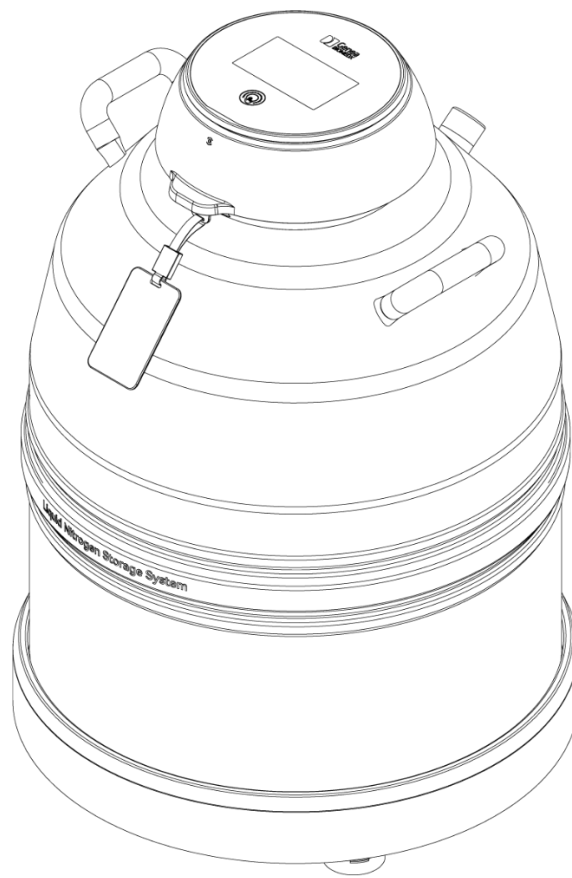


Gelida 47

User Manual

Software version: V1



Genea Biomedx Pty Ltd

FCC Warning

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

GENERAL INFORMATION

Copyright

This user manual and all contents contained herein are subject to copyright. All rights reserved. No part of this user manual may be reproduced, copied, translated or transmitted in any form or by any means without the prior written approval of Genea Biomedx.

Technical Support

Manufacturer

If any serious incident has occurred in relation to this device, it should be reported to directly to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



Genea Biomedx Pty Ltd
Level 2, 321 Kent Street
Sydney, New South Wales, 2000, Australia
Country of origin: China
Email: info@geneabiomedx.com
Web: www.geneabiomedx.com

Authorized European Representative



DONAWA LIFESCIENCE CONSULTING SRL
Piazza Albania, 10
00153 Rome
Italy



Introduction

We appreciate your selection of Gelida 47 provided by Genea Biomedx Pty Ltd.

The User Manual provides handy, easily understandable guidance regarding the operation and maintenance of the product, including but not limited to, vital safety instructions, installation procedures, usage protocols, and maintenance information.

It is the owner's responsibility to ensure that all users of the Gelida 47 have read and understood this user manual before operating the instrument. Please carefully read the User Manual before operation to ensure the proper use of this product.

Keep the User Manual for quick reference in case of any issues. Any further updates or changes to the User Manual shall be incorporated into supplemental or specialized training.

Notice: reading the manual does not automatically confer the authority or demonstrate the competence to use this product.

Product configuration:

Gelida 47 is offered in two configurations and 4 product codes, as shown below:

| Code | Description |
|---------------|---|
| GELI-01-US | Gelida 47L - Canister Variant (US only) |
| GELI-02-US | Gelida 47L - Rack Variant (US only) |
| GELI-01-CE | Gelida 47L - Canister Variant (CE only) |
| GELI-02-CE | Gelida 47L - Rack Variant (CE only) |
| GELI-01-RUO | Gelida 47L - Canister Variant (RUO only) |
| GELI-02- RUO | Gelida 47L - Rack Variant (RUO only) |
| GELI-01-DEMO | Gelida 47L - Canister Variant (DEMO only) |
| GELI-02- DEMO | Gelida 47L - Rack Variant (DEMO only) |

List of accessories

| No. | Content | GELI-01-CE/GELI-01-US/ GELI-01-RUO/ GELI-01-DEMO | GELI-02-CE/GELI-02-US/ GELI-02-RUO/ GELI-02-DEMO |
|-----|------------------------------|---|---|
| 1 | Liquid nitrogen storage tank | 1 | 1 |
| 2 | Canister | 10 | / |
| 3 | Rack | / | 6 |
| 4 | Insulation cap /plug | 1 | 1 |
| 5 | User Manual / IFU | 1 | 1 |
| 6 | Power adapter | 1 | 1 |
| 7 | Charing cable | 1 | 1 |
| 8 | Battery | 1 | 1 |

| | | | |
|----|---------------|---|---|
| 9 | Emergency Key | 1 | 1 |
| 10 | Tag | 1 | 1 |
| 11 | Packing List | 1 | 1 |
| 12 | Warranty Form | 1 | 1 |
| 13 | Roller Base | 1 | 1 |

In case of any missing accessories, please promptly contact your local Genea Biomedx representative.

This product does not contain any parts that are prone to wear and tear or loss. The accessories require replacement only in the event of damage.

***Note:** In some cases, the “User Manual” can be obtained digitally, please contact your local Genea Biomedx representative to get the latest version of the IFU.

Copyright description

This manual contains proprietary information protected by copyright law. All rights reserved. Reproduction, photography, or translation of any part of the Manual into other languages is prohibited without the express written consent of the manufacturer.

November 2024

See the label for the date of manufacture.

Table of contents

| | |
|---|-----------|
| 1. Introduction | 9 |
| 1.1 Product Overview | 9 |
| 1.2 Intended Use | 9 |
| 1.2.1 Indications for Use | 9 |
| 1.2.2 Patient target group | 9 |
| 1.2.3 Intended users: | 10 |
| 1.3 Device Structure & Key Features | 10 |
| 1.4 Contraindications | 10 |
| 1.5 Technical Data and Performance Characteristics | 11 |
| 1.6 Shipping, Unpacking & Inspection | 11 |
| 1.7 Conditions for Operation & Storage | 13 |
| 1.8 Safety & Precautions | 14 |
| 1.9 Definition of icons, symbols and abbreviations | 17 |
| 2. Use of Gelida 47 | 20 |
| 2.1 Product structure | 20 |
| 2.1.1 Layout & Configurations | 20 |
| 2.2 Included accessories | 23 |
| 2.2.1 Emergency Key | 23 |
| 2.2.2 Battery | 24 |
| 2.2.3 Power supply | 25 |
| 2.2.4 Power adapter and charging cable | 25 |
| 2.2.4.1 Charging | 25 |
| 2.2.4.2 Replacing the battery: | 26 |
| 2.2.5 Insulation plug | 29 |
| 2.3 Product setup & installation | 30 |
| 2.3.1 Installation space | 30 |
| 2.3.2 Installation method | 32 |
| 2.3.3 Opening the Tank Lid | 32 |
| 2.3.4 Filling Liquid Nitrogen | 33 |
| 2.4 User operation | 35 |
| 2.4.1 Turning on and using the 5Display | 37 |
| 2.4.2 Warning & Faults Management | 38 |
| 2.4.3 User Password Modification | 39 |

| | | |
|---------------|--|-----------|
| 2.4.4 | System Access Logs | 39 |
| 2.4.5 | Alarms & Muting Alarms | 40 |
| 2.4.6 | Lid operation | 41 |
| 2.4.6.1 | Unlocking lid | 41 |
| 2.4.6.2 | Locking lid | 41 |
| 2.4.7 | Sample access | 43 |
| 2.4.7.1 | Accessing a Canister/Rack & Sample | 43 |
| 2.4.7.2 | Replacing a Canister/Racks & Sample | 44 |
| 2.4.8 | Liquid LN2 Level Estimate | 45 |
| 2.4.9 | Temperature Display | 46 |
| 2.4.10 | Settings | 47 |
| 2.4.10.1 | Wi-Fi & IP settings | 48 |
| 2.4.11 | Date & Time Setup | 50 |
| 2.4.12 | User management | 52 |
| 2.4.12.1 | Create user | 52 |
| 2.4.12.2 | Delete user | 52 |
| 2.4.13 | Administrator password modification | 52 |
| 2.4.14 | Language | 53 |
| 2.4.14.1 | Alarm Temp of the Upper Probe (°C) | 53 |
| 2.4.14.2 | Alarm Temp of the Lower Probe (°C) | 53 |
| 2.4.14.3 | Lid Open Time (Min) Before Alarm | 53 |
| 2.4.14.4 | Screen brightness (%) | 54 |
| 2.4.14.5 | Volume Adjustment (%) | 54 |
| 2.4.14.6 | GPS Location | 55 |
| 2.4.14.7 | Wi-Fi toggle | 56 |
| 2.4.14.8 | Single/dual password verification | 57 |
| 3. | Technical Specifications | 58 |
| 4. | Product Maintenance & Support | 60 |
| 4.1 | Product Service Life | 60 |
| 4.2 | Routine maintenance & calibration | 60 |
| 4.2.1 | Temperature Calibration | 60 |
| 4.2.2 | Defrosting the Dewar | 60 |
| 4.2.3 | Tank Inspection & Monitoring | 60 |
| 4.2.4 | Decontamination | 61 |

| | | |
|-----|--|----|
| 4.3 | Device Disposal | 61 |
| 4.4 | Warnings & Faults: Troubleshooting | 61 |

1. Introduction

1.1 Product Overview

The Gelida 47 is a state-of-the-art liquid nitrogen storage system provided by Genea Biomedx Pty Ltd. It is specifically designed for use in hospitals, clinics, laboratories, or research units.

Gelida 47 addresses the critical need for long-term, static sample storage with a focus on providing robust, efficient, and intelligent monitoring capabilities, thereby mitigating the risk of biological sample degradation. For sample preservation, the protocol involves placing the samples in designated storage containers, which are then securely placed within the Gelida 47 for effective cryogenic preservation.

It offers real-time monitoring of internal temperature conditions. In instances of temperature deviations beyond user set thresholds, the system promptly initiates alert and user notification mechanisms. Two temperature sensors placed within the tank allow for the platform to infer liquid nitrogen levels within the Gelida 47 system. Audio and visual alarms are emitted from the tank lid. Additional remote alarms & notifications are provided via Wi-Fi connection to external monitoring software sold separately.

Access to samples within the tank are protected by a user associated password, which connects to an electromechanical lock; it safeguards against unauthorized manipulation of the stored samples, and provides traceability of tank access, thus ensuring their integrity and safety.

1.2 Intended Use

This product is designed for prolonged cryogenic preservation & storage of laboratory samples like cells, tissues, and other biological samples. Storage is at extremely low cryogenic temperatures using liquid nitrogen.

1.2.1 Indications for Use

No condition treated. Device is intended to facilitate low temperature storage of biological samples in a laboratory or clinic environment.

1.2.2 Patient target group

No therapy is applied to any patients. The tank is used to store biological samples in liquid nitrogen. Gelida 47 parts or accessories do not interact directly with any patients for their function.

1.2.3 Intended users:

Laboratory Professionals in hospitals, clinics, laboratories, or research institutions environment.

1.3 Device Structure & Key Features

The Gelida 47 consists of a vacuum insulated liquid nitrogen storage tank, with a smart lid. The smart lid incorporates connected temperature sensors, a control/monitoring system, Wi-Fi connectivity, a display screen, a digital electromechanical lock, and an audible alarm system.

1.4 Contraindications

There are no known contraindications.

1.5 Technical Data and Performance Characteristics

Refer to specific product specification sheet in Section 3 or contact Genea Biomedx for further information.

Standards Compliance:

Electrical safety:

The system is designed, inspected, and tested in accordance with EN 61010-1:2010+A1:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements. And IEC 61010-1:2010+AMD1:2016 Safety requirements for electrical equipment for measurement, control, and laboratory use -Part 1:General requirements

Electromagnetic Compatibility:

EN IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements

Radio Frequency:

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

1.6 Shipping, Unpacking & Inspection

The Gelida 47 from Genea Biomedx are supplied in new condition. For your own protection, schedule enough time to check for any external damage on delivery. Mishandling of the equipment, including transport and shipping of units in non-approved orientations, may damage the product and contents. If the tank experiences a sufficiently severe drop or impact, it may result in tank failure.

Open the freight container and check that all items are present. Record all components on the packing list before disposing of any transport material. Contact the logistics carrier and your local Genea Biomedx Distributor/Representative if there are signs of shipping damage or any

missing items or damage.

1.7 Conditions for Operation & Storage

Usage environment:

| | |
|----------------------------|----------------------------------|
| Usage site: | Well-ventilated indoor area. |
| Altitude: | Below 2,000 meters. |
| Environmental temperature: | +5°C to +40°C. |
| Environmental humidity: | 20% RH to 80% RH, non-condensing |

Storage environment

| | |
|----------------------------|----------------------------------|
| Environmental temperature: | +5°C to +40°C. |
| Environmental humidity: | 20% RH to 80% RH, non-condensing |

Transport Environment

| | |
|----------------------------|---------------------------------|
| Environmental temperature: | +5°C to +40°C. |
| Environmental humidity: | 20%RH to 80%RH, non-condensing. |
















NOTE:
For safe transportation, always maintain the tank in an upright position. Securely fasten the system to prevent any movement or overturning. To absorb any impacts, place sponge or similar shock absorbing material at the base.






1.8 Safety & Precautions




This product is to be used only by personnel trained by the manufacturer. It is the owner's responsibility to ensure that all users of Gelida 47 have read and understood these warnings and cautions before operating the instrument. The protections and warranties provided with the product may be voided if the product is not used in accordance with the methods specified herewith in.

It is the owner responsibility to validate the device to ensure safety to items prior to use.

| | |
|--|---|
|  | <p>WARNING:</p> <p>It is the owner's responsibility to ensure that all users of Gelida 47:</p> <ul style="list-style-type: none"> • are trained in all laboratory safety procedures, including the handling of hazardous materials • have read and understood the instructions and warnings contained in this user manual <p>have received adequate training in the correct operation of instrument</p> |
|       | <p>WARNING:</p> <p>Liquid nitrogen is extremely cold. To avoid injury by frostbite, use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects which have come in contact with liquid nitrogen.</p> <ul style="list-style-type: none"> • Appropriate cryogenic protective gear must be worn to prevent cryogenic burns; leave no areas of skin exposed. <ul style="list-style-type: none"> ○ Safety attire over clothing ○ Face shield ○ Cryogenic gloves ○ Cryogenic apron • Use extreme care to prevent spilling and splashing liquid nitrogen during transfer. • Always keep vessel in upright position. Do not tilt or lay the vessel on side. • Get immediate medical attention for any frostbite injuries due to liquid nitrogen. • Immediately remove any clothing or safety attire on which liquid nitrogen has spilled. • When refilling with liquid nitrogen, pre-cool the system with a small amount of liquid nitrogen before refilling. The refilling process should be gradual to avoid splashing and potential cryogenic burn related injuries. |
|  | <p>WARNING:</p> <p>Do not store or use container in areas that are small and enclosed or have poor ventilation.</p> <p>The venting of nitrogen gas may deplete oxygen in the air, possibly leading to</p> |









| | |
|---|--|
| | asphyxiation or even death. It is recommended to add an oxygen concentration monitor for environmental monitoring. |
|  | <p>WARNING:</p> <p>Do not tightly seal liquid nitrogen container or prevent nitrogen gas from escaping. Avoid excessive humidity levels or exposure to liquid ingress that could result in freezing of the insulation plug, and possible explosion.</p> |
|  | <p>CAUTION:</p> <p>Do not force the insulation plug into place.</p> <p>Do not modify the insulation plug in any way.</p> <p>The insulation cap should be carefully aligned with the markings and inserted without force. Damage or modification to the insulation cap may result in degraded product safety and performance.</p> <p>If the insulation cap is damaged, excessive LN2 usage may occur, or in severe cases, excessive pressure may build up which could result in explosion. transfer samples to a backup cryostorage solution and contact your local Genea Biomedx representative for support.</p> |
|  | <p>WARNING:</p> <p>Never use a hollow tube to measure liquid nitrogen level. This could lead to thermal injury.</p> <p>The device is equipped with 2 temperature sensors which are used to approximate the liquid level in the tank.</p> <p>Contact local your Genea Biomedx representative if you need alternative methods to measure liquid nitrogen level.</p> |
|   | <p>CAUTION:</p> <p>Handle the cryopreservation vessel with care during use, failure to handle with care may impact the product safety and performance and may void warranty.</p> <ul style="list-style-type: none"> • Never overfill vessels with liquid nitrogen. Liquid nitrogen should always be below the bottom of the neck tube. Overfilling the tank may cause immediate or premature vacuum failure to occur. • Never ship Gelida 47 on its side or upside down. • Remove and insert inventories carefully. Do not scratch neck tube area. Scratches can cause premature vacuum failure. • Never tamper with or removing the vacuum valve as this may result in vacuum failure. • Never drop or hit the unit. • Never spill liquid nitrogen on or near vacuum valve. • Never leave the vessel in outdoor conditions. • Never place the unit near a heat source. • Never have items stacked on top of the product. • Performance data available for the instrument is based on static conditions |













| | |
|---|---|
| | <p>only. Actual performance will vary upon the nature of use. Addition or removal of samples, addition on non-validated accessories, along with vibration will decrease the working duration of these products.</p> |
|  | <p>CAUTION:</p> <p>The vacuum valve is designed with a structure that allows for repeated air extraction. Tank vacuum maintenance should be carried out by the manufacturer or trained Genea Biomedx service representative.</p> <p>Customers are prohibited from attempting these procedures themselves to avoid negative impacts to the product's performance and avoid voiding warranty.</p> |
|  | <p>WARNING:</p> <p>The Gelida 47 is exclusively designed to be used with liquid nitrogen ONLY and should not be used to store any other cryogenic substances.</p> |
|  | <p>WARNING:</p> <p>Use only the original Genea Biomedx Gelida 47 parts with the Gelida 47. Substitutes from other products (e.g. insulation plug, canisters and rack holders) are not allowed.</p> |
|  | <p>WARNING:</p> <p>To reduce the risk of electric shock:</p> <ul style="list-style-type: none"> • Liquids, including liquid nitrogen, must not make contact the tank lid or electronics; doing so may result in electrical short circuits. • do not attempt to repair or modify any part of the instrument; • do not remove any of the instrument panels or covers; • do not place the instrument where it will be exposed to excessive moisture; • do not replace the supplied charging power cord and/or power adapter with an incorrect rated cord or adapter; • connect the charging power adapter only to an electrical power source with the proper voltage and frequency; • immediately replace the power cord if it becomes damaged, frayed, cracked or broken. |
|  | <p>CAUTION:</p> <p>If a sudden increase in evaporation loss is found, or if excessive frost & condensation appears on the exterior surface of the product, this may indicate tank damage or loss of tank vacuum. Ensure that tanks are inspected on a regular schedule according to your lab protocol.</p> <p>In such cases:</p> <ul style="list-style-type: none"> • Stop using the product immediately and contact local service representative. • Do not remove frost with hard objects to prevent further damage to the tube. • If samples are stored, carefully and quickly move them to alternative cryogenic |


| | |
|---|--|
| | storage. |
|  | <p>WARNING:</p> <p>Only authorised service personal should calibrate, repair or replace parts within the Gelida 47 or perform other service and repair activities.</p> <p>Attempting untrained repair may result personal injury, loss of product features and performance, or voiding of product warranty.</p> |
|  | <p>CAUTION:</p> <p>When accessing frozen samples work quickly and carefully to avoid premature thawing and unnecessary sample loss.</p> |
|  | <p>WARNING:</p> <p>Do not place or use instrument near a strong source of RF radiation (e.g., an unshielded radio frequency (RF) source). Doing so may interfere with the electronics and communication functionality of the instrument.</p> |

1.9 Definition of icons, symbols and abbreviations

Definition of icons, symbols and abbreviations used on the labels of the product is as follows:

| Sign | Description |
|---|---|
|  | Warning; Low temperature/Freezing Conditions |
|  | <p>Indicates that caution is necessary when:</p> <ul style="list-style-type: none"> operating the device or control close to where the symbol is placed; the current situation needs operator awareness or operator action to avoid undesirable consequences. |
|  | Indicates additional information which may assist in product use |
|  | Unlock direction |
|  | Charging port voltage |
|  | Power button |
|  | Indicates the device manufacturer |
|  | Indicates the date when the device was manufactured |

| | |
|---|--|
|  | Indicates the manufacturer's serial number so that a specific device can be identified |
|  | Indicates the need for the user to consult the user manual |
|  | Contents of the distribution packages are fragile therefore it shall be handled with care |
|  | This is the correct upright position of the distribution packages for transport and/or storage |
|  | Distribution packages shall not be rolled or turned over |
|  | Distribution packages shall be kept away from rain and be kept in dry conditions |
|  | Distribution packages shall not be exposed to sunlight |
|  | This Instrument is Subject to Laws Regarding the Disposal of Electronic Medical Equipment as Outlined in the WEEE Directive (2006/96/EC) |
|  | Temperature limit |
|  | Humidity limitation |
|  | FCC Compliant |
|  For original symbol - refer to symbol 5.7.7 of ISO 15223 | Medical Device |

| | |
|---|---|
| <div data-bbox="268 215 539 295"> <div>EC</div> <div>REP</div> </div> <hr/> <p>For original symbol - Refer to symbol 5.1.2 of ISO 15223</p> | <p>Authorized representative in the European community/European Union</p> |
|  | <p>Product complies with applicable European Union (EU) regulations</p> |

2. Use of Gelida 47

2.1 Product structure

2.1.1 Layout & Configurations

The hardware configurations of the Gelida 47 are shown in the figures below:

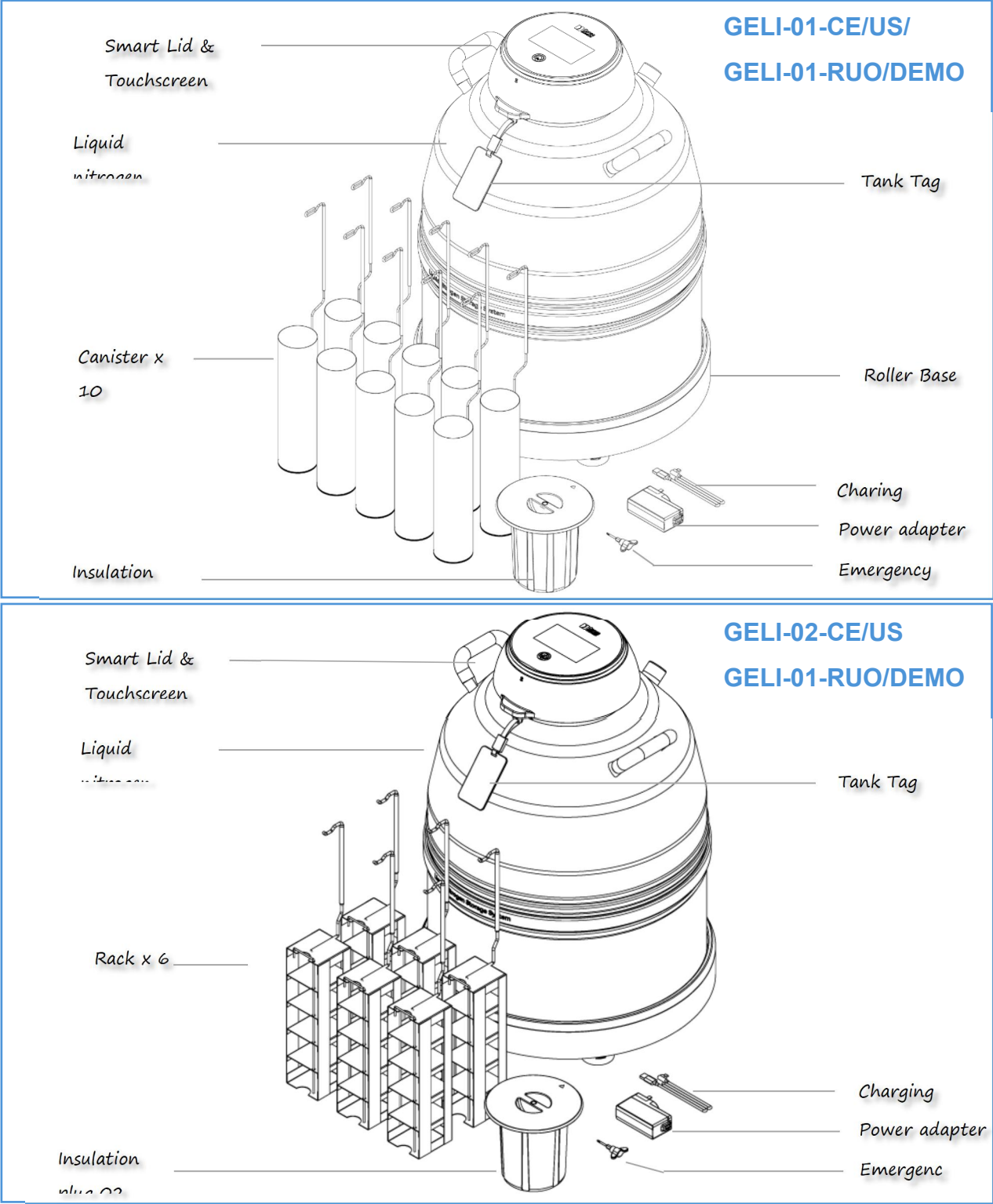


Figure 2-1 Basic Hardware Configuration (GELI-01-CE/US/RUO/DEMO & GELI-02-CE/US/RUO/DEMO)

The Gelida 47 tank composed of a smart lid and a tank, as shown in Figure 2-2:

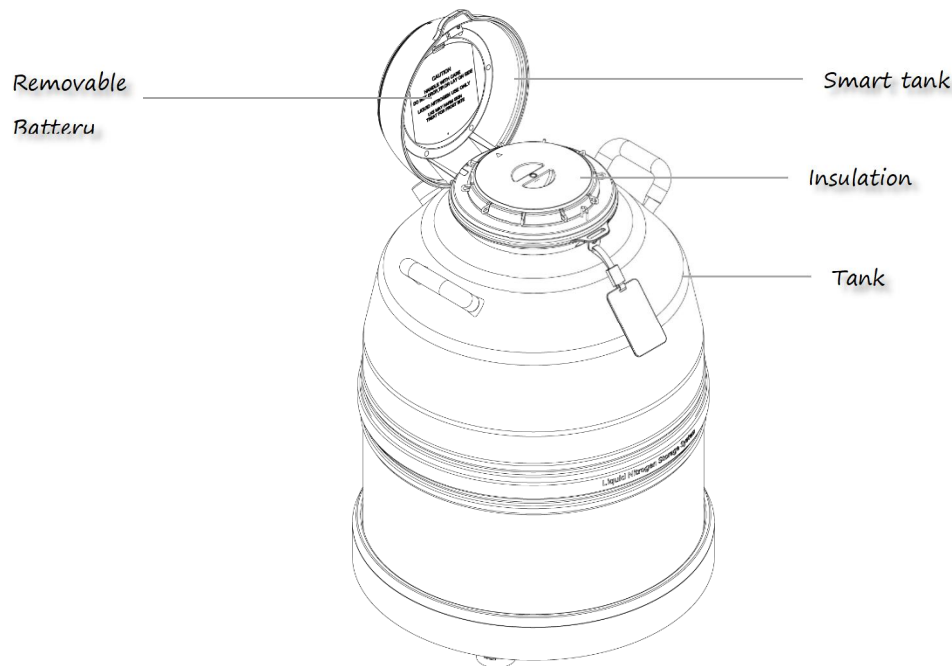


Figure 2-2 Configuration of the Liquid Nitrogen Storage Tank

a. Components of the tank lid:

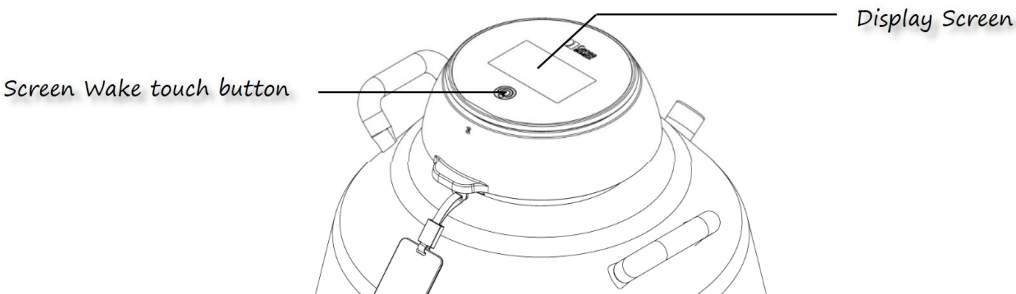


Figure 2-3 Tank Lid - Front View

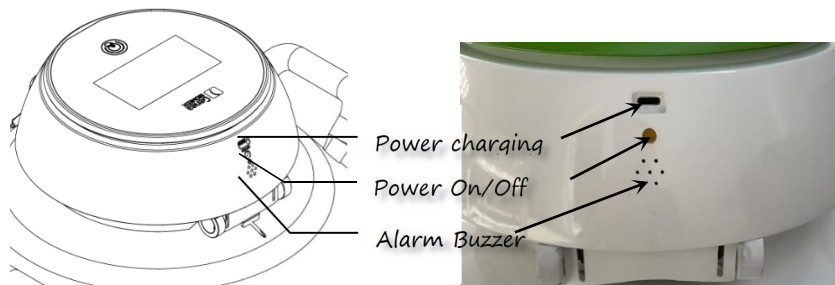


Figure 2-4 Tank Lid - Rear View

b. Tank and accessories:

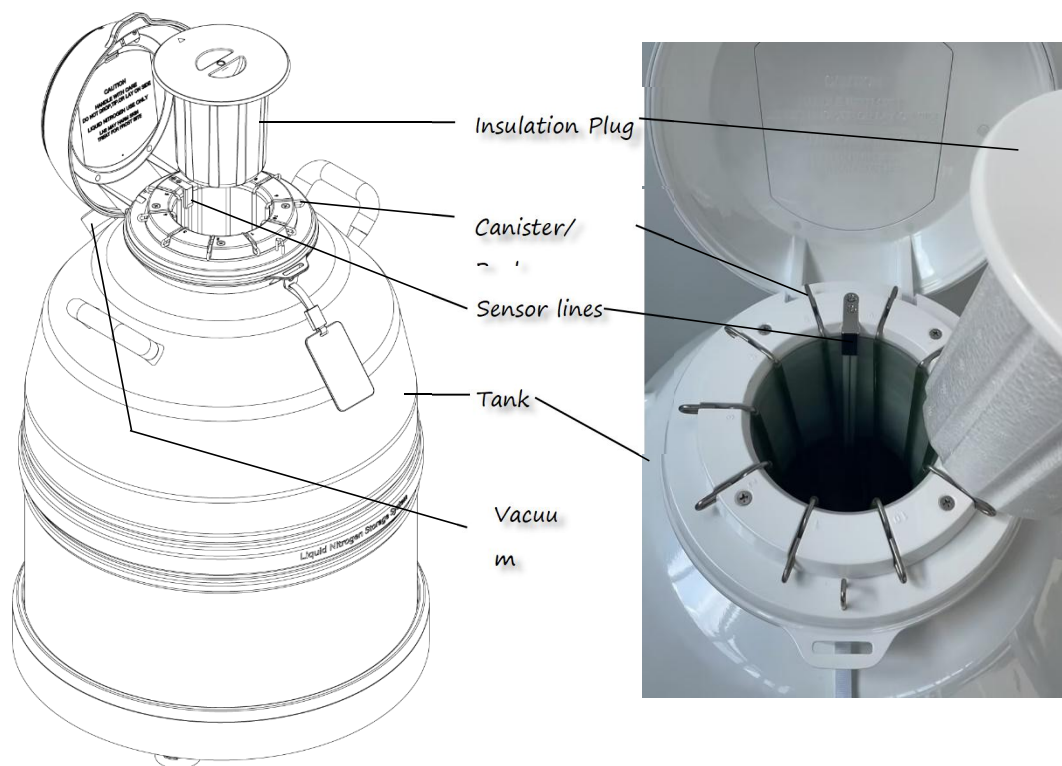




Figure 2-5 Tank and Accessories

| | |
|---|---|
|  | <p>CAUTION:</p> <p>The insulation plug, canisters and racks are not designed to be interchangeable between the canister and rack models (GELI-01-CE/US/RUO/DEMO and GELI-02-CE/US/RUO/DEMO, respectively).</p> <p>Do not mix and match canisters, racks or insulation plugs, use non approved components, or attempt to modify the device to accept non-approved components.</p> <p>Doing so may cause damage to the product, negatively impact product performance, cause malfunction of product features or void the product warranty.</p> |
|  | <p>CAUTION:</p> <p>The vacuum valve is designed with a structure that allows for repeated air extraction. Tank vacuum maintenance should be carried out by the manufacturer or trained Genea Biomedx service representative.</p> <p>Customers are prohibited from attempting these procedures themselves to avoid negative impacts to the product's performance and avoid voiding warranty.</p> |

2.2 Included accessories

2.2.1 Emergency Key

In the event of an emergency or an unlocking fault the following symbol will be displayed in the top right-hand corner of the display as shown below:



Figure 2-6 Lock Fault Icon

In this situation an emergency key is required to open the tank lid.

The steps are as follows:

- 1) Press the power button to power off the device, then insert the key into the emergency key slot as shown in Figure 2-7.

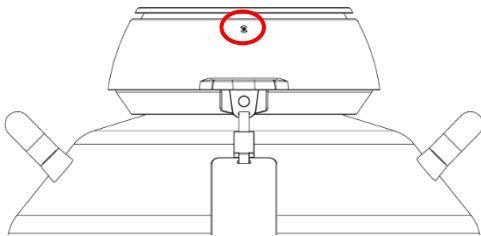


Figure 2-7 Emergency Key Slot

- 2) Align the key with the slot and turn it clockwise until it unlocks.

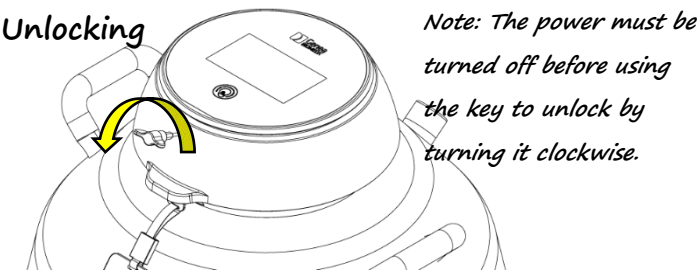


Figure 2-8 Unlocking Operation

- 3) Upon resolving the fault, press the power on/off button to restore power to the device.

| | |
|--|---|
| | <p>NOTE:</p> <p>The emergency key bypasses the digital logging and user password verification features; and retain a log of historical access when the manual emergency key is used to open the tank.</p> <p>If the lock is not functioning correctly, contact your authorized Genea Biomedx</p> |
|--|---|

| | |
|--|---|
| | service representative to organize a repair or service visit. |
|--|---|

2.2.2 Battery

The Gelida 47 comes with a removable and rechargeable lithium-ion battery. The battery consists of charge status indicator light with LED indicating the current charge state, a battery on/off button for power safety protections.

To turn on the battery: Press the power on/off button on the side of the battery. The battery indicator lights will illuminate.

To turn off the battery: Press and hold the power on/off button on the side of the battery for more than 2 seconds. The indicator lights will turn off.

Battery indicator light: When the LED light is on and flashing, it indicates the battery is low and needs to be recharged and or replaced (see Section 2.2.4).

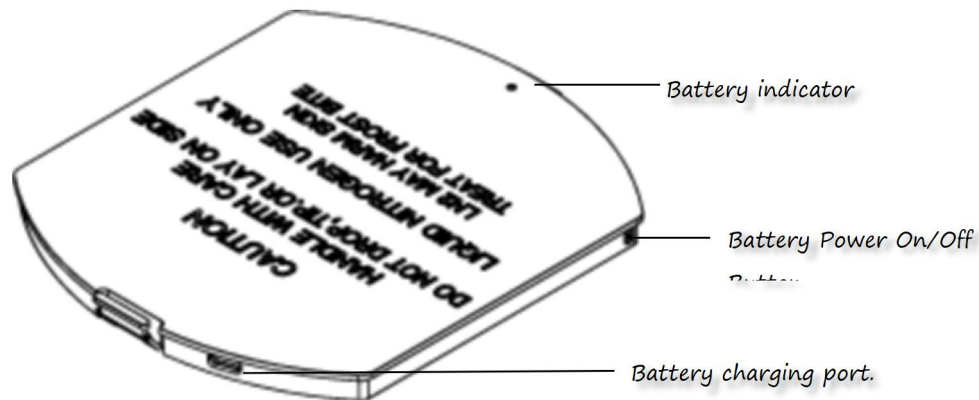



Figure 2-9 Battery

| | |
|---|--|
|  | <p>WARNING:</p> <p>Misusing or mishandling the battery may result in fire or explosion. Only use the battery within the listed specifications provided with the battery pack.</p> <p>Only use with the Gelida 47 and Battery with the approved charging accessories.</p> <p>If the battery is visibly damaged or exhibiting signs of possible damage, please discontinue use immediately and contact your local Genea Biomedx representative.</p> |
|---|--|

2.2.3 Power supply

The tank can be connected to a 110-220V electrical supply via an external power adapter during operation. When the external power adapter is connected, the external power adapter supplies power to the device and charges the installed battery. When there is no external power adapter connected, the installed battery discharges and directly powers the device.

2.2.4 Power adapter and charging cable

2.2.4.1 Charging

Connect the power adapter to the wall socket. Connect the charging cable to the power adapter and insert the USB-C end of the charging cable into the power charging port on the back of the lid (Figure 2-10). The lid should be powered on when charging. When charging, the battery indicator light will blink according to its charge state.

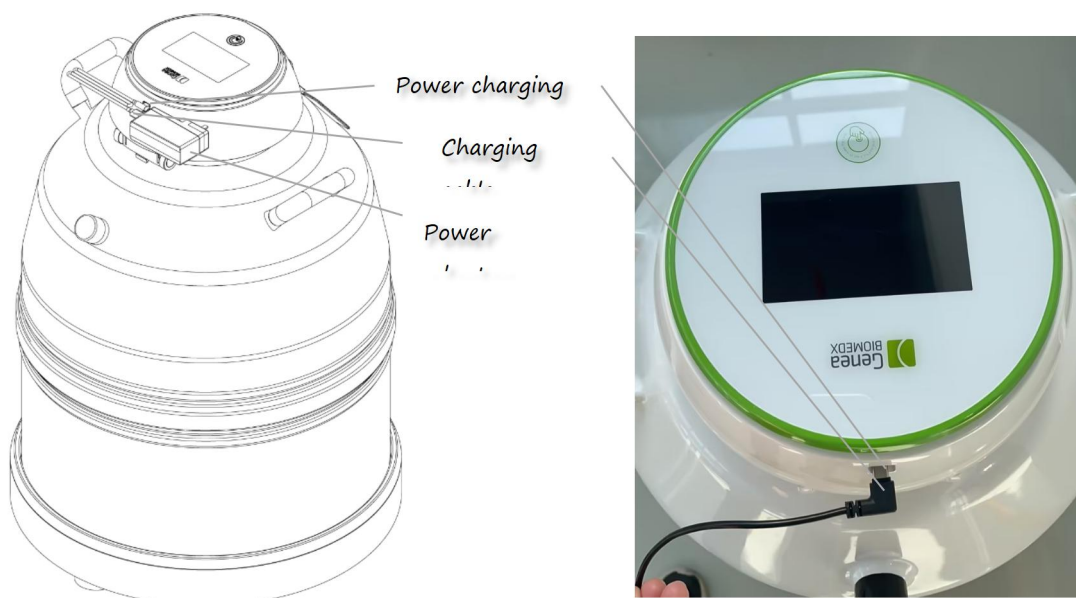



Figure 2-10 Charging Device

| | |
|---|---|
|  | <p>WARNING:</p> <p>To reduce the risk of electric shock:</p> <ul style="list-style-type: none"> • Liquids, including liquid nitrogen, must not make contact the tank lid or electronics; doing so may result in electrical short circuits. • do not replace the supplied charging power cord and/or power adapter with an incorrectly rated cord or adapter; • connect the charging power adapter only to an electrical power source with the proper voltage and frequency; • immediately replace the power cord if it becomes damaged, frayed, cracked or broken. |
|---|---|

2.2.4.2 Replacing the battery

When the device is low on battery, the depleted battery can be replaced with a fully charged battery pack. The battery replacement touchpoints are indicated in Figure 2-11.

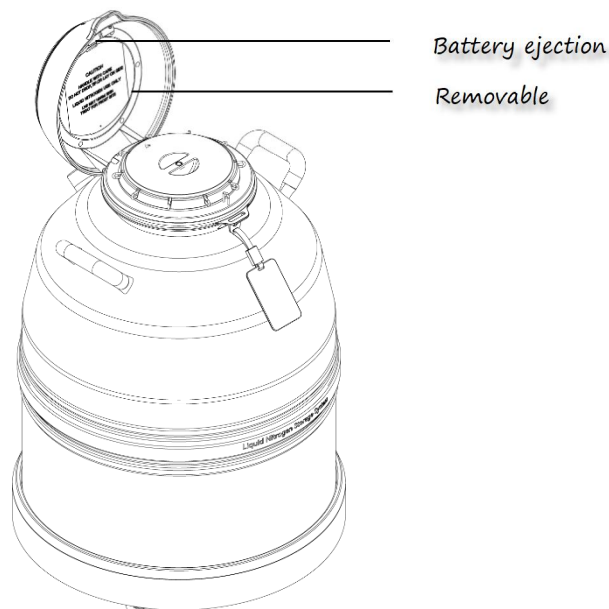


Figure 2-11 Battery removal and ejection touchpoints

To eject the battery: Before removing the battery, press the power on/off on the back of the Gelida 47 Lid to power off the device (Figure 2-5). Then open the lid, and can be removed by hand (Figure 2-12, Steps 1,2 and 3).

To insert the battery: Check the battery power is on (Section 2.2.2) and has sufficient charge. Open the lid and put the new battery in place (Figure 2-12, Steps 4,5 and 6) taking care to align the locating tab into the lid correctly. Then close the lid and the inner flap, press the power on/off on the back of the Gelida 47 Lid to power on the device. Confirm that the display wakes.



NOTE:

Perform battery replacement operations with care and ensure all retention mechanisms are correctly engaged.

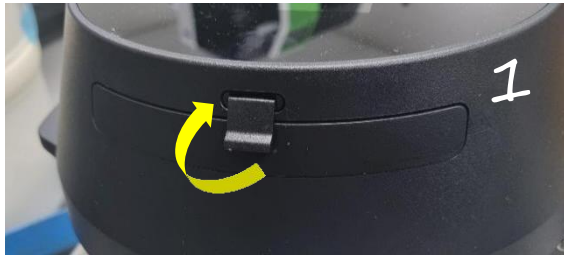
BATTERY EJECTION



BATTERY INSERTION



Figure 2-12 Battery replacement: Ejection (left 3 figures) and Insertion (right 3 figures)



2.2.5 Insulation plug

The insulation plug provides non-sealed insulation to maintain low temperatures within the tank, but allowing for gas to gradually escape as LN2 boils off. Correct installation of the insulation plug is as shown in the figure 2-13. The insulation plug should be positioned with the “Alignment Arrow” pointing vertically towards the hinge of the tank lid. The insulation plug should not require significant force to remove or reinsert. Ensure the cap is flush with the surface (not protruding) before closing the lid.

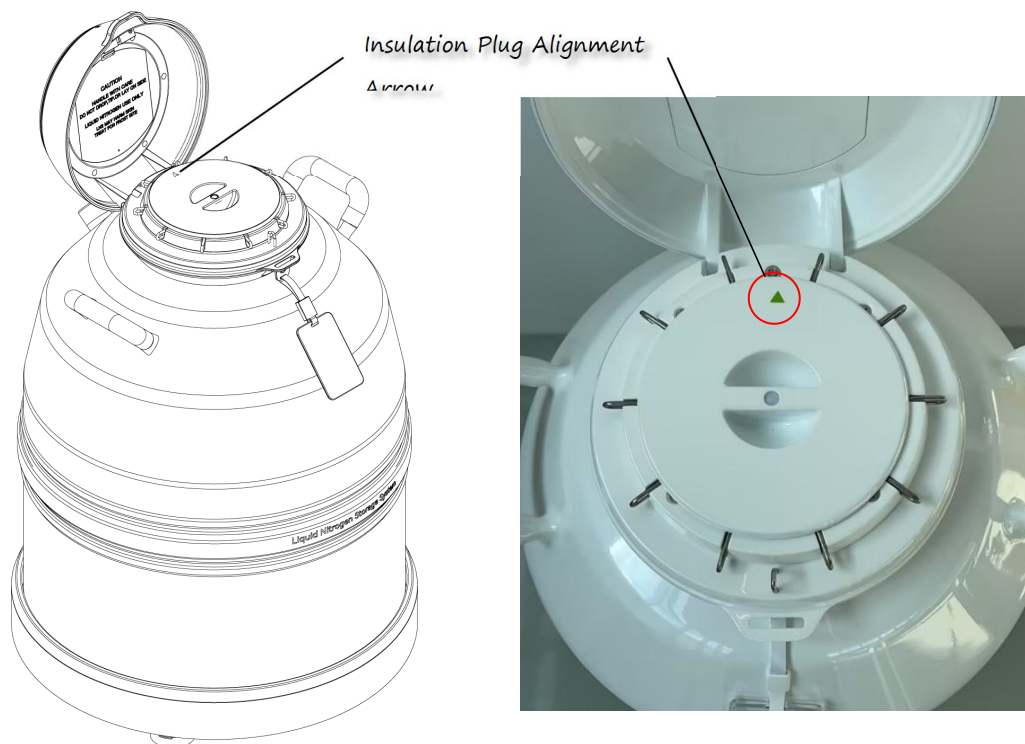




Figure 2-13 Insulation Plug Installation and correct orientation

| | |
|---|---|
|  | <p>CAUTION:</p> <p>Do not force the insulation plug into place. Do not modify the insulation plug in any way.</p> <p>Damage or modification to the insulation plug may result in degraded product safety and performance.</p> <p>If the insulation plug is damaged, excessive LN2 usage may occur, or in severe cases, excessive pressure may build up which could result in explosion. Transfer samples to a backup cryostorage solution and contact your local Genea Biomedx representative for support.</p> |
|  | <p>Note:</p> <p>The insulation plugs are unique to each variant and are not interchangeable between the rack and canister models.</p> |

2.3 Product setup & installation

The commissioning & installation of the product before first use should be done by a certified Genea Biomedx Field Service Engineer (FSE). The following instructions are guidance instructions which can be actioned by the customer after the FSE has installed the unit.

2.3.1 Installation space

Ensure the device is not placed in a location that makes it difficult to access, move, or open the lid.

Adequate space should be reserved around the device as shown in Figure 2-14 (units in mm). Ensure that there is sufficient space above the unit to allow users to open the tank, read the screen. Ensure there is some clearance on the sides of the tank where the handles are located so that the tank handles can be accessed, and to minimise risk of knocking into other tanks or objects.

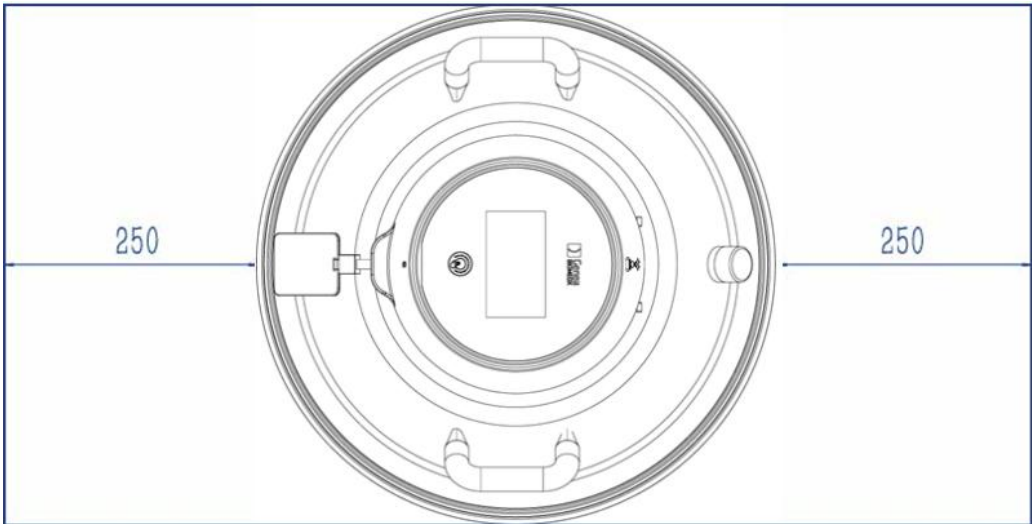







Figure 2-14 Minimum recommended spacing in front and behind tank (units in mm)

| | |
|---|--|
|  | <p>WARNING:</p> <p>Do not store or use container in areas that are small and enclosed or have poor ventilation.</p> <p>The venting of nitrogen gas may deplete oxygen in the air, possibly leading to asphyxiation or even death. It is recommended to add an oxygen concentration monitor for environmental monitoring.</p> |
|  | <p>WARNING:</p> <p>Do not tightly seal liquid nitrogen container or prevent nitrogen gas from escaping. Avoid excessive humidity levels or exposure to liquid ingress that could result in freezing of the insulation plug, and possible explosion.</p> |
|  | <p>CAUTION:</p> <p>Handle the cryopreservation vessel with care during use, failure to handle with care may impact the product safety and performance and may void warranty.</p> <ul style="list-style-type: none"> • Never overfill Gelida 47 with liquid nitrogen. Liquid nitrogen should always be below the bottom of the neck tube. Overfilling the tank may cause immediate or premature vacuum failure to occur. • Never ship Gelida 47 on its side or upside down. • Remove and insert inventories carefully. Do not scratch neck tube area. Scratches can cause premature vacuum failure. • Never tamper with or removing the vacuum port as this may result in vacuum |

| | |
|--|--|
| | <p>failure.</p> <ul style="list-style-type: none"> • Never drop or hit the unit. • Never spill liquid nitrogen on or near vacuum port. • Never leave the vessel in outdoor conditions. • Never place the unit near a heat source. • Never have items stacked on top of the product. • Performance data available for the instrument is based on static conditions only. Actual performance will vary upon the nature of use. Addition or removal of samples, addition on non-validated accessories, along with vibration will decrease the working duration of these products. |
|  | <p>WARNING:</p> <p>Do not place or use instrument near a strong source of RF radiation (e.g., an unshielded radio frequency (RF) source). Doing so may interfere with the electronics and communication functionality of the instrument.</p> |
|  | <p>NOTE:</p> <p>It is recommended to keep a spare tank filled with liquid nitrogen on hand for emergency should a tank in service become damaged or lose vacuum, enabling rapid transfer of samples to the spare tank.</p> <p>It is the customers responsibility to ensure adequate safety procedures are in place to save the samples contained within the tank.</p> |

2.3.2 Installation method

1. Remove the Gelida 47 from its packaging and place it in the selected installation location.
2. Install the removable battery follow the instructions as outlined in Section 2.2.2 to power on the battery and Section 2.2.4.2 to install.
3. Open the lid and put the new battery in place and taking care to align the locating tab into the lid correctly taking care to align the locating tab into the lid correctly.
 - a. Note: The device must be equipped with a battery. Using an incorrect battery model may pose a risk of explosion or fire.
4. Press the power on/off button to turn the device on.
5. The screen should automatically wake. If not, slightly touch the wake button on the tank lid to check if the screen can be normally awakened.
6. Connect the power adapter to the charging cable, then insert the cable into the power charging port to confirm normal charging.

Note: When charging, the battery indicator light will blink. The charger can be removed once the battery is fully charged.

2.3.3 Opening the Tank Lid



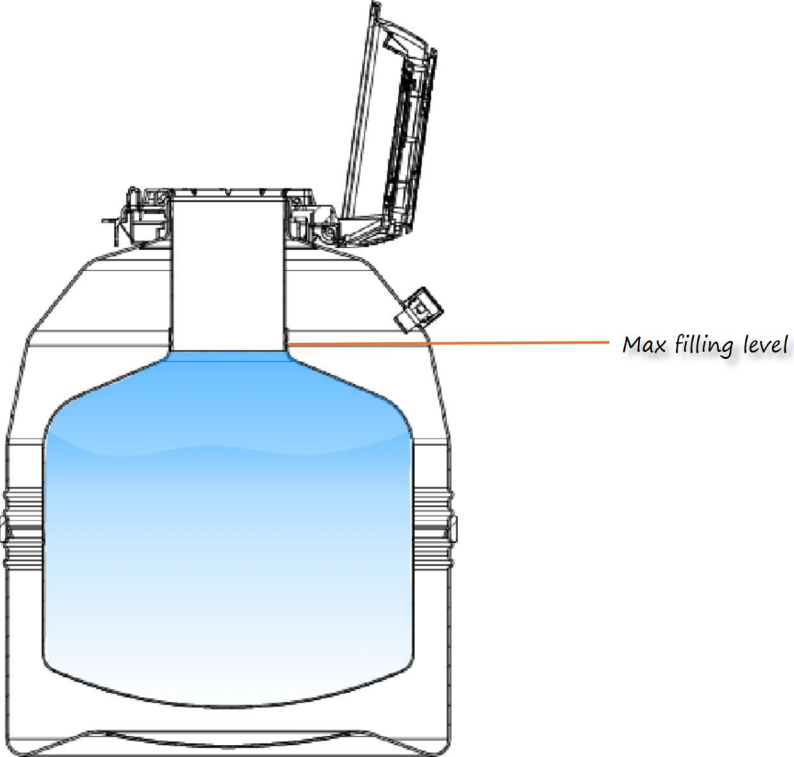
1. Open the tank lid and lift up the insulation plug.





- a. If the lid is locked, wake the screen using the Wake Button on the lid, and follow the instructions in Section 2.4.6 to open the lid using the touch display.
 - b. If there is an unlocking failure, follow the instructions in Section 2.2.1 to use the Emergency key to bypass the electronic lock.
2. Remove any shipping packaging within the tank.
3. Confirm the presence of the canister/rack inside the Gelida 47 for every numbered location.

2.3.4 Filling Liquid Nitrogen

First Use:

- red
-

| | |
|---|---|
|  | <p>WARNING:</p> <p>The Gelida 47 is exclusively designed to be used with liquid nitrogen ONLY and should not be used to store any other cryogenic substances.</p> |
|  | <div style="text-align: center;">  </div> <p>CAUTION:</p> <p>Never overfill vessels with liquid nitrogen. Liquid nitrogen should always be below the bottom of the neck tube (approximately 47.4L). Overfilling may cause immediate or premature vacuum failure to occur, and it may also cause spillage, which can damage the tank and the electronic components on the lid.</p> |

| | |
|---|--|
|  | <p>WARNING:</p> <p>Liquid nitrogen is extremely cold. To avoid injury by frostbite, use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects which have come in contact with liquid nitrogen.</p> <ul style="list-style-type: none"> • Appropriate cryogenic protective gear must be worn to prevent cryogenic burns; leave no areas of skin exposed. <ul style="list-style-type: none"> ○ Safety attire over clothing ○ Face shield ○ Cryogenic gloves ○ Cryogenic apron • Use extreme care to prevent spilling and splashing liquid nitrogen during transfer. • Always keep vessel in upright position. Do not tilt or lay the vessel on side. • Get immediate medical attention for any frostbite injuries due to liquid nitrogen. • Immediately remove any clothing or safety attire on which liquid nitrogen has spilled. • When refilling with liquid nitrogen, pre-cool the system with a small amount of liquid nitrogen before refilling. The refilling process should be gradual to avoid splashing and potential cryogenic burn related injuries. <div data-bbox="438 1081 1189 1216">  </div> |
|  | <p>WARNING:</p> <p>To reduce the risk of electric shock:</p> <ul style="list-style-type: none"> • Liquids, including liquid nitrogen, must not make contact the tank lid or electronics; doing so may result in electrical short circuits. • do not attempt to repair or modify any part of the instrument. |
|  | <p>NOTE:</p> <p>The full capacity of Gelida 47 tank is designed to accept up to ~47L of liquid nitrogen.</p> <p>The actual volume of LN2 required to fill the tank may vary this amount if the tank if the tank temperature has warmed sufficiently.</p> |

2.4 User operation

GELIDA 47 HOMEPAGE

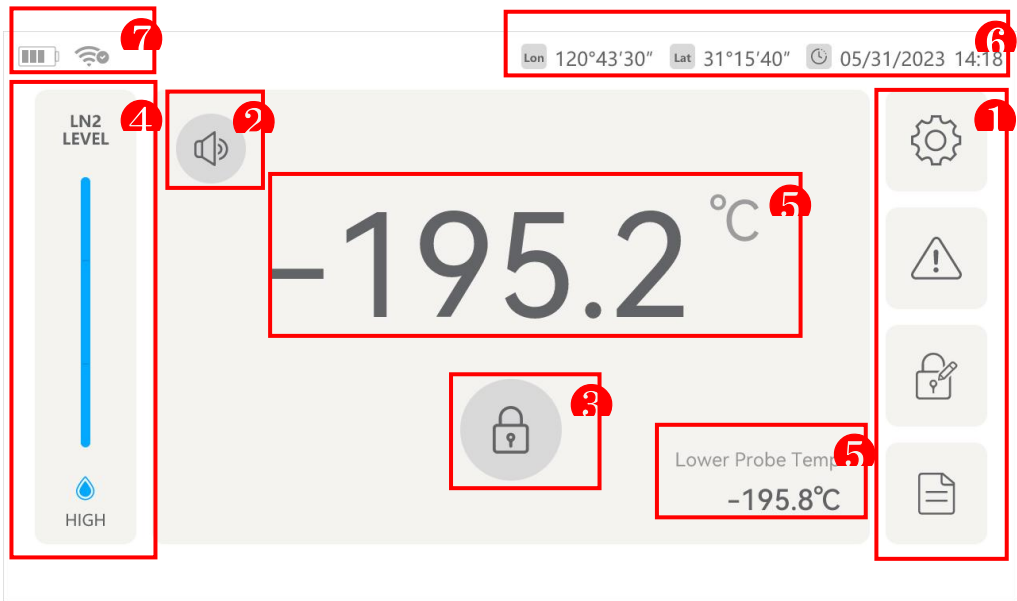


Figure 2-15 Homepage/Main Interface of Gelida 47 Display Screen

| # | Description | Section Reference |
|---|-------------------------------------|-----------------------------------|
| 1 | Settings, Warnings, Security & Logs | 2.4.11 2.4.2 2.4.3 2.4.4 |
| 2 | Alarm Mute Button | 2.4.5 |
| 3 | Lid Locking/Unlocking/Status Button | 2.4.6 2.4.7 |
| 4 | LN2 Level Indicator | 2.4.8 |
| 5 | Temperature Display | 2.4.9 |
| 6 | GPS Location and Time | 2.4.11.11 2.4.11.2 |
| 7 | Wi-Fi Status, Battery | 2.4.11.1 |

| | | |
|--|--|--------|
| | | 2.4.10 |
|--|--|--------|

2.4.1 Turning on and using the Display

To turn on the touch display, tap the wake button on the lid. Ensure that the device is powered on.

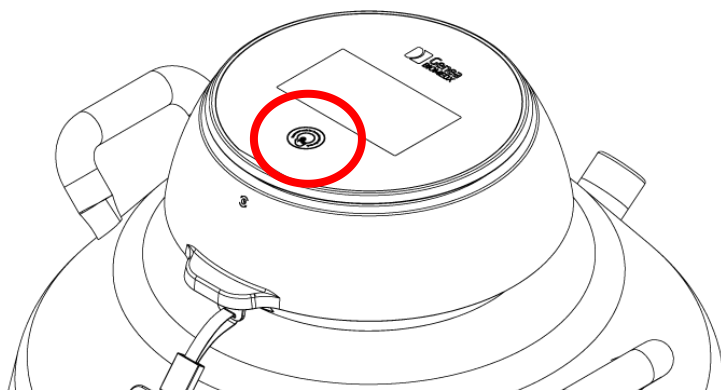







Figure 2-16 Screen wake touch sensitive button

| | |
|---|--|
|  | <p>NOTE:</p> <p>The lid wake button and touch screen are capacitive. Touch functionality may be impacted by the type of gloves worn when using the touch features.</p> <p>A slightly longer press may be required for the display elements to respond. Alternatively try touch functionality without using gloves or with alternative gloves if screen remains non responsive using existing PPE.</p> |
|---|--|

2.4.2 Warning & Faults Management

On the main interface, click on the "Warning" button to access the Warning & Fault records interface. Descriptions of Warnings & Faults can be viewed in Section 4.4.

| Icon | Description |
|---|---|
|  | No active warnings: Historical warnings and faults can be viewed |
|  | Active Warning or Faults which require user intervention to resolve |

If there are many warnings, the list will be distributed across multiple pages. The pages can be navigated by clicking on the  and  buttons on the lower bar of the display. The current page number is displayed in between the navigation arrows. Warnings & faults must be completely resolved before the Warning Indicator will reset.

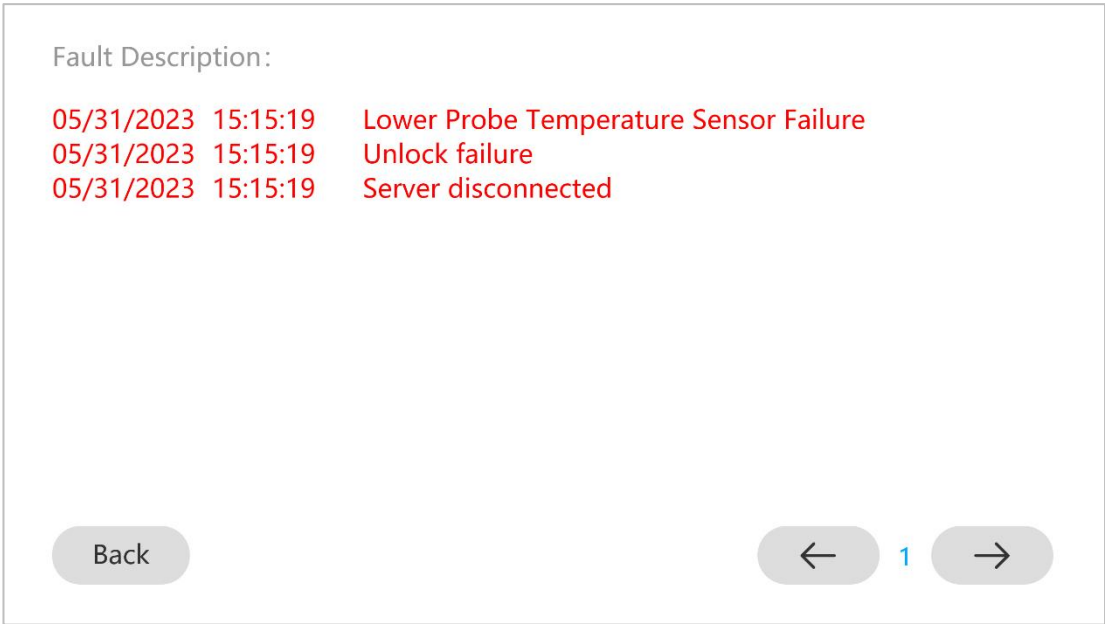




Figure 2-17 Fault Description

| | |
|---|--|
|  | <p>NOTE: A maximum of 100 of the most recent warnings or faults can be stored.</p> <p>If the tank is linked to a monitoring system, warnings and faults can also be viewed there.</p> |
|---|--|

2.4.3 User Password Modification

To modify the password, click on the  button on the homepage to navigate to the following interface. Enter the correct user name and current password. If there is an error in the input, a red font warning will be displayed. Upon correct entry of the details, input the new password and confirm the password, ensuring both entries are identical. Click on "Confirm" to receive a prompt about the modification result. Once the prompt indicates successful modification, the new password can be used to log in.

Username Already Exists

User Name:

Password:

Confirm Password:

BackConfirm

Figure 2-18 Password Modification Interface

2.4.4 System Access Logs



On the homepage, click on the button to be redirected to the password input interface. The local administrator password is required to access detailed information in the operational logs for the Gelida 47 unit.

For assistance with the Administrator password, refer to Section 2.4.11.4

123+/-.

4560⌫

789↶↵

Figure 2-19 Password Input Interface

The Access Log Inquiry Interface indicates the time of the log event, the access event type, the user, and the witness. If there are many log entries, the list will be distributed across multiple pages. The pages can be navigated by clicking on the “arrow” buttons on the lower bar of the display. The current page number is displayed in between the navigation arrows. Click the “Back” button to go back to the Homescreen.

| Operation Time | Event | Operator | Witness |
|---------------------|--------|----------|---------|
| 05/31/2023 15:19:31 | Lock | | |
| 05/31/2023 15:18:31 | Unlock | 001 | |
| 05/31/2023 15:16:20 | Lock | | |
| 05/31/2023 15:15:19 | Unlock | 001 | 002 |

Back

←

1



→


Figure 2-20 Log Inquiry Interface

2.4.5 Alarms & Muting Alarms

The audible alarm will be triggered when an alarm condition is met which requires user intervention to resolve.





When the buzzer emits an alarm sound, the silence/mute button can be clicked to silence the sound, the icon's background colour changes to blue, and the alarm sound ceases. Ten minutes after clicking the mute button, the mute is released and the alarm sounds again.

| Alarm Display | Status | Description |
|---|-------------|---|
|  | Alarm On | If the icon appears like this, the alarm buzzer is on, and will emit and audible sound in an alarm condition. |
|  | Alarm Muted | The audible alarm is temporarily muted for 10 minutes. The button can be tapped again to un-mute the audible alarm at any time. |

| | |
|---|---|
|  | <p>Note:</p> <p>Muting the alarm is temporary, the system will continue to alarm if the original cause is not addressed. The alarm condition will also still be communicated to the monitoring system if connected even when muted.</p> <p>To identify and address the alarm condition, referring to Warnings Module in section 2.4.1.</p> |
|---|---|

2.4.6 Lid operation

The Gelida 47 tank is equipped with a digitally controlled electromechanical lock with single or dual password authentication. The lock icon and statuses are located on top right of the display as indicated in Figure 2-15 Icon 3.

| Icon | Status |
|---|---|
|  | Lid Locked Tap this icon to enter credentials to unlock tank lid. |
|  | Lid Unlocked |
|  | Lid Locking Fault Audible Alarm – Consult Section 4.4 for troubleshooting |
|  | Lid Unlocking Fault Audible Alarm – Consult Section 4.4 for troubleshooting or use the emergency access key |

When the device has single-password verification enabled, the lid opening and closing operation is as follows:

2.4.6.1 Unlocking lid

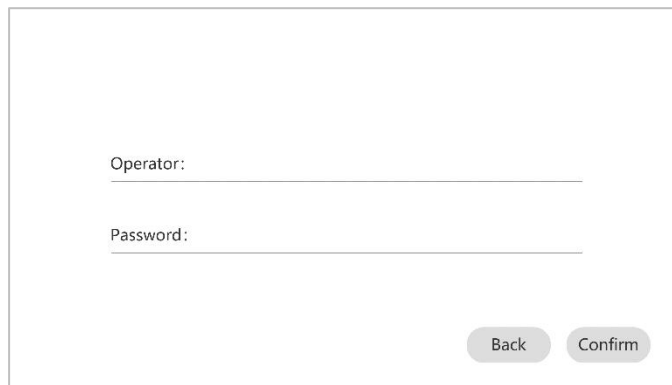
Click on the lock icon (Icon 3 in Figure 2-15), enter the operator's user name and password and press the “confirm” button. Upon successful entry, the lock opens, and the lock icon changes to lid unlocking status.

In case of a fault, the lock icon remains unchanged and the color turns red, the buzzer emits an audible alarm, and a record of the fault is added to the device log.

2.4.6.2 Locking lid

Ensure the canister or racks have been replaced, and the insulation plug has been correctly placed. Close the lid and wait. After 3 seconds the lid will be automatically locked, and the lock icon changes to lid locking status.

In case of a fault, the lock icon remains unchanged and the color turns red, the buzzer will emit an audible alarm, and a record is added to the Warnings & Faults log.



Operator: _____

Password: _____

Back Confirm

Figure 2-21 Unlocking Password Input Interface

When the device has Dual Password Authentication enabled:

The lid opening and closing operation requires:

- 1) Operator user name and password.
- 2) Witness user name and password.

The lock will only open if both the operator's and witness's user names and passwords are correctly entered.




Witness: _____

Password: _____

Back Confirm

Figure 2-22 Witness Login Interface

| | |
|---|---|
|  | <p>NOTE:</p> <p>If the screen lights up and there is no operation for more than 3 minutes, the screen will automatically turn off and enter sleep mode, but electronic and monitoring components are still running internally.</p> <p>To determine if the device has entered sleep mode by touching the screen. If the touch screen does not light up upon touch, it means that the device has entered sleep mode.</p> |
|---|---|

2.4.7 Sample access

2.4.7.1 Accessing a Canister/Rack & Sample

After opening the tank lid, carefully take out the insulation cap, and take out the canister/rack of choice. For ease of access and location tracking, the canister positions are numbered next to the locators as circled in Figure 2-23.

Lift the desired canister or rack by the handle which is hooked on the neck of the lid. Ensure that your approved lab procedure is followed when handling all cryogenically stored samples.

Add or remove the required sample(s) and return the canister or rack to the original position. The position is indicated on the plastic rim of the lid.

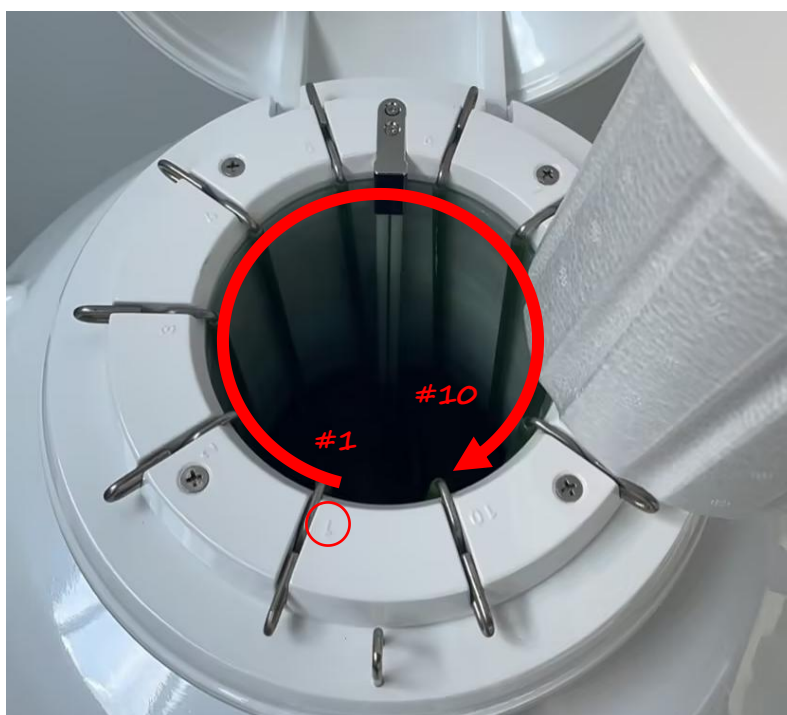




Figure 2-23 Numbered positions of canisters and racks

2.4.7.2 Replacing a Canister/Racks & Sample

Before closing the lid, replace the sample into the canister or rack, and ensuring that it cannot fall out. For the Rack variant, ensure that the retaining bar which holds the boxes in place.



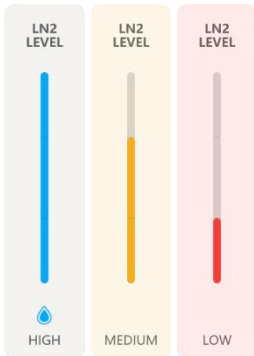
Carefully lower the canister or rack into the tank, being careful not to damage or scratch the internal structure of the tank. Check that the rack is returned to the correct position it was removed from.

Ensure the handle is correctly engaged with the correct position in the lid, and carefully replace the insulation cap.

| | |
|---|---|
|  | <p>WARNING:</p> <p>Liquid nitrogen is extremely cold. To avoid injury by frostbite, use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects which have come in contact with liquid nitrogen.</p> <ul style="list-style-type: none">• Appropriate cryogenic protective gear must be worn to prevent cryogenic burns; leave no areas of skin exposed.<ul style="list-style-type: none">○ Safety attire over clothing○ Face shield○ Cryogenic gloves○ Cryogenic apron• Use extreme care to prevent spilling and splashing liquid nitrogen during transfer.• Always keep vessel in upright position. Do not tilt or lay the vessel on side.• Get immediate medical attention for any frostbite injuries due to liquid nitrogen.• Immediately remove any clothing or safety attire on which liquid nitrogen has spilled.• When refilling with liquid nitrogen, Pre-cool the system with a small amount of liquid nitrogen before refilling. The refilling process should be gradual to avoid splashing and potential cryogenic burn related injuries. |
|  | <p>CAUTION:</p> <p>When accessing frozen samples work quickly and carefully to avoid premature thawing and unnecessary sample loss.</p> |

2.4.8 Liquid LN2 Level Estimate



The Gelida 47 has two temperature sensors that allow for estimation of LN2 liquid level. The upper temperature sensor and the lower sensor are located 21.6cm (8.5") and 7.1cm (2.8") from the tank bottom respectively. As the LN2 liquid level reduces, the liquid level will pass the temperature sensor resulting in an increase in measured temperature. The monitoring system interprets the temperature differential between the top and bottom sensors based on the set limits, and displays an estimate as High, Medium or Low.

| Icon | Meaning | Approx. LN2 Volume* |
|---|---|---|
|  | <p>Homescreen display shows an estimate for the current liquid level determined from the temperature of the upper and lower tank temperature sensors.</p> <p>The LN2 level estimate can be high, medium, or low. With the current estimate coloured, and non-active levels in grey.</p> |  |
|  | The display is blue and the LN2 level is estimated to be high. | 34L – 47L |
| | The display is orange and the LN2 level is estimated to be between high and low: replenish, or plan to replenish LN2 soon. | 34L – 14L |
| | The display is red and the LN2 level is estimated to be low, immediately replenish LN2 to protect stored samples. | < 14L |

*Note: Values based on upper and lower temperature sensor limits set to -195°C as shown in the table below. It is recommended to validate the levels according to your internal risk profile for the samples to be stored.

The table below indicates the expected liquid level estimation behaviour with the upper and lower temperature sensor limits set to -195°C. It is recommended to validate the temperature sensor limits and liquid level estimation according to the use case. Alarm temperature limits can also be set by the user (see Section 2.4.11.6 & 2.4.11.7).

| Displayed Estimate | Upper Temperature Sensor Reading | Lower Temperature Sensor Reading |
|---------------------|----------------------------------|----------------------------------|
| High Liquid Level | $\leq -195^{\circ}\text{C}$ | $\leq -195^{\circ}\text{C}$ |
| Medium Liquid Level | $> -195^{\circ}\text{C}$ | $\leq -195^{\circ}\text{C}$ |
| Low Liquid Level | $> -195^{\circ}\text{C}$ | $> -195^{\circ}\text{C}$ |

| | |
|---|--|
|  | <p>WARNING:</p> <p>Never use a hollow tube to measure liquid nitrogen level. This could lead to thermal injury.</p> <p>The device is equipped with 2 temperature sensors which are used to approximate the liquid level in the tank.</p> <p>Contact local your Genea Biomedx representative if you need alternative methods to measure liquid nitrogen level.</p> |
|  | <p>Note:</p> <p>Upon powering on the device, it's normal for the liquid level icon to appear grey as data is being acquired and refreshed.</p> <p>When either the high or low temperature sensors experience a fault, all liquid level icons will remain grey. Contact your authorised Genea Biomedx Service representative immediately for servicing.</p> |

2.4.9 Temperature Display

The temperature displayed in the centre of the Homescreen is the reading from the “Upper Probe Temperature Sensor” (Figure 2-24 A). The “Lower Probe Temperature” displays the reading from the “Lower Probe Temperature Sensor” (Figure 2-24 B).

When the temperature of either sensor exceeds the set limit, the temperature reading will change from **grey to red**, and an alarm will sound.

If the tank is linked to a monitoring system, an alarm notification will also be sent.

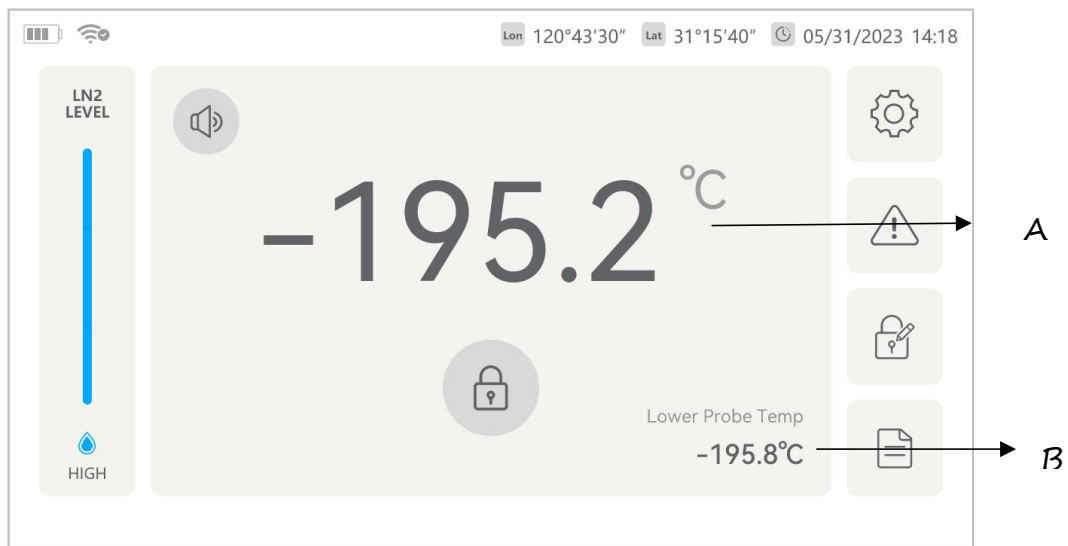


Figure 2-24

2.4.10 Battery Level Display

The battery level of the tank lid is displayed in the upper left corner of the Homescreen. There are five states of battery level, and any abnormalities are colored.

| Icon | Meaning |
|------|---|
| | The display is grey and the battery level is indicated between 75% and 100%. |
| | The display is grey and the battery level is indicated between 50% and 75%. |
| | The display is orange and the battery level is indicated between 25% and 50%. |
| | The display is red and the battery level is indicated less than 25%. When the icon is flashing, it indicates the battery is low and needs to be recharged and or replaced . |
| | The display is green and it indicates that it is being charged. |

2.4.11 Settings

Click on the button, enter the administrator password, to access the settings interface. The default administrator password can be found in Section 2.4.11.4.

The screenshot displays the 'Settings Interface' with a top navigation bar containing icons and labels for 'IP', 'Date & Time', 'User', and 'Language'. Below this, the settings are organized into three columns:

- Column 1:**
 - 'Alarm Temp of the Upper Probe (°C)' with a text input field containing '-195.3'.
 - 'Alarm Temp of the Lower Probe (°C)' with a text input field containing '-195.3'.
 - 'Lid Open Time (Min) Before Alarm' with a text input field containing '5'.
- Column 2:**
 - 'Screen Brightness (%)' with a slider control set to '100'.
 - 'Single Password Authentication' with a blue toggle switch turned 'ON'.
 - 'Dual Password Authentication' with a grey toggle switch turned 'OFF'.
- Column 3:**
 - 'Volume Adjustment(%)' with a slider control set to '10'.
 - 'GPS' with a grey toggle switch turned 'OFF'.
 - 'Wi-Fi' with a grey toggle switch turned 'OFF'.

At the bottom of the interface, there is a 'Software Version: V1' label on the left, and three buttons: 'Change Administrator Password', 'Back', and 'Confirm'.

Figure 2-25 Settings Interface

2.4.11.1 Wi-Fi & IP settings

The device Wi-Fi must be enabled to connect to the Gelida 47 Tank to the monitoring systems. The monitoring system allows for additional functionality with the Gelida 47 tank and Gelida Ecosystem, such as remote tank monitoring, alarms, notification, permissions management and additional sample management.

To enable connection to the Monitoring system, contact your local Biomedx Representative for more information.

- 1) Tap the IP button in the Setting Interface
- 2) The IP Settings page will appear as in Figure 2-26
- 3) Select Monitoring system IP, and enter the server:
 - a. IP address.
 - b. Server Port
 - c. Wi-Fi SSID
 - d. Wi-Fi Password
- 4) Review details and click "Confirm".

Local IP:

Server IP:

Server Port:



SSID:

Password:

Back

Confirm

Figure 2-26 IP Settings

| | |
|--|--|
|  | <p>NOTE:</p> <p>The Monitoring system & Gelida 47 Tank must be on the same local network or virtual network to ensure a stable connection.</p> <p>Contact your local Biomedx representative for more information or for setup assistance.</p> |
|  | <p>CAUTION:</p> <p>Do not place or use instrument near a strong source of RF radiation (e.g., an unshielded radio frequency (RF) source). Doing so may interfere with the electronics and communication functionality of the instrument.</p> |

2.4.11.2 Date & Time Setup

Sets the date and time of the internal clock on the Gelida 47. Tap the Datetime button in the top bar of the setting screen. Click on the button, input the date and time, then click "Confirm".

The date format: DD / MM / YYYY (numerical)

The time format: HH : MM : SS (24 hour time)

Date: 05 / 31 / 2023

Time: 14 : 26 : 09

Back Confirm

Figure 2-27 Time Calibration

2.4.11.3 User management

After tapping the "User" button on the "Setting" interface, users can enter the user management page.

The lower bar is the functional zone which allows for user profile management and contains the "Create User" and "Delete User" buttons, as well as page navigation arrows. The upper part a table which displays currently registered users and information, such as User "Serial Number", "User Name" and "User Creation Time".

User Serial number is automatically sorted by creation time. If there are many authorised users, the list will be distributed across multiple pages. The pages can be navigated by clicking on the ← and → buttons on the lower bar of the display. The current page number is displayed in between the navigation arrows.

| Serial Number | User Name | Creation Time |
|---------------|-----------|---------------------|
| 1 | 006 | 05/31/2023 14:26:09 |
| 2 | 008 | 05/31/2023 14:02:57 |

Create User Delete User ← 1 → Back

Figure 2-28 User Management Interface

The following table outlines the 3 different levels of permission on the Gelida 47 Tank, and the tank functions available functions at each level.

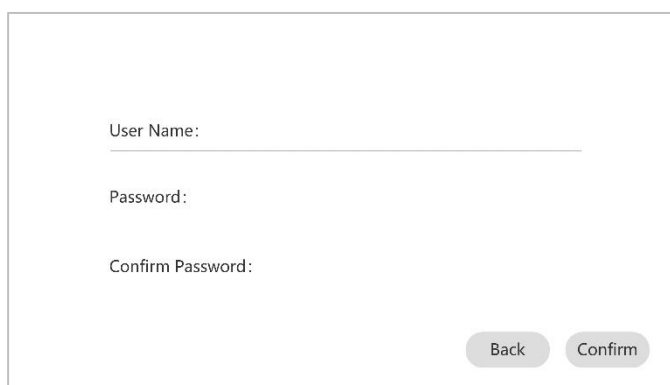
| Functions | No Login | Operator | Administrator |
|--|----------|----------|---------------|
| Access information such as temperature readings, GPS location, time, Wi-Fi connection status | ✓ | ✓ | ✓ |
| View Warnings, Faults and Mute Alarm | ✓ | ✓ | ✓ |
| Open Tank Lid | ✗ | ✓ | ✗ |
| Enter and edit the device settings | ✗ | ✗ | ✓ |
| Create and Modify Users & Password | ✗ | ✗ | ✓ |
| View and clear Access Logs | ✗ | ✗ | ✓ |

a) Create user

Click on the "Create User" button in user management to navigate to Figure 2-29.

- 1) Enter the User Name (three-digit numerical code).
- 2) Enter the User Passcode (numeric only and must be 6 digits long).
- 3) Re-enter to confirm User Passcode. Note: The passcode and confirm passcode must match; if they do not, a red font warning will appear on the interface.
- 4) Click "Confirm". If the user creation was successful, the new user will appear in the list in the user management interface.

Note: There is a maximum of 100 users (001-100) not including the administrator account. If the range is exceeded, a "Username must be 001 to 100" prompt will appear.



The screenshot shows a 'Create User' form with three input fields: 'User Name:', 'Password:', and 'Confirm Password:'. Each field has a corresponding text input area. At the bottom right of the form, there are two buttons: 'Back' and 'Confirm'.

Figure 2-29 'Create User' Interface

b) Delete user

Click on the "Delete User" button in user management, which redirects to Figure 2-30.

Enter the “User name” of the user to be deleted. If the entered username is incorrect, a red font warning will appear on the interface; clicking "Delete" will proceed to delete the user, and they will no longer appear in the user management interface.

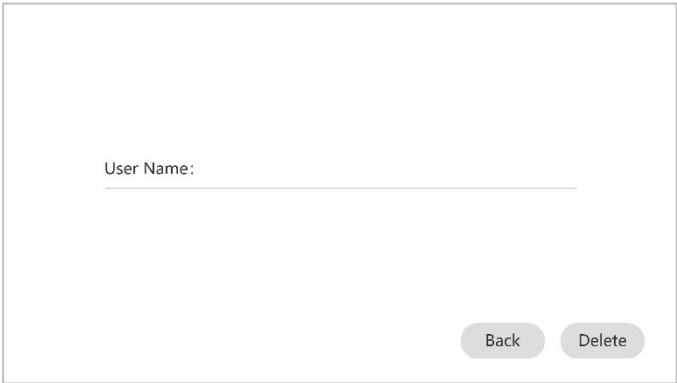



Figure 2-30 ‘Delete User’ Interface

| | |
|---|--|
|  | <p>NOTE:</p> <p>If the Gelida 47 Tank is connected and registered to a monitoring system, it is recommended to not create or delete users on the Gelida 47 only.</p> <p>Contact your local Biomedx representative for more information or for setup assistance.</p> |
|---|--|

2.4.11.4 Administrator password modification

The default administrator account allows for advanced access to key settings and user administration. By default, the administrator password is: 777777. To update the password, select the “Change Administrator Password”. Enter the new password and confirm new password and click "Confirm". The password is numeric only and must be 6 digits long. If the "Configuration Successful" appears on the screen, it indicates that the password has been successfully reset.

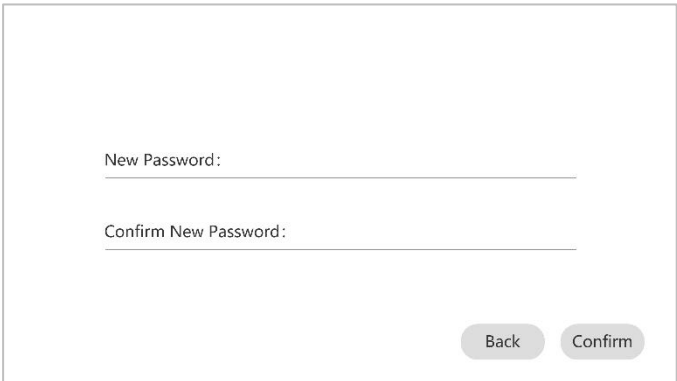


Figure 2-31 Administrator Password Modification

**Note:**

It is recommended to change the administrator password for security of access and to prevent undesired access or tampering with the system.

Do not forget the administrator password once it has been changed. In the case of a forgotten administrator password, contact your local Genea Biomedx representative.

For assistance with the Administrator password, refer to Section 2.4.13.

2.4.11.5 Language

Select the Language to switch the device language: When the background colour of the Chinese icon is white and English is black, it means that the current language is Chinese; when the background colour of the Chinese icon is white and English is grey, it means that the current language is English.

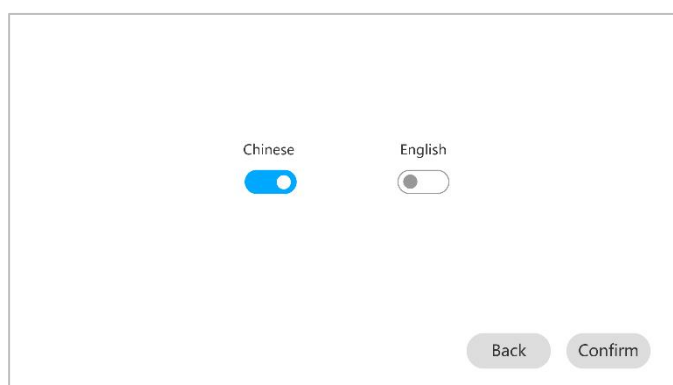


Figure 2-32 Language Setting Interface

2.4.11.6 Alarm Temp of the Upper Probe (°C)

Set the upper temperature limit for the upper part of the Gelida 47: When the temperature in the upper part exceeds this limit, an audible alarm will be triggered, the temperature display shifts to red, and an additional anomaly record is logged.

2.4.11.7 Alarm Temp of the Lower Probe (°C)

Set the upper limit of temperature for the lower part of the Gelida 47: When the temperature in the lower part exceeds this limit, an audible alarm will be triggered, the temperature display shifts to red, and an additional anomaly record is logged.

2.4.11.8 Lid Open Time (Min) Before Alarm

Sets the maximum duration (in minutes) allowable for the lid to remain open on the tank. If the lid is opened for too long or forgotten to be closed, the buzzer will send out an audible alarm and logged. The maximum allowable value is 30 minutes.

2.4.11.9 Screen brightness (%)



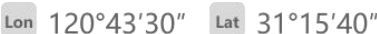

Set the screen brightness, value: 10-100. The higher the value, the brighter the screen.

2.4.11.10 Volume Adjustment (%)

Set the volume of audible alarms, value: 0-100. The higher the value, the louder the alarm volume.

2.4.11.11 GPS Location



The GPS function is designed to assist in tracking and geo-locating the tank.

| Icon | Description |
|---|--|
|  | GPS Functionality is disabled |
|  | GPS Functionality is enabled |
|  | GPS co-ordinates on Homescreen: shown as Longitude (E) and Latitude (N) in DMS (Degrees, Minutes, Seconds) |
|  | GPS is turned on, and no GPS co-ordinates detected |

To enable GPS, enter the settings menu. Tap the "GPS:" button. When activated, the background colour of the button turns from white to grey. When deactivated the button will turn from grey to white. To lock in the change, click the "Confirm" button.





After clicking the "Return" button and a waiting period of 2-3 minutes, the device's current longitude (E) and latitude (N) in DMS can be viewed in the lower-left corner of the main interface, indicating the device's current position.

If the tank is placed somewhere with a weak GPS signal or interference, the tank may not reliably be able to determine the GPS co-ordinates. In this situation, the "Weak GPS signal" prompt will be displayed in the lower left corner of the main interface.

| | |
|---|---|
|  | <p>NOTE:</p> <p>GPS Functionality is not available in all regions and may not be available on your specific model.</p> <p>Please contact your local Genea Biomedx representative for more information.</p> |
|  | <p>CAUTION:</p> <p>Do not place or use instrument near a strong source of RF radiation (e.g., an unshielded radio frequency (RF) source). Doing so may interfere with the electronics and communication functionality of the instrument.</p> |

2.4.11.12 Wi-Fi toggle

Enable or disable Wi-Fi and interact with the monitoring system. The monitoring system provides centralised monitoring, remote alarms and sample tracking for one or more Gelida 47 tanks and it is sold separately. Connection and setup of the monitoring system should be completed by a qualified Genea Biomedx service representative. Refer to the monitoring system user manual.

| Icon | Description | Icon | Description |
|---|-------------------|---|------------------------------------|
|  | Wi-Fi is disabled |  | Wi-Fi is disabled or not connected |
|  | Wi-Fi is enabled |  | Wi-Fi is enabled and connected |

Within Settings, if the Wi-Fi is disabled, the button will display as white. Tap the button to enable Wi-Fi, the background colour of the button turns blue. Upon clicking "Confirm" button, the colour will permanently change to grey. Once the connection is successfully established, the Wi-Fi icon shifts from red to grey.

The table below outlines faults which may appear on the Homescreen display:

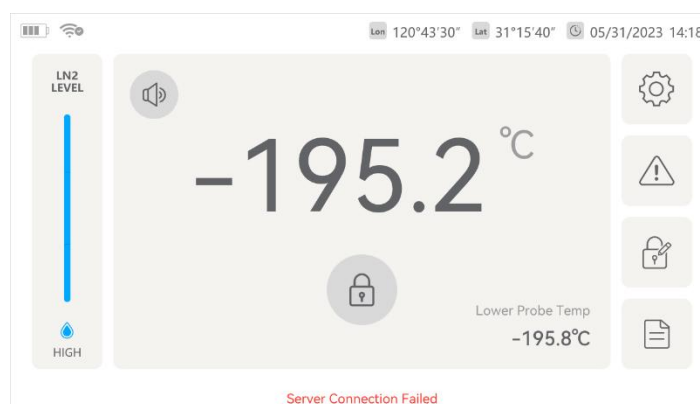


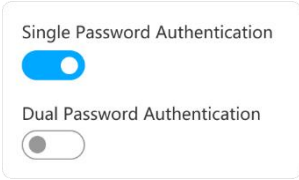
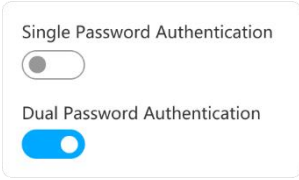
Figure 2-33

| Fault Display | Description |
|---|--|
| Router Connection Failed | The Wi-Fi SSID or password parameters in the IP settings are incorrectly set. No Alarm. |
| Server Connection Failed | Initial connection to the monitoring system has failed, and a record is added to the exception record. Triggers Alarm. |
| Server Disconnected | A previously stable connection to the monitoring system was interrupted or disconnected for <2 seconds. No Alarm. |
| In all cases, a record of the exception is logged and can be reviewed in "Warnings and Faults" (Section | |

2.4.2).

2.4.11.13 Single/dual password verification

All Gelida 47 Unlocking operations require password verification, which can be either single-password or dual password Authentication. There must be a minimum of two users created in the system for dual password verification to function. Refer to Section 2.4.12 on how to create additional users.

| Operation Mode | Icon Display | Description |
|---|--|---|
| Single Password Verification |  The icon display shows two toggle switches. The top switch is labeled 'Single Password Authentication' and is turned on (blue). The bottom switch is labeled 'Dual Password Authentication' and is turned off (grey). | Single-password verification requires the correct entry of one operator's username and Password to open the tank. |
| Dual Password Authentication |  The icon display shows two toggle switches. The top switch is labeled 'Single Password Authentication' and is turned off (grey). The bottom switch is labeled 'Dual Password Authentication' and is turned on (blue). | Dual Password Authentication requires the correct entry of both an operator's and witness's usernames and Passwords to open the tank. |
| Note: Selecting one option, automatically disables the other verification option. | | |

3. Technical Specifications

| Product Specifications | |
|--|---|
| Effective volume (L) | 47.4±2.3L |
| Liquid nitrogen consumption | ≤ 0.7 L/day Consumption may vary depending on storage conditions and frequency of tank opening. |
| Temperature detection error (°C) | At -196°C, the error is ≤ ± 5° C |
| Battery life | ≥ 10 days in sleep mode Device static with minimal tank access, Wi-Fi and GPS disabled, display on maximum brightness. |
| Packaging dimensions (mm) | 600 × 600 × 930 (Length x Width x Height) |
| Device dimensions (mm) | 540 × 540 × 785 (Length x Width x Height) |
| Net weight (kg) | 30.3±3 kg |
| Approximate weight when full of LN2 | 68.7 kg |
| Canister Dimensions (mm) | 278 x 72 (L x Diameter) |
| Maximum Box size for Rack (mm) | 78 x 78 x 59 (Depth x Width x Height) – 5 boxes per rack |
| Service Life | 5 years – extendable with repairs and maintenance |
| Operational Specifications | |
| Usage environment | Usage site: well-ventilated indoor area. Altitude: Below 2,000 meters. Environmental temperature: 5°C to 40°C. Environmental humidity: 20%RH to 80%RH, non-condensing. |
| Storage environment | Environmental temperature: 5°C to 40°C. Environmental humidity: 20%RH to 80%RH, non-condensing |
| Other Requirements | The product must always be kept upright, handled gently, and not tilted, laid horizontally, inverted, compressed, struck with other items, or subjected to impact. |
| Liquid ingress protection rating | IPX0 |
| Operation Mode | Continuous Operation |
| Installation Type (Permanent or Non-Permanent) | Non-permanent installation / Mobile |
| Electrical Specifications & Standards | |
| Power Adapter | Input: 100-240V~,50/60Hz,0.5A Output:5.0V --- 3.0A,15.0W |
| Device Charging Port | Input: 5.0V --- 3A Connector: USB Type C |
| Removable Battery | Model: GELI-BAT-01 Input:5.0V --- 2A Output: 5.0V --- 2A Rated Battery Capacity: 9.5 Ah / 35.15Wh Battery Type: Lithium Polymer Battery |
| MCU model | STM32L431VCT6 |
| Display Type | 5.0-inch colour 1280 × 720 capacitive multi touch |
| Alarm Type | Audible Speaker – Single Tone Continuous Beeping |
| Electrical Safety | EN 61010-1:2010+A1:2019 Safety requirements for electrical |

| | |
|---|--|
| | equipment for measurement, control, and laboratory use -- Part 1: General requirements. IEC 61010-1:2010+AMD1:2016 Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements. |
| Electromagnetic Compatibility: | EN IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements |
| Network Connectivity Specifications | |
| Network Connectivity | Wireless 802.11b/g/n |
| Network architecture | Client-Server (C/S) |
| Network bandwidth | No less than 10Mbit/s |
| Network type | LAN |
| Communications Protocol | TCP/IP protocol over a wireless network connection. |
| Network security feature configuration | No external interfaces are available. Remote access control is disabled, and no configuration is required. |
| Data Encryption | AES-256 encryption algorithm |
| FCC information | Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. |
| Software & Security Specifications | |
| Essential software | N/A |
| External software environment and security software updates | Not User Serviceable – trained field service engineer only |
| Ready-made software list | N/A |
| Security software compatibility list | No security software applicable |
| Data backup and disaster recovery | Not applicable |
| Connectable Software | Contact your local Genea Biomedx representative about connectable software options |

4. Product Maintenance & Support

4.1 Product Service Life

The expected service life of the Gelida 47 tank is 5 years. The products usable life may be extended through routine maintenance & calibration, preventative maintenance or service plans.

4.2 Routine maintenance & calibration

Periodic preventative maintenance and calibration should only be performed by personnel specifically trained by the manufacturer, such as a qualified Genea Biomedx service engineer.

4.2.1 Temperature Calibration

It is recommended that tank temperature sensor calibration should be conducted once a year. Schedule in annual calibration with your authorised Genea Biomedx Service representative.

4.2.2 Defrosting the Dewar

Liquid nitrogen storage systems can have ice and frost build up over time if the lid is left open for prolonged periods or if the liquid level gets too close to the underside of the lid. Contact your authorised Genea Biomedx Service representative for guidance on frost removal.



WARNING:

Do not remove frost with hard objects to prevent further damage to the tube.

4.2.3 Tank Inspection & Monitoring

If a sudden increase in LN2 evaporation loss is found, or if excessive frost & condensation appears on the exterior surface of the Gelida 47, this may indicate tank damage or loss of tank vacuum. Ensure that tanks are inspected by operators on a regular schedule according to your lab protocol and risk management. Minor frost at the top of after filling is expected.

In such cases stop using the product immediately and contact local Genea Biomedx service representative. If samples are stored within the tank, carefully and quickly move them to alternative cryogenic storage.





CAUTION:

Tank vacuum maintenance and repair should be carried out by the manufacturer or trained Genea Biomedx service representative.

Customers are prohibited from attempting these procedures themselves to avoid negative impacts to the product's performance and avoid voiding warranty.

4.2.4 Decontamination

For cleaning, only the exterior of the tank should be cleaned using a clean dust-free cloth moistened with 75% alcohol, gently clean the tank lid and the exterior of the Gelida 47. The interior of the tank should only be cleaned by a trained Genea Biomedx service representative. Interior tank cleaning requires removal of all LN2 and samples to complete.


| | |
|---|---|
|  | <p>WARNING:</p> <p>Only authorised service personal should calibrate, repair or replace parts within the Gelida 47 or perform other service and repair activities.</p> <p>Attempting untrained repair may result personal injury, loss product features and performance, or voiding of product warranty.</p> |
|  | <p>WARNING:</p> <p>To reduce the risk of electric shock:</p> <ul style="list-style-type: none">• do not attempt to repair or modify any part of the instrument;• do not remove any of the instrument panels or covers. |

4.3 Device Disposal

At the end of the product life, do not dispose of the tank with normal waste.



The tank is made from high quality aluminium alloy. The canisters and racks are constructed with stainless steel. The smart lid is comprised of moulded thermoplastic and incorporates electronic PCBs, electrical wiring and a digital display. The battery is removable and is a lithium polymer chemistry. The charging adapter and cable consist of electronic power supply components and electrical cabling. Dispose of this device in accordance with local regulations.

Contact your local Genea Biomedx service representative for more information.

| | |
|---|--|
|  | <p>NOTE:</p> <p>This Instrument is Subject to Laws Regarding the Disposal of Electronic Medical Equipment as Outlined in the WEEE Directive (2006/96/EC).</p> |
|---|--|

4.4 Warnings & Faults: Troubleshooting

| Problem | Cause | Solution |
|---------|-------|----------|
|---------|-------|----------|

| Problem | Cause | Solution |
|---|---|---|
|  | Abnormal Lock Mechanism – Tank Unlocked | Power off the device and attempt a reset using the emergency key, as detailed in Section "2.2.1". If the issue persists, please contact the local service representative. |
|  | Abnormal Lock Mechanism – Tank Locked | Contact the local service representative. If Emergency access to samples is required, please use the emergency key as detailed in Section "2.2.1". |
| Lock icon disappears | Immediately attempting to opening the lid after closing it can result in the latch not being properly positioned. | Power off the device and attempt a reset using the emergency key, as detailed in Section "2.2.1". If the issue persists, please contact the local service representative. |
| Router Connection Failed | Incorrect SSID or password parameter settings in IP configuration. | Confirm that the wireless network is functional, re-enter the correct SSID or password, and restart WI-FI. |
| Server Connection Failed | Failure in establishing a connection with the server for the first time. | Ensure that the server is functioning properly and that the server IP or server Port parameters are correct. Then, restart both the server and WIFI to re-establish the connection. |
| Server Disconnected | Previously stable connection to the server lost | Ensure that the server and network are functioning properly. |
| Device shuts down automatically after switching to battery, and at the same time, the battery LED light goes out automatically. | The battery is not powered on/activated. | Remove the battery and press and hold its side button. See Section "2.2.4" for further instructions. |
| The device does not wake up using the wake-up button but responds to screen taps. | The device has not entered sleep mode. | Power off the device and attempt a reset using the emergency key, as detailed in Section "2.2.1". If the issue persists, please contact your local Genea Biomedx service representative. |
| Abnormal screen colour | Abnormal screen LCD | Power off and then restart the device. If the issue persists, Contact the local Genea Biomedx service representative. |
| Touch functions not working | Abnormal touch screen or touch sensitive button behaviour | Remove gloves and try touch elements or touch display with finger. If this resolves the issue, the glove type may not be compatible with the display Otherwise, power off and then restart the device. If the issue persists, contact the local Genea Biomedx service representative. |

| Problem | Cause | Solution |
|---|--|--|
| High/low position sensor fault | Sensor faulty or recalibration needed. | Contact the local Genea Biomedx service representative. |
| High position temperature lower than low position | Recalibration is required. | Contact the local Genea Biomedx service representative. |
| Forgotten or Deleted User Profile/Password | Administrator privileges required | In case of a forgotten password, users should contact the local administrator for a password reset or for user to be added. |
| Forgotten Administrator Password | Unable to access administrator only features | In case of a forgotten password, users should contact the local Genea Biomedx administrator for an administrator password reset. |