Instructions For Use

IVD Rx only

REF LAM301-01

LOAA Analyzer

ON-POINT

For *in vitro* Diagnostic (IVD) Use

OPTOLANE Technologies, Inc.

Table of Contents

I. Intended Use of LOAA Analyzer

LOAA Analyzer is Real-time PCR instrument which is an in vitro diagnostic (IVD) medical device used to amplify specific genes (DNA or RNA) designed for use with LOAA Dr. PCR cartridges. PCR reaction data is automatically analyzed by the dedicated software installed in the device and results are delivered to users through on-screen display or export to external memory for further processing. This device is limited to professional use only.

II. Features of LOAA Analyzer

LOAA Analyzer is a diagnostic device to detect specific genes (DNA or RNA) of various target diseases by analyzing PCR reaction data from the CMOS photo sensor-based cartridge. It is equipped with a thermal controller to perform thermal cycling of PCR reaction, processing blocks and software to control the workflows of raw data acquisition from PCR reaction, raw data analysis, result calculation for diagnosis. It is also equipped with 5.5-inch touch LCD display for user to control/check the device operations and USB port, WiFi module to communicate with other devices.

III. Customer and Technical Support Team

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For customers outside of Republic of Korea, please contact your local sales representative or authorized distributors first for customer and technical support.

IV. Safety Warnings and Precautions

1) This device is a medical device and is not intended for any purposes other than in vitro diagnosis.
2) This document should only be used for the purpose of operating the LOAA Analyzer.
3) Before using this device, be sure to read the formal manual carefully and check the components included in the product.
4) No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of OPTOLANE Technologies, Inc.
5) Keep the device in the specified working sequence. If the device is used in a manner not specified by OPTOLANE Technologies, Inc, the protective function of the device may be impaired.
6) Disposable cartridges used in the experiment should be handled in accordance with the instructions for use and be disposed of in the manner prescribed by law.
7) All test procedures should follow the safety rules of each testing laboratory.

V. Indicators of LOAA Analyzer

A. Safety indicator attached on LOAA Analyzer

Safety symbol	Description
	**CAUTION!** Do not operate at low temperature. It may occur malfunction due to condensed water vapor.
	**Warning!** Pay attention to the door operation. Be careful when open and close the door. Do not force open or close the door.
	**WARNIG! Risk of electrical shock!** Do not disassemble the equipment. There is a risk of electric shock.
	**Warning; Hot surface** To warn of a hot surface

B. Electric indicator of LOAA Analyzer

Symbol and indicator	Description
	Indicates the ‘ON/OFF’ switch of the main power.

C. Environmental indicator of LOAA Analyzer

Symbol and indicator	Description
	Do not dispose of LOAA Analyzer as unsorted waste. In order to minimize the environmental impact of wasted electric and electronic equipment, please comply with applicable laws and regulations on wastes.

VI. Safety Warnings and Precautions of LOAA Analyzer

Warnings and precautions are for proper use and safe operation of the equipment. Users who handle the equipment should observe all the following matters for safety. OPTOLANE Technologies, Inc is not responsible for any failure to comply with the following safety warnings and precautions.

A. Precautions for using the equipment

(1) Check whether the power cord is connected to the external power source (100-240V~, 50/60Hz), and whether it is properly installed in the equipment. Incorrect connection of the power cord may cause damage or failure of the equipment when the equipment is turned on.

(2) This equipment is used for nucleic acid amplification, so please use it for the proper purpose.

(3) Do not turn off the power or unplug the power cable when the equipment is running. An error may occur, causing equipment to fail or affecting the results of the experiment.

(4) Install the equipment on a flat surface.

(5) Do not drive the equipment with wet hands as it may cause electric shock or equipment failure. When touching the power cord, work with water-free hands as well.

(6) If the user makes a mistake, including the use of inappropriate accessories, or if the equipment is forcibly stopped during normal use, the equipment may be stopped.

(7) Do not place anything on the front and back of the equipment. Blocking the airflow of the cooling fan may reduce the cooling performance of the equipment.

(8) Do not insert foreign objects into the ventilation openings on the front, rear, or life side of the equipment. The performance of the cooling fan may be deteriorated due to foreign objects, causing the equipment to overheat and causing a fire.

B. Precautions for electrical environment

(1) Do not use the equipment with a damaged power cord. Overheating the power cord may cause electric shock or fire.

(2) Do not connect multiple devices to one external power source. Overheating may cause fire.

(3) When connecting or disconnecting the power cord from an external power source, make sure that your hands are dry. Moisture may cause electric shock.

(4) Use only the power cord supplied by the company.

(5) The socket outlet should be installed at least 1.5 m from the sink or basin.

(6) Do not repair the power outlet with insulating tape. Moisture can penetrate into the tape.

(7) If you use a power cord other than that supplied by the company, you must use the one that meets the rated voltage and current.

(8) The plug must be suitable for the socket outlet.

(9) To prevent fire due to overheating, disconnect the power cord from LOAA Analyzer when not using it for a long time.

(10) Use of improper high-voltage power may damage the wiring system of the equipment, which causes fire. Before applying power to the equipment, make sure that the power supplied to the laboratory matches the power of the equipment.

C. Precautions on the operating environment

(1) Do not place anything near the equipment.

(2) Do not install the equipment in a dusty place. Excessive dust may cause equipment failure or damage.

(3) Do not install the equipment near a heat source. There is a risk of fire.

(4) Do not install the equipment near water or damp places. It may cause electric shock, fire or equipment failure.

(5) Do not install the equipment near corrosive or flammable gases. If a corrosive or flammable gas leaks, do not touch the power cord, but open the window for ventilation. Sparks on the power cord may cause fire and explosion.

(6) Do not disassemble or modify the equipment in any way. It may cause fire, electric shock or equipment failure, and in this case, the equipment cannot be guaranteed.

D. Warnings and Precautions on the equipment installation

(1) Do not install this equipment in a place exposed to direct sunlight.

(2) Please install the equipment on a stable flat surface.

(3) When installing the equipment, install it at least 15 cm from the nearest wall.

E. Warnings and Precautions for operating the equipment

(1) Remove dust around the power plug and connect it securely so that the plug does not shake. Incomplete connections may cause fire.

(2) Operate the equipment at a temperature between 15℃~30℃(59~86℉). Exposure of the equipment at high temperature may affect the equipment, causing inaccurate results.

(3) Operate the equipment in the recommended humidity range (20 ~ 80 %, free of moisture condensation). Moisture may cause equipment corrosion or failure.

(4) Do not place anything on the side or back of the equipment. It may cause equipment failure.

(5) This equipment contains precision machined parts. Do not drop or shake it violently. It may break and damage the safety of the equipment.

(6) If the equipment is not used for a long time, please turn off the power of the equipment and block the external power supply. Otherwise, there is a risk of overheating and fire.

(7) It may cause burns to your hands or body. Do not manually open the cover during operation.

(8) If you touch ventilation openings or parts of equipment in operation, be careful as your hands may be pushed, torn or subjected to static electricity shock.

F. Warnings and Precautions for using and maintaining the product

(1) Please use this product for nucleic acid amplification purpose. Do not use the equipment for any purpose other than those specified in the Instructions For Use.

(2) Use only the supplied accessories and recommended cartridges.

(3) Do not modify or delete the equipment-related information displayed on the equipment.

(4) When using the touch LCD screen, do not use your fingernails or other sharp materials as they may cause damage to the product.

(5) Do not use a strong surfactant or solvent to clean the surface of the equipment. The color of the equipment may change. If this kind of material spills onto the equipment, wipe it off with soft cloth immediately.

(6) Do not store the equipment in a humid place. If stored in such a place, it may be damaged by moisture, and the damaged equipment cannot be guaranteed. In this case, repair may not be possible.

(7) If the equipment is disassembled or remodeled, it cannot be guaranteed, and the service may be refused.

(8) Do not disconnect the power cord while using the equipment. It may cause equipment failure.

(9) If there is a burning smell or if the equipment in operation is very hot, stop operating the equipment immediately and contact customer service or your sales representative.

(10) Do not drop the equipment or apply any impact on it. The equipment may be damaged directly and may not be guaranteed.

G. Precautions when moving the equipment

Improper lifting of the equipment may cause serious and permanent injuries to the waist. Depending on the weight, more than two people may be required to move the equipment.

H. Warnings on Biological and Chemical Hazard Safety

(1) Biological samples such as tissues, body fluids and blood derived from human body may potentially carry infectious diseases. Be sure to follow the regulations in your area and country. Wear safety goggles, laboratory gowns and gloves during the experiment.

(2) Before handling chemicals, be sure to read the Material Safety Data Sheets (MSDS) issued by the manufacturer carefully and check the relevant precautions.

(3) Before making changes to the contents of equipment components and reagents, always check which chemicals have been used. Wear appropriate safety goggles, laboratory gowns and gloves when using the equipment.

(4) Minimize contact with chemicals. Wear personal protective equipment when handling chemical substances.

VII. FCC Statement

- 15.105 (a) For a Class A digital device or peripheral, the instructions furnished the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

LOAA Analyzer has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
- For product available in the USA/Canada market, only channel 1~11 can be operated. Selection of other channels is not possible.
- This device is going to be operated in 5.15~5.25GHz frequency range, it is restricted in indoor environment only.
- **IMPORTANT NOTE:**

FCC Radiation Exposure Statement:

LOAA Analyzer complies with FCC radiation exposure limits set forth for an uncontrolled environment.

LOAA Analyzer should be installed and operated with minimum distance 20cm between the radiator & your body.

LOAA Analyzer and its antenna(s) must not be co-located or operation in conjunction with any other antenna or transmitter.

1. Introduction of LOAA Analyzer

1.1. Intended use of LOAA Analyzer

LOAA Analyzer (Model name: On-Point) is Real-time PCR instrument which is an in vitro diagnostic (IVD) medical device used to amplify specific genes (DNA or RNA) designed for use with LOAA Dr. PCR cartridges. PCR reaction data is automatically analyzed by the dedicated software installed in the device and results are delivered to users through on-screen display or export to external memory for further processing. This device is limited to professional use only.

Figure 1. Appearance of LOAA Analyzer (Model name: On-Point)

1.2. Use restrictions

- This product can only use LOAA cartridges.
- For in vitro diagnostic medical devices only
- Use only the supplied adapter when connecting the device to a power source
- Do not reuse cartridges related to errors, incomplete tests or invalid results

1.3. Dr. PCR Cartridge

LOAA PCR Cartridge (Figure 2) is a disposable and closed-system product containing primers and probes required for amplification and detection of target nucleic acid samples. The cartridge mainly consists of a CMOS photosensor with a well array where nucleic acid is amplified, and fluorescence is detected, a microfluidic component where PCR mixture solution is delivered into each well, and a solid plastic body. Real-time gene amplification (including reverse transcription PCR) and results analysis are performed through a reader system called LOAA Analyzer. Since all the information for a diagnostic item and the PCR protocol is written inside the CMOS semiconductor chip, by simply loading the cartridge in the analyzer real-time PCR can start without any handy PCR parameter setting.

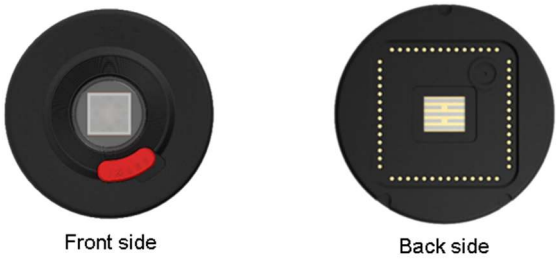


Figure 2. Dr. PCR Cartridge

Fluorescence intensity at each well is detected by the CMOS photosensor chip at each thermal cycle during PCR amplification. The fluorescence intensity real-time curve is generated and analyzed by the LOAA software in the analyzer to determine if targets are detected at each well.

1.3.1. LOAA Sample Loader (Model name: POSTMAN) and Dr. PCR Cartridge Interaction

Before starting the test, Dr. PCR cartridge should be loaded into LOAA Sample Loader (Model name: POSTMAN) in order to deliver appropriated amount of sample solution into the well array. Put the liquid reagent prepared with the purified nucleic acid and PCR reagents into the cartridge injection port using a disposable pipette. When you press the activating button on the LOAA Sample Loader (Model name: POSTMAN), the sample mixture automatically enters the individual well inside the cartridge and the operation stops automatically when the injection is complete.

1.3.2. Interaction between LOAA Analyzer and cartridge

The mixture of purified nucleic acid and sample master mix amplifies both the control material and the target identified by the cartridge. Cartridge and equipment perform reverse transcription and/or thermal cycling (heating and cooling of the solution) for PCR reaction. Thermal cycle control parameters are set appropriately according to the associated test protocol for each specific reagent cartridge and sample type.

1.3.3. PCR reaction analysis

To identify the target in a positive PCR reaction, LOAA performs a fluorescence amplification curve analysis. During each PCR cycle, multiple images of PCR well array are captured and fluorescence levels of valid wells are calculated and fluorescence amplification curve is generated at each PCR cycle by the software installed in LOAA. Based on this curve, if it turns out to be a valid PCR reaction through PCR control reaction result analysis, PCR reaction result that which targets are detected in the sample is delivered to user. Validation of proper operation of the optical system included in LOAA Analyzer is monitored through device self-check operation and cartridge PCR control reactions.

1.4. LOAA Analyzer Software

LOAA Analyzer software provides the system controls the operation of LOAA Analyzer. The software also collects, analyzes, and archives data generated by the device. The analysis results are presented in the test result table. Detailed information on the features and operation of LOAA Analyzer software is provided in Chapter 5.

2. Installation of LOAA Analyzer for Cartridge System

2.1. Installation requirements

Choose a location for LOAA Analyzer system with a clean, well-ventilated flat table where you can place LOAA Analyzer.

- Keep space of at least 15 cm between the product and the wall.
- Power specifications: 100~240 Vac, 50/60Hz 1.3A (Output: 24 Vdc, 3.75A) use a rated adaptor.

LOAA Analyzer complies with the emission and immunity requirements of IEC 61326-1. It is recommended that you evaluate the electromagnetic environment before operating the device.

Caution!

Do not position the LOAA Analyzer and LOAA Sample Loader in such a way that it is difficult to disconnect the power adapter and cord set from the devices.

2.2. LOAA Analyzer System Components

Each system is provided with devices, Instructions For Use, DC adapter and cord. The contents of each box are shows in Figure 3.

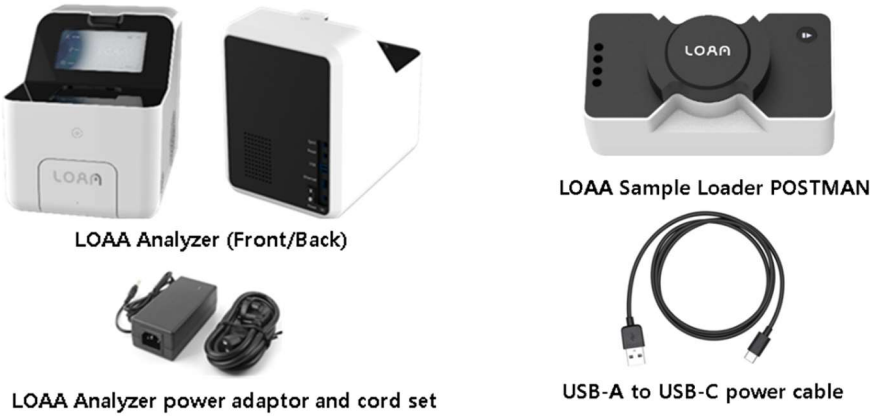


Figure 3.LOAA Analyzer Components

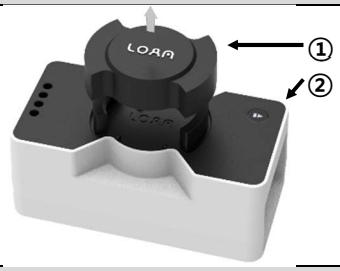
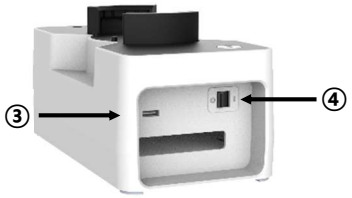
Note The LOAA Sample Loader (Model name: POSTMAN) is delivered separately in its own box. USB-A to USB-C power cable is provided and any USB power adaptor with output power rating of 5V, 1A or more can be used as a power supply for LOAA Sample Loader (Model name: POSTMAN).

2.3. Appearance of LOAA Analyzer

Front	Back
	

No.	Name	Description
①	Bar code scanner	1D/ 2D bar code scanner to read sample ID
②	LCD touch screen	LCD display with multi-touch function
③	Cartridge loader door	Cover for cartridge loading area
④	Power button	Equipment power ON/OFF button
⑤	Right-side vent	Inhale external air for cooling module
⑥	Cartridge loader	Tray to install cartridge and move to/from inside of the device
⑦	Back-side vent	Exhausting warm air from cooling module
⑧	Eject Button / Reset button	Buttons for cartridge manual eject / device reset
⑨	USB port	USB memory connection port for data export or software update
⑩	Ethernet port	RJ45 ethernet cable connection port
⑪	DC adapter port	24 V DC power input for the device
⑫	Main power switch	Control main power supply to the device

2.4. Appearance of LOAA Sample Loader (Model name: POSTMAN)

Front	Back
	

No.	Name	Description
①	Lid	Dust protection cover
②	Operation switch	Equipment operation switch
③	USB C-Type power supply plug hole	Equipment power terminal
④	Power switch	Equipment power ON (I) / OFF (O) switch

2.5. Installation of LOAA Analyzer System

1) Unpack the equipment and place it on a solid, flat surface.
2) Connect the equipment power adapter to the DC connector on the back of the equipment (dashed rectangle).
3) Turn on the main power switch at the bottom of the equipment rear panel.
4) Start the LOAA Analyzer by pressing the power button on the front center for about 4 seconds.
5) Set up the initial environment settings such as language, network configuration, date/time, brightness, volume, administrator password, user password, and general information. You need to set it up once at the beginning.

※ Initial environment settings can be reconfigured later in the setting menu. (See Section 5.6)

6) When the LOAA Analyzer is powered on, the login screen (Figure 4) is displayed and you can go to the main screen after entering correct user password (Figure 5, Figure 6). User password has been set in initial configuration step.

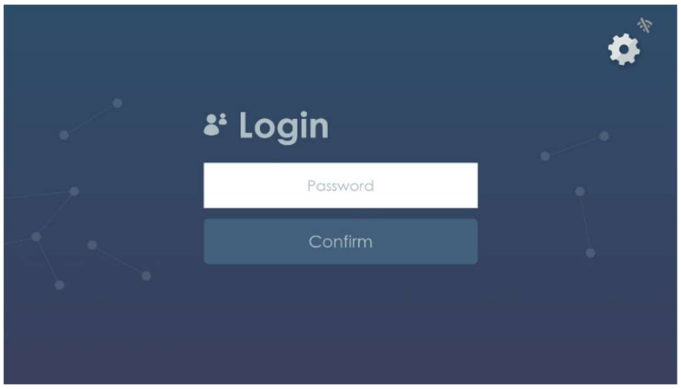


Figure 4. Login screen of LOAA Analyzer (Network connection OFF)

※ For how set a password, refer to Section 5.6.

※ For network setting method, refer to Section 5.6.

Figure 5. Home screen of LOAA Analyzer (wireless network OFF)

Figure 6. Home screen of LOAA Analyzer (Ethernet network ON)

7) For LOAA sample loader POSTMAN, connect provided DC adaptor to USB-C port at the one side of the device (③ in section 2.4). Turn on the power switch at the same side with USB-C ports (④ in section 2.4). Once power is supplied, activating button at the top surface (② in section 2.4) will light in green color.

2.6. LOAA Analyzer Device status

The status is displayed on the front LED light of the LOAA Analyzer.

- Rainbow color random flashing: device is not in PCR operation
- Green flashing: device is in PCR operation

Please keep the packing materials and the box as the equipment may be shipped to the OPTOLANE Technologies, Inc. for A/S.

Before requesting A/S, be sure to check Chapter 7 preventative maintenance and troubleshooting described in the Instructions For Use.

If the problem is not solved, please contact our Customer Support Team (+82-31-881-9600) or your sales representative.

3. Operating Principles

LOAA Analyzer is an in vitro diagnostic system that diagnoses targets in the clinical sample by using multiplex real-time PCR to synthesize cDNA from nucleic acids extracted from whole blood, plasma, serum or urine, and to amplify the synthesized cDNA as template.

Users of LOAA Analyzer system install the cartridge to the LOAA Sample Loader POSTMAN, inject the extracted nucleic acid sample to the cartridge, place it on the device and start the test.

LOAA Analyzer interacts with a cartridge to amplify the RNA or DNA sequence of the pathogens in the sample under examination. The resultant PCR products are automatically measured and analyzed by LOAA Analyzer to display the test results.

3.1. Basics of PCR

Polymerase chain reaction (PCR) is a process that produces billions of copies of DNA. If the target is RNA, reverse transcription is performed at 50°C to synthesize cDNA. Then DNA double strand is split into two single strands at 95°C and the probe is bound to the specific gene sequence at 60°C. While duplicating a specific gene sequence, the fluorescence level will increase and it is measured in real time. While temperature cycle changes alternately between 95°C and 60°C, fluorescence measurement is performed periodically at the specific step during each cycle.

4. Technical Data

<table>
<tr><th>Specification Item</th><th>Specification</th></tr>
<tr><td>Performance</td><td>
<table>
<tr><th>Performance Item</th><th>Specification</th></tr>
<tr><td>sample processing</td><td>1 test at a time per LOAA, 1 sample / test</td></tr>
<tr><td>Light source</td><td>460nm LED</td></tr>
<tr><td>Heating ramp rates (max.)</td><td>10℃/sec from 60℃ to 95℃</td></tr>
<tr><td>Cooling ramp rates (max.)</td><td>5℃/sec from 95℃ to 60℃</td></tr>
<tr><td>Temperature accuracy</td><td>Within ±0.5℃</td></tr>
<tr><td>Maximum power consumption</td><td>Less than 90 W</td></tr>
</table>
</td></tr>
<tr><td>Operating conditions</td><td>• Temperature: 15℃~30℃
• Relative humidity: 20 to 80% (noncondensing)
• Ambient pressure: 700hPa to 1,060hPa
• Indoor use only</td></tr>
<tr><td>Storage conditions</td><td>• Temperature: 2℃ to 50℃ (35.6℉ to 122℉) in manufacturer’s package
• Relative humidity: 20% to 80% humidity
• Ambient pressure: 700hPa to 1,060hPa</td></tr>
<tr><td>Transport conditions</td><td>• Temperature: -10℃ to 50℃ (14℉ to 122℉) in manufacturer’s package
• Relative humidity: 10% to 85% humidity
• Ambient pressure: 700hPa to 1,060hPa</td></tr>
<tr><td>Power requirements</td><td>• 100-240V~ 50~60Hz 1.3A input, 24 Vdc. output, 3.75A, 90W</td></tr>
<tr><td>Dimensions and weight</td><td>• 242 x 253 x 206 mm (H x D x W)
• Total weight: 4.1 Kg
- Analyzer: 3.2 Kg (With adaptor: 3.7 Kg)
- LOAA Sample Loader (Model name: POSTMAN) 0.34 Kg</td></tr>
<tr><td>EMC requirements</td><td>LOAA Analyzer system complies with the emission and immunity requirements of IEC 61326-1: 2012 (Class A).</td></tr>
<tr><td>CPU</td><td>Cortex-A53 Octa core 1.4 GHz</td></tr>
<tr><td>Storage and Memory</td><td>• 2GB DDR3
• 8GB eMMC
• 1TB HDD</td></tr>
<tr><td>Interface and peripherals</td><td>• One Ethernet network interface
• 2 USB ports for storage (Located on the lower back)
• Wi-Fi antenna: 5Ghz/2.4Ghz</td></tr>
<tr><td>Display</td><td>5.5” TFT LCD with touch
• 68.04x120.96mm active area
• 1920x1080 FHD resolution
• multi-touch support</td></tr>
<tr><td>Operating system</td><td>Android 7.1 (Nougat)</td></tr>
<tr><td>Software version</td><td>3.0.0</td></tr>
<tr><td>Overvoltage category</td><td>II</td></tr>
<tr><td>Pollution degree</td><td>2</td></tr>
</table>

5. Instructions for Use of LOAA Analyzer

Note Cartridge preparation may vary depending on the cartridge type. For specific preparation steps, refer to the Instructions for Use for each Dr. PCR cartridge kit.

There are three main steps to take when using LOAA Analyzer system.

1) Inject and dispense the sample mixture into cartridge using LOAA Sample Loader (Model Name: POSTMAN).
2) Install the Cartridge to the LOAA Analyzer and operate the device.
3) Check the PCR results.

5.1. Dr. PCR Cartridge Kit

Each kit contains the reagents and cartridges needed for PCR test to be performed in LOAA Analyzer. Components vary depending on the kit type. Please refer to the Instructions For Use or Quick Guide for specific preparation and test procedures.

Note. Cartridge may vary depending on the kit type.

Caution:
Do not use the components of one LOAA cartridge kit to prepare another type of LOAA cartridge. Components are specific to each LOAA cartridge.

5.2. Preparation before PCR test

5.2.1. General precautions

It is recommended that the handling of potentially infected samples be carried out in a biological safety cabinet or hood, or behind a protective shield. Overall procedure starts with DNA/RNA extraction and purification using commercially available prep kit. Recommended samples for LOAA Diagnosis are nucleic acids extracted from whole blood, plasma and serum. The mixed solution is loaded into cartridge by using sample loader. Finally, the sample loaded cartridge is inserted in the analyzer and starts test. The detail steps starting from the sample loading is addressed below.

One of the most important guidelines related to tests using PCR is to prevent contamination.
The followings are some of important rules.

1) Sample collection, cartridge injection, cartridge loading and LOAA Analyzer device operation must be performed in separate locations or work areas.
2) Do not leave the work area or return to the previous work area without completing the decontamination procedure at first (cleaning the area and changing protective clothes and gloves).
3) Prepare only one cartridge at a time.
4) Always dispose of used cartridges or cartridges in contact with samples in biological hazardous waste containers. Replace gloves after handling used cartridges.

LOAA cartridges are stored in individually packed pouches. Always check the availability and operation of LOAA Analyzer device before removing the individual package to install the cartridge.

5.2.2. Preparation of the LOAA Analyzer and LOAA Sample Loader

LOAA Analyzer and LOAA sample loader should be ready for PCR test by following the operation steps described in 3.4.

5.2.3. Sample loading into Dr. PCR Cartridge

1) Take the cartridge out from the box and remove the protective sticker on the window.

2) While pressing the cartridge guide at the center of LOAA Sample Loader (POSTMAN) in the direction of the arrow shown in Figure 7 (left image), insert the cartridge into POSTMAN by matching the three grooves at the bottom edge of the LOAA cartridge with the three protrusions at the edge of the POSTMAN top plate (right image).

Figure 7. Plating description 1

3) Fully seat the cartridge on POSTMAN by pressing it down until it clicks.

4) While holding the top of the cartridge lid with both hands, turn the lid in the clockwise direction shown in Figure 8 until it clicks. If it is done correctly, the lid will be locked, and will not rotate in counterclockwise direction. Also, check that the logo ( ) at the top of the cartridge lid is aligned with the black arrow (▼) at the top center of POSTMAN.

Figure 8. Plating description 2

5) Open the red rubber at the cartridge inlet. Inject the sample to test into the cartridge (Figure 9 for injection hole location) using a disposable pipette and close the red rubber.

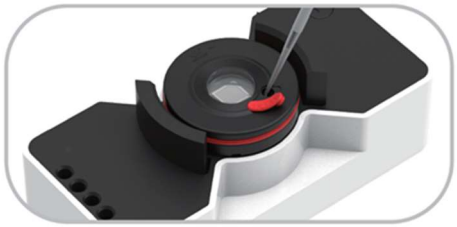


Figure 9. Dr. PCR Cartridge inlet location

6) Press the activating button (red circle in Figure 10) on the LOAA Sample Loader (POSTMAN) for about 1 second. Then, activating button will turn into solid red color and pump operation sound will be heard.

Figure 10. Operating LOAA Sample Loader

7) The sample is automatically loaded so that uniform volume is injected into the wells in the cartridge.

8) When the sample loading is finished, the LOAA Sample Loader (POSTMAN) automatically stops running and the button will blink in random colors. (it takes about 60 seconds)

9) Press the cartridge guide toward the center to release the cartridge from POSTMAN (Figure 11).

Figure 11. Separate Dr. PCR Cartridge

10) Hold the cartridge with both hands and lock it in place by pressing the top and bottom cases in various directions as shown in Figure 12.

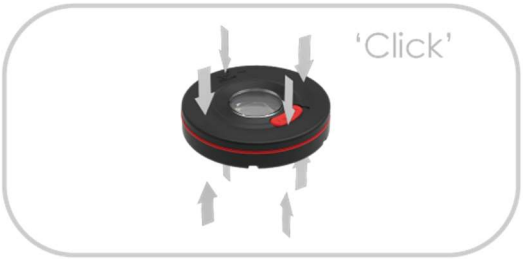


Figure 12. Dr. PCR Cartridge Lock direction

5.2.4. Starting to operate LOAA Analyzer

LOAA software includes:

1) Guides the user to place the cartridge in the LOAA Analyzer

2) Checking the problems of the cartridge installed and,

3) Depending on cartridge types, importing cartridge information from the memory inside the cartridge or input the information from user. To start test, touch New Test on the home screen.

5.3. PCR test using LOAA Analyzer

5.3.1. ‘Home’ screen of User Interface

The LOAA Analyzer's home screen is the main starting point for interacting with the features built into the LOAA Analyzer Graphical User Interface. There are two main buttons (①, ②) on the home screen.

Table 1. Home screen components

LOAA touch screen OSD (On-Screen Display)		
		
No.	**Name**	**Description**
①	Start test (New Test)	It is used to start PCR test.
②	Test history (Record)	Used to check or delete the previous test history.
③		Used to check the notice sent by the manufacturer to the user.
④		You can use functions such as language, brightness, sound, network settings, USB update, and administrator mode
⑤		Used to switch to the login screen.
⑥	Network connection status notification	You can check the connection status of ethernet ( ) or Wi-Fi (/).

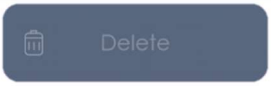
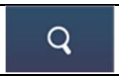
① New Test (start test): Home>New test

Pressing the New test button on the home screen starts the PCR test procedure on the LOAA Analyzer Refer to Section 5.4 for the test procedure.

② Record (test history): Home>Record

Pressing the Record button on the home screen switches to the test history screen. The test history screen shows the entire test and you can check the results of each test. Users can navigate through the list of files and delete them by pressing the scroll arrow button.

Table 2. Fuction icons in Record Screen

Function icon	Description
	Export report in PDF format
	Delete test result
	Sort test results by date and product name
	Search for product name

5.4. Test Procedure

5.4.1. Enter sample ID

Figure 13. Enter Sample ID Screen

Enter sample ID HOME>New Test

1) When touch New test, sample ID entering menu will appear.
2) On the screen, there are 5 input boxes where user can enter ID's of samples.
3) Maximum number of sample ID's user can enter is 5 and user can proceed to the next step without entering any sample ID by touching **next** button.
4) Default sample ID entering method is by using QR scanner built in the device. QR scanner will be automatically turned on for about 10 seconds and waiting for user to scan sample ID one by one. When one sample ID is scanned successfully, QR scanner will be turned off and then turned on again after a few seconds. Then user can scan next sample ID while QR scanner is turned on. This process will repeat until maximum 5 sample ID's are scanned.
5) User can also enter sample ID manually by touching empty input box while QR scanner is turned on and off repeatedly.
6) Sample ID entering operation will finish in the following 2 cases: one is when all 5 sample ID's are scanned and in this case, device will proceed to next scene automatically. The other is when user touches the **next** button.
7) User can modify entered sample ID by touching corresponding input box.
8) All sample ID's entered should be unique. Any 2 sample ID's can not be the same and when trying to enter already existing sample ID, this will be discarded.

Loading the cartridge **HOME>New Test>Sample ID>Next**

1) When entering sample ID operation is done, LOAA Analyzer's front-side shutter opens to load the cartridge, and the cartridge loader comes forward.

2) Place the locked cartridge in the cartridge loader.

   Note. The cartridge must be locked and there must not be a gap between the top/bottom parts of the cartridge case and the red rubber ring at the center when viewed from the side.

3) Place the cartridge with the bottom side facing down, so that the Optolane company logo on the top of the cartridge is aligned with the triangular mark (circled in red) on the top of the loader of the LOAA Analyzer (Figure 14).

4) Finally, once the cartridge is securely in place, even if you gently push the cartridge to the left or right by hand, it should not move because the cartridge is fully seated.

⚠ **Caution:**
If the Cartridge is not fully loaded in place, the device and software will not advance to the next step and the door will open again automatically. Remove the cartridge and reload it in the correct position.
Since the cartridge window is where the light source passes through, user should be careful not to hold this area with your bare hands and be sure to get any foreign matter off.

Figure 14. Alignment mark on the cartridge loader of LOAA Analyzer

5.4.2. Validating well structures inside the Dr. PCR Cartridge

Figure 15. Verifying Cartridge Screen

Figure 16. Analyzing Cartridge Screen

Cartridge analysis HOME>New Test>Sample ID>Next>Next

1) When you press Next button on the screen, the loader automatically moves back in the equipment and the door is closed.

2) It automatically checks the cartridge status (completed within about 30 seconds).

Caution:
If there is no problem in the cartridge to be used, it will proceed to the next step to start test, but if there is any error message occurred, please, refer to section 7 for error code specific to cartridge or device problems for further action.

5.4.3. Start the test

When cartridge verification and analysis is done successfully, test will start automatically.

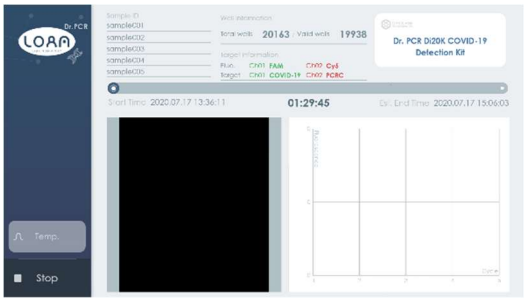


Figure 17. Test screen

Test Progress Start Test>Test process>Temperature

1) Press the Temp. button on the Temperature and Process Cycle screen of the test to see temperature and cycle progress during the test.

2) Press the Fluo. button on the Temperature and Process Cycle screens to switch to the Fluorescent Graph screen during the test†.

※ Fluorescence graph does not appear in “Stage 1” during PCR stage.

3) Press the> Stop button to terminate the test in the middle of run. The intermediate result of the stopped test will be deleted.

Test Result Test Result Screen

Figure 18. Test result Screen

1) When the test is completed, the test result is automatically displayed on the screen (Scatter chart screen in Figure 18).

2) On the left side of the screen, start and end date and time of test are shown. On the top of the screen, sample ID, concentration information is displayed.

3) In the middle of the screen, a well image is displayed. Yellow means negative well (-), green means green channel positive, red channel negative (+-), red means red channel positive, green channel negative, and blue means both channel positive wells.

4) Scatter chart shows the result of distribution of fluorescence values detected in each well in two dimensions. The displayed distribution is based on a real-time curve, which is the most important advantage of Dr. PCR, and requires no threshold adjustment.

5) Press the play button (⏵) to see the scatter chart distribution move from cycle 1 to the last cycle set. You can stop at the desired cycle by pressing the stop button.

6) Press Graph button to see real-time PCR curve of each channel (Figure 19, Figure 20).

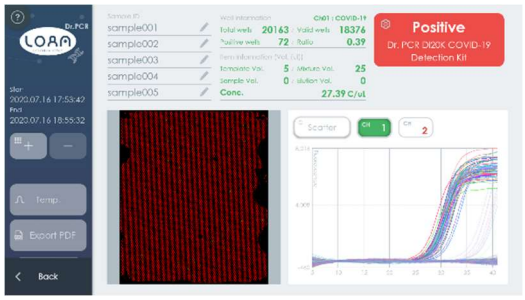


Figure 19. CH1 Digital PCR Result Screen

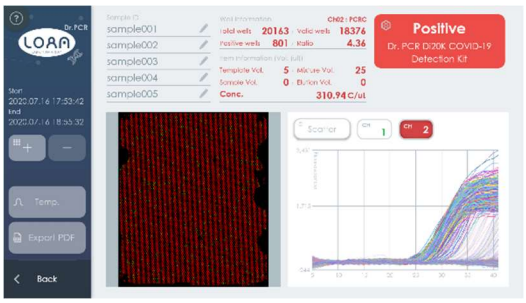


Figure 20. CH2 Digital PCR Result Screen

7) Press Ch 1 to display the real-time PCR result corresponding to the green channel (Figure 19). Target name, well information and item information are displayed at the top center of the screen.

8) Press Ch 2 to display the real-time PCR result corresponding to the red channel (Figure 20). Target name, well information and item information are displayed at the top center of the screen.

Figure 21. Review and analyzer Screen

You can review and analyze the result data.

Result Result Screen>well +/-

Button to enlarge / reduce the well image.

Result Result Screen>Temp.

1) Press the Temp. button to display the temperature information applied to the test.

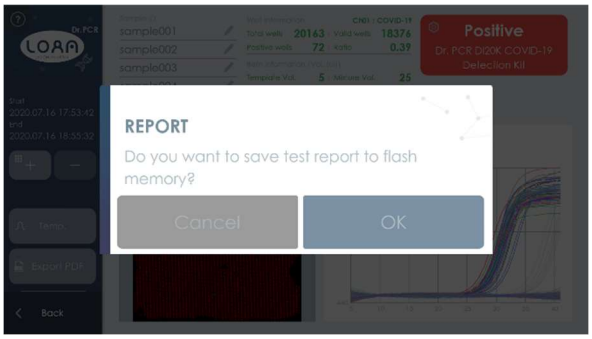


Figure 22. Export PDF Screen

Result **Result Screen>Export PDF**

1) If you want to save the report, first press the Export PDF button with the USB memory plugged into the USB port on the back of the instrument.

2) A message appears asking if you want to save the test result report to USB memory. If you select OK, it is saved to the USB memory (Figure 22).

Result **Result Screen>Back**

Figure 23. Cartridge Remove Screen

1) Press the **Back** button to switch to the cartridge removal screen. If you want to continue to another test, select the new test.

2) Otherwise, the door will be opened automatically. Then remove the cartridge and press the **Move Home** button to go to the home screen.

5.4.4. Stop running during the test

If the test stops before it is completed, all data generated during that test will not be available for analysis. Stopped test cannot be restarted or re-performed.

5.5. LOAA Analyzer record menu

Test history **Home>Record**

This is a screen where you can manage the history of all the results of tests performed in the LOAA Analyzer (Figure 24).

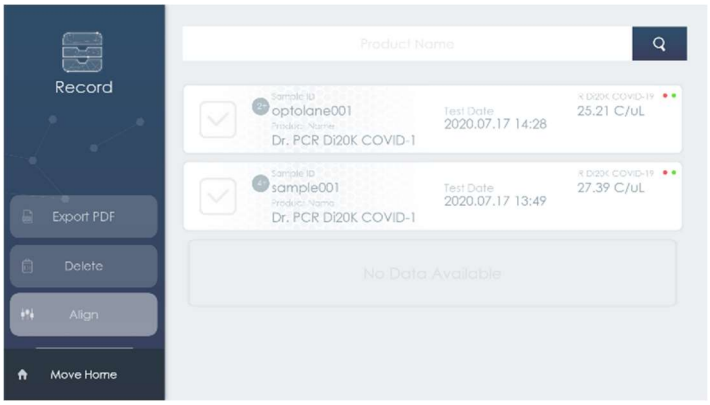


Figure 24. Record menu Screen

Test history Home>Record>test result

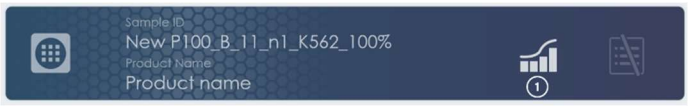


Figure 25. Test Result Screen

1) Press the graph view button (①) to switch to the graph view screen.

Test history Home>Record>Product name search

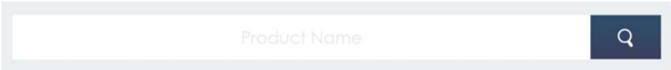


Figure 26. Product Name Search Screen

1) If you press the “Product Name” part or the magnifying glass icon button, the input keyboard is displayed on the screen.

2) After entering a partial word or full name of the product name to be searched, press the Search (①) button to search.

3) Click the close (②) button to cancel the search.

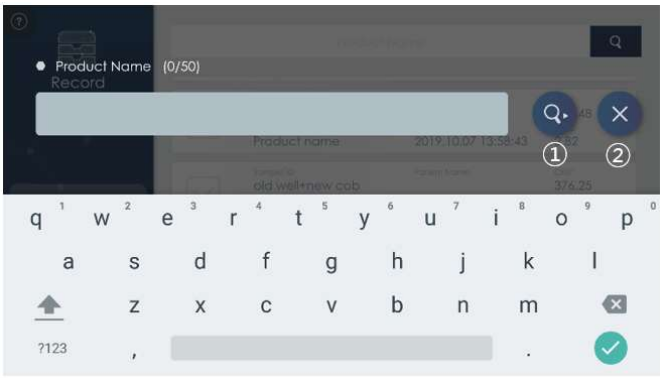


Figure 27. Product Name Search Keyboard Screen

Test history Home>Record>test report export

1) If you click the check box button of the result item to save the report and then click the export PDF button, a guide message of “do you want to save it to the USB memory?” will appear, and the report is saved by clicking >OK.

2) Click the checkbox button again to cancel the selection.

※ Caution: Before exporting PDF, you must have a USB memory connected to the back of the device.

Test history Home>Record>Align

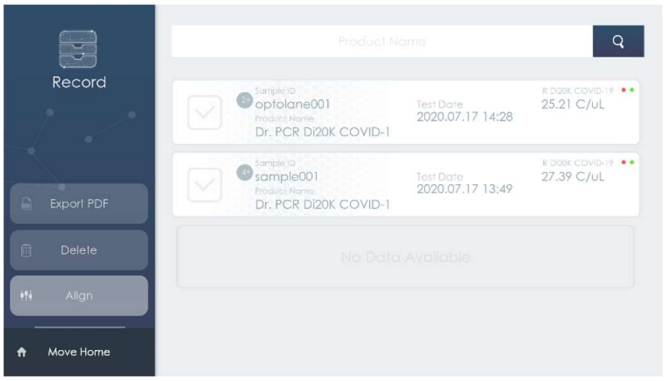


Figure 28. Record Align Screen

1) If you click the sort button, the test history is displayed in ascending or descending order by date and product name.
2) If you press the date and product name button, the arrow changes up/down and is displayed in ascending or descending order.

Test history Home>Record>Delete

1) Click the check box (①) button of the item to be selected from the test list to select it, and click the Delete (②) button.
2) The selected test item is deleted.
3) Press the “Move Home” button to switch to the home screen.

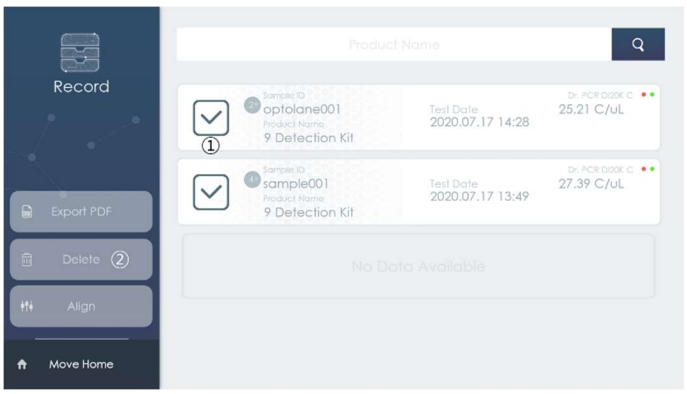


Figure 29. Record Delete Screen

5.6. LOAA Analyzer device setup

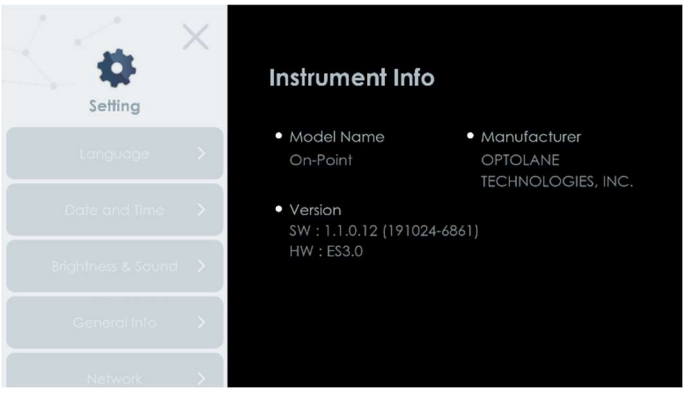


Figure 30. Setting Screen

Setting Home>Setting

If a user of LOAA Analyzer presses 'Setting' button on the Home screen, the user can change settings such as hardware setting, language and password.

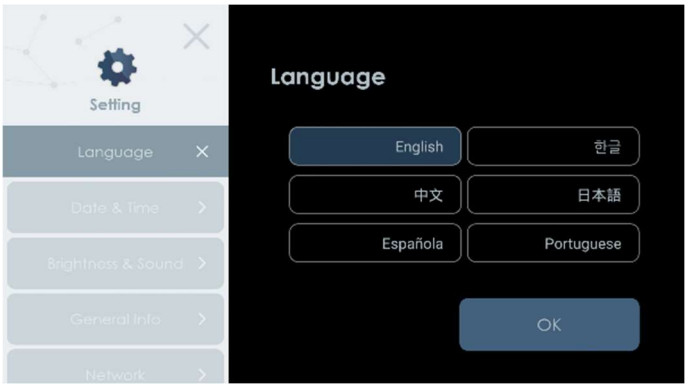


Figure 31. Setting Screen - Language

Setting Home>Setting>Language

1) A screen for selecting the desired language is displayed.

2) Press the language button you want to set and press OK button.

3) The language of the screen changes to the language you selected.

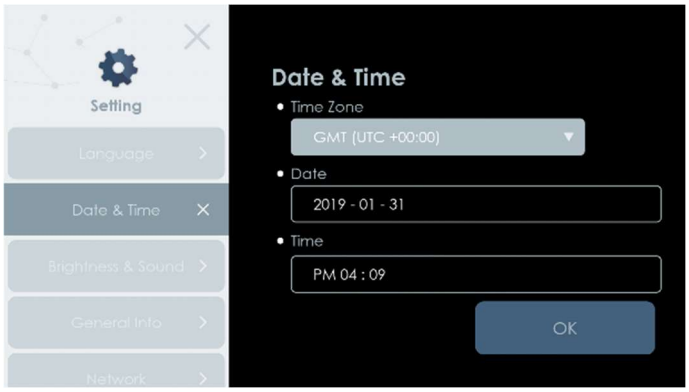


Figure 32. Setting Screen – Date & Time

Setting Home>Setting>Date & Time

1) The currently set date (year-month-day) and time are displayed on the time and date screen.

2) You can edit time and date by pressing time selection text box or date input text box.

3) You can select the desired time zone by using Time Zone combo box.

4) Press >OK button to save the modified contents and press >Close button to move to Home screen.

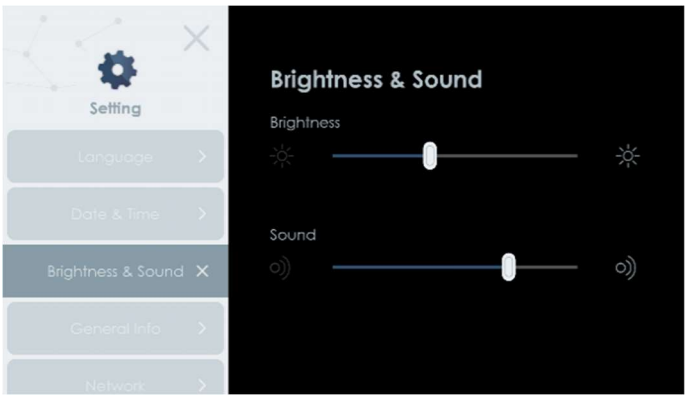


Figure 33. Setting Screen – Brightness & Sound

Setting Home>Setting> Brightness & Sound

You can adjust the brightness of LCD screen and the level of speaker sound.

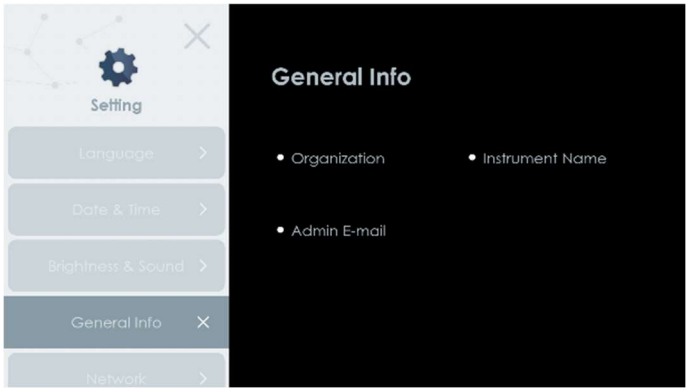


Figure 34.Setting Screen – General Info

Setting Home>Setting>General Info

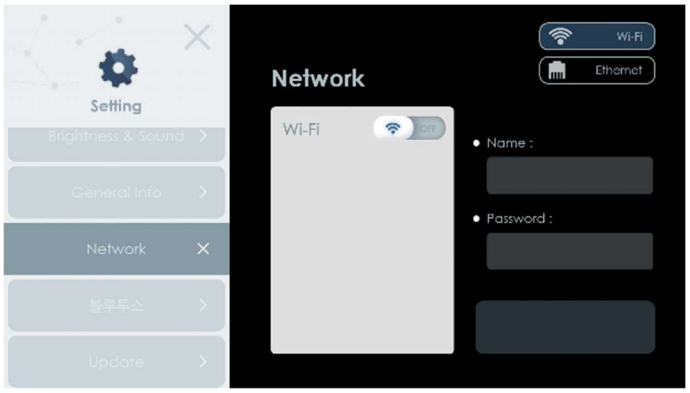
1) General information set by the administrator is displayed.

- Organization

- Instrument Name

- Admin E-mail

2) Press >X button to move to Home screen.

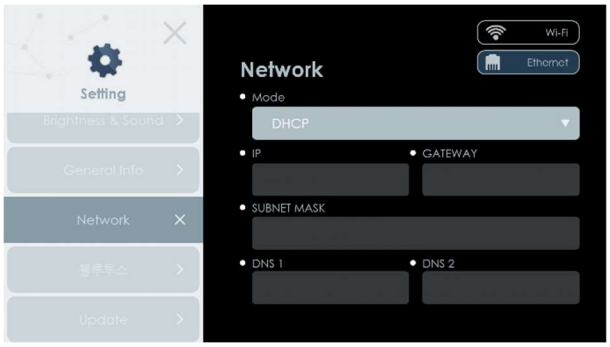


Setting Home>Setting>Network

Network settings **Network>Wi-Fi**

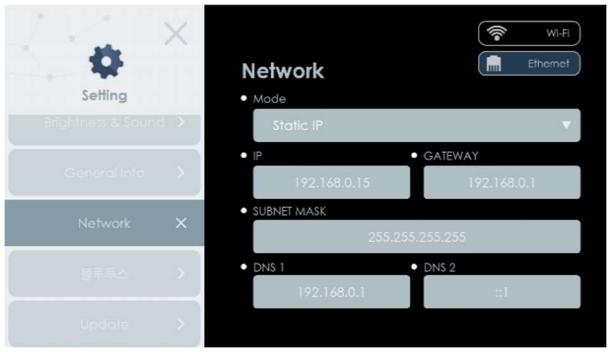
1) On the network setting screen, icon to set Wi-Fi or Ethernet is displayed on the top right.
2) If you select Wi-Fi on the right top menu and set the ON/OFF button to ON the middle, then after search, the AP name that is available for connection will be automatically displayed in the list.
3) If you select the AP name you want to connect from the list, the name of selected AP will be automatically displayed in the name field . After user enters the correct password and click the connect button, the wireless network set up is done.

※ When Wi-Fi is set up, the status of Wi-Fi connection is displayed on the top right of the setting icon in Login and 'Home' screen.

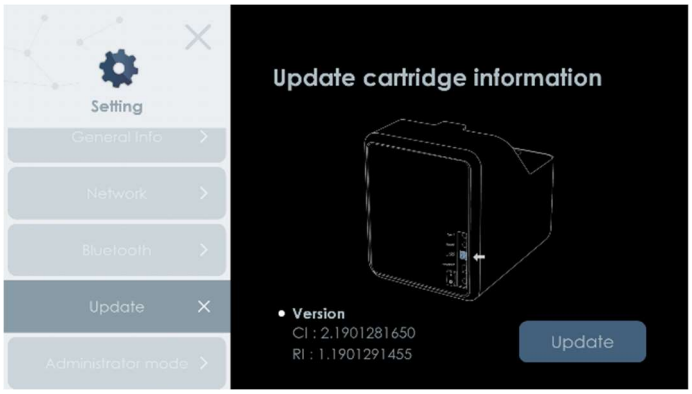


Network settings **Network>Ethernet**

1) On the network setting screen, icon to set Wi-Fi or Ethernet is displayed on the top right.
2) If you select Ethernet, select DHCP or static IP mode on the setting screen.
3) If you select DHCP, IP, Gateway, DNS1 and DNS 2 text boxes are disabled and the result of connection attempt is displayed as a message.
4) If you select Static IP mode and then enter the network information in the IP, Gateway, DNS 1 and DNS 2 text boxes, the result of connection attempt is displayed as a message.



※ When the Ethernet is set up, the status of Ethernet connection is displayed on the top right of the setting icon in Login and 'Home' screen.



Setting Home>Settings>Update
USB cartridge / report information update

1) Enter the settings on the 'Home' screen and press the Update button on the left.
2) Insert the USB memory containing LOAA cartridge information and/or report information update files into the USB port on the back of the LOAA Analyzer.
3) Press the Update button on the right to start update.

※ For other option for update operation, please contact the technical support team for details.

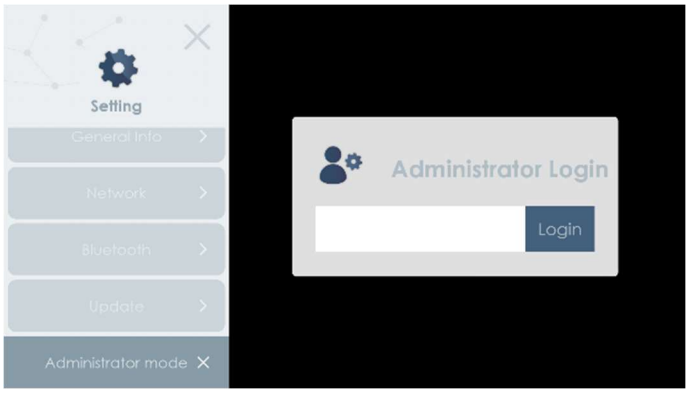
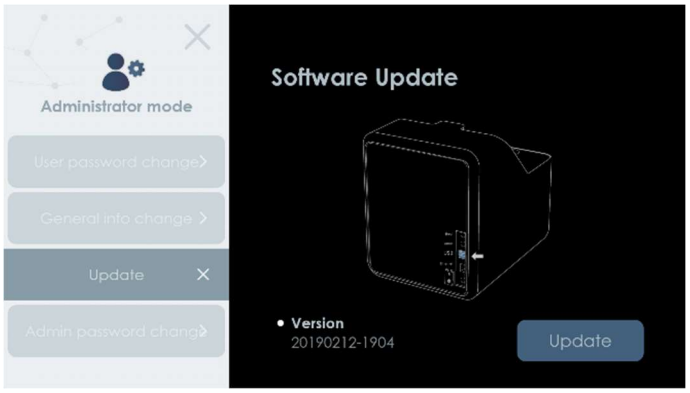


Figure 35.Setting Screen – Administration mode

Setting Home>Setting>Administrator mode

1) Enter the administrator password to log in.



Setting HOME>Settings>Administrator mode>Update
Software update via USB

1) Enter the settings on the 'Home' screen and select the administrator mode to log in as an administrator.
2) You can update LOAA software by selecting the update item in the menu listed on the left pane.
3) Insert the USB memory containing up-to-date LOAA Analyzer software into the USB port on the back of the LOAA Analyzer.
4) Press the Update button to start update.
5) When the update is completed, the update completion message appears, and the system will reboot automatically.

※ For other option for update operation, please contact the technical support team for details.

Setting Home>Settings>Administrator mode> Change user password

1) Press Change user password button to move to the change screen.
2) After changing the password, press Apply button to make changed new password in effect.
3) Press >Close button to move to Home screen.

Setting Home>Settings>Administrator mode>Change general information

1) Press General information button to move to the change general information screen.

2) After entering information on organization, instrument name of the device and e-mail address of administrator to be changed, press Apply button to save the changes.

3) Press >Close button to move to Home screen.

Setting Home>Settings>Administrator mode>Change administrator password

1) Press Administrator password button to move to Change administrator password screen.

2) After changing the password, press Apply button to make changed new password in effect.

3) Press >Close button to move to Home screen.

5.7. LOAA Analyzer Application termination

Exit screen

If you press power button on the front side of LOAA Analyzer for more than 5 seconds, an exit message box will appear. Press OK to proceed power off sequence of the LOAA Analyzer.

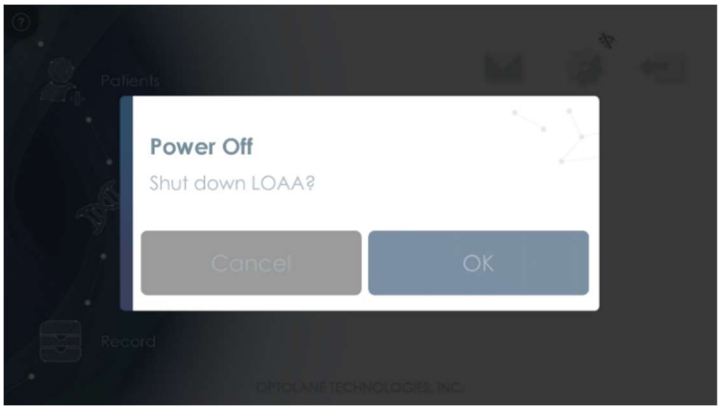


Figure 36. Power Off Screen

6. Precautions in advance during work using LOAA Analyzer

6.1. Laboratory safety and biological risks

6.1.1. General precautions

LOAA Analyzer device do not have biological risks of their own, but according to the standard for non-clinical test control, it is recommended that all wasted materials be treated as a substance with potential biological risk.

1) Follow all safety instructions printed or attached to the LOAA Analyzer devices.
2) Observe all general safety precautions applicable to electrical devices.
3) Never touch the switch or power cords with wet hands.
4) Do not open the LOAA Analyzer devices or cartridges.

⚠ **Caution:**
Be careful not to pinch your fingers when the device door is automatically closed.

6.1.2. Laboratory precautions

Treat all specimens and wasted materials as if they are infectious. Or refer to other appropriate biological safety procedures.

Comply with the safety guideline of the Occupationally Acquired Infections, Approved Guideline M29 Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers or other appropriate safety guidelines.

Wear personal protective equipment and disposable latex gloves while handling reagents or samples, and change gloves frequently. Wash hands thoroughly after conducting the test.

⚠ **Caution:**
User should be careful in removing cartridge from the device. If the cartridge is broken or leaked, the device and surrounding areas may be contaminated. Dispose of the cartridge in the waste container for biologically risky materials.

6.1.3. General PCR precautions

One of the most important guidelines when performing PCR is to prevent contamination. here are some important rules.

1) Sample collection, sample loading to cartridge and LOAA Analyzer operation must be performed in separate locations or work areas.
2) Do not leave the work area or return to the previous work area without completing the decontamination procedure at first (cleaning the area and changing protective clothes and latex gloves).

6.2. Decontamination and cleaning procedures

The proposed decontamination and cleaning procedures are intended to limit the spread of contamination due to cartridge breakage or leakage. Decontamination is necessary to prevent false positives in subsequent tests.

If cartridge leaks or is broken, replace gloves and other personal protective equipment that may be exposed to potential risk of contamination. Replace disposable gloves frequently, especially during the first stage of decontamination and before touching a clean surface, during the decontamination process. All disposable protective equipment must be disposed of properly after decontamination.

⚠ **Caution:**
Contaminated substances of leaked or broken cartridges must be cleaned immediately. A broken cartridge after PCR may contain a large amount of contaminants. Even if this material is not infectious, it can easily spread

through people's normal activities. Thus, very small amounts (molecules) can be also amplified by PCR in subsequent operation, which may be identified to be positive in LOAA Analyzer device. Handle all broken cartridges as if they could contaminate the work area.

Biological risk:
If the cartridge contains potentially infectious substance, there is a risk of biological contamination as well as sample contamination.

6.2.1. Cleaning materials

This list contains items required to keep the pollution level to a minimum in the laboratory.

- Sterile distilled water in a squeeze bottle or a spray bottle
- RNAZap or equivalent RNA degradation system
- Soft cloth
- Cotton swabs

6.2.2. LOAA Sample Loader (Model name: POSTMAN) decontamination

Regular cleaning of the LOAA Sample Loader POSTMAN uses a cotton swab moistened with sterile distilled water and two sheets of wet wipes each time a new cartridge is loaded.

If the sample has been spilled or a cartridge has leaked, perform the following decontamination procedure.

1) Wear clean personal protective equipment such as laboratory gowns and gloves.
2) Moisten a cotton swab with RNAZap or equivalent RNA degradation system solution and wipe the inside of the front center and the inside of the guide. Replace gloves.
3) Dampen a soft cloth with distilled water and wipe the entire sound pressure device.
4) Repeat step 3 with new gloves and cloth.

6.2.3. Decontamination related to Dr. PCR Cartridge leakage

If a cartridge leaks, follow the below precautions to prevent contamination.

1) Wear clean personal protective equipment such as laboratory gowns and gloves.
2) Ensure that no one is using equipment or potentially contaminated areas until decontamination is completed.
3) Use the following steps to remove contamination from devices the work area and dispose of cartridges.
   a. Disposed of potentially contaminated gloves and wear clean gloves.
   b. Dispose of potentially contaminated laboratory gowns and wear clean laboratory gowns.
   c. Dispose of the leaked cartridge in a biological hazardous container.
   d. Replace gloves.
   e. Follow the guidelines below to clean devices and affected work areas.

Caution:
Use only 5% leach solution and/or distilled water to remove contaminants from devices and sound pressure devices.

6.2.4. Decontamination of devices

1) Decontamination of cartridge loaders

   a. Wear latex gloves on both hands and wipe the inside of the cartridge loader with a clean, soft cotton swab. Be careful not to touch the measuring part.

   b. Dispose of used cotton swabs with care not to contaminate elsewhere.

   c. Do not disassemble the equipment or immerse it in water or cleaning solution. Also, do not clean it with water or other solutions.

2) Decontamination of device enclosure

   a. Wear latex gloves on both hands and wipe the outside of the equipment with a soft cloth moistened with distilled water.

   b. Do not pour or spray water directly on the equipment when cleaning it. Also, do not use excessive cleaning fluid, as it may damage the equipment.

   c. After 10 minutes, dampen the cloth with distilled water and thoroughly wipe the outside of the equipment.

   d. Dispose of used cloth with care not to contaminate elsewhere.

6.2.5. Cleaning the touch LCD screen

1) Clean the touch LCD screen using commercially available LCD cleaning products.
2) Use a soft cloth not to make scratches on the screen.

6.2.6. Decontamination of bench top and other areas

1) Wear clean personal protective equipment such as laboratory gowns and latex gloves.
2) Spray 10% bleaching solution on possible contamination area. Allow the bleaching solution to reach with all contaminants on the surface for at least 10 minutes.
3) Wipe this area with clean paper towel. Replace latex gloves.
4) Repeat steps 2 and 3 twice to clean with total three sheets of tissue.
5) Replace latex gloves. Spray distilled water to this area.
6) Wipe this area with new paper towel to dry it. Replace latex gloves.
7) Spray RNAZap or equivalent products to this area. Follow the product guidelines for proper use.
8) Spray distilled water to this area, rinse and wipe to dry.

7. Prevention Maintenance and Troubleshooting

7.1. Introduction

This chapter provides step-by-step guidelines for users to perform basic maintenance, updates and troubleshooting for LOAA Analyzer.

Caution:
Before performing the regular cleaning steps on the LOAA Analyzer, wear appropriate personal protective equipment, switch off the device and unplug the power cable.

7.2. General maintenance

In addition to the regular cleaning steps below, there is no general maintenance required for LOAA Analyzer devices.

1) Wipe the surface of LOAA Analyzer devices, including the internal cartridge loading tray, with cloth or paper towel moistened with 70% ethanol, and then cleanse it off with water.
2) Clean the lens of the scanner with lens cloth and lens cleaner.
3) The cartridge loading tray must be wiped off between every test, and should be decontaminated daily or every time there is leak in the pouch (refer to decontamination and cleaning procedures in Chapter 0.

7.3. Device setup and management

Users can make changes to LOAA Analyzer's hardware, language and password settings. The description of function icons in each 'Setting' menu is as follows.

For more information, refer to section 5.6 LOAA Analyzer device setup.

If you click a gear-shaped setting icon on the 'Home screen, the relevant setting items will be displayed as shown on the screen.
Date & time information setting, brightness & sound setting, general information, network setting, update and administrator mode buttons are aligned on the left screen.

- Language: Can select the desired language and change the language to be used.
- Date & time: Can set the date and time.
- Brightness & sound: Can set brightness and sound.
- General information: Can check the name of organizations, equipment name and the administrator e-mail information.
- Network: Can set Wi-Fi or Ethernet.
- Update: Can update cartridge information using USB memory.
- Administrator mode: Can set user password change, general information change, software update using USB memory and administrator password change.

※ For other option for update operation, please contact the technical support team for details.

7.4. Error reporting tool

LOAA Analyzer performs a self-test of the cartridge for each test. Malfunctions are reported as errors to the user with guidelines on how to correct them. Record the error message to help troubleshoot the problem. If you have any questions, please contact the manufacturer's technical support team.

7.5. Troubleshooting when an error occurs

[Hardware troubleshooting]

The following table shows solutions to resolve potential symptoms and problems with LOAA Analyzer hardware. If the problem persists after applying the recommended solution, please contact the technical support team for assistance.

If there is any error message popped up, please, refer to **[Diagnostic error]** section for recommended further actions.

Symptom	Available solution
Power is not turned on.	1) Check whether adapter power cord is connected to external power source. 2) Check whether the adapter power cord is connected to the equipment. 3) Check whether the main power switch on the back of the equipment is off. 4) Check whether the ON/OFF switch on the front of the equipment is off. 5) If all of the above items are checked but the power is not turned on, please contact the technical support team for assistance.
Power is turned on, but system is not initialized.	1) Check whether power is off abnormally. 2) Identify and remove substances that interfere with system operation. 3) Turn on the power and check whether the system is initialized. 4) If all of the above items are checked but the system does not operate normally, please contact the technical support team for assistance.
The touch LCD screen is not turned on.	1) As this problem is a problem inside the system, please contact the technical support team for assistance.
The system does not start even by pressing the "Start test" button.	1) Check whether the system is initialized normally when the power is turned on. 2) The system may not operate because a certain substance interferes with the cartridge loader entering the inside. Identify and remove the substance. 3) Check whether all accessories are correctly installed. 4) If all of the above items are checked but the system does not operate normally, please contact the technical support team for assistance.
The system is running, but it does not function property as per the protocol.	1) Identify and remove substances that interfere with system operation. 2) Check whether all accessories are correctly installed. 3) If all of the above items are checked but the system does not operate normally, please contact the technical support team for assistance.
The front cover of the equipment is not closed.	1) Touch the screen to see if the cover opens and closes automatically. 2) If all of the above items are checked but the system does not operate normally, please contact the technical support team for assistance.
The front cover of the equipment does not move.	1) As there is a problem in cover assembly, please contact the technical support team for assistance.
Cartridge not recognized when loading to or removing from the device	1) Check whether the cartridge is correctly loaded to the device. 2) Power off the device and turn it on again. 3) If the problem persists, please contact the technical support team for assistance.
Software does not recognize auto close / open status due to loader reciprocation.	1) Turn off the device. 2) Check and reconnect the power cable. 3) Turn the device on. If the problem persists, please contact the technical support team for assistance.
The test is not in progress	1) Check whether the cartridge is correctly loaded to the device. 2) Check whether all critical information is entered to the software and then touch "Start test." If the problem persists, please contact the technical support team for assistance.
The actual operation of the equipment is different from the expected one.	1) Check whether you've pressed the "Start test" button more than once. 2) Restart the equipment by pressing reset button on the back. 3) If all of the above items are checked but the system does not operate normally, please contact the technical support team for assistance.

[Barcode scanner]

The barcode scanner is pre-programmed to read the cartridge test items and etc.

If the problem persists even after applying the recommended solutions listed in the table below, please contact the technical support team for assistance.

Symptom	Available solution
Barcode scan not performed	• Reposition the barcode and then scan again. • Clean the barcode scanner. • If the problem persists, please contact the technical support team for assistance.

[Diagnostic error]

Diagnostic errors are often used by technical support representatives to resolve device problems.

The table below lists potential error messages and possible solution. If the error persists even after applying the recommended solution, contact the technical support team for assistance.

Before contacting the technical support team, note all error messages and numbers as well as the device serial number and the required cartridge lot number. The technical support team member will use this information to identify and resolve the problem.

Error code	Possible solution
OC_00010	Please, reload the cartridge in use
OC_00011	Used cartridge. Please, load a new cartridge
OC_00012	Cartridge has expired. Please, load a new cartridge.
OC_00013	Please, load a new cartridge
OC_00100	Please, reload the cartridge, If the problem continues, please contact the technical support team for assistance
OC_00101	
OC_00102	
OC_00103	
OC_00104	
OC_00120	
OC_00121	
OC_00122	
OC_00123	
OC_00124	
OB_00200	Please, contact the technical support team for assistance.
OB_00201	
OB_00202	Can not read barcode, Please, try again.
OB_00203	
OB_00204	
OA_00300	Please, contact the technical support team for assistance.
OA_00301	
OA_00302	
OA_00303	
OA_00304	
OA_00305	
OA_00306	
OA_00307	
OA_00308	
OA_00309	
OA_00310	
OF_00400	
OF_00401	
OF_00402	
OF_00410	
OM_00500	
OM_00501	
OM_00510	
OM_00511	
OM_00512	
OM_00513	
OM_00514	
OM_00515	
OM_00516	
OM_00530	
OM_00531	
OM_00532	

OM_00533	
OM_00534	
OM_00535	
OM_00536	
OM_00537	
OS_00600	
OS_00601	
UC_00001	Please, update the cartridge information file with the latest version.
UC_00002	
UC_00003	
UC_00004	
UC_00005	
UC_00006	Please, contact the technical support team for assistance
UC_00007	
UC_00008	
UC_00009	
UM_00010	Please, update the cartridge information file with the latest version. Please, refer to section 5.6 for how to update the file.
UM_00011	
UM_00012	
UM_00013	There is not enough space for storage in LOAA. Please, remove unnecessary data.
UM_00014	Please, contact the technical support team for assistance.
UM_00015	Please, update the report information file with the latest version.
UM_00016	
UM_00017	Please, connect just one flash memory.
UR_00020	Please, contact the technical support team for assistance.
UR_00021	Please, update the report information file with the latest version. Please, refer to section 5.6 for how to update the file.
UR_00022	
UR_00023	
UR_00024	Please, contact the technical support team for assistance.
UR_00025	
UR_00026	
UR_00027	
UR_00028	Not enough space for storage in the USB memory.
UD_00101	Please, contact the technical support team for assistance.
UD_00102	
UD_00103	
UD_00104	
UD_00105	
UD_00106	
UD_00107	
UD_00108	
UD_00109	
UD_00110	
UD_00111	
UD_00112	
UD_00113	
UD_00114	
UD_00115	
UD_00116	
UD_00117	
UD_00118	
UD_00119	
UD_00120	
UD_00121	
UD_00122	
UD_00123	
UD_00124	
UD_00125	

UD_00126	No results found.
UD_00127	Please, contact the technical support team for assistance.
UD_00128	
UP_00201	
UP_00202	
UP_00203	
UP_00204	
UP_00205	
UP_00206	
UP_00207	
UP_00208	
UP_00209	
UP_00210	
UP_00211	
UP_00212	
UP_00213	
UP_00214	
UP_00215	
UP_00216	
UP_00217	
UP_00218	
UP_00219	
UP_00220	
UP_00221	
UH_00301	
UH_00302	
UH_00303	
US_1005	Please check the internet connection status
US_1006	
US_1010	
US_1011	
US_1012	
US_1013	
US_1014	
US_1015	
US_1016	
US_1017	
US_1018	
US_1022	

[Cartridge troubleshooting]

For problems occurred while using the LOAA cartridges, refer to the possible solutions below. If cartridge leaks, refer to chapter 0 for proper decontamination procedures.

Problem	Possible cause of error	Solution
Cartridge pouch's individual package is not sealed.	Cartridge contamination and moisture buildup is possible.	Discard the cartridge and test the sample using a new cartridge.
The sample to be loaded into the cartridge does not start to spread out over the well area after starting POSTMAN operation.	There may be bubbles in the cartridge inlet after sample injection.	Discard the cartridge and test the sample using a new cartridge.
Operation failure	Cartridge does not function properly.	Test with the new cartridge.
		If operation fails repeatedly, Please, contact the technical support team for assistance.

8. Quality Guarantee

We, OPTOLANE Technologies, Inc. warrants the materials and the defects during the production process for 1-year warranty period from the date when the customer takes over the product. Accessories are considered as a consumable, so quality is guaranteed for only 3 months. If defects occur after the warranty period, shipping and handling costs may be charged by OPTOLANE Technologies, Inc. with the cost of repairing or replacing the product.

8.1. Limited warranty and exclusion

We, OPTOLANE Technologies, Inc. do not guarantee the followings.

1) Damages in appearance such as scratches, dents, plastic damages, etc. occurred during transportation.
2) Damages due to external factors such as accidents, abuse, flood, fire or earthquake.
3) All parts or products modified without written consent of OPTOLANE Technologies, Inc.
4) Damages caused by service provided by an engineer or a service provider that is not authorized by the company.

8.2. Request for warranty service

Before requesting the warranty service, please read the Instructions For Use supplied with the product carefully and contact our online support team or local dealers as described in the Instructions For Use.

9. Symbols

Symbol	Meaning	Symbol	Meaning
	Direct current		Catalog number
	Date of manufacture		Serial Number
	Manufacturer		Caution
	WEEE Symbol		Keep away from rain
	Operator's manual; Operating instructions		In vitro diagnostic medical device
	CE Marking (IVD, RED)		FCC Logo
	EU Representative		NEMKO listing mark for Canada and the USA
	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner(U.S. Only)		

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