HORIZON
MED TECH

Brammi

INFANT THERMOREGULATION SYSTEM

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USER RESPONSIBILITY

This user manual provides essential information for the correct assembly, operation, and maintenance of the Infant thermoregulation device.

Failure to follow the instructions provided may result in:

- Ineffective treatment delivery
- Harmful effects on the health of the patient, the user, or others
- Premature deterioration or damage to the equipment

Important notes:

- The user is responsible for regularly inspecting the device for damage, wear, or missing components, and for arranging timely maintenance and repair.
- The product must be periodically checked throughout its expected service life of eight years.
- Do not use a defective product.
- Any parts that are broken, missing, worn, distorted, or contaminated must be replaced immediately.
- This product and its components should only be repaired in accordance with the official instructions provided by the manufacturer.
- No alterations or modifications should be made to the product without prior written approval from the manufacturer.

The owner of this product bears full responsibility for any malfunction resulting from improper use, inadequate maintenance, unauthorised repair, physical damage, or modification carried out by anyone other than the manufacturer or manufacturer-authorised service personnel.

Instructions for Use
Ref no: UM-7.2.3-48A
Model: Brammi
Issue: 06
Date: April 15, 2026

Declaration of language translation:

This device comes to you as a package, complete with labels, user manual, and related documents, all of which are in English. The product targets the customers who are proficient in the language and can read the instructions and understand the product better. This user manual will be supplied in the local language upon request to EU customers

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1. Introduction

The Brammi is a medical thermoregulation device designed to administer cooling and warming therapy for neonates. It circulates fluid that is either cooled or warmed within the device through a specialised mattress to deliver controlled temperature therapy. This system is predominantly used to administer thermoregulation treatment to neonates affected by Hypoxic-Ischaemic Encephalopathy (HIE), a type of brain injury caused by oxygen deprivation and/or restricted blood flow during birth.

1.1 System overview

The Brammi infant thermoregulation system functions as a control unit that continuously monitors and maintains the neonate's core temperature. The fluid is circulated through the specially designed mattress by a motor, with the temperature precisely regulated using thermoelectric devices to ensure safe and optimal therapeutic conditions.

Key features

- Flexible mattress design: A single size for a neonate, allowing warm or cold water to circulate. The design ensures close contact with the neonate's head and body for optimal energy transfer.
- Dual-phase mechanism: The device supports both cooling and warming functions. During each phase, the set temperature is maintained with minimal fluctuation to ensure effective treatment.
- Temperature monitoring: The neonate's core temperature can be monitored via a rectal temperature probe, while skin temperature is monitored through a skin probe.

1.2 Main components

The device is equipped with several specialised components to facilitate its cooling and warming functions:

Cooling and warming generating device: The primary component is a specialised semiconductor (Peltier) which creates and sustains the required temperature.

Long hose: Connects the mattress to the main device, allowing the circulation of fluid.

Water filling bottle: The bottle is used to fill and drain water to and from the device, respectively.Bis

Biocompatible mattress: The flexible mattress is designed to wrap around the neonate for efficient energy transfer.

Temperature probes: Includes separate skin and rectal temperature probes for reliable temperature monitoring.

1.3 Operating modes

The device is equipped with different specialised modes.

Servo controlled mode: Automatically adjusts the mattress temperature to maintain the desired core temperature of the neonate. Provides both cooling and re-warming based on the user settings in a controlled manner.

Mattress mode: Maintains a consistent mattress temperature, regardless of changes in the neonate's core temperature. It can be used as a pre-warm/pre-cool mode to prepare the mattress prior to the therapy.

Cooling mode: Provides servo-controlled cooling to lower the neonate's temperature.

Warming mode: Provides servo-controlled warming to raise the neonate's body temperature.

1.4 Intended use

Brammi is a thermoregulation device intended to provide precise temperature control (cooling and warming) for neonates. Its primary clinical use is to deliver therapeutic hypothermia for the treatment of neonates affected by Hypoxic–Ischemic Encephalopathy (HIE). The device is intended to be used in hospital environment such as Neonatal Intensive Care Units (NICUs) and Pediatric Intensive Care Units (PICUs,) under the supervision of a licensed medical practitioner.

1.5 Safety and monitoring

To ensure the safety and effectiveness of the therapy:

Continuous monitoring: The neonate's skin and core temperatures are continuously measured. These readings are communicated to the device's operating system in real time to ensure precise temperature control.

Minimal fluctuation: The device is designed to maintain the set temperature with minimal fluctuation, ensuring consistent therapy delivery during both cooling and warming phases.

1.6 Typographical conventions

Format Style	Meaning / Usage
Italic	Used to emphasize important terms or refer to definitions
ALL CAPS / Bold	Used for critical warnings, labels, or section headings
Bold Italic	Used for text copied directly from the device screen or display (e.g., Start button text)
Bulleted Lists (•)	Used for general information, safety notes, or grouped conditions

1.7 Quick instructions for use

Preparation

- Connect the long hose to the mattress and the main device.
- Fill the mattress with the required amount of circulating water using the filling bottle, and attach the filled mattress to the device.

Operating the device

- Choose the desired therapy mode based on the clinical requirements.
- Set the target temperature and therapy duration for the cooling or warming phase.
- Place the mattress around the neonate, ensuring close contact with the head and body.
- Monitor the neonate's temperature using skin and rectal temperature probes.

During therapy

- Regularly check the device display to monitor the neonate's temperature and adjust settings as needed.
- Ensure that all connections are secure and that the fluid is circulating properly.

After therapy

- Gradually re-warm the neonate if cooling therapy is used.
- Disconnect the mattress and probes once the therapy is complete.
- Empty the internal tank and mattress.
- Clean all components according to the hospital's infection control protocols.

Check the cleaning section in this manual for a detailed explanation.

1.8 Maintenance and troubleshooting

Regular maintenance of the device is essential to ensure its longevity and functionality. Refer to the device maintenance section for detailed guidelines on routine checks and troubleshooting common issues.

1.9 Contraindications for use

No general contraindications are known. However, the manufacturer advises that the device should not be used when therapeutic hypothermia is clinically contraindicated, or in patients whose medical condition does not allow safe temperature reduction, as determined by the attending clinician.

Specific precautions

- Do not allow the mattress or cooling wrap to come into direct contact with fresh or non-closed wounds, infectious areas, areas with ulceration, abscesses, rashes, or burns. This precaution is to prevent aggravation of the condition and reduce the risk of infection.
- Therapeutic whole body hypothermia is a systemic treatment method. Be careful when choosing the target temperatures during cooling.
- Patients with known hypersensitivity to cooling and warming must only be treated under supervision.

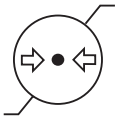
It is recommended to consult a licensed healthcare practitioner before administering therapy to assess the suitability of this device for each individual neonate, especially in the presence of these conditions.

2. Symbols and Definitions

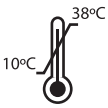
This section identifies the symbols that are displayed on the screen and labels pasted on the device and its accessories.

2.1 Standard symbols

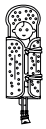
	**Refer to the user manual:** Follow the instructions provided for use
	**Note:** A note clarifies procedures or conditions that may otherwise be misinterpreted or overlooked. A note may also be used to clarify apparently contradictory or confusing situations
	**Warning!** A warning calls attention to hazardous or dangerous situations inherent to the operation, cleaning, and maintenance of the device that may result in injury
	**Caution:** A caution draws attention to a procedure that, if not carried out correctly, can lead to damage to equipment
	Safe disposal of the device at the end of its life
	Details of the manufacturer of the device
	Authorised European representative

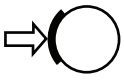
	Pressure limitation
	Type B applied part as per standard IEC 60601-1
	Alternating current
	Fuse
	Protective earth (PE)
	Serial number
	European conformity mark
	Date of manufacturing
	Safe working load

	Fragile
	Humidity limitation
	USB Port
	Nonsterile
	Do not place heavy objects on the device or trolley.

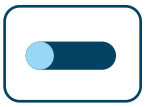
	Keep dry
	Temperature limitation
	Do not reuse
	RS232 port
	Medical device

2.2 Manufacturer defined symbols

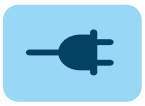
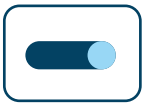
	Mattress port: Connect the mattress to this port using the long hose
	Ensure the neonate is wrapped in the mattress during therapy
	Water filling port: Connect the filling bottle to this port to fill the mattress with water

	Ensure the casters are locked during therapy
	Use only the coolant fluid recommended as circulating fluid
	Inlet fan air filter inserted into air filter tray

2.3 Functional icons

 Servo-controlled temperature mode	 Alarms muted
 constant mattress temperature mode	 Resume therapy
 Screen saver mode OFF	 Date settings
 Cooling phase/mode	 Save and move icon
 Warming phase/mode	 Disabled save and move icon
 Save icon	 Screen touch and unlock icon
 Filling mode	 Screen touch and unlock icon
 Draining mode	 Brightness and contrast settings
 Start Icon	 Date and time settings
 Back to previous screen	 Status screen
 Tap to mute present alarms	 Decrease

 Time settings	 Therapy parameter settings
 Reset to default	 Event log
 Previous page of trends	 Ready to transfer file to USB drive
 Stop therapy icon	 Mothers name
 Data transfer icon	 Time elapsed duration
 Menu	 Water level- 10% filled
 Touch calibration	 Water level empty
 Increase	 User confirmatory Icon
 Next page of trends	Battery level indicator
 Transfer file to USB	 Shutdown icon

 Running in AC power	 Pause therapy
 Brightness	 Contrast
 Water level - 50% filled	 Water level- 100% filled
 Water level sensor - Failed	 Screen saver mode ON

2.4 Abbreviations

Abbreviation	Full form
HIE	*Hypoxic Ischemic Encephalopathy*
kg	*Kilogram*
g	*Gram*
mm	*Millimeter*
cm	*Centimeter*
CSK	*Countersink Type Screws*
SHTD	*Socket Head Type Screws*
LCD	*Liquid Crystal Display*
LED	*Light Emitting Diode*
TFT	*Thin Film Transistor*
NICU	*Neonatal Intensive Care Unit*
PICU	*Pediatric Intensive Care Unit*
SHTD	*Socket Head Type Screws*
BOM	*Bill of Materials*
IEC	*International Electrotechnical commision*
EMI	*Electromagnetic Interface*
EMC	*Electromagnetic Compatibility*
IP	*Ingress Protection*
V	*Volts*
Hz	*Hertz*
dB	*Decibels*
SPL	*Sound Pressure Level*
USB	*Universal Serial Port*
MRI	*Magnetic Resonance Imaging*
TUV	*Technischer Überwachungsverein (technical inspection association)*
RF	*Radio Frequency*
TPU	*Thermoplastic Polyurethane*
LD	*Low Density*
Li-ion	*Lithium-ion*
EN	*European Norm*
CPC	*Circular Plastic Connector*
S. No.	*Serial Number*
mLPM	*Millilitres per Minute*

3. Operating precautions

Users should read and understand this manual's content before operating the equipment.

3.1 Operator safety

- Familiarity with the Instructions for Use should enable the user to manage alarms and situations under single-fault conditions.

When positioning the device adjacent circumstances movements of the position, operators, and other personnel must be taken into consideration at all times.

Use only the recommended mattress fluid. Do not use de-ionised water, as it may cause corrosion and sedimentation of plumbing system components. Do not use tap water, as minerals and deposits can damage system components and may cause infection control issues.

3.2 Device safety

- This device should be used and operated only by trained personnel and under the direction of qualified healthcare professionals who are familiar with the currently known risks and the usage of this equipment.
- The pre-use checks should be performed before the device is first put into use and after every disassembly for cleaning or servicing.
- The use of accessories other than those specified in this user manual is not recommended. For the list of approved accessories, refer to Section 4.4 – Accessories
- Do not place other devices over the top plate of the device trolley.
- Do not place any weight on top of the device.
- Ensure that the castors are locked during use to prevent device and/or mattress movement which could cause injury to the patient.
- No modification of the device is allowed without authorisation from the manufacturer. If the device is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the device.
- The device may not work properly if any part has been damaged or submerged in water.

- The backup battery is intended for short-term use only. It is not intended to be a primary power source.
- The device should not be used if a system failure alarm occurs.
- Servicing should only be carried out by qualified personnel.

3.3 Precaution notes for unit placement

- The device should be positioned at least 15 cm away from any obstructions when in operation, to ensure unhindered airflow between the left, right, and rear sides of the device.
- Do not cover the device during operation.
- Do not place the mattress or long hose on any hot surfaces during operation.
- Do not place the device near intensive heat sources during operation.
- Ensure that sufficient space is left around the device to avoid obstructing the movement of personnel. Ensure that the long hose, power cord, and temperature probes do not creates obstacle.
- Do not place the device directly under any warmers.
- The device should be positioned so that visual alarms are clearly visible, and acoustic alarms are clearly audible.
- Use only the power cord provided by the manufacturer.

3.4 Patient safety

- Ensure that the device is in good working order and condition before patient use.
- Do not use the device to treat neonates weighing more than 5 kg.
- Do not position the device or the mattress in direct sunlight or under other sources of radiant heat.
- Other devices that produce sparks should not be used close to this device.
- Ensure that the device settings are appropriate for the neonatal use. The user manual describes how to respond to the alarms, but it does not describe how to respond to the patient. Clinical supervision of the patient is required.

- Close monitoring of the patient's condition is required whenever an alarm is paused
- Do not leave the patient unattended during treatment. The patient should be frequently monitored.
- Mattress ties should be secured properly to ensure the patient's whole body remains within the mattress area during therapy.

3.5 Electrical precautions

- To avoid the risk of electric shock, the device should be connected to the mains supply with a protective earth (PE).
- Do not operate the device if it has a damaged power cord or casing.
- The device is provided with a detachable power cord. In the event of a damaged power cord, contact the manufacturer for a replacement.
- Do not use the device if the operating electrical power does not fall within the specified range.
- To avoid electric shock, disconnect the electrical supply from the device before cleaning.
- Due to the risk of electric shocks, servicing should be performed only by qualified personnel with an appropriate service manual
- Do not leave the power cord on the ground, as it could pose a hazard.
- Do not expose any electrical components (for example, electrical boards or batteries) to water.
- Ensure the I/O switch is in the Off (O) position before connecting the device to, or disconnecting it from, an external source.
- Ensure that the power source is compatible with the electrical specifications marked on the device.
- The power cord shall be periodically inspected for signs of damage.

3.6 Grounding precautions

- Do not use extension cords or adapters of any type. The use of such items may lead to short circuits. If an extension cord or adapter must be used, a qualified electrician must install it in accordance with the applicable electrical code.
- To ensure that the grounding is reliable, connect the AC power cord only to a properly grounded three-wire hospital-grade or hospital-use outlet (230 V/50 Hz or 110 V/60 Hz). If there is any doubt about the grounding connection, do not operate the equipment.
- Do not connect the device to a faulty electrical grounding system, as the patient probes are not isolated from the protective earth (PE).

3.7 Explosion precautions

- To prevent explosion hazards, do not use the device in the presence of flammable anaesthetics.
- Never expose the battery to direct flame.
- Do not use the device in environments where explosive gases or other flammable anaesthetic agents are present.

3.8 Servicing precautions

- Only competent individuals, trained and authorised by the manufacturer or an appointed representative, should service this device.
- Disconnect power to the device and allow it to cool before servicing or performing any maintenance, to avoid the possibility of burns.
- The device should be subjected to maintenance, servicing, control, and any applicable upgrades in accordance with manufacturer's instructions.
- The device shall only be repaired or modified in accordance with the manufacturer's service manuals or by service technicians authorised by the manufacturer.
- Do not attempt to service or repair the device by yourself under any circumstances. If you do so, the manufacturer will no longer be responsible for the performance and/or safety of the device. Furthermore, no warranty will be valid.

3.9 Transport precautions

The device should be transported only in the condition indicated below:

- No load should be placed on the top of the device when it is being moved.
- Do not use the pillar of the trolley or any parts of the device to move. Use the handle at the front.
- Ensure that all the castor wheel brakes are unlocked before moving, to avoid tipping and potential damage to the device.

3.10 Environmental precautions

- Do not use the device outside the operating environmental conditions specified in the Instructions for Use.
- The device should be appropriately stored to ensure its safety.
- Do not use the device in any toxic environment.
- Unused mattresses should be stored in their original packaging, in a dark and dry environment.

- The device is not suitable for use in a Magnetic Resonance Imaging (MRI) environment.
- Do not keep the device in a dusty environment. Ensure that the air filter is cleaned regularly.

3.11 Ambient conditions for use

To ensure the correct operation during normal use, pay attention to the following conditions:

Protection: The device should be protected from dampness and wetness (e.g., splashed water).

- For full cooling power, the ambient temperature should ideally not exceed 30°C; otherwise, the system may not achieve the lowest possible set temperature of the mattress.
- Relative humidity during treatment should be within a range of 10% - 80% non condensing.
- Ensure that during treatment or operation, no installations are intended to operate next to this device, which produce:
    - Strong electromagnetic radiation.
    - Ultraviolet radiation.
    - Intense infrared radiation.
    - Mechanical shocks, vibrations.
- Do not intensively illuminate the device.

3.12 Cleaning and maintenance

- The device should be cleaned and maintained in accordance with the Instructions for Use.
- Clean the device before starting use on a new patient and weekly whilst in use.
- Disconnect power to the device and allow it to cool before cleaning, to avoid the possibility of burns.
- Use cleaning solution sparingly on a cloth when cleaning the device. Excessive solution may damage internal components.
- After use, empty the unit and clean it using the tank cleaning loop (see the cleaning section).
- Disinfect the hose and place it back into the box or plastic envelope.
- Dispose of single-use probes and mattresses in accordance with local guidance.
- Do not use non-recommended solutions to clean electrical or electronic parts. Do not allow liquid to spill into the control unit.

- Do not autoclave or gas sterilise the temperature probes and mattress.
- Do not immerse the probe in a liquid cleaner.

3.13 Rectal, skin temperature probes & Mattress

- Use only manufacturer-provided temperature probes. The device may not function as expected if other probes are used.
- For detailed instructions on correct probe placement, insertion depth, securing method, and visual guidance, please refer to Section 4.4 – Accessories (rectal and skin temperature probes).
- Check the patient frequently to ensure that the sensor is securely placed.
- The device will not function in servo mode if the rectal temperature probe is not connected to the unit.
- Do not cover the skin temperature sensors to avoid incorrect temperature measurement.
- Avoid placing excessive strain on the probe lead. Always remove the probe by grasping the plug on the panel. Do not pull on the probe lead.

3.14 EMI & EMC precautions

- The use of mobile phones or other radio frequency (RF) emitting devices, which exceed electromagnetic interference levels specified in "Guidance and manufacturer's declaration – electromagnetic immunity", near this device may cause unexpected or adverse operation. Monitor the function of the device when RF emitters, including RFID readers and interrogators, are in the vicinity
- Do not use any portable and mobile RF telecommunication device (such as mobile phones) within the minimum distance specified in IEC 60601-1-2. These devices may affect the performance of the device.
- Infant thermoregulation system is intended for use in the electromagnetic environment specified below.

Emissions test	Compliance Level	Electromagnetic Environment - Requirements
Conducted emissions CISPR 11, Class A	*Quasi Peak 0.15MHz - 0.50MHz: 79 dBµV 0.50MHz - 30 MHz: 73 dBµV Average 0.15MHz - 0.50MHz: 66 dBµV 0.50MHz - 30 MHz: 60 dBµV*	*The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.*
Radiated Emissions/ CISPR 11, Class A	*Quasi Peak 30-230 MHz : 40 dBµV/m 230-1000 MHz : 47 dBµV/m*	*The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.*
Harmonic emissions/ IEC 61000-3-2	*Class A*	*Brammi is suitable for use in professional healthcare settings.*
Flicker emission/ IEC 61000-3-3	*Short Term Flicker Pst <1, Highest dt(%) < 3.3% Time(ms) > dt <500 ms, Highest dc (%) < 3.3% Highest dmax (%) < 4%*	

Immunity test	Compliance Level	Electromagnetic Environment - Requirements
Electrostatic Discharge (ESD) IEC 61000-4-2	*Contact discharge ±8 kV Air discharge ±15 kV*	*Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.*
Radiated RF IEC 61000-4-3	*80 MHz to 2.7 GHz, 3 V/m, 1 KHz, 80%AM*	*Portable and mobile RF communications equipment should not be used close to any part of the device.*
Electrical fast Transient/burst IEC 61000-4-4	*±2 kV, 100 KHz repetition frequency*	*Mains power quality should be that of a typical commercial or hospital environment.*
Surges IEC 61000-4-5	*Upto ±1 kV, for differential mode, Upto ±2 kV, for Common mode*	*Mains power quality should be that of a typical commercial or hospital environment.*
Conducted RF IEC 61000-4-6	*3 V/m, 0.15 MHz – 80 MHz 6 V/m in ISM bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz*	*Portable and mobile RF communications equipment should not be used close to any part of the device.*
Voltage dips, short Interruptions IEC 61000-4-11	*0% short interruption for 250cycles, 70% dips for 25 cycles, 0% of AC mains voltage for 0.5 cycles & 1 cycles.*	*Mains power quality should be that of a typical commercial or hospital environment.*

4. Product Description

4.1 Part identifications

Front view/side view

1. Touch display
2. Push ON button
3. Skin probe jack
4. Rectal probe jack
5. Mattress port
6. Water filling port
7. Air vent
8. Alarm LED indicator

Rear view

1. USB port
2. RS232 port
3. Power cord socket with fuse
4. AC ON/OFF switch

4.2 Product overview

Modules and main components

1. Handle
2. Long hose
3. Basket
4. Trolley Pillar
5. Trolley Base
6. 3” Castor wheel

4.3 Functional description

Head unit :

Figure 4.3.A: Head unit front view

Figure 4.3.B: Location of air filter
Click here to release the tray from the slot

Figure 4.3.C: Removal of air filter tray

After cleaning the tray, insert it into the guide and press firmly to attach it to the unit.

A. Long hose

- Inspect before use for any damage or blockage.
- Only use an approved extension hose if required.
- Avoid overbending or twisting the hose.

Part Number : 1C000203

Indication : To establish coolant flow between the device and the water mattress.

Figure A : Long Hose

Product description :

- Made from white polyurethane tubing with a thermal shielding envelope of blue silicone foam.
- Equipped with self-sealing male quick-disconnect couplings on both ends.
- One end of the hose connects to the device mattress port (female connector); the other end connects to the mattress inlet port (female connector).
- All connectors are self-sealing for quick connection and disconnection.
- Standard hose length: 2 metre.

Instructions for use:

- Connect one end to the device mattress port (front panel)
- Connect the other end to the mattress inlet port.
- Ensure all connection are secure and leak free.

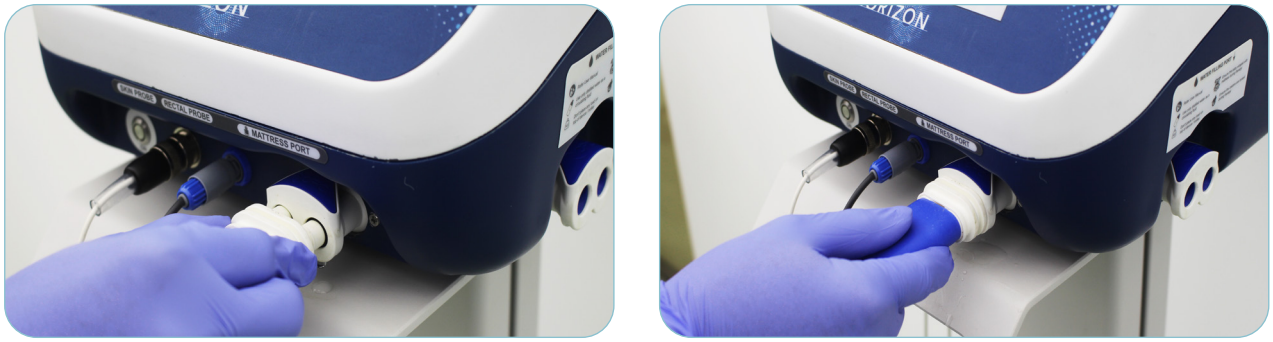


Figure A.1: Long hose connection with head unit

B. Filling/draining bottle

- Ensure tight connection during filling or draining.
- Monitor to prevent air bubbles.

Part Number : 1C000202

Indication: For initial filling, refilling, or draining coolant from the system.

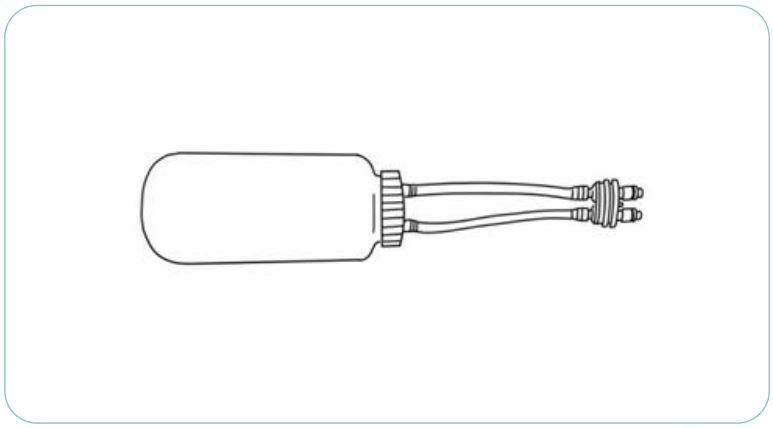


Figure. B: Filling/Draining bottle

Product description:

- Constructed from low-density polyethylene with 1000 ml capacity.
- Equipped with male quick-disconnect couplings.

Instructions for use:

- For device filling: connect to the device's filling port.
- For mattress filling: connect directly to the mattress inlet, elevate, press gently, release slowly.

C. Mattress ties

- Ensure that the ties are not applied too tightly, as this may compromise circulation or breathing. arly check tie security.

Part Number: 1C000207

Indication:

- To secure the neonate safely within the mattress during therapy.

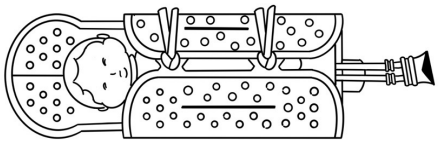


Figure.C: Mattress ties

Product description:

- Designed for use with the water mattress.

Instructions for use:

- Wrap ties around the mattress flaps and secure around the patient as per instructions.

D. Tank cleaning loop

Part Number: 1C000201

Indication:

- Used during device cleaning to circulate disinfectant in the internal reservoir.

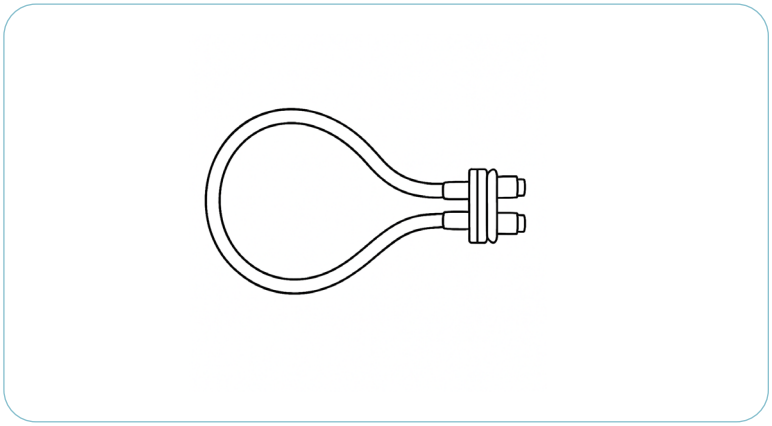


Figure. D: Loop

Instructions for use:

- Connect to the device mattress port to create a closed cleaning loop.
- Follow detailed cleaning protocol as per manual.

Figure D.1: Filling/Draining bottle connection with head unit

E. Extension hose

- Inspect before use for any damage or blockage.

Part Number: 1C000204

Indication:

To extend the hose length when the mattress is positioned beyond 3.5 metres from the device.

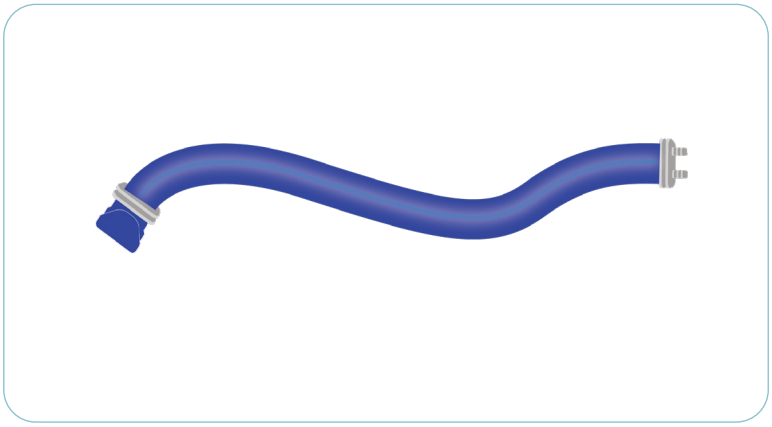


Figure. E: Extension Hose

Product description:

- Similar construction to long hose, with a female quick-disconnect coupling at one end.

Instructions for use:

- Connect the long hose and the mattress inlet.

F. Bridge coupler

Part Number: 1C000205

Indication:

- To connect the long hose or extension hose with the filling/draining bottle for complete coolant drainage.

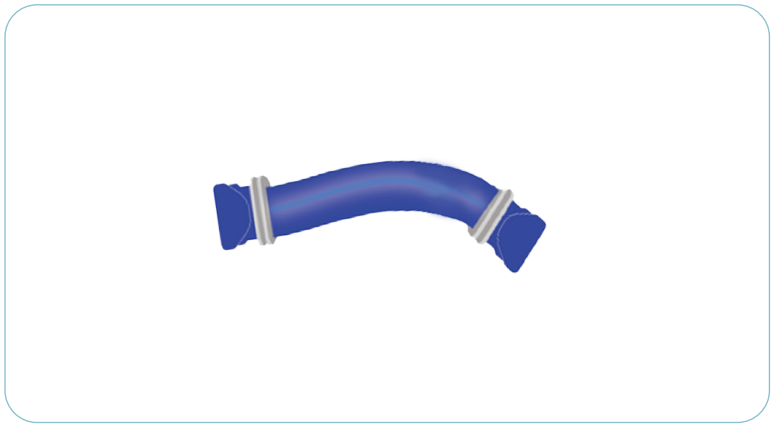


Figure. F: Bridge Coupler

Product description:

- Quick-connect coupling accessory.

Instructions for use:

- Attach between the hose and the bottle when draining the system.

4.4 Accessories

- Inspect accessories before each use for integrity and cleanliness.
- Only use original accessories supplied or recommended by the manufacturer.
- Follow maintenance and cleaning instructions precisely.
- Improper accessory use may compromise device performance and patient safety.
- Do not use damaged probes, as this may result in inaccurate readings or device malfunction.

The following accessories are supplied with the device. Always verify part numbers when ordering replacements.

A. Rectal temperature probe

- See Section 3.13 for probe compatibility and warnings.
- Do not operate the device in a servo-controlled mode without the rectal temperature probe correctly placed.
- Frequently check the probe's placement and connection during therapy.
- Avoid strain on the probe lead; always handle by the connector.
- Ensure the neonate is fully wrapped in the mattress during therapy.
- Regularly check for hose kinking, which may restrict water flow.
- Continuously monitor the neonate's core temperature during therapy.
- It is recommended to replace the rectal probe every 24 hours during therapy.

Part Number: 1C000206

Indication:

- For continuous core body temperature monitoring during therapy.
- Mandatory for servo-controlled modes.

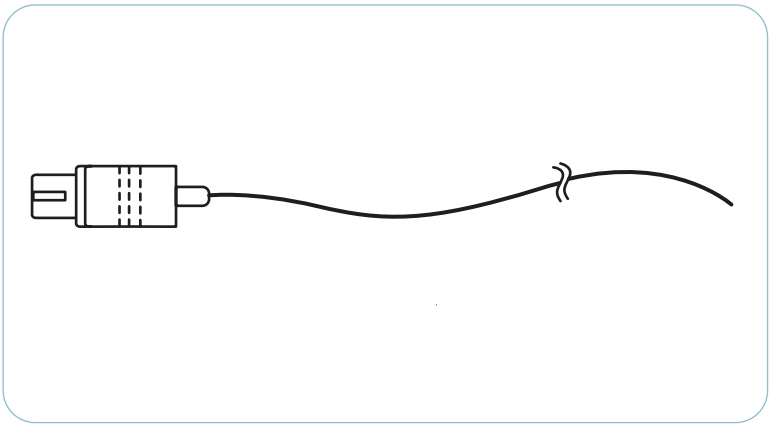


Figure. A: Rectal temperature probe

Product description:

- The rectal temperature probe includes a reusable adaptor with a single-use rectal probe.

Instructions for use:

1. Connecting the rectal temperature probe:

- Connect the circular two-pin (yellow colour) end of the adaptor to the dedicated socket on the front panel.
- Ensure correct alignment by matching the connector groove with the socket.
- Connect the other end of the adaptor to the rectal probe.
- Confirm that all connections are securely fitted.

Figure .A.1: Match with the groove

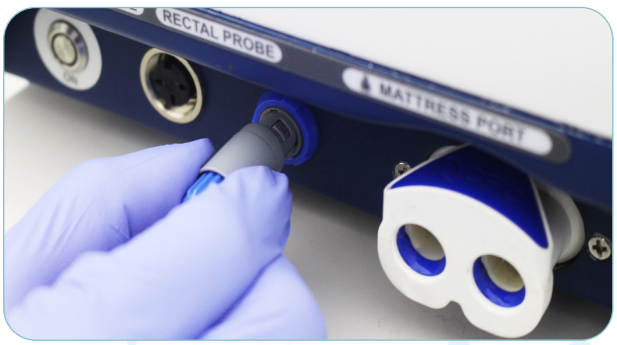


Figure A.2: Connecting rectal temperature probe

2. Insertion and securing of the probe:

- Gently insert the probe 3–6 cm into the neonate's rectum, following hospital guidelines.
- Secure the probe approximately 10 cm from the insertion point, typically to the upper thigh, using medical tape to prevent displacement.
- Ensure correct placement — the probe must maintain proper contact with tissue (no gaps).

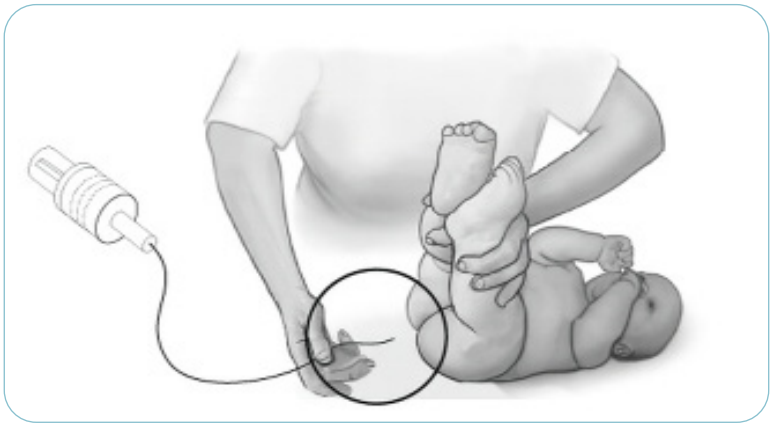


Figure. A.3: Inserting rectal temperature probe into neonate's rectum

B. Skin temperature probe

- Refer to Section 3.13 for critical compatibility guidance.
- Secure properly to prevent displacement during therapy.

Part Numbers: 1C000005 (Single Use) / 1C000004 (Reuse)

Indication: To monitor skin temperature of the neonate for effective temperature management.

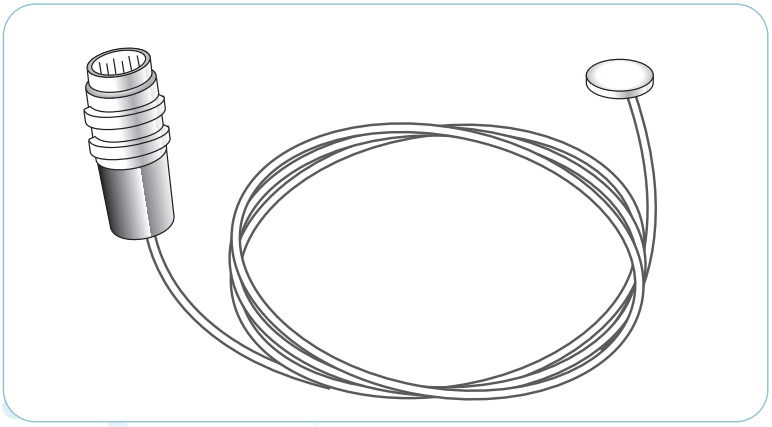


Figure. B: Skin temperature probe

Product description:

- Used for monitoring skin temperature.
- Two skin probe options are available based on user requirements: reusable (1C000004) and single-use (1C000005).

Instructions for use:

1. Connecting the skin temperature probe:

- Connect the probe to the designated skin temperature probe socket on the device front panel.
- Ensure correct alignment by matching the groove on the connector with the socket.
- Always hold the connector when plugging or unplugging — do not pull the cable.

Figure B.1: Connecting skin probe

2. Placement of the skin temperature probe:

- Place the probe over the neonate's abdomen or at a clinically recommended site.
- Secure using the provided reflective adhesive tape to ensure it stays in position throughout therapy.

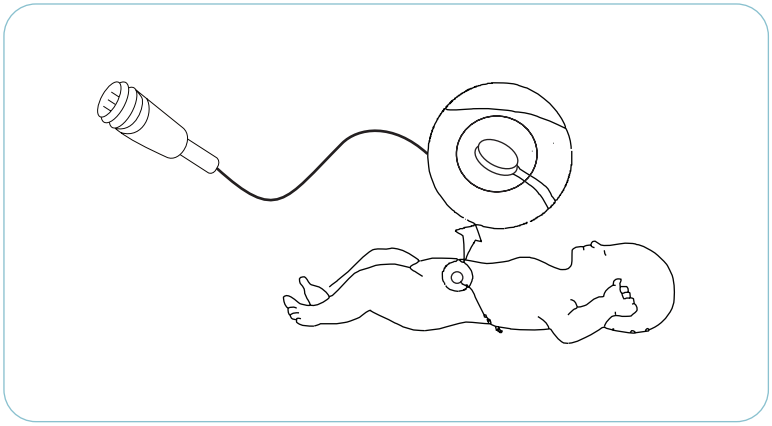


Figure. B.2: Placing skin probe over neonate's skin

Cleaning procedure - 1C000004

- Use an alcohol-based solution comprising ethanol, 2-propanol, and 1-propanol, as recommended by the manufacturer.
- Moisten a soft, clean, lint-free cloth with the recommended solution.
- Gently wipe the entire surface of the probe for a minimum of 1 minute.
- Do not apply the solution directly to the probe
- After cleaning and disinfection, allow the probe to dry completely.

- Do not exceed the maximum number of permitted uses (150 cycles) for reusable probes.
- Do not use the probe if it is damaged, contaminated, or not completely dry, as this may lead to malfunction, inaccurate readings, or electrical hazards.
- Do not immerse the probe in any liquid at any time.
- Use only manufacturer-recommended disinfectant solutions or equivalent solutions; do not use harsh or non-recommended chemicals.

C. Mattress

- Refer to Section 3.4 – Patient Safety for guidance on safe mattress use in neonates with wounds or skin issues.
- Refer to Section 3.4 – Patient Safety for tie securing precautions to ensure safe positioning.

Part Number : 1C000093

Indication: To provide controlled body cooling or warming of neonates during therapy.

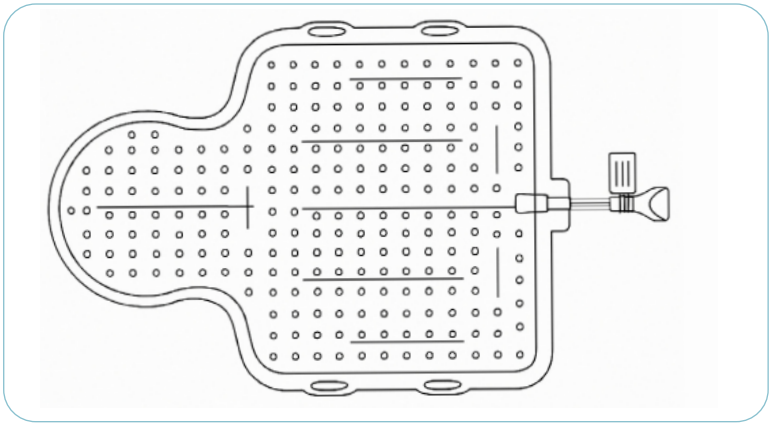


Figure. C: Mattress

Product description:

- Single-use water mattress with a pressure limit of <0.35 bar.
- Circulating capacity: ~600 ml coolant.
- Includes mattress ties for securing mattress.

Instructions for use:

- Connect to the device using the long hose.
- Place neonate directly on mattress
- Use ties to secure mattress.

5. Unpacking and Installation

5.1 Packing, unpacking, and installation

The device and its accessories are supplied in corrugated boxes. The main unit and mattress are provided in separate boxes. The trolley is supplied as an optional accessory upon customer request. Carefully open all boxes and remove the contents. The device is provided in a partially disassembled state and requires assembly prior to use.

Two people are required to load or unload the device and unpack it.

Packing list:

Check the availability of main components and accessories of device against the packaging list inside the main device packaging.

Mattress box packaging

S.No	Description	Quantity (nos.)
1	Water Mattress	3
2	Mattress knots	6

Trolley box packaging - Accessories

S.No	Description	Quantity (nos.)
1	Base with 3" Castor	1
2	120X80X900mm Extrusion pillar	1
3	Trolley Top plate	1
4	Basket	1
5	M4x35mm Butterlfy screws	2
6	M10x40mm Socket Head Allen Screws	4

S.No	Description	Quantity (nos.)
7	M10x40mm CSK Allen screws	4
8	M10 spring washers for Pillar top	4
9	M10 flat washers for pillar bottom	4
10	M6 Allen Key	1
11	M8 Allen key	1
12	M4 Plane washers for butterfly screws	2

Main device and its accessories packaging

Head Unit box

S.No	Description	Quantity (nos.)
1	Brammi unit	1
2	Skin Probe with Serial number tag and its box with Hologram sticker	1
3	Rectal Probe with Serial number tag and its box with Hologram sticker	3
4	Power Cord	1
5	Filling Bottle with NRV valve	1
6	Tank Cleaning Loop	1
7	Long Hose - 2 meters	1
8	Air filter tray	1+2
9	Extension hose - 2 meters (Optional)	1
10	Bridge coupler	1
11	Instructions for Use	1
12	RTP- Adaptor	1

Unpacking the device

Tools required for unpacking device package

The following tools are required for unpacking:

- Knife
- Scissors

Inspect the packaging for any damage.

- Provided there is no damage, remove the contents from the boxes carefully. Save the box and packing materials.
- If the packaging boxes are damaged, carefully continue to remove the contents from the boxes. Note any dents or scratches on the device. Save the damaged shipping packaging and packing material for the carrier's inspection.

Do a visual inspection:

- Make sure the Brammi unit, trolley, and accessories are intact. If there is any physical damage, such as bent or broken parts, dents, or scratches, call device supplier immediately
- Check the standard accessories against the packaging list. If any accessories are missing, contact the device supplier

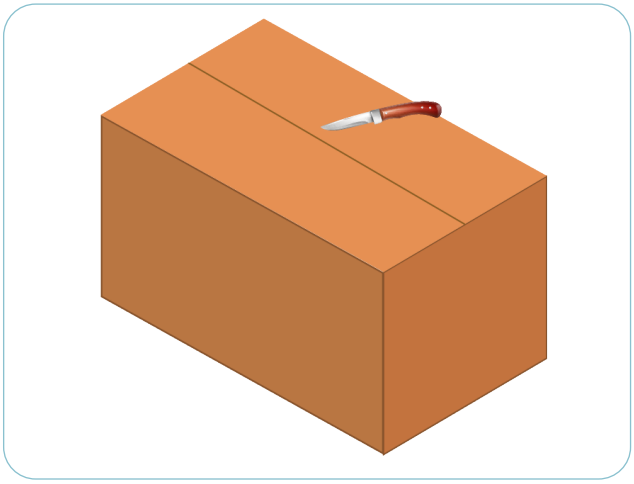
Steps to unpack the Mattress packaging:

- **Step 1 :** First, take the mattress box (pack of 3) and open it using a knife carefully.
- **Step 2 :** Unpack it and remove the individual mattress covers using scissors.

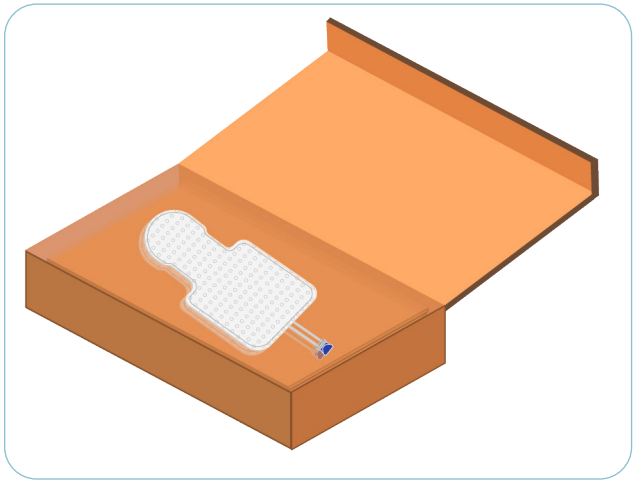
Steps to unpack the Trolley packaging: (Accessories)

- **Step 1 :** Remove the basket.
- **Step 2 :** Remove the base with castors carefully and remove the cover using a knife carefully.
- **Step 3 :**Take out the top plate and remove the tapes using a knife carefully.
- **Step 4 :** Take out the pillar and remove the cover using a knife carefully.

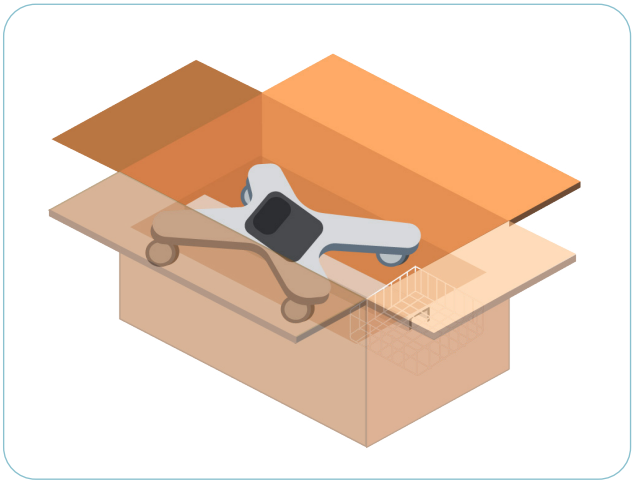
Step 1 :



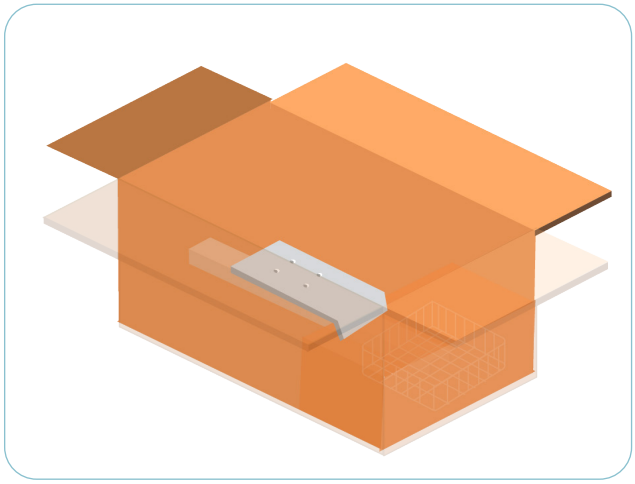
Step 2 :



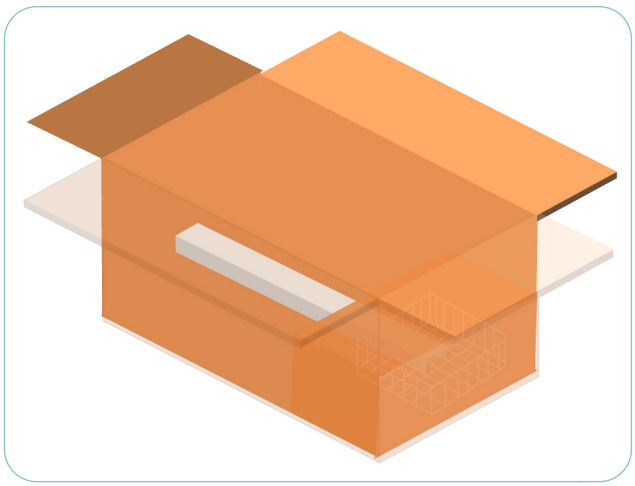
Step 3 :



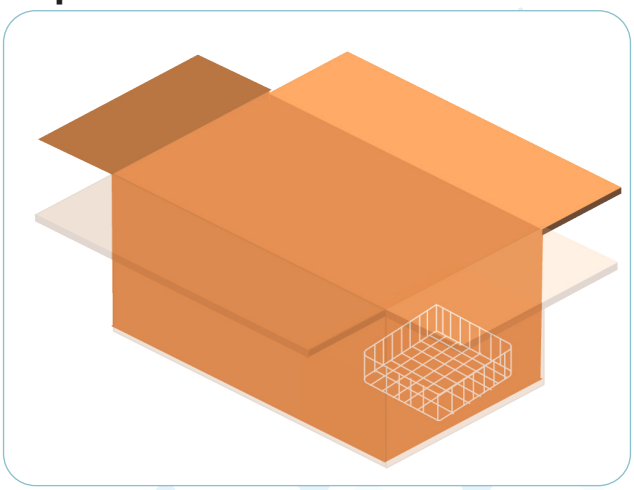
Step 4 :



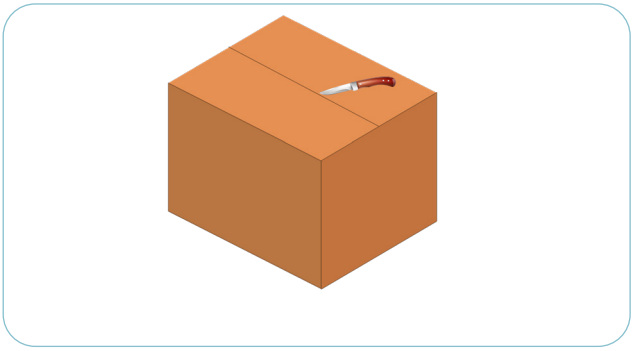
Step 5 :

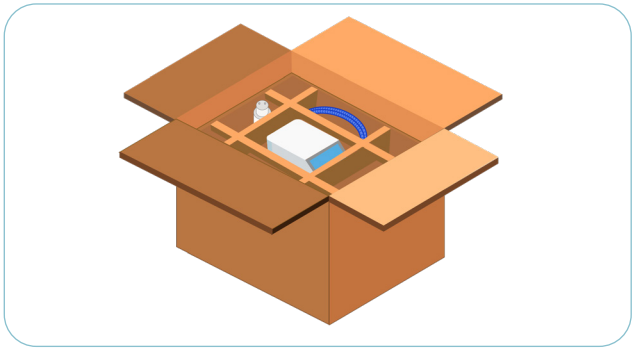


Step 6 :



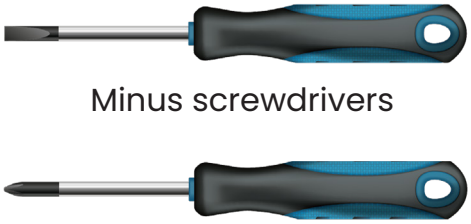
Unpack the Head unit packaging:





Tools required for installation

The following tools are required for installing the device:



When using the device for the first time, follow the instructions below

Read Section 3: Safety Information before setting up and using the device.

Do not use the device or components that appear to be damaged and contact the device supplier if the cause of the damage cannot be determined.

- Check that all main components and ordered accessories have been delivered (refer to the packing note or the invoice, if available).
- Ensure that the device is in good condition.
- If stored for more than 1 month, connect the device to the AC power supply and switch ON the ON/OFF switch to recharge the internal battery.
- Refer to Section 4.3: Air Filter Tray Removal for instructions on cleaning and reinserting the air filter.
- Assemble the trolley by screwing the pillar with the base using M10x40mm CSK. Allen screws (4 nos)

- Assemble the top plate with the pillar matching the wider part of the base from the pillar with the handle part of the top plate. Screws used: M10x40 mm socket head allen screws, 4 nos
- Attach the basket to the pillar using M5x10mm CSK star screws (4 nos).
- Finally, place the device on the trolley facing the handle and match the nylon bushes on the four slots given on the trolley top plate.
- Screw from the bottom using M4x35 mm butterfly screws (2 nos) with m4 plate washer(2nos) to stabilise the head unit on the trolley

Assembly sequence

The device must be assembled in the following sequence.

Base assembly

1. Take the assembled base with 4 wheels.
2. Place the pillar in the vertical position.

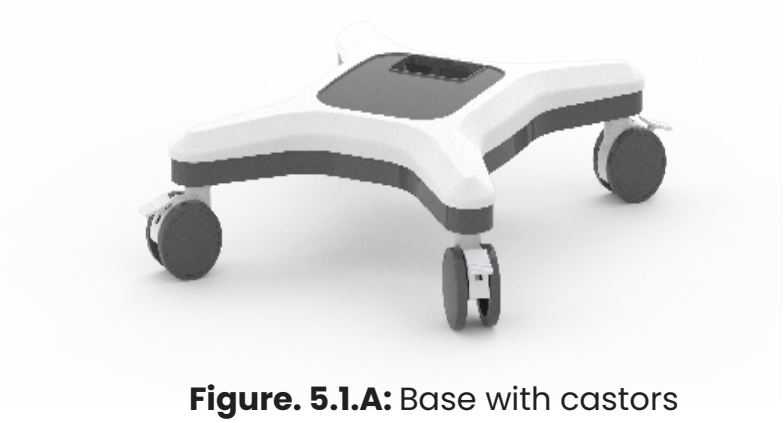


Figure. 5.1.A: Base with castors

3. Place the pillar in the base.
4. Use M10x40 CSK Allen screws with M8 Allen key to fix the pillar and base.

Figure. 5.1.B: Base with pillar attached using 4 allen screws

- Do not step on the device.
- Do not push the device with castor wheels locked.
- Do not push the device on an incline with castor wheels locked.
- Safe working load: 5 kg

Basket assembly with pillar

1. The basket is supplied with M5X10 mm CSK star screws pre-installed. Loosen the screws and attach the basket to the pillar's rail by guilding the basket clamps on both sides of the rail.
2. Adjust the basket to the required height and tighten the screw to secure it in position.

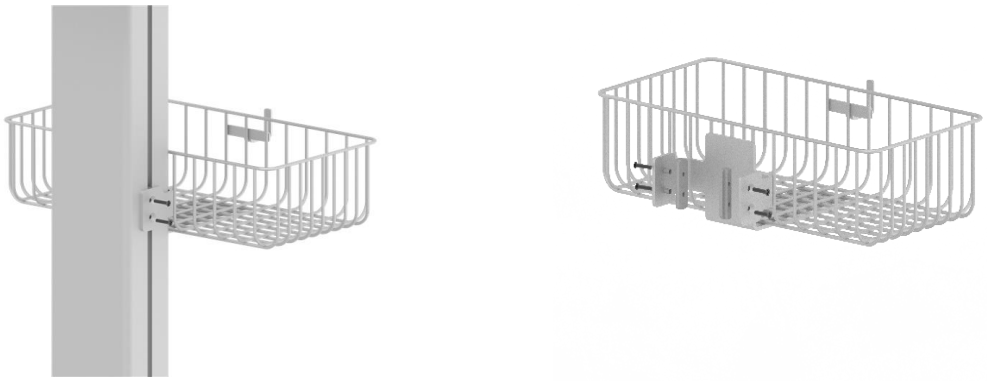


Figure. 5.1.C: Basket assembly

Top plate assembly with pillar

1. Assemble the top plate on top of the pillar using M10x40 mm socket head allen screw & spring washers (4 nos) such that the handle faces the wider part of the base from the pillar.

Figure. 5.1.D: Top plate with handle

Head unit

1. Place the head unit over the top plate in a way that the bushes at the bottom of the device fit into the slots in the top plate.
2. Secure the head unit to the top plate using two M4x35 mm butterfly screws with M4 plate washer from the bottom and hand-tighten only.

Figure. 5.1.E: Bushes matching with slots of top plate

Figure.5.1.F: Trolley with device attached

Place the device

- Place the device trolley on an even, solid surface facing the patient.
- Lock the brakes on the casters.

Read section 3.10: Ensure environmental conditions are suitable before using the device

Pre-operation check-up

Before using the device, ensure all installation, safety, and accessory checks have been completed as outlined in:

- Section 3.2: Device Safety
- Section 3.4: Patient Safety
- Section 4.4: Accessories

Settings and verification of installation:

- Remove the scratch film from the display.
- Switch ON the unit.
- Go to the Status menu and set the date and time.
- Perform a touch calibration.
- Adjust the contrast and brightness of the display according to the ambient lighting.
- Connect the temperature probes and check whether the corresponding numeric is displayed.
- Run the unit in constant mattress temperature mode with a set temperature of 39^{O} C for 10 minutes. Check whether the temperature reaches the set value.
- Connect the USB drive used for patient data transfer and check that the patient data is recorded.

6. Technical specifications

6.1 Mode specification

S.No	Mode	Setting Parameter	Range	
			Min	Max
1	Servo-controlled (cooling and rewarming) mode	Target core temperature	32°C	35°C
		Cooling phase duration	1 hour	100 hours
		Final core temperature	36°C	39°C
		Warming phase duration	Changes dynamically based on temperature	24 hours
2	Mattress-controlled mode (non-servo)	Mattress Temperature	12°C	39°C
		Time Duration	1 hour	100 hours
3	Cooling mode	Target core temperature	32°C	35°C
		Cooling phase duration	1 hour	100 hours
4	Warming Mode	Target core temperature	36°C	39°C
		Warming phase duration	Changes dynamically based on temperature	24 hours

- The temperature increment/decrement is 0.1°C in all modes
- The duration increment/decrement is 1 hour in all modes
- The rate per hour changes dynamically based on the total duration and initial and final temperature set in servo-heating phase and in warming mode
- The temperature override is at 37°C in all modes

6.2 Physical specification

S.No	Parameter	Specification
1	Overall dimensions of head unit	*Length x Width x Height* *400 mm x 310 mm x 220 mm*
2	Head unit weight (without accessories and internal tank empty)	*10.0 Kg*
3	Overall weight of the device along with accessories and trolley	*26.0 Kg*
4	Safe working load of the device	*16 Kg*
5	Footprint of trolley with castors	*Length x Width x Depth: 725 mm x 630 mm x 180 mm*
6	Weight of trolley without head unit	*11.5 Kg*
7	Trolley height without head unit	*910 mm*
8	Total trolley height with head unit	*1135 mm*
9	Castors	*3" castors*
10	Trolley handle thickness	*5 mm*
11	Pillar dimension	*Length x Width x Height:* *= 120 mm x 80 mm x 900 mm*
12	Base dimension	*60 mm thickness*
13	Ground clearance	*120 mm in height (lowest point of trolley to floor)*
14	Weight of all accessories with its packaging	*4.0 Kg*
15	Air filter	*Length x Width: 97.5 mm x 91 mm*
16	Display dimension	*7-inch TFT, active area (154 W x 92 H mm)*

6.3 Environmental specification

S.No	Environmental features	Operation	Transport/Storage
1	Ambient Temperature	*18°C to 30°C*	*-10°C to 60°C*
2	Relative Humidity	*10% to 80% (non-condensing)*	*10% to 90% (non-condensing)*
3	Atmospheric Pressure	*700-1060 hPa*	*500-1060 hPa*

6.4 Rectal & skin temperature probe specification

S.No	Parameter	Specification
1	*Temperature Range*	*6°C to 50°C*
2	Accuracy	*±0.2°C*
3	Sensor type	*5k NTC thermistor*
4	Probe length - skin temperatureprobe	*1.5 Meters*
5	Probe length - rectal temperature probe	*2.5 Meters*
6	Probe OD - rectal temperature probe	*2 ±0.3 mm*

6.5 Hydraulic circulation system

S.No	Parameter	Specification
1	Coolant fluid	*Sterile water*
2	Fluid flow rate in operation	*300 to 600 mLPM*
3	Circulation system pressure	*0.5-1 bar*
4	Internal water reservoir + hydraulic circuit capacity	*300 ml*
5	Connectors/ Coupling	*Quick disconnect couplings (CPC)*
6	Long connecting hose	*2 meters in length*
7	Filling bottle capacity	*1 Litre*
8	Tank cleaning loop	*500 mm with male CPC connector*
9	Long hose / Loop / Mattress tubing	*TPU tubes with ID 5mm, OD 8 mm*

6.6 Mattress specification

S.No	Parameter	Specification
1	Mattress material	*Thermoplastic polyurethane (TPU)*
2	Overall Dimension of mattress	*Length x Width: 720 mm x 445 mm*
3	Water Mattress Capacity	*600 ml circulating volume*
4	Dry Weight	*190 grams*
5	Filled weight	*790 grams*
6	Maximum safe weight on mattress	*5 kg*

6.7 Electrical specification

S.No	Electrical supply	Specification
1	Working Voltage	*100 - 240V AC*
2	Frequency	*50/60 Hz, Single phase*
3	Maximum Power Consumption	*80 W*
4	Fuse rating	*Voltage - 250 V AC Current T6.3AL Size - 5*20 mm* *Operating Speed - Slow Blow* *Breaking Capacity (AC) - 35A or 10In* *(Rated current) whichever is greater*
5	Accessories	*Type B applied parts (water mattress, rectal probe, and skin probe)*
6	Battery Backup Time	*1 hour from 100% charge*
7	Battery	*10.8 V DC, 9000mAh, Li- ion Battery pack*
8	Battery Charging Time	*Approximately 8 hours (from <10% to >90%)*
9	Working voltage of Secondary Circuits	*14.2 VDC Peak in SMPS mode* *10.8 VDC in Battery mode*

6.8 Electrical classification

S.No	Feature	Classification
1	Type of protection against electric shock	*Class 1 - Applied part-Type B*
2	Mode of Operation	*Continuous*

6.9 Technical specification

S.No	Parameter	Specification
1	IP Rating	*IP X0*
2	Unit noise level	*<60 dB*
3	Alarm sound pressure level	*Red alarm: 65 to 75 dB yellow alarm: 60 to 70 dB Short yellow alarm: 60 to 70 dB Information: 60 to 70 dB*
4	Temperature Unit	*°C default*
5	Efficiency in Servo mode	*39°C to 33.5°C within 50 mins (Rectal temp) at 28°C - 30°C ambient*
6	Screen Saver Time	*4 to 5 minutes default*
7	Alarm mute timeout period	*10 minutes default*
8	Data logging	*Up to 10 babies (108 hours (about 9 days) data per session thereafter FIFO)*
9	Event log	*Up to 63 pages of events, 8 events per page (total 504 counts of events), thereafter FIFO*

7. Functional Overview

7.1 Device operation

Step 1: Connecting the device to the AC power source

Read section 3.5, Electrical Safety, carefully to make sure all conditions are fulfilled and considered.

- Plug the provided power cord into the power inlet AC socket of the device
- Connect the power cord to the AC power source with protective earth (PE).

Figure. 7.1.A: Connecting power cord into power inlet

Figure. 7.1.B: Power cord connected

Step 2: Pre-checks

Prior to putting the device into operation, check the conditions below to ensure safe and proper operation:

- For reliable and safe operation, use only original components, accessories, and spare parts supplied or recommended by the manufacturer.
- The rectal temperature probe must be plugged in to the port if servo-controlled cooling and warming modes are required
- Check that only the recommended coolant fluid is used as a circulating fluid.
- Check that the temperature probe connectors match their respective sockets— rectal and skin temperature probes on the device's front panel.

Step 3: Switching device ON

- Switch ON the AC supply by pressing the AC ON/OFF switch located as shown in figure 7.1.c
- Press the push button in the front panel to switch ON the device as shown in figure 7.1.d

Figure. 7.1.C: ON/OFF switch

Figure. 7.1.D: Push ON button

7.2 Startup screen

When the device is switched ON, the initial startup (the Horizon logo) screen appears as shown below. Figures 7.1.A and 7.1.B show the device software version of the user interface/control board & the self-test status (Pass/Fail) of the internal components displayed sequentially for a few seconds.

Figure 7.2.A: Start-up screen displaying pass status

Figure 7.2.B: Start-up screen displaying fail status

Self Test Conditions Displayed

The self-test checks for,

1. PELTIER PASS
2. BATTERY PASS
3. MOTOR PASS
4. FAN PASS
5. POWER SUPPLY PASS
6. LEVEL SENSOR PASS
7. SKIN TEMPERATURE PROBE PASS
8. WATER FLOW PASS
9. RECTAL TEMPERATUREPROBE PASS
10. MAT PROBE PASS
11. EEPROM CHECK PASS
12 .FLASH CHECK PASS

Self-test failure:

If any critical components for the correct functioning of the device have failed, the device will enter the system failure screen indicating the list of failure(s) and contact details for troubleshooting the issues.

7.3 System failure screen

The system may encounter two types of failure conditions:

System Failure 1

This occurs when the self-test fails during startup.

System Failure 2

This occurs when a failure is detected during therapy.

The system will begin to give high-priority alarms prior to the screen given below.

Immediate attention is required

Press the power-off icon and confirm to shut down the device.

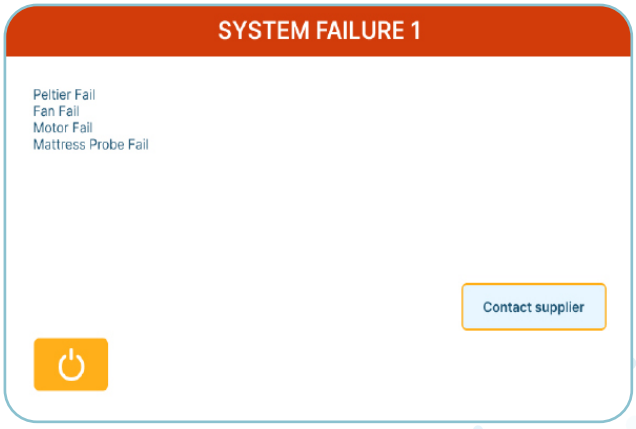


Figure 7.3.A: System failure screen

7.4 Patient ID screen

- A screen with a keypad and a disabled ***"Save and Move"*** icon appears
- This screen can be skipped. If the user chooses to skip the screen, then a temporary patient ID will be assigned automatically by the system (e.g.: PatientNo 1, PatientNo 2). This number will be incremented for every new session
- If the user chooses to enter the actual Patient ID, then press "**Save and Move**" icon will be enabled.

- Press the "**Save and Move**" icon to save patient ID, then screen will then proceed to filling instruction screen
- If the user attempt to press "**Save and Move**" icon without entering patient ID, an error message will be displayed, as shown in the figure.

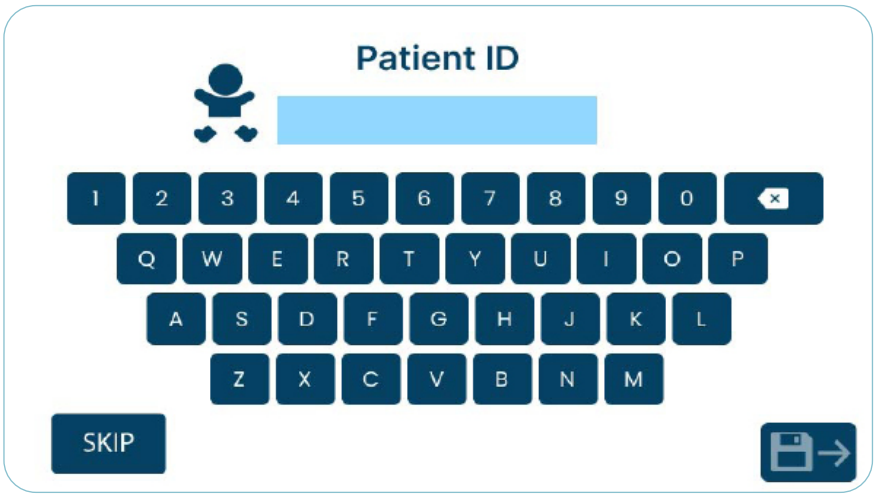


Figure 7.4.A: Virtual keypad screen (initial view)

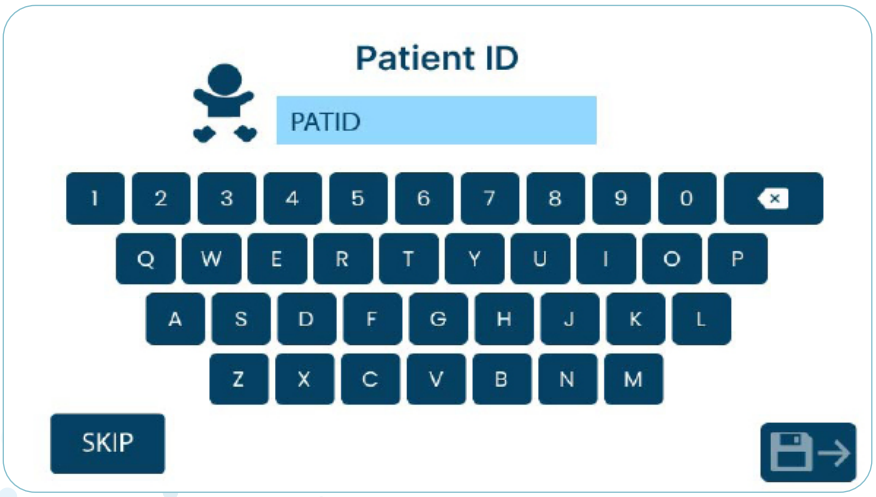


Figure 7.4.B: Virtual keypad screen with "***Patient ID***" entered

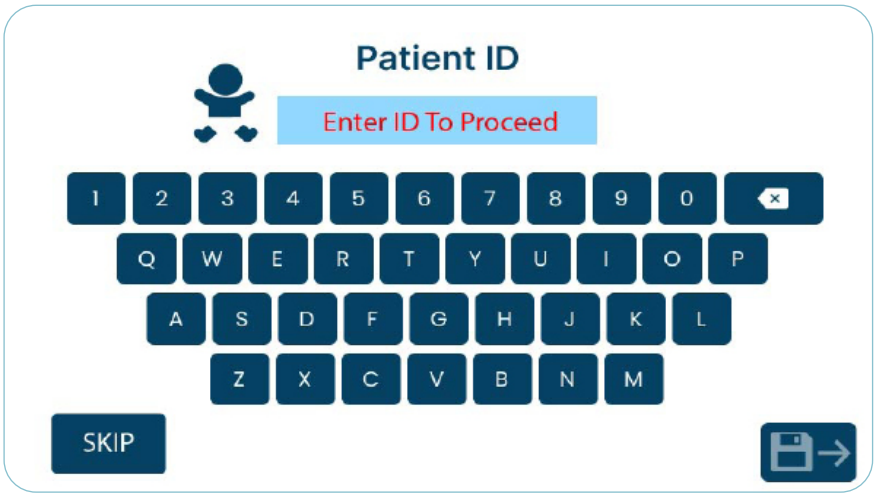


Figure 7.4.C: Virtual keypad screen showing error when "***Patient ID***" is not entered

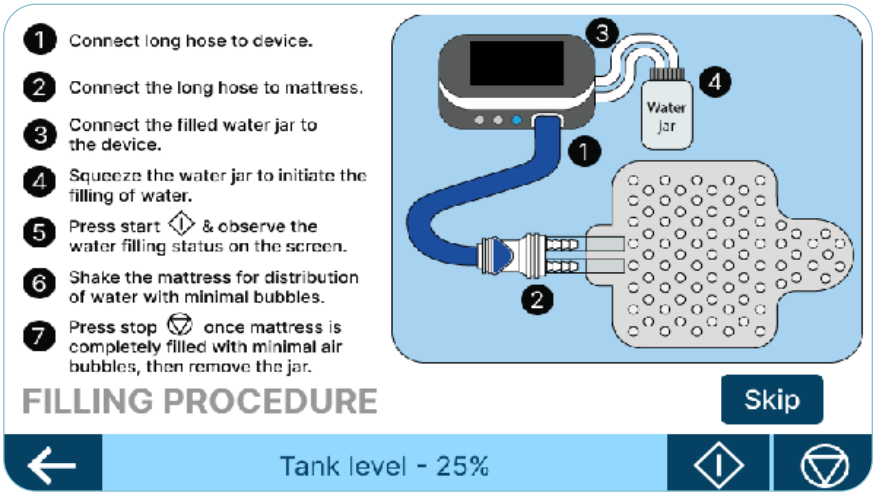


Figure 7.4.D: Skippable filling instructions screen

7.5 Filling mode:

To fill the internal tank and the mattress, press the ***"Filling*** Mode" icon and follow the instructions displayed on the screen (Figure. 7.5.A)

Figure 7.5.A: Selecting ***Filling*** mode

Instruction for filling

- Follow the on-screen instructions as shown in Figure 7.5.B until the device shows "***Tank level – 100%"***.
- The "***Motor Fail"*** error is shown in Figure 7.5.C and indicates a pump failure.

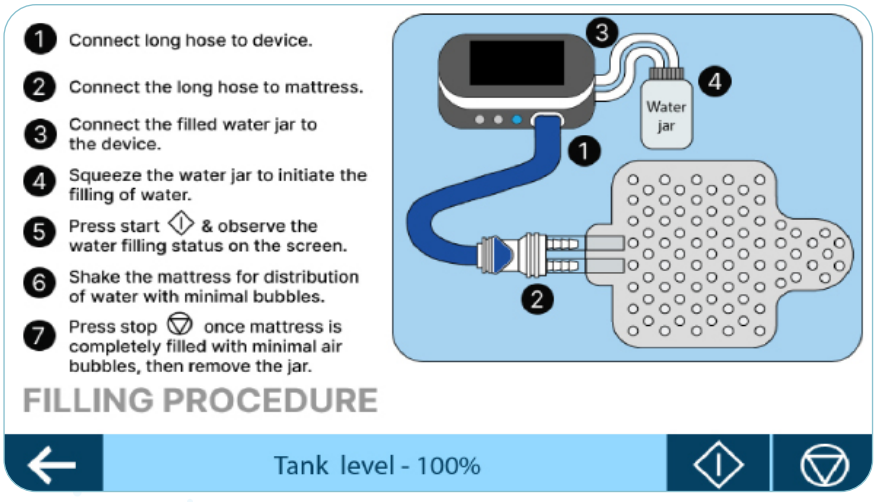


Figure 7.5.B: Filling instructions on screen with live tank level indication

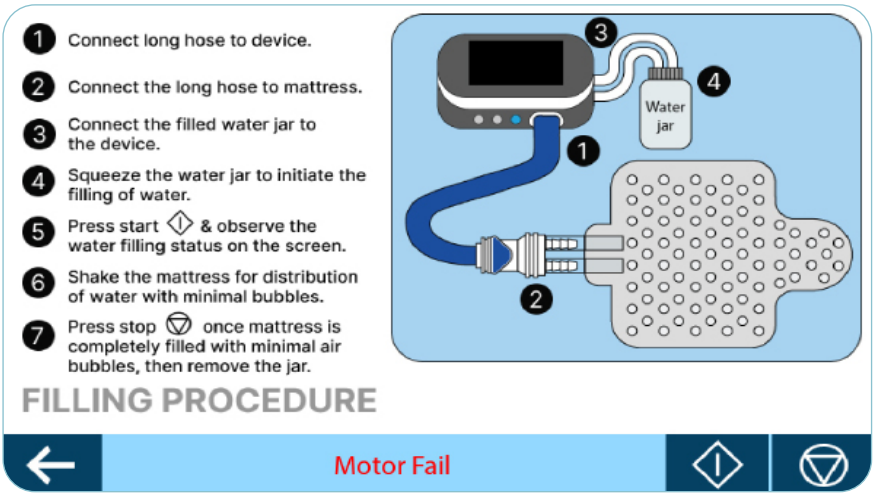


Figure 7.5.C: Filling instructions screen with "***Motor fail"*** message

Kinking of the hose may restrict the flow of fluid, cause improper circulation or even blockage.

If mattress defects or punctures occur, do not attempt to repair the mattress, but replace it. Contact the supplier if a manufacturing defect is identified.

7.6 Draining mode:

Press the "**Draining**" mode icon to initiate the draining of the tank and mattress. Draining instructions are provided on the screen as shown in Figure. 7.6.A

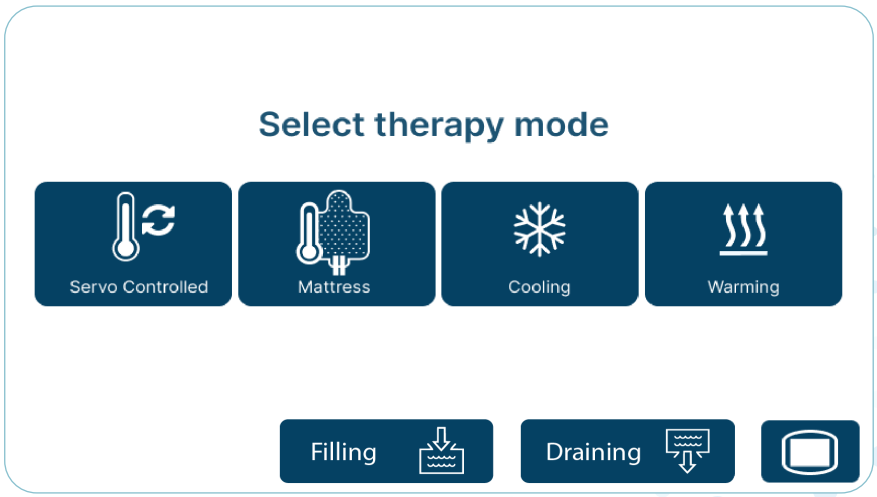


Figure 7.6.A: Selecting "***Draining"*** mode

Instructions for draining:

- Follow the on-screen instructions as shown in Figure 7.6.B until the "***Draining completed***" message is shown in the screen as in Figure 7.6.C
- If the pump fails while draining, the system will display an error message in red as shown in the Figure 7.6.D

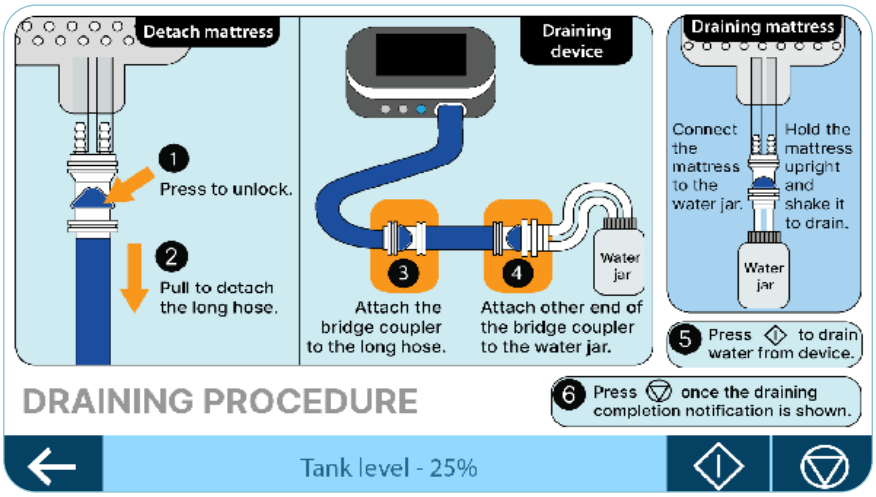


Figure 7.6.B: Draining Instructions on screen with live tank level

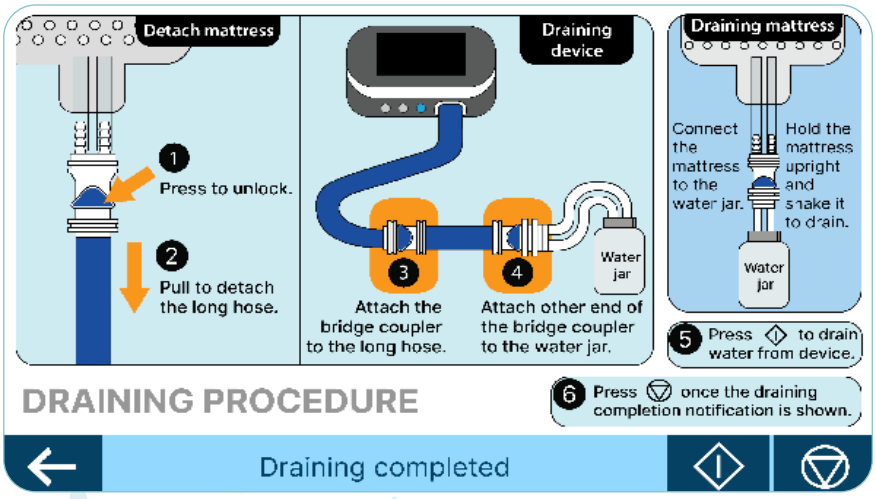


Figure 7.6.C: Draining Instructions screen with "***Draining completed***" message

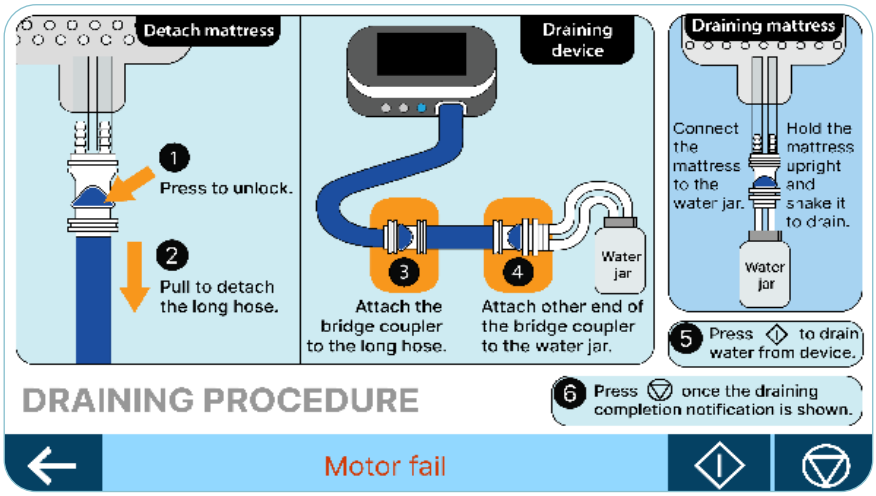


Figure 7.6.D: Draining Instructions screen with "***Motor fail***" message

7.7 Mode settings

The device has four modes:

- Servo Controlled mode
- Mattress mode
- Cooling mode
- Warming mode

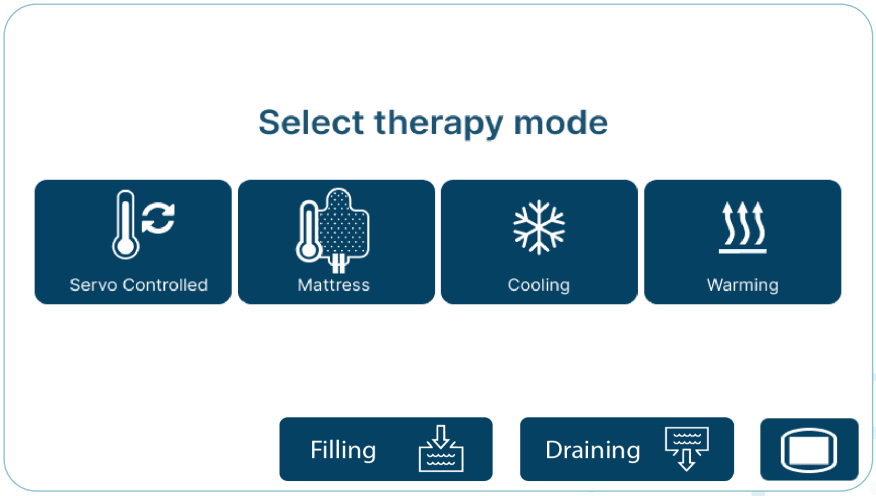


Figure 7.7.A: "***Select therapy mode***" screen

7.7.1 Servo-Controlled mode

Servo-Controlled mode is designed for inducing total body hypothermia with subsequent rewarming in patients. The device circulates the coolant fluid through the mattress. The control unit will maintain the desired (user set) core temperature by adjusting the temperature of the circulating fluid in response to feedback from the rectal temperature probe. When the core temperature reaches the set temperature, the system will adjust the cooling/warming automatically. Once the cooling phase is completed, the device automatically starts the rewarming phase. The duration of the rewarming phase can be preset (and adjusted) by the user, and the speed of rewarming will change dynamically based on the final core temperature.

The minimum heating phase duration will automatically be set based on the final core temperature.

The rewarming phase duration can be extended from the minimum device set duration up to maximum duration of 24 hours.

*Warming mode is enabled only if the user enters and starts therapy either in "**servo-Controlled**" or "**Cooling**" mode.*

*The device will prompt the alarm- "**Rectal temperature probe dislocated**", if the rectal temperature probe becomes dislodged or records a reading near ambient temperature.*

Working principle

Once the servo-mode has been started, the device will automatically run the following sequential steps:

- Rapid cooling from the current core temperature to the set target temperature of the patient.
- After reaching the target temperature, the device will continue to maintain the same core temperature within ±0.5°C.
- The set core temperature is maintained until the cooling phase duration has elapsed.
- Once the cooling therapy is complete, the device will automatically start to re-warm gradually based on the final set temperature and duration and rate of change.
- The increase in the temperature per hour is based on the set rate of change.
- Temperature increase per hour is calculated by the device and will slowly restores the patient's normal body temperature.
- Finally, the device will notify the therapy mode completion indication on the screen

Select therapy (Servo Controlled mode)

The screen should indicate the core temperature clearly and be visible from a distance (operator position)

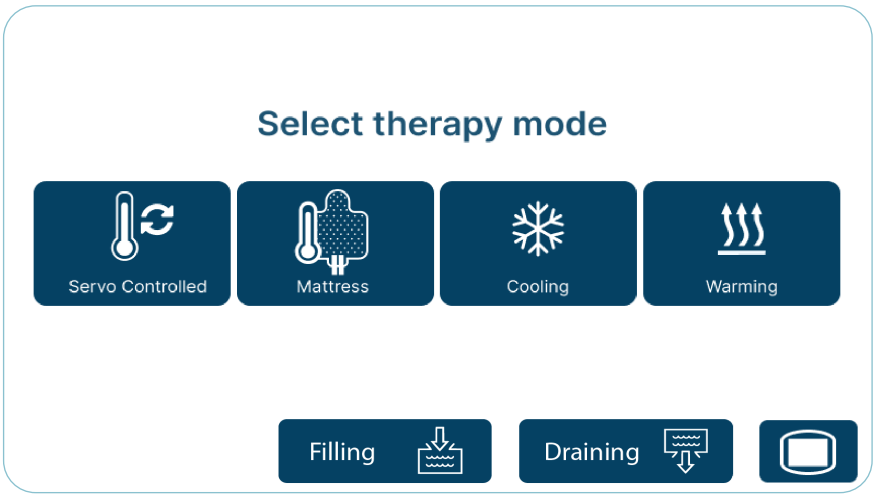


Figure 7.7.1.A: Select "***Servo Controlled"*** mode

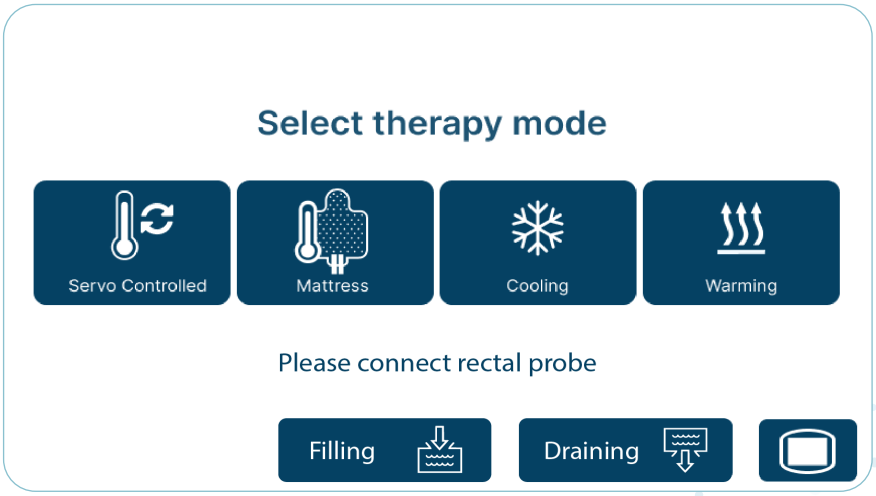


Figure 7.7.1.B: Rectal temperature probe disconnected indication before start "***Servo Controlled***" mode

Parameter setting screen

If Servo Controlled Mode has been chosen, set the desired parameters

- For the parameter range, refer to Chapter 6.1 Mode Specification
- Set the parameters using the increment/decrement key
- Once the parameter has set, press the “Start” icon
- The screen will navigate to the monitoring screen.

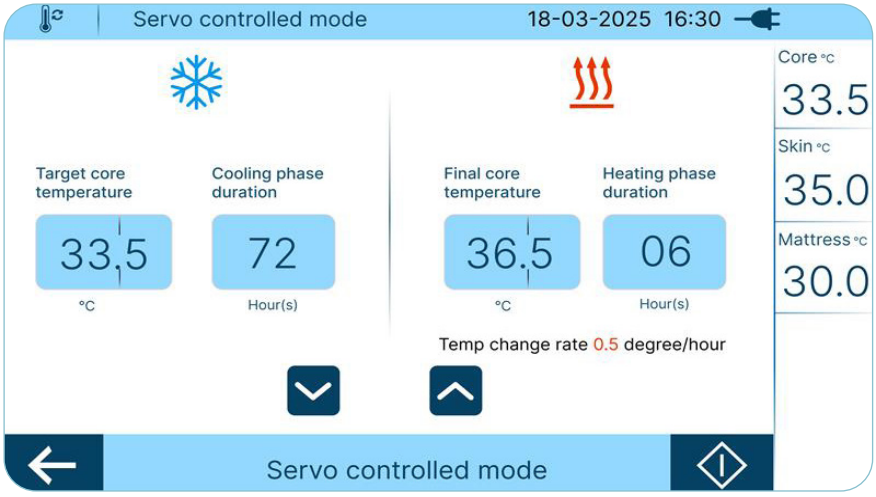


Figure 7.7.1.C: *Servo Controlled mode* with default parameter settings

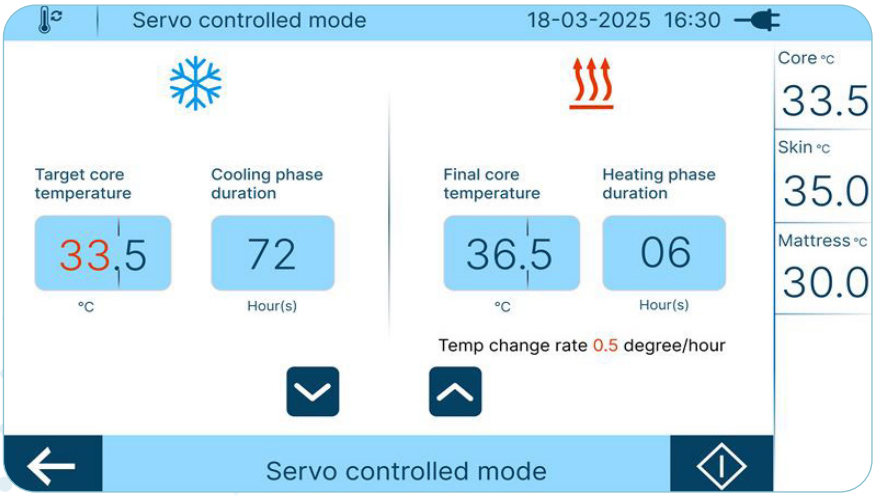


Figure 7.7.1.D: *Target core temperature* primary value selected

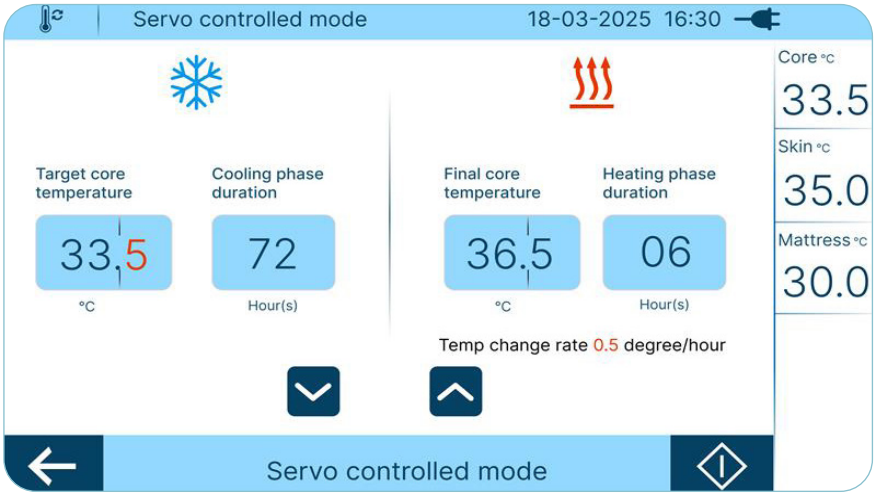


Figure 7.7.1.E: *Target core temperature* secondary value selected

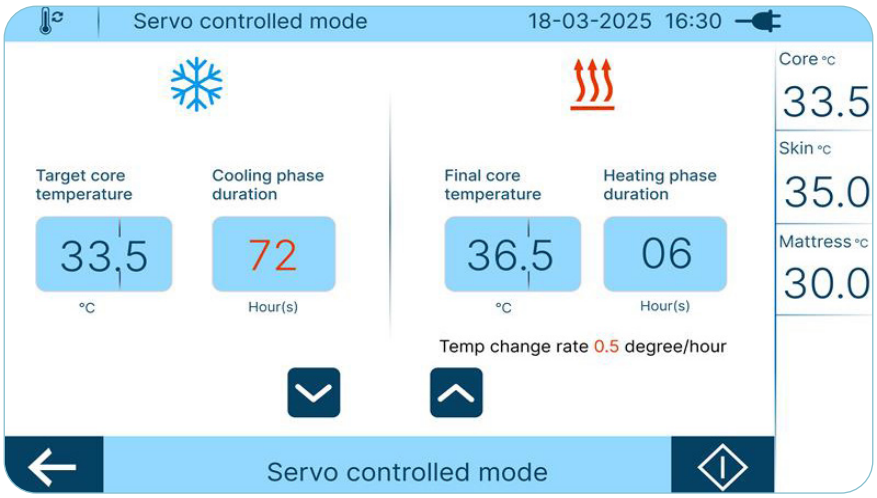


Figure 7.7.1.F: *Cooling phase duration* selected.

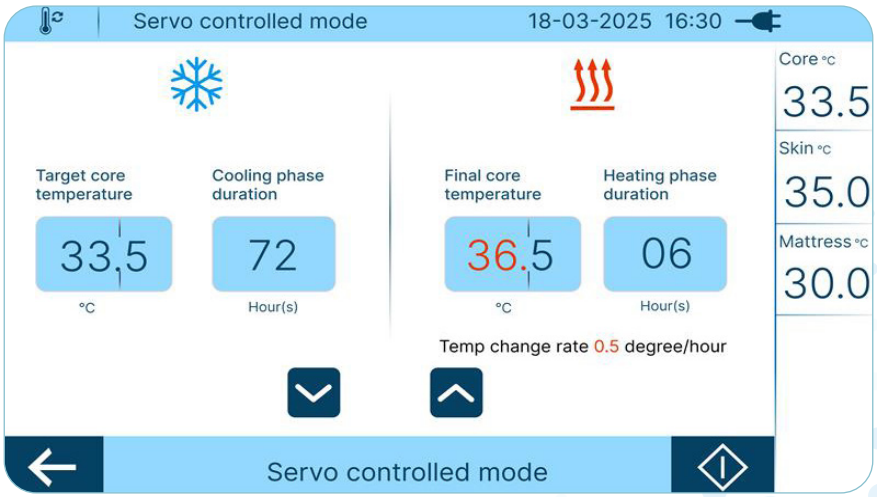


Figure 7.7.1.G: *Final core temperature* primary value selected.

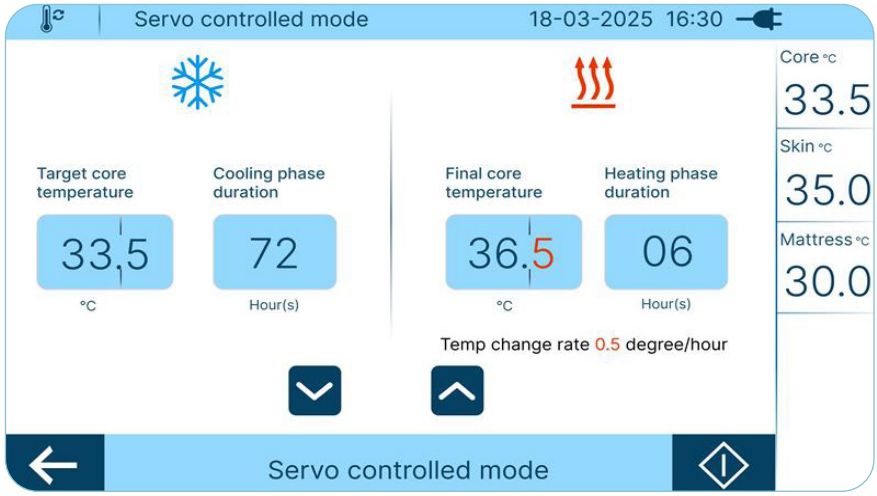


Figure 7.7.1.H: ***Final core temperature*** secondary value selected

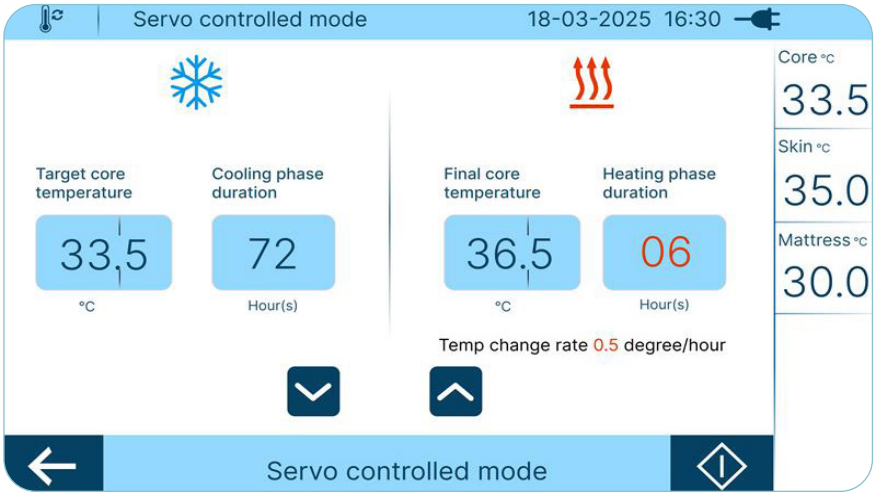


Figure 7.7.1.I: ***Heating phase duration*** selected

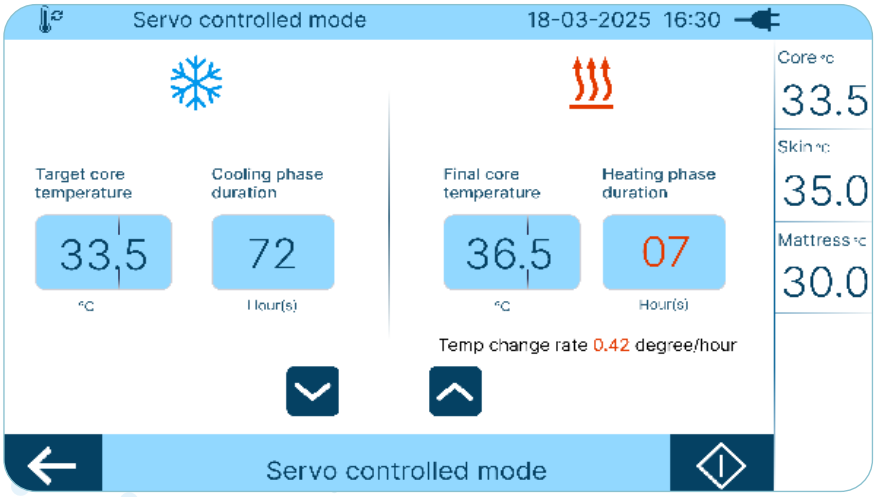


Figure 7.7.1.J: Change in temperature increment rate with respect to set ***Heating phase duration***

Monitoring screen

- Once the therapy has started, the monitoring screen will display the real-time temperature values. A graphical waveform (trends) will be generated according to the core temperature and duration in real time.
- During the therapy, if any of the parameters need to be changed, click on the "**Set parameter** "icon on the screen.
- At that point, the currently activated mode can be altered.

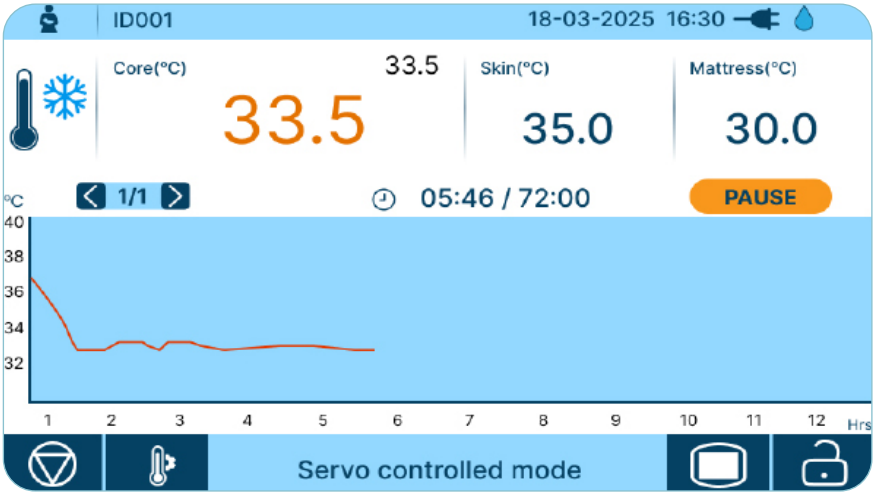


Figure 7.7.1.K: Monitoring screen in ***Servo controlled mode***

All parameters can be changed from the set value at any time as required

Once therapy starts, always set the screen lock key to avoid unintentional settings/mode changes

7.7.2 Mattress mode

Constant mattress mode can be used as a pre-cool/pre-warm mode.

Constant mattress temperature mode is designed to maintain the desired mattress temperature, but it will not automatically adjust for the patient's temperature. Therefore, it is not recommended to give full cycle of therapeutic hypothermia using this mode. When in use, monitor the patient's core temperature closely.

In this mode, the core temperature will be measured in real time but not used as feedback; instead, the mattress probe will be used to directly control the temperature of the mattress.

Select mode (Mattress mode)

To select constant mattress temperature mode, click on the icon "***Mattress***" in "***Select therapy mode***" screen

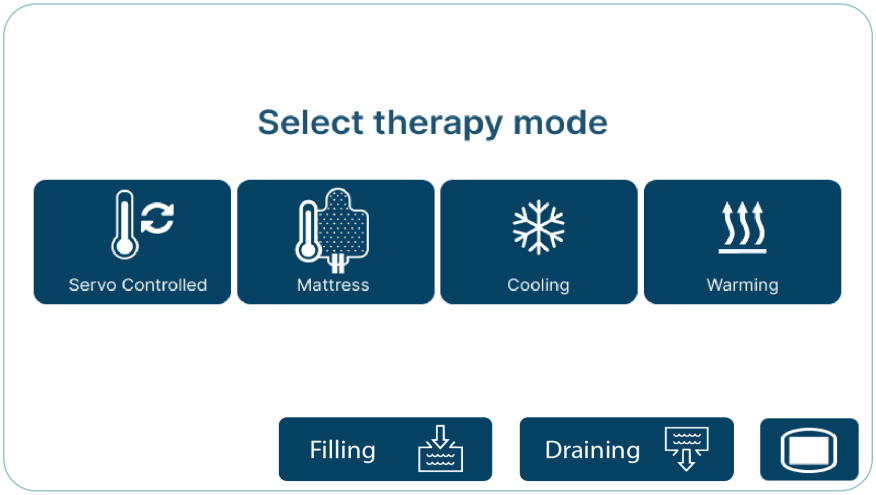


Figure 7.7.2.A: Select ***Mattress*** mode

- If constant ***mattress*** temperature mode has been chosen, set the desired parameters.
- For the parameter range, refer to 6.1 mode specifications. Set the parameters using the increment/decrement key.

- Once the parameter has been set, press the "**Start**" icon.
- The screen will navigate to the monitoring screen.

Parameter setting screen

The temperature and therapy hours can be either increased or decreased using the increment/ decrement keys.

Values can be adjusted (increment/decrement) in 1 step or 0.1 step by clicking on the number.

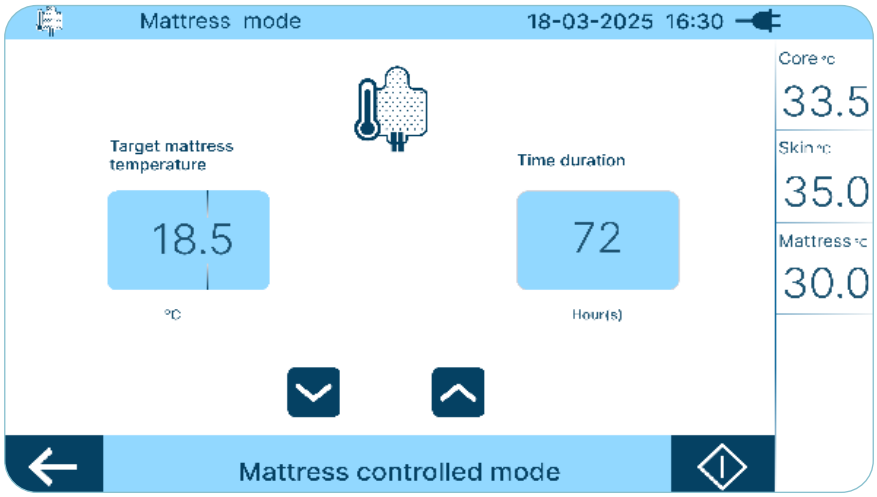


Figure 7.7.2.B: *Mattress mode* with default parameter settings

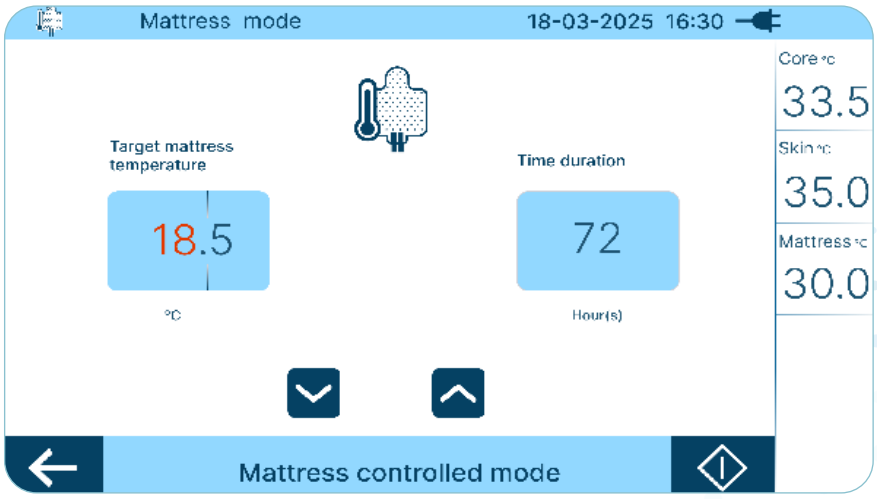


Figure 7.7.2.C: *Target mattress temperature* with primary value selected

Figure 7.7.2.D: ***Target mattress temperature*** with secondary value selected

Figure 7.7.2.E: Target mattress temperature with ***Time duration*** selected

Monitoring screen

- Once the mode has started, the monitoring screen will display the real-time temperature values. Then the graphical waveform will be generated according to the temperature and duration in real time

- During the therapy, if any of the parameters need to be changed, tap the set **parameter icon** on the screen.

All parameters can be changed from set value at any time when the need arises

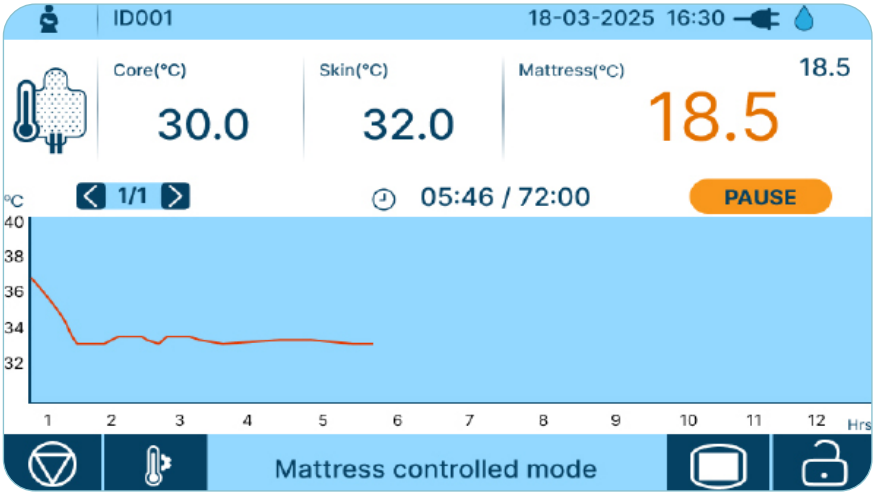


Figure 7.7.2.F: Monitoring screen of ***Mattress controlled mode***

7.7.3 Cooling mode

- ***Cooling*** mode is designed for inducing hypothermia in a patient by total body cooling via the mattress. The control device will maintain the set core temperature by adjusting the temperature of the circulating fluid via feedback from the rectal temperature probe. Once the cooling phase is completed, the ***"Therapy completed"*** message will be displayed. Users must manually select the rewarming mode for inducing normothermia.

Select therapy (Cooling mode)

- To Select the Cooling mode, click on the icon ***"Cooling"*** in Select therapy mode scree

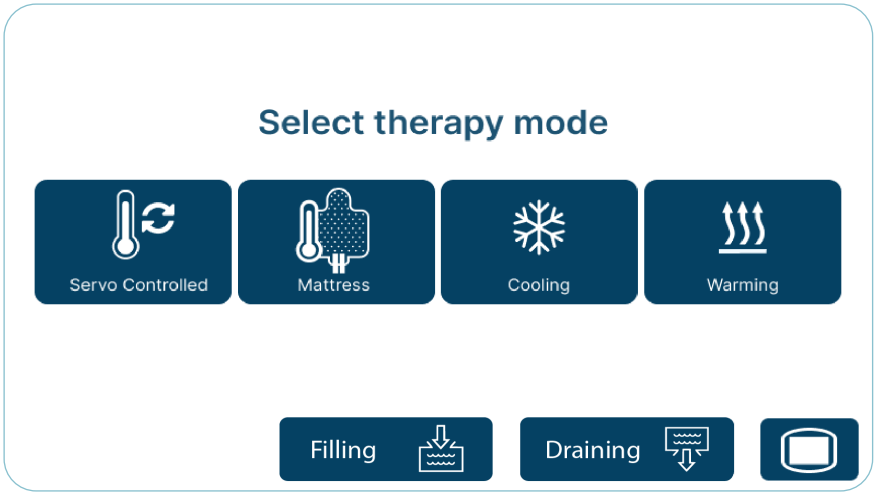


Figure 7.7.3.A: Select ***Cooling*** mode.

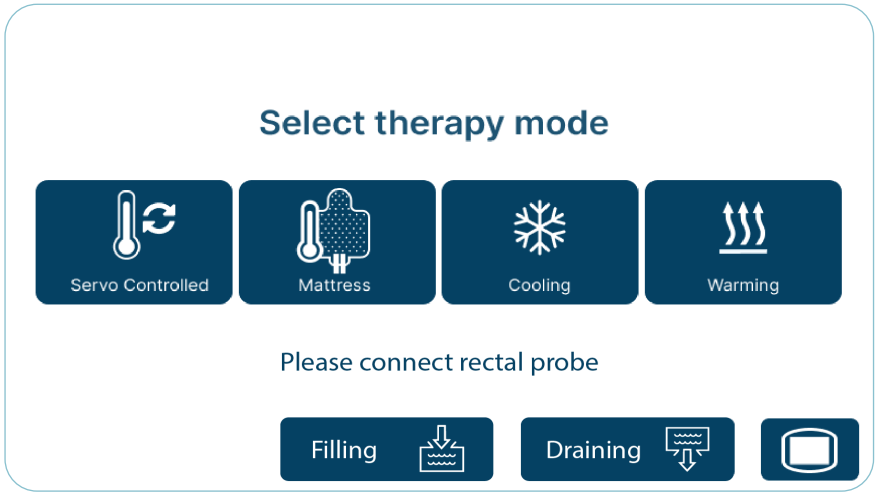


Figure 7.7.3.B: *"Please connect rectal probe"* displayed when the rectal temperature probe is not connected prior to starting servo therapy

Parameter setting screen

- If Cooling mode has been chosen, set the desired parameters
- For the parameter range, refer to 6.1 mode specification
- Set the parameters using the increment/decrement key
- Once the parameter has been set, press the "Start" icon.
- The screen will navigate to the monitoring screen.

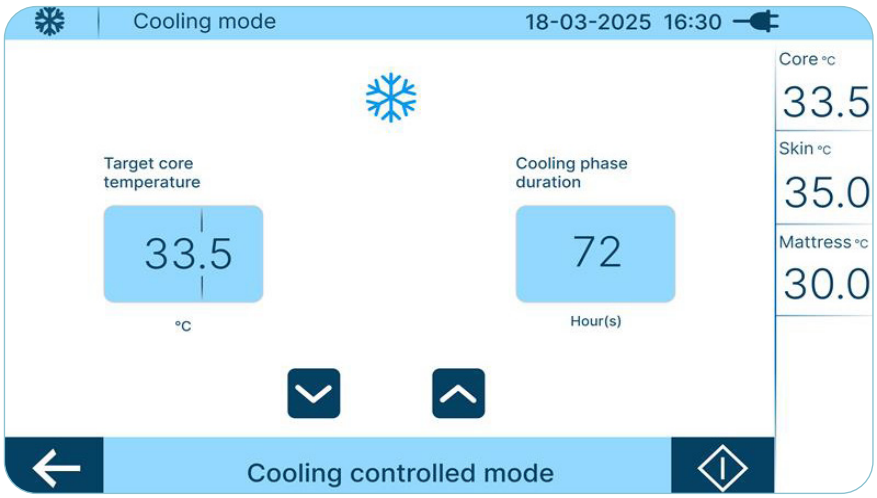


Figure 7.7.3.C: *Cooling controlled mode* with default parameter settings

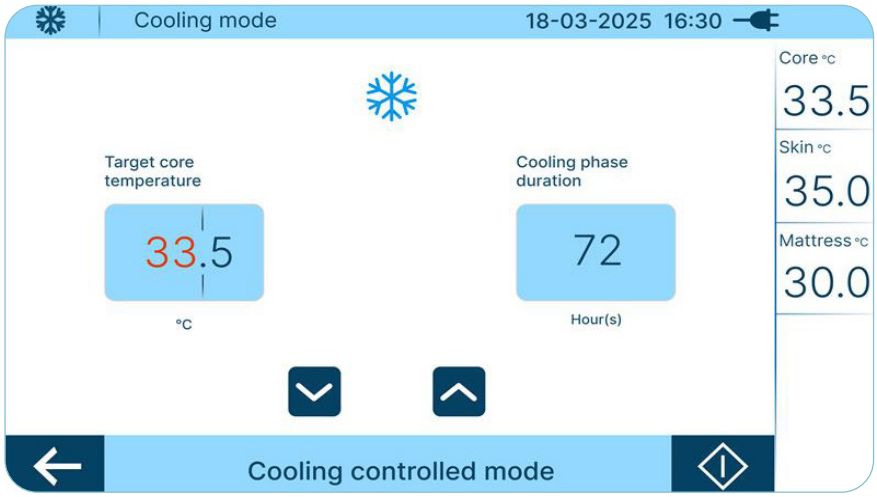


Figure 7.7.3.D: *Target core temperature* with primary value selected

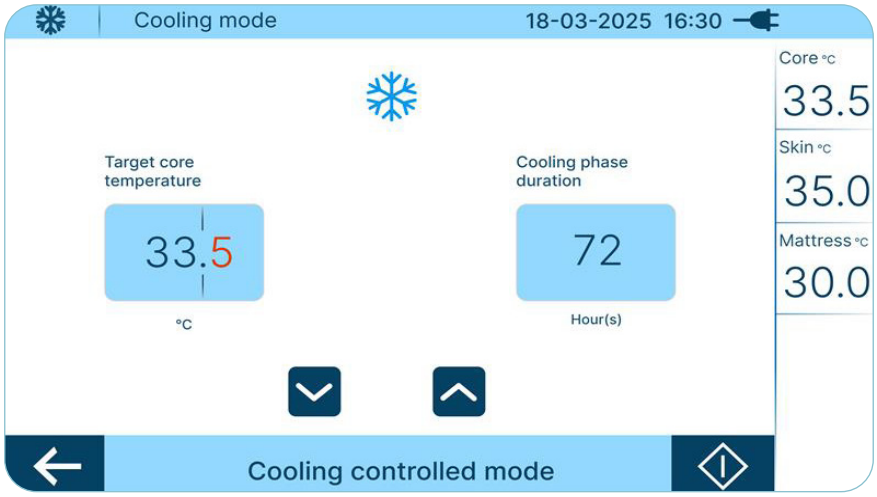


Figure 7.7.3.E: ***Target core temperature*** with secondary value selected

Figure 7.7.3.F: ***Target core temperature*** with ***Cooling phase duration*** selected

Monitoring screen

- Once the therapy has started, the monitoring screen will display the real-time temperature values. Then the graphical waveform will be generated according to the temperature and duration in real time.
- During the therapy, if any of the parameters need to be changed, tap the set parameter icon on the screen.

All parameters can be changed from set value at any time when the need arises

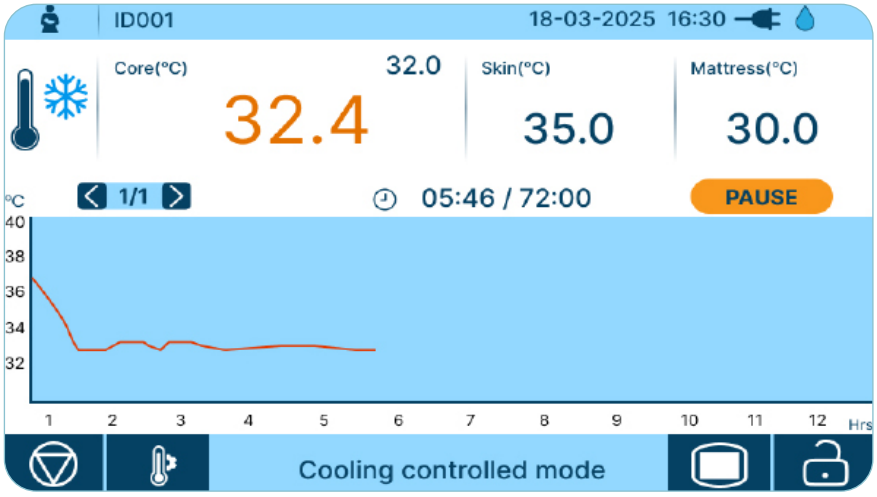


Figure 7.7.3.G: Monitoring screen of ***Cooling controlled mode***

7.7.4 Warming mode

Patient body mass may severely influence the rewarming. The larger the mass, the slower the rewarming.

The ***Warming*** mode is designed for inducing normothermia in a patient by total body warming via the mattress. The device will achieve the desired (set) core temperature by adjusting the temperature of the circulating fluid via feedback from the rectal temperature probe. Once the warming phase is completed, the "***Therapy completed***" message will be displayed

Select mode (Warming mode)

To select the ***Warming*** mode, click on the icon "***Warming***" in ***Select therapy mode*** screen

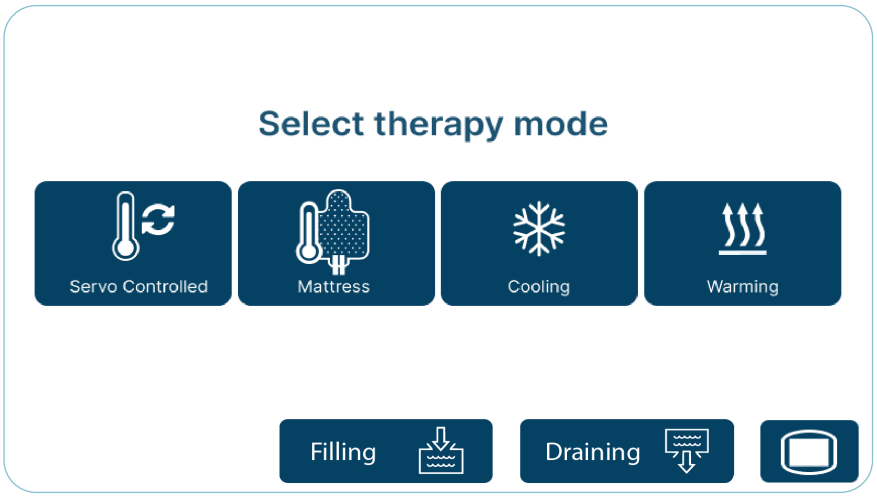


Figure 7.7.4.A: Select ***Warming*** mode

Parameter setting screen

- If ***Warming*** mode has been chosen, set the desired parameters.• For the parameter range, refer to 6.1 mode specification.
- Set the parameters using the increment/decrement key.
- Once the parameter has been set, press the "**Start**" icon.
- The screen will navigate to the monitoring screen.

Figure 7.7.4.B: ***Warming mode*** with default parameter settings.

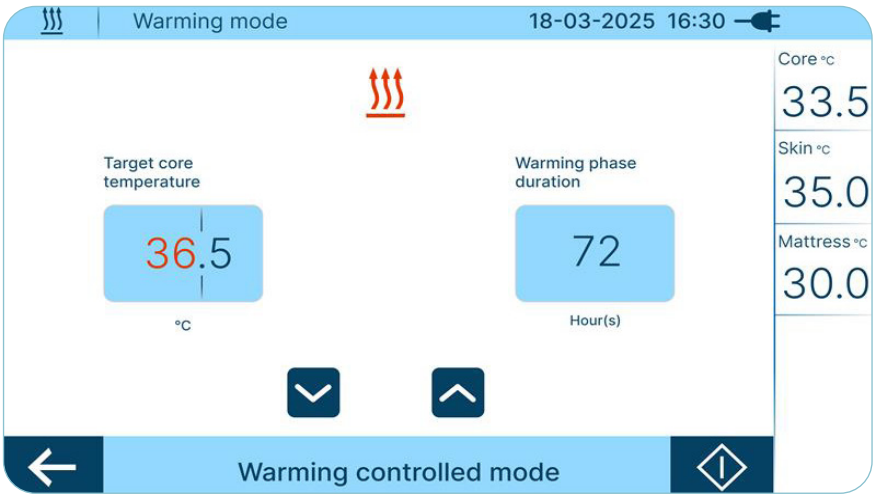


Figure 7.7.4.C: *Target core temperature* with primary value selected.

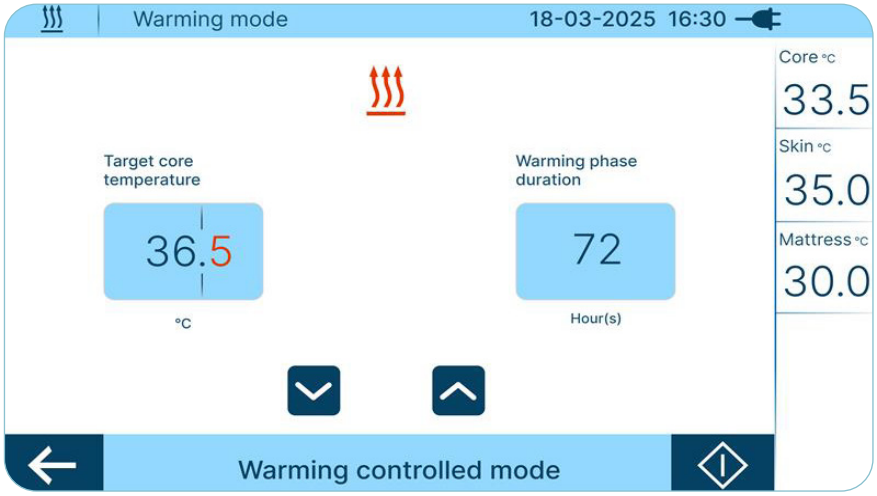


Figure 7.7.4.D: *Target core temperature* with secondary value selected.

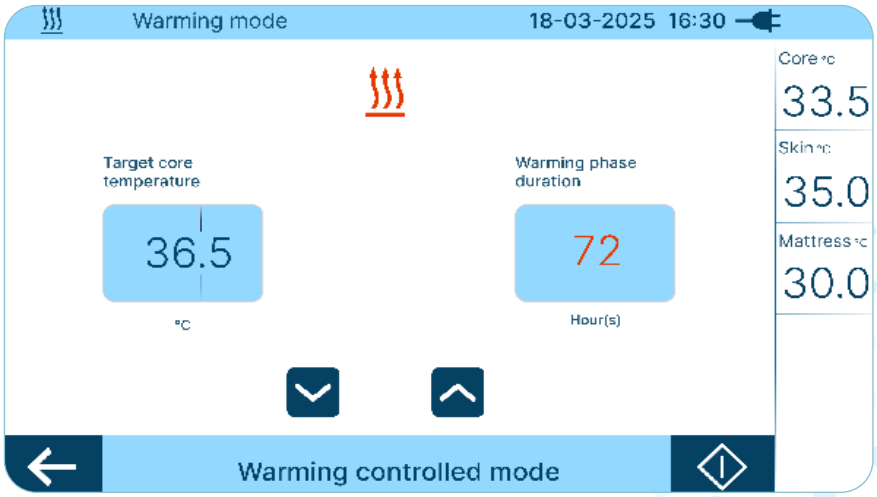


Figure 7.7.4.E: *Warming phase duration* selected.

Monitoring screen

- Once the therapy has started, the monitoring screen will display the real-time temperature values. Then the graphical waveform will be generated according to the temperature and duration in real time.
- If any of the parameters need to be changed, tap the set parameter icon on the screen.

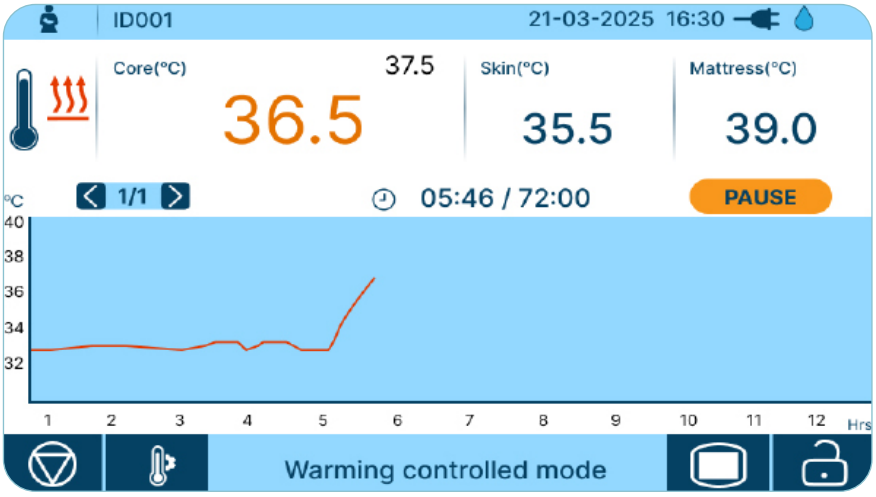


Figure 7.7.4.F: Monitoring screen of ***Warming controlled mode***

7.8 Temperature override

When the final core temperature or the mattress temperature value reaches 37.0 degrees Celsius, a pop-up appears with the message ***"Confirm to override the temperature,"*** prompting the user to confirm whether they wish to exceed this value.

If "YES" is pressed, the override temperature can be set.

If "NO" is pressed, the override will not be permitted.

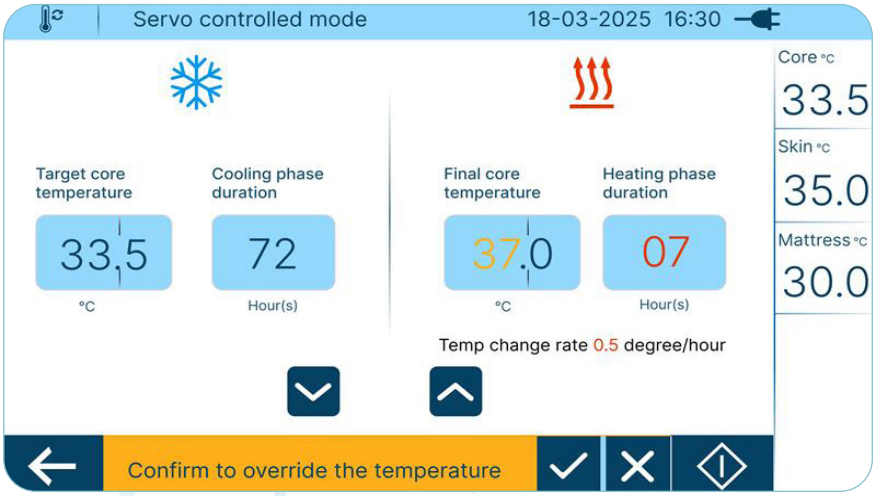


Figure 7.8.A: Override temperature ***(Servo Controlled mode)***

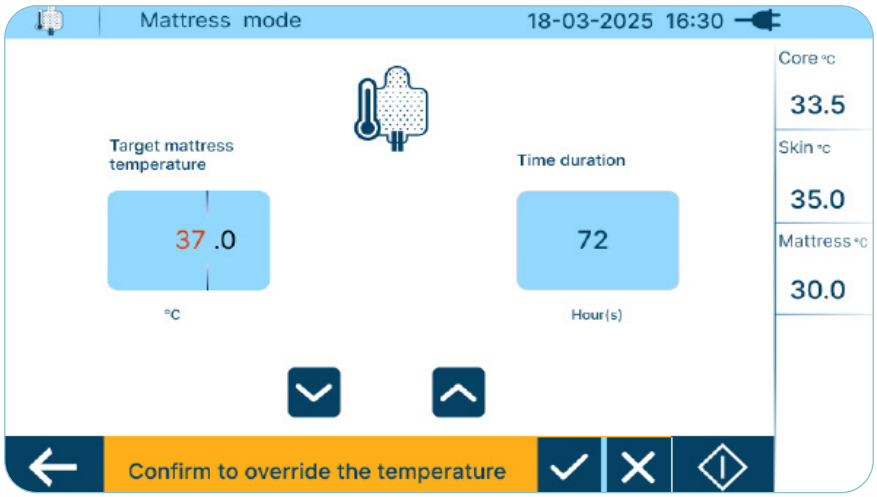


Figure 7.8.B: Override temperature
(Mattress mode)

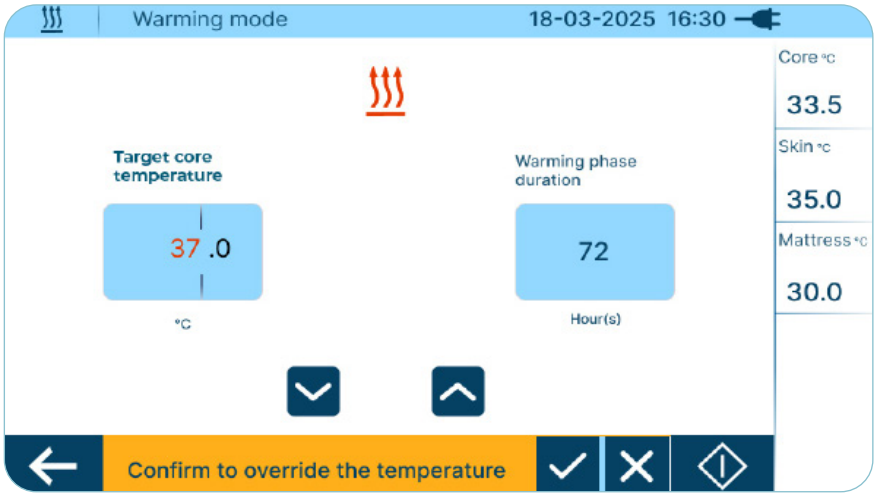


Figure 7.8.C: Override temperature
(Warming mode)

7.9 Stopping therapy

- During the therapy, if the mode needs to be changed, tap the "**Stop Icon**" on the monitoring screen (refer to Figure 7.9.A monitoring screen)
- This screen will ask for confirmation, "***Confirm to stop and exit therapy,***" as shown in Figure 7.8.b
- If "YES" is pressed, the screen terminates to select therapy mode.
- Then it will navigate to the mode setting screen with all four modes ***(Servo Controlled*** mode**,** ***Mattress*** mode**,** ***Cooling*** mode, and ***Warming*** mode**)**
- If "NO" is pressed, the mode will continue

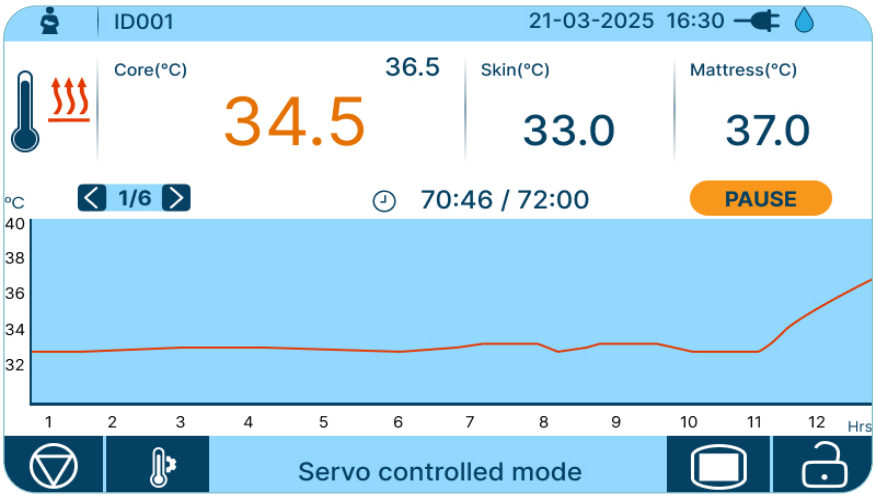


Figure 7.9.A: Select stop therapy icon

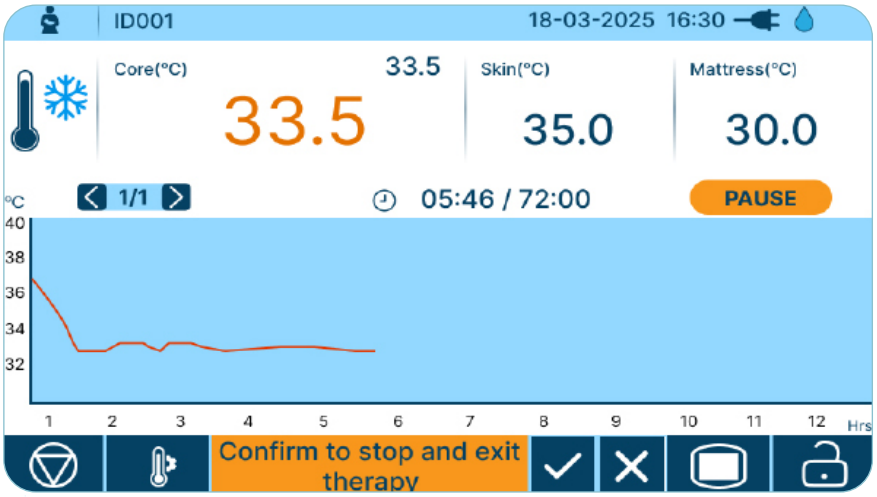


Figure 7.9.B: User confirmation "***Confirm to stop and exit therapy***" displayed

7.10 Viewing trends

- The device is provided with a graphical trend for core temperature, which can be viewed and stored. The real-time data is fetched and plotted in the graph for **108 hours**.
- Each page has 12 hours of data, and the subsequent data is stored on other pages.
- Press the left or right navigation buttons above the graph to go forward or backward in time as shown in Figure 7.10.A and 7.10.B

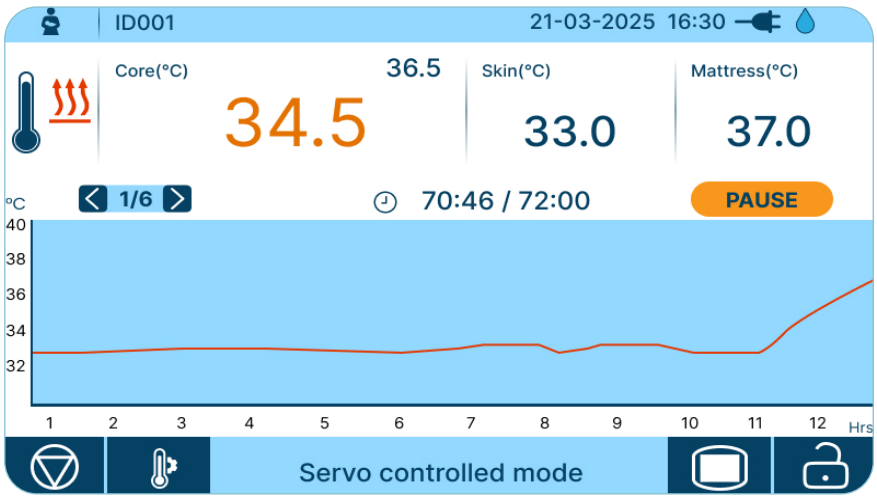


Figure 7.10.A: Page 1/6 of trends ***(Servo controlled mode)***

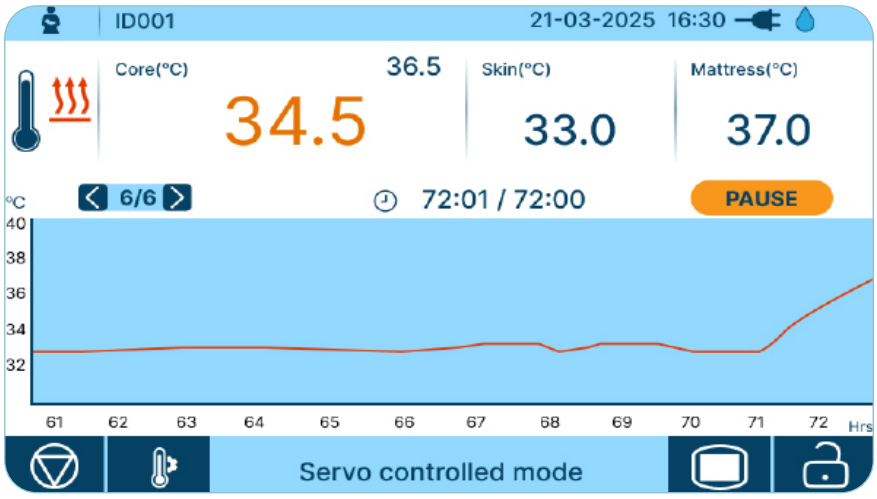


Figure 7.10.B: Page 6/6 of trends ***(Servo controlled mode)***

7.11 Pause or resume therapy

- The device is provided with a feature to pause and resume therapy without having to reset the time duration in the middle of the therapy.
- Therapy can be paused and resumed at any time. Refer to Figure7.11.A, Figure 7.11.B and Figure7.11.C

Use this feature only in emergency conditions to temporarily stop the cooling/warming therapy. Therapy will resume only when the operator manually presses the **Resume** *button.*

This feature only resumes from the last elapsed duration and will not maintain the recent patient's core temperature

Therapy settings cannot be changed in paused state.

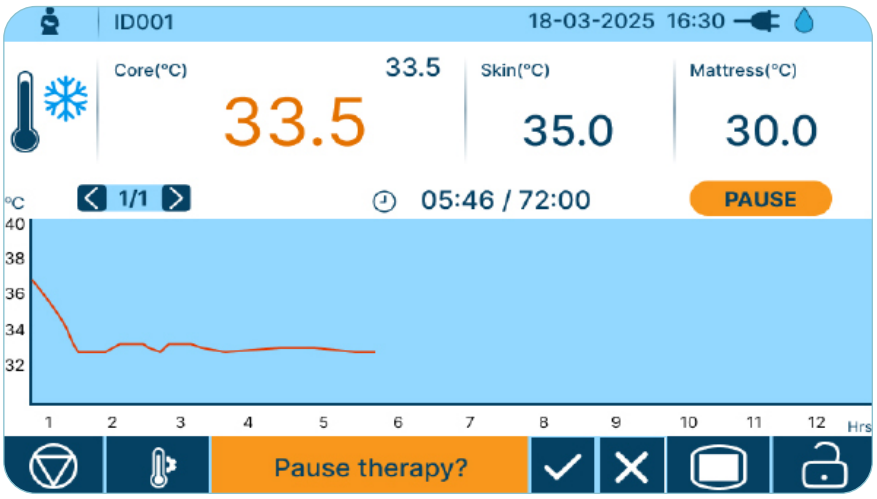


Figure 7.11.A: "*Pause therapy?*" pop-up message

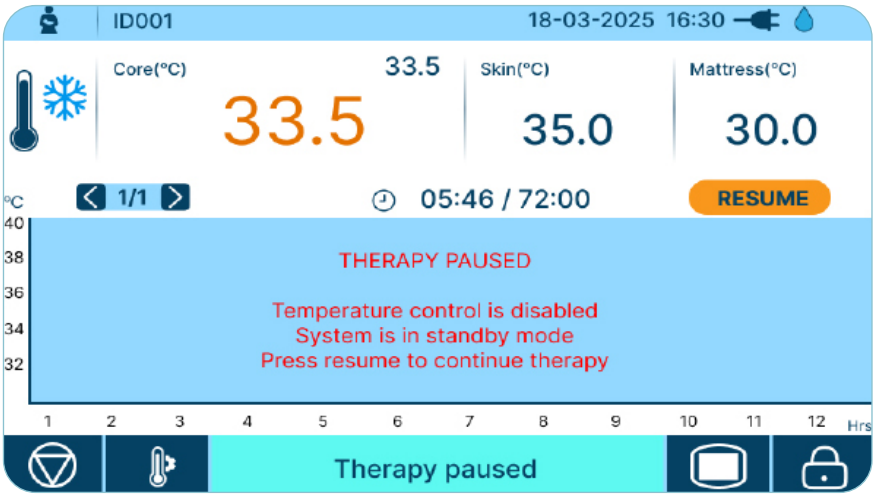


Figure 7.11.B: "*Therapy paused*" screen

Figure 7.11.C: "*Confirm resume*" pop-up message.

7.12 Menu screen

Follow these steps to view menu screen:

*This **Menu** icon is common in all the four modes (servo controlled, constant mattress temperature mode, cooling mode and warming mode)*

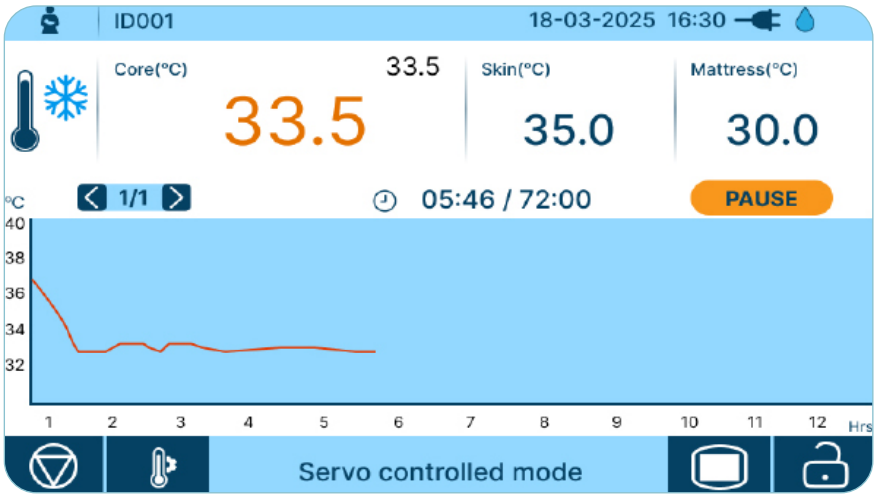


Figure 7.12.A: Click on menu.

Figure 7.12.B: Menu screen

7.13 System shutdown

To shut down the device, press the system shutdown icon and confirm as shown in Figure7.13.A

Figure 7.13.A: System shutdow.

7.14 Display setting

7.14.1 Brightness & contrast

- Adjust the screen brightness and contrast by using the “+” and “-” icons on the screen.
- After changing the parameters, press the save icon to save the changes.
- Press the Reset icon to reset to its default setting.

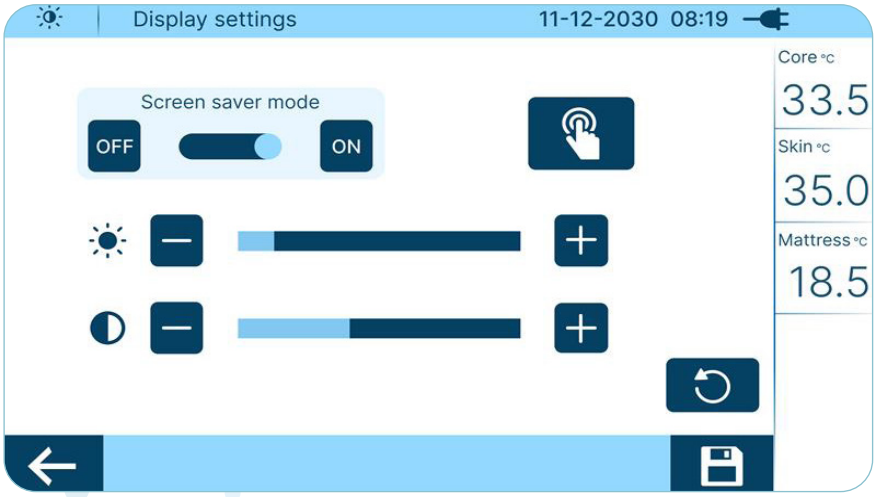


Figure 7.14.1.A: Brightness and contrast settings

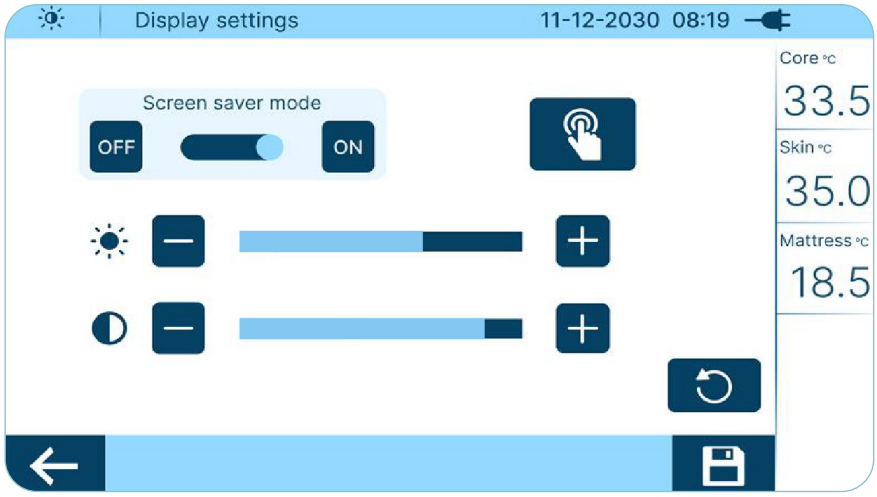


Figure 7.14.1.B: Brightness & contrast settings changed

7.14.2 Screensaver mode

By default, screensaver mode is in the "**ON**" condition.

- The screen saver can be toggled ON/OFF using the controls as shown in Figure 7.14.2.A and Figure 7.14.2.B

If the screensaver mode is ON:

- The device monitors for any alarms for the next 2 minutes and 40 seconds after the last user interaction.
- If an alarm is generated during this time, the main screen remains active to display the alert.
- If no alarm is detected and there is no user interaction for 2 minutes and 40 seconds, the device will automatically switch to screensaver mode.

The screensaver is activated only when there are no active alarms and no user interaction during the 2-minute-40-second period.

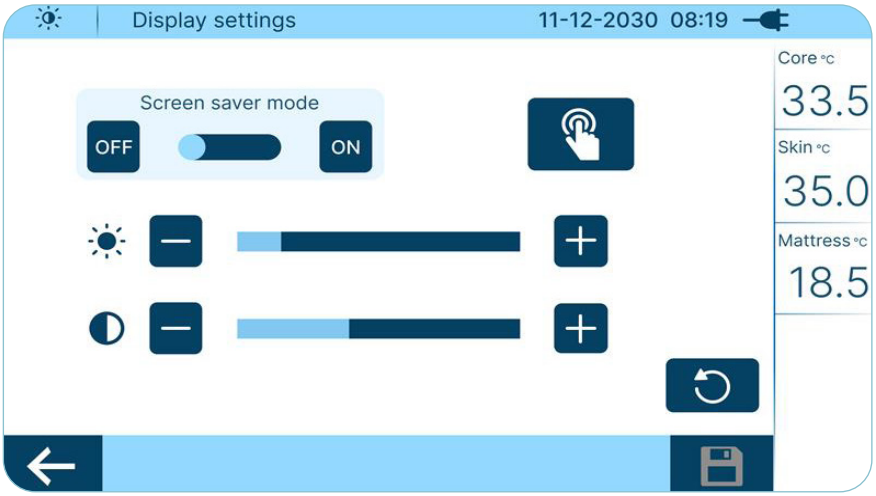


Figure 7.14.2.A: *Screen saver mode* OFF

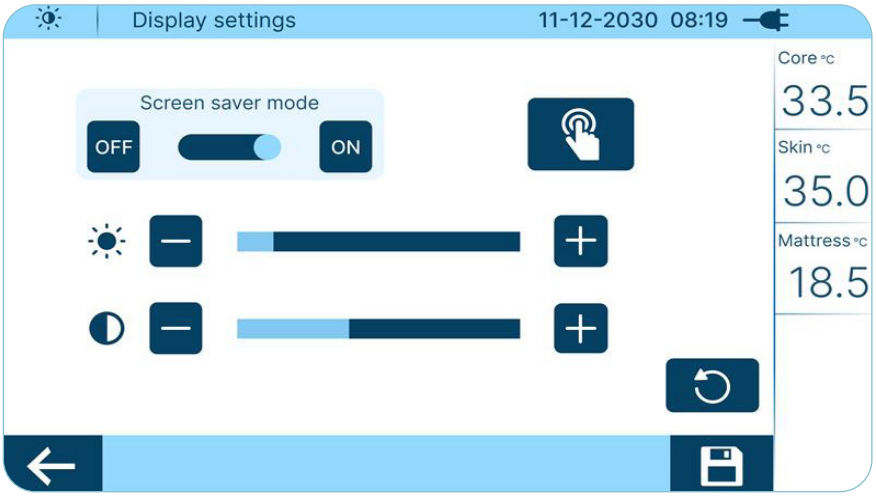


Figure 7.14.2.B: *Screen saver mode* ON

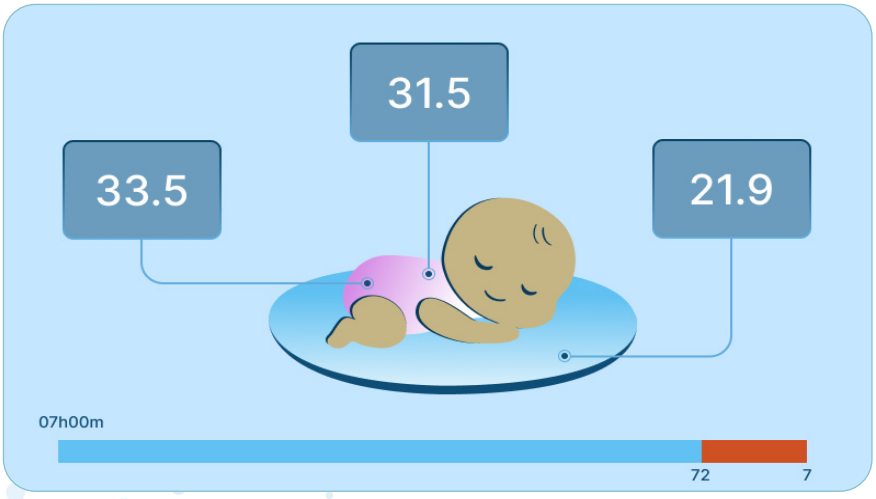


Figure 7.14.2.C: Screensaver screen displayed after 4 minutes of no user interaction or active alarms.

7.14.3 Touch calibration

To calibrate the touch display of the device, press the touch calibration icon, confirm, and follow the on-screen instructions as shown in Figure 7.14.3. A

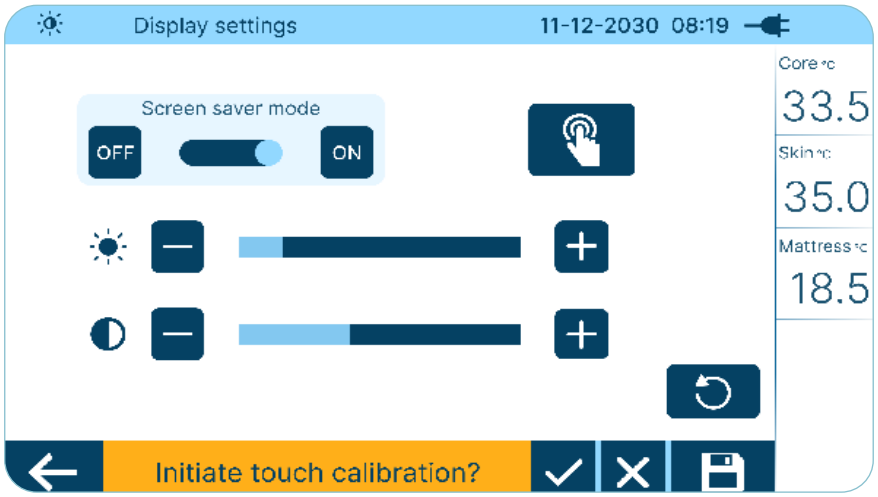


Figure 7.14.3.A: Touch calibration

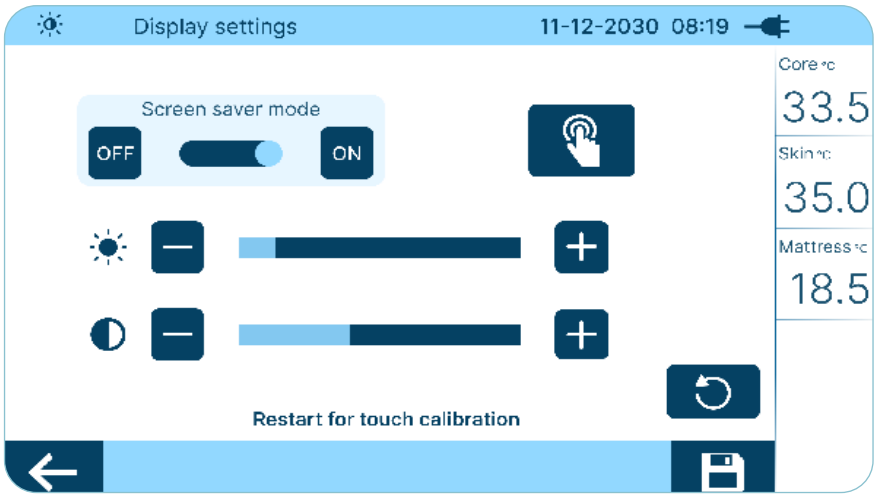


Figure.7.14.3.B: Information to user "***Restart for touch calibration***"

Touch calibration procedure

- After restarting, the touch calibration screen will appear as shown in figure 7.14.3.C.
- Press all touch target points ('+') precisely using a stylus or any non-metallic pointed object (such as a plastic tipped pen) for accurate and successful touch calibration.
- Once this procedure is completed, the unit will restart for normal use.

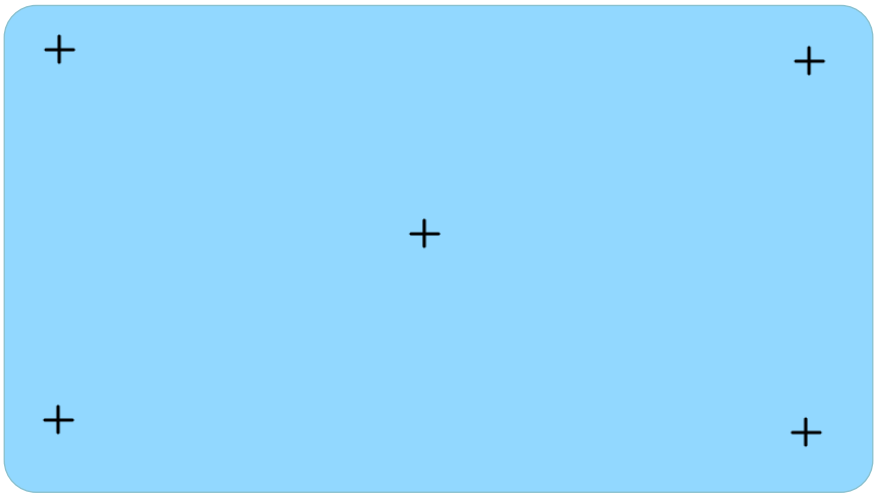


Figure 7.14.3.C: Touch calibration

7.15 Data transfer to USB drive

Figure 7.15.A: Data transfer screen display error message

Figure 7.15.B: Connecting USB drive to USB port

1. *The device can hold up to data of 10 babies, after that 1st entered patient's data will be erased and newly added patient's data will be recorded.*
2. *All the Set, Core, Skin and Mattress temperature along with mode, therapy duration and alarms with patient's name are recorded and can be transferred.*

- The USB port is in the top left corner at the back of the device.
- It is used to transfer data from the device to a USB drive.
- Insert the USB drive in the USB port **(FAT 32 (DEFAULT)** format.
- Then tap the Data transfer icon to transfer the data from the device to a compatible USB storage device.
- Then data transfer progress will appear at the screen bottom
- It is advised to stop the therapy mode before transferring data to the USB drive/USB storage devices, to avoid any potential loss (e.g. last few minutes of recorded data)

Figure 7.15.C: Patient ID and selection and data transfer

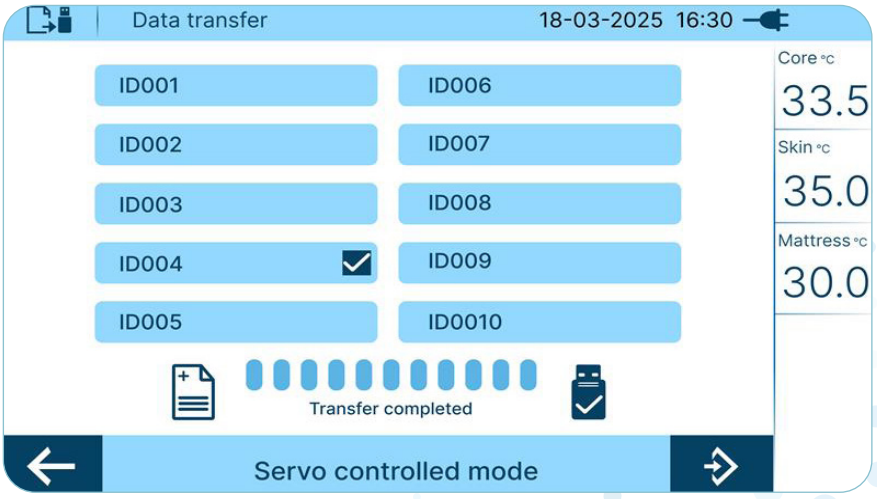


Figure 7.15.D: Data transfer completed indication

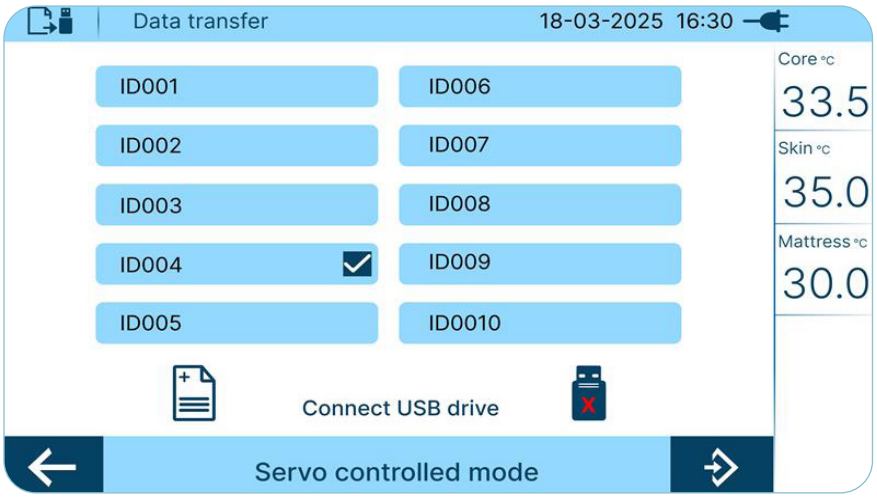


Figure 7.15.D: *Connect USB drive* indication

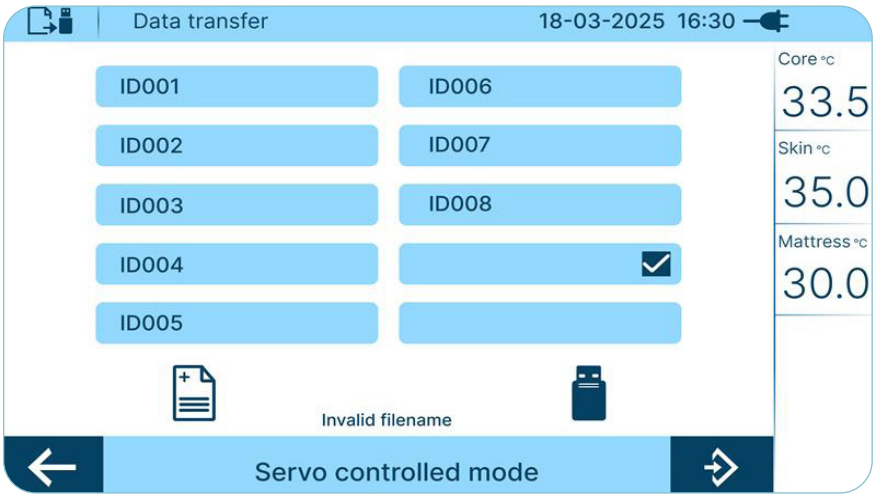


Figure 7.15.E: *Invalid filename* displayed

- *Do not leave the USB drive connected to the device for extended periods, as it may overheat and affect the USB drive's functionality. Remove the USB drive immediately after data transfer is complete.*
- *Only USB drives should be connected to the USB port. Do not connect devices such as a mouse, keyboard, or printer.*
- *Do not use the USB port for charging purposes.*

The device supports only FAT32-formatted, empty USB drive for data transfer and safety purposes.

Data transfer is not permitted during therapy.

Alarm code

Alarm Code	Alarm Message
00	*System error(Motor)*
01	*System error(Fan)*
02	*System error(Peltier)*
03	*Water flow fail*
05	*Mattress probe fail*
06	*Mattress too cold*
07	*Rectal probe fail*
08	*Rectal probe dislocated*
09	*Baby core temp too low*
10	*Baby core over temp*
11	*Mattress over temp*
13	*Baby core temp high*
14	*Baby core temp low*
15	*Power fail*

Alarm Code	Alarm Message
16	*Battery critically low*
17	*Mattress temp low*
18	*Mattress temp high*
19	*Set temp not reached*
20	*Therapy completed*
21	*Communication error*
22	*Replace old water*
23	*Battery low*
24	*Water level low*
25	*Water level sensor fail*
26	*Servo mode*
27	*Mattress mode*
28	*Cooling mode*
29	*Warming mode*
30	*New patient added*

7.16 Event log

Check the "**Event log**" to view the Events/Alarms Name, In time and Out time.

Events and alarms are logged in real time. Once the log reaches 63 pages, the oldest records will be automatically overwritten by new entries.

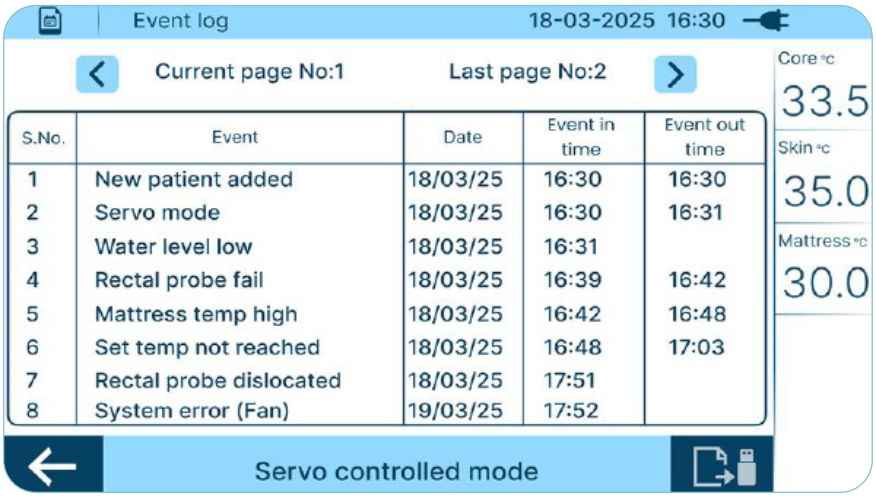


Figure 7.16.A: An ***Event log*** screen

7.17 Date & time settings

- To set the date and ttime of the device, navigate to the menu screen and tap the calendar icon.
- The time is adjustable in 24 hours format, tap in date: Day/Month/Year or in time: Hour/Minute.
- Type the number using the keypad.
- Click on save icon after setting the date and time.

Ensure whether the device is displaying current date and time correctly, if not, set it before starting the therapy.

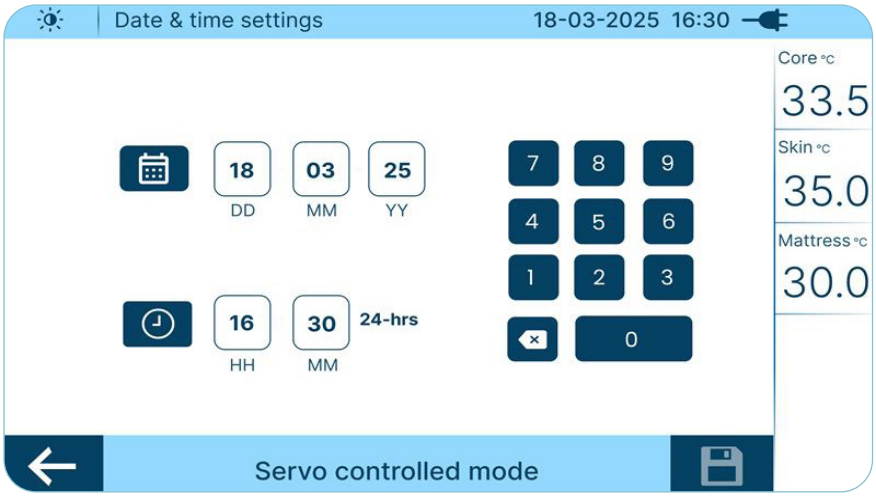


Figure 7.17.A: ***Date & time settings***

Figure 7.17.B: ***Date and time setting*** selected

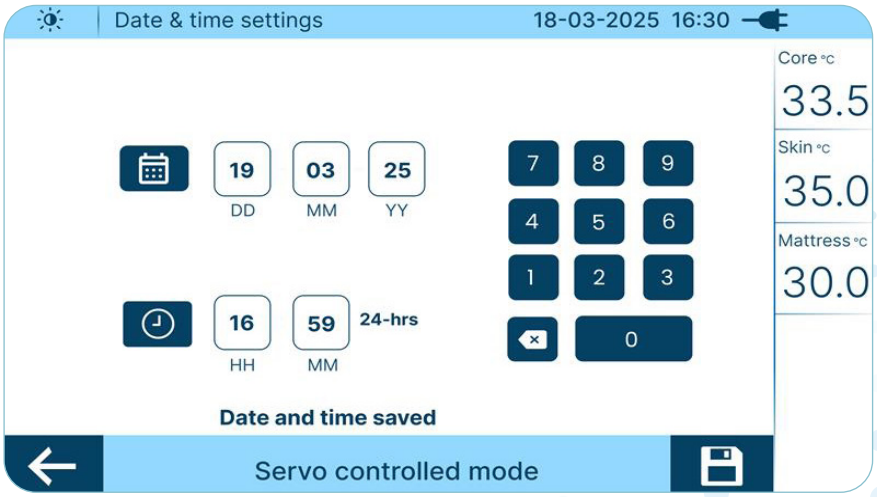


Figure 7.17.C: Date and time saved

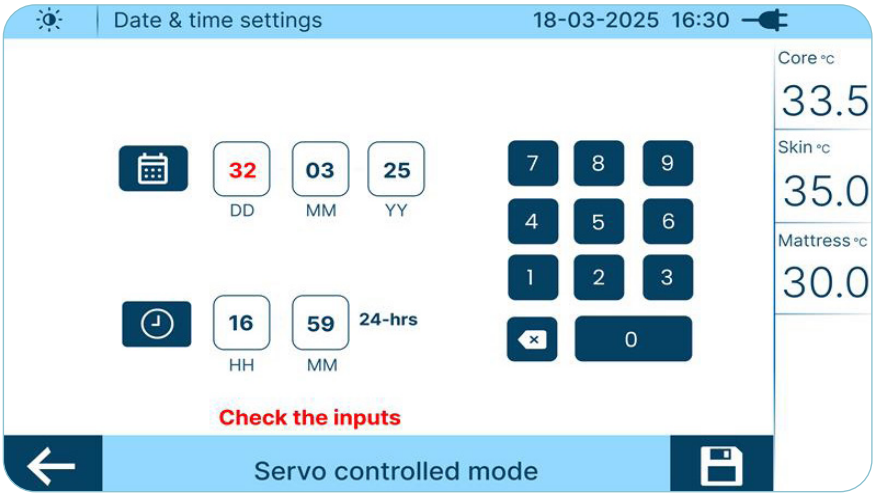


Figure 7.17.D: Invalid input date (day)

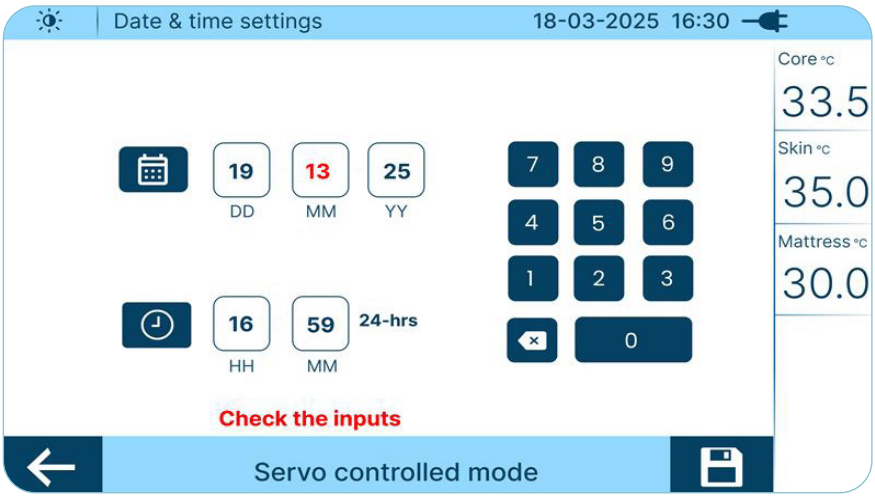


Figure 7.17.E: Invalid input date (Month)

7.18 Status screen

The status of power, battery, water level, water flow, and display systems and control systems software version will be displayed in the status screen as shown in Figure 7.18.A and Figure 7.18.B

This screen will display the current software versions installed

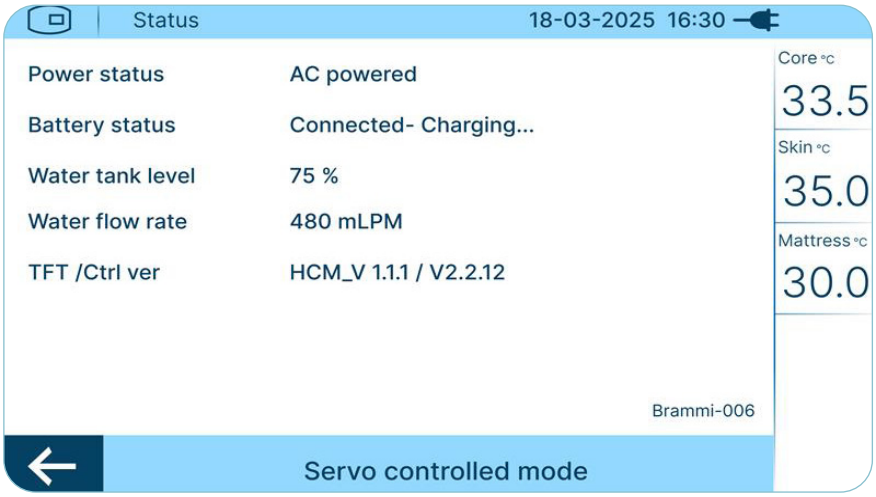


Figure 7.18.A: Status screen showing AC powered

Figure 7.18.B: Status screen showing battery powered

7.19 Edit patient ID

- The patient ID can be edited later by the operator if the patient ID is not entered at commencement of patient episode.
- The Edit icon will take to the keyboard screen where the **Patient ID** can be entered.
- The Temporary patient ID (e.g. PatientNo1) will be replaced with the actual ID.

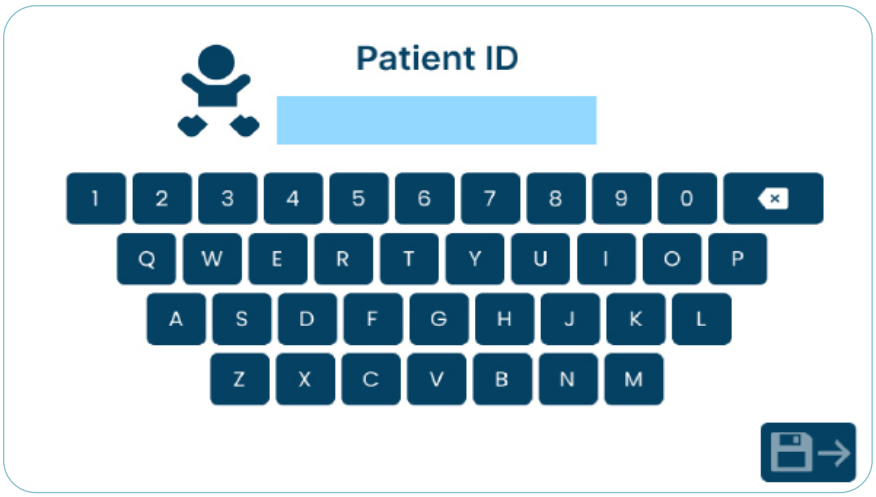


Figure 7.19.A: Keyboard screen showing the edited name

8. Alarms and Messages

Introduction

Perform alarm test before connecting the device to the patient but not during the therapy

If an alarm occurs, attend to the patient before troubleshooting or doing any repair procedures

- This device is equipped with an alarm system to ensure the safety of the patient.
- The alarms may be high, medium, or Low priority alarm or an Informational signal
- When an alarm occurs during therapy, audible tone patterns will be sound, a flashing alarm LED will illuminate, and text message(s) will be displayed at the bottom of the monitor screen.
- Visual and audible alarms give warnings about the patient's body temperature, mattress temperature, probe failure and dislocation, technical issues, and hardware and software failure.
- Press the alarm mute key to silence the audible alarm for 10 minutes.

8.1 Visual alarm message

When an alarm occurs, the following information is displayed on the screen.

For example: **High priority Alarm**

- A text message indicates the cause of an alarm condition, displayed at the bottom of the screen.
- If the measured value exceeded the internal alarm limit, the alarms will flash.

If audio tones are not audible or the alarm lights does not function properly when the device is ON, do not use the device. Contact an authorised service representative

8.2 Alarm priorities

The device can indicate three types of alarms and informational signals. The audible signal tone pattern indicates the priority/urgency of the active alarm condition.

The visual alarm indicator flashes red or yellow according to the alarm priority

High Priority Alarm

Text – White Text with RED background

Colour – RED flashing LEDs with higher frequency

Audio – Higher frequency tone with increased level of urgency

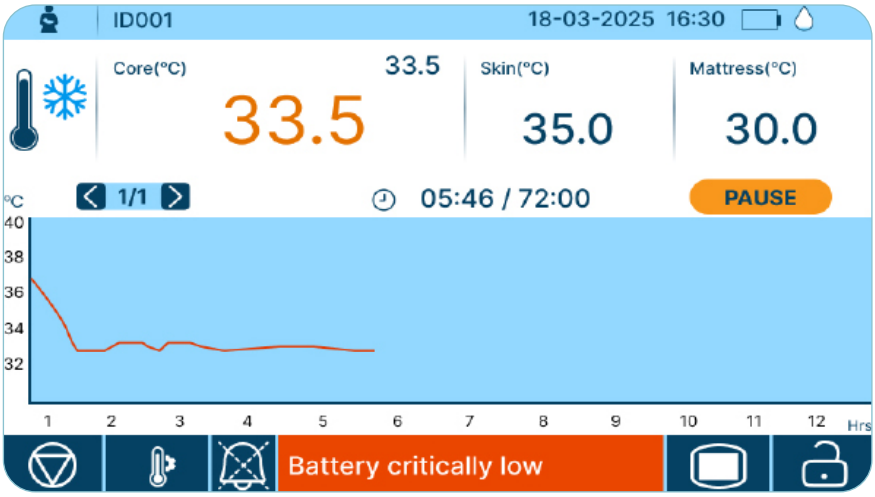


Figure 8.2.A: High Priority Alarm Message

Medium Priority Alarm

Text - Black Text with YELLOW background

Colour - YELLOW flashing LEDs with lower frequency

Audio - Medium frequency tone with standard level of urgency

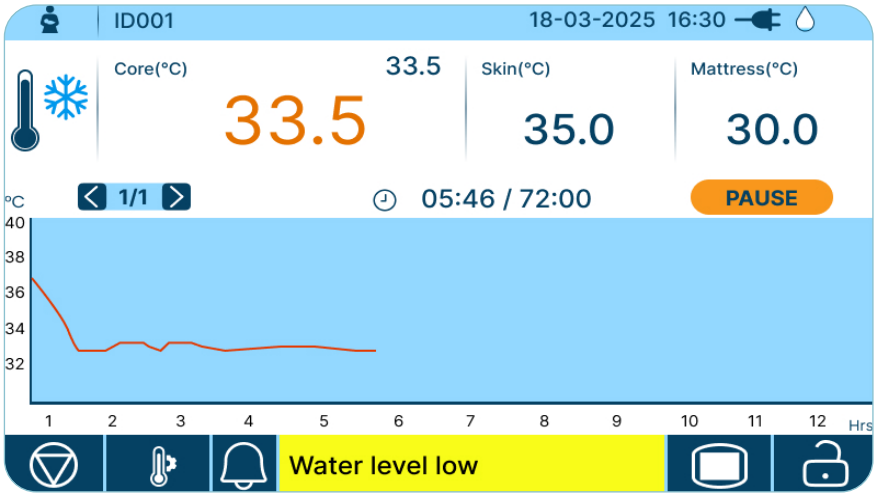


Figure 8.2.B: Medium Priority Alarm Message

Low Priority Alarm

Text - Black Text with YELLOW background

Colour - Single Constant glow of YELLOW LEDs

Audio - Two burst of tones with lowest level of urgency

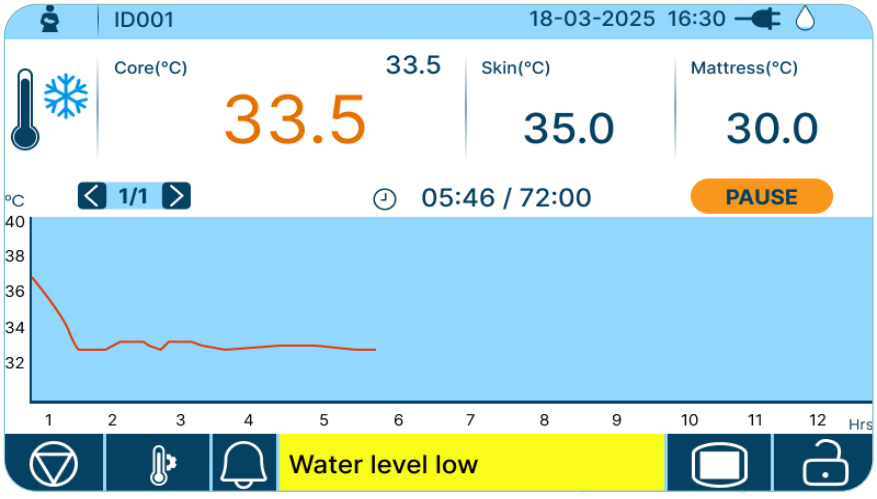


Figure 8.2.C: Low Priority Alarm Message

Informational Signal

Text – Black Text with CYAN background

Colour – No glow of LEDs

Audio – Two burst of information sound

Refer to figure 7.11.B for therapy paused Indication

8.3 Responding to an alarm

If any alarm occurs, check the patient immediately. The procedure for responding to critical alarms is different from that for medium and low priority alarms. All alarms can be silenced for 10 minutes if needed. However, All alarms can be paused until the cause is resolved or the condition clears automatically, for safety reasons

For technical errors, the first step to do is to switch off the device and restart it.

8.4 Alarm pause

- When the error message shows in the alarm/notification panel at the bottom of the screen. The device starts to alarm.
- To mute/pause the alarm(s), tap the alarm bell icon in the monitoring screen (refer the Figure 8.4 A). Once pressed, the icon will be changed to crossed bell , meaning all current alarm audio are muted (refer the Figure 8.4 B)

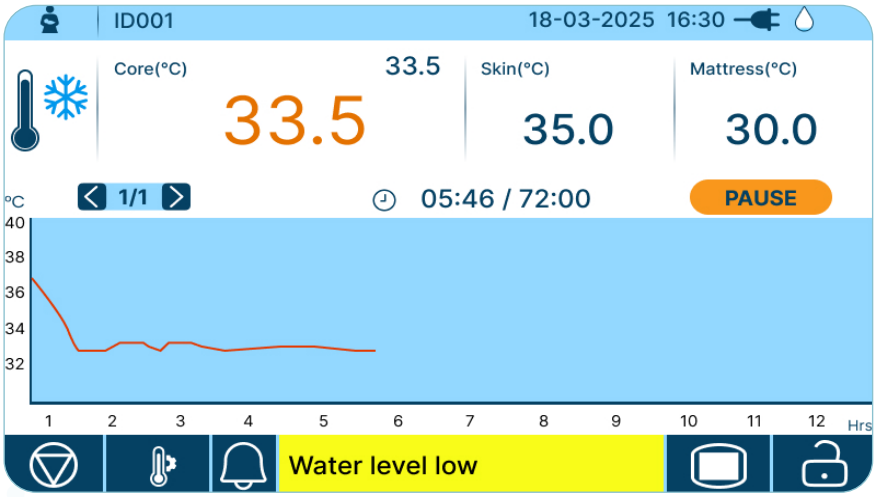


Figure 8.4.A: *Water level low* alarm before audio pause/ mute

Alarms will reset whenever therapy mode has been changed or paused.

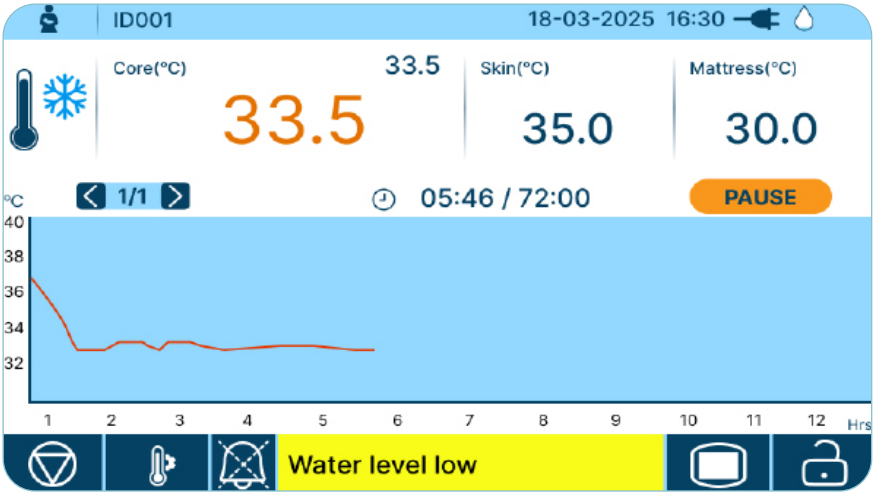


Figure 8.4.B: *Water level low* alarm after audio pause/ mute

8.5 Alarm functions

Visual and audio alarm indications, including colour coding and priority descriptions, are detailed in Sections 8.1–8.2. Refer to those sections for complete guidance on interpreting alarm messages.

Special Display Conditions:

These conditions appear on the numeric display in specific alarm scenarios:

- **Dash (—) :** Indicates temperature probe is disconnected or not detecting a reading.
- **Alarm Fail :** Indicates temperature probe malfunction.
- **Over Temp :** Indicates measured value exceeds 50 °C.

Sound Pressure Level (Measured at 3-metre distance and 1.5-metre height from display screen) at a base noise level of 45 dB

S.No	Priority	Sound Level
1	*High*	*65 to 75 dB*
2	*Medium*	*60 to 75 dB*
3	*Low*	*60 to 75 dB*
4	*Information*	*60 to 75 dB*

1		*Critical alarm—high priority*
2		*Medium priority*
3		*Low priority*
4		*Information*

In this device, the alarm limits cannot be configured by user, they are automatically controlled by the device.

Physiological Alarms

S.No.	Mode	Alarm Indication	Alarm Criteria	Priority	Actual Delay
1	Servo Mode	Baby Core Temp Too Low	Baby core temperature below 31.5°C	HIGH	4.5 s
2	Servo Mode	Baby Core Over Temp	Baby core temperature above 39.5°C	HIGH	4.5 s
3	Servo Mode	Baby Core Temp Low	Baby core temperature 0.5°C below set value	LOW	3 s
4	Servo Mode	Baby Core Temp High	Baby core temperature 0.5°C above set value	LOW	2.5 s

Technical Alarms:

S.No.	Mode	Alarm Indication	Alarm Criteria	Priority	Actual Delay
1	All Modes	System Error (Motor)	Motor loose connection with control board/Motor Failed	HIGH	15 s
2	All Modes	System Error (Fan)	Fans loose connection with the control board/ Fans fail	HIGH	2 min
3	All Modes	System Error (Peltier)	Peltiers loose connection with the control board/ Peltiers failed.	HIGH	6 min
4	All Modes	Water flow fail	Obstruction of flow/ Water level is 10% or below/Flow sensor fail.	HIGH	25 s
5	All Modes	Mattress Probe Fail	Mattress probe has a loose connection with the control board/ mattress probe failed	HIGH	7 s
6	Servo/ Cooling/ Warming Mode	Rectal temperature probe Fail	The probe is not connected or loosely connected/Rectal temperature probe failed.	HIGH	7 s
7	All Modes	Battery level Low	Battery is less than 20%	Medium	8 s
8	All Modes	Connect to mains	Battery is less than 10%	HIGH	6.5 s

S.No.	Mode	Alarm Indication	Alarm Criteria	Priority	Actual Delay
9	All Modes	Water level sensor fail	Level sensor loose connection with control board/Level sensor failed	MEDIUM	4 s
10	All Modes	Communication error	No communication between the control board and display TFT board	HIGH	7 s
11	All Modes	Power Fail	No AC power supply from the source itself, or fuse is blown	LOW	10 s
12	All Modes	Water level low	The internal tank water level is 10%	MEDIUM	4.5 s
13	Servo/ Cooling/ Warming Modes	Mattress Too Cold	Mattress temperature is less than 11.5°	MEDIUM	5 s
14	Servo/ Cooling/ Warming Modes	Mattress Over Temp	Mattress temperature is greater than 39.5°C	MEDIUM	4.5 s
15	Mattress Mode	Mattress Too Cold	Mattress temperature less than 11.5°C	High	6.5 s
16	Mattress Mode	Mattress Over Temp	Mattress temperature greater than 39.5°C	High	6.5 s
17	Mattress Mode	Mattress Temp Low	Mattress temperature 1.0°C below the set value	LOW	7 s
18	Mattress Mode	Mattress Temp High	Mattress temperature 1.0°C above the set value	LOW	7 s
19	Servo / Cooling / Warming Mode	Rectal probe Dislocated	The rectal temperature probe dislocated from the Patient 's rectum during therapy	HIGH	5 min
20	Servo/ Cooling / Warming Mode	Set temp not reached	If the rectal temperature probe doesn't reach set + or – 0.5°C after one hour from the start of the therapy	MEDIUM	6.5 s

Special Display Conditions:

S.No.	Mode	Alarm Indication	Alarm Criteria	Prioity	Alarm Delay
1	*All Modes*	*Therapy Completed*	*Mode has completed set duration*		*Immediately*
2	*All Modes*	*Therapy Paused*	*Mode pause button is pressed*		*Immediately*
3	*All Modes*	*Replace old water*	*After one complete therapy*		*Immediately*

The following alarms are suspended for a specific duration to avoid 'false positive triggers' which are as follows

Alarms	When new therapy is started	When set temperature/ duration is changed in the middle of therapy	When paused & resumed in the middle of therapy
Patient Core Temp Low (Servo)	*30 mins*	*30 mins*	*30 mins*
Patient Core Temp High (Servo)	*30 mins*	*30 mins*	*30 mins*
Mattress Temp Low (Mattress)	*30 mins*	*30 mins*	*30 mins*
Mattress Temp High (Mattress)	*30 mins*	*30 mins*	*30 mins*
Set Temp not reached	*60 mins*	*60 mins*	*60 mins*

9. Troubleshooting

- This chapter lists and describes alarms, self-tests, and troubleshooting. It also provides information about the immediate action to be taken for potential causes.
- It explains the critical and non-critical alarms and the reason for the cause

Most technical errors require the attention of manufacturer approved service technician.

9.1 Alarm potential causes and remedies

Only authorised personnel should troubleshoot the device. Troubleshooting by unauthorised personnel could result in injury to patients and/or personnel and/or damage to equipment. If the fault cannot be identified or rectified, remove the unit from use and refer the servicing to qualified personnel.

S.No.	Alarm Message	Potential Cause	Actions/Remedies
1	System Error (Motor)	Motor loose connection with control board	Contact authorised service technician
		Motor failed	
2	System Error (Fan)	Fans loose connection with control board	
		Fans failed	
3	System Error (Peltier)	Peltiers loose connection with control board	
		Peltiers failed	

S.No.	Alarm Message	Potential Cause	Actions/Remedies
4	Water flow fail	Water level is 10% and below	Fill water level to 100%
		The mattress port is either not connected to the long hose of the mattress, or the mattress itself is not properly attached to the long hose.	Connect the mattress with long hose and other end of long hose with device mattress port
			Contact authorised service technician
		Flow sensor fail	Remove excessive loads on the mattress and kinks in the tubes
		Obstruction of flow, such as kinking of tubes of mattress/ long hose Flow is restricted due to an overload of more than 5 kg placed on the mattress	
5	Mattress Probe Fail	Mattress probe loose connection with control board	Contact authorised service technician
		The mattress probe failed	
6	Rectal temperature probe fail	When probe is not connected or loosely connected	Connect the rectal temperature probe. Check whether the rectal temperature probe is inserted properly in its socket
		The rectal temperature probe failed.	Replace the rectal temperature probe. If the problem persists, contact service.
7	Battery level Low	When the battery is less than 20%	Connect the device to AC power source; rapid action is required
8	Connect to mains	When the battery is less than 10%	Connect the device to AC power source, immediate action is required
9	Water level sensor fail	Level loose connection with control board	Contact authorised service technician
		The level sensor failed	
10	Communication error	No communication between the control board and display TFT board	
11	Power Fail	When there is no AC power supply from the source itself or fuse is blown	Restore power before battery runs out (max. 1 hr), or connect to alternate source (100-240v) or replace backup fuse in the device
		When power cord is loosely connected or not connected to AC source	Replace the power cord if necessary. Connect the power cord to device properly and turn ON the switch at the back of the device

S.No.	Alarm Message	Potential Cause	Actions/Remedies
12	Water level low	When internal tank water level is 10%	Fill water level to 100%
13	Mattress Too Cold	When mattress temperature is less than 11.5°C	Remove external heat or cold sources. Mute the alarm and wait for it to go off.
14	Mattress Over Temp	When mattress temperature is over 39.5°C	No action needed, if the problem persists, contact device supplier
15	Mattress Temp Low	When the mattress temperature is 1 °C below the set value	No action needed, if the problem persists, contact device supplier
16	Mattress Temp High	When the mattress temperature is 1 °C above the set value	No action needed, if the problem persists, contact device supplier
17	Rectal temperature probe Dislocated	When the rectal temperature probe is dislodged from the patient 's rectum during the therapy	Check whether the rectal temperature probe is inserted properly into the patient's rectum as per hospital guideline
18	Patient Core Temp Too Lo	When the patient core temperature is less than 31.5°	Monitor the patient closely/Consult a healthcare professional
19	Patient Core Over Temp	When the patient 's core temperature is greater than 39.5 °	Monitor the patient closely/Consult a healthcare professional
20	Patient Core Temp Low	When the patient core temperature is 0.5°C below the set value	Monitor the patient closely/Consult a healthcare professional
21	Patient Core Temp High	When the patient core temperature is 0.5°C above the set value	Monitor the patient closely/Consult a healthcare professional
22	Therapy Completed	When the therapy has completed	Check whether the therapy duration has reached the set duration
23	Therapy Paused	When the Pause button is pressed	Press resume to continue cooling/ rewarming. Monitor the patient closely
24	Set temp not reached	When the patient core temperature did not reach the set value	Monitor the patient closely. Consult a healthcare professional.

9.2 General troubleshooting

S.No.	Problems	Action	Measures
1	Water leakage in hose or mattress	Check whether the connectors to the hose and the mattress are connected firmly.	Replace the damaged part.
		Check for any visible punctures in the mattress.	
2	Broken connectors	Check whether the connectors are loose or damaged	If the connectors in the device are damaged or loose, switch off the device and contact authorised service technician.
			If the damaged connector is part of the mattress, fill the bottle or loop and replace the damaged part.
3	Water Leakage from the device	Check if fluid is leaking from the sides of the device.	Switch off the device. Remove from clinical use. Contact authorised service technician.
4	Formation of air bubbles in mattress	Check if water level is filled	Make sure that the mattress is placed on a flat surface. Ensure that the water tank is filled. Turn the mattress upside down while running in mattress mode to remove all the air bubbles.
5	System Error/ Failures and Mattress probe fail	Check the power and restart the device.	If the alarm persists, the device will stop within 15 mins; remove it from clinical use and contact service.
6	Alarm LED and Speaker not working	Do not use the device if alarm system malfunctions	Contact authorised service technician.
7	Display not turning ON and touch not working	Check for any physical damage to the display	Restart the device; if not restored, contact authorised service technician.
8	Probes Fail	Check for backup	Contact authorised service technician.

The RS232 port shall be used by authorised service personnel only.

10. Cleaning and Maintenance

Follow these maintenance procedures to ensure the safety and reliability of the device. All the procedures in this manual are intended to be performed by the operator. For further maintenance, contact the service representative.

All replaced parts must be disposed of in accordance with local environmental regulations regarding the disposal of used devices and waste.

Do not use non-recommended cleaning solutions, which can cause degradation of the product.

Use of cleaning solutions containing chemicals (i.e., alcohol, acetone, etc.) or chemicals in greater concentrations may cause damage to the device.

Use the cleaning solution sparingly on a cloth when cleaning the device. Excessive solution causes damage to the internal components. Never allow liquids to seep into the head of the device.

Exposure to sterilising agents may reduce the useful life of certain parts. Using more than one sterilization technique on a single part may damage the environment.

Always be careful when cleaning to ensure that you do not damage any part of the device.

SOP of manufacturer recommended solutions manufacturer to always be followed

Do not try to sterilise the mattress.

Do not sterilise the mattress, the interior, or the exterior of the device, except when performing the approved cleaning cycle described in Section 10.3

Do not use water or any other liquid to clean electrical or electronic parts.

Prior to cleaning, switch off the system and unplug it from the AC mains.

10.1 Patient-contact accessories (mattress and probes)

Applicable Items: Mattress, rectal probes, skin probes

Preparation & Solutions:

- These are single-use only for one patient, one time.
- Do not sterilize. You may clean the surface before first use if desired.
- Dispose of accessories immediately if they become soiled during therapy.

Cleaning Method:

- Not required (single-use only)

Disinfection Method:

- Not required. Dispose of after use.

10.2 Non-patient-contact standard parts

Applicable Items: Long hoses, loop, bridge coupler, extension hose, filling bottle, connectors.

Cleaning Method:

- Routine hospital Infection Prevention/Control (IPC)-approved products for cleaning can be used
- It is recommended to use detergent-impregnated disposable wipes or a general-purpose neutral detergent in a warm water solution (approximately 0.1%).
- Wipe surfaces with a cloth dampened in detergent solution (Applies to detergent solution method).
- Remove extra solution and let parts air dry (Applies to detergent solution method).
- Do not use strongly caustic or acidic products.

10.3 Main device and trolley

Applicable Items: Device housing, display, vents, base, bottom panel, front connectors, trolley handle, pillar, basket guide, basket, wheels.

Cleaning Method:

- Refer to Section 10.2 for the cleaning method.

10.4 Internal hydraulic system

Applicable Items: Internal water tank and hydraulic pathways

Cleaning & Disinfection Method:

- Drain water until 0%.
- Connect tank-cleaning loop to long hose connected to the mattress port.
- Include extension hose, if necessary to clean.
- Prepare chlorine water (1 tablet per 1 litre sterile water, 10–50 ppm).
- Fill the tank and run mattress mode at 39°C for 2–3 minutes.
- Drain and rinse twice with sterile water.
- Clean the tank monthly or immediately if foamy

10.5 Cleaning air filter

Applicable Items: Air filter and tray (lower left side of device).

Cleaning Method:

- Switch off and unplug the device.
- Release and remove the filter tray.
- Wipe gently with cloth dampened in detergent solution or detergent-impregnated disposable wipes.
- Rinse tray and filter pores with clean water.
- Ensure pores are not blocked before reuse.
- Dry completely and reinstall.

Check and clean the air filter weekly to maintain airflow and cooling. More frequent cleaning may be necessary if operated in dusty environments, as clogged filters can impair cooling efficiency and affect device performance. If the filter is damaged or cannot be cleaned, dispose of it and use a new, clean air-filter tray.

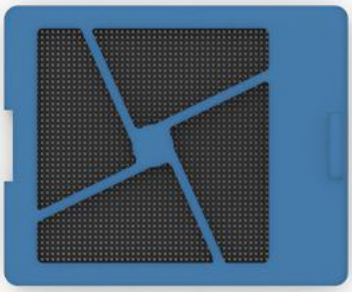


Figure 10.5.A: Air filter

11. Maintenance and Preuse Checks

11.1 Regular maintenance control

Regular maintenance inspections and controls shall be carried out at least every 6 months.

Do not use the device and contact your responsible device supplier for an inspection of the device in the event of:

1. Unexpected patient symptoms during treatment
2. Unexplained performance or sound changes during operation.
3. Suspected damage to the device

Visual Inspection

Items to check before use	Description
Appearance	*The device should be completely cleaned as per Chapter 10. Both the main device and the mattress should be free of damage*
Castors level with floor and its brakes	*Should function properly.*
Alarm system (LED and Speaker)	*Should work on a self-test.*
Push ON button	*Should turn the power on/off reliably and green light should glow.*
AC Power switch	*Should turn the power on/off reliably.*
Air Filter	*Should be clean*
Touch Calibration	*As described in 11.5 Touch calibration*
Touch Calibration	*As described in 6.7: Electrical Specification* *As described in 6.3: Environmental Specification*
Battery	*As described in 11.7 Battery maintenance*

Testing

Items to Check	Procedure	Description
Mattress Probe Temperature	*Set the temperature to 36.0°C in mattress mode with mattress connected*	*After 30 mins, displayed mattress temperature should be stable at 36.0 ± 0.5°C*
Alarm trigger checks	*Turn the power on and then remove the power plug from the power outlet.*	*Check that the "Power Fail" alarm indicator comes on*
	Disconnect the long hose/ loop from unit while running	*Check that the "Water flow Fail and Mattress probe Fail" alarm indicator comes on.*
	Empty water tank to 10% and run the unit.	*Check that "Water level low" indicator comes on.*

11.2 Service and repair

If any defect or malfunction is identified during inspection or operation:

- Clearly mark the device as "Out of Order" to prevent further use.
- Immediately notify the manufacturer or authorised service provider for assistance.

Any functional issues or errors identified during testing, inspection must be corrected exclusively by authorised service personnel in accordance with the manufacturer's service protocols and applicable regulatory requirements.

11.3 Touch calibration

To perform a touch Calibration,

Go to "Menu." touch symbol for calibration.

It displays "Initiate touch calibration." "Press to start calibration.

System restarts, and it displays "+" at four points; press finger on the centre points of those symbols to achieve proper calibration of touch.

11.4 Maintenance of battery

In case of a power failure, the internal battery continues to power the device for a maximum of 1 hour, from its fully charged state.

The performance of the device, remains the same when operated in the battery or while recharging, except in Low battery Alarm Conditions.

The backup battery is intended for short-term use only. It is not intended to be a primary power source

Never leave the patient unattended during battery operation.

Only manufacturer authorised service personnel should replace the battery

Dispose of the batteries according to local regulations

Battery handling, safety, and charging instructions

To ensure maximum battery life and optimal performance:

- Recharge the battery promptly when the charge level reaches approximately 30%.
- Before clinical use, the manufacturer recommends fully charging the battery. If the battery is not fully charged and an AC power failure occurs during operation, continuously monitor the remaining battery charge level to ensure uninterrupted functionality.

Battery safety precautions

- Keep the battery away from sparks, open flames, and heat sources.
- Never short-circuit the battery terminals.
- Do not dispose of the battery in fire or incinerate it, as this may result in explosion or fire.
- Do not expose the battery or any electrical components (e.g., battery, circuit boards) to water or other liquids.
- Do not subject the battery to direct flames, high temperatures, or physical damage.

Battery disposal

- Dispose of depleted or damaged batteries through authorised recycling centres in accordance with applicable local, regional, or national environmental regulations.

11.5 Maintenance of fuse

Purpose

The fuse protects the device from electrical overloads and ensures safe operation. Regular inspection and proper replacement of the fuse are essential to maintain electrical safety and device functionality.

Maintenance instructions

Inspection frequency

- Inspect the fuse condition at least once every 12 months.
- Additionally, inspect the fuse if the device fails to power ON or shows signs of electrical malfunction.

Identification

- The fuse type, rating, and location are specified on the device label or in the Technical Specifications section of this manual (Chapter 6).

Safety precautions

- Disconnect the device from the mains power supply before inspecting or replacing the fuse.
- Only qualified service personnel should perform fuse replacement.
- Use only fuses of the specified type and rating. Substituting with incorrect fuses may compromise device safety and void the warranty.

Fuse replacement procedure

- Turn OFF the device and unplug it from the power source.
- Locate the fuse holder (near the power inlet).
- Remove the fuse holder using an appropriate tool.
- Carefully remove the blown fuse.
- Insert a new fuse of the same type and rating.
- Reinstall the fuse holder securely.
- Reconnect the device and verify proper operation.

Post replacement procedure

- Ensure that the device powers ON and operates normally.
- If the fuse blows repeatedly, do not replace it again. Contact an authorised service provider for further inspection.

Do not bypass or short-circuit the fuse.

Do not use makeshift or modified fuses.

Using incorrect fuses may result in electric shock, fire hazard, or permanent device damage.

11.6 Periodic replacement parts

- The actual replacement interval may vary depending on usage frequency, environmental conditions, and operating circumstances. For guidance on replacement timing and recommended service schedules, please consult the authorised service provider.
- Refer to the tables below for a list of periodic replacement parts.
- For detailed procedures on inspection, repair, and replacement of these components, please refer to the device's service manual

S.No.	Part Number	Part Description
1	*2SP00475*	*Water Flow Sensor*
2	*2SP00476*	*BLDC Motor/Pump*
3	*2SP00477*	*Heat Engine DC FAN*
4	*2SP00478*	*Control Board*
5	*2SP00479*	*TFT Board*
6	*2SP00480*	*SMPS*
7	*2SP00481*	*Battery*
8	*2SP00482*	*EMI filter*
9	*2SP00483*	*Power cord*
10	*2SP00484*	*Push button*

S.No.	Part Number	Part Description
11	2SP00485	Water Level Sensor
12	2SP00486	Safety valve
13	2SP00487	Alarm LED PCB
14	2SP00488	Speaker
15	2SP00489	Mattress Probe t-connector
16	2SP00490	TFT Display
17	2SP00491	CPC Female Connector
18	2SP00492	Heat Engine
19	1C000201	Tank cleaning loop
20	2SP00493	Tank with level sensor
21	2SP00494	Hydraulic tube
22	2SP00495	Front Panel sticker
23	2SP00496	Top cover
24	2SP00497	Bottom cover
25	2SP00498	Nylon bush with screws
26	2SP00499	USB port
27	1C000202	Filling jar
28	1C000203	Long hose
29	1C000204	Extension hose
30	1C000205	Bridge coupler

11.7 Disposal

Electronic waste (Device)

- The main device contains electronic components and must be disposed of in compliance with applicable local, regional, and national regulations governing electronic waste (e-waste).
- Do not dispose of the device with general household or municipal waste.
- Utilise authorised e-waste collection and recycling facilities or return the product to the supplier if a take-back or product stewardship program is available.

Clinical waste (accessories: mattress, skin probes (1C000005), rectal temperature probes)

- The provided accessories intended for (such as the mattress, skin probes (1C000005), and rectal temperature probes) may be contaminated following patient use. These items must be treated as clinical waste and disposed of in accordance with applicable biomedical waste disposal regulations and applicable guidelines.

General disposal of device, accessories, and replaced parts

- The device, all associated accessories, and any replaced components must be disposed of and recycled in accordance with local environmental regulations pertaining to used medical devices and waste management.
- Metal Components: All metal parts are recyclable and can be processed through standard re-melting recycling methods.
- Plastic Packaging Materials: The plastic sheets used for wrapping, and the polystyrene packing materials provided with the device, are not recyclable. These should be disposed of in accordance with applicable environmental disposal regulations.

12. Warranty

Warranty terms and conditions

The warranty covers manufacturing defects and defects in workmanship for a period of one (1) year from the date of purchase.

Consumables and disposable items:

All consumables and disposable accessories are warranted to be free from defects only at the time of dispatch. No further warranty applies to these items after delivery.

Warranty service:

- During the warranty period, any defective parts, except for consumables and disposable items, will be repaired or replaced free of charge. Labour charges for replacement of parts will not apply when service is performed within the state of the original purchase.

Warranty exclusions

This warranty shall be void and not applicable under the following conditions:

- Damage resulting from misuse, mishandling, negligence, or improper operation of the device.
- Failure to properly maintain or service the device in accordance with the manufacturer's guidelines.
- Use of unauthorised parts, accessories, or fittings not recommended or approved by the manufacturer.
- Repairs, modifications, or service performed by unauthorised personnel or service providers.

Limitation of liability

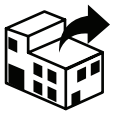
The manufacturer shall not be liable for any incidental, indirect, or consequential damages, including but not limited to:

- Loss of use
- Damage to property
- Personal injury arising from or related to any breach of this warranty.

In case any serious incident occurs in relation to the device, it should be reported to the manufacturer and to the competent authority of your country. If you are in a member country of the European Union (EU), or in the United Kingdom (UK), you may also report it to the manufacturer's European Authorised Representative or UK Responsible Person, as applicable

13. Contact Information

Manufacturer
Phoenix Medical Systems (P) Ltd.
DP-42, SIDCO Industrial Estate,
Thirumudivakkam,
Chennai – 600132, INDIA.



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