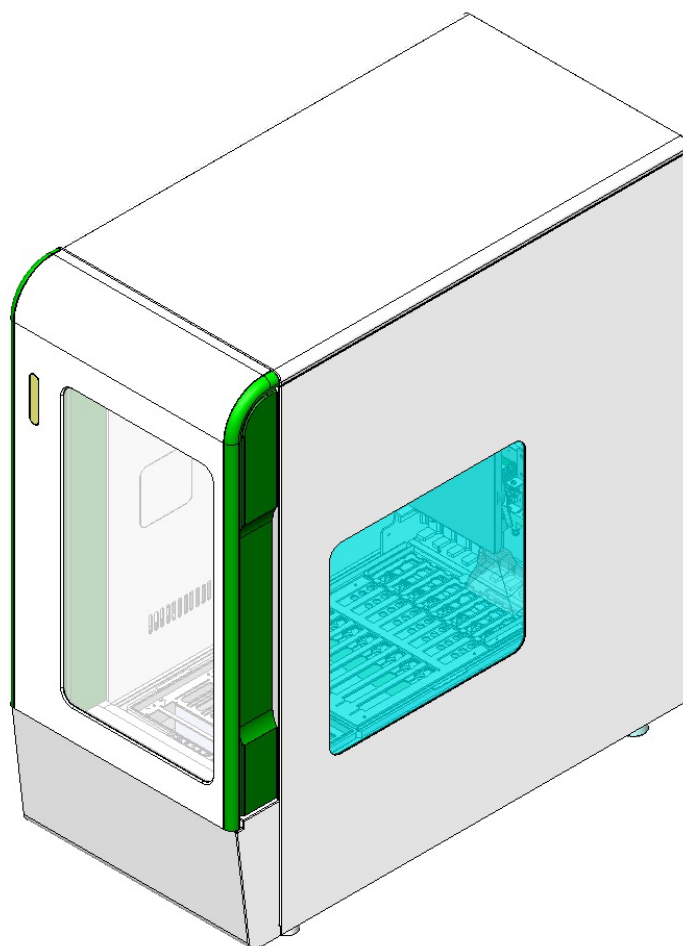


geneLEAD VIII User Manual



Rev. 2 2022/06



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1 Introduction

1.1 Description

The geneLEAD VIII is automated instrument of extraction, temperature cycle, fluorescence detection and data gathering. The instrument is controlled by geneLEAD VIII software, internal PC and external PC. The software is designed only for geneLEAD VIII, to process pre defined assay. The user guidance allows simple operation of routine job.

1.1.1 Intended use

geneLEAD VIII is a fully automated instrument that extracts and purifies nucleic acids, amplifies and detects target sequences by real-time polymerase chain reaction (RT-PCR), and interprets the results. geneLEAD VIII is suitable with multiple sample types for qualitative and quantitative in vitro diagnostics applications.

This instrument can be used in combination with proprietary extraction and amplification reagents as well as custom amplification reagents, and dedicated accessories indicated in the instruction for use of geneLEAD VIII.

1.2 Customer support

If there are any questions about geneLEAD VIII, please contact with your local customer support representative to answer your questions.

Please notice to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established, in case where any serious incident has occurred in relation to the device.

1.3 Proprietary statement

The geneLEAD VIII system software programs and system documentation are protected copyright laws, all right are reserved. The software and manual are developed dedicated for use of geneLEAD VIII for in vitro diagnostics applications as defined operation instructions. The information, documents and related graphics published herein are property of Precision System Science Co.,Ltd. (PSS)

Each person shoulder full responsibility and risks arising from use of the documentation. The documentation may include technical inaccuracies or typographical errors. PSS Group reserves the right to make additions, definitions or modifications to the documentation at any time without any prior notification.

1.4 Authorization and disclaimer about Documentation

Information in this document are based on experience and knowledge gathered by PSS Group. This document refers to access at highest level. Working with lower level access may not enough. The user manual and geneLEAD VIII instrument are to be used by authorized person only.

Operate the instrument, please follow the indications and indications and procedures described in this instructions for geneLEAD VIII system.

Please follow all warnings, cautions and notes indicated in geneLEAD VIII operation manual. If not, it cause human injuries or instrument damage.

All examples, illustrations, graphics and so on in this document are only for information and explanation purpose, not for use of clinical or other evaluation. Data in screen or sample printouts are not actual test result.

This document cannot be substitutive of PSS Group training. System usage by the person who did not enough trained by PSS Group may cause instrument damage, sample losses or injury. This is not applied for operation under following cases.

- a) The person who is certified as enough knowledge and experience by PSS Group or representative
- b) Under direct supervision of PSS Group technical staff or service representative

If any user make any questions, suggestions or any other items written or electronic feedback to PSS Group shall be considered as non-confidential except user name. PSS Group can edit, use the information for maintenance, research, further improvement and so on without notice to customer.

PSS Group may update the document in hardcopy or softcopy, please always refer to latest version for the most recent information.

1.5 geneLEAD VIII Warranty

PSS Group warrant instruments sold by representative in short time of 18 months after original shipment date or 12 months after installation.

This warranty does not cover following defects or malfunctions.

- a) No report for PSS Group or representative
- b) Chemical decomposition or corrosion
- c) The result of action do not follow instructions
- d) The results of maintenance, repair or modifications without PSS Group or representative authorization
- e) Normal wear

1.6 Notes and Symbols

1.6.1 Display of Warning and Notes

Danger



The signal "**Danger**" and the relating marking mean immediate dangers.

The non-observance of a danger warning will result in death or at least serious injury. Also cause serious damage to the system.

Warning



The signal "**Warning**" and the relating marking mean potential dangers.

The non-observance of a warning will result in serious irreversible injury. Also cause damage to the system.

Caution



The signal "**Caution**" and the relating marking mean potential dangers/problems.

The non-observance of caution may result in minor injuries. Also cause damage to the system.





Caution



The signal "**Caution**" mean potential problems. The non-observance of a caution may result in damage to the system.

note








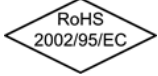



The signal "Note" mean potential problems. The non-observance of notes may affect to the system functionality.



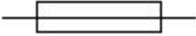
1.6.2 Utilized Warning Symbols

	Caution, risk of danger for person or damage instrument. Verify instructions for use
	Biohazard
	Electrical hazard
	LED hazard

	Caution, hot surface
	Mechanical hazard

1.6.3 Other Symbols

	Manufactured by
	Country of manufacture (the two letters in symbol) and Manufactured date
	In Vitro Diagnostic medical devices ((eu) 2017/746)
	CE mark
	ID number
	Serial number
	UL mark
	RoHS mark
	Check instructions for use
	Disposal of Electrical and Electronic Equipment In the EU, electrical and electronic equipment must not be disposed of with other household-type waste and must be collected separately. Please observe the appropriate regulations of each country.
	Biological risk

	Caution
	Authorized Representative in the European Community
	Fuse

1.7 Hazard instructions

1.7.1 General Safety

The following safety instructions must be followed anytime during system operation. Safety instructions are intended to keep safety through system operation, please read and completely understand following explanation before start using geneLEAD VIII system.

- a) Properly ventilated room is needed to handle reagent or chemicals to prevent from health problem for operator.
- b) Do not proceed following actions to keep reliability of geneLEAD VIII system.
 - i) Do not remove fixed cover of the instrument.
 - ii) Do not change components
 - iii) Do not remove safety devices
- c) Installation and service the system only performed by authorized person approved by PSS Group or representative.
- d) The user manual must be accessible for all users.
- e) Caution indicated on operation instruction and geneLEAD VIII instrument are prepared by certain verification, but unexpected phenomena can be happen.
Please completely follow operation instruction during operation and maintenance.
- f) It is mandatory to allow approved person by PSS Group or representative to proceed defined periodical maintenance to keep the system to be reliable for all functionality.
- g) In case of emergency, switch off main power, Unplug from the outlet of power supply cable and call service.
In case of emergency, please set up space so that the power plug can be pulled out immediately, without putting things around the outlet.
- h) The impossible operation of equipment and operation screen displays error and immediately equipment turn off the guidance of PSS Group or representative service staff.

1.7.2 Liability

geneLEAD VIII system is designed and manufactured in compliance with safety requirements for medical systems. Operator should follow local and national regulation or laboratory procedures for instrument operation.

PSS Group have proceeded possible measures for electrically and mechanically safe. Information in this document are based on experience and knowledge gathered by PSS Group. PSS Group is not responsible for any loss or damage came from misuse or negligence of instruction.

- a) geneLEAD VIII instrument is only for intended use and handling
- b) geneLEAD VIII instrument only allow to use dedicated consumables for geneLEAD VIII supplied by PSS Group or representative

1.7.3 Electrical Hazards

geneLEAD VIII system will be no problem for use if connected appropriate power supply defined in chapter 9.1. Please observe and follow local regulations prior to usage. Electric servicing is allowed for qualified person only. Important electrical hazard concern are as follows, but these are not all of the attentions needed.

- a) Install the instrument properly
- b) UPS needed in case of installing unstable power supply condition
- c) Use electric connection and extension with enough electric capability
- d) Connect ground properly through electric power cable
- e) Do not disconnect power supply plug during instrument / system switch on.
- f) Prevent from liquid contact with electric cable / plug.
- g) Prevent from touch switches or connectors by wet hand
- h) Wipe out liquid immediately in case of spilled
- i) Keep clean inside / around instrument
- j) Disconnect power supply of instrument before maintenance / cleaning inside and around instrument by liquid.
- k) Disconnect power supply immediately in case of instrument damage and clearly show to be “damaged and no use”.
- l) Do not use damaged cable / do not put other items on cable / do not connect other instrument with same cable.
- m) In case of finding instrument damage, immediately shut down, disconnect unplug from the outlet of power supply cord and clearly show “ do not use” until PSS Group or representative service staff arrival.

In case of emergency, please set up space so that the power plug can be pulled out immediately, without putting things around the outlet.

- n) Replacement of the fuse shall be made by field service personnel authorized by PSS. Contact us

for fuse replacement.

Danger



Electric / Fire Hazard

Follow concerned rules and regulations, unless it may cause serious injury / instrument damage.

Connect system in proper way, unless it may cause serious injury / instrument damage.

Damaged system may cause serious injury / instrument damage

In case of accidentally damage electric parts / connectors, switch off the instrument, remove power supply cord and contact with PSS Group or representative service staff.

Danger



Danger of electric or mechanical

Make it sure to disconnect power supply prior to maintenance activities. Unless it may cause serious injury / instrument damage by electrically or mechanically.

Warning



Danger of inappropriate installation position

In appropriate installation position may cause serious injury / system damage such as firing by overheating and so on.

1.7.4 Mechanical Hazards

geneLEAD VIII is automated diagnostics system operated by computer software, there is possibility of injury during operation by moving parts.

Important mechanical hazard concerns are as follows, but these are not all of the attentions needed.

- Do not by pass or remove safety device
- Keep all covers at original positions
- Keep away your body from moving area during operation
- Do not were close or accessories can be caught by the system
- In case of system malfunction or unexpected movement can cause injury, keep away, shut down and remove power supply in such case.
- Keep clear, never cover ventilation slot

1.7.5 Heat Hazards

Heat Block for DNA Extraction, Hot collar and PCR block is installed in the working area to attach / remove Reagent Cartridge, PCR cartridge and tube. To minimize risk of user, the system turn decrease the temperature after completion of PCR process.

Caution

Pay attention to heated area of the user access area.

1.7.6 Biological Hazards

There are risk of biological hazard during following activities.

- a) Sample handling
- b) Elution manual handling
- c) Waste disposal
- d) Maintenance / cleaning

Important biological hazard concerns are as follows, but these are not all of the attentions needed.

- a) All samples, reagents, materials for extraction to assay testing can be infectious, handle compliance with lab / local / national rule or regulations.
- b) Wear appropriate protection such as disposable gloves / lab coat / eye protection to prevent from exposure.
- c) Do not eat or drink at lab
- d) Keep always clean around instrument
- e) In case of spills of reagent or samples, wash and clean by using 70% alcohol and dispose as potentially infectious.

1.7.7 Chemical Hazards

There is possibility of hazardous chemicals exposure through handling of reagents, calibrators or controls, proceed as follows to minimize the risk.

- a) Read carefully MSDS of each assay and follow guidance.
- b) Wear appropriate protection such as disposable gloves / lab coat / eye protection to prevent from exposure.
- c) In case of exposure, consult with doctor and follow the guidance.

Caution



Handling please go with human expertise or guidance.

The non-observance of caution may result in minor injuries. Also cause damage to the system.

1.7.8 Periodic Maintenance

Periodic maintenance needs to be performed to minimize the risks as follows.

- a) detection sensitivity shifting
- b) excitation light intensity shifting
- c) cross talk coefficient shifting
- e) position data shifting

1.7.9 User Operation

There are risk of operational hazard during following activities.

- a) installation and removal of consumables, Reagent Cartridges
- b) software operation
- c) input of sample information and reading results

To minimize that risk, please note the following operation

- a) Sample Rack and Reagent Cassette Rack should be installed on the instrument stage certainly.
- b) Consumables and Reagent Cartridges should be installed and removed by the rack.
- c) Consumables and Reagent Cartridges should not be re-used.
- d) In use of the software, please understand enough Operation Manual.
- e) The system clock should not be changed unintentionally.
- f) Please be careful to input the sample information and to read the result data.

1.7.10 Electromagnetic wave interference

geneLEAD VIII is designed and manufactured in compliance of EMC standards.

Only use instrument and cables supplied by PSS Group to keep compliance. Installation should be done only by service staff approved by PSS Group or representative.

Do not use the instrument near by electromagnetic wave source such as instrument without shield, not validated and so on.

1.8 Safety residual risks for User

This section is to explain user to share residual risks after proceeding certain safety measures. User should read carefully and understand residual risks and follow guidance to use geneLEAD VIII system in safe.

1.8.1 Safety design and manufacturing process

geneLEAD VIII system is designed and manufactured applying risk management system based on actual usage to eliminate or reduce risk as possible as PSS Group can. Also there are explanation for user about kind of protective items needed.

For usage of geneLEAD VIII system, user must carefully read the instruction about appropriate usage of the instrument. Only use those tools supplied by PSS Group or representative, the usage of not approved item will cause problem for human safety of damage the system.

1.8.2 Ergonomics

geneLEAD VIII is designed by considering ergonomics principles to reduce discomfort, fatigue, physical user stress under standard usage.

1.8.3 Power supply interruption

geneLEAD VIII system do not automatically start after power interruption, operator need to re-start the system.

1.8.4 Protection against mechanical hazards

geneLEAD VIII instrument is designed and manufactured to do not have sharp edge our rough surface to minimize risk of injury during operation. Also the instrument have interlock system to stop when door opened. It is strictly prohibited to remove covers, adjust or change safety mechanism to use the instrument in safe.

1.8.5 Protection against biological hazards

It is mandatory for user to follow laboratory internal rule, local and national regulations to minimize biological hazard risk, also keep following guidance.

- a) Do not touch geneLEAD VIII system, consumables or potentially contaminated items without wearing safety equipment
- b) Do not handle sample without wearing coat and gloves.

1.8.6 Protection against electrical hazards

The geneLEAD VIII system is designed and produced to prevent from electrical nature hazard or electro static hazard. Inlet fuse is installed for overcurrent protection. Follow strictly local and national regulations for safety.

The geneLEAD VIII system is not designed for operation in explosive atmosphere. End user is

responsible to verify that the instrument do not installed into explosive atmosphere,
also keep following guidance.

- a) Do not interrupt the electrical ground contact
- b) Do not connect other electric devices in same plug (except done by PSS Group or distributor)
- c) Do not use damaged wiring
- d) If safe use is impossible, disconnect the system from main power supply. Do not use damaged instrument.
- e) Do not open the locked cover during operation.

1.8.7 Protection against high temperature hazard

Hot collar is installed for the system to prevent from condensation. There is hot warning seal attached beside of hot collar, handle with care.

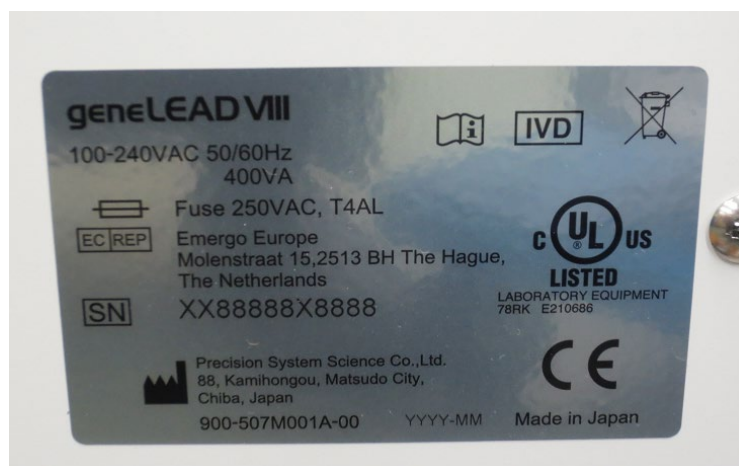
1.8.8 Protection against noise hazard

The instrument is designed and produced to keep the A-weighted emission sound to be within 70dB.

1.9 Safety labels / Instrument labelling

1.9.1 Instrument Type Plate

Instrument serial number are explained on instrument type plate.
Serial number is unique for each instrument.



1.9.2 Switch labels

Power Switch is installed on the left side of the instrument. In case of emergency, user can stop instrument by using this switch.

1.9.3 High temperature label

Hot surface warning label is attached front of hot collar and heating block. Even if the hot collar or heating block do not always turn on, but the label is attached for user attention.



1.9.4 Pinching fingers label

Moving parts is inside. Even if geneLEAD VIII system have safety lock if open door, label is attached for user attention.



1.9.5 Biohazard label

Biohazard label is attached inside of instrument. There is risk of user exposure to potential biohazard. Operator must wear suit and glove. Also it is mandatory to follow strictly lab, local and national regulations for safety.



1.9.6 Caution label for UV Lamp

Caution label is attached right side of instrument.

CAUTION UV emitted from this product.

IEC62471 Risk Group 2

Avoid looking directly at the UV light. Do not expose your skin to UV light.



1.10 Operational precautions and limitations

To use the instrument in safe and get reliable result, user have to follow the guidance to operate the system in properly. Unless it may cause not reliable results or instrument damage.

1.10.1 General requirement

- a) Keep away heat generating device and direct sunlight from the instrument, operate within defined operation temperature range.
- b) Keep defined minimum space all side of the system. (more than 50mm)

This is important for

- i) Reliable temperature control
- ii) Keep functionality of electric and detection system
- iii) Keep enough lifetime of the system
- iv) Easy access or maintenance

Warning



Danger of inappropriate installation position

In appropriate installation position may cause overheating the system and cause serious system damage.

1.11 Installation of the system

The geneLEAD VIII system installation have to be done by PSS Group or distributor. The geneLEAD VIII system must be connected with grounding, only use power supply cable shipped with the instrument.

Caution



The geneLEAD VIII system is only installed by PSS Group or distributor.

Caution



The geneLEAD VIII system is not designed for explosive atmosphere. User is responsible for verify the installation area is not explosive.

1.12 Removal of the system

In case of removal the geneLEAD VIII system for new place, user should call PSS Group or distributor.

Caution

The geneLEAD VIII system is only remove by PSS Group or distributor.

1.13 Transportation of the system

In case of transfer the geneLEAD VIII system for new place, user should call PSS Group or distributor.

Caution

The geneLEAD VIII system is only remove by PSS Group or distributor.

1.14 Disposal of the system

In case of dispose the geneLEAD VIII system for new place, user should call PSS Group or distributor.

Caution

The geneLEAD VIII system is only disposed by PSS Group or distributor.

1.15 Contact information



Precision System Science Co., Ltd.

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E-mail : service@pss.co.jp

Precision System Science USA, Inc.

5673 West Las Positas Blvd., Suite 202, Pleasanton, CA 94588, U.S.A.

E-mail : contact@pssbio.com

Precision System Science Europe GmbH

55122 Mainz, Mombacher Str. 93, Germany

E-mail : contact-psse@pss.co.jp



Emergo Europe

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Distributor

Please attach the contact information of
distributor here

1.16 System Components

1.16.1 Accessories

- Power Cable



Power Cable for 125VAC



Power Cable for 250VAC

- D-Rings and Silicon Grease



D-Rings

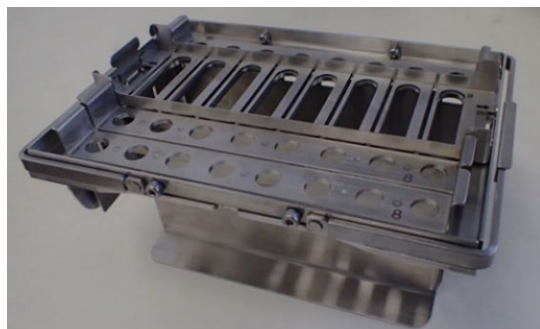


Silicon Grease

- Reagent Cassette Rack



- Sample Rack



1.16.2 Consumables

Please use the following consumables for geneLEAD VIII

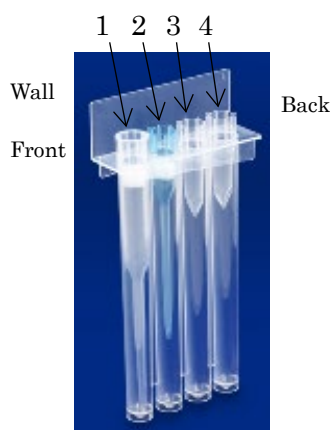
Please check the instruction manual (IFU) of each consumable before using.

Product Code	Product Name	Units
F8900	geneLEAD VIII Consumable Set	48 test

Components

- Tip and Tip Holder 48 set

- 1 : DN100N tip
- 2 : ME200 tip
- 3 : PP75 Pierce Tip
- 4 : PP75 Pierce Tip



- Sample Tube and Elution Tube: each.50 set



Sample Tube



Elution Tube

Product Code	Product Name	Unit
F8820	geneLEAD VIII PCR Reagent Cassette Set	192 test

Component

- .PCR Reagent Cassette 192 pcs

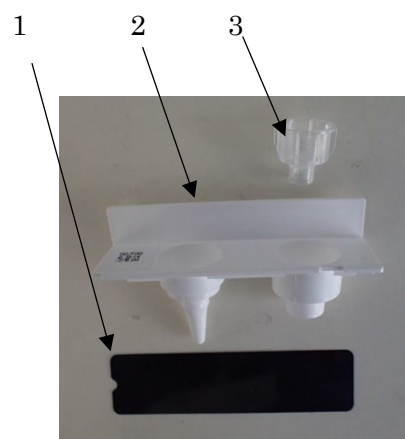


Product Code	Product Name	Unit
F8840	geneLEAD VIII PCR Reagent Cassette Set	192 test

Component

- . PCR Reaction Cassette:192 set

- 1:Cover
- 2:PCR Reaction Cassette
- 3:PCR Cap



2 Extraction / amplification / detection of the geneLEAD VIII

2.1 Principle

The geneLEAD VIII instrument performs nucleic acid extraction / amplification and detection. Main functions are as follows.

1) Extraction of nucleic acid from samples

The system is available for using specially designed extraction reagent cartridge and filter tip for Magtration ® system.

2) Amplification of nucleic acid by real time PCR process

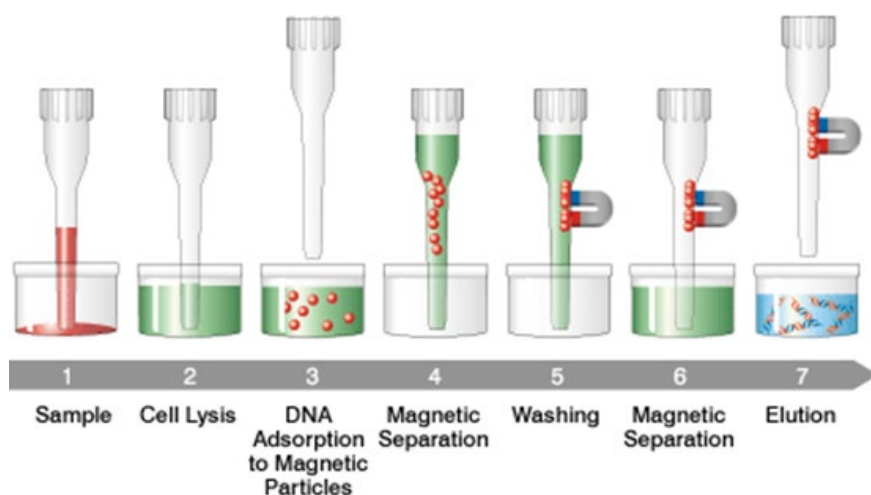
The system is available for PCR thermal cycle with real time florescence monitoring maximum up to 6 channels.

3) Melting point analysis after amplification

The system is available for temperature profile of melting point analysis with real time florescence monitoring maximum up to 6 channels.

2.2 Extraction

The geneLEAD VIII instrument performs nucleic acid extraction based on Magtration ® technology.



Extraction step by using Magtration ® technology

2.3 Extraction reagent

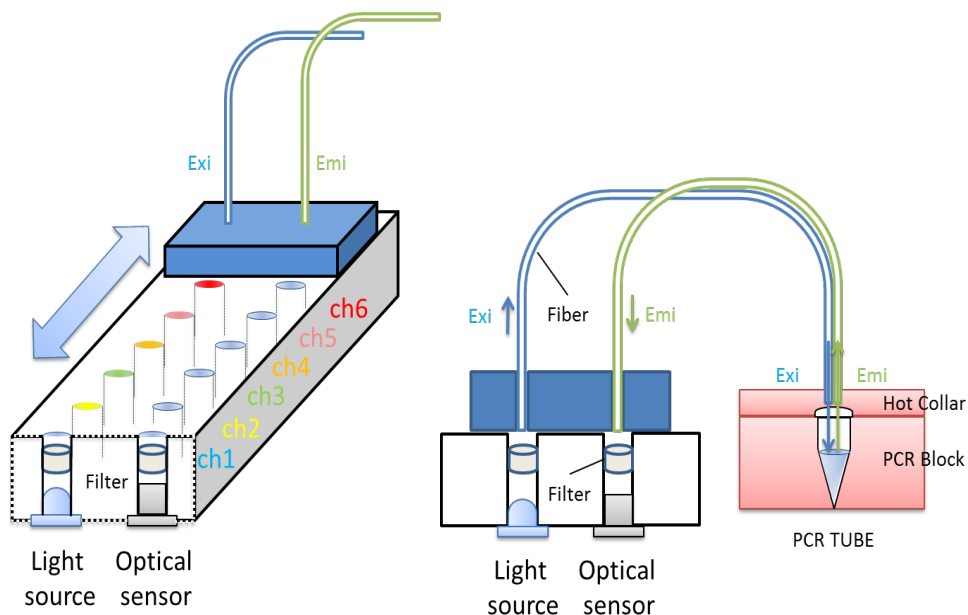
The geneLEAD VIII instrument is available for using dedicated extraction reagent “MagDEA Dx”.



Pre packed reagent “MagDEA Dx”

2.4 Optical fluorescence detection system

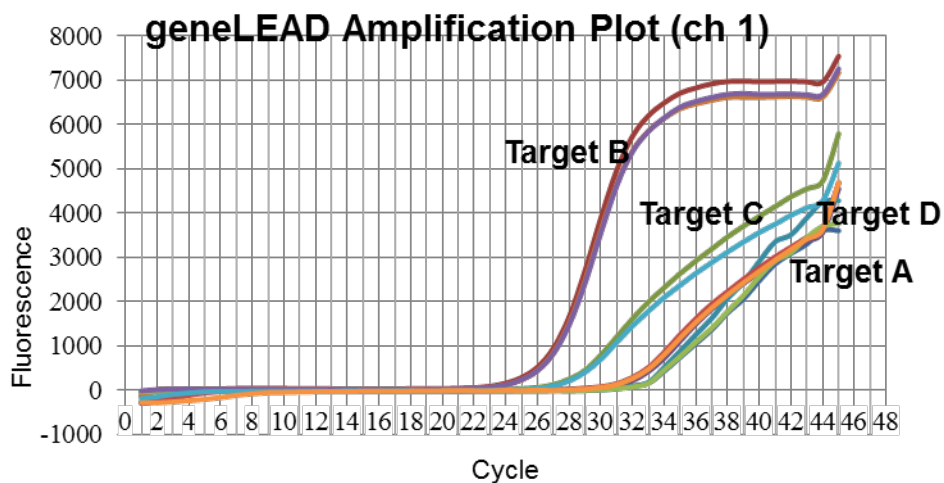
The geneLEAD VIII instrument contains six pairs of excitation light source and optical sensor.



By moving fibers across those light source and optical sensor, the geneLEAD VIII system pick up fluorescence signal of each sample / each channel.

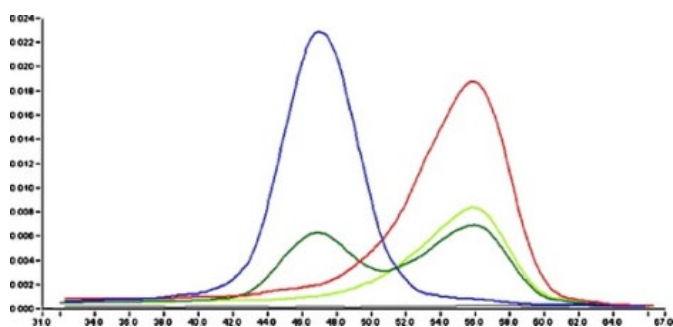
2.5 Gathering data for amplification plot

The geneLEAD VIII system is available for gathering data for amplification plot as follows.



2.6 Melting analysis

After amplification, by proceeding annealing step under real time fluorescence signal monitoring, the geneLEAD VIII system is available for melting analysis.



3 Use of System

The aim of this chapter is for the operator to acquire the skills to run assays while checking the content of the chapter. It also provides an explanation of the flow of running assays to checking results using this system.

NOTE

Log out of the system before leaving.

NOTE

Inserting external media carries a risk of virus infection. Insert media after running a virus check.

NOTE

When connected to a network, the database could be modified via unauthorized access. If instructed to do so, disconnect from the network.

NOTE

When connected to a network, system files could be modified via unauthorized access. If instructed to do so, disconnect from the network.

NOTE

When connected to a network, the system could be subjected to a cyber attack. If instructed to do so, disconnect from the network.

NOTE

Contact the distributor if the system is unstable.



Ground the power cord before use.

3.1 Logging in

The login screen below will be displayed when the power on the left side of the system is turned on.

Enter your User Name and Password to launch geneLEAD VIII (electricity check and axis homing). This operation will take about five minutes.

- Values to enter on first launch

User Name	Password	Role (*)
PSSAdmin	adminpss0064	Administrator

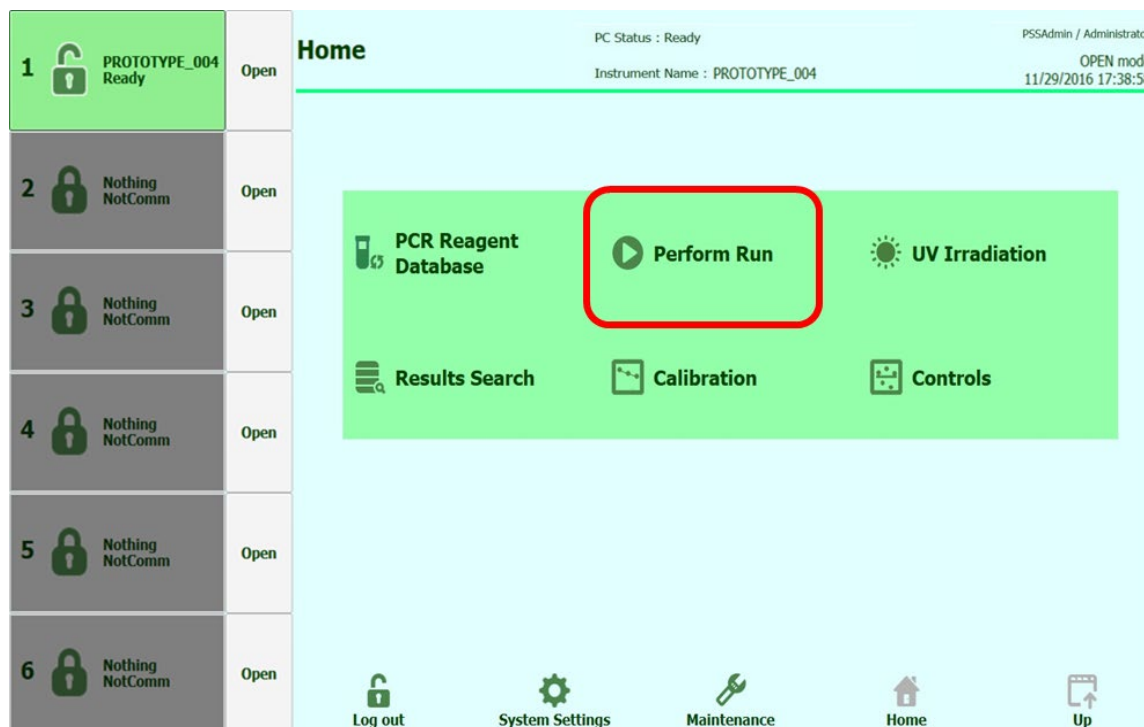
*There are three kinds of roles set for the User Account under System Settings.

	System Settings	Approve Data	Perform Run
Administrator	○	○	○
Analyst		○	○
Operator			○

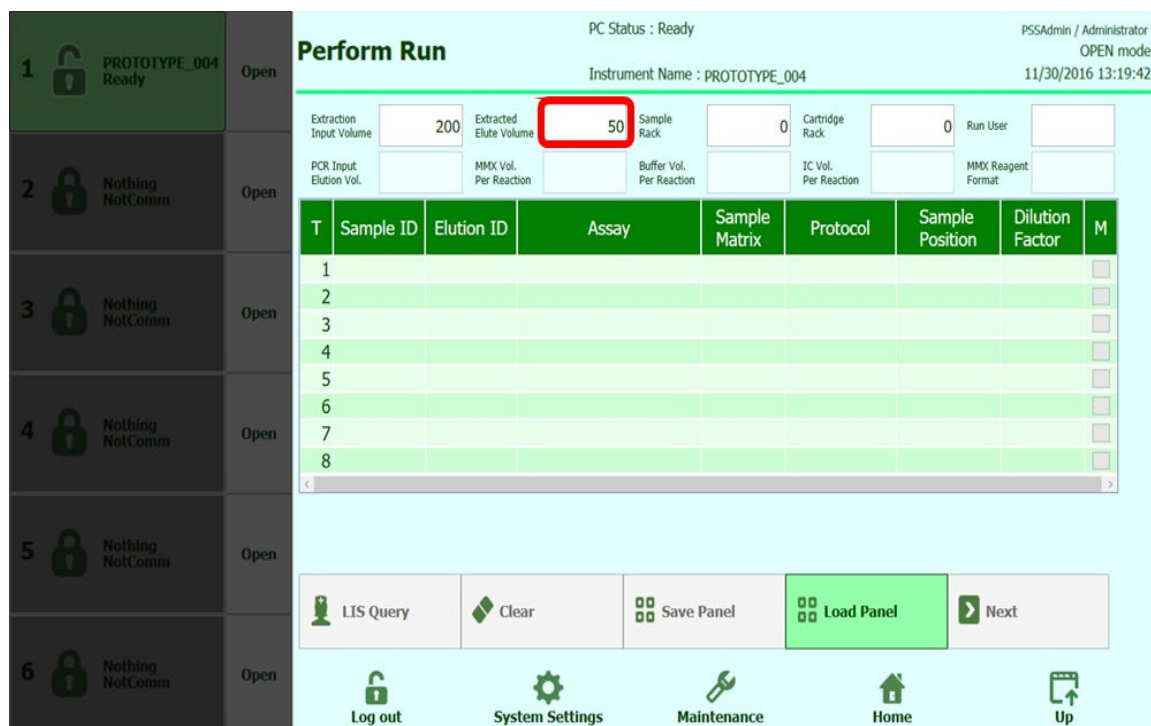
3.2 Running registered assays

3.2.1 Selecting assay, installing consumables and launching operations

Click the Perform Run button to open the Assay selection screen.



Select elution volume. (This information is linked to the registered assay file. The volume cannot be changed on this screen.)



Select Sample Rack and register the rack to be used for the run. Do the same for Reagent Cassette Rack.

Rack registration is performed using the supplied hand-held barcode reader.

*This item is only for operating multiple systems using one external PC

Perform Run PC Status : Ready PSSAdmin / Administrator
Instrument Name : PROTOTYPE_004 OPEN mode 11/30/2016 13:19:42

Extraction Input Volume: 200 Extracted Elute Volume: 5 Sample Rack: 0 Cartridge Rack: 0 Run User:
 PCR Input Elution Vol. MMX Vol. Per Reaction Buffer Vol. Per Reaction MMX Reagent Format

T	Sample ID	Elution ID	Assay	Sample Matrix	Protocol	Sample Position	Dilution Factor	M
1								
2								
3								
4								
5								
6								
7								
8								

LIS Query Clear Save Panel Load Panel Next

Log out System Settings Maintenance Home Up

Sample Rack Information

Cutout of the rack

Pattern 1

Pattern 2

Rack Number

1

OK Cancel

Rack Number:

1:Sample Rack
2:Reagent Cassette Rack

Select the user that will perform the run.

1

PROTOTYPE_004

Ready

Open

2

Nothing NotComm

Open

3

Nothing NotComm

Open

4

Nothing NotComm

Open

5

Nothing NotComm

Open

6

Nothing NotComm

Open

PC Status : Ready

PSSAdmin / Administrator

OPEN mode

11/30/2016 13:19:42

Perform Run

Instrument Name : PROTOTYPE_004

Extraction Input Volume

200

Extracted Elute Volume

50

Sample Rack

0

Cartridge Rack

0

Run User

PCR Input Elution Vol.

MMX Vol. Per Reaction

Buffer Vol. Per Reaction

IC Vol. Per Reaction

MMX Reagent Format

T	Sample ID	Elution ID	Assay	Sample Matrix	Protocol	Sample Position	Dilution Factor	M
1								
2								
3								
4								
5								
6								
7								
8								

LIS Query

Clear

Save Panel

Load Panel

Next

Log out

System Settings

Maintenance

Home

Up

Set the assay file and operation for each track.

Select the assay.

Enter the Sample ID and Elution ID to be displayed in the results. Enter the IDs by clicking the box and using the keyboard or by using the hand-held barcode reader.

Information other than the Sample ID and Elution ID can also be registered using the Save Panel button.

To load a registered Panel, use the Load Panel button.

If the wrong assay was selected, use the Clear button to delete it.

T:	Track (=Lane)
Sample ID:	Sample ID to be displayed in report
Elution ID:	Elution ID to be displayed in report
Assay:	Select from registered list
Sample Matrix:	Information linked to assay file (cannot be changed)
Protocol:	Select “Extract+PCR”, “Extract Only” or “PCR Only”
Sample Position:	Displayed automatically based on protocol selected
Dilution Factor:	Information linked to assay file
M:	Box will be checked for assay files including melting (cannot be changed)

Click the Next button to proceed to the consumables installation screen.

Perform Run PC Status : Ready PSSAdmin / Administrator
Instrument Name : PROTOTYPE_004 OPEN mode 11/30/2016 13:19:42

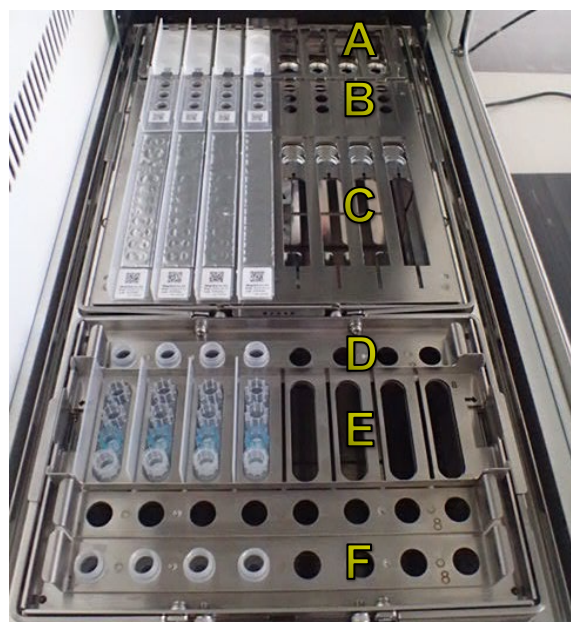
Extraction Input Volume: 200 Extracted Elute Volume: 50 Sample Rack: 0 Cartridge Rack: 0 Run User:
 PCR Input Elution Vol. MMX Vol. Per Reaction Buffer Vol. Per Reaction IC Vol. Per Reaction MMX Reagent Format

T	Sample ID	Elution ID	Assay	Sample Matrix	Protocol	Sample Position	Dilution Factor	M
1								
2								
3								
4								
5								
6								
7								
8								

LIS Query Clear Save Panel Load Panel **Next**

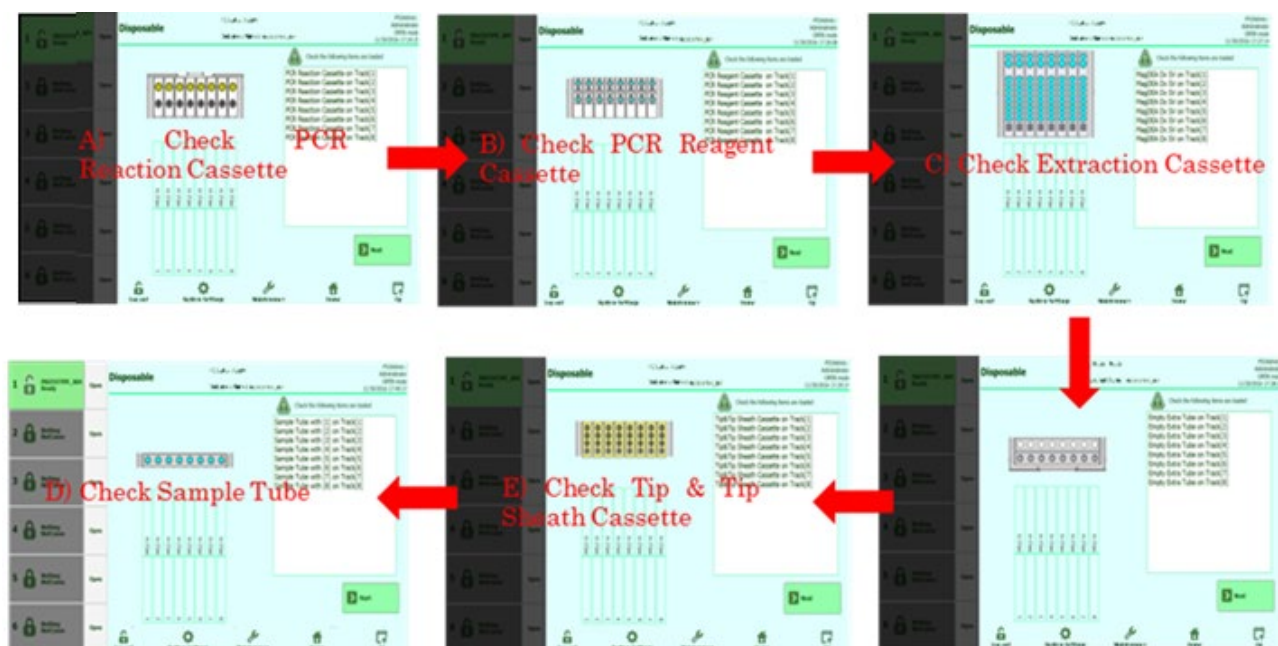
Log out System Settings Maintenance Home Up

Follow the GUI to install the consumables.



Reagent Cassette Rack

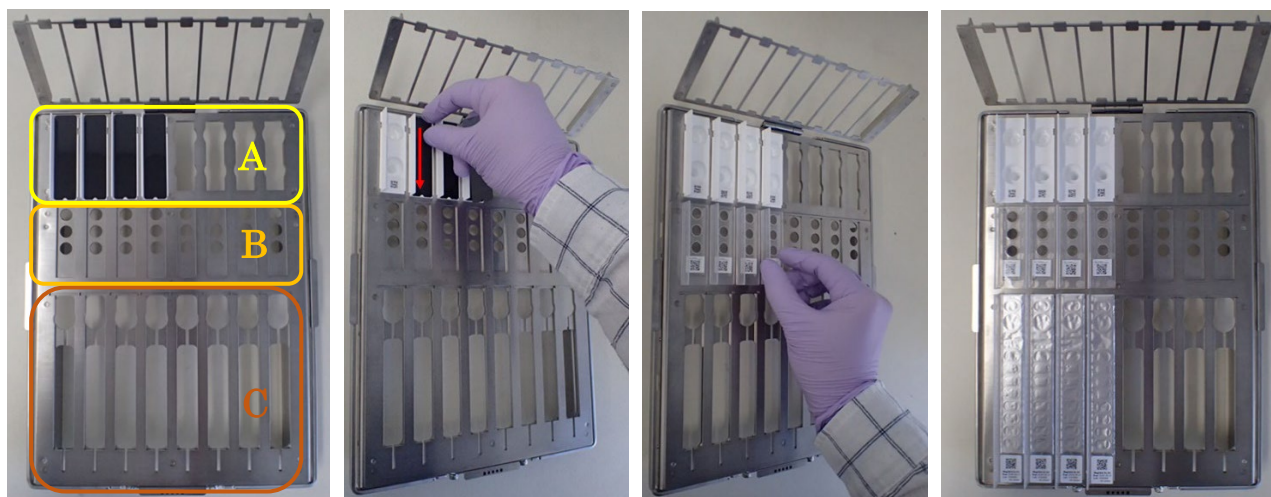
Sample Rack



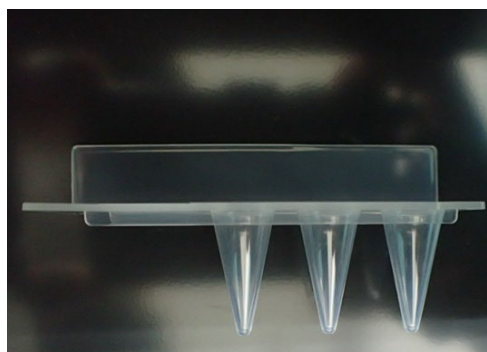
How to Install PCR Reaction Cassette (A) / PCR Reagent Cassette (B) / Reagent Cartridge (C)

With the Reagent Cassette Rack's PCR Cassette clamp lifted, install the PCR Reaction Cassette and remove the black cover.

Install the PCR Reagent Cassette and Reagent Cartridge and lower the PCR Cassette clamp.



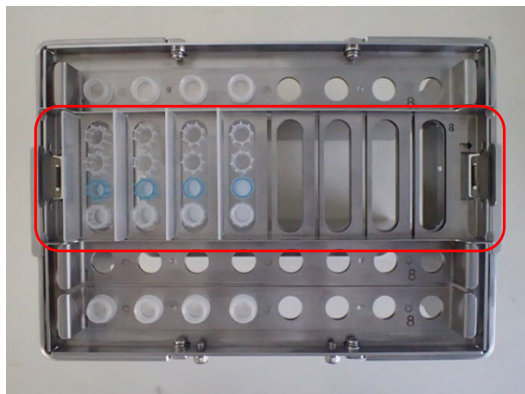
* Dead volume of PCR Reagent Cassette 5 μ l



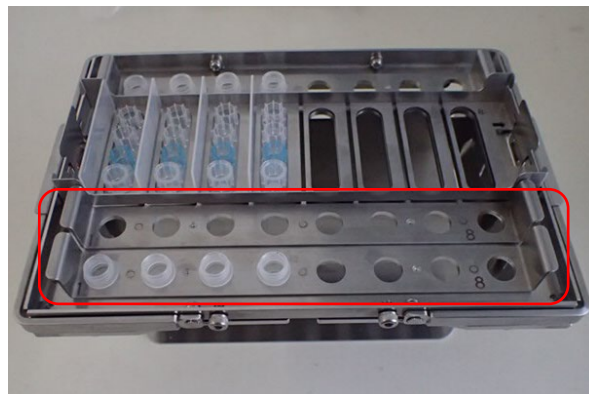
How to Install Tip Cassette (E) / Elution Tube (F) / Sample Tube (D)

Install the items as shown in the photographs below in the designated place on the Sample Rack.

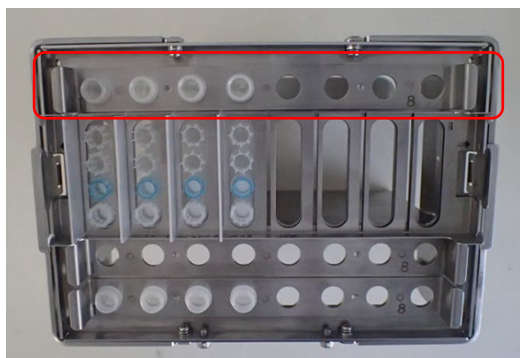
E. Tip Cassette



F. Elution Tube



D. Sample Tube



****Minimum volume of Elution Tube 30 μ l**



How to Install Reagent Cassette Rack and Sample Rack in System

Install the racks in the system holding the handles and then fold them down the left and right.

Reagent Cassette Rack



Sample Rack



3.2.2 Obtaining and saving results

Check the Ct value from the Result tab and the graph using the Graph button.

If you are logged in with a role other than Operator, the Approve button will be active, and you can approve the results.

The screenshot shows the 'Results Display' window. On the left, there is a sidebar with six status indicators, all labeled 'Nothing NotComm' and 'Open'. The main area displays 'PC Status : Ready', 'PSSAdmin / Administrator', 'OPEN mode', and 'Instrument Name : PROTOTYPE_004'. Below this, the 'Graph' button is highlighted with a red box. Other buttons include 'Export Data', 'Approve', 'Print', and 'End of Run'. The assay details show 'PROTOTYPE004 Assay start : 12/01/2016 10:01:51 end : 12/01/2016 10:05:55'. A table lists assay results for tracks 1 through 8, including Sample ID, Elution ID, Assay Name, Protocol, Dilution Factor, and Result (N M13: - Ct(Meas=...)).

Track	Sample ID	Elution ID	Assay Name	Protocol	Dilution Factor	Result
1	1		M13 H	Extract + PCR 1		N M13: - Ct(Meas=29.99)
2	2		M13 H	Extract + PCR 1		N M13: - Ct(Meas=29.94)
3	3		M13 H	Extract + PCR 1		N M13: - Ct(Meas=29.76)
4	4		M13 H	Extract + PCR 1		N M13: - Ct(Meas=30.07)
5	5		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.6)
6	6		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.68)
7	7		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.72)
8	8		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.54)

The data can be saved to a USB memory stick using the Export Data and Print buttons.

Note: Past data can be approved and saved from Result Search on the Home screen as well.

Export Data: Save four files (****_Raw, ****RawCrossTalk, ****_Run, ****_Data_1~12) in CSV format.

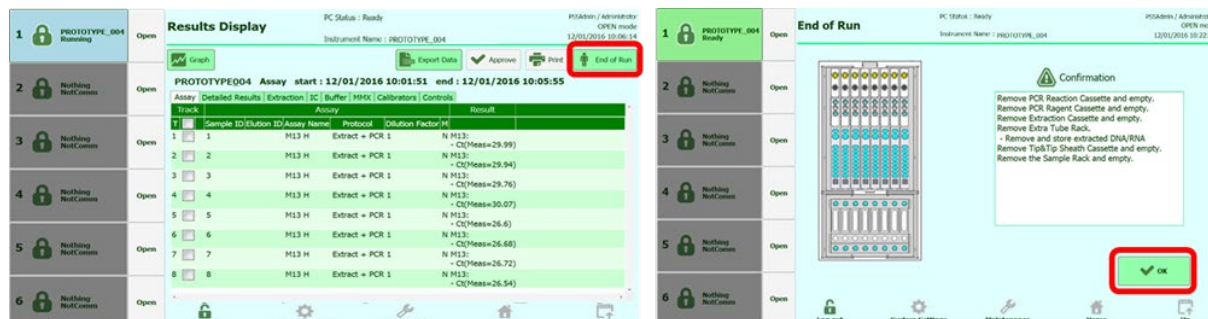
Print: Save a report with the Ct value, Tm value, amplification curve, reagent lot, etc.

This screenshot is similar to the previous one, but the 'Export Data' and 'Print' buttons are highlighted with red boxes. Additionally, the checkbox for 'Track 1' in the table is checked, and its corresponding row is highlighted in red.

Track	Sample ID	Elution ID	Assay Name	Protocol	Dilution Factor	Result
1	1		M13 H	Extract + PCR 1		N M13: - Ct(Meas=29.99)
2	2		M13 H	Extract + PCR 1		N M13: - Ct(Meas=29.94)
3	3		M13 H	Extract + PCR 1		N M13: - Ct(Meas=29.76)
4	4		M13 H	Extract + PCR 1		N M13: - Ct(Meas=30.07)
5	5		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.6)
6	6		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.68)
7	7		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.72)
8	8		M13 H	Extract + PCR 1		N M13: - Ct(Meas=26.54)

3.2.3 Ending operation

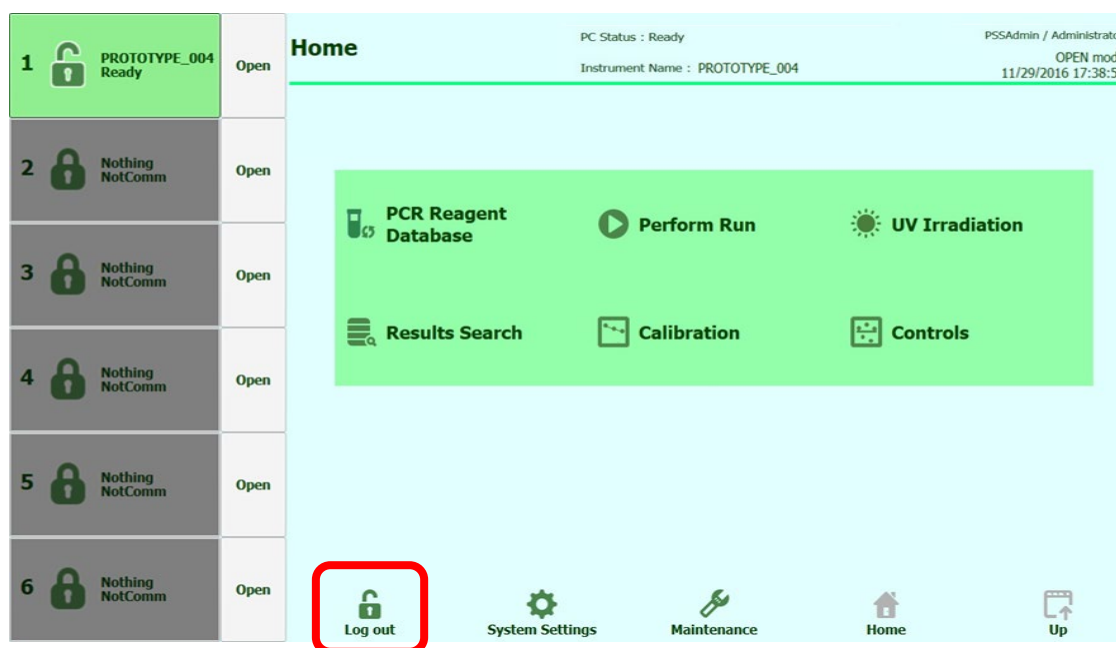
Click the End of Run button to end the operation.



Open the door and discard the consumables.

Click the Log out button to shut down geneLEAD VIII.

Make sure the consumables have been discarded, set UV irradiation and turn off the power.



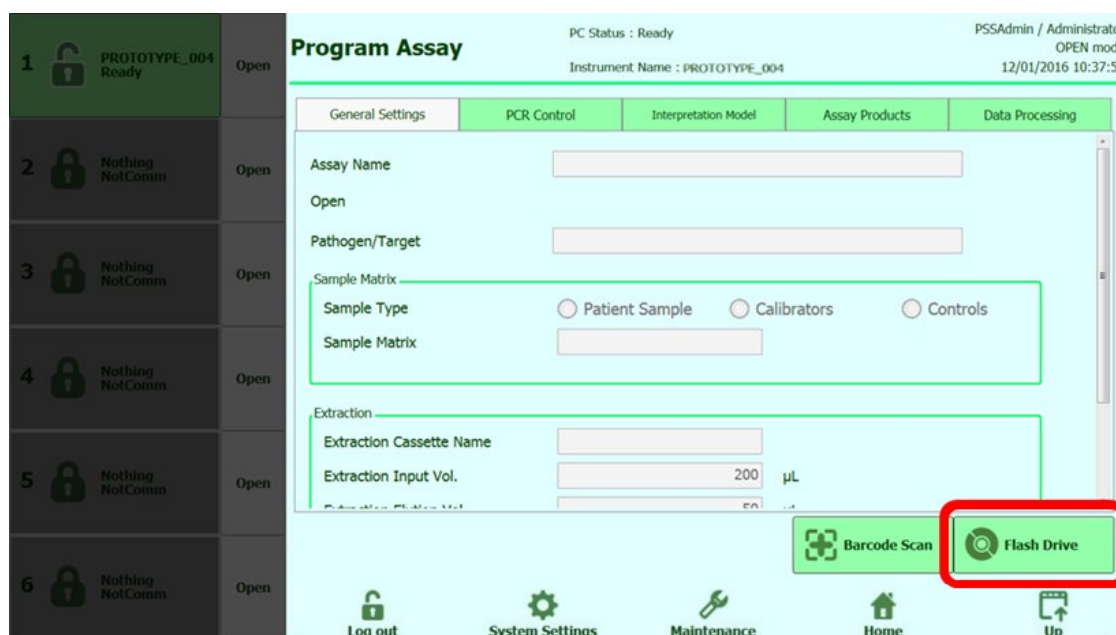
3.3 Creating New Assay from Barcode and Flash Memory Information

*This can only be performed by a user with Administrator role

Select Program Assay under System Settings.



To register a file from flash memory (USB memory), insert the USB memory with the assay file into the USB port on the external PC and register it using the Flash Drive button.



To register a file from barcode information, click the Barcode Scan button and register it by scanning the barcode with the hand-held barcode reader.

The screenshot displays the 'Program Assay' interface of the geneLEAD VIII system. On the left, a vertical sidebar lists six assay slots, each with a lock icon, status (e.g., 'PROTOTYPE_004 Ready' or 'Nothing NotComm'), and an 'Open' button. The main area is titled 'Program Assay' and shows system status (PC Status: Ready, Instrument Name: PROTOTYPE_004) and user information (PSSAdmin / Administrator, OPEN mode, 12/01/2016 10:37:50). Below this is a tabbed menu with 'General Settings', 'PCR Control', 'Interpretation Model', 'Assay Products', and 'Data Processing'. The 'General Settings' tab is active, showing fields for 'Assay Name', 'Pathogen/Target', 'Sample Matrix' (with 'Sample Type' options: Patient Sample, Calibrators, Controls), and 'Extraction' (with 'Extraction Cassette Name' and 'Extraction Input Vol.' set to 200 µL). At the bottom right, a 'Barcode Scan' button with a barcode icon is highlighted with a red rectangle, next to a 'Flash Drive' button. A bottom navigation bar includes 'Log out', 'System Settings', 'Maintenance', 'Home', and 'Up' icons.

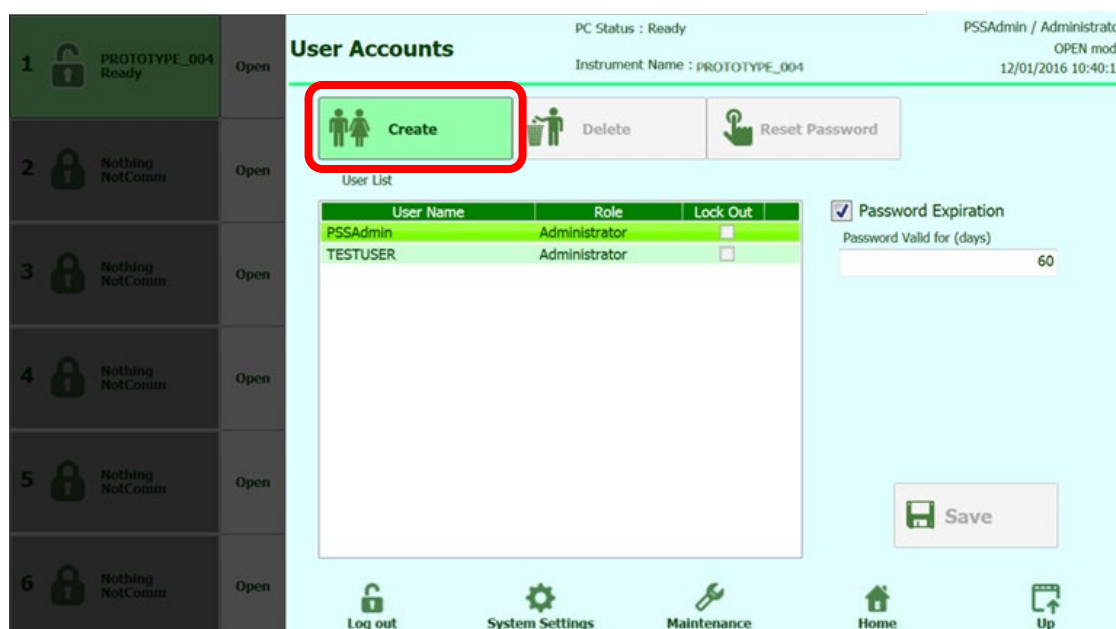
3.4 How to Configure User Accounts

***This can only be performed by a user with Administrator role**

Open User Accounts under System Settings.



Use the Create button to create a new account.



Enter the User Name, role and password. The password can be a combination of 8-32 letters and numbers.

User Name

Role

Password

Confirmation

OK

Cancel

3.5 What To Do If An Error Occurs During An Operation

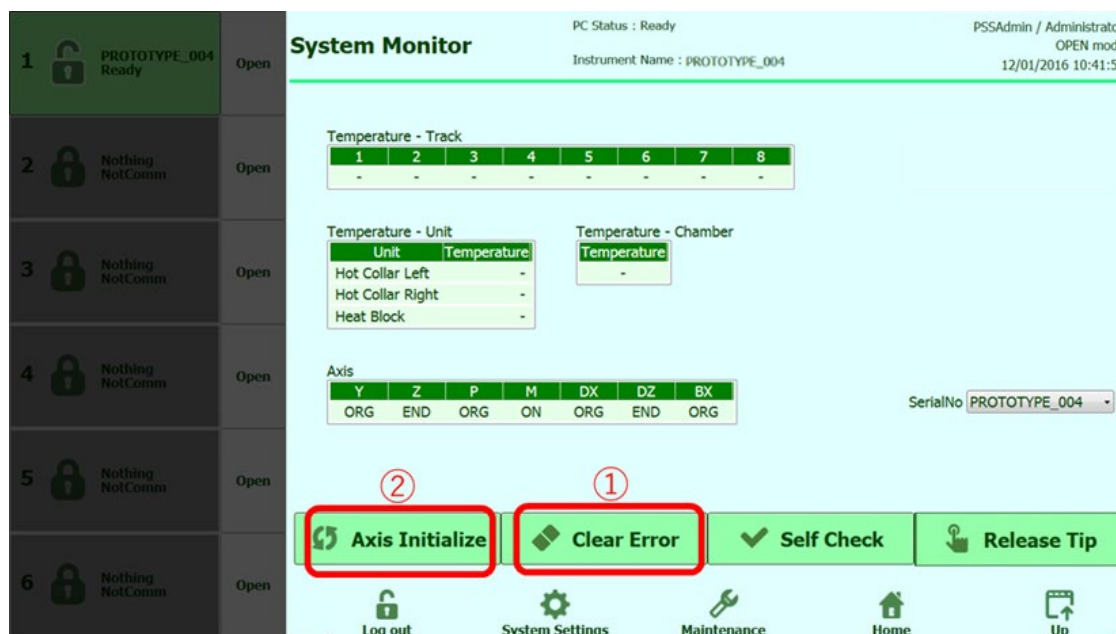
*This can only be performed by a user with Administrator role

3.5.1 Error cancellation and axis homing

Open System Monitor under System Settings.



Click the Clear Error and Axis Initialize buttons in that order to home the axis.



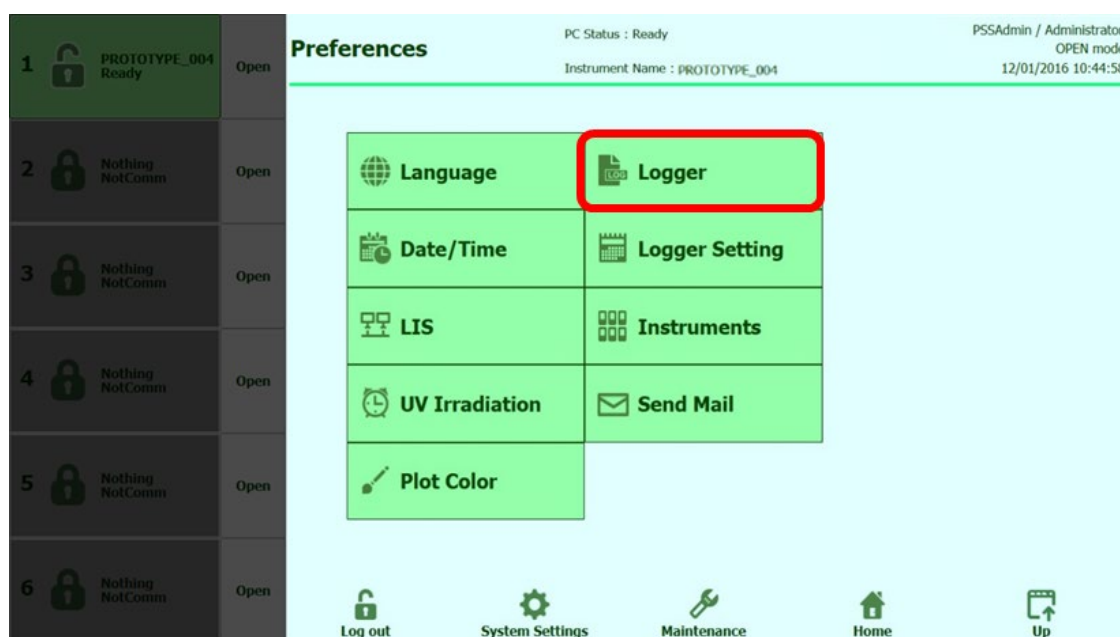
3.5.2 Exporting external PC log

Insert the USB memory stick to save the log to into the USB port on the external PC.

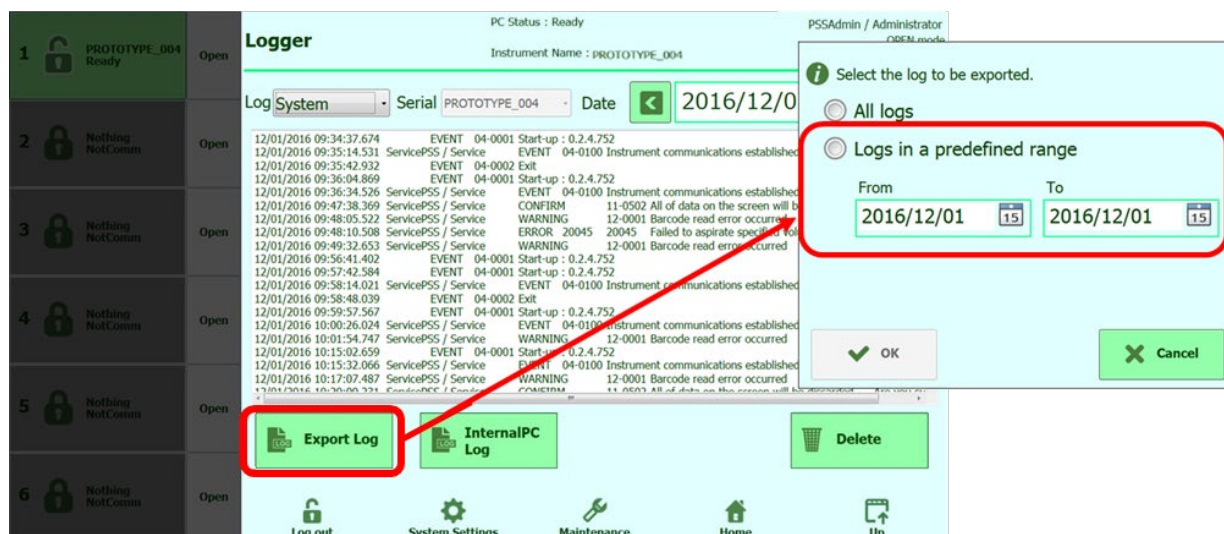
Open Preferences under System Settings.



Select Logger.



Select “Logs in a predefined range” from the Export Log button and set the date.



Select the USB memory as the save location for the log from the OK button and save the log.

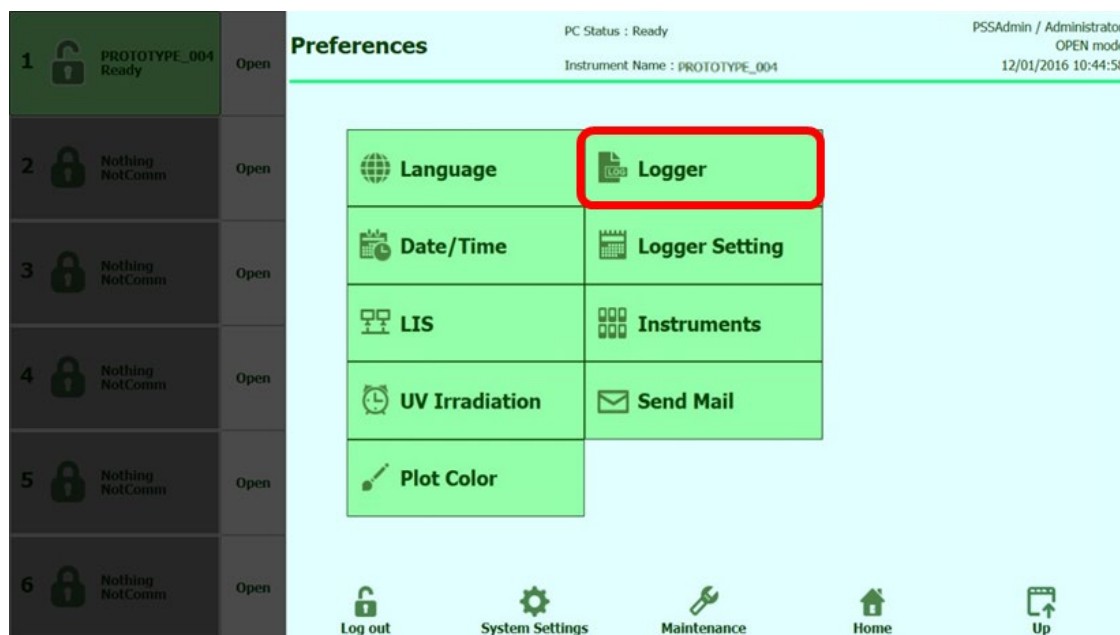
3.5.3 Exporting internal PC log

Insert the USB memory stick to save the log to into the USB port on the external PC.

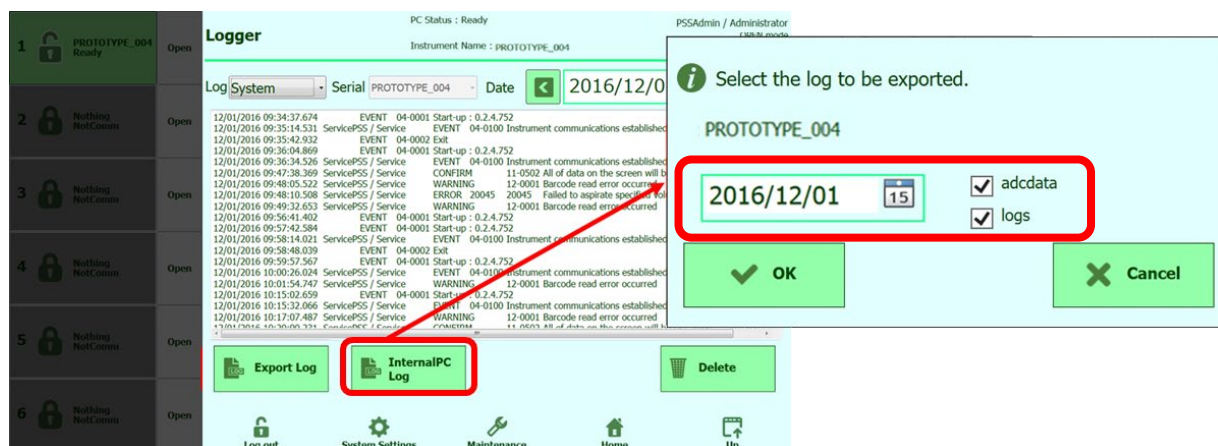
Open Preferences under System Settings.



Select Logger.



Click the Internal PC Log button, and set the data (ADC Data and Log) to acquire from the selected system and the date.



Select the USB memory as the save location for the log from the OK button and save the log.

4 Maintenance

4.1 Safety concerns

Danger



Electrical hazard
Refer to Chapter 1.7.3

Danger



Biological hazard
Refer to Chapter 1.7.6

4.2 Periodic Maintenance

Periodic maintenance by PSS or the dealer is required to maintain proper performance of the geneLEAD VIII system. PSS or the dealer will perform proper maintenance and implement preventive measures. Except in cases where PSS or the dealer cannot warranty the system, this is essential.

4.3 User Maintenance

Caution



70% ethanol solution is combustible. Make sure there are no open flames nearby when using it.

4.3.1 Maintenance every two weeks

4.3.1.1 D ring lubrication

The geneLEAD system requires D ring lubrication every two weeks.

[Procedure]

Wipe down the D ring with a lab towel soaked in a 70% ethanol solution.

Apply grease after that using a cotton swab.

Too much grease applied cause bad connection of nozzle and tip. Wipe off the excess of grease.

4.3.1.2 Cleaning inside of well

With the geneLEAD VIII system, it is necessary to clean the inside of the heat block weekly. Clean off any dust or grease stuck to the inside.

[Procedure]

Clean inside the heat block with a cotton swab soaked in a 70% ethanol solution.

Do not use acetone or other heavy-duty detergents.

4.3.2 Daily maintenance

Clean the inside of the geneLEAD VIII system daily.

4.3.2.1 Stage surface

Clean the stage surface of the geneLEAD VIII system daily.

[Procedure]

Clean the inside of the well with a dust towel soaked in a 70% ethanol solution.

Do not use acetone or other heavy-duty detergents.

Caution



Do this according to the instructions of an expert or the directions.

Only use the designated chemicals. If you are unsure which chemicals to use, ask PSS or the dealer.

Failure to observe the precautions could lead to minor injury. It could also damage the system.

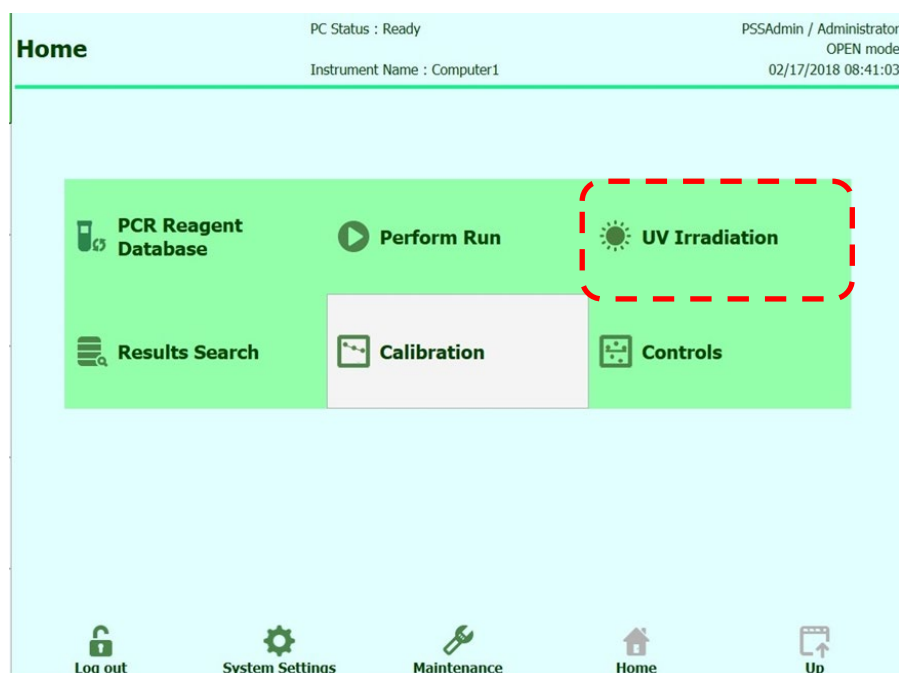
4.3.3 UV Irradiation

geneLEAD must be irradiated with a UV lamp after use to minimize the risk of contamination.

[Procedure]

Remove all consumables and reagents after using the system.

Select UV Irradiation on the Home screen.



The selected system will be subjected to UV irradiation.



NOTE

A check mark will be displayed next to the selected system in the system selection area.

NOTE

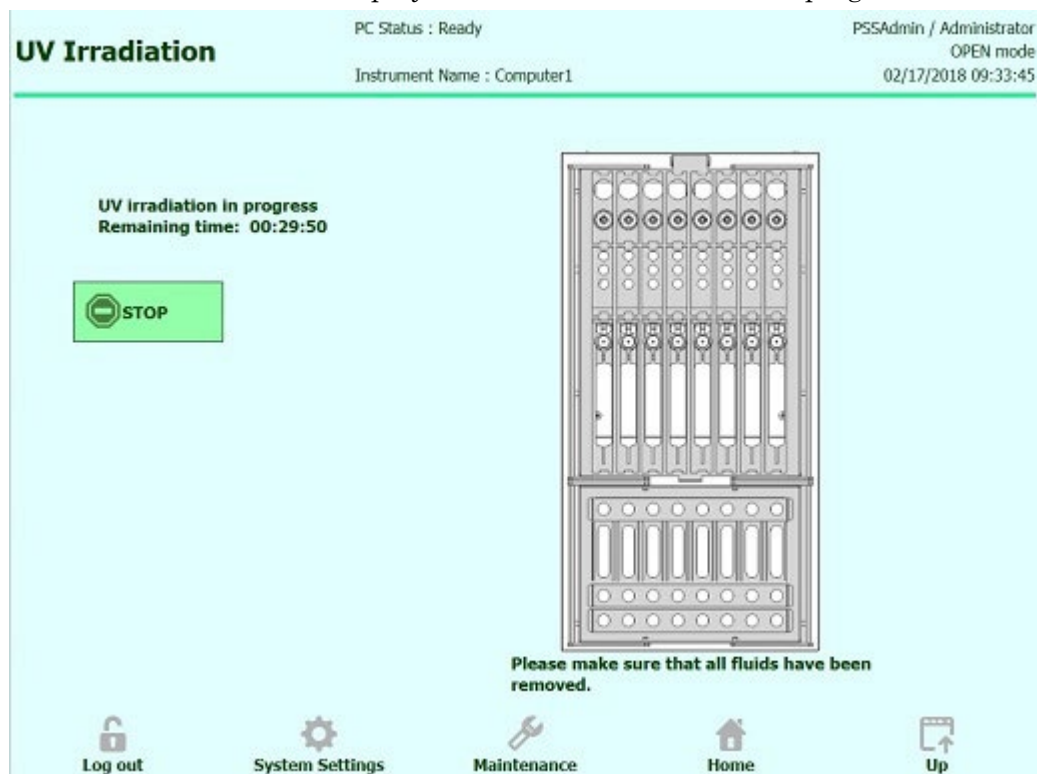
To perform UV irradiation on all systems, place a check mark in "Select All."



A pop-up message will be displayed when the OK button is clicked.
Close the front door and click the OK button to begin UV irradiation.



The screen below will be displayed while UV irradiation is in progress.



NOTE

The front door will be locked while UV irradiation is in progress.

NOTE

UV irradiation can be stopped by clicking the “Stop” button.

NOTE

If the external PC and the system are disconnected, it will be necessary to reconnect them in order to complete UV irradiation.

NOTE

The UV irradiation time can be changed.

NOTE

If communication is interrupted while UV irradiation is in progress, the following will occur:

- When only one system is registered

The UV irradiation screen will persist until the connection is re-established.

Press the Alt and F4 buttons to force termination of the application.

- When multiple systems are registered

The Switch Systems button on the left can be used to switch to the screens of other systems.

The UV irradiation screen will persist until the connection is re-established.

5 Troubleshooting and Error Messages

5.1 Error and information messages

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20004	Error	Error message	Liquid was remaining after dispensing with DN100N.[Track{n}] *{n}: Track number
		Error description	Liquid remained on the DN100N tip after dispensing.
		Possible causes	There was no liquid to dispense inside the dispensing tip (DN100N). The dispensing tip (DN100N) is clogged. The dispensing tip (DN100N) fell off the nozzle.
		Action	Click the OK button to close the dialog. If using internal control, check amplification. If there is amplification, the extraction process is normal.
20005	Error	Error message	No liquid found to aspirate (DN100N tip).[Track{n}] *{n}: Track number
		Error description	There is no liquid for aspiration.
		Possible causes	There was no liquid in the extraction reagent cartridge tube. There was no liquid in the PCR reagent cartridge tube. There was no liquid in the sample tube. The extraction reagent cartridge has not been installed. The PCR reagent cartridge has not been installed. The sample tube has not been installed.
		Action	Click the OK button to close the dialog. If using internal control, check amplification. If there is amplification, the extraction process is normal.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20009	Error	Error message	Failed to aspirate Monoreagent.[Track{n}] *{n}: Track number
		Error description	There is no monoreagent for aspiration.
		Possible causes	There was no monoreagent solution in the PCR reagent cartridge. The PCR reagent cartridge has not been installed.
		Action	Check the monoreagent solution in the PCR reagent cartridge. Install the PCR reagent cartridge. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20010	Error	Error message	Liquid was remaining after dispensing of Monoreagent.[Track{n}] *{n}: Track number
		Error description	Liquid remained on the small volume tip after dispensing the monoreagent.
		Possible causes	There was no liquid to dispense inside the dispensing tip (ME200). The dispensing tip (ME200) is clogged. The dispensing tip (ME200) fell off the nozzle.
		Action	Click the OK button to close the dialog. If using internal control, check amplification. If there is amplification, the PCR process is normal.
20011	Warning	Error message	Failed to eject piercing tip (PP75). Please check that the nozzle has no Tip. [Track{n}] (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	The PP75 tip cannot be removed from the nozzle.
		Possible causes	The PP75 tip could not be ejected from the nozzle. The nozzle is clogged.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Action	<p>Remove the PP75 tip from the nozzle.</p> <p>After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.</p>
20012	Warning	Error message	<p>Failed to eject DN100N tip. Please check that the nozzle has no Tip.[Track{n}]</p> <p>(Caution! Heat Block is hot. Do not touch.)</p> <p>*{n}: Track number</p>
		Error description	The DN100N tip cannot be removed from the nozzle.
		Possible causes	<p>The DN100N tip could not be ejected from the nozzle.</p> <p>The nozzle is clogged.</p>
		Action	<p>Remove the DN100N tip from the nozzle.</p> <p>Rescan button: Restart the process.</p> <p>Abort button: Stop the process.</p> <p>After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.</p>
20013	Warning	Error message	<p>Failed to pickup piercing tip (PP75).[Track{n}]</p> <p>Check piercing tips in tip rack.</p> <p>(Caution! Heat Block is hot. Do not touch.)</p> <p>*{n}: Track number</p>
		Error description	<p>1. There is no PP75 tip.</p> <p>2. The PP75 tip cannot be removed.</p>
		Possible causes	<p>The tip holder has not been installed.</p> <p>The PP75 tip has not been installed.</p> <p>The PP75 tip could not be installed due to a manufacturing defect.</p>

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Action	<p>Install the tip holder.</p> <p>Install the PP75 tip.</p> <p>After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.</p>
20014	Warning	Error message	<p>Failed to eject ME200 tip. Please check that the nozzle has no Tip.[Track{n}]</p> <p>(Caution! Heat Block is hot. Do not touch.)</p> <p>*{n}: Track number</p>
		Error description	The ME200 tip cannot be removed from the nozzle.
		Possible causes	<p>The ME200 tip could not be ejected from the nozzle.</p> <p>The nozzle is clogged.</p>
		Action	<p>Remove the ME200 tip from the nozzle.</p> <p>After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.</p>
20015	Warning	Error message	<p>Failed to pickup DN100N tip.[Track{n}]</p> <p>Check DN100N tips in tip rack.</p> <p>(Caution! Heat Block is hot. Do not touch.)</p> <p>*{n}: Track number</p>
		Error description	<p>1. There is no DN100N tip.</p> <p>2. The DN100N tip cannot be removed.</p>
		Possible causes	<p>The tip holder has not been installed.</p> <p>The DN100N tip has not been installed.</p> <p>The DN100N tip is clogged.</p> <p>The DN100N tip could not be installed due to a manufacturing defect.</p>

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Action	<p>Install the tip holder.</p> <p>Install the DN100N tip.</p> <p>Replace the DN100N tip.</p> <p>After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.</p>
20016	Warning	Error message	<p>Failed to pickup ME200 tip.[Track{n}]</p> <p>Check ME200 tips in tip rack.</p> <p>(Caution! Heat Block is hot. Do not touch.)</p> <p>*{n}: Track number</p>
		Error description	<p>1. There is no ME200 tip.</p> <p>2. The ME200 tip cannot be removed.</p>
		Possible causes	<p>The tip holder has not been installed.</p> <p>The ME200 tip has not been installed.</p> <p>The ME200 tip is clogged.</p> <p>The ME200 tip could not be installed due to a manufacturing defect.</p>
		Action	<p>Install the tip holder.</p> <p>Install the ME200 tip.</p> <p>Replace the ME200 tip.</p> <p>After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.</p>
20025	Warning	Error message	Magnet is not extended
		Error description	The M axis is not in the Mag On sensor position during magtration.
		Possible causes	<p>M axis malfunction.</p> <p>Mag On sensor malfunction.</p>
		Action	<p>Click the OK button to close the dialog.</p> <p>If using internal control, check amplification. If there is amplification, the extraction process is normal.</p>

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20026	Warning	Error message	No sample found.[Track{n}] Check sample(s) placement. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	There is no sample in the sample tube.
		Possible causes	There is no sample in the sample tube. The sample tube has not been installed.
		Action	Check the sample in the sample tube. Install the sample tube. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20027	Warning	Error message	No PCR cap found.[Track{n}] Check PCR cap(s) placement. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	There is no PCR cap on the PCR cartridge.
		Possible causes	There is no PCR reaction cartridge. There is no PCR cap. Fluorescent unit malfunction.
		Action	Install the PCR reaction cartridge. Install the PCR cap. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20028	Warning	Error message	No Buffer found.[Track{n}] Check Buffer(s) placement. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	No buffer found. Check buffer placement.
		Possible causes	There was no buffer(s) in the PCR reagent cartridge. The PCR reagent cartridge has not been installed.
		Action	Check the buffer(s) in the PCR reagent cartridge. Install the PCR reagent cartridge. Rescan button: Restart the process. Abort button: Stop the process. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20031	Warning	Error message	No Monoreagent found.[Track{n}] Check Monoreagent(s) placement. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	There is no monoreagent in the PCR reagent cartridge.
		Possible causes	There was no monoreagent solution in the PCR reagent cartridge. The PCR reagent cartridge has not been installed.
		Action	Check the monoreagent solution in the PCR reagent cartridge. Install the PCR reagent cartridge. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20036	Error	Error message	Liquid was remaining after eluate dispensing.[Track{n}] *{n}: Track number

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Error description	Liquid remained on the tip after dispensing the eluate.
		Possible causes	There was no liquid to dispense inside the dispensing tip (ME200). The dispensing tip (ME200) is clogged. The dispensing tip (ME200) fell off the nozzle.
		Action	Click the OK button to close the dialog. If using internal control, check amplification. If there is amplification, the PCR process is normal.
20037	Error	Error message	Liquid was remaining after IC dispensing.[Track{n}] *{n}: Track number
		Error description	Liquid remained on the tip after dispensing the IC.
		Possible causes	There was no liquid inside the dispensing tip (DN100). The dispensing tip (DN100) is clogged. The dispensing tip (DN100) fell off the nozzle.
		Action	Click the OK button to close the dialog. If using internal control, check amplification. If there is amplification, the PCR process is normal.
20042	Error	Error message	Failed to aspirate eluate.[Track{n}] *{n}: Track number
		Error description	There is no elution for aspiration.
		Possible causes	There was no liquid in the Elution Tube. The Elution Tube has not been installed.
		Action	Check the liquid in the Elution Tube. Install the Elution Tube. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20043	Error	Error message	Failed to aspirate IC.[Track{n}] *{n}: Track number
		Error description	There is no IC for aspiration.
		Possible causes	There was not enough IC in the PCR reagent cartridge. The PCR reagent cartridge has not been installed. IC: Internal control
		Action	Check the IC in the PCR reagent cartridge. Install the PCR reagent cartridge. IC: Internal control After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20047	Warning	Error message	Unnecessary DN100N tip found.[Track{n}] Remove from DN100 tip holder. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	The DN100N tip is installed on the tip holder of a track not in use.
		Possible causes	The DN100N tip was installed on a track not in use.
		Action	Remove the tip holder from the track not in use. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20051	Warning	Error message	Unnecessary ME200 tip found.[Track{n}] Remove from ME200 tip holder. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Error description	The ME200 tip is installed on the tip holder of a track not in use.
		Possible causes	The ME200 tip was installed on a track not in use.
		Action	Remove the tip holder from the track not in use. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20052	Warning	Error message	Unnecessary PCR cap found.[Track{n}] Remove from PCR cartridge. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	A PCR cap is installed in the PCR cartridge of a track not in use.
		Possible causes	A PCR reaction cartridge and PCR cap were installed on a track not in use.
		Action	Remove the PCR reaction cartridge from the track not in use. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20053	Warning	Error message	Unnecessary PP75 tip found.[Track{n}] Remove from PP75 tip holder. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	The PP75 tip is installed on the tip holder of a track not in use.
		Possible causes	The PP75 tip was installed on a track not in use.
		Action	Remove the tip holder from the track not in use. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20054	Warning	Error message	No IC found.[Track{n}] Set IC(s). (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	There is no IC in the PCR reagent cartridge.
		Possible causes	There was not enough IC in the PCR reagent cartridge. The PCR reagent cartridge has not been installed. IC: Internal control
		Action	Click the OK button to close the dialog. If using internal control, check amplification. If there is amplification, the extraction process is normal.
20055	Warning	Error message	No eluate found.[Track{n}] Set eluate(s). (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	No elution.
		Possible causes	The Elution Tube has not been installed. There was no DNA elution in the Elution Tube.
		Action	Install the Elution Tube. Put DNA elution in the Elution Tube. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20070	Warning	Error message	Piercing tip (PP75) was dropped unexpectedly. Please put the dropped tip to the Tip Holder.[Track{n}] (Caution! Heat Block is hot. Do not touch.) *{n}: Track number

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Error description	The piercing tip (PP75) came off during piercing.
		Possible causes	The piercing tip (PP75) came off during piercing.
		Action	Contact the distributor. Send the log.
20075	Warning	Error message	DN100N tip clogged.[Track{n}] Replace the DN100N tip. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	The DN100 tip is clogged.
		Possible causes	The dispensing tip (DN100N) is clogged. The nozzle is clogged.
		Action	Replace the dispensing tip (DN100). After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20077	Warning	Error message	Please confirm the setting of the consumables of the stage.
		Error description	The consumables are not properly placed on the stage.
		Possible causes	The rack is not installed properly. The consumables are not placed properly.
		Action	Install the rack properly. Place the consumables properly. After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20084	Warning	Error message	ME200 tip clogged.[Track{n}] Replace the ME200 tip. (Caution! Heat Block is hot. Do not touch.) *{n}: Track number
		Error description	The ME200 tip is clogged. Replace the ME200 tip.
		Possible causes	The dispensing tip (ME200) is clogged. The nozzle is clogged.
		Action	Replace the dispensing tip (ME200). After checking the system, restart the process using the Rescan button. If it still does not work, use Abort to stop.
20090	Warning	Error message	Y Axis Operation Check Error.
		Error description	Y axis operation error
		Possible causes	Y axis malfunction. Y axis home sensor malfunction.
		Action	Turn off the power and reboot the system.
20091	Warning	Error message	Z Axis Operation Check Error.
		Error description	Z axis operation error
		Possible causes	Z axis malfunction. Z axis home sensor malfunction.
		Action	Turn off the power and reboot the system.
20092	Warning	Error message	P Axis Operation Check Error.
		Error description	P axis operation error
		Possible causes	P axis malfunction. P axis home sensor malfunction.
		Action	Turn off the power and reboot the system.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
20093	Warning	Error message	M Axis Operation Check Error.
		Error description	M axis operation error
		Possible causes	M axis malfunction. M axis home sensor malfunction.
		Action	Turn off the power and reboot the system.
20094	Warning	Error message	BX Axis Operation Check Error.
		Error description	BX axis operation error
		Possible causes	BX axis malfunction. BX axis home sensor malfunction.
		Action	Turn off the power and reboot the system.
20095	Warning	Error message	DX Axis Operation Check Error.
		Error description	DX axis operation error
		Possible causes	DX axis malfunction. DX axis home sensor malfunction.
		Action	Turn off the power and reboot the system.
20096	Warning	Error message	DZ Axis Operation Check Error.
		Error description	DZ axis operation error
		Possible causes	DZ axis malfunction. DZ axis home sensor malfunction.
		Action	Turn off the power and reboot the system.
20097	Warning	Error message	An error was detected by PP75 tip drop check. Please check that the nozzle has no Tip and Press Rescan button.[Track{n}] (Caution! Heat Block is hot. Do not touch.) *{n}: Track number

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Error description	8-Strip dispensing nozzle is clogged.
		Possible causes	8-Strip dispensing nozzle is clogged.
		Action	Contact the distributor. Send the log.
30101	Error	Error message	{n}: Ct calculation error – Error *{n}: Ct value
		Error description	An unknown error occurred when calculating the Ct value.
		Possible causes	The log must be analyzed to identify the cause.
		Action	Contact the distributor. Send the log.
30102	Error	Error message	{n}: Ct calculation error - Parameter Error *{n}: Ct value
		Error description	Parameters were incorrect when calculating the Ct value.
		Possible causes	Sufficient fluorescent data for analysis may not have been acquired.
		Action	Contact the distributor. Send the log.
30103	Error	Error message	{n}: Ct calculation error - If significant amplification is observed in PCR plot, target detected. Input template concentration is too high for Ct calculation. *{n}: Ct value
		Error description	A highly concentrated sample was used.
		Possible causes	The assay settings may not be appropriate.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Action	Contact the distributor. Send the log.
30104	Error	Error message	{n}: Ct calculation error – Undetermined *{n}: Ct value
		Error description	Cannot determine the Ct value.
		Possible causes	The assay settings may not be appropriate.
		Action	Contact the distributor. Send the log.
30105	Error	Error message	{n}: Ct calculation error - non-EXP *{n}: Ct value
		Error description	Could not obtain the expected amplification result.
		Possible causes	The assay settings may not be appropriate.
		Action	Contact the distributor. Send the log.
30106	Error	Error message	{n}: Ct calculation error - Base line error *{n}: Ct value
		Error description	Baseline calculation could not be performed correctly.
		Possible causes	The assay settings may not be appropriate.
		Action	Contact the distributor. Send the log.
30107	Error	Error message	{n}: Ct calculation error - Threshold error *{n}: Ct value
		Error description	Threshold setting is not appropriate.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Possible causes	The assay settings may not be appropriate.
		Action	Contact the distributor. Send the log.
30201	Error	Error message	{n}: Tm calculation error – Error {n}: Tm value
		Error description	An unknown error occurred when calculating the Tm value.
		Possible causes	The log must be analyzed to identify the cause.
		Action	Contact the distributor. Send the log.
30202	Error	Error message	{n}: Tm calculation error - Parameter Error {n}: Tm value
		Error description	Parameters were incorrect when calculating the Tm value.
		Possible causes	Sufficient fluorescent data for analysis may not have been acquired.
		Action	Contact the distributor. Send the log.
31001	Error	Error message	Time of the PC is changed after Run has begun.
		Error description	The PC and system clocks became out of sync during the run.
		Possible causes	The PC clock may have been adjusted during the run.
		Action	It may have affected the run time, so check the results.
31002	Error	Error message	Ignored the error by "continue run" button in "Cutout Error".
		Error description	Cutout error was ignored using “continue run” button.

Error code	Level	Error message	
		Error description	
		Possible causes	
		Action	
		Possible causes	The run was performed without checking proper rack placement.
		Action	None
31003	Error	Error message	Ignored the error by "continue run" button in "Barcode Read Error".
		Error description	Barcode read error was ignored using “continue run” button.
		Possible causes	The run was performed without checking QR codes of consumables.
		Action	None

6 Technical Data

6.1 Electric power supply and external connection

Power requirements: 100-240VAC 50/60Hz, 400VA

Fuses: 250VAC T4.0AL (Time-Lag) 5x20mm

Over voltage category: II

Transient overvoltage : 2500V

Connect the supplied power cable to the system and plug it in.

When using the geneLEAD VIII system, it must be properly grounded.



Power switch (left side of system)



Inlet filter and fuse (back of system)

Caution



To avoid outages, fires and other problems, always use the supplied power cable.

Caution



To keep the performance stability of geneLEAD VIII, turn off the power of the device once a week at least.

Connect the external PC to the LAN port on the back of the system.



LAN connector (back of system)

6.2 Hand-held Barcode Reader

***Do not use barcode readers other than those provided by PSS or the dealer.**

Connect the hand-held barcode reader to the USB port of the external PC.

6.3 Instrument Dimensions

Width: 350 mm Depth: 700 mm (Door closed) Height: 764 mm (Door closed)

6.4 Instrument Weight

System: 77 kg (excluding accessories)
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6.5 System Clearance

The geneLEAD system requires the clearance below to maintain its performance.

Side: min 50mm

Backside: min 50mm

6.6 Environmental Conditions

Temperature	Operating +15 to 30°C
	Storage +5 to 40°C
	Transport -25 to 60°C

Humidity	Operating +20 to 80% no condensation
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Storage +15 to 75% no condensation
Transport +15 to 75% no condensation

Barometric pressure	Storage	70kPa (Min.)
	Transport	70kPa (Min.)

Altitude 0 to 2000m

Pollution degree 2

Installation Site Indoor Use Only

Sunlight Operating / Storage No direct sunlight