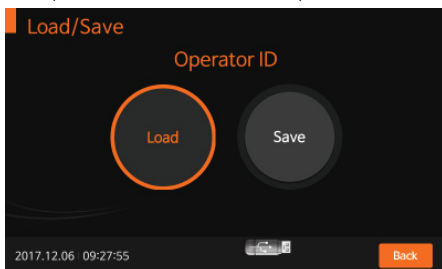
3. When the procedure of loading data is completed, the screen will promptly show the message that the data has loaded successfully. Then press 'OK' to confirm.



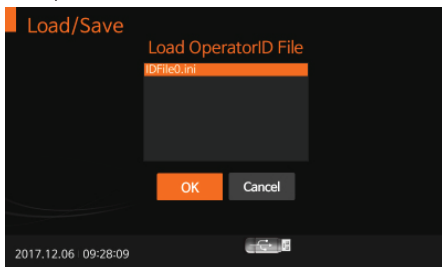
4. To save the analyzer setting data that clone or duplicate the setting of the first, press 'Save'. When the procedure of saving data is completed, press 'OK' to confirm.



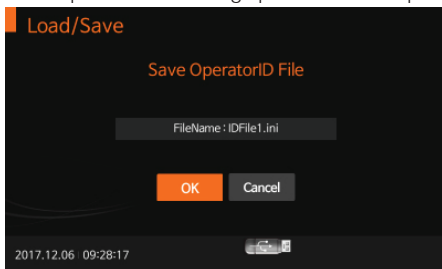
5. The operator can also load saved operator ID of the first by pressing 'Load'.



6. When the procedure of loading operator ID is completed, the screen will promptly show the message that the operator ID has loaded successfully. Then press 'OK' to confirm.



7. In addition, the operator can save the operator ID by pressing 'Save'. When the the procedure of saving operator ID is completed, press 'OK' to confirm.



Note

The analyzer's test results may be exported and saved to USB memory. Saved data is to be managed by the supervisor and all records of the test results can be displayed and printed.

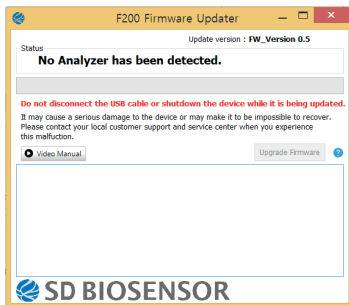
4th step: Supervisor > Update

FIRMWARE UPDATE PROCEDURE

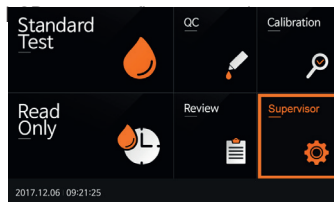
PROCEDURE FOR THE COMPUTER

1. Run firmware update program
'F200FirmwareUpdater_X_X.exe'.

F200FirmwareUpdater_0.5	2017-11-23 오후 1: 응용 프로그램
F200FirmwareUpdater_0.5	2017-12-18 오후 5: 엑스플 관리자



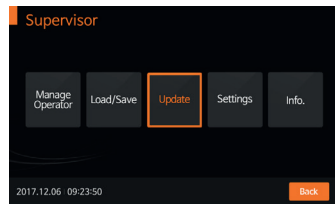
2. Select menu button on the F200



<Select the 'Supervisor'>



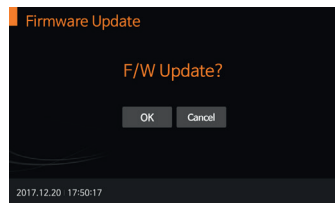
<Enter the password '0000'>



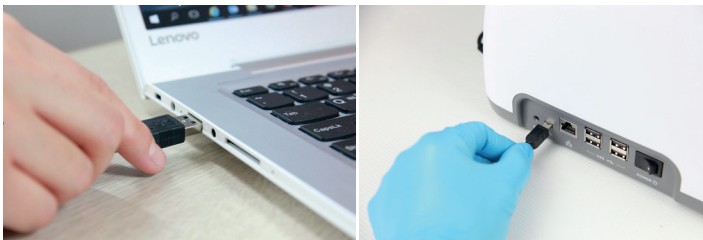
<Select the 'Update'>



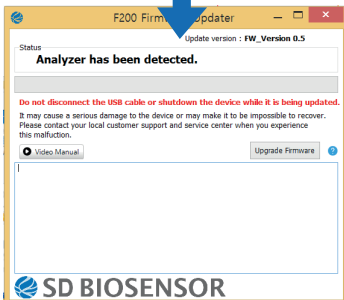
<Select the 'F/W Update'>



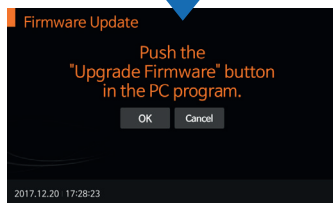
<Select the 'OK'>



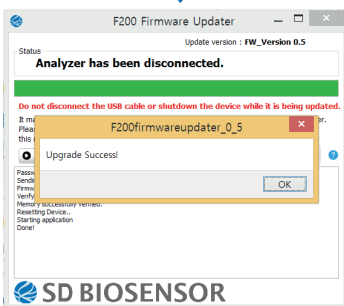
<Connect 'Mini-5pin USB cable' to computer and F200 Analyzer>



<Push the 'Upgrade Firmware' button once it is activated>



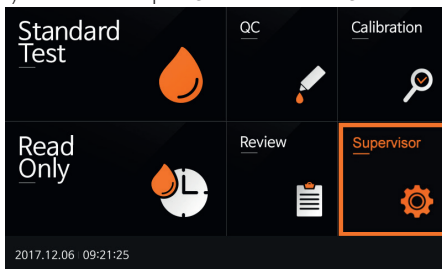
<Push the 'OK' button>



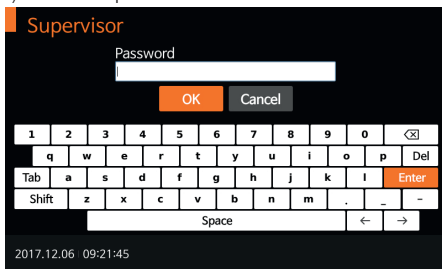
<F200 Firmware update is completed>

SOFTWARE UPDATE PROCEDURE

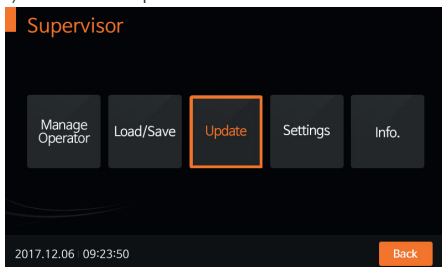
1. Preparing USB memory for F200 software update
 - 1) Prepare an USB memory for F200 software update.
 - 2) Format the USB memory with 'FAT32' file system.
 - 3) Download the software file to the USB memory.
2. Connecting USB memory to the F200 analyzer
 - 1) Connect USB memory to the USB port on the F200 analyzer.
 - 2) The USB image will be displayed on the LCD screen of F200 analyzer.
3. Updating F200 analyzer's software
 - 1) Select the 'Supervisor' menu on the screen.



- 2) Enter the password '0000'



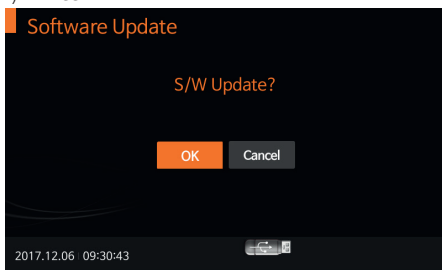
- 3) Select the 'Update' menu.



- 4) Select the 'S/W Update' menu.



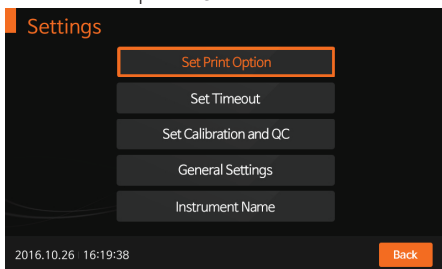
- 5) Press the 'OK' button.



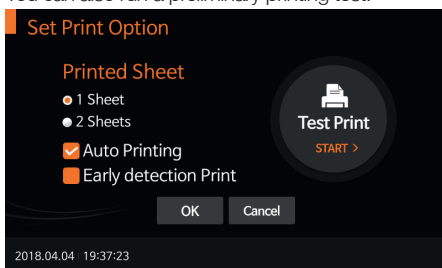
- 6) Software update will finish automatically.
7) Once the S/W update is completed, F 200 shuts down automatically.
Please turn on again to start using F200.

5th: Supervisor > Settings

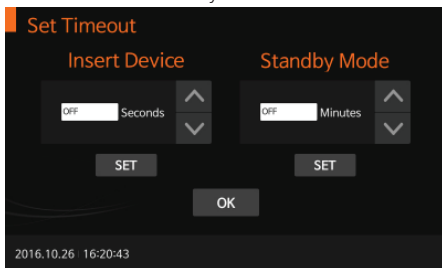
1. To set the print option, automatic turn-off time, calibration and QC period, general settings or instrument name, enter the 'Settings' menu. Press 'Back' to return to the previous menu.



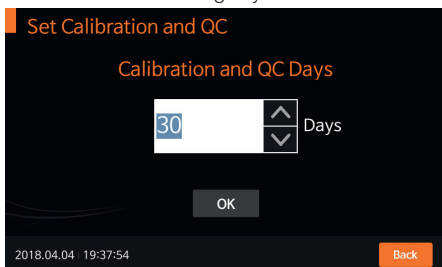
2. To set the numbers of printed sheet in 1, 2 and auto-printing mode (ON/OFF) enter the 'Set Print Option' menu. Auto-printing means the analyzer allows the built-in printer to automatically print every test result out at the end of each test. You can also run a preliminary printing test.



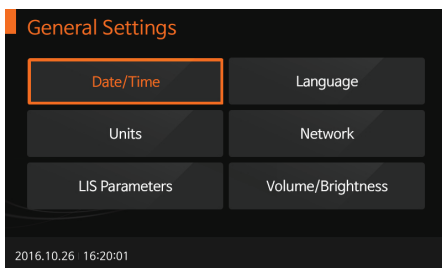
3. To control the analyzer's automatic turn-off time for power saving, enter the 'Set Timeout' menu. Insert test device stage procedure means that the user doesn't any action after inserting test device to the analyzer, and then the test is finished. Standby mode means the user doesn't any action even inserting test device into the analyzer.



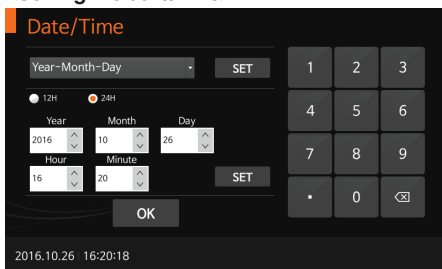
4. To set the time period for calibration and QC, enter the 'Set Calibration and QC' menu. After calibration and QC procedure is completed, the analyzer will check the date of calibration and QC and warn the alarm to indicate passed calibration and QC setting days.



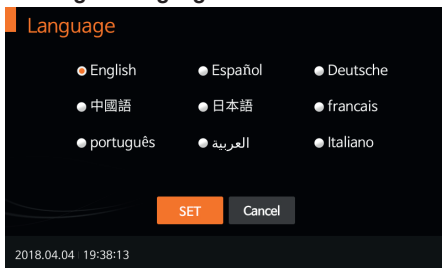
5. To set the date/time, language, test parameter's unit, network, LIS parameter, sound volume, or LCD brightness, enter the 'General Settings' menu. Especially, in case unit setting, the analyzer is capable of setting test parameters corresponding to test type and the parameters can be adjusted larger by updating of analyzer software.



<Setting the date/time>



<Setting the language>



<Setting the test parameter's unit>

Units

u-ALB	mg/L	1/1
CRP	mg/L	
HbA1c	[NGSP], [IFCC], [mg/dL]	
PCT	ng/ml	
D-dimer	ug/ml FEU	

SET **Cancel**

2018.04.04 19:38:25

<Setting the network>

Network

IP Address 192.168.33.201

Gateway 192.168.33.1

Subnet Mask 255.255.255.0

SET **Cancel**

2018.07.31 10:05:02

<Setting the LIS parameter>

LIS Parameters

IP Address 192.168.33.200

Port Number 65501

Auto Send ☒ On ☐ Off

Resend Function ☐ On ☒ Off

SET **Cancel**

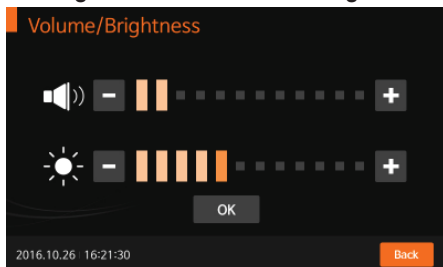
2018.04.04 19:38:38



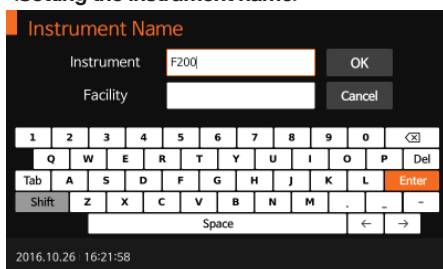
Note

It is recommended to consult with the technician as for the setting the network or the LIS parameter.

<Setting the sound volume/LCD brightness>

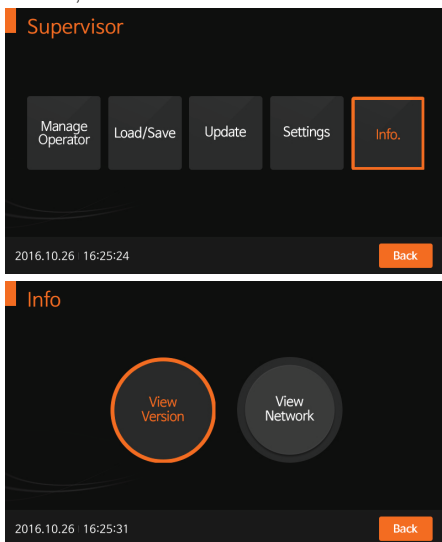


<Setting the instrument name>

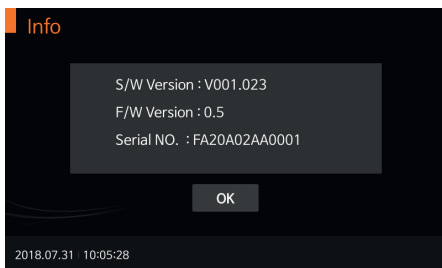


6th: Supervisor > Info

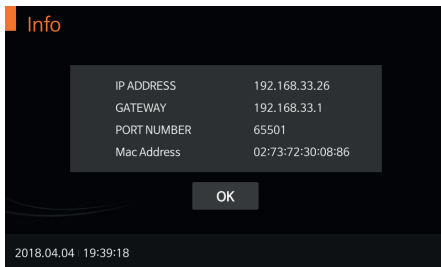
1. To display and view the analyzer's current version of software, firmware or network, enter the 'Info' menu.



2. When selecting 'View Version', the version information of the software and firmware will be displayed. Press 'OK' to confirm.



3. When selecting 'View Network', the information of the network will be displayed. Press 'OK' to confirm.



Performing a Measurement

Check the following before performing the measurement:

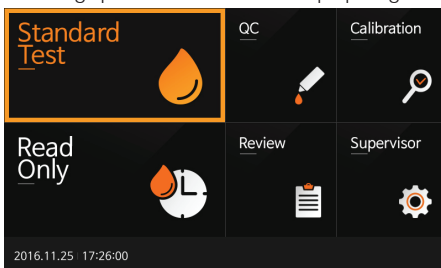
- Is the analyzer connected with AC/DC adaptor?
- Are date and time correct?
- Have you checked the analyzer's setting?

Select the Desired Test Mode

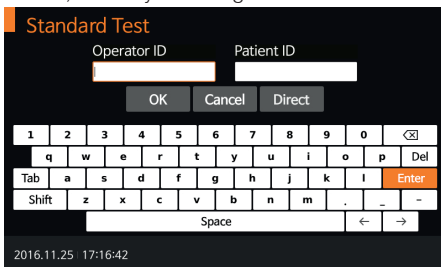
Standard Test Mode may be most convenient for reading a single patient sample, as the user can standard test during the development period. **Read Only Mode** may be most convenient for analysis of large numbers as the analyzer can quickly read multiple patient samples sequentially.

Standard Test Mode

1. First, select 'Standard Test' mode. Refer to assay specific package insert for collecting specimen for the test and preparing the test procedure.



2. Input operator ID, patient ID, and order #. The operator ID can also be input with the barcode scanner. If the ID is not input into the analyzer with touching 'Direct', the analyzer will regard the test as that of the guest.



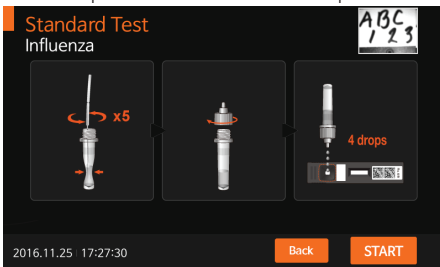
3. Once the 'Insert Device' is displayed on the screen, insert the specified test device into the analyzer's test slot.



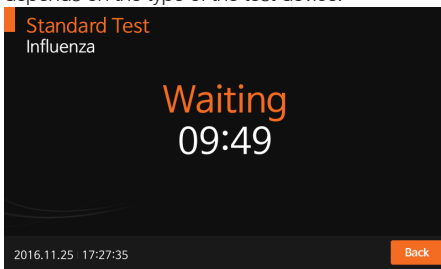
4. When inserting the test device to the analyzer, the analyzer will automatically check whether it is used or not. Also, the analyzer will read the barcode data and check the test device is valid to start the test.



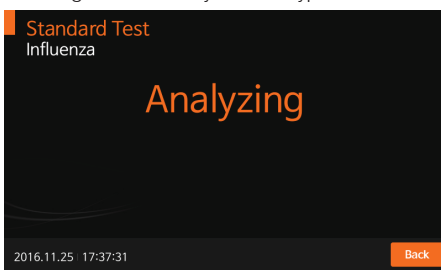
5. When the procedure of checking the test device is completed, apply the specimen to the sample well of the test device and press the 'START' immediately.



6. The test device is developed in the analyzer. The time for development depends on the type of the test device.



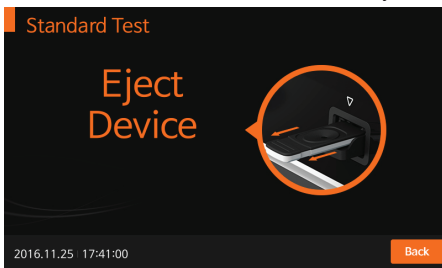
7. Then, the analyzer will automatically scan and analyze the test results. The scanning times can vary with the type of the test device.



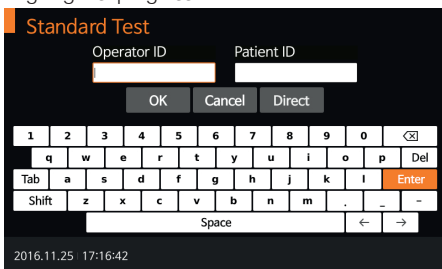
8. Once the development time is finished, the test results will be displayed. Also, the analyzer will be able to print out the test results when auto-printing is on.



- When pressing 'OK', 'Eject Device' message will be displayed. Then, you should remove the test device from the analyzer.

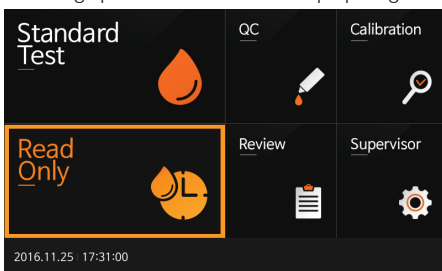


- When test device is ejected, the analyzer will move to another test log-in menu to perform the next test. Press 'Cancel' at any procedure to quit the ongoing test progress.



Read Only Mode

- First, select 'Read Only' mode. Refer to assay specific package insert for collecting specimen for the test and preparing the test procedure.



2. Input operator ID, patient ID, and order #. The operator ID can also be input with the barcode scanner. If the ID is not input into the analyzer with touching 'Direct', the analyzer will regard the test as that of the guest.

Read Only

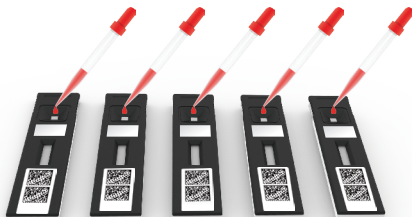
Operator ID Patient ID

OK Cancel Direct

1	2	3	4	5	6	7	8	9	0	<X>
q	w	e	r	t	y	u	i	o	p	Del
Tab	a	s	d	f	g	h	j	k	l	Enter
Shift	z	x	c	v	b	n	m	.	-	-
Space										← →

2016.11.25 17:36:50

3. Prepare test device, label the test device accordingly and place them.
 - Add prepared specimen #1 to the test device #1, then immediately set your timer to the designated development time as indicated in the assay-specific package insert.
 - One minute later, add specimen #2 to the test device #2.
 - Continue to add the appropriate prepared specimen to its appropriate test device at an interval of one minute.



- When the timer goes off for test device #1, then insert test device #1 into the analyzer, the analyzer will display the result in approximately ten seconds.



- When inserting the test device to the analyzer, the analyzer will automatically check whether it is used or not. Also, the analyzer will read the barcode data and check the test device is valid to start the test.



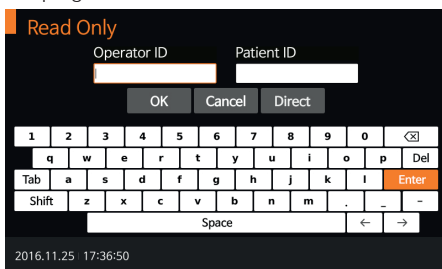
- Then, the analyzer will automatically scan and analyze the test results on the screen.



7. When pressing 'OK', 'Eject Device' message will be displayed. Then, you should remove the test device from the analyzer.



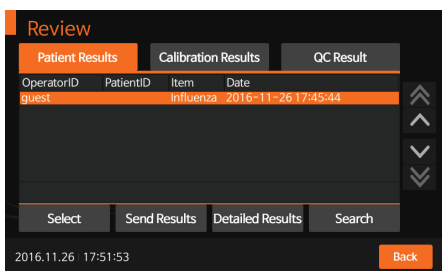
8. When test device is ejected, the analyzer will move to another test log-in menu to perform the next test. Press 'Cancel' at any procedure to quit the ongoing test progress.



CHAPTER 04. Using the Analyzer Memory and Data Transfer

Displaying Stored Measured Values

1. The STANDARD F200 Analyzer has 3000 measured memories together with date, time and flags allowing you to review them in order from the most recent to the oldest. When the memory is full and a new result is added, the analyzer will delete out the oldest one.
2. You can review QC calibration, and patient result separately in review menu. And if you press a record, you can see the detailed result and send it to PC or LIS/HIS server with LAN connection. You can also delete the records as well.

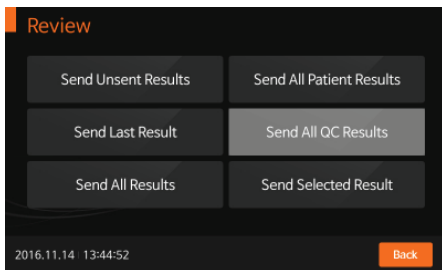


3. In any list of the test results, you may select specific record. After selecting the required record, you can check and print it in detail.

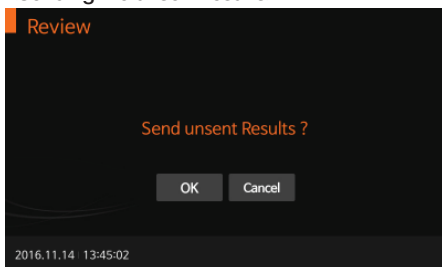


Send Results

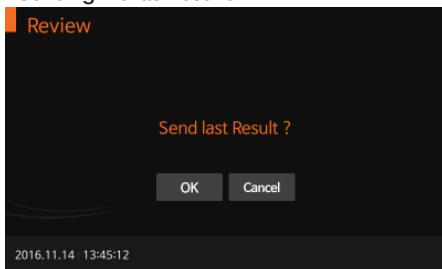
1. Among several ways to send the test result, you can choose the proper way to communicate with data server.



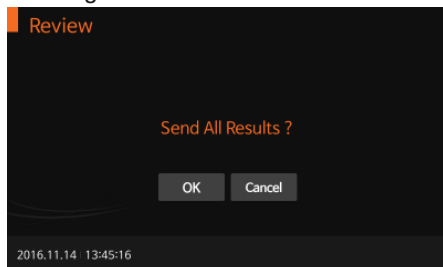
<Sending the unsent results>



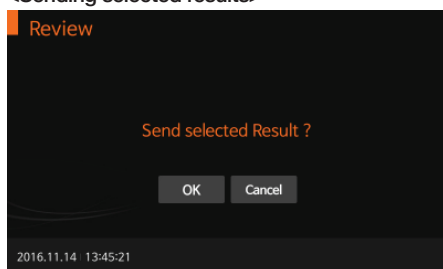
<Sending the last results>



<Sending all results>



<Sending selected results>



CHAPTER 05. Quality Control

Control Test

It is important to perform control tests with more than one level of control to assure your system is working properly and your testing technique is good.

When to use the control

- Using the analyzer for the first time.
- To check the test device when you open a new device packaging.
- If you drop the analyzer.
- Whenever your result does not agree with the way you feel.
- If you repeat a test, and the result is still lower or higher than expected.
- When you want to check the performance of the analyzer and test device.

Before using the control

- Check the expiration date. Do not use after expiration or discard date (date opened plus three months), whichever comes first.

How to Run the Quality Control

1. To run the quality control according to the specific test type. Refer to the assay-specific package insert for preparing the test with QC control that is proper for the each type of the test device. Enter operator ID and CS Info before the starting.

QC

Operator ID Control ID

OK Cancel Direct

1 2 3 4 5 6 7 8 9 0 <X>

q w e r t y u i o p Del

Tab a s d f g h j k l Enter

Shift z x c v b n m . _ ~

Space ← →

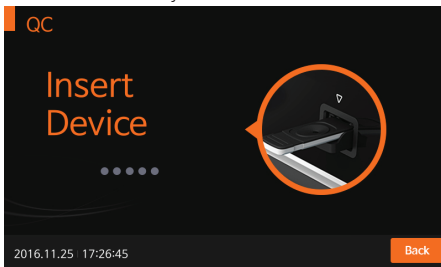
2018.04.04 20:14:15



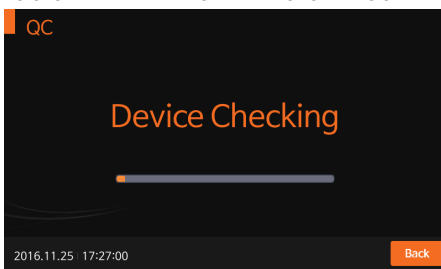
Note

The operator ID and CS Info can be entered into the analyzer with touch panel or USB keyboard. And they can be entered with SDB barcode reader as well which is purchased separately.

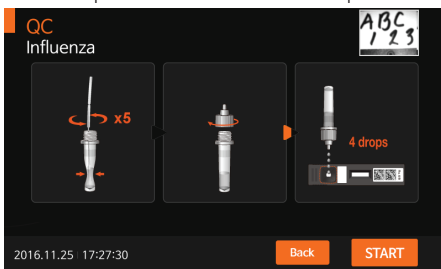
2. Once the 'Insert Device' is displayed on the screen, insert the specified test device into the analyzer's test slot.



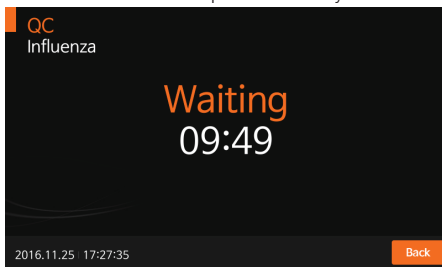
3. When inserting the test device to the analyzer, the analyzer will automatically check whether it is unused or not. Also, the analyzer will read the barcode data and check the test device is valid to start the test.



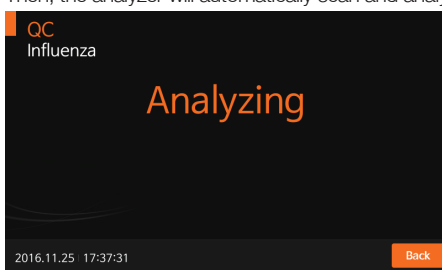
4. When the procedure of checking the test device is completed, apply the control to the sample well of the test device and press the 'START' immediately.



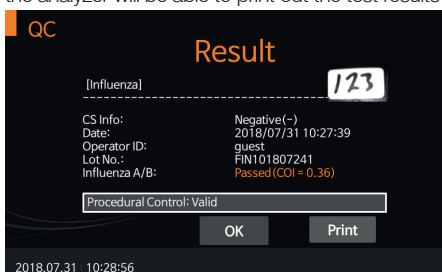
5. The test device is developed in the analyzer.



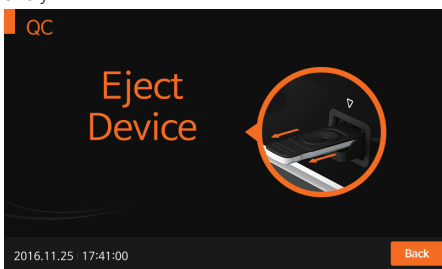
6. Then, the analyzer will automatically scan and analyze the test results.



7. Once the development time is finished, the test results will be displayed. Also, the analyzer will be able to print out the test results when auto-printing is on.



8. After the procedure of analyzing the test device is completed, 'Eject Device' message will be displayed. Then, you should remove the test device from the analyzer.



CHAPTER 06. Calibration Set

Calibration Set Test

Calibration set test is the required function that ensures optimal performance by checking the designated method.

When to use calibration set

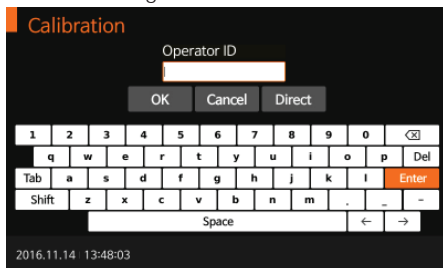
- Whenever the analyzer is powered on.
- When you drop the analyzer.
- Whenever you do not agree with your result.
- When you want to check the performance of an analyzer and test device.

Precautions and warnings

- The calibration set test cannot be replaced with the control test.

How to Run the Calibration Set Test

1. To run the calibration set test, select the 'Calibration' menu. Enter operator ID before the starting calibration set test.



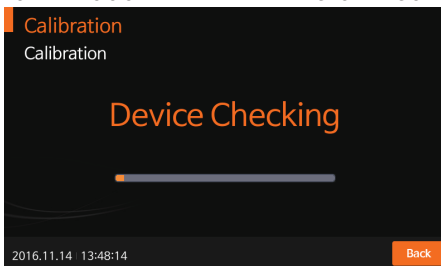
Note

The operator ID can be entered into the analyzer with touch panel or USB keyboard. And they can be entered with SDB barcode reader as well which is purchased separately.

2. Once the 'Insert Device' is displayed on the screen, insert the CAL-1 into the analyzer's test slot.



3. When inserting the test device to the analyzer, the analyzer will automatically check whether the CAL-1 is used or not. Additionally, the analyzer will read the barcode data and check the device is valid to start the calibration set test.



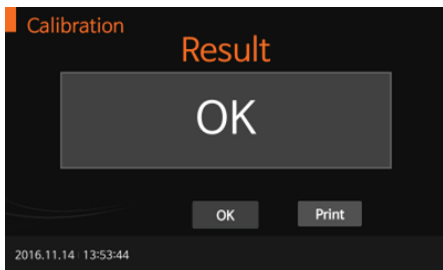
4. Next, insert CAL-2 for UV testing.



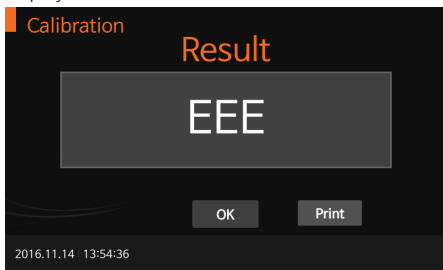
5. Insert CAL-3 for RGB-LED testing. Ensure that insert CAL-2 and CAL-3 in order. Never change the order.



6. If measured value is within the normal range, 'OK' message will be displayed on the screen.



7. If measured value is not within the normal range, 'EEE' message will be displayed on the screen.



CHAPTER 07. Cleaning and Maintenance

Cleaning the Analyzer

To prevent malfunction of the analyzer, keep the test slot free from specimen moisture or dust. Use lint-free cloths. For cleaning, there are suitable solutions such as mild suds, 70 % ethanol or isopropyl alcohol. At the professional case (e.g. doctor's surgery), a mixture of 1-propanol, 2-propanol and glutaraldehyde is recommended.



Caution

Do not use an abrasive cloth or antiseptic solution, as these may damage the display screen. Always switch off the analyzer before cleaning it.

Maintenance and Transportation

When turning analyzer on, it will automatically tests its own system every time and let you know if something is wrong.

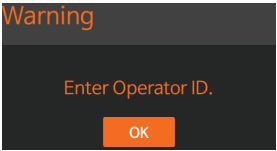
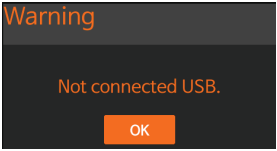
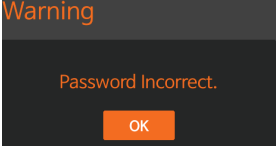
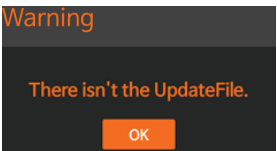
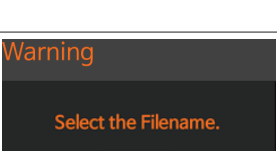


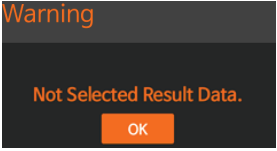
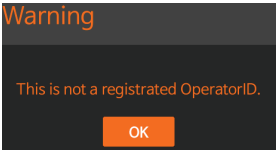
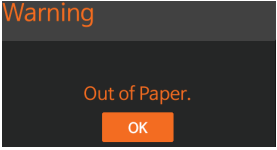
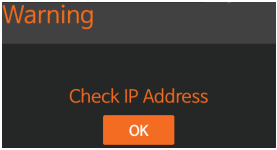
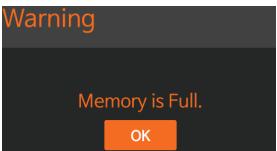
Note

- Keep the test slot and internal part of analyzer free from dust.
- The carrying case was designed to store a variety of supplies and protect your analyzer.
- For transporting the analyzer, it needs to be stored at -20 to 50°C (-4 to 122°F) and 10% to 93% RH.

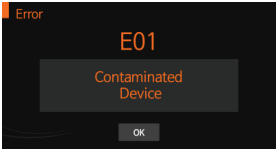
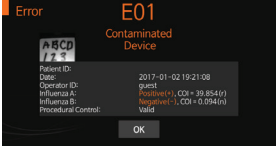
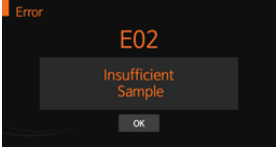
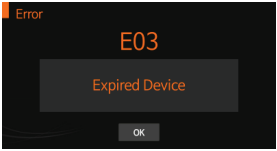
CHAPTER 08. Screen Messages and Troubleshooting

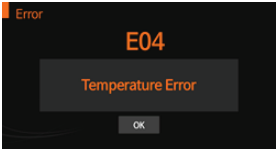

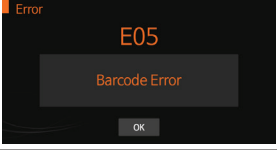
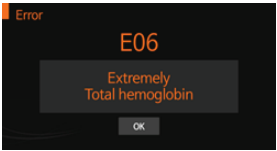

Warning Messages

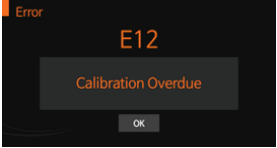
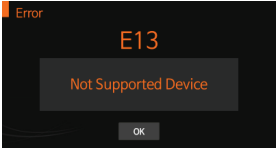
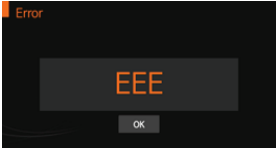
Indication	Warning description
 <p>A dark gray screen with the word 'Warning' in orange at the top. Below it, the text 'Enter Operator ID.' is displayed in orange. At the bottom, there is an orange button with the text 'OK' in white.</p>	<p>Warning: Operator ID Press 'OK' not entering the operator's ID.</p> <p>Solution Enter the operator's ID First, and then press 'OK'</p>
 <p>A dark gray screen with the word 'Warning' in orange at the top. Below it, the text 'Not connected USB.' is displayed in orange. At the bottom, there is an orange button with the text 'OK' in white.</p>	<p>Warning: Not connected USB Not inserting USB.</p> <p>Solution Confirm USB is inserted correctly.</p>
 <p>A dark gray screen with the word 'Warning' in orange at the top. Below it, the text 'Password Incorrect.' is displayed in orange. At the bottom, there is an orange button with the text 'OK' in white.</p>	<p>Warning: Password Entering incorrect password of supervisor.</p> <p>Solution Enter valid and correct password.</p>
 <p>A dark gray screen with the word 'Warning' in orange at the top. Below it, the text 'There isn't the UpdateFile.' is displayed in orange. At the bottom, there is an orange button with the text 'OK' in white.</p>	<p>Warning: There isn't the UpdateFile. Updated file doesn't exist in the USB.</p> <p>Solution Confirm that the updated file is in USB. When ensuring the updated file, insert USB and press 'OK'.</p>
 <p>A dark gray screen with the word 'Warning' in orange at the top. Below it, the text 'Select the Filename.' is displayed in orange. At the bottom, there is an orange button with the text 'OK' in white.</p>	<p>Warning: Select the Filename. Not selecting the setting file in 'Load Settings' menu.</p> <p>Solution Check the file name and select it correctly.</p>

Indication	Warning description
 <p>Warning</p> <p>Not Selected Result Data.</p> <p>OK</p>	<p>Warning: Review Not selecting in review data list.</p> <p>Solution Press 'Send selected result' after selecting the result.</p>
 <p>Warning</p> <p>This is not a registered OperatorID.</p> <p>OK</p>	<p>Warning: Unregistered Operator ID Entered operator ID does not be registered.</p> <p>Solution Add operator ID in set mode.</p>
 <p>Warning</p> <p>Out of Paper.</p> <p>OK</p>	<p>Warning: Out of Paper There is no printer paper in analyzer.</p> <p>Solution Refill printer paper.</p>
 <p>Warning</p> <p>Check IP Address</p> <p>OK</p>	<p>Warning: Incorrect IP address Check IP address.</p> <p>Solution Confirm that entered IP address and input correct IP address.</p>
 <p>Warning</p> <p>Memory is Full.</p> <p>OK</p>	<p>Warning: Full memory Store the maximum of 3000 data.</p> <p>Solution If the next test result is measured after this warning, the oldest result is erased.</p>

Error Messages

Indication	Error description
	<p>E01: Test Device Error The test device is damaged or inserted improperly.</p>
	<p>Solution Discard the test device and re-test with a new test device and a new specimen.</p>
	<p>E02: Blood Specimen Error An insufficient blood has been applied.</p> <p>Solution Re-test with the new test device with an enough specimen, ensuring that blood is placed to the narrow channel in the top edge of the test device.</p>
	<p>E03: Expired Test Device The test devices are expired.</p> <p>Solution Re-test with the new test device with non-expired date.</p>

Indication	Error description
	<p>E04: Temperature Error Unknown Barcode The environmental temperature is above or below the operating range of the analyzer.</p> <p>Solution Move to an area in the acceptable temperature range for the test device, and perform the test. Do not heat or cool the analyzer artificially.</p>
	<p>E05: Communication Error The communication between analyzer and barcode or printer is failed.</p> <p>Solution Connect again between analyzer and external device. If the error continues after turning ON/OFF the analyzer, please contact SD BIOSENSOR, Inc.</p>
	<p>Solution Connect again between analyzer and external device. If the error continues after turning ON/OFF the analyzer, please contact SD BIOSENSOR, Inc.</p>
	<p>E06: Out of total hemoglobin The measured total hemoglobin is out of the range of 7 to 23g/dL.</p> <p>Solution This error occurs with a specimen known to have total hemoglobin in the abnormal range. If the error continues after turning ON/OFF the analyzer, please contact SD BIOSENSOR, Inc.</p>
	<p>Result: Extremely Low C line The test is invalid.</p> <p>Solution Re-test with the new test device and the new patient's specimen. If the error continues after turning ON/OFF the analyzer, please contact SD BIOSENSOR, Inc.</p>

Indication	Error description
	<p>E12: Calibration Overdue The calibration is overdue.</p> <p>Solution If the error continues after turning ON/OFF the analyzer, please contact SD BIOSENSOR, Inc.</p>
	<p>E13: Not Supported Test Device Loading test device is not proper for the analyzer.</p> <p>Solution Check the type of the test device whether it is manufactured by SD Biosensor, Inc.</p>
	<p>EEE: Internal Error Message for the Analyzer Internal error has appeared.</p> <p>Solution If the error continues after turning ON/OFF the analyzer, please contact SD BIOSENSOR, Inc.</p>

ANNEX 01. Information for Healthcare Professionals

Protection against Infections

There is a potential risk of infection. Medical staff using the STANDARD F200 Analyzer to perform measurements for more than one patient must be aware that any object coming into contact with human specimen is a potential source of infection.

- Use gloves.
- Apply sample outside the analyzer.
- Follow all other locally applicable guidelines and regulations on health and safety.

Electromagnetic Compatibility

The STANDARD F200 Analyzer meets the electromagnetic immunity requirements as per EN ISO 15197 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, it meets the electro-magnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low. Interference from other electrically driven equipment is not to be anticipated.

ANNEX 02. Reference

1. American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes care, Vol. 26. Supplement 1. p.22.
2. Stedman, TL. Stedman's Medical Dictionary, 27th Edition, 1999, p. 2082.
3. Ellen T. Chen, James H. Nichols, Show-Hong Duh, Glen Hortin, MD: Diabetes Technology & Therapeutics, Performance Evaluation of Blood Glucose Monitoring Devices, Oct 2003, Vol. 5, No. 5: 749 -768.

Disposal

The STANDARD F200 Analyzer must be disposed according to the local regulations concerning the disposal of electrical and electronic equipment. The Waste Electrical and Electronic Equipment (WEEE) regulation implement provisions of the European Parliament and Council Directive 2002/96/EC aimed to reducing the amount of EEE waste going for final disposal. Please contact our representatives in your area for the respective instructions before disposing.





F200



Authorized Representative



MT Promedt Consulting GmbH

Altenhofstrasse 80 D-66386 St. Ingbert Germany

Phone : +49 6894 581020, Fax : +49 6894 581021

Manufactured by



SD Biosensor, Inc.

Head Office

G-4th&5th, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

Manufacturing Site

74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
www.sdbiosensor.com