

Ver. 1.0

GENTi™ 32

**GENTi Automatic Extraction Equipment
User Manual (Instruction for Use)**
Automated Nucleic Acid Extraction System

CONTENTS

| | |
|---|----|
| Introduction | 3 |
| 1. Product intended Use..... | 3 |
| 2. Product description | 3 |
| 3. Product characteristics | 3 |
| 4. Product specifications | 4 |
| GENTi Automated Nucleic Acid Extraction System requirements | 4 |
| Product Components..... | 5 |
| WEEE | 5 |
| Precautions before using the product | 6 |
| Unpacking andInstalling process | 7 |
| 1. How to unpack the "GENTi" | 7 |
| 2. How to install the "GENTi" | 8 |
| 3. Hardware overview..... | 9 |
| 4. The switch mechanism of GENTi..... | 9 |
| User Interface | 10 |
| 1. User interface for home screen | 10 |
| 2. Instruction in Plate set-up | 11 |
| 3. Instruction in Strip set-up..... | 12 |
| 4. Implementation of GENTi | 13 |
| 5. Camera systemon GENTi..... | 15 |
| 6. Warning code for GENTi..... | 15 |
| 7. Error code for GENTi | 16 |
| 8. Regular maintenance | 17 |
| 9. More information about GENTi..... | 18 |
| Troubleshooting | 18 |
| Warranty | 19 |
| Constraint on Warranty | 20 |
| Symbols..... | 20 |

This user manual introduces into the detail of "GENTi Automatic Extraction Equipment" and protocols through the

contents. It also contains the specification of the "GENTi Automatic Extraction Equipment" for further information.

Before using the "GENTi ", it is a recommendation of the user to read this equipment user manual carefully and understand specifically on Safety Information.

Introduction

1. Product intended use

The "GENTi 32" is intended to be used as a combination with "GENTi Extraction kits" that provide automated extraction of nucleic acid from samples.

Diagnostic results would be obtained by using the nucleic acids extracted with this equipment and it must be interpreted in conjunction with other clinical, laboratory or other experiment data.

Extracted nucleic acid through "GENTi system" can be used for various downstream application such as molecular diagnostics, PCR, sequencing and so on.

The automated steps performed by "GENTi Automatic Extraction Equipment" include:

- Sample lysis and binding of nucleic acids to magnetic beads
- Washing of nucleic acids
- Elution of nucleic acids

2. Product Description

The "GENTi Automatic Extraction Equipment" is automatic nucleic acid extraction equipment based on magnetic bead separation technology with integrated magnetic rods. The equipment adapted two configurations (96-well plate and strip tube) for maximize flexibility of sample load. The equipment extracts nucleic acid from various sample through lysis, binding, washing and elution steps. Intuitive interface allows users simple operation by touching just one button.

3. Product Characteristics

- System control or test can be implemented with the touch monitor (No PC or tablet needed)
- UV lamp exists on the equipment to aid in sanitizing the equipment
- Easy-to-use system (application of optimal protocols for DNA, RNA extraction)
- The equipment has a preprogrammed protocol for nucleic acid purification
- The equipment gives the high efficiency of nucleic acids purification to use
- The user will shorten he hands-on-time by using "GENTi 32" product.
- Max. 32 samples can be run in a single run

4. Specifications

- Average processing time: approx. 5-30 minutes (it is various depends on how many products/samples are set on the equipment)
- Number of samples: samples can be set up to 32
- Standard configuration: ~200 $\mu\ell$ of sample volume
- Weight: 33.9 kg (74lb)
- Dimensions: 365(W) x 390(D)x 435(H)mm (14.4 (W) x 15.4(D) x 17.1(H) inch)

System Requirements for "GENTi Automatic Extraction Equipment"

To use this equipment, system requirements are applied in general condition at room temperature 25 °C (77 °F).

unless there is other specific notice or indications.

When user needs to store for a long period of time, it must be packed in a vacuum.

If the equipment has not been used for a long time, it must be used after inspection.

Regulation of Voltage

Please, make sure that the range of voltage is as follow:

Input Voltage: 220 - 240V

Power requirements: 50/60Hz, 2A

Environmental requirements

| | | |
|------------------|-----------|--------------------------|
| Temperature | Operation | 10-40°C |
| | Storage | 10-50°C |
| Humidity | Operation | 10-80% RH, Non-condensed |
| | Storage | 10-80% RH, Non-condensed |
| Maximum altitude | 2000m | |

The equipment should be operated indoors. For, indoor use only.

Product Components

Please check and inspect the package carefully to make sure that all GENTi equipment components are included prior to use.

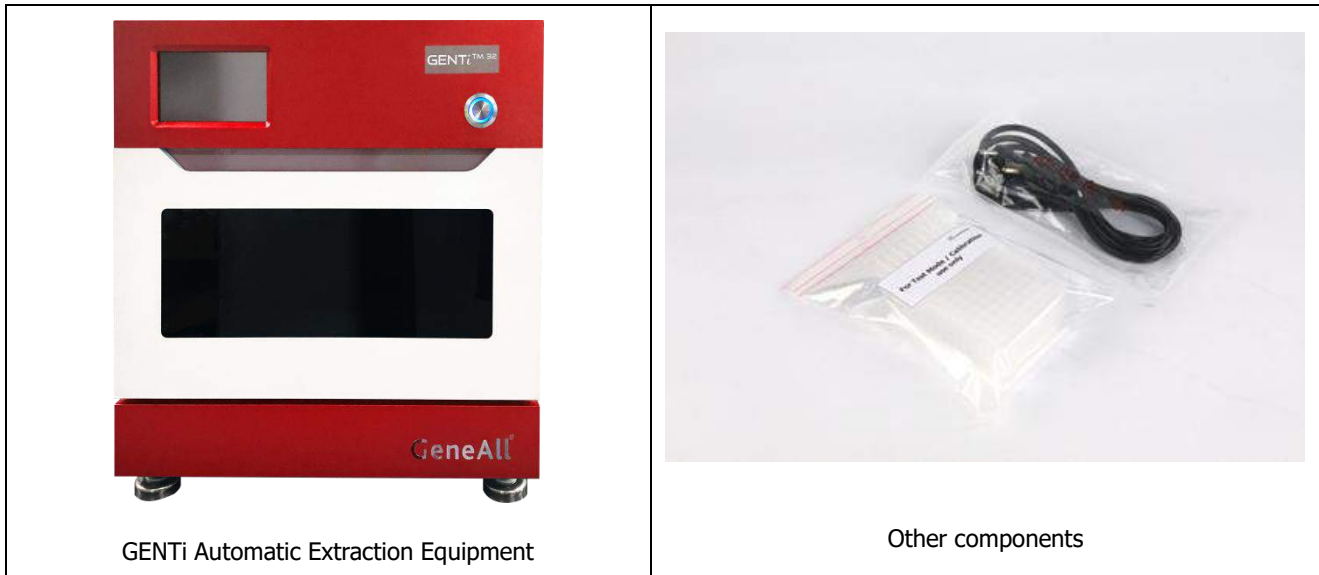


Figure 1. Components of GENTi Automatic Extraction Equipment

- GENTi Automatic Extraction Equipment: 1 ea
- Power cable: 1 ea
- 8-strip (for the test mode/calibration use **only**): 2 ea
- 96-well plate (for the test mode/calibration use **only**): 2 ea

WEEE

- The components below, they shall be disposed and/or replaced based on the WEEE (Waste Electrical and Electronic Equipment Directive) standard.
- UV lamp
- LED lamp
- Power cable
- Touch monitor
- External case
- Front door

Precautions before using the product



Please read the precautions for correct use of the product.


- This IVD equipment complies with the EMC test requirements and described in IEC61326 and the safety requirements of IEC 61010.
- This product complies with the European Directives described in 2006/95/EC and 2004/108/EC for CE marking.
- **Do NOT** use the GENTi Automatic Extraction Equipment with other voltages out of the range specified (220~240V±10%, 50/60Hz) on the equipment.
- The equipment must be installed to allow easy connection of the power line to the power inlet.
- **DO NOT** use the GENTi Automatic Extraction Equipment with a damaged power supply or loose socket.
- Please **KEEP** the equipment on a flattened surface and provide minimum of a feet at every side of the equipment for air circulation.
- A strong impact on the equipment may causes severe damage and thus malfunction.
- **DO NOT** connects multiple equipments into a single wall outlet. The load may cause an overload and fire.
- GENTi Extraction Equipment vibrates when it is operated. **DO NOT** place any devices and/or supplements on the equipment that might be damaged by vibration.
- **DO NOT** place any devices that produce vibration or heat besides "GENTi 32".
- **DO NOT** install and/or store the equipment in dusty place
- **DO NOT** install and/or store the equipment near heat sources.
- **DO NOT** install and/or store the equipment near water or moist place before/while user use
- **DO NOT** attempt to change or modify the equipment without GeneAll's permission.
- **DO NOT** try to connect the power plug with wet hands.
- GNETi Automatic Extraction Equipment is closed system thus it is exclusively optimized to use in combination with the "**GENTi** Extraction reagents. **DO NOT** attempt to use any other brand of the kit or reagents.
- Please make sure that pre-filled 96- well and check the plate if it is set in correct position on the plate tray.
- **DO NOT** disassemble the equipment. It may cause fire, electrical shock and malfunction and the warranty shall NOT be guaranteed if disassembled.
- **DO NOT** use this equipment with any purpose other than its intended use.
- **DO NOT** pour any liquid on the GENTi equipment.
- **DO NOT** place other vibration sensitive equipments near equipment.
- The front door must be **CLOSED** during the operation of equipment.
- Please **DO NOT** operate the equipment in the place near flammable gases or liquids.

- Dispose the UV bulb in accordance with country, federal, state and local regulations and laws since it contains mercury.
- Please disconnect the power before cleaning or performing routine maintenance.
- There is a possibility to be exposed by UV rays due to the UV lamp of equipment. DO NOT turn on the UV lamp unless completely close the front door.
- Please make ensure that magnetic rod covers and plates have been securely inserted in their correct positions and orientation. Failure may result in damage to the equipment.
- Before using the operation system, please check the magnetic rod position to prevent the damage to the equipment
- Use the switch in order to shut off the power supply safely
- DO NOT operate the system if malfunction is expected.
- As the touch panel is made with LCD screen, please use the touch panel slightly and smoothly with soft finger touch and the LCD screen will response back from user's activation order. Instead of using Sharp tools- such as Knife, Nail or pen, not finger; it may cause damages on the LCD screen.
- This equipment is intended for use with human-derived samples. Please use appropriate personal protective apparatus (i.e.-gloves, safety goggles, lab coat, etc.) for handling and disposing of biological-hazardous materials safely.
- Keep hands clear out from equipment platform as it moves in and out of the equipment.
- Keep the surface of equipment clean once you use.
- When there is any SIGN OF FIRE (smoke, burning smell etc) while operating the equipment or stand-by mode, Please STOP the operation IMMEDIATELY, and DISCONNECT the power cable from the unit and contact to Customer Service or Manufacturer immediately
- The equipment shall be sterilized with UV lamp at all time. DO NOT look or touch UV lamp directly. It may damage to eyes or skin.
- If the equipment is stained by reagents, samples or dirt after use, please disinfect the equipment with 70% ethanol and turn off the equipment after the stain is completely cleared out.
- The Plate tray will be heated automatically during operation of the equipment. It may cause the skin burn easily if any part of the body got touched with plate tray. DO NOT touch the plate tray directly with any part of the body if the equipment is activated at any circumstance while using.
- Please discard the plate and magnetic rod cover into the biological-hazard disposable container after use.
- If any part of the body; especially when the eye is exposed to reagents, please keep the eye(s) open and flush out with eye wash or tap water and go to the hospital immediately.
- Dispose of the equipment in accordance with national, federal, state and local regulations and laws.


Unpacking and Installation

1. Unpacking the GENTi Automatic Extraction Equipment

The GENTi is operated by step motor which is movable. Therefore, the equipment and supplements are fixed and delivered to prevent equipment damages.

| | |
|---|---|
| WARNING  | Risk of personal injury and material damage Please ensure that the fixture must be removed before connecting the power. |
|---|---|

- 1) Please cut and remove all of tapes or straps around the box to open the shipping box
- 2) Before using, or after open the box, please check whether GENTi Automatic Extraction Equipment is intact or not. If there is any damage on equipment or unusable supplements, please DO NOT use defected equipment and contact Technical service team to get better/further assistance. The power supply should be switched off unless the equipment is operating the test.
- 3) Please remove the fixture to use the equipment.

| | |
|---|--|
| WARNING  | Risk of personal injury and material damage Please ensure that the main power must be switched off before release the fixture. |
|---|--|

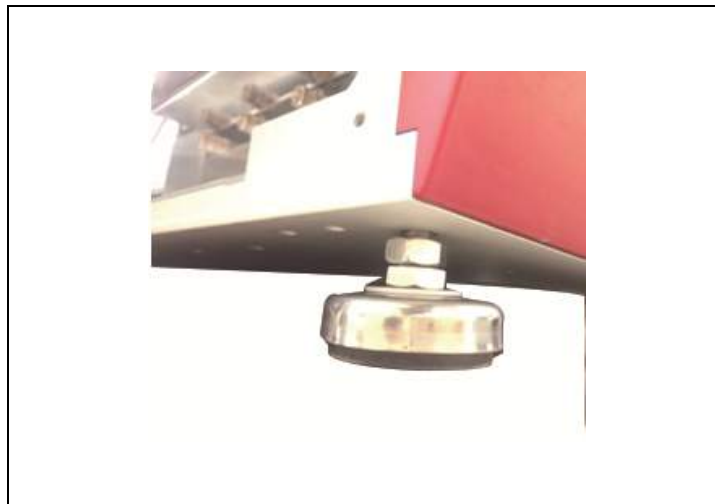


Figure 2. Adjust the horizontality by turning/balancing the rubber feet (Bottom view)

1. Please maintain the level by using rubber feet as shown in Figure 2.

2. How to install the GENTi

The GENTi is intended for indoor use only.

Before installing the GENTi 32, please install the equipment in a location that meets the following criteria:

- Locate the equipment on a sturdy, horizon level surface or place area.
- Avoid dusty areas or places that might cause damage the equipment.
- Please **_DO NOT** place the equipment near or where the surface generates heats constantly.
- Try to locate away from direct sunlight and avoid the equipment away from heat sources.
- Please put all vibration and electrical interference sources away from installed area to prevent safety.
- DO NOT connect a large number of powers from other equipment into an outlet. It may cause the major

electrical fire while using.

- DO NOT leave any thing anything at front side of the equipment to not to disturb the operation.
- DO NOT use the equipment near to flammable gases or liquids for safety.
- Locate a distance at least minimum clearance 10cm at the sides and rear of GENTi.

3. Hardware Overview

External features



Figure 3. External feature of GENTi Automatic Extraction Equipment

Internal features

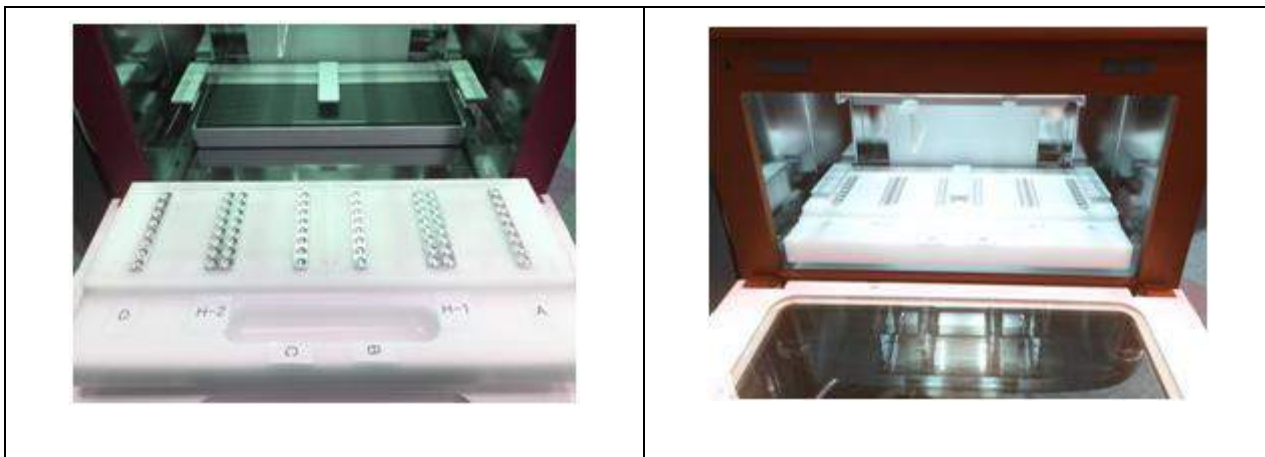


Figure 4. Internal features of GENTi Automatic Extraction Equipment

4. Switching on the GENTi

After connecting the equipment to a power outlet, user may switch on the equipment. The power switch is located on the Front of the equipment. (Figure. 5)



Figure 5. Power switch

The LED power switch can be used during the operation of experiment in case user wants to check the extraction process, the switch is located next to touch monitor of front side (on the upper right side).



Figure 6. LED Power switch

Magnetic Rod will automatically moves to its original position when it is initialized.

User Interface for GENTi

1. User interface for home screen

The start-up on screen page is showed up on the touch monitor and initializes the sensors after turn the equipment on.



Figure 7. The Booting image on the screen window.

If everything is completed without any problems, the main home screen will be appeared as below._

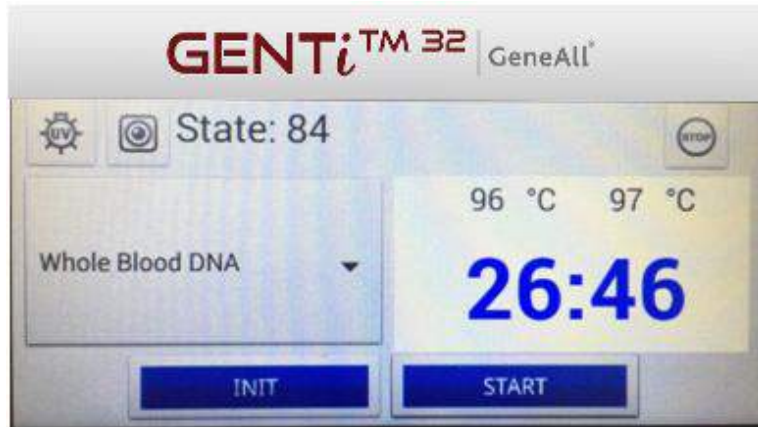



Figure 8. Home screen window

2. Plate set up for equipment


The exclusive 96-well plate must be set by following the instructions.

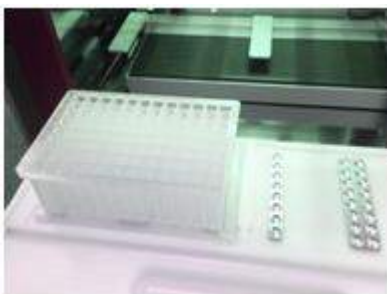
- A. Open the front door and pull out the plate tray from the equipment to set 96-well plate for test.

| | |
|---|---|
| <p>WARNING</p>  | <p>Risk of injury and material damage Be cautious not to get finger caught between the door and plate tray when pulling/pushing out the plate tray. Excessive force applied may damage user's finger(s) and the equipment. Open the door slowly. Otherwise, it may damage the equipment.</p> |
|---|---|

- B. Insert the plate on the hole of plate tray.

- C. Push the plate tray into the equipment for ready to operate. Please make ensure that the tray has been inserted to the end in order to operate the equipment properly.

| | |
|---|--|
| <p>WARNING</p>  | <p>Risk of material damage Make ensure that the 96-well plate is located into the correct position of the heating tray.</p> |
|---|--|



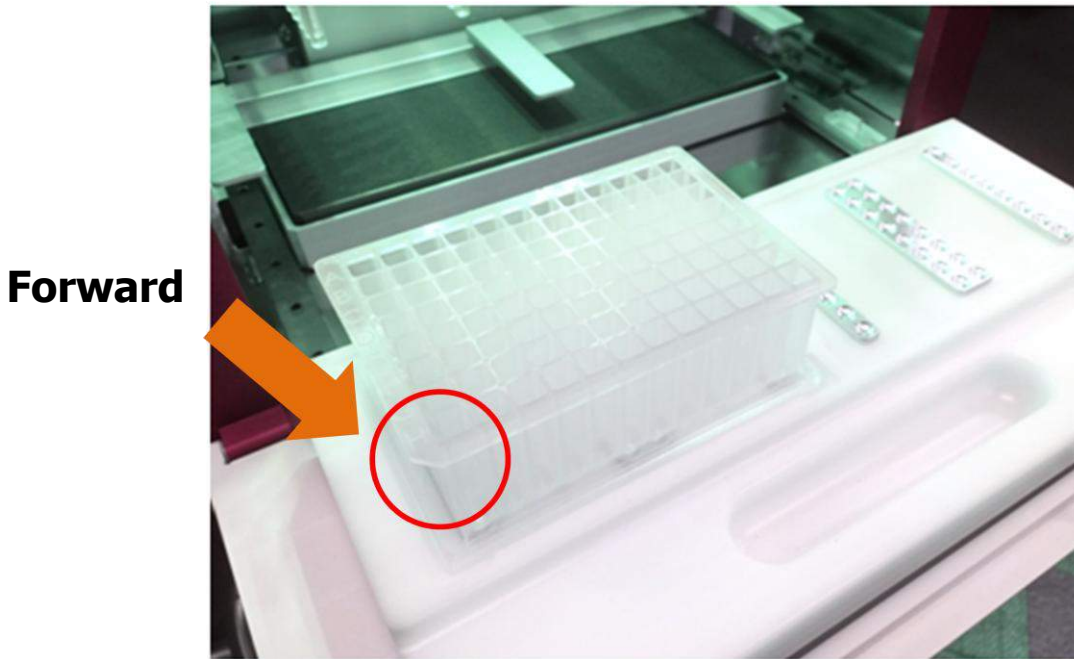


Figure 9. Correct and incorrect way of inserting the plate into the plate tray

Please insert the plate into the plate tray as shown in Figure 9. Please make it sure the plate is in a right position that diagonally cut edge of plate faces forward plate tray. If it is inserted incorrectly or upside down, it may cause an operating error and extraction may not work.

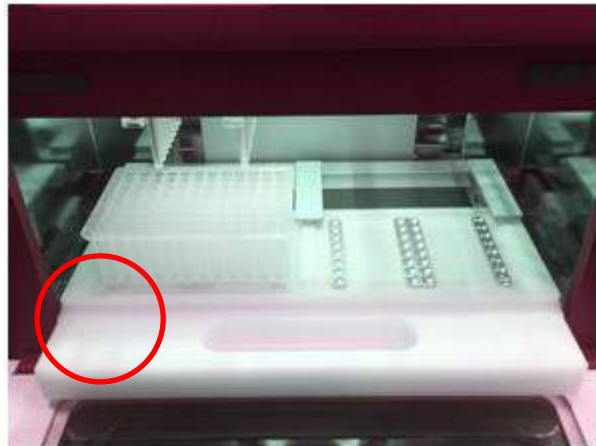



Figure 10. Correct and incorrect way of inserting plate on plate tray

3. Strip set up

- A. Please load the strip to strip bracket and to load properly, please insert the magnetic rod cover carefully to the end to strip bracket.
- B. Close the front door and ready to start.

| | |
|---|--|
| WARNING  | Risk of material damage Please ensure that the magnetic rod cover is inserted into the end of the magnetic rod cover bracket. Push the magnetic rod cover until 'Click' sound is heard from the equipment. The magnetic rod cover and/or magnetic rod may break and cause the malfunction of the equipment if it is not pushed until the far end. |
|---|--|

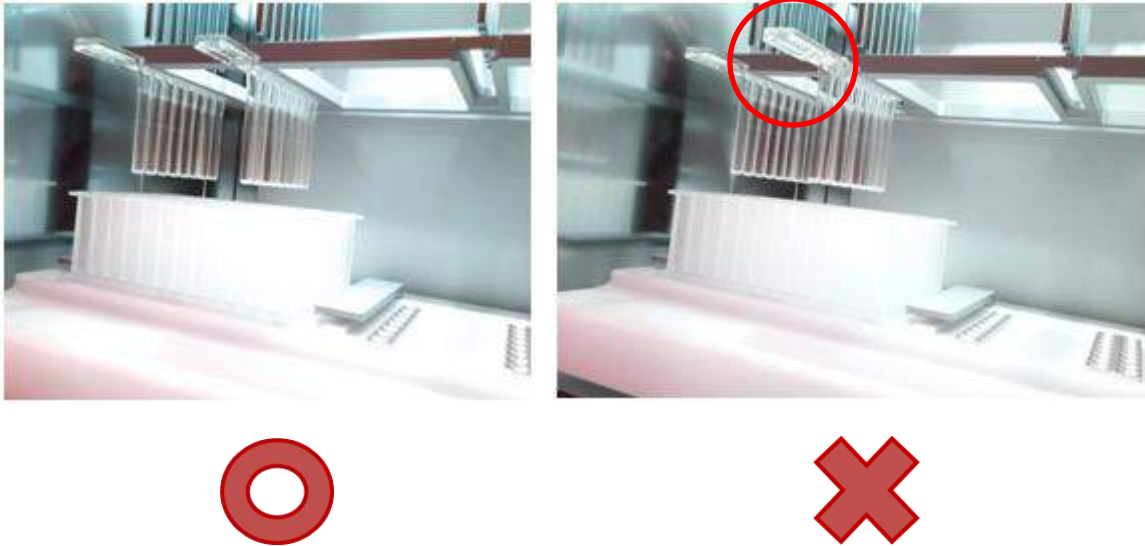


Figure 11. The way of insert/hold the Strip in the device properly.

4. Implementation of GENTi 32

If the 96-well plate and magnetic rod covers are set on correctly, please follow the next step as below.

- A. Press the "Whole Blood DNA" button on touch monitor and initial Setting to process.

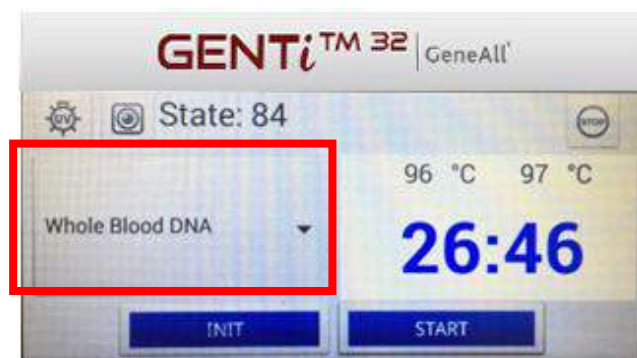


Figure 12. Whole Blood DNA menu section on the touch screen

- B. Select the specific button for whole blood sample extraction as Figure 13 below. Select relevant icons for extraction of other samples depend on the applied kit.

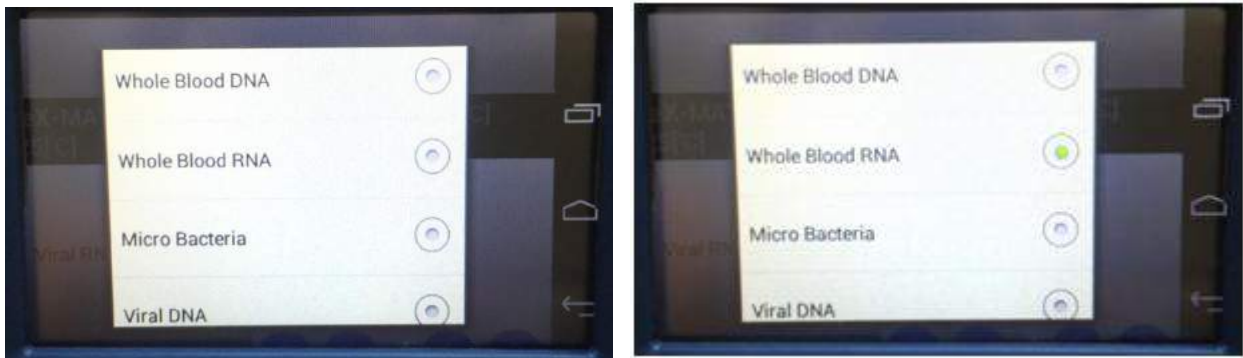


Figure 12 The selection for whole blood extraction on the menu screen

C. To perform the extraction, please press the 'INIT' button and the 'Start' button to perform extraction. After pressing buttons, it will be started automatically and indicates the remaining time (a) on the screen (Refer to Figure 14). After completion, it gives a beep sound and user may check the progress of step through the window of touch monitor.

Time on the LCD screen does not run during magnetic rod positioning. There are approximately 3~4 minutes of magnetic rod positioning during the operation.

- 1) The equipment can be forcibly stopped by 'Pause' (b) button.
- 2) The equipment can be forcibly canceled by 'stop' (c) button.
- 3) Opening the door during operation put it on hold and re-activated once closed.

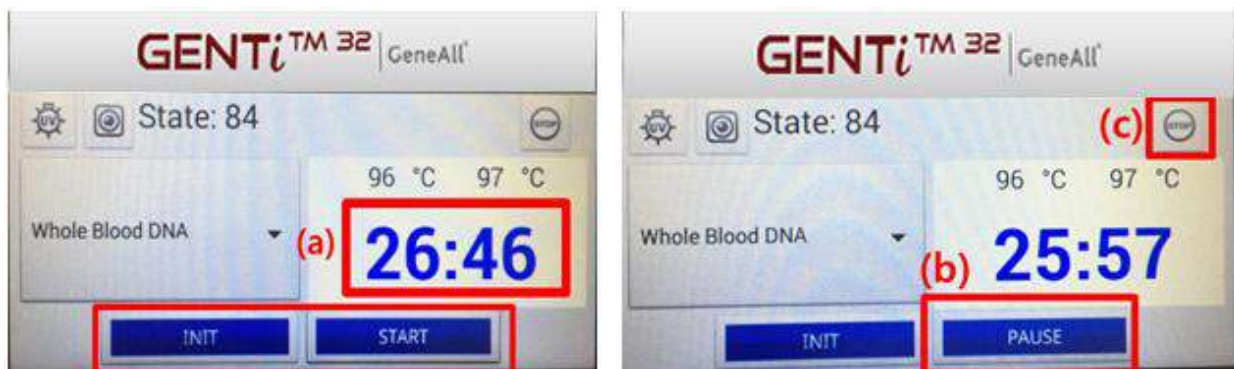


Figure 13. Procedure on touch screen

| | |
|----------------|--|
| WARNING | <p>Risk of personal injury and material damage</p> <p>Do not put a hand inside of the device when it is operational at any circumstances. Please insert and remove the plate and magnetic rod cover only when the equipment is not in operation. Do not touch any internal part of the device at any circumstances.</p> |
|----------------|--|

The Alarm will ring along with the '00:00' that display show as Figure 15. below upon completion of extraction.

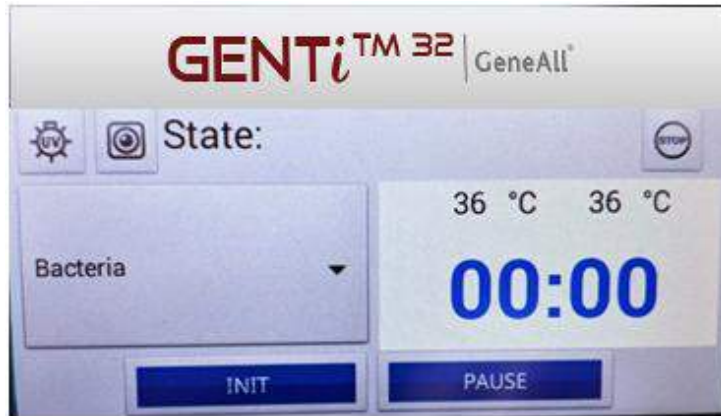



Figure 14 .Completion signal on the touch screen

Please open the front door and pull plate tray and remove the plate upon completion of experiment. The plate shall be removed first since the magnetic rod cover may be contaminated with magnetic beads . Please disinfect the plates and magnetic rod covers with UV lamp before disposal to prevent contamination.

| | |
|---|---|
| <p>WARNING</p>  | <p>Risk of injury Be cautious not to spill or spurt reagents to any part of the body during plate removal. Special caution is necessary with wells with samples.</p> |
|---|---|

5. Camera of GENTi 32

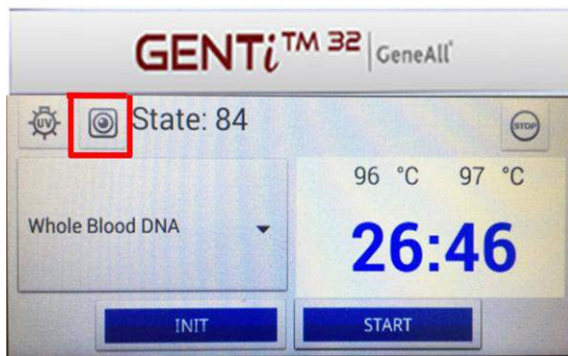


Figure 15. Camera View

GENTi has camera view inside of equipment. It could be called as "show machine room".

To use the camera view to see inside of the equipment, please press 'CAMERA' button it could be show inside of GENTi

6. Warning Code

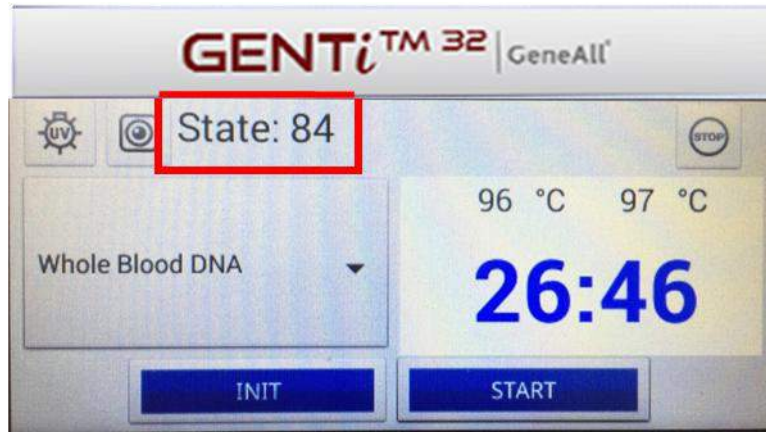


Figure 17. Warning code on the view location.

There are warning list that each explains and which might appear during application.

1. 71: UV lamp is out of control.
2. 80: Low temperature than target at heating module.
3. 81: Occurred over current at heating module.
4. 82: When the set temperature has not been reached after a certain period of time has elapsed.
5. 84: Over temperature than target at heating module.
6. 90: Occurred over current at strip module motor.
7. 91: Occurred over current at magnet module motor.
8. 92: Occurred over current at tray module motor

7. Error Code

There are 6 errors which might appear during application.

1. Er:13: EEPROM has problem at read/write.
2. Er:14: when the door OR tray is open
3. Er:21: when the heater has problem.
4. Er:30: Step motor-A FUSE short circuit of strip module.
5. Er:31: Step motor-B FUSE short circuit of magnet module.
6. Er:32: Step motor-C FUSE short circuit of tray module.
7. Er:33: Step motor-A OR sensor problem of strip module.
8. Er:34: Step motor-B OR sensor problem of magnet module.
9. Er:35: Step motor-C OR sensor problem of tray module.
10. Er:40: Tray moving Error.
11. Er:49: appears when the NTC thermistor has problem

*** Please refer to figures below for each error.**

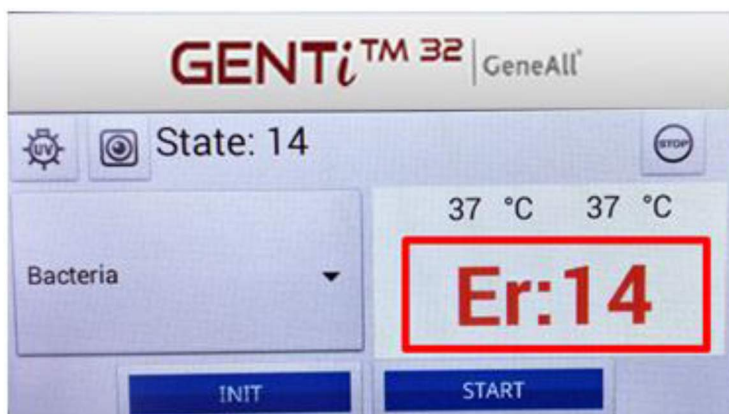


Figure 18. Error code on the view location.

8. Regular maintenance

If regular maintenance is required to use the equipment, it is not only to retain the nucleic acid extraction quality, but it is to stabilize safety and extend useful life of the equipment.

① Cleaning

There are possibilities of sample residual after several extractions. Therefore, internal parts are included as magnetic rods, heating block etc. shall be cleaned regularly to minimized possibility of potential infection.

- A. Please open the door and pull down magnetic bracket.
- B. Clean magnetic rods using 70(%) percentages concentration of ethanol and clean with cloth.
- C. Pull out the plate tray and clean plate tray including heating block using 70% percentages concentration of ethanol and clean with cloth.



Figure 19 cleaning internal parts

WARNING



Risk of personal injury

- Wear glove to prevent infection from unwanted extraction residue.

② UV lamp sterilization

Regular UV sterilization eliminates bacteria and virus, hence it minimizes internal pollution within the equipment. Therefore UV lamp sterilization shall be applied before and after extraction.

9. Other information

If power input is cut due to certain circumstances, such as black out; the entire procedure will get initialized automatically. It is highly recommended to user to restart the test with new kit, otherwise data may be compromised.

A. Please, start fixing the equipment with fixtures 15 minutes after deactivation to avoid any skin burn from heated heating blocks.

B. Please lift magnetic rods and rod covers brackets by holding outside of each bracket when it is needed (Ex. For transporting). Lifting the inner part of each bracket may damage bolts that connect the device.

C. Do not tighten screw inside fixture too much as it may cause malfunction of the equipment, but bottom of the equipment shall be tightened well.

Troubleshooting

| Problem | Possible causes and comments |
|--|--|
| Equipment does not turn on. | <ul style="list-style-type: none"> • Make sure to connect the power cable to the equipment. • Check whether the equipment is plugged at 220~240V power outlet. • Contact your local distributors or technical service team if the problem continues. |
| Equipment is leaned | <ul style="list-style-type: none"> • Adjust Rubber and Feet to maintain level |
| If the motor is not working after switching on the equipment. | <ul style="list-style-type: none"> • Check whether fixtures (Both inside and bottom side of the equipment are completely removed. • Confirm absence of any foreign substances on sensor. • Check that the front door has been closed. • Contact your local distributors or technical service team. |
| IF the touch monitor doesn't display anything after switching on LED power switch. | <ul style="list-style-type: none"> • In case of motor doesn't work, <ul style="list-style-type: none"> ➢ Ensure that the power cable is plugged in. ➢ Check the fuse connection next to the power cable. • In case of motor works, <ul style="list-style-type: none"> ➢ Touch monitor could be disconnected from the power or out of order. • Contact your local distributors or technical service team. |
| If LED lamp doesn't switch on | <ul style="list-style-type: none"> • Make sure to connect the power cable to the equipment and turn on the equipment. • Check whether the equipment is plugged at 220~240V power outlet. • Contact your local distributors or technical service team if problem continues. |

| | |
|--|---|
| Not available to locate the Plate and Magnetic Rod Cover at the right position | <ul style="list-style-type: none"> • Check whether the plate and magnetic rod cover are inserted at the right position. • Confirm absence of any foreign substances on plate tray and magnetic rod cover bracket. • Check whether the plate and magnetic rod cover are deformed or bent. <ul style="list-style-type: none"> ➢ Deformed or bent plate and magnetic rod cover may cause malfunction of the equipment. • Contact your local distributors or technical service team if problem continues. |
| Front door is not closed | <ul style="list-style-type: none"> • Check whether the plate tray is inserted till the end. • Confirm absence of any foreign substances behind of the front door. • Contact your local distributors or technical service team if problem continues. |
| UV lamp doesn't switch on | <ul style="list-style-type: none"> • The lifespan of UV lamp is about 6,000 hours and it should be changed. • The UV lamp could be disconnected from the power or out of order. • Contact your local distributors or technical service team if problem continues. |
| The equipment stops during operation | <ul style="list-style-type: none"> • Check whether the power cable is connected properly. • Contact local distributors or technical service team if problem continues but LCD screen is turned on. |
| Equipment is not working properly | <ul style="list-style-type: none"> • Check whether the 'Whole blood DNA' button in home screen is pressed. Improper extraction result may derive if processed by 'Test Mode'. • Check whether the plate and magnetic rod cover are properly placed. • Make sure fixtures are completely removed. • Contact your local distributors or technical service team if problem continues. |
| Heating blocks are not heated | <ul style="list-style-type: none"> • Make sure the plate tray is inserted until the end. • Contact local distributors or technical service team if problem continues. |
| Extraction without the Magnetic Rod Cover | <ul style="list-style-type: none"> • If extraction is preceded without the magnetic rod cover, the beads will adhere on magnetic rods, hence affects further tests. It is highly recommended to replace magnetic rods. • Contact your local distributors or technical service team for the replacement of magnetic rods. |
| Unfavorable extraction result | <ul style="list-style-type: none"> • Review manuals for procedures and trouble shooting. • Contact your local distributors or technical service team if problem continues. |

Warranty

GeneAll Co., Ltd. offers one (1) year warranty for GENTi 32 Automatic Extraction Equipment

GeneAll Co., Ltd. guarantees five (5) years of supply of spare parts from the date of last manufacture.

Limitations of Warranty

This warranty is subject to the following exceptions and limitations.














1. GeneAll Co.,Ltd. shall not be required to replace any units at any circumstances which are damaged or malfunctioned by abuse, accidents, alteration, neglect, misuse, maintenance by someone than GeneAllCo.,Ltd. or failure to operate, in accordance with the equipment.
2. GeneAll Co.,Ltd. shall not be required to provide the warranty for the equipment that are dismantled without authorization.
3. GeneAll Co.,Ltd. shall not be required to provide the warranty for malfunction of the equipment by forced majeure.
4. GeneAll Co.,Ltd. reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured equipments.

Refer to Trouble Shooting Guide when problem occurs. Contact your customer service and/or local distributor for warranty service if problem is consistent.

128 GeneAll Bldg., Ogum-dong, Songpa-gu, Seoul, 138-859, Korea

TEL. +82-2-407-0096 / FAX. +82-2-407-0779 / Website: <http://www.geneall.com>

Symbols

| | |
|---|---|
|  | Serial number |
|  | Catalogue number |
|  | Consult Instruction For Use |
|  | Caution |
|  | Temperature limitation |
|  | Expiry date |
|  | Manufacturer |
|  | Do not reuse |
|  | The risk of electrical shock |
|  | Hot surface |
|  | Waste Electrical and Electronic Equipment Directive |
|  | UV lamp caution |
|  | Date of manufacture |



Product: GeneAll Biotechnology Co., Ltd.

Address: 128 GeneAll Bldg., Ogum-dong, Songpa-gu, Seoul, 138-859, Korea

Phone Number : +82-2-407-0096

Web Site : www.geneall.com

2018.01