FOR VETERINARY USE ONLY

USER MANUAL

V200

FLUORESCENT IMMUNOASSAY SYSTEMS



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Thank you for your purchase of the BIONOTE V200

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 insert 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.bionote.co.kr for product demonstrations.

Thank you again for choosing the BIONOTE V200.

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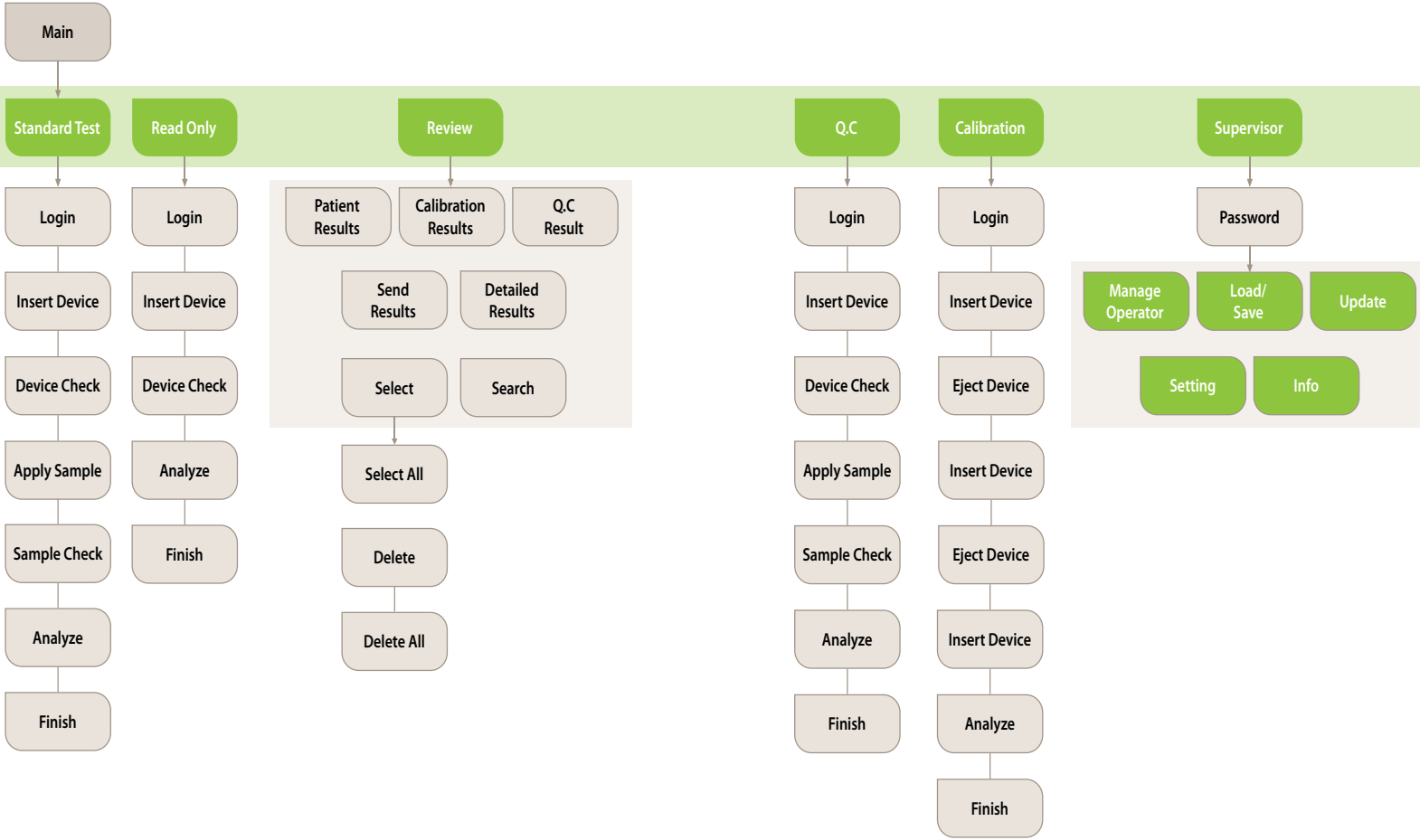
ANNEX 01. Information for Healthcare Professionals

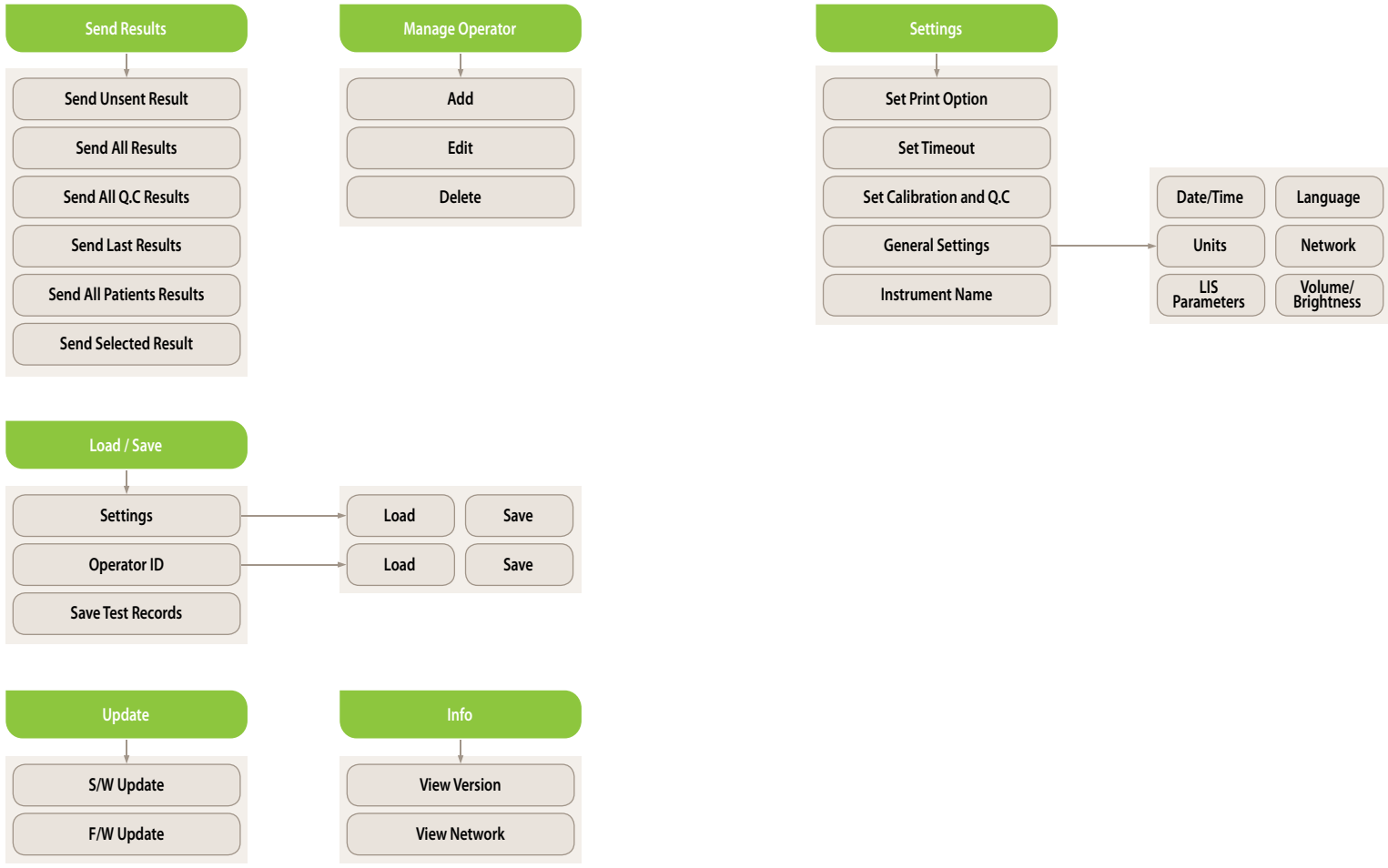
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Main Menu Structure




Send Results
Send Unsent Result
Send All Results
Send All Q.C Results
Send Last Results
Send All Patients Results
Send Selected Result
Manage Operator
Add
Edit
Delete
Settings
Set Print Option
Set Timeout
Set Calibration and Q.C
General Settings
Instrument Name
Date/Time
Language
Units
Network
LIS Parameters
Volume/ Brightness
Load / Save
Settings
Operator ID
Save Test Records
Load
Save
Load
Save
Update
S/W Update
F/W Update
Info
View Version
View Network

Symbols and Abbreviation

Symbols

These symbols and abbreviations may appear on the packaging, on the labels, and in the instructions for the BIONOTE V200.

Symbol	Description
	Manufacturer
	Consult instructions for use
	Reference number
	Date of manufacture To indicate the date of analyzer manufacture
	Serial number
	Note
	Indicates that the product is fragile and to handle it with care
	Batch code To indicate the lot number
	Indicates to discard it separately from other household waste
	This product fulfills the requirements of European Low Voltage Directive 2014/35/EU (Low Voltage Directive, LVD), Electromagnetic Compatibility Directive 2014/30/EU (EMC Directive), RoHS Directive 2011/65/EU
	Indicate that you should keep the product dry
	Caution! Indicate a situation, which if not avoided could result in damage to the analyzer or incorrect results

Abbreviation

Abbreviation	Description
cCRP	Canine C-Reactive Protein
fSAA	Feline Serum Amyloid A
Comm	Communication
LIS	Laboratory Information System
HIS	Hospital Information System
GUI	Graphic User Interface
S/W	Software
F/W	Firmware
BN	BIONOTE, Inc.

Brief Precautions and Limitations


Caution

To reduce the risk of analyzer damage

- Keep the BIONOTE V200 analyzer on a flat and dry surface
- Avoid direct sunlight when operating the analyzer
- The analyzer has an internal adjustment for normal ambient light conditions, but highly intense light entering the analyzer may cause significant interference with the results and must be avoided
- Do not attempt to disassemble the analyzer
- Do not immerse the analyzer in water or cleaning solutions

To reduce the risk of incorrect results

- Only trained operators should use the analyzer
- Using expired test devices may cause inaccuracy of the results.
- Do not use if the analyzer is displaying an error message which cannot be corrected
- To obtain accurate results, refer to the test device package insert for test storage and system operating conditions


Potential Biohazard!

To reduce the biohazard risk

- The used test and all specimens should be discarded as biohazard waste and must be handled according to local regulations.
- Handle all specimens with caution as if they contain infectious agents.
- Seek appropriate training or refer to the instructions if you are not experienced with collecting and handling specimens
- Wear personal protective equipment, such as gloves and lab coats, when handling the specimen and kit reagents. Wash hands thoroughly after the test.

CHAPTER 02. Introduction

Intended Use

The BIONOTE V200 analyzer efficiently tests quantitative or qualitative biomarkers in the laboratory and point-of-care settings using the body fluid parameters. The analyzer is to test and diagnose in clinical settings by healthcare professionals. The analyzer should only be used with the test device produced by BioNote. For more information on each specific test, refer to the assay-specific package insert.

Product Description

The BIONOTE V200 analyzer automatically recognizes the lot of the inserted test device by reading its 2D barcodes. Once the test device is inserted into the BIONOTE V200 analyzer, UV or RGB LED (light-emitting diode) illuminates the test device's application well through scanning. The type of light used determines how the test device should be analyzed before performing the actual measurement. An enzymatic reaction occurs when the specimen is applied, forming a dye and the amount of formed dye is proportional to the analyte concentration. The intensity of the visual color or fluorescence can be measured by illumination with motor and LED, and detected by the reflectance photometry. The measured value considers the light's signal power, a blank value measured, and information read, including 2D barcode data. As a final step, the test result is displayed on the screen and stored simultaneously in the analyzer's memory.

Before You Start Testing


Note

Read and follow the instructions carefully in the user's manual and the instructions to use the test device and control. It is crucial to follow the instructions to prevent incorrect results or improper treatments.

Specimens

The BIONOTE V200 analyzer should only be used with specific test devices for the analyzer. Follow the instructions for each test device insert because each specimen is different for each parameter.

Safety information

Due to a potential risk of infection, healthcare professionals using the BIONOTE V200 analyzer should wear protective equipment and follow local health and safety regulations.

Operating conditions

To ensure a proper function of the BIONOTE V200 analyzer, refer to the following guidelines:

- The BIONOTE V200 analyzer is recommended to be used at 15 ~ 30°C.
- Operate the analyzer only within the acceptable environmental conditions. The acceptable temperature range varies depending on each reagent.
- To perform a measurement, place the analyzer on a flat surface.
- Strong electromagnetic fields may affect the functions of the analyzer. Do not use the analyzer close to sources of intense electromagnetic radiation.
- The analyzer's air vents must be free for ventilation (Do not cover the air vents).
- Unplug the adapter from the outlet in case of a sudden malfunction with the analyzer.

System Components

After unpacking the shipping container, inspect the unit and components for damage.

Analyzer	BIONOTE V200 Analyzer
Calibration Set	BIONOTE Vcheck Calibration Set
DC Power Supply	Input: AC100~240V, 50/60Hz (Voltage tolerance ±10%) Output: DC12V/5A
Display	7" Color TFT LCD (800x480)
Display Controls	Graphical User Interface
Power Consumption	Max 60W
Over Voltage Category	II
Pollution Degree	II
Memory	2000
RTC	RTC Backup Battery Included
Size	214.9 x 261 x 203 mm
Labeling	User Manual
Barcode Scanner (Optional)	Barcode Scanner
LAN transfer rate (bps)	100M
LAN cable	CAT 5

Note

- BioNote does not supply the AC/DC power adapter. All users must use an approved adapter. (VDE, UL, TUV, etc.)
- Do not connect to the power supply other than the specified AC/DC adapter rating.
- The size of a jack that connects with the DC power adapter is 5.5 mm (external diameter) and 2.5 mm (internal diameter).
- All users must check the adapter polarity before plugging the adapter into the device.



Overview of BIONOTE V200 analyzer



A. Color TFT LCD
Use for displaying the test screen and interacting with the graphical user interface

B. Test Slot
Slot for inserting a test device into the analyzer

C. Test Device
Use for initiating 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 the power supply adapter 12V/5A to its compartment

G. Power switch
Use for turning on/off the analyzer

H. USB x 4
Use for connecting the keyboard, barcode scanner, and USB drive

I. LAN
Use for communicating through the local area network

J. Mini USB
Use for upgrading the F/W upgrade by connecting to a PC

K. Additional Device Port
Use for connecting to specific devices manufactured by BioNote, Inc.

Accessories of the BIONOTE V200 analyzer

Included	Calibration set	
	Pipette Set	
	Protection cover	
	12V/5A AC/DC power adapter	
Optional	Test device	
	Barcode scanner (For patient ID recognition)	
	Print paper (57mm width Thermal paper is used) If a smaller paper is used, the "No Paper" error message may be displayed due to sensor malfunction.	

CHAPTER 03. Setting and Performance

Operating the Analyzer

STEP 1. Connect AC/DC adapter jack

1-1 Place the analyzer to a suitable location for testing, within reach of an electrical outlet. Ensure the located surface is stable, flat, and dry. Ensure there is adequate space for the analyzer and barcode scanner stand.

1-2 Plug the DC power cord into the power port in the back of the analyzer. Plug the country-specific AC/DC adapter power cord into an available electrical outlet.

1-3 The analyzer is ready for use once the connection is complete.

STEP 2. Setup the analyzer

2-1 To turn on the V200 analyzer, press the power button located on the side of the analyzer for 3 seconds.

2-2 Register the operator's ID when setting up the analyzer for the first time. The initial supervisor password is 0000.

2-3 It is recommended to acknowledge the table presented 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 & Q.C	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: Configuring the setup mode

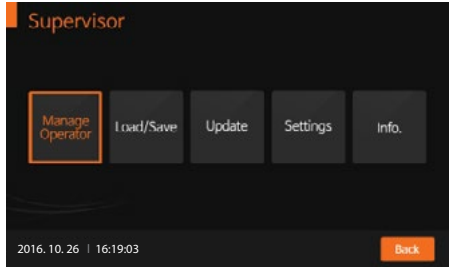
1. Select 'Supervisor' on the screen in the main menu to configure the setup mode.



2. Input the password and press 'OK'. The initial password is 0000. Press 'Cancel' if you want to return to the previous setting.

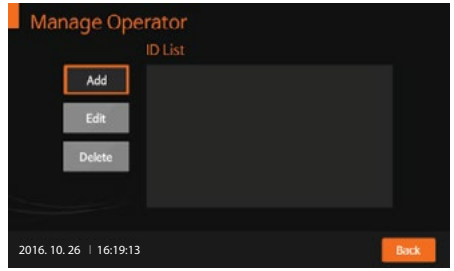


3. The supervisor menu allows the operator to access and personalize additional functionality and security options.

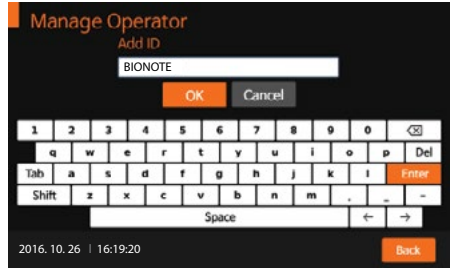


2nd step: Supervisor>Manage Operator

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



3. Press 'OK' to confirm the ID addition. The added operator's ID will be registered in the analyzer.

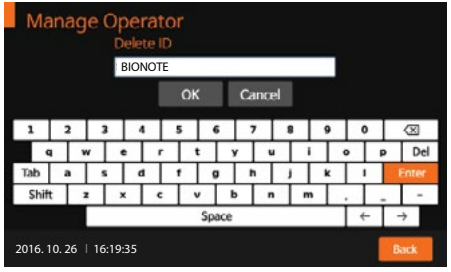


4. Press 'Edit' to edit the currently registered operator's ID.





5. Press 'Delete' to delete the currently registered operator's ID.



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 whenever the analyzer's power is on.

1. From the Supervisor menu, press 'Load/Save'. Then press 'Settings' to proceed to the next step.



2. Press 'Load' to load the analyzer data according to the test type. This can be done by inserting the USB device containing data that can be loaded into the analyzer.



3. After appropriate data has been loaded, 'Loading Setting File' message indicating a successful data load will be shown. Press 'OK' to confirm.



4. To save analyzer settings that have been duplicated from another device settings, press 'Save'. Press 'OK' to confirm after the data save procedure is completed.



5. To load the saved operator's ID, press 'Load'.



6. After the operator's ID has been loaded, 'Load Operator ID File' message indicating a successful operator's ID has will be shown. Press 'OK' to confirm.



7. To save the operator's ID file, press 'Save'. Then press 'OK' to confirm.



Note

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

4th step: Supervisor > Update

1. To update the analyzer's software or firmware, press 'Update' from the 'Supervisor' menu after connecting the USB device containing the S/W or F/W update.



1-1. Press 'OK' to update the new analyzer software. The analyzer will read the new software to be installed.



1-2. Press 'OK' to update the new analyzer firmware. The analyzer will read the new firmware to be installed.

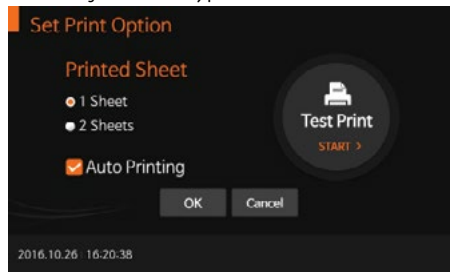


5th: Supervisor > Settings

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



2. To set the number of printed sheets as 1, 2, or auto-printing mode (ON/OFF), press 'Set Print Option'. Check 'Auto Printing' to automatically print all test results at the end of each test.



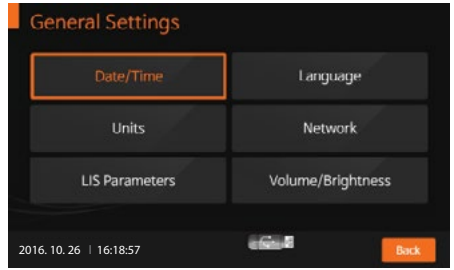
3. To control the analyzer's automatic turn-off time for power saving, press 'Set Timeout'. 'Insert Device' allows users to set the appropriate timeout value for inserting a test device. If the user passes the set value, the previous test procedure will be displayed. 'Standby Mode' allows users to set the appropriate timeout value for the whole device. If the user passes the set value, a screensaver will be displayed.



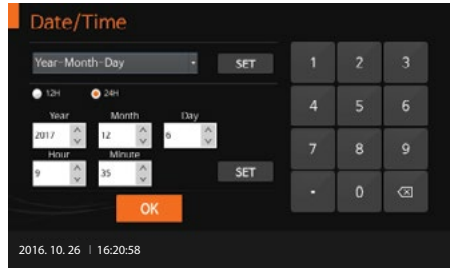
4. To set the time for calibration and QC, press 'Set Calibration and QC Days'. After the calibration and QC procedure is completed, the analyzer will check the QC date and activate an alarm to indicate the number of days since the last QC.



5. To set the date/time, language, test unit parameters, network, LIS parameters, sound volume, or LCD brightness, press 'General Settings'. Test parameters corresponding to the test type can be set under the unit settings, and the parameters can be adjusted by updating the analyzer software.



<Setting the date/time>



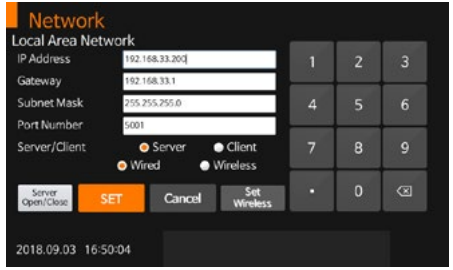
<Setting the language>



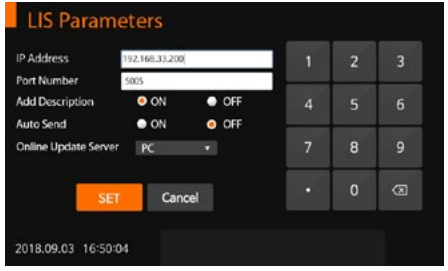
<Setting the test parameter's unit>



<Setting the network>



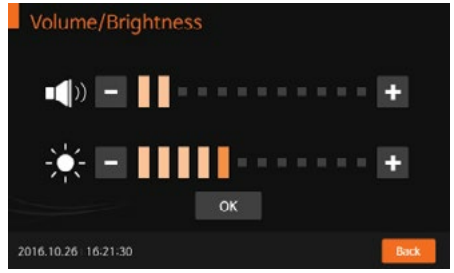
<Setting the LIS parameter>



Note

Consult a technician for the network settings information or for the LIS parameters.

<Setting the sound volume/LCD brightness>

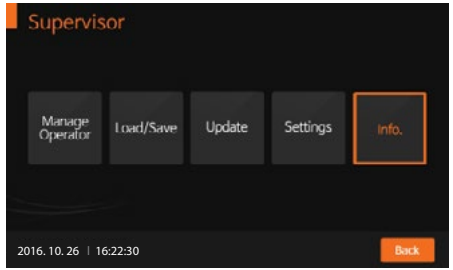


<Setting the instrument name>



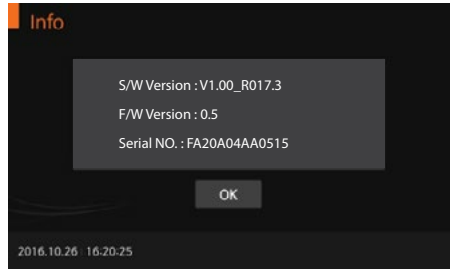
6th: Supervisor > Info

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

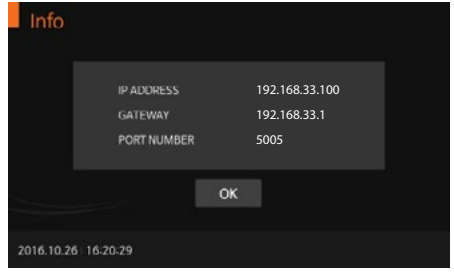




2. Press 'View Version' to display the version information for the software and firmware. Press 'OK' to confirm.



3. Press 'View Network' to display the information about the network. Press 'OK' to confirm.



Performing a Measurement

Check the following before performing a measurement:

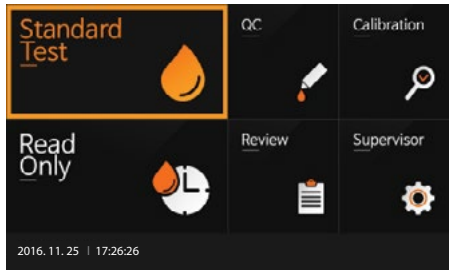
- Is the analyzer connected to the AC/DC adapter?
- Are the date and time correct?
- Has the analyzer settings been checked?

Select the desired test mode

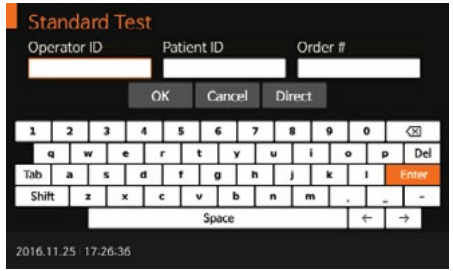
The Standard Test mode may be the most convenient for reading a single patient sample, as the user can perform a Standard Test during the analysis period. The Read Only mode may be the most convenient for extensive volume testing as the analyzer can quickly read multiple patient samples sequentially.

Standard Test mode

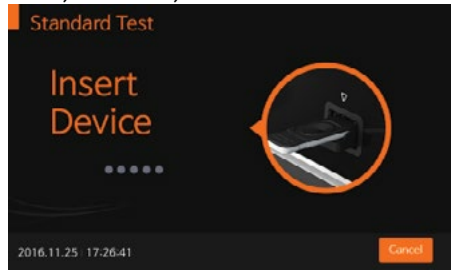
1. Select the 'Standard Test' mode. Refer to the assay-specific package insert when collecting specimens for the test and preparing the test procedure.



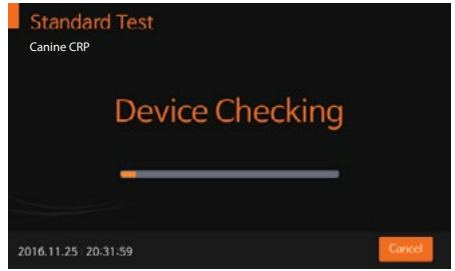
2. Enter the operator's ID, patient ID, and the order #. The operator's ID can also be entered with the barcode scanner. If the ID is not entered into the analyzer, the analyzer will regard the operator as a guest user.



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



4. Once the test device is inserted into the analyzer, the analyzer will automatically check whether the device has been used or not. The analyzer also reads the barcode data and confirms the test device is valid before starting the test.



5. After device checking, apply the specimen to the sample well and immediately press 'START'. If 'START' is not pressed within 20 seconds after applying the specimen, the analyzer will display an error message indicating that the test cannot be performed.



6. The analyzer will automatically recognize the test device. The time required for analysis depends on type of test device.



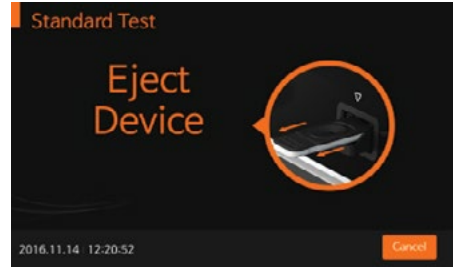
7. The analyzer will automatically scan the test device and analyze the test results. The scanning time can vary with the type of test device.



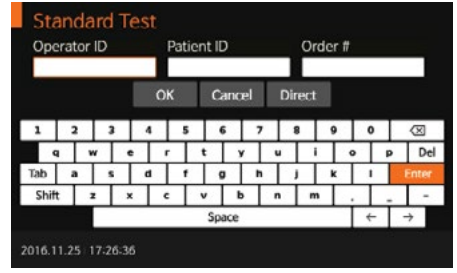
8. Once the analysis is finished, the test results will be displayed. The analyzer will print the test results if auto-printing is enabled.



9. Press 'OK' to display the 'Eject Device' screen. The test device can then be removed from the analyzer.

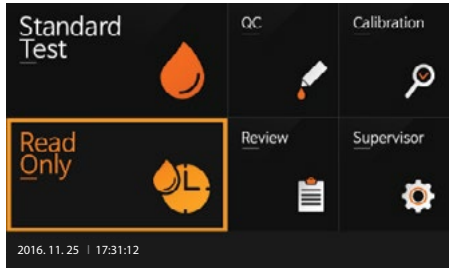


10. Once the test device is ejected, the analyzer will move to another test log-in menu for the next test. Press 'Cancel' to stop the test progress at any time.



Read Only mode

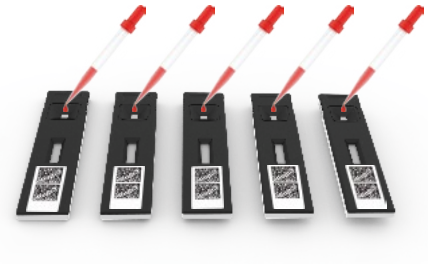
1. Select 'Read Only'. Refer to the assay-specific package insert when collecting the specimen for the test and preparing the test procedure. [Read only] mode is available only for "Vcheck RDT" products and is not available for the quantitative tests.
   * Please check if 'Read only' mode is available by referring to the item's insert.

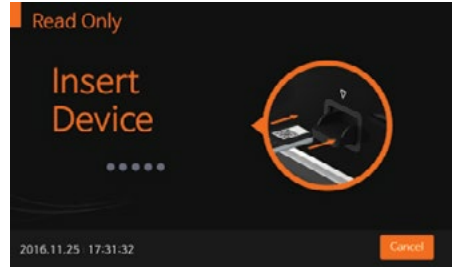


2. Enter operator's ID, patient ID, and order #. The operator's ID can also be entered with the barcode scanner. If the ID is not entered into the analyzer, the analyzer will regard the operator as a guest user.

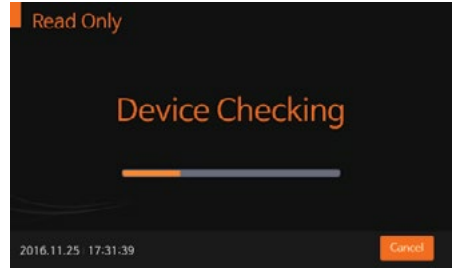


3. Prepare the test device and label it accordingly.
   - Add prepared specimen #1 to test device #1, then immediately set the timer to the designated processing time, as indicated in the assay-specific package insert.
   - Add specimen #2 to test device #2 after one minute.
   - Continue adding the appropriately prepared specimen to the appropriate test device at an interval of one minute.
   - When the timer goes off for test device #1, insert test device #1 into the analyzer, and the analyzer will display the result in approximately ten seconds.

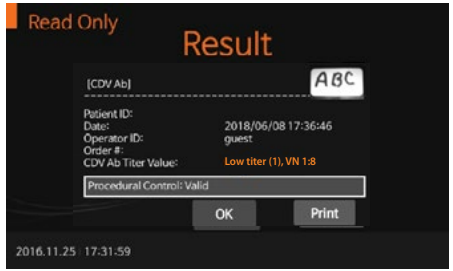




4. Once the test device is inserted into the analyzer, the analyzer will automatically check whether the test device has been used previously or not. The analyzer also reads the barcode data and confirms that the test device is valid before starting the test.



5. The analyzer will automatically scan the test device and analyze the test results on the screen within 10 seconds.



6. Press 'OK' to display the 'Eject Device' screen. The test device can then be removed from the analyzer.



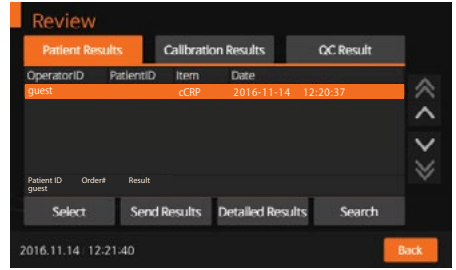
7. When the test device is ejected, the analyzer will move to another test log-in menu for the next test. Press `Cancel' to stop the test progress at any time.



CHAPTER 04. Using the Analyzer Memory and Data Transfer

Displaying Stored Measured Values

1. The BIONOTE V200 analyzer can store 2000 records together with the date, time, and flags, allowing the records to be reviewed in order from the most recent to the oldest. When the memory is full, the analyzer will delete the oldest record to add a new result.
2. The QC details, calibration information, and patient results can be reviewed separately in the review menu. If you select an entry, you can view the detailed results and send them to a PC or LIS/HIS server through a LAN connection. You can also delete the records.

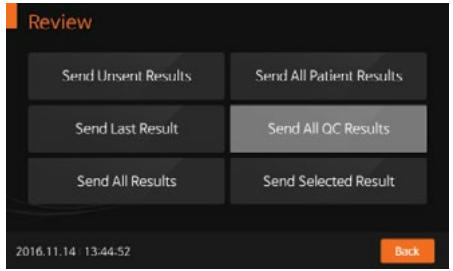


3. You may select a test results list. After selecting the desired record, you can view or print it in detail.

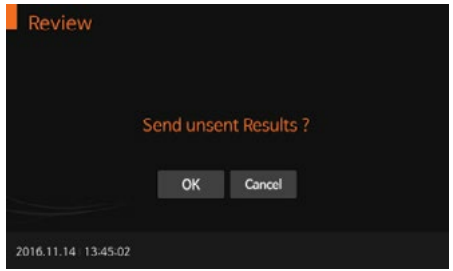


Send Results

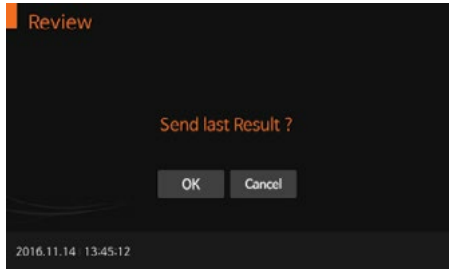
1. With several options available for sending the test results, you can choose the most appropriate method to communicate with the data server.



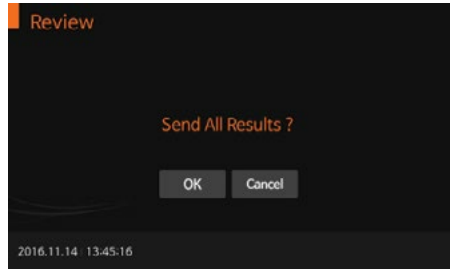
<Sending the unsent Results>



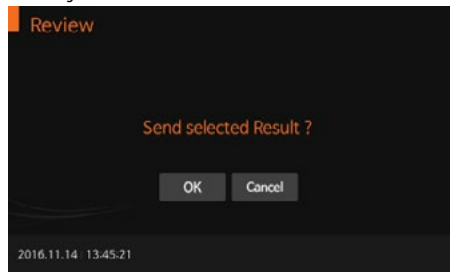
<Sending the last Result>



<Sending All Results>



<Sending selected Results>



CHAPTER 05. Quality Control

Control Test

Control tests can be run if you suspect your system isn't working correctly or to verify you are performing the test correctly.

When to use the control

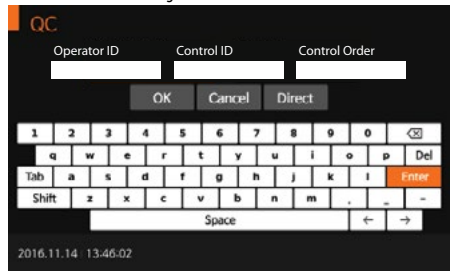
- Whenever your results are not in accordance with your expectations.
- If you have repeated a test, and the result is still lower or higher than expected.
- When you want to check the performance of the analyzer and test device.
- If you drop the analyzer.

Before using the control

- Check the expiration date on the control solution container. Do not use after the expiration date.

How to Perform Quality Control

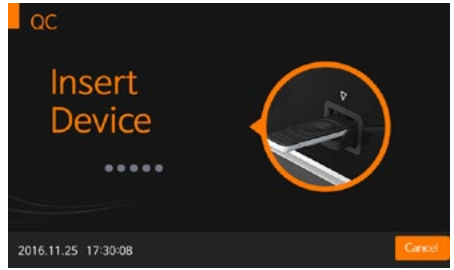
1. To perform quality control according to the specific test type, refer to the assay-specific package insert when preparing the test with the appropriate QC control solution for each type of test device. Enter the operator ID and CS Info before starting.



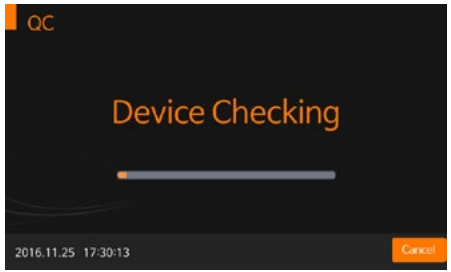
Note

The operator ID and CS Info can be entered into the analyzer with the touch panel or a USB keyboard. This information can also be entered with a BN barcode reader, which is sold separately.

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



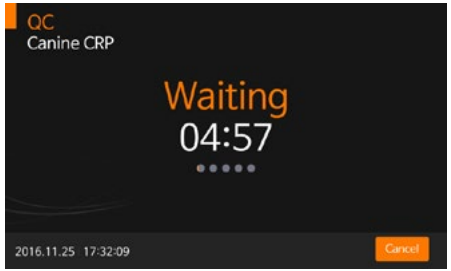
3. Once the test device is inserted into the analyzer, the analyzer will automatically check whether the device has been used or not. The analyzer will also read the barcode data and confirm that the test device is valid before starting the test.



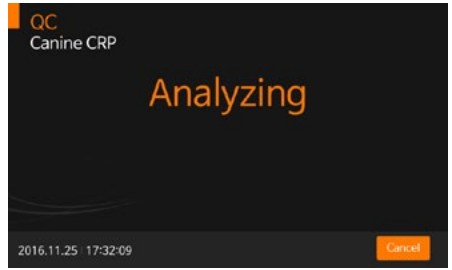
4. When the procedure for checking the test device is completed, apply the control solution to the sample well of the test device and press 'START' immediately.



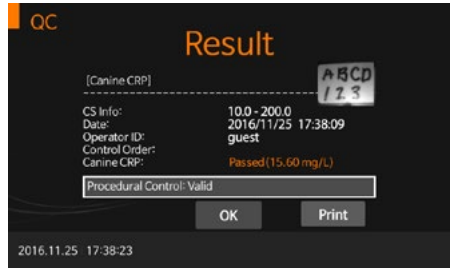
5. The Waiting screen will be displayed once the test device is being processed in the analyzer.



6. The analyzer will automatically scan and analyze the test results.



7. Once the analysis is finished, the test results will be displayed. The analyzer will print the test results if auto-printing is enabled.



8. 'Eject Device' will be displayed after the test device analysis is complete. The test device can then be removed from the analyzer.



CHAPTER 06. Calibration

Calibration Set Test

The calibration set test is a required function that ensures optimal performance by checking the designated method.

When to the calibration set

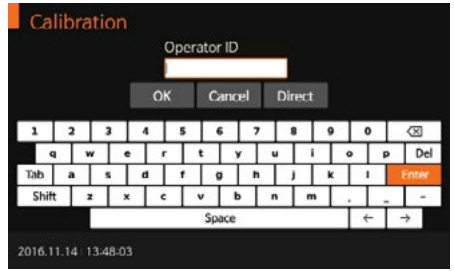
- Whenever the analyzer is powered on
- When you drop the analyzer
- Whenever you do not agree with the results
- When you want to check the performance of an analyzer and the test device

Precautions and warnings

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

How to Use the Calibration Set Test

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



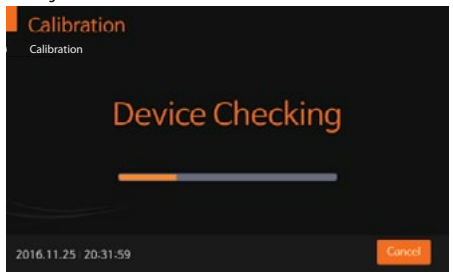
Note

The operator's ID can be entered into the analyzer with the touch panel or a USB keyboard. The ID can also be entered with a BN barcode reader, which is sold separately.

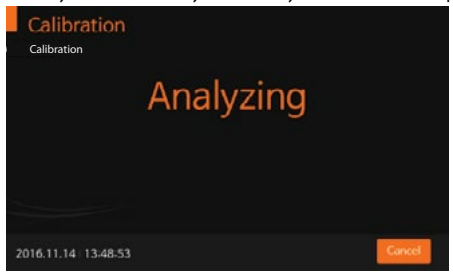
2. Once 'Insert Device' is displayed on the screen, insert CAL-1 into the test slot.



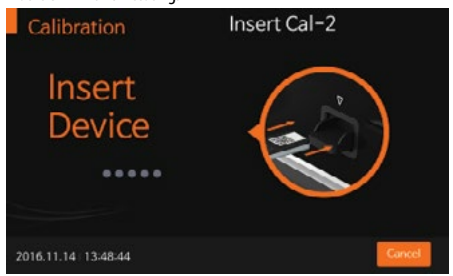
3. Once the device is inserted into the analyzer, the analyzer will automatically check whether CAL-1 has been used or not. Additionally, the analyzer will read the barcode data and confirm the device validity before starting the calibration set test.



4. The analyzer will automatically scan and analyze CAL-1. This will take approximately 15 seconds.



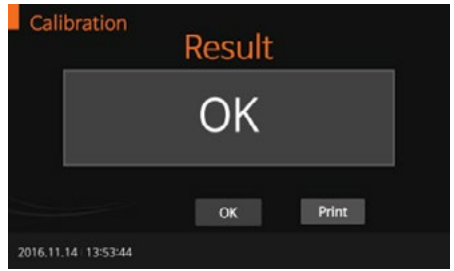
5. Insert CAL-2 for UV testing.



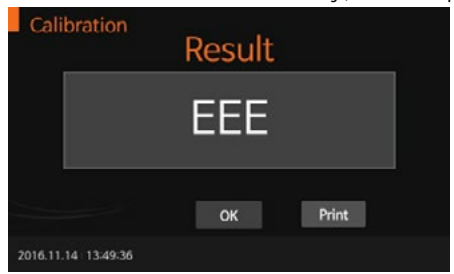
6. Insert CAL-3 for RGB-LED testing. Ensure that CAL-2 and CAL-3 are inserted in order. Do not change the order.



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



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



CHAPTER 07. Cleaning and Maintenance

Cleaning the Analyzer

To prevent analyzer malfunction, keep the test slot free from blood, moisture, or dust. Use a lint-free cloth. Suitable cleaning solutions are mild suds, 70 % ethanol, or isopropyl alcohol. For professional use (e.g.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!

Maintenance and Transportation

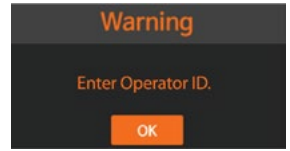
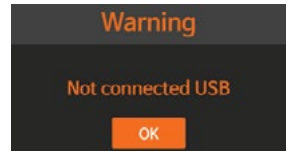
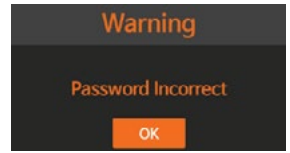
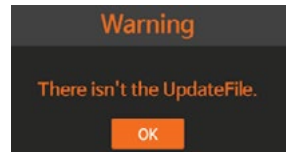
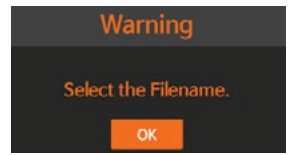
Each time the analyzer is turned on, it will automatically perform a self-test and will let you know if something is wrong.

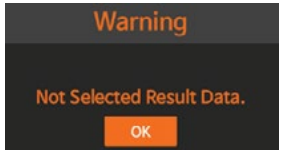
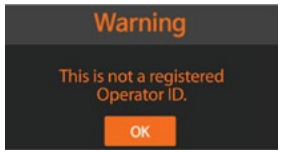
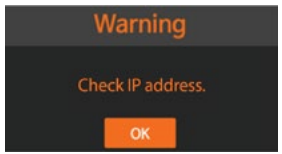
Note

- Keep the test slot and internal part of the analyzer free from dust.
- The carrying case was designed to store a variety of supplies and to protect your analyzer.
- For transportation, the analyzer should be stored at -20 to 50℃ (-4 to122℉) and 10% to 93% RH.

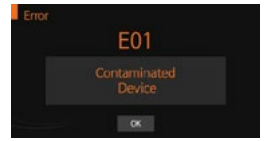
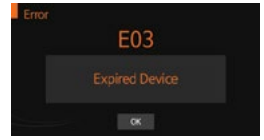
CHAPTER 08. Screen Messages and Troubleshooting

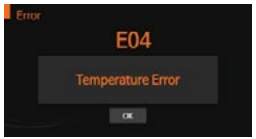
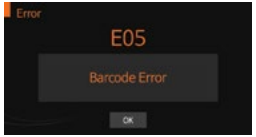
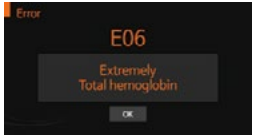
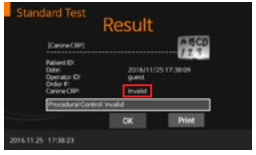
Warning Messages

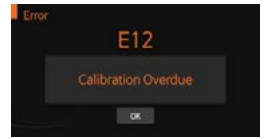
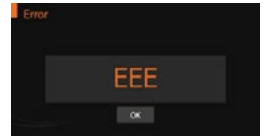
Indication	Warning description
	**Warning: Operator ID.** Pressed `OK' without entering the Operator ID. **Solution** Enter the operator's ID first, then press 'OK'.
	**Warning: USB not connected** USB device is not connected. **Solution** Confirm USB device is connected correctly.
	**Warning: Password** Entered an incorrect supervisor password. **Solution** Enter a valid password.
	**Warning: Update File Not Found.** The update file does not exist on the USB device. **Solution** Confirm that the update file is on the USB device. After ensuring the update file is on the USB drive, connect the drive and press `OK'.
	**Warning: Select Filename.** The settings file is not selected in the `Load Settings' menu. **Solution** Check the file name and select the correct file.

Indication	Warning description
	**Warning: Result data not selected** No selection in the result data list. **Solution** Press 'Send Selected Result' after selecting the result.
	**Warning: Unregistered Operator ID** Entered operator ID is not registered. **Solution** Add operator ID in set mode.
	**Warning: Out of Paper** There is no printer paper in the analyzer. **Solution** Refill the printer paper.
	**Warning: Incorrect IP address** Check the IP address. **Solution** Confirm the entered IP address.
	**Warning: Full memory** The maximum of 2000 records has been stored. **Solution** If the next test result is saved after this warning, the oldest result has already been erased.

Error Messages

Indication	Error description
	**E01: Contaminated Device** **Cause 1:** Start button is not pressed immediately after applying the sample. (sample already started migrating before reading). **Solution:** Try with a new device and press the start button immediately after applying the sample on the device.
	Cause 2: Used test kit **Solution:** Try with new device.
	Cause 3: Too much volume of sample may contaminate the device. **Solution:** Try with new device and be careful with sample volume.
	Cause 4: Defective device (unlikely) ; Device itself is contaminated. (Scratch/ Damage) **Solution:** Try with a new device with a different lot number.
	Cause 5: Defective machine ; If none of the above causes are found, it could be due to an analyzer defect. **Solution:** Report to BIONOTE with the error message.
	**E02: Insufficient Sample** **Cause 1:** Too much foam while mixing the tablet. **Solution:** Try with a new device and be careful with the foam during sample preparation.
	Cause 2: Small volume of sample is applied. **Solution:** Double-check pipette sample volume.
	Cause 3: Sticky sample **Solution:** Centrifuge the specimen and use only the supernatant.
	Cause 4: Too hot and dry temperature **Solution:** Try again at room temperature(15-30°C) or turn off the heater.
	Cause 5: Defective device interrupt proper migration. **Solution:** Check if migration is done and report to BIONOTE with the error message.
	**E03: Expired Test Device** **Cause 1:** Expired Device **Solution:** Check if the analyzer Date/Time is not properly set. * Setting> General Setting > Date/Time

Indication	Error description
	**E04: Temperature Error** **Cause 1:** Device temperature is not between 15~30°C. **Solution:** Try with a new device after incubating at room temperature.
	**Cause 2:** Analyzer temperature is not between 15~30°C. **Solution:** Try turning on Analyzer after incubating at room temperature. **Cause 3:** Defective temperature sensor **Solution:** Try after incubation and report to BIONOTE with the error message.
	**E05: Communication Error** **Cause 1:** Communication between the analyzer and barcode reader or printer has failed. **Solution:** Reconnect the analyzer and the external device. If the error continues after turning the analyzer ON/OFF, report to BIONOTE with the error message.
	**Cause 2:** Damaged barcode. **Solution:** Check if there is a damage on the barcode.
	**E06: Extremely Total Hemoglobin** **Cause 1:** Sample is hemolyzed much (The measured total hemoglobin is not in the range of 7 to 23g/dL.) **Solution:** 1. This error occurs with specimens known to have total hemoglobin in the abnormal range. 2. Specimen with high hemolysis can not be used. Prepare the specimen again. 3. If the test kit allows whole-blood sample, this error will not be reported.
	**Result: Invalid** **Cause 1 :** The test is invalid. **Solution:** Retest with a new test device and a new specimen. If the error continues after turning the analyzer ON/OFF, report to BIONOTE with the error message.
	Cause 2: C-line is out of range. **Solution:** Double-check if tablet melting process is completed.

Indication	Error description
	**E12: Calibration Overdue** **Cause 1:** The calibration is overdue. **Solution:** Calibrate analyzer or set up calibration period longer. * Setting> general setting > Set Calibration and QC If the error continues after turning the analyzer ON/OFF, report to BIONOTE with the error message.
	**E13: Unsupported Test Device** **Cause 1:** Loaded test device is not appropriate for the analyzer. **Solution:** Check the type of test device and confirm it is manufactured by BIONOTE **Cause 2:** Invalid software **Solution:** Update software.
	**EEE: Internal Error Message for the Analyzer** **Cause 1:** An internal error has occurred. **Solution:** If the error continues after turning the analyzer ON/OFF, report to BIONOTE with the error message.

CHAPTER 09. On-Line Update Configuration

Wireless LAN Connection Settings

1. Insert the wireless LAN card into the USB PORT located in the lower left corner of the device.



Note

Usable Wireless Lan Card Types
- ipTime N100mini
- netis WF2120
- Bless ZIO 1570NU

2. In the main menu, press 'Supervisor' to configure the setup mode.

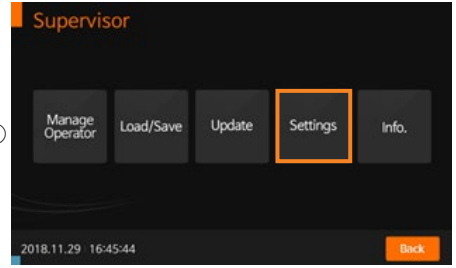


3. Input the password and press 'OK' (The initial supervisor password is 0000).

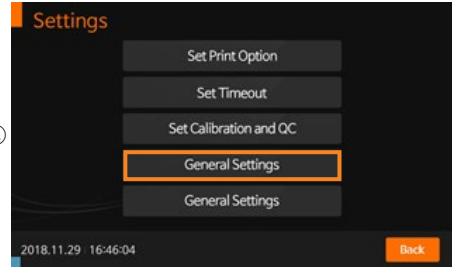


4. In the Supervisor menu, press ① **Settings** > ② **General Setting** > ③ **LIS Parameters**.

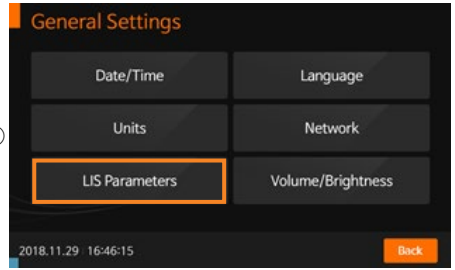
①



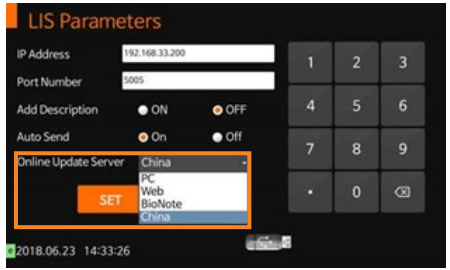
②



③



5. In the LIS Parameters menu, select a server from the 'Online Update Server' list to perform the online update.



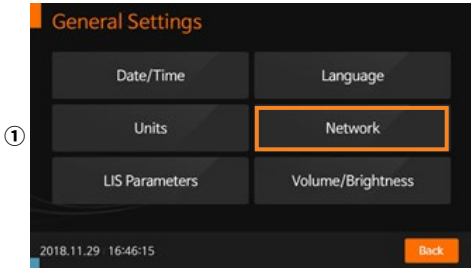
Note

Online Update Server List

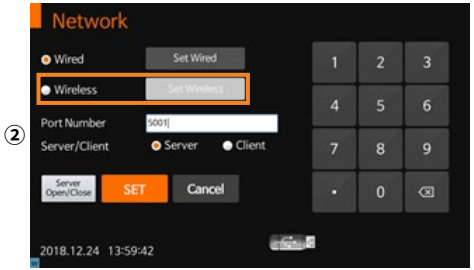
- PC : Update Server access via PC
- Web : Update Server access via Wireless LAN
- Bionote : Update Server access via Bionote computer network (Not available)
- China : Update Server access via wireless LAN (China only)

6. Return to the General Settings menu and press ① **Network** > ② **Set Wireless.**

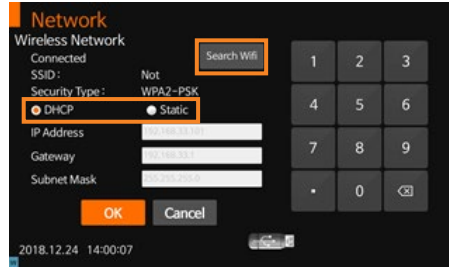
①



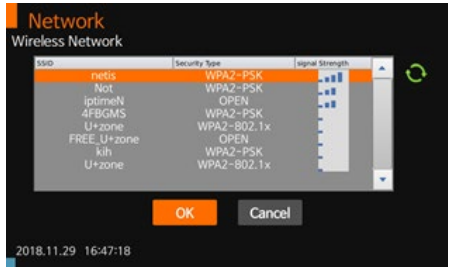
②



7. Press 'Search WiFi' to find the WiFi network you want to use. To setup IP, select your preference between DHCP (automatically designated) and Static (manual specified).



8. Select the desired WiFi network from the 'Wireless Network' to connect. If a successful connection is made, 'Connected' will be displayed on the top-left corner, and a 'W' mark will appear in the lower-left corner.

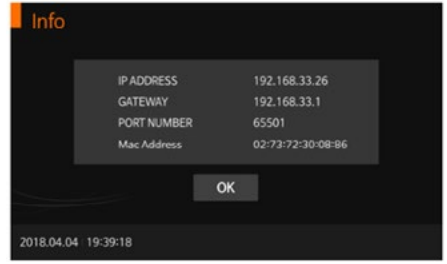




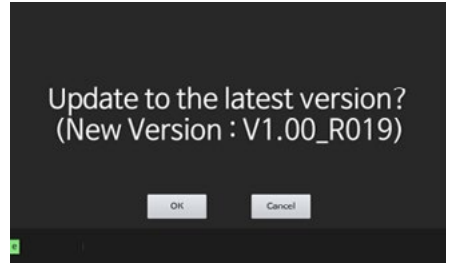
< Wireless LAN Connection Verification>

1. In the Supervisor menu, press **Info. > View Network** to confirm the displayed IP address.





2. If the SW of the server is higher than the SW of the device, the message below will be printed when turning the device back on.



ANNEX 01. Information for Healthcare Professionals

Protection against Infections

There is a potential risk of infection. Healthcare professionals using the BIONOTE V200 analyzer to perform the test must be aware that any object coming into contact with a patient sample is a potential infection source.

- Wear protective equipment.
- Apply samples outside the analyzer.
- Follow all other locally applicable guidelines and regulations on health and safety.

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.

Warranty

You are a valued customer of BioNote, Inc. It is important to us that you are completely satisfied with the BIONOTE V200 analyzer. BioNote, Inc. guarantees the analyzer to be free from defects and warranty for two years from the original purchase date. If the analyzer does not work properly during this period because of a defect in materials, BioNote, Inc. agrees to replace or repair, free of charge, any and all parts proven to be defective and subject to warranty. This warranty is in lieu of all other warranties, expressed or implied, including any implied warranty of merchantability of fitness for any purpose other than stated herein. This warranty does not apply to the performance of an analyzer that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. This warranty only applies to the original purchaser of the analyzer and/or its agents.

Return

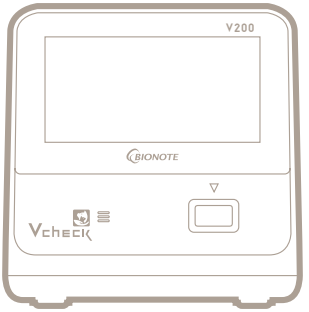
You must contact BioNote, Inc. before returning your analyzer and will be instructed with specifications on the return procedures. Analyzers returned without authorization will not be accepted.

Disposal

The BIONOTE V200 analyzer must be disposed of according to the local regulations concerning electrical and electronic equipment disposal. The Waste Electrical and Electronic Equipment (WEEE) regulation implements the provisions of the European Parliament and Council Directive 2002/96/EC to reduce the amount of EEE waste for final disposal. Please contact our representatives in your area for the respective instructions before disposal.

MEMO

MEMO


V200
BIONOTE
Vcheck