

FOR VETERINARY USE ONLY

USER MANUAL

V200

FLUORESCENT IMMUNOASSAY SYSTEMS





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www.bionote.co.kr



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

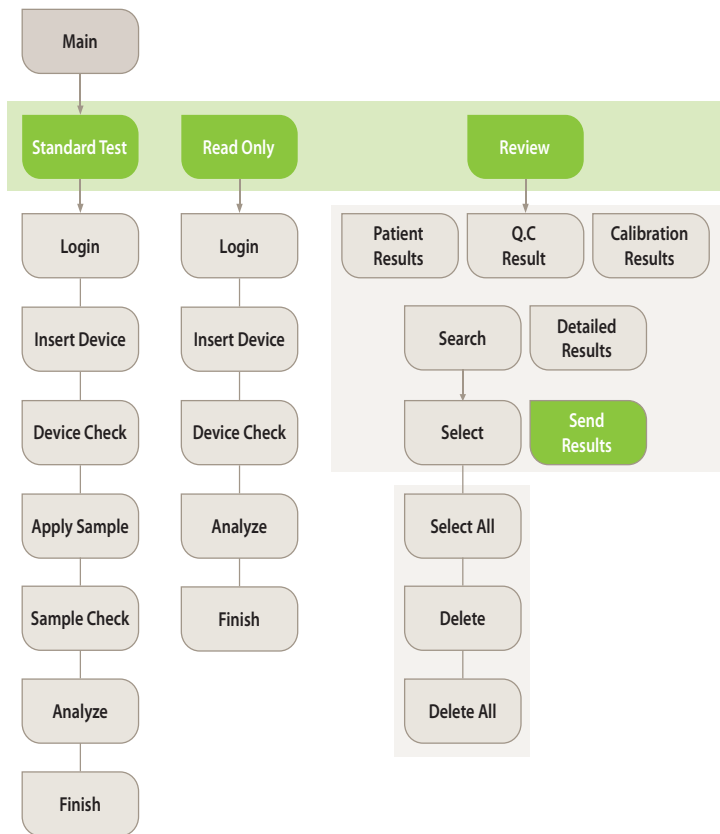
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CHAPTER 01. General Information

Main Menu Structure



Q.C

Login

Insert Device

Device Check

Apply Sample

Sample Check

Analyze

Finish

Calibration

Login

Insert Device

Eject Device

Insert Device

Eject Device

Insert Device

Analyze

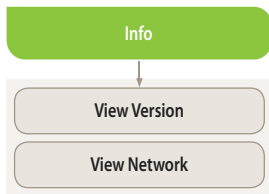
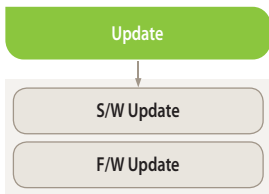
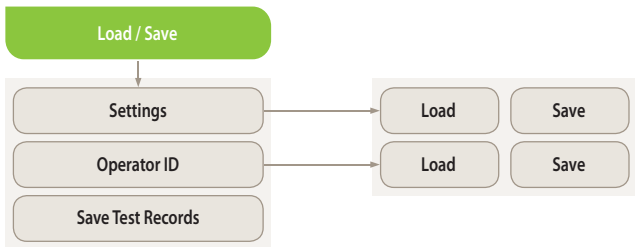
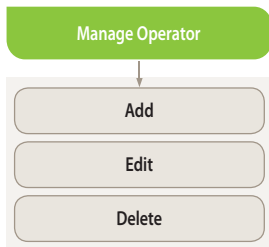
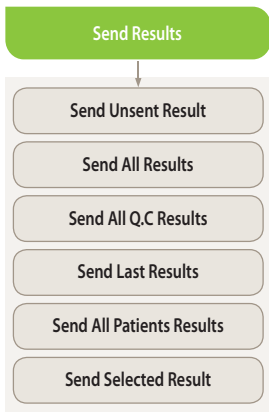
Finish

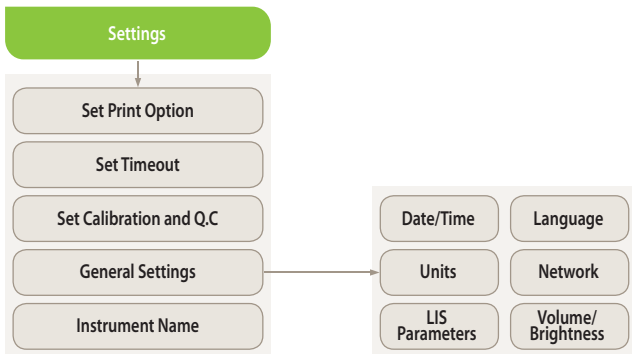
Supervisor

Password

Manage Operator Load/Save Update

Setting Info

















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 : Indicate the lot number for the analyzer |
|  | 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



To reduce the risk of analyzer damage

- Keep the BIONOTE V200 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 entering the analyzer may cause serious interference with the results and thus must be avoided
- Never move the analyzer while a test is in progress
- Do not drop the analyzer as the unit could be damaged
- 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 results, refer to the test device package insert for test storage and system operating conditions
- Using test devices that are expired can cause the results to be inaccurate



To reduce the biohazard risk

- 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 BIONOTE V200 analyzer is effective for measuring quantitative or qualitative biomarkers using body fluid in the laboratory and point-of-care settings. The analyzer is indicated for monitoring and diagnoses using body fluid parameters in clinical settings by healthcare professionals. The analyzer should be used with the specified test device produced by BioNote, Inc. Refer to the assay-specific package insert for details on specific tests.

Product Description

The BIONOTE V200 analyzer automatically recognizes the lot of the specific test devices in use by reading their 2D barcodes. While the test device is inserted into the BIONOTE V200 analyzer, the application well of the test device is 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 analysed. When the specimen is applied, an enzymatic reaction occurs forming a dye and the amount of formed dye is proportional to the concentration of the analyte. 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 a blank value and information read including 2D barcode data. Finally, the test result is displayed on the screen and 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 the Instructions for use of the test device and control. It is very important to follow the instructions to prevent incorrect results or improper treatment.

Specimens

The BIONOTE V200 analyzer should only be used with specific test devices for the analyzer. Because specimens are quite different for each parameter, follow the instructions from each test device insert.

Safety information

There is a potential risk of infection. Healthcare professionals using the BIONOTE V200 analyzer to perform measurements for more than one patient should use gloves and follow all other locally applicable health and safety regulations.

Operating conditions

To ensure proper function of the BIONOTE V200 analyzer, observe the following guidelines.

- Operate the analyzer only within the acceptable environmental conditions. Within the above range, the acceptable temperature range varies depending on the reagent.
- 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 ventilation (Do not cover the air vents).
- If the analyzer experiences a sudden malfunction, unplug the adaptor from the outlet.

System Components

Unpack the shipping container and 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 $\pm 10\%$) Output: DC12V/5A |
| Display | 7" Color TFT LCD (800x480) |
| Display Controls | Graphical User Interface |
| Power Consumption | Max 50W |
| Over Voltage Category | II |
| Pollution Degree | II |
| Memory | 3000 |
| RTC | RTC Backup Battery Included |
| Size | 214.9 x 261 x 203 mm |
| Labeling | User Manual |
| Barcode Scanner (Optional) | Barcode Scanner |

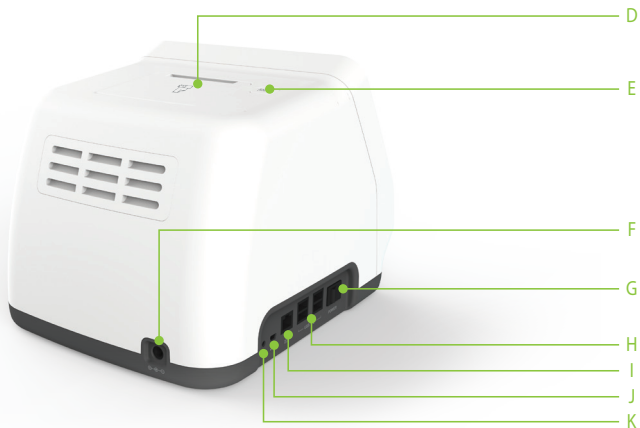


Note

- The AC/DC power adaptor is not supplied by BioNote, Inc. All users must use approved Adaptor. (VDE, UL, TUV and etc.)
- Do not connect to the power supply other than AC/DC adaptor specified rating in the specification.
- The size of Jack which connects with DC power adaptor is 5.5 mm, 2.5 mm (External, Internal diameter).
- Must check adaptor polarity when plugging the adaptor 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 adaptor 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 |  |
| Optional | Test device |  |
| | Barcode scanner (For patient ID recognition) |  |
| | 12V/5A AC/DC power adaptor |  |
| | Print paper |  |

CHAPTER 03. Setting and Performance

Operating the Analyzer

STEP 1. Connect AC/DC adaptor jack

- 1-1. Place the analyzer on a bench top within reach of an electrical outlet. The unit is portable and can be moved to a suitable location for testing. Ensure the bench top is stable, flat and dry. Also ensure the bench provides 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. Once the connection is complete, the analyzer is ready for use.

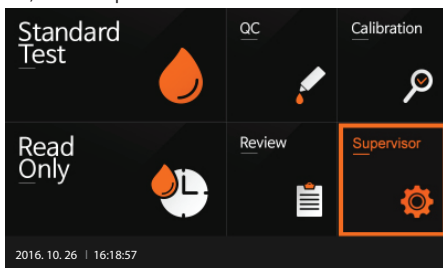
STEP 2. Setup the analyzer

- 2-1 When setting up the analyzer for the first time, the operator's ID should be registered. The initial supervisor password is 0000.
- 2-2 It is recommended to acknowledge the table presented on the supervisor menu.

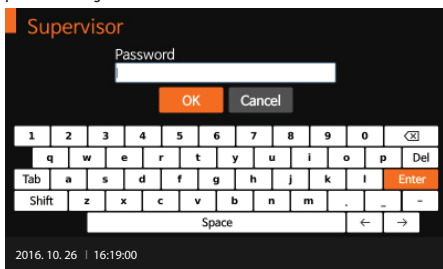
| Stage | Menu | Sub menu | |
|-------|-----------------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Manage Operator | Add / Edit / Delete | |
| 2 | Load/Save | 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: Entering setup mode

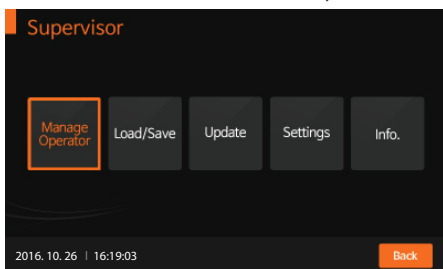
1. First, touch the 'Supervisor' button on the screen in the main menu to enter setup mode and begin the test.



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

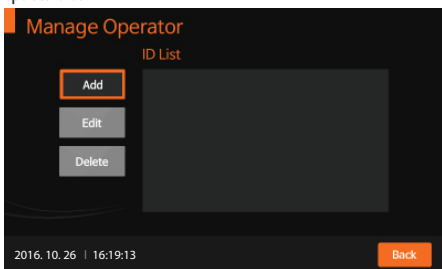


3. The supervisor menu allows the operator to access additional functionality and security options depending on the work environment and the location of the analyzer.

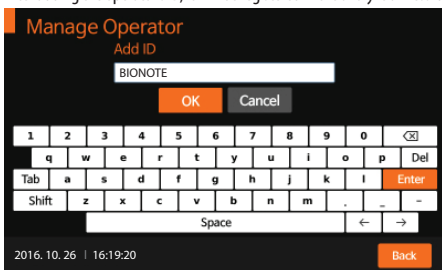


2nd step: Supervisor>Manage operator

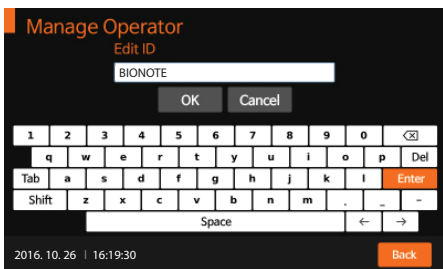
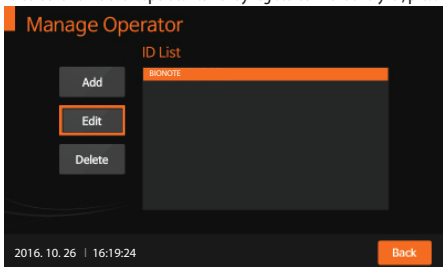
1. Select the 'Manage Operator' button on the screen to add, edit or delete the operator's ID. Press the 'Back' button if you want to return to the previous setting.
2. To add the operator's ID, press 'Add'. Use the touch panel keyboard or a USB connected keyboard to add the operator's ID.



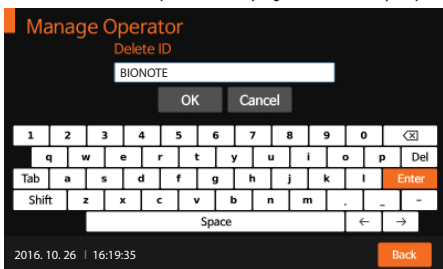
3. After adding the operator's ID, it will be registered in the analyzer. Press 'OK' to confirm.



4. To edit the name of an operator currently registered in the analyzer, press 'Edit'.



5. To delete the name of an operator currently registered in the analyzer, press 'Delete'.



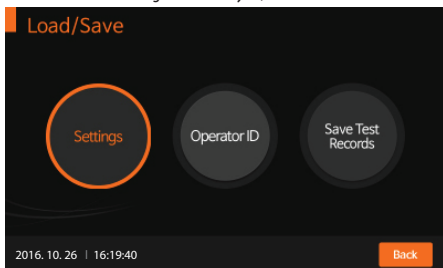
3rd step: Supervisor > Load/Save



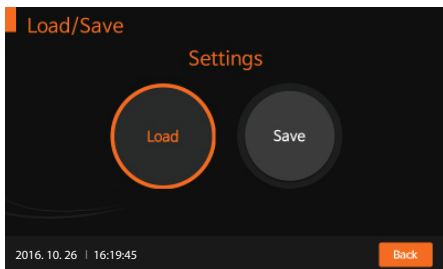
Note

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.

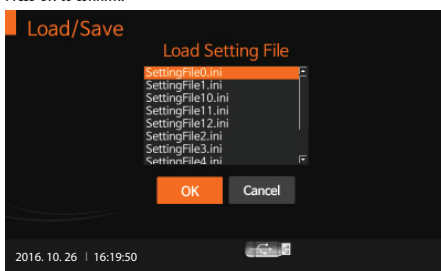
1. To load or save the settings for the analyzer, enter the 'Load/Save' menu and press 'Settings' to proceed.



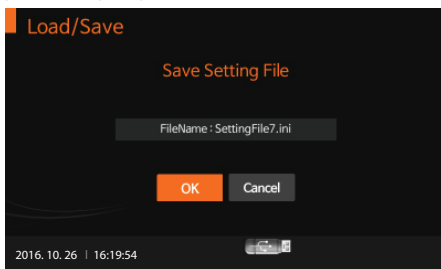
2. To load the appropriate analyzer data according to the test type, press 'Load'. This can be done by inserting the USB device containing data that can be loaded into the analyzer.



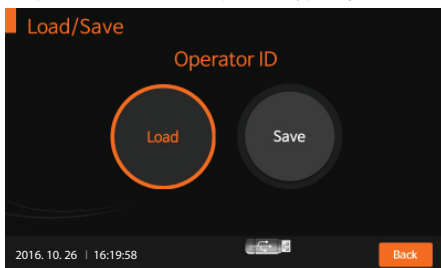
- When the data is loaded, the screen will promptly show a message indicating that the data has loaded successfully. Press 'OK' to confirm.



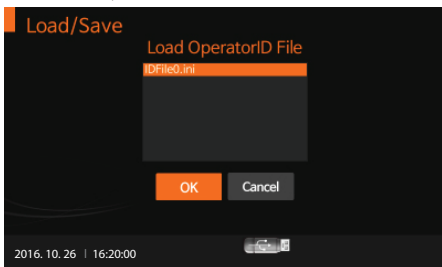
- To save analyzer settings that are cloned or duplicate settings from another device, press 'Save'. When the data save procedure is completed, press 'OK' to confirm.



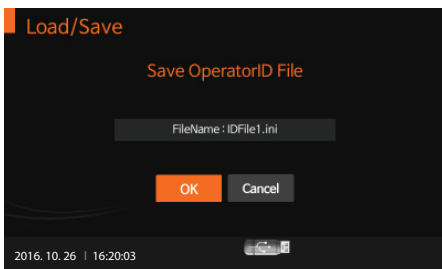
- The operator can also load the saved operator's ID by pressing 'Load'.



6. When the operator's ID is loaded, the screen will promptly show a message indicating that the operator's ID has loaded successfully. Press 'OK' to confirm.



7. In addition, the operator can save the operator's ID by pressing 'Save'. When operator's ID is saved, press 'OK' to confirm.

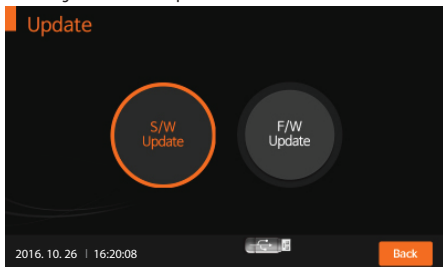


Note

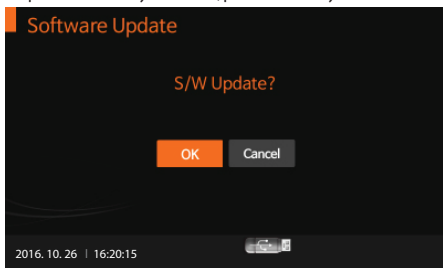
The analyzer's test results may be exported and saved to a USB drive. Saved data is to be managed by the supervisor and all records of the test results can be displayed and printed.

4th step: Supervisor > Update

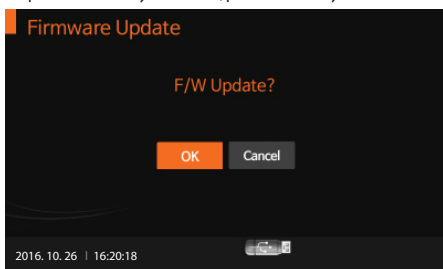
1. To update the analyzer's software or firmware, enter the 'Update' menu after connecting the USB device containing the S/W or F/W update.



2. To update the new analyzer software, press 'OK'. The analyzer will read the new software to be installed.

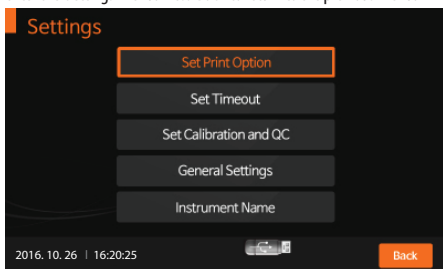


3. To update the new analyzer firmware, press 'OK'. The analyzer will read the new software to be installed.

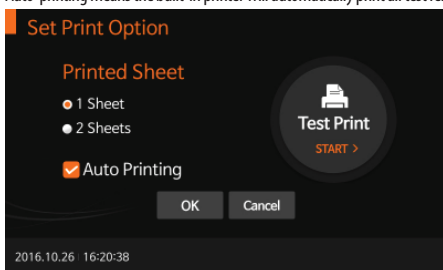


5th: Supervisor > Settings

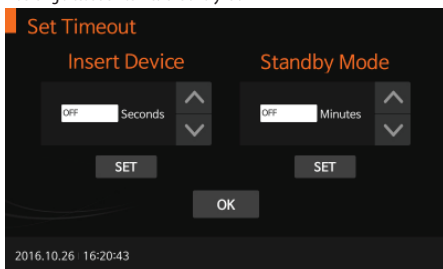
1. To set the print option, automatic turn-off time, calibration and Q.C date, general settings or instrument name, enter the 'Settings' menu. Press 'Back' to return to the previous menu.



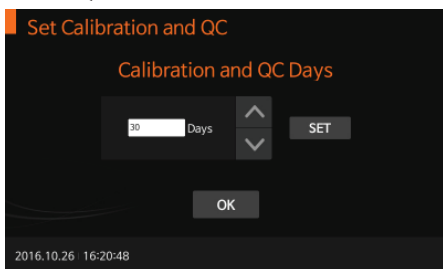
2. To set the number of printed sheets as 1, 2 or auto-printing mode (ON/OFF) enter the 'Set Print Option' menu. Auto-printing means the built-in printer will automatically print all test results at the end of each test.



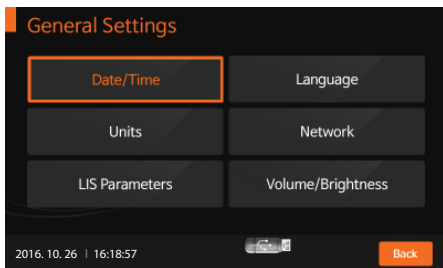
- To control the analyzer's automatic turn-off time for power saving, enter the 'Set Timeout' menu. Insert test device stage procedure means that the user doesn't require any action after inserting test device in to the analyzer, and when the test is finished. Standby mode means the user doesn't require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



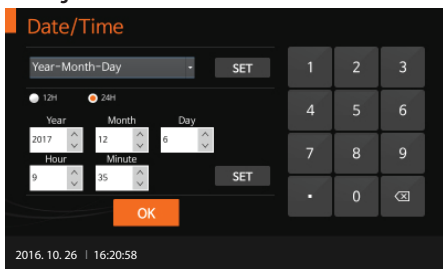
- To set the time period for calibration and Q.C, enter the 'Set Calibration and Q.C' menu. After the calibration and Q.C procedure is completed, the analyzer will check the Q.C date and activate an alarm to indicate the number of days since the last Q.C.



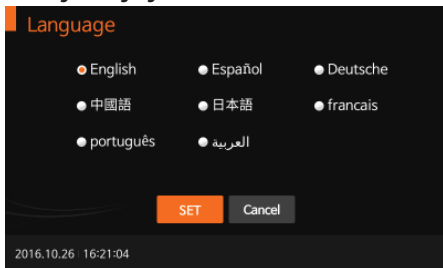
5. To set the date/time, language, test unit parameters, network, LIS parameters, sound volume, or LCD brightness, enter the 'General Settings' menu. Especially, under unit settings, test parameters corresponding to the test type can be set and the parameters can be adjusted by updating the analyzer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



<Setting the date/time>



<Setting the language>



<Setting the test parameter's unit>

Units

| | | |
|------------|-------|---|
| Canine CRP | mg/L | ▼ |
| fSAA | μg/mL | ▼ |
| | | ▼ |
| | | ▼ |
| | | ▼ |

1/1

▲

▼

SET Cancel

2016.10.26 16:21:11

<Setting the network>

Network

IP Address 192.168.33.100

Gateway 192.168.33.1

SET Cancel

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

2016.10.26 16:21:17

<Setting the LIS parameter>

LIS Parameters

IP Address 192.168.33.200

Port Number 5005

Auto Send On Off

SET Cancel

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

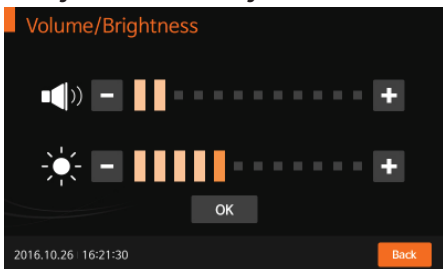
2016.10.26 16:21:24



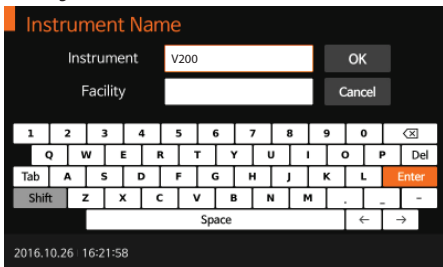
Note

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

<Setting the sound volume/LCD brightness>

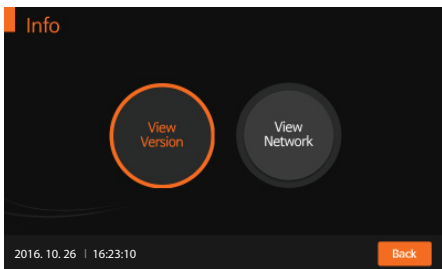
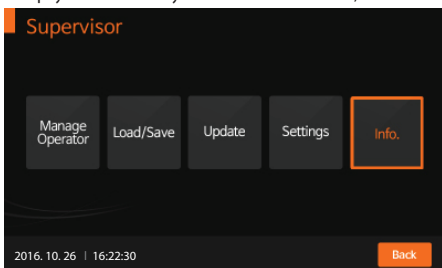


<Setting the instrument name>

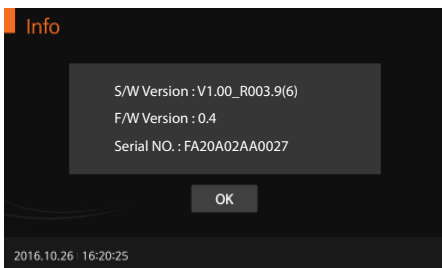


6th: Supervisor > Info

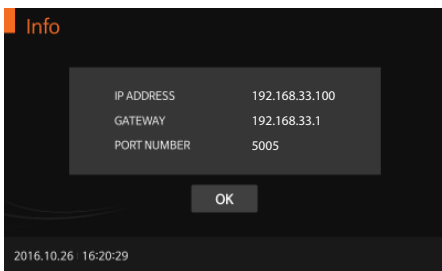
1. To display and view the analyzer's current software version, firmware or network, enter the 'Info' menu.



- When 'View Version' is selected, the version information for the software and firmware will be displayed. Press 'OK' to confirm.



- When 'View Network' is selected, information about the network will be displayed. Press 'OK' to confirm.



Performing a Measurement

Check the following before performing a measurement:

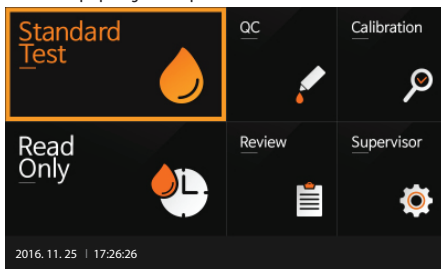
- Is the analyzer connected to the AC/DC adaptor?
- Are date and time correct?
- Have you checked the analyzer settings?

Select the desired test mode

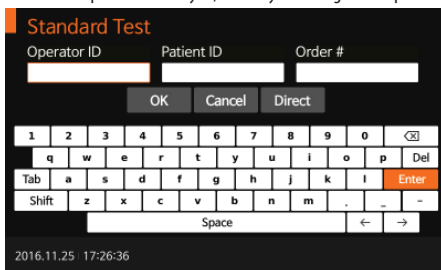
The Standard Test mode may be the most convenient for reading a single patient sample, as the user can perform a Standard Test during the analysis period. The Read Only mode may be the most convenient for large volume testing as the analyzer can quickly read multiple patient samples sequentially.

Standard Test mode

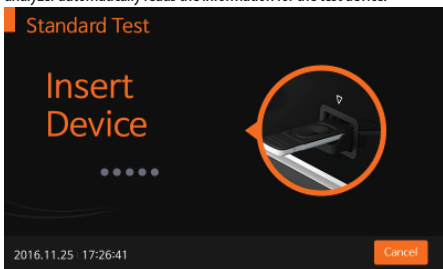
1. First, select the 'Standard Test' mode. Refer to the assay-specific package insert when collecting specimens for the test and preparing the test procedure.



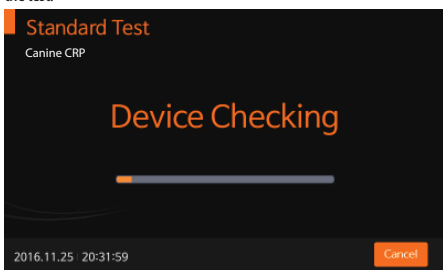
2. Input the operator's ID, patient ID, and order #. The operator's ID can also be input with the barcode scanner. If the ID is not input into the analyzer, the analyzer will regard the operator as a guest user.



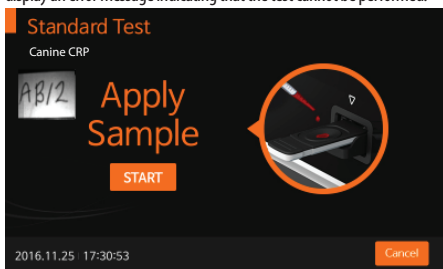
- Once 'Insert Device' is displayed on the screen, insert the specified test device into the analyzer's test slot. The analyzer automatically reads the information for the test device.



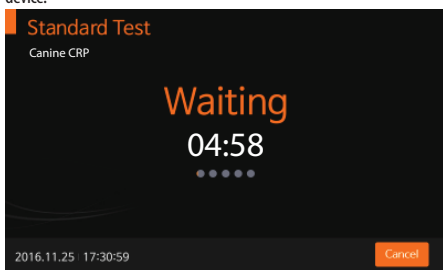
- When inserting the test device into the analyzer, the analyzer will automatically check whether the device has been used or not. The analyzer also reads the barcode data and confirms the test device is valid before starting the test.



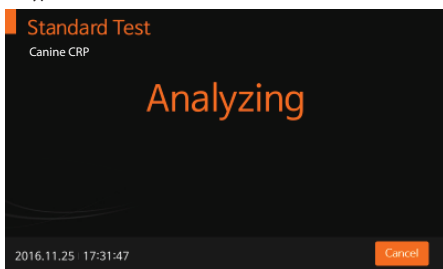
5. When the test device has been checked, apply the specimen to the sample well and press the 'START' button immediately. If the 'START' button is not pressed within 20 seconds after applying the specimen, the analyzer will display an error message indicating that the test cannot be performed.



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



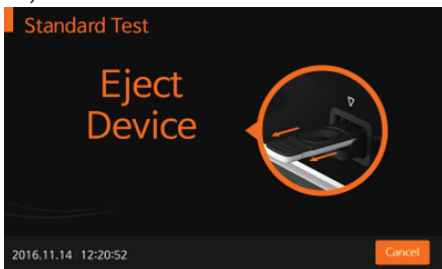
7. The analyzer will automatically scan the test device and analyze the test results. The scanning time can vary with the type of test device.



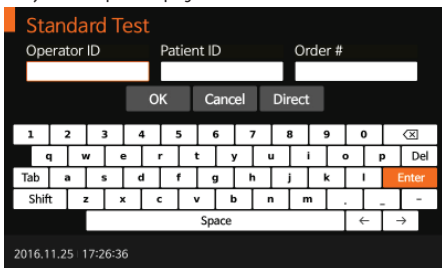
- Once the analysis is finished, the test results will be displayed. The analyzer will print the test results if auto-printing is enabled.



- When the 'OK' button is pressed, 'Eject Device' will be displayed. The test device can then be removed from the analyzer.

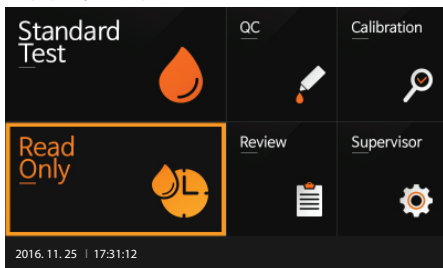


- When the test device is ejected, the analyzer will move to another test log-in menu for the next test. Press 'Cancel' at any time to stop the test progress.

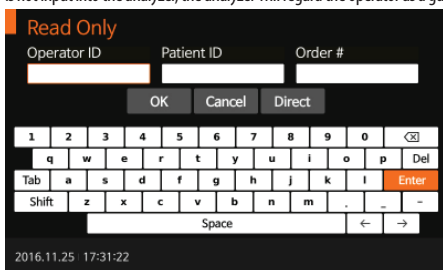


Read Only mode

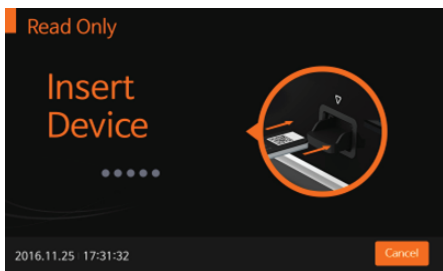
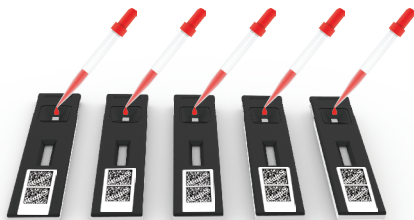
1. First, select Read Only' mode. Refer to the assay specific package insert when collecting the specimen for the test and preparing the test procedure.



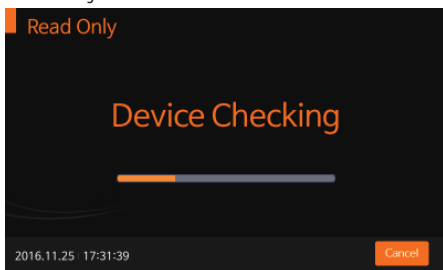
2. Input operator's ID, patient ID, and order #. The operator's ID can also be input with the barcode scanner. If the ID is not input into the analyzer, the analyzer will regard the operator as a guest user.



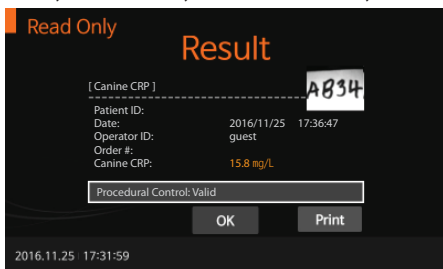
3. Prepare test device and label the test device accordingly.
 - Add prepared specimen #1 to test device #1, then immediately set your timer to the designated processing time as indicated in the assay-specific package insert.
 - One minute later, add specimen #2 to test device #2.
 - Continue adding the appropriate 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, the analyzer will display the result in approximately ten seconds.



4. When inserting the test device 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 the test device is valid before starting the test.



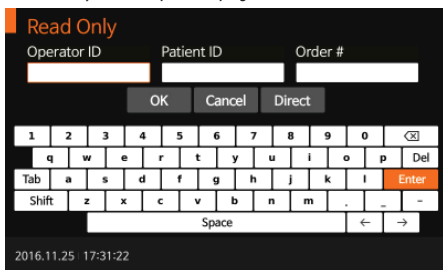
5. The analyzer will automatically scan the test device and analyze the test results on the screen within 10 seconds.



6. When the 'OK' button is pressed, 'Eject Device' will be displayed. The test device can then be removed from the analyzer.



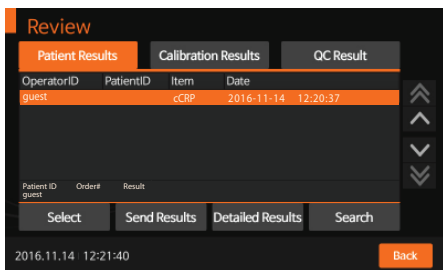
7. When the test device is ejected, the analyzer will move to another test log-in menu for the next test. Press 'Cancel' at any time to stop the test progress.



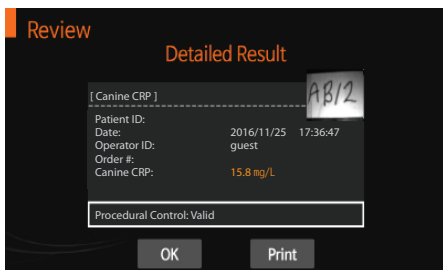
CHAPTER 04. Using the Analyzer Memory and Data Transfer

Displaying Stored Measured Values

1. The BIONOTE V200 analyzer can store 3000 records together with date, time and flags, allowing the records to be reviewed in order from the most recent to the oldest. When the memory is full and a new result is added, the analyzer will delete the oldest record.
2. The Q.C 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 as well.

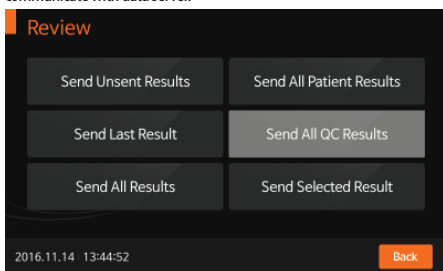


3. In any test results list, you may select a specific record. After selecting the desired record, you can view or print it in detail.

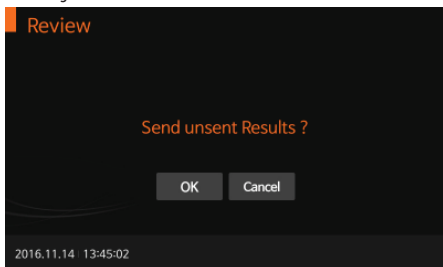


Send Results

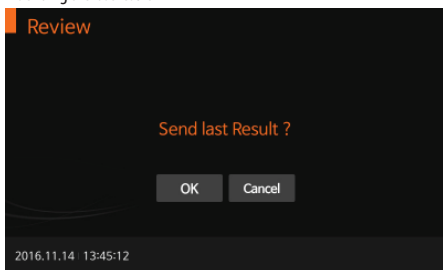
1. With several options available for sending the test results, you can choose the most appropriate method to communicate with data server.



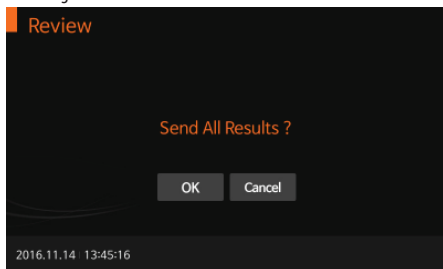
<Sending the unsent results>



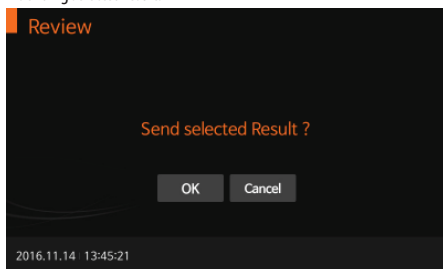
<Sending the last result>



<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 adequate.

When to use the control

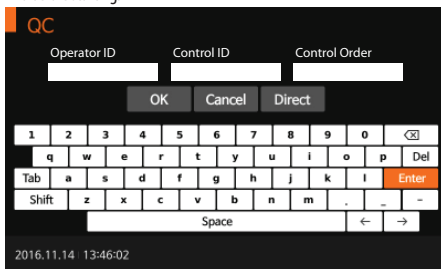
- Before using the BIONOTEV200 analyzer for the first time.
- To check the test device when you unpack a new device.
- If you drop the analyzer.
- Whenever your results are not in accordance with your expectations.
- If you have repeated a test, and the result is still lower or higher than expected.
- When you want to check the performance of the analyzer and test device.

Before using the control

- Check the expiration date on the control solution container. Do not use after the expiration or discard date (date opened plus three months), whichever comes first.
- Shake the container, discard the first drop of the control solution, and wipe off the tip to ensure a proper sample and an accurate result.

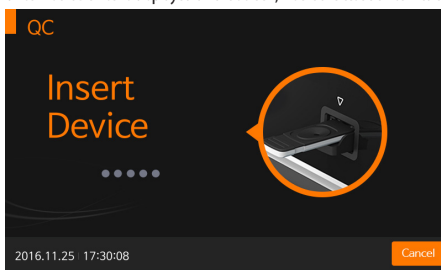
How to Perform Quality Control

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 Q.C control solution for each type of test device. Enter the operator ID and CS Info before starting.

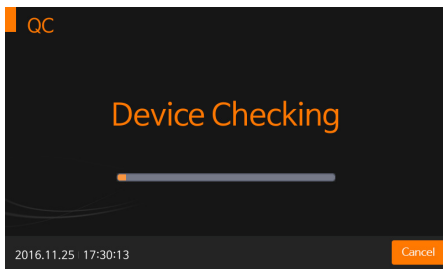


The operator ID and CS Info can be entered into the analyzer with the touch panel or a USB keyboard. This information can also be entered with the BN barcode reader, which is sold separately.

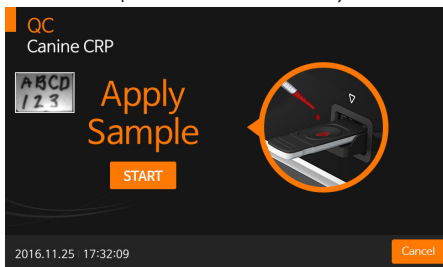
2. Once 'Insert Device' is displayed on the screen, insert the test device into the test slot.



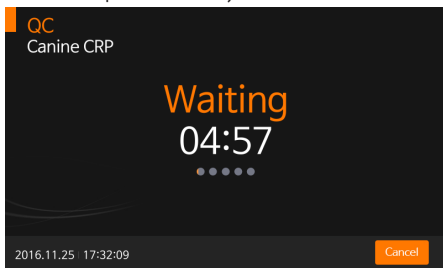
- When the test device is inserted into the analyzer, the analyzer will automatically check whether the device is unused or not. Also, the analyzer will read the barcode data and confirm the test device is valid before starting the test.



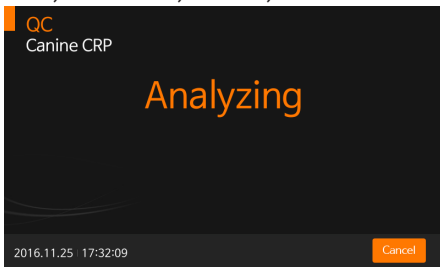
- When the procedure for checking the test device is completed, apply the control solution to the sample well of the test device and press the 'START' button immediately.



- The test device is 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. After the procedure of analyzing the test device is completed, 'Eject Device' will be displayed. 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 use 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 test device

Precautions and warnings

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

How to Use the Calibration Set Test

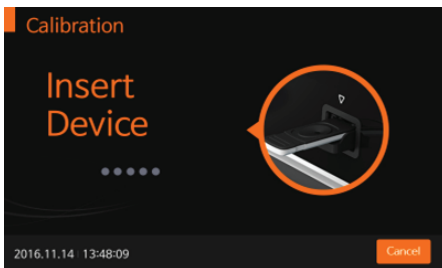
1. To run the calibration set test, select the 'Calibration' menu. Enter the operator's ID before starting the calibration set test.



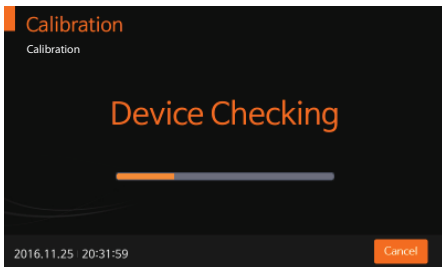
Note

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 the BN barcode reader, which is sold separately.

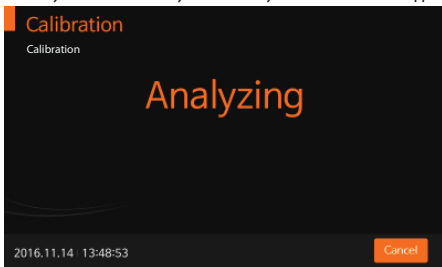
2. Once 'Insert Device' is displayed on the screen, insert CAL-1 into the test slot. The analyzer will automatically read the test device information.



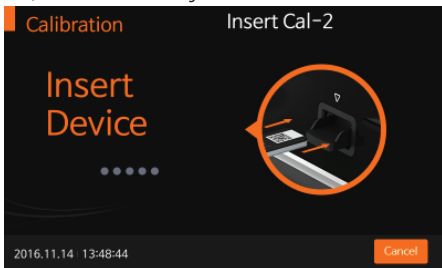
- When the device is inserted into the analyzer, the analyzer will automatically check whether CAL-1 is unused or not. Additionally, the analyzer will read the barcode data and confirm the device is valid before starting the calibration set test.



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



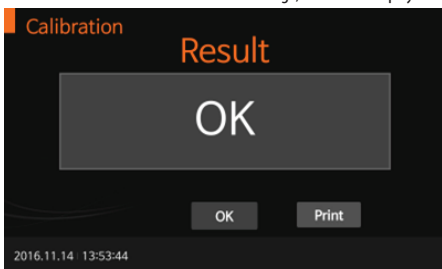
- Next, insert CAL-2 for UV testing.



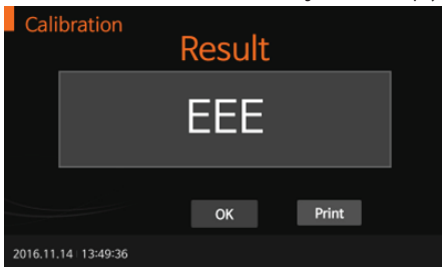
6. Insert CAL-3 for RGB-LED testing. Ensure that CAL-2 and CAL-3 are inserted in order. Never change the order.



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 lint-free cloth. For cleaning, suitable 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.

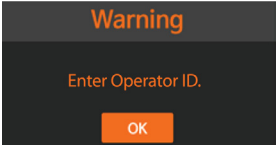
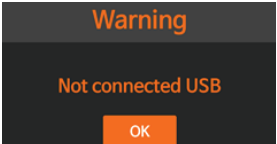
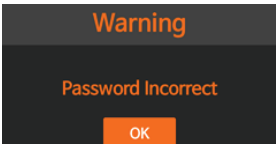
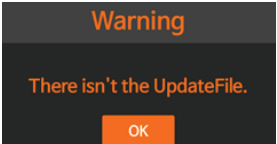
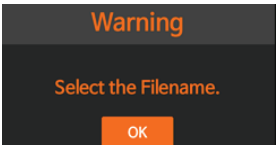


Note

- 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°C (-4 to 122°F) and 10% to 93% RH.

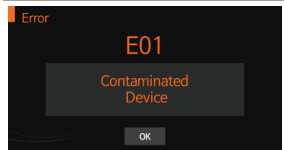
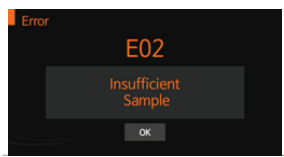
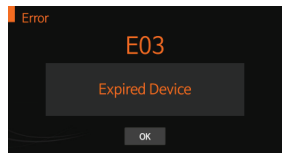
CHAPTER 08. Screen Messages and Troubleshooting

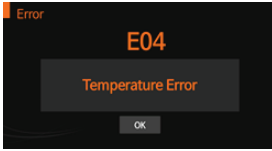
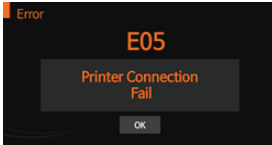
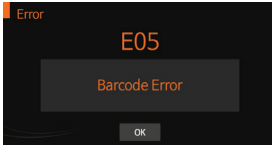
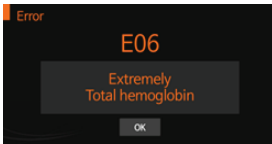

Warning Messages

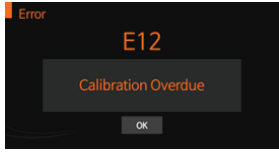
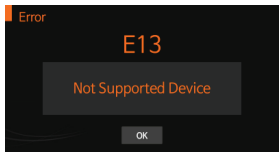
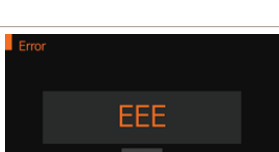
| Indication | Warning description |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>Warning</p> <p>Enter Operator ID.</p> <p>OK</p> | <p>Warning: Operator ID. Pressed `OK` without entering the Operator ID.</p> <p>Solution Enter the operator's ID first, then press `OK`.</p> |
|  <p>Warning</p> <p>Not connected USB</p> <p>OK</p> | <p>Warning: USB not connected USB device is not connected.</p> <p>Solution Confirm USB device is connected correctly.</p> |
|  <p>Warning</p> <p>Password Incorrect</p> <p>OK</p> | <p>Warning: Password Entered incorrect supervisor password.</p> <p>Solution Enter valid password.</p> |
|  <p>Warning</p> <p>There isn't the UpdateFile.</p> <p>OK</p> | <p>Warning: Update File Not Found. The update file does not exist on the USB device.</p> <p>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`.</p> |
|  <p>Warning</p> <p>Select the Filename.</p> <p>OK</p> | <p>Warning: Select Filename. The settings file is not selected in the `Load Settings` menu.</p> <p>Solution Check the file name and select the correct file.</p> |

| Indication | Warning description |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p style="text-align: center;">Warning</p> <p style="text-align: center;">Not Selected Result Data.</p> <p style="text-align: center;">OK</p> | <p>Warning: Review No selection in the review data list.</p> <p>Solution Press 'Send selected result' after selecting the result.</p> |
| <p style="text-align: center;">Warning</p> <p style="text-align: center;">This is not a registered Operator ID.</p> <p style="text-align: center;">OK</p> | <p>Warning: Unregistered Operator ID Entered operator ID is not registered.</p> <p>Solution Add operator ID in set mode.</p> |
| <p style="text-align: center;">Warning</p> <p style="text-align: center;">Out of Paper</p> <p style="text-align: center;">OK</p> | <p>Warning: Out of Paper There is no printer paper in the analyzer.</p> <p>Solution Refill printer paper.</p> |
| <p style="text-align: center;">Warning</p> <p style="text-align: center;">Check IP address.</p> <p style="text-align: center;">OK</p> | <p>Warning: Incorrect IP address Check IP address.</p> <p>Solution Confirm an IP address was entered.</p> |
| <p style="text-align: center;">Warning</p> <p style="text-align: center;">Memory is Full.</p> <p style="text-align: center;">OK</p> | <p>Warning: Full memory The maximum of 3000 records has been stored.</p> <p>Solution If the next test result is saved after this warning, the oldest result is erased.</p> |

Error Messages

| Indication | Error description |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>The screenshot shows an error message on a dark background. At the top left, the word "Error" is written in orange. In the center, "E01" is displayed in large orange font. Below it, a grey box contains the text "Contaminated Device" in orange. At the bottom, there is a grey button with "OK" written on it.</p> | <p>E01: Test Device Error The test device is damaged or inserted improperly.</p> <p>Solution Discard the test device and retest with a new test device and a new specimen.</p> |
|  <p>The screenshot shows an error message on a dark background. At the top left, the word "Error" is written in orange. In the center, "E02" is displayed in large orange font. Below it, a grey box contains the text "Insufficient Sample" in orange. At the bottom, there is a grey button with "OK" written on it.</p> | <p>E02: Blood Specimen Error An insufficient amount of blood has been applied.</p> <p>Solution Retest with a new test device with enough blood, ensuring that the sample is placed in the narrow channel at the top of the test device.</p> |
|  <p>The screenshot shows an error message on a dark background. At the top left, the word "Error" is written in orange. In the center, "E03" is displayed in large orange font. Below it, a grey box contains the text "Expired Device" in orange. At the bottom, there is a grey button with "OK" written on it.</p> | <p>E03: Expired Test Device The test devices are expired.</p> <p>Solution Retest with a new test device with a non-expired date.</p> |

| Indication | Error description |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>E04: Temperature Error Unknown Barcode</p> <p>The environmental temperature is above or below the operating range of the analyzer.</p> <p>Solution</p> <p>Move to an area in the acceptable temperature range for the analyzer and perform the test. Do not heat or cool the analyzer artificially.</p> |
|  | <p>E05: Communication Error</p> <p>Communication between the analyzer and barcode reader or printer has failed.</p> <p>Solution</p> <p>Reconnect the analyzer and the external device. If the error continues after turning the analyzer ON/OFF, please contact BioNote, Inc.</p> |
|  | <p>E05: Communication Error</p> <p>Communication between the analyzer and barcode reader or printer has failed.</p> <p>Solution</p> <p>Reconnect the analyzer and the external device. If the error continues after turning the analyzer ON/OFF, please contact BioNote, Inc.</p> |
|  | <p>E06: Total hemoglobin out of range</p> <p>The measured total hemoglobin is outside the range of 7 to 23g/dL.</p> <p>Solution</p> <p>This error occurs with specimens known to have total hemoglobin in the abnormal range. If the error continues after turning the analyzer ON/OFF, please contact BioNote, Inc.</p> |
|  | <p>Result: Invalid</p> <p>The test is invalid.</p> <p>Solution</p> <p>Retest with a new test device and a new specimen. If the error continues after turning the analyzer ON/OFF, please contact BioNote, Inc.</p> |

| Indication | Error description |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>The screenshot shows a black background with the word 'Error' in the top left corner. In the center, the code 'E12' is displayed in large orange letters. Below it, the text 'Calibration Overdue' is shown in a smaller orange font. At the bottom center, there is a grey button with the text 'OK' in white.</p> | <p>E12: Calibration Overdue The calibration is overdue.</p> <p>Solution If the error continues after turning the analyzer ON/OFF, please contact BioNote, Inc.</p> |
|  <p>The screenshot shows a black background with the word 'Error' in the top left corner. In the center, the code 'E13' is displayed in large orange letters. Below it, the text 'Not Supported Device' is shown in a smaller orange font. At the bottom center, there is a grey button with the text 'OK' in white.</p> | <p>E13: Unsupported Test Device Loaded test device is not appropriate for the analyzer.</p> <p>Solution Check the type of test device and confirm it is manufactured by BioNote, Inc.</p> |
|  <p>The screenshot shows a black background with the word 'Error' in the top left corner. In the center, the code 'EEE' is displayed in large orange letters. At the bottom center, there is a grey button with the text 'OK' in white.</p> | <p>EEE: Internal Error Message for the Analyzer An internal error has occurred.</p> <p>Solution If the error continues after turning the analyzer ON/OFF, please contact BioNote, Inc.</p> |

ANNEX 01. Information for Healthcare Professionals

Protection against Infections

There is a potential risk of infection. Medical staff using the BIONOTE V200 analyzer to perform measurements for more than one patient must be aware that any object coming into contact with the patient sample 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.

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 will be free from defects in materials and workmanship for a period of two years from the date of original purchase. If the analyzer does not work properly during this period because of a defect in materials or workmanship, 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 you will be instructed on how to do so. Analyzers returned without authorization will not be accepted.

Disposal

The BIONOTE V200 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 implements the provisions of the European Parliament and Council Directive 2002/96/EC aimed at reducing the amount of EEE waste for final disposal. Please contact our representatives in your area for the respective instructions before disposal.

