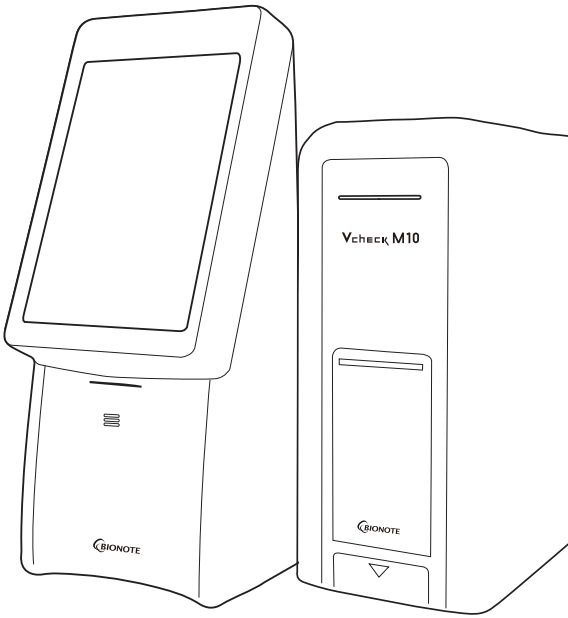
FOR VETERINARY USE ONLY

Vcheck M10

USER MANUAL



BIONOTE

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Thank you for purchasing Vcheck M10.

This user manual contains all information about the analyzer. Please carefully read this user manual and the instructions included in each test cartridge package before using the analyzer. In addition, please familiarize yourself with the necessary preparation and the procedures.

For further inquiries about the analyzer, please contact your local dealer.
Product demonstrations can be found at www.bionote.co.kr

TABLE OF CONTENTS

CHAPTER 1

General Information

1. Main Menu Structure 06
2. Symbols and Abbreviations 07
3. Precautions 09
4. Warranty and Free Warranty Period Service Policy 10

CHAPTER 2

Overview

1. Intended Use 11
2. Product Overview 11
3. Components of Vcheck M10 13
4. Software GUI Description 15
5. Components 16
6. Specifications 17
7. Unpacking 17
8. Precautions Before Measurement 18

CHAPTER 3

Log On and Setting

1. Initial Setup 19
   - 1.1 Installation
   - 1.2 Analyzer LogIn
   - 1.3 Analyzer Status Light
   - 1.4 Analyzer Settings

CHAPTER 4 **Run Test Mode**

1. Run Test 36
2. Result 41
3. Review 42

CHAPTER 5 **QC**

1. QC Test 43

CHAPTER 6 **Cleaning and Maintenance**

1. Analyzer Cleaning 46
2. Maintenance and Transportation 46

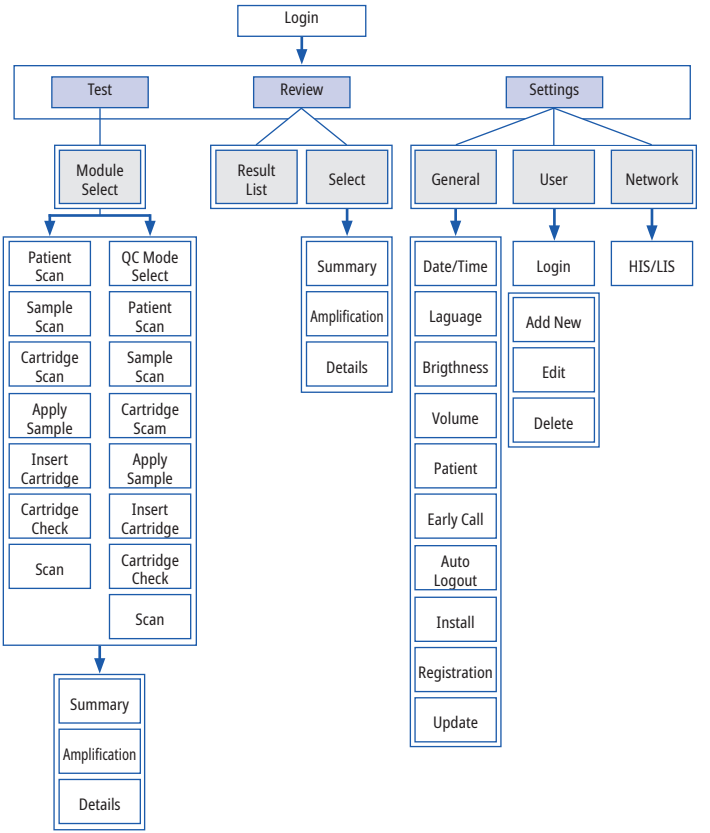
CHAPTER 7 **Warning/Info/Error Messages**

1. Warning Messages 47
2. Info Messages 48
3. Error Messages 50

CHAPTER 1

General Information

1. Main Menu Structure



2. Symbols and Abbreviations

The symbols and abbreviations presented below are stated in the user manual, labels, and external packages of Vcheck M10 System.

Symbols

Electrical Symbols on analyzer

Symbols	Description
	Indicates the ON position of the main power switch.
	Indicates the OFF position of the main power switch.
	Indicates the ON/OFF position of the main power switch.

Safety Symbols

Symbols	Description
	Caution Indicates a situation, which if not avoided, could result in damage to the analyzer or incorrect results.
	Indicates the presence of a laser inside the analyzer and to proceed with appropriate caution.

Environmental Symbols

Symbols	Description
	WEEE; crossed-out wheeled bin Discard separately from other disposal wastes

Symbols

Symbols	Description
	Manufacturer
	Consult instructions for use
	Reference number
	Date of manufacture Indicates the date of manufacture
	Serial number
	Note
	Indicates that the analyzer is fragile, and must therefore be handled with care
	Fulfills the requirements of Electro Magnetic Compatibility Directive 2014/30/EU, Low Voltage Directive 2014/35/EU
	Indicates to keep the analyzer dry that you should keep the analyzer dry
	EU Representative
	Temperature limit
	Humidity limitation

Abbreviations

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

3. Precautions

1. If the error message occurs repeatedly, do not use it.
2. Do not use the barcode for any purposes other than inputting the sample and cartridge barcode.
3. Be careful as the barcode light may damage your eyes.
4. Do not use the analyzer screen with sharp tools. Please note that it may cause malfunction due to a damaged screen.
5. Only designated technicians can perform related repairs and service activities.
6. Do not touch the switch button or the power supply with your wet hands.
7. Do not apply other products manufactured by the third party.
8. Before use, check the latest software with your dealer or BIONOTE. Then, start your updating.
9. It must be installed where the power supply and power switch are easily accessible, and easily disconnectable. (Installing the analyzer in an inappropriate location, such as where the system cannot be easily disconnected from the power supply, may cause fire or lead to a serious damage to the system.)
10. Use an approved adapter.

To Reduce the Risk of Damaging the Analyzer

- Use only for veterinary diagnostic.
- Store in a flat, dry place and avoid direct sunlight.
- Avoid extremely strong light as it can seriously interfere with test results.
- Do not move the analyzer during the test.
- Do not drop the analyzer as it may damage the analyzer.
- Do not disassemble the analyzer.
- Do not immerse the analyzer in water or cleaning solution.

To Reduce the Risk of Inaccurate Results

- For Veterinarian Use Only.
- Do not use if error messages occur repeatedly.
- Refer to the instructions included in each test cartridge package for precautions to ensure accurate results for each assay.
- Do not use any expired Vcheck M cartridges.

To Reduce the Risk of Biological Risk

- Used specimens must be properly disposed in accordance with the methods established by the 'Personal Information Protection Act' and hospital regulations. Specimens must be considered as potential biohazards.
- If you have no experience in specimen collection and handling procedures, you must receive appropriate training or guidance.
- Nitrile latex gloves are recommended when handling specimens.

4. Warranty and Free Warranty Period Service Policy

1. The free warranty period of Vcheck M10 System is 2 years from the date of product installation. In the case of consumable parts, a separate warranty period is not provided.
2. In order to receive the free warranty period, installation information must be provided to the manufacturer. (Inquiry separately)
3. During the free warranty period, the agency or corporation is responsible for handling the service for the products sold.

CHAPTER 2

Overview

1. Intended Use

The Vcheck M10 analyzer measures quantitative or qualitative biomarkers of specimens such as blood, feces, and nasal mucus in a laboratory or POCT environment.

Vcheck M10 consists of Vcheck M10 Console and Vcheck M10 Module (Cartridge analysis function). The Vcheck M10 Console is a analyzer that operates the Vcheck M10 Module based on the information obtained by scanning the 2D barcode of the cartridge.

The Vcheck M10 Console displays the results of monitoring and diagnosis of the inserted specimen. It must be used with designated test cartridges produced by BIONOTE Inc. For details on specific tests, refer to the instructions included in each of test cartridge packages.

2. Product Overview

The Vcheck M10 is a real-time PCR analyzer which automatically performs nucleic acid extraction and amplification, and detection of the target sequences in various specimens. Vcheck M10 is a closed system which is only used with BIONOTE Vcheck M cartridge. This Vcheck M10 analyzer consists of the Vcheck M10 Module and the Vcheck M10 Console. The entire PCR process is carried out inside the Module, and the Console controls the process and shows the results.

The cartridge is inserted into the Module to be nucleic acid extracted and thermo-cycled to achieve target amplification. In each cycle of the PCR, fluorescence intensity is measured and analyzed by the Console software to determine the presence of target pathogen in the specimen. The result is displayed on the Console screen and data is recorded in the memory.

[Vcheck M Cartridge]

Vcheck M **Assay Cartridge**	

3. Components of Vcheck M10

1) Vcheck M10 Console

Front	Side	Back

Item	Name	Description
A	Color TFT LCD screen	Displaying test screen and interacting with the graphic user interface.
B	Barcode reader	Used for scanning specimen IDs and cartridges barcodes.
C	Speaker	Audio output location.
D	USB port	Used for connecting with keyboard, printer and USB memory.
E	Power switch	Used for turning on/off the Console.
F	D-sub cable port	Used for connecting console and module using D-sub cable.
G	LAN port	Used for communicating through the local area network.
H	AC power port	Used for connecting AC Power cord.

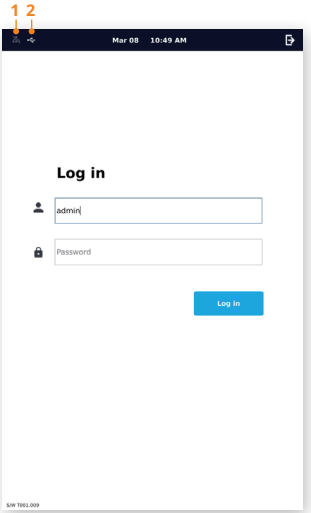
2) Vcheck M10 Module

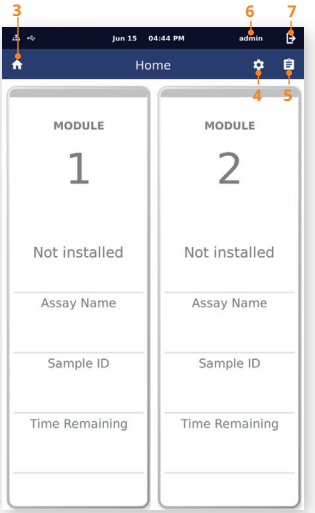
Front	Side	Back

A	Status notification LED	LED for indicating Module status.
B	Door	Insert or remove the test cartridge from the chamber inside the door.
C	Repair Cover	Cover for manual rotation of the rotating motor.
D	Fan Filter Cover	Cover for replacing the fan filter mounted on the vent that discharges heat to the outside.
E	Air Intake Filter Cover	Cover for replacing the filter mounted on the external air intake.
F	Mini-USB port	USB port for developers for FW update (not for users).
H	D-sub cable port	Used for connecting console and module using D-sub cable.
J	AC power port	Input port to connect power.
K	Power switch	Used to turn the Module on/off.
L	AC power port	Output port to connect power.

* G(USB port) and I(LAN port) functions are not provided to user.

4. Software GUI Description





No	Item	Name	Description
1		LAN	Indicate the status of wired LAN connection
2		USB	Indicate the status of USB connection
3		Home	Move to the Home screen
4		Setting	User setting
5		Review	Check accumulated results
6	admin	User	Indicate user's name
7		Log-Out	User Log-out

5. Components

1) Vcheck M10 Console

Item	Appearance	Description
D-sub cable		Connect D-sub between console and module
AC power cable		Connect AC power of console

2) Vcheck M10 Module

Item	Appearance	Description
Gender		Connect AC power/ D-sub between modules
AC cover		Terminate AC power of module (block the user contact)
Bracket		Connect upper side of the modules
AC power cable		Connect AC power of module

3) Accessory

Item	Appearance	Description
D-sub cable		Connect D-sub between console and module
Side Bracket		Connect modules which located up and down

6. Specifications

Item		Description
Input voltage		AC100~240V, 50/60Hz
Display control		Graphic User Interface (TFT LCD)
Power consumption		- Vcheck M10 Console : 84W - Vcheck M10 Module : 84W (Maximum 700VA when connecting 8 modules)
Number of memory		5,000
Communication		Ethernet, USB, d-sub
Number of cartridge per test		1 cartridge per test
Fluorescent channel		3 Channel (FAM, HEX, CY5)
Nucleic acid extraction	Sample type	Liquid media
	Technology	Silica technology
	Operation	Syringe air pressure
Temperature control	Temperature rise speed	≤ 3.5℃/sec
	Temperature drop speed	≤ 3.0℃/sec
	Accuracy	± 0.5℃
	Uniformity	± 0.3℃

7. Unpacking

Unpack the analyzer on a clean, level, and stable surface. The air vents on the analyzer are on the back. These vents must not be blocked when installing the analyzer. Avoid placing the analyzer in direct sunlight. Inspect for any obvious signs of damage. Report any damages immediately to BIONOTE. Allow the analyzer to equilibrate to room temperature at least 30 minutes before operating.

8. Precautions Before Measurement

Carefully read and follow this user manual and the instructions for the test cartridge and controls, so you can prevent inaccurate results and handle the analyzer safely. No modification of this analyzer is allowed.

Specimen

The Vcheck M10 must be used with a test cartridge suitable for particular tests. In addition, since different specimens are applied to each test, you must follow the instructions provided with each test cartridge.

Safety Information

There is the risk of infection. When professional veterinary personnel examines patients with the Vcheck M10 system, it is recommended to always wear gloves and follow other relevant health and safety regulations.

Operating Conditions

To correctly operate the Vcheck M10, please follow the guidelines below. The Vcheck M10 system must be operated in the permitted temperature range. Since the range is different for each test, please refer to the manual of the test cartridge suitable for the specific test. To perform a test on the Vcheck M10 system, place the system on a flat surface. Do not use the Vcheck M10 system near strong sources of electromagnetic radiation, because the strong electromagnetic fields may impair the function of the analyzer. There must be no foreign objects in the vents of the analyzer. (Do not block the vents.) If analyzer malfunction suddenly occurred, please unplug the power cable from the outlet. The power adapter must be IEC 60950-1 and IEC 60601-1 approved.

CHAPTER 3

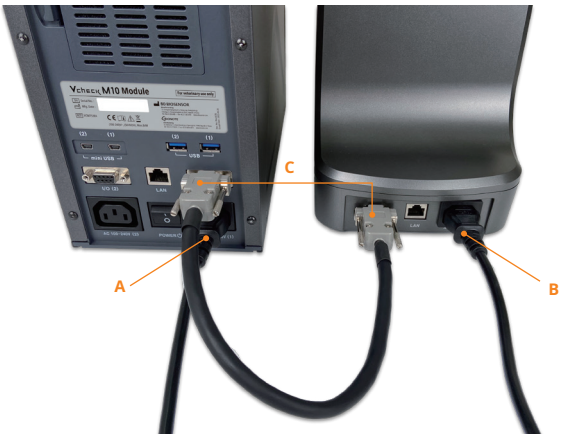
Log On and Setting

1. Initial Setup

1.1 Installation

1) M10 Console - M10 Module

- Place the analyzer in a suitable environment.
- Connect the supplied communication cable (D-sub cable) at the back of the Vcheck M10 Console and Vcheck M10 Module to link them together.
- Connect the supplied AC power cable to the Vcheck M10 Console and the Vcheck M10 Module respectively.
- Connect the power cord of AC cable to a power outlet



A. Vcheck M10 Module power cable (AC power cable)

B. Vcheck M10 Console power cable (AC power cable)

C. Communication cable (D-Sub cable)

2-1) Installing additional M10 Modules

- Connect the M10 Modules using the bracket and screws supplied with M10 Module.

Bracket

- Connect the supplied gender at the back of the M10 Module (#1) and M10 Module (#2) to link them together.

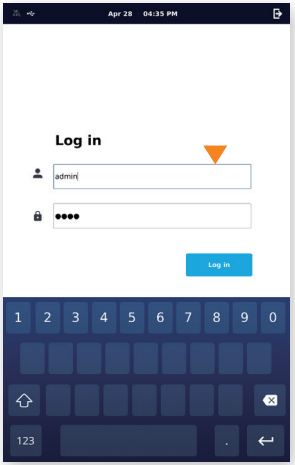
2-2) Installing additional M10 Modules

- Connect multiple modules using bracket and side bracket.

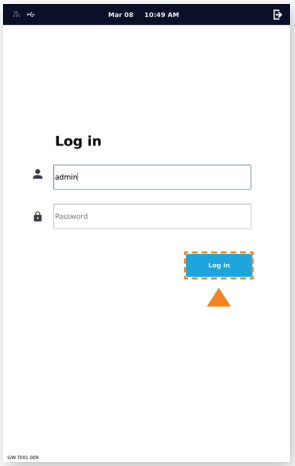
Bracket

Side Bracket

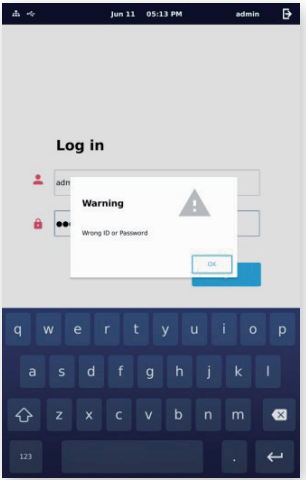
1.2 Analyzer LogIn



- To start, login after power on.
- Click the input box to create a virtual keyboard.
- Login ID is admin and password is 1111. (Change the password of "admin" account at initial log on for further security.)
- Click the input box to create a virtual keyboard.



- After entering the ID and password, press the Log in button to enter the Home screen.



- If you enter an incorrect ID or password, the icon may turn red and the warning pop-up may appear.

- If you log in successfully, an installation will proceed automatically.
- The installed modules are recognized in the order in which they are connected.

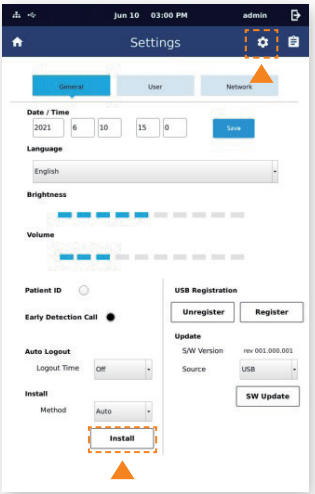
1.3 Analyzer Status Light

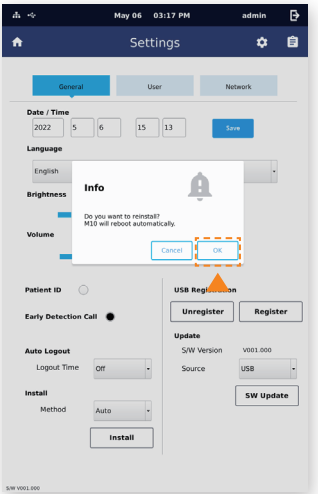
State	Red	Yellow
Indication	Not connected	Installing
LED sign		

State	Blue	Green
Indication	Connected	Running
LED sign		

When the connection is completed, you can use the analyzer.

- Re-installation is required for following situations.
  - When the number of M10 Module has changed.
  - When the position of M10 Module has changed.
  - If the number of connected M10 Module and the number of M10 Module recognized on UI are different. Please check the connection cables or gender.
- Re-installation Procedure
  - Only the admin account is able to proceed this task.
  - Click the install button on the Settings menu to proceed.
  - During the process, the yellow LED light may flash.
  - If the problem continues, check the connection between the console and modules. Turn off all power at least for 5 seconds and reboot.



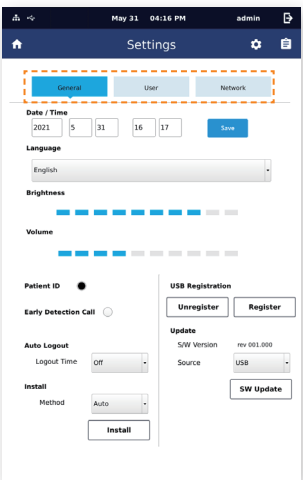


1.4 Analyzer Settings

- For the cyber security, the admin password must be changed at initial login.
- Important functions of the system, including updating of the system, can be changed and applied only by admin account. (After resetting the admin's password, it is very recommended to be noted.)
- While running the assays, the "Update", "Install", and "Network" functions are blocked, as these functions may affect the results.
- For details of the Settings menu, refer to the following.

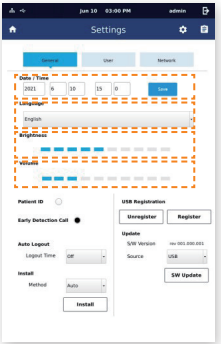
Stage	Menu	Sub Menu
1	General	Date/Time
		Language
		Brightness / Volume
		Patient ID
		Early Detection Call
		Auto Logout
		Install
		USB Registration
		Update
2	User	Add, Edit, Delete
3	Network	Network, HIS/LIS

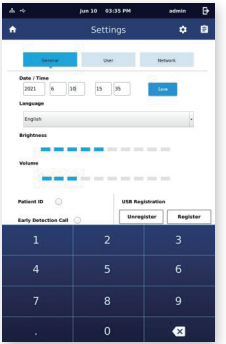
1. Select on the main menu screen to enter the Settings menu.



2. Settings menu consists of General, User, and Network.

3. In General category, you can set Date/Time, Language, Brightness/Volume, process updates, and Module installation.

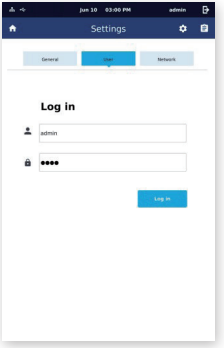




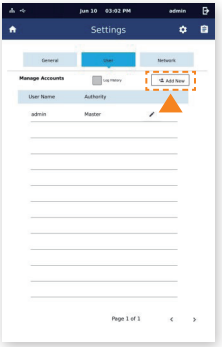
Menu	Description
Date/Time	You can set the year, month, day, hour, and minute. If you click the input box, a number keyboard will appear.
Language	English is the default.
Brightness	Adjust a total of 10 levels of brightness.
Volume	Adjust a total of 10 levels of volume, the minimum level is mute.
Patient ID	Turns ON/OFF whether to use Patient ID or not when performing a test.
Early Detection Call	If you use the Early Detection Call function, you can check the positive result while running.
Install	If the number of modules changes or there are issues with initial auto installation, please proceed with the re-installation.
USB Registration	For cyber security, only admin account can register or unregister the USB memory stick by using the Register button and the Unregister button.
Auto Logout	Set the automatic logout time. It has 'Off', '12 Hour', '24 Hour', '1 week'.
Update	Displays S/W version and F/W version and you can update S/W with USB.
Auto Logout, Update, Install functions can only be performed by an administrator.	

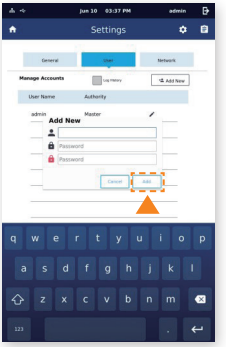
4. In User category, Operator ID can be registered, edited, and deleted.

5. If you click the input box, a keyboard will appear. In User category, the password is same as the Password when you logged in.

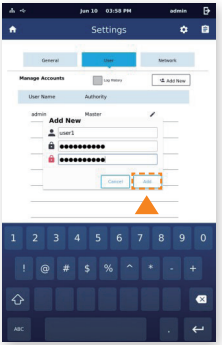


6. In User category, you can add an Operator ID by clicking the Add New button.

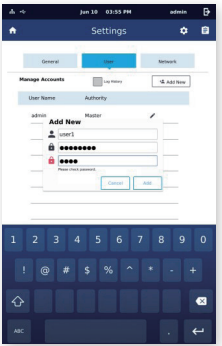




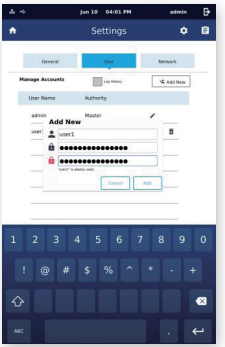
- Enter the ID and password to be added. Click the Add button.



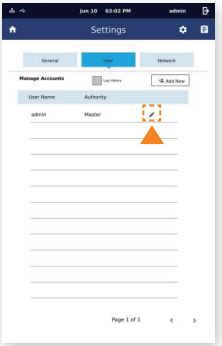
- If the password is incorrect, the '**Please check password**' will appear.

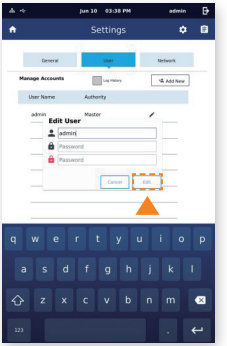


- If the same ID exists, '**User ID is already used**' will appear.
- Make sure that PW consists of 8 to 15 characters including numbers and lowercase letters.

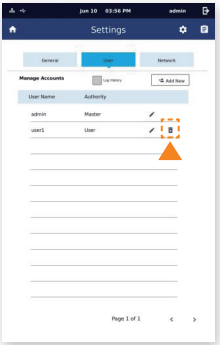


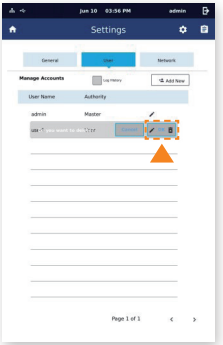
7. To edit the Operator ID, select the ID to be modified. Press [✎] button on the Edit screen.
- After modifying the ID and password, click the [Edit] button.





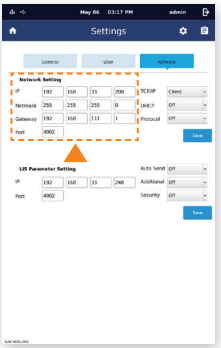
8. To delete the Operator ID, select the ID to be deleted and press button. Then press the OK button on Delete screen.



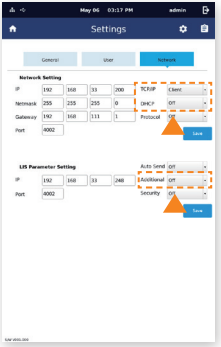


9. In Network category, you can set the Network of HIS/LIS and analyzer.

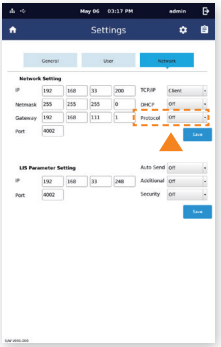
- Set the network IP, Netmask, Gateway, Port of the M10 Console. Apply it through the Save button.



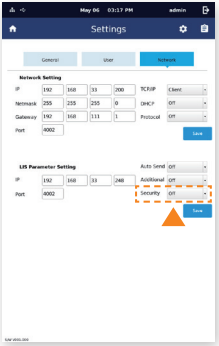
- This is the UI for TCP/IP, DHCP, and Additional to use extensions. This is not currently used.



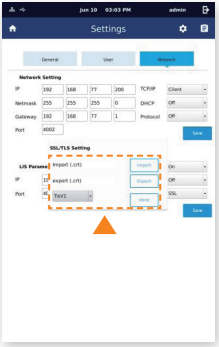
- Protocol has Off/HL7/LAW methods. Select the desired communication method among them. After that, click the Save button to apply the desired results. (If Off is selected, the result data for the patient will not be transmitted even if the Auto send function is activated.)



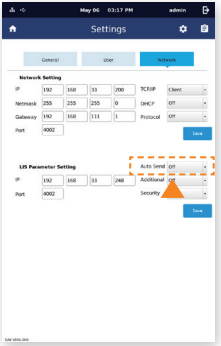
- Security can be set to Off or SSL. If SSL(Off) is selected, it operates according to the protocol Off/HL7/LAW set above. If SSL(Off) is selected, a pop-up window will appear.



- When you click Import, the *.crt file in the USB memory will install the certificate into the M10 Console. When you click Export, the certificate in the M10 Console is saved as a USB memory address (the top path of the inserted USB memory/Certificate/sddev.crt). Check the certificate regarding the designated person and the issuer "M10 Self Signed".



- Auto Send sets whether to send the result data after testing the patient to the server, applying the set protocol and security. When set to On, the setting is activated. (For example, if protocol HL7 setting and Security Off are set, the patient's test result is transmitted to the server without security through HL7 communication.)



CHAPTER 4

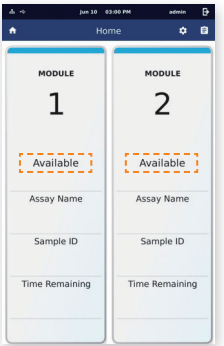
Run Test Mode

Check the followings before performing assays.

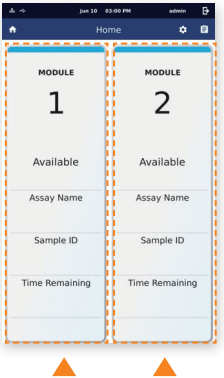
- Is the power cable connected to the analyzer?
- Is the set date and time on the analyzer correct?
- Have you checked the analyzer settings?

1. Run Test

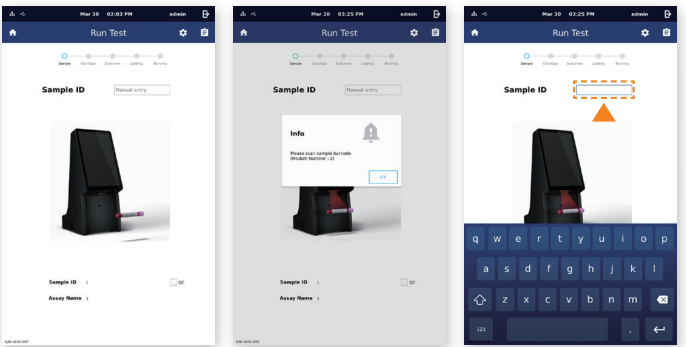
1. By selecting button, you can check the progress status of M10 on the Main screen. Depending on the operation status of M10, the progress status is displayed as Running, Completed, Available.



2. Select the M10 Module to drive press to move to the next step. (Only M10 Modules in Completed or Available status can be operated.)



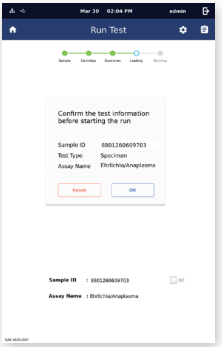
3. Scan the barcode of the sample or manually type the sample ID. If the input is successful, it automatically moves to the next step. Before starting the test, remove any cartridges or materials inside the module. If not, a pop-up will appear asking you to remove it.



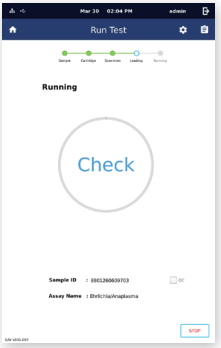
4. Scan the barcode of the cartridge to be used. If the input is successful, it automatically moves to the next step.

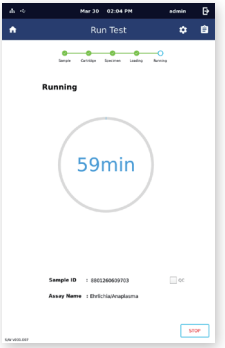
5. Inject the specimens into the test cartridge. Then touch the screen or wait 9 seconds. Place the cartridge in the M10 Module immediately. Close the M10 Module door manually. (Refer to Procedure in the assay specific Vcheck M Cartridge instructions for further details.)

6. If the cartridge is inserted into the M10 Module, the next screen will be displayed. Select OK to proceed, or select Reset to restart.

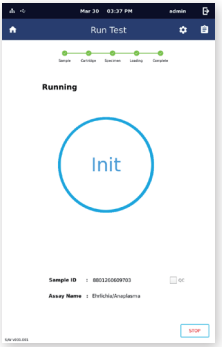


7. It automatically checks the surface temperature of the cartridge and the proper operation of the optical module. After that, the test proceeds.





8. When the assay is completed, the M10 Module Door opens automatically. Once the operation is completed, remove the used cartridge immediately. Dispose of as biohazardous waste and dispose of immediately.

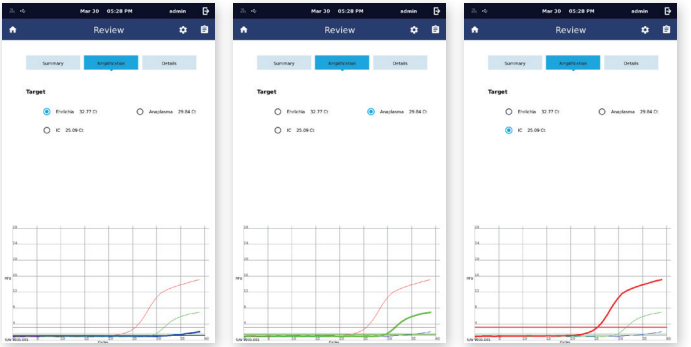


2. Result

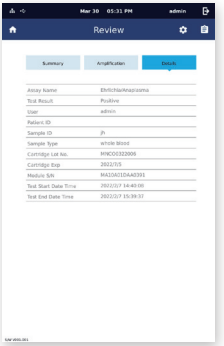
In Result, you can check the test results.

1. You can check the summary of a result in the Summary tab.

2. You can check the target amplification graph for each item in the Amplification tab.

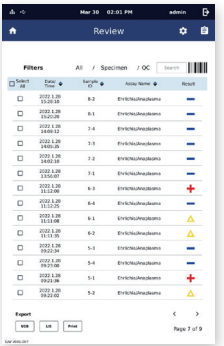


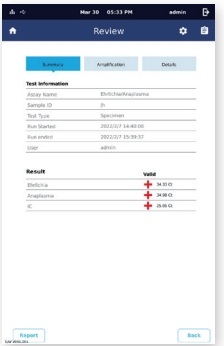
3. You can check detailed result information in the Details tab.



3. Review

You can check the accumulated test results in Review . You can check the detailed results of each test.





CHAPTER 5

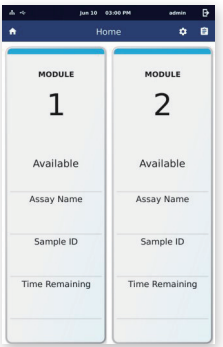
QC

Check the following before performing measurements.

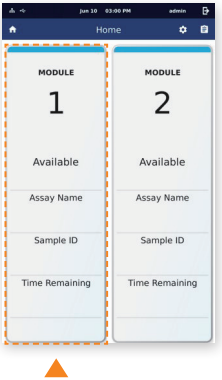
- Is the power cable connected to the analyzer?
- Is the set date and time on the analyzer correct?
- Have you checked the analyzer settings?
- Is the QC control solution ready?

1. QC Test

1. By selecting button, you can check the progress status of M10 on the Main screen. Depending on the operation status of M10, the progress status is displayed as Running, Completed, Available.

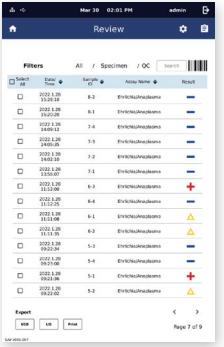


2. Select the M10 Module to move the next step. (Only the analyzer with Completed or Available status can be operated)



3. The barcode of the specified QC Solution should be scanned. If the barcode of the QC to be tested is recognized, it automatically moves to the next stage. If you scan the QC barcode provided by the BIONOTE, the QC check box is automatically checked.

4. The next step will be proceeded the same as the Run Test.
5. If the test is completed, the result will be recorded in Review. If you click the QC filter, you can review only QC results.



CHAPTER 6

Cleaning and Maintenance

1. Analyzer Cleaning

To prevent malfunction of the analyzer, a test cartridge inlet should be free of moisture or dust from the specimen. Clean the analyzer using lint-free cloth and appropriate cleaning solution (ex: mild soapy water, 70% of ethanol or isopropyl alcohol etc.). When using the analyzer for professional purposes (ex: operating room), it is recommended to clean it with a mixture of 1-propanol, 2-propanol, and glutaraldehyde (trade name “Bacillol plus”).

Do not use abrasive cloth or antiseptic solution as this may damage the display screen. Always turn off the analyzer and remove the power cable before cleaning.

2. Maintenance and Transportation

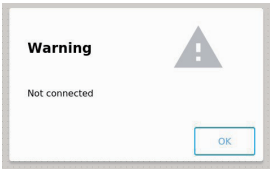
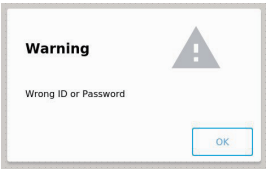
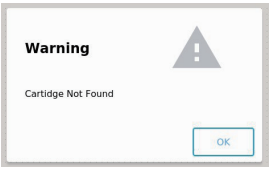
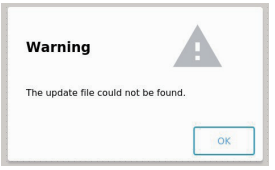
If there is any problem on the Vcheck M10 system, the Console automatically shows what went wrong for each time the system is powered on.

- Be careful that test device insertion and analyzer internal parts should not be contaminated by dust.
- Transport case is designed to store the supplied components and protect the analyzer.
- Store the analyzer at -20°C ~ 50°C / 0% ~ 93% RH.

CHAPTER 7

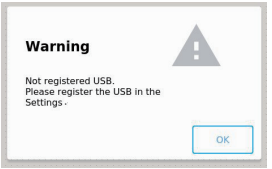
Warning/Info/Error Messages

1. Warning Messages

Indication	Warning Description
	**Warning: Not connected USB** USB is not connected to analyzer. **Solution** Confirm that USB is correctly inserted into analyzer.
	**Warning: Wrong ID or Password** Wrong ID or password is input. **Solution** Input the correct ID or password.
	**Warning: Cartridge Not Found** The door is closed but there is no cartridge inserted. **Solution** Open the door and insert the cartridge to re-test.
	**Warning: The update file could not be found.** There is no update file in USB. **Solution** Check if there is an update file on the USB. If you confirm that there is an update file, insert the USB and press 'OK'.

Warning: Please reject cartridge.
Please remove any cartridges or stuck material inside the M10 Module before proceeding the test.

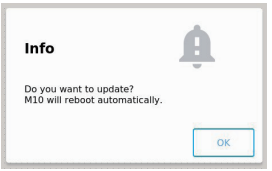
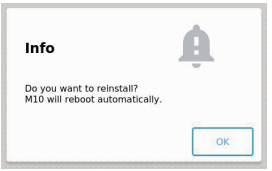
Solution
After removing the cartridge or stuck material inside the M10 Module, click the OK button..

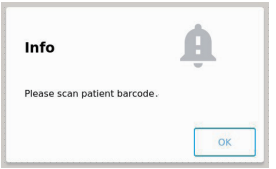


Warning: Not registered USB.
The USB memory stick inserted into the M10 Console is not registered.

Solution
In the order of "Setting -> USB Registration -> Register," register the use of USB memory.

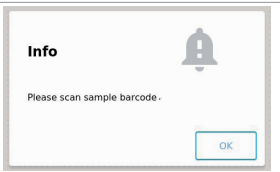
2. Info Messages

Indication	Info Description
	**Information: Check updates.** **Solution** Check for updates.
	**Information: Check if M10 Module is reinstalled.** **Solution** Check for reinstall.



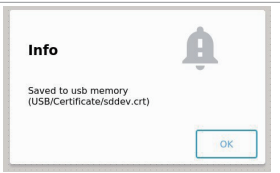
Information: Please scan patient barcode.

Solution
As this error occurs when scanning the Vcheck M Cartridge, please scan the patient barcode.

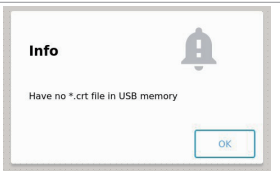


Information: Please scan sample barcode.

Solution
As this error occurs when scanning the Vcheck M Cartridge, please scan the sample barcode.

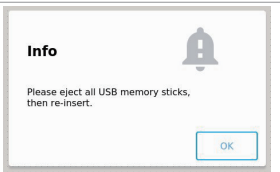


Information: Saved to USB memory



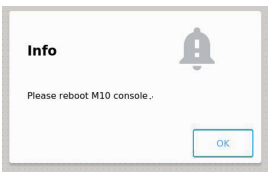
Information: Have no *.crt file in USB memory

Solution
Copy the certificate file (*.crt) you want to install into the USB memory and try again.



Information: Please eject all USB memory sticks, then Then re-insert it.

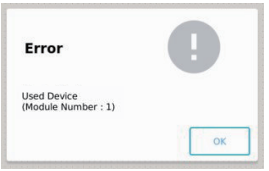
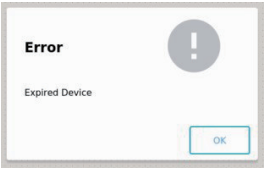
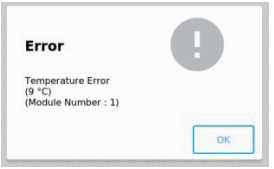
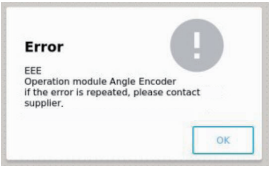
Solution
This is an alarm when trying to register USB security. After removing all USB memory, insert it again and proceed registering USB security.

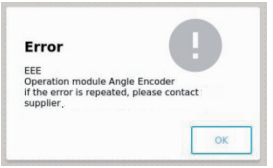


Information: Please reboot M10 Console.

Solution
It is an alarm related to the provided function and the UI. There is no problem in operation, but a reboot is recommended.

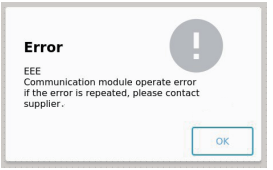
3. Error Messages

Indication	Error Description
	**Error: Used Device** Test cartridge is damaged or inaccurately inserted into the analyzer. **Solution** Discard the failed test cartridge and re-test with a new test cartridge and new specimen.
	**Error: Expired Device** Expired test cartridge is used. **Solution** Re-run the test with a new test cartridge that has not expired.
	**Error: Temperature Error** The cartridge temperature is out of. **Solution** The analyzer and the inspection cartridge are moved within an appropriate temperature range and the test is performed. Do not artificially heat or cool the analyzer.
	**Error: Operation module Angle Encoder Error** While operating the cartridge in the M10, problem occurred in the operation of lower angle motor. **Solution** If error occurs, the tests will be canceled and the door of M10 Module will be opened. Proceed the test with a new cartridge. If the symptom recurs, contact the supplier.



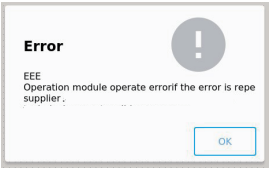
Error: Operation module Piston Encoder Error
While operating the cartridge in the M10 Module there was a problem with the operation of the vertical piston motor.

Solution
If error occurs, the tests will be canceled and the door of M10 Module will be opened. Proceed the test with a new cartridge. If the symptom recurs, contact the supplier.



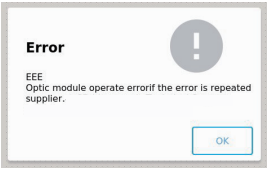
Error: Check the connected module information
Error occurring in M10 communication control module.

Solution
If the Connect number is displayed differently from the Total number, turn off the power of M10 Console and M10 Module and check if the cable and gender are properly connected.



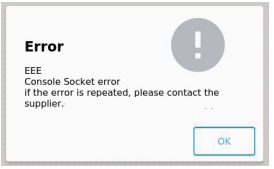
Error: Operation module operation error
Error occurring in M10 motor operation module.

Solution
Turn off the power of M10 Console and M10 Module and check if the cable and gender are properly connected.



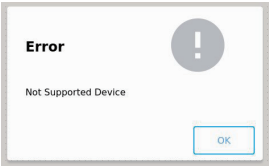
Error: Optic module operation error
Error in M10 Optical Measurement Module.

Solution
Turn off the power of M10 Console and M10 and check if the cable and gender are properly connected.



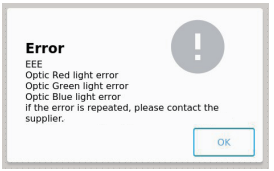
Error: Console Socket error
Error occurring in M10 socket communication console.

Solution
Turn Off the power of M10 Console and M10 Module and check if the cable and gender are properly connected.



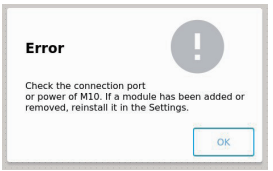
Error: Not Supported Device

Solution
Use the cartridge barcode provided by BIONOTE.



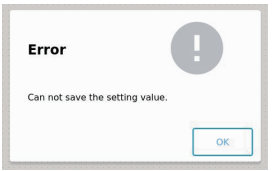
Error: Optic Detail Error.
Error in M10 Optical Measurement Module.

Solution
Turn off the power of M10 Console and M10 Module and check if the cable and gender are properly connected.



Error: Check the connected module information
Connect UI number and it must be identical to the number of physically installed M10.

Solution
If the Connect number is displayed differently from the Total number, turn off the power of M10 Console and M10 Module and check if the cable and gender are properly connected.



Error: Network setting is not properly completed.
The setting of network related to the Network and LIS of M10 Console is incorrect.

Solution
Check the network settings again, and contact the network administrator.