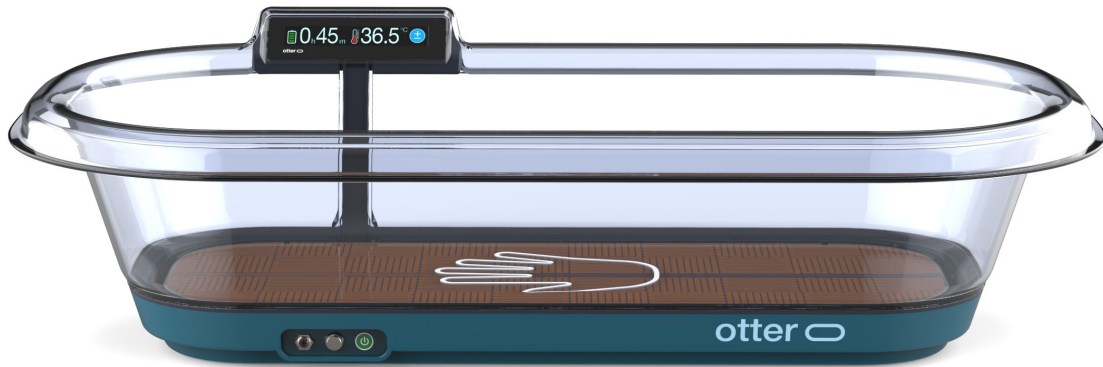


otter



User Manual

MD Infant Conductive Warmer

Otter

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www.mtts-asia.com

CE 2265

 **MTTS**

Contents

Company Information	04
Introduction	05
Device Description	06
Safety Information	08
Setting up the Device	11
Using the Device	12
Alarm System	15
Cleaning and Disinfection	18
Maintenance	19
Specifications	20
Explanation of Symbols	22
Warranty Policy	23



MEDICAL TECHNOLOGY TRANSFER AND SERVICES Co., LTD
House No. 26, Alley 41, An Duong Vuong Street, Tay Ho District, Hanoi City, Vietnam
SRN: VN-MF-000036669

Tel: +84 24 3766 6521
Fax: +84 24 3718 8050
Email: assistance@mtts-asia.com
www.mtts-asia.com

Logic s.r.l.
Via Antonio Pigafetta 1
34147 Trieste, Italy
SRN: IT-AR-000012301



Intended purpose

The intended purpose of Otter Conductive Warmer is to keep newborn babies normothermic. Otter is designed for hospital use only.

Intended users

- a) The device is to be operated by qualified personnel only.
- b) Knowledge (minimum):
 - Understands basic principles of conductive warmer
 - Understands the specialized care needed for pre-term and full-term neonates
- c) Language Understanding: Can read and comprehend user manual
- d) Experience (minimum): Qualified medical professional with experience neonatal care

Intended patient population

- Age: Premature and full-term neonates
- Weight: < 5kg
- Nationality: Any
- Patient State: patient is not user

Indications

Conductive warmers are used to prevent and reduce temperature loss in newborns who are not able to maintain their body temperature (e.g. hypothermia...). Conductive warmers provide conductive heating either below or around the patient while also allowing health care workers with visibility and access to the baby.

Contraindications

There are some contraindications to neonatal conductive warmer devices:

- Conductive heating should not be used when an infant has open wounds.
- Infants with conditions: fever, dermatitis.
- Infants with circulatory compromise – severe hypothermia, sepsis.
- Infants with brain damage, asphyxia, hydrocephalus: thermo-regulation center in brain may be permanently damaged, thus mask signs of temperature instability.

Limitations

- The effective surface area is 48 cm x 18 cm (864 cm²)

Clinical Benefit

The clinical benefit is the ability to maintain the patient's target temperature within the normal range (36.5–37.5°C), reducing the risk of hypothermia by 10%.

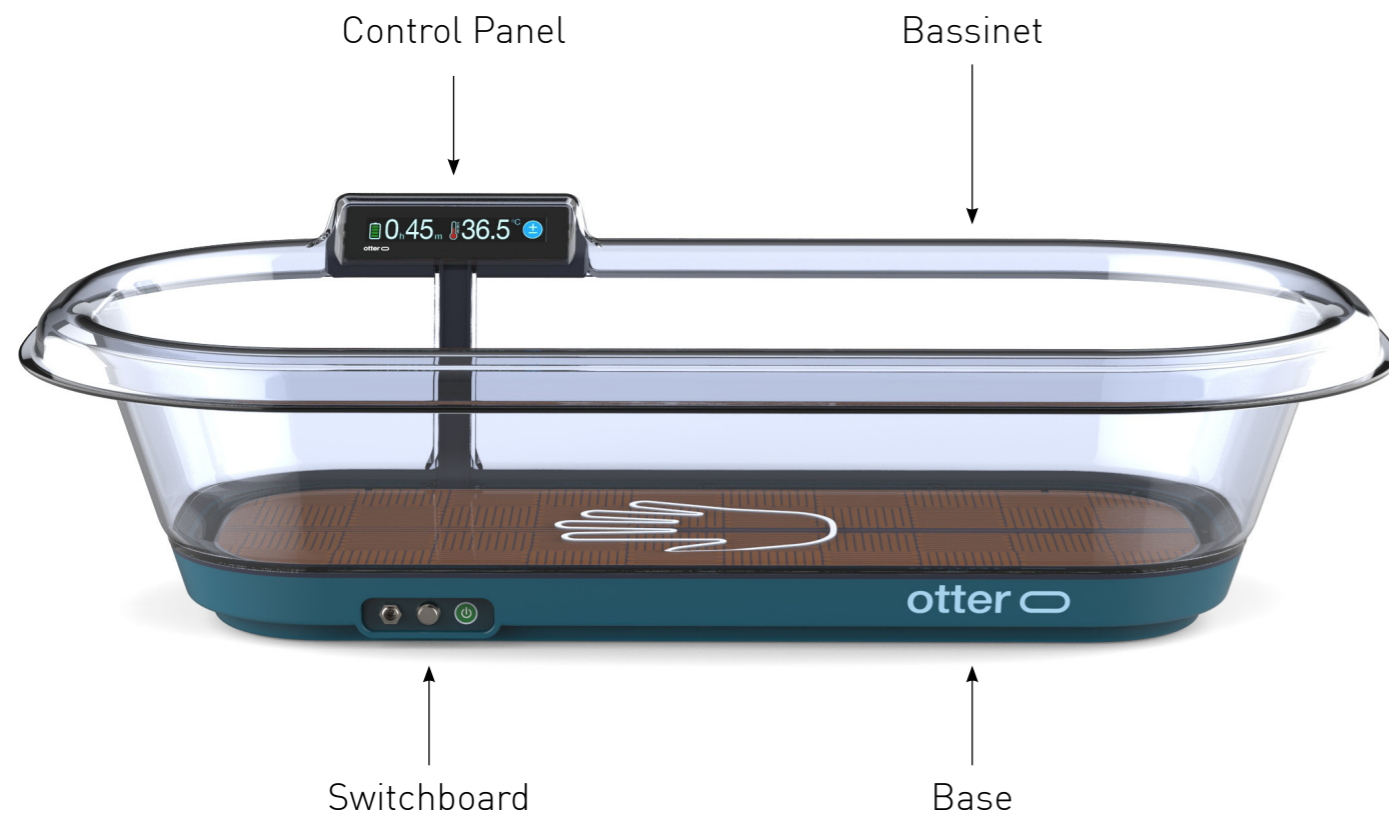
Side effects

Conductive layer warming units, like other heating devices, have the potential to cause burn injuries. Patient burns can result from use of the device for extended periods of time on high temperature settings.

NOTE: Any serious incident that has occurred in relation to the device should be reported to MTTS and the competent authority of the Member State in which the user and/or patient is established.

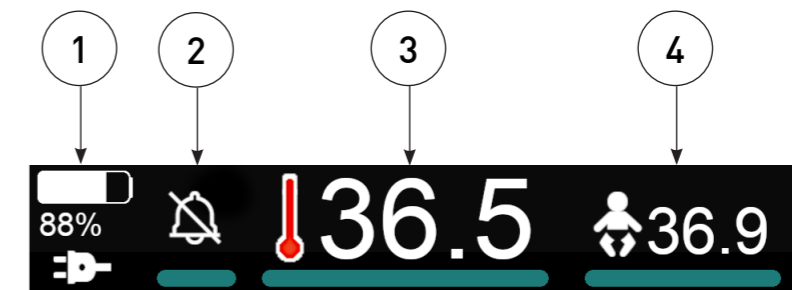
Device Description

Overview



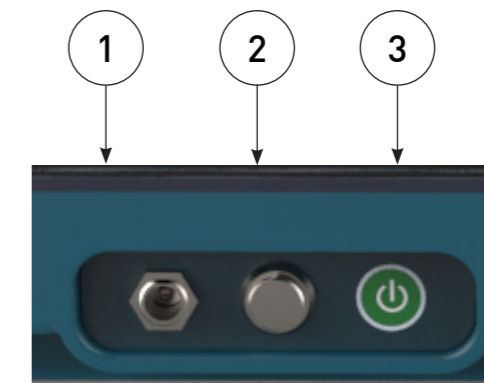
Device Description

Control Panel



1	Power Status	Information on the power source and battery time remaining
2	Alarm Mute	Temporarily silence alarm sounds for 10 minutes
3	Set Temperature	Set point selection and display
4	Skin Temperature	Skin temperature display (when skin sensor connected)

Switchboard



1	Power Inlet	Connect Otter Power Supply.
2	Skin Sensor (optional)	Connect Otter Skin Sensor.
3	ON/OFF button	Press this button to turn Otter display and functions on and off.

Safety Information

Warnings

- The device should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known risks and benefits of conductivewarmer equipment use.
- Using the device outside of the specified ambient temperature range (15-35°C) or humidity range (0-90%RH) can compromise performance.
- If used with other sources of heat, e.g. radiant heaters, the patient must be monitored to exclude any hazard due to excessive body temperatures. Combinations with radiant heaters with skin monitors or radiant heaters without skin monitors must be adjusted so that the bassinet surface does not exceed the indicated actual value.
- A cold bassinet, or a basinet which is cooling down due to the heating being switched off, will decrease the body temperature of the baby. Likewise, a too warm bassinet can induce fever.
- Covering a patient with a pillow or other heavy heat insulating material can lead to overheating of the patient.
- The presence of electro-surgical devices, shortwave or microwave equipment near this device could lead to electrical interference that negatively affects the function of the device.
- The optional temperature monitor is intended for added safety purposes only, please use a dedicated hospital grade precision thermometer, and a method in accordance to hospital procedures for precise measurements of the patients actual body temperature.
- The device cannot measure or control the baby's skin temperature if the skin sensor is not correctly positioned on the baby.

Safety Information

- Use only MTTS skin sensors to measure the baby's skin temperature.
- Regularly check that the skin sensor remains correctly positioned on the baby.
- Ensure that the skin sensor is always in direct contact with the baby's skin.
- Never place an obstruction between the heater and the skin sensor.

Caution

- Always place the device on the stable surface before starting the treatment.
- Do NOT position the device in a location that impairs its ventilation.
- Do NOT modify this equipment without authorization of the manufacturer.
- DO NOT disassemble any part of the device. None of the parts of the device are designated to be repaired or replaced by service personnel. In case of any problems, contact the nearest MTTS representative.
- DO NOT use non-standard power cords with the device. Using non-standard power cords can result in damaging the device.
- DO NOT use the device if it appears that any part of the device is not functioning properly or if any parts appear damaged. Contact MTTS.
- In case of any malfunction DO NOT attempt to service this machine. Otter Conductive Warmer should only be serviced by a qualified MTTS technician.

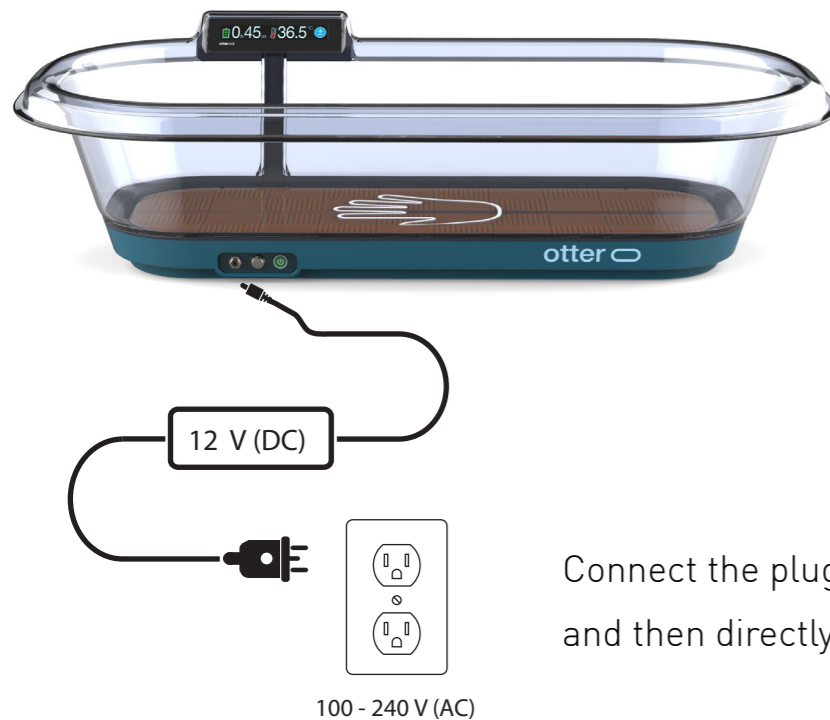
Setting up the Device

Box content

Each Otter set includes:

- Otter unit
- External power supply
- Screwdriver (to access batteries inside the base)
- Blanket (optional)
- Skin sensor (optional)
- Skin sensor clip (optional)
- Skin sensor tape (optional, to attach sensor to the patient)

Plug in and power up



Connect the plugs into the Otter switchboard and then directly into the power outlet in the wall.

⚠ Caution

- Only use the cable and connector that is provided by MTTs.
- The device should only be used with the power outlets that have a protective earth (ground) pin.

Setting up the Device

Adding and removing the batteries

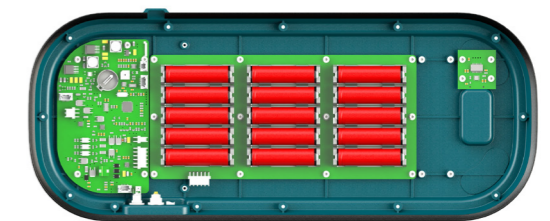
The battery backup allows operating the device for up to 6 hours without AC power supply. The backup activates automatically as soon as the AC power supply is off. The back time depends on the number of battery cells installed.

⚠ Caution

- Use only AWT IMR18650, 3.7V, 3000mAh battery type or equivalent.
- The batteries must be installed in series of 3 (e.g. 3, 6, 9, 12 or 15)
- The batteries might have to be removed for the transportation by air. Refer to latest IATA and airlines specific requirements for more information.



Remove all 13 screws connecting base to the bassinet using a screwdriver



Access the batteries located at the bottom of the base.

Add / remove in series of 3.

Keep the equal distribution for better balance of the device.



Using the Device

Placing the patient

- Place the infant inside the bassinet only when the desired (set point) temperature is reached.
- Position the lightly dressed infant (diaper, long arm T-shirt, bare legs and a cap on very small ones) on its back in the bassinet.
- Cover the patient with suitable cover if necessary, such as 1-3 layers of cotton blankets.

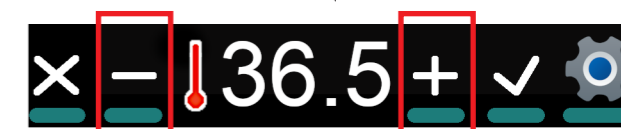
Temperature setting

- All babies are individuals, and their temperature must be controlled frequently until you are familiar with the baby's reaction to the water temperature. Overheating is often caused by covering the baby too much.
- 37°C is a good starting temperature for slightly hypothermic babies and for babies weighing less than 1000g.
- 36.5°C is the most common temperature for babies weighing more than 1000g
- As the baby's weight increases, the temperature is primarily controlled by changing the number of blankets that cover the baby and secondly by changing the temperature in 0.5°C increments.
- When the lightly dressed and covered baby is maintaining body temperature with a set point temperature of about 35.5 - 36°C, then the baby is most often ready for a standard cot that has no warming.

Using the Device



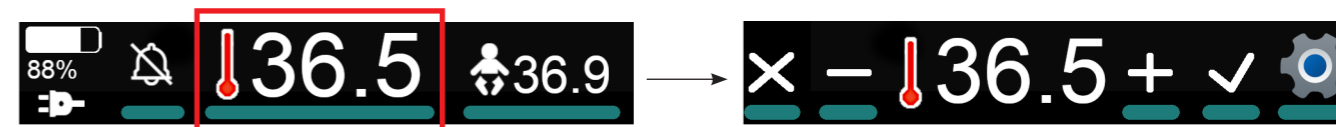
Adjust set temperature up or down



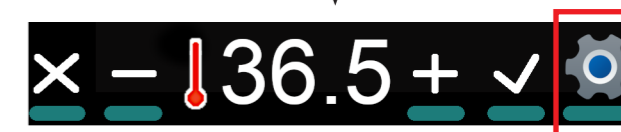
Accept or cancel selection



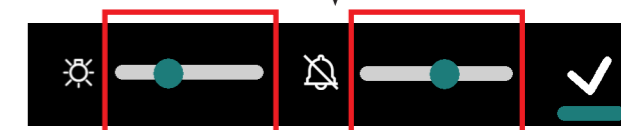
Other settings



Other settings



Adjust brightness and volume



Accept selection



Using the Device

Skin Temperature Information

When skin temperature sensor is connected the measured temperature is displayed.

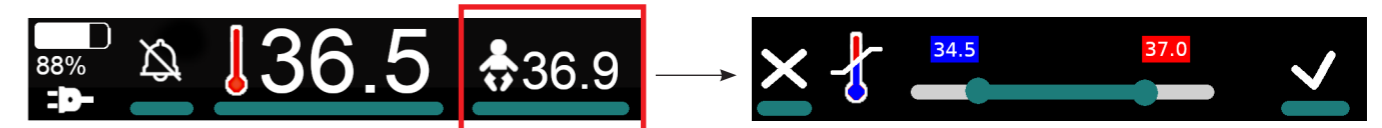


When skin temperature sensor is disconnected "--.-" is displayed.



Alarm System

Skin Temperature Alarms



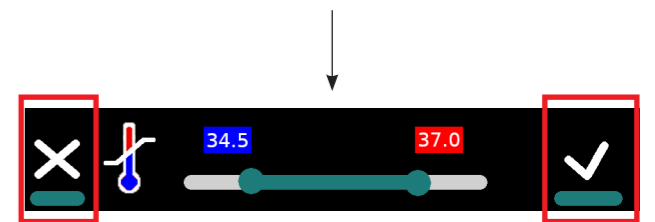
Set upper and lower range of the alarm.



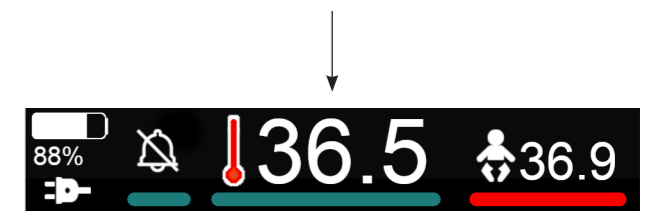
Accept or cancel selection.



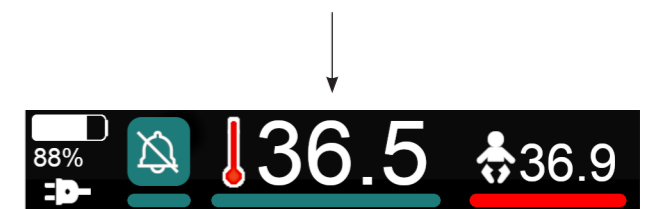
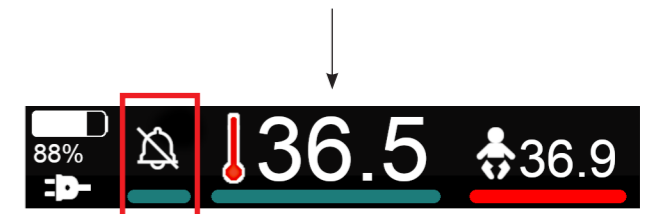
LOW or HIGH skin temp. alarm is indicated by flashing red bar under skin temperature display. The alarm goes off when the actual temperature exceeds the set point by more than 1°C.



Mute the alarm.



Alarm mute is indicated by colour-marked mute symbol. The device can be muted for max 10 min.



Alarm System

Device Temperature Alarm

LOW or HIGH device temp. alarm is indicated by flashing red bar under device temperature display. The alarm goes off when the actual temperature exceeds the set point by more than 1°C.



Battery Status and Alarm

When the device is connected to AC power source, the charging status is displayed.



When the device runs on batteries, the estimated remaining time of operation is displayed.



When the batteries reach 20% of the charge level, the battery symbol turns yellow.



When the batteries reach 0% of the charge level, the battery symbol turns red.



! Caution

Once the batteries level reach 0% of the charge level, the device turns into emergency mode for 5 minutes and then it shuts down.

Alarm System

System Error Alarm

If the device detects a system failure, it will display the error code and shut itself down.



! Caution

Turn the machine off and then on again. If the error message is still present, note the error number and contact your MTTs representative.

Alarm System Test

To verify the operation of auditory and visual alarms, perform the following procedure:

Skin Temperature Alarms

1. Plug in the skin temperature sensor.
2. Adjust the upper and lower range of the alarm to be outside the actual skin temperature sensor reading.

Device Temperature Alarm

1. Power on the device.
2. The device temperature alarm is active until the device temperature is below 1°C from the set point.

Cleaning and Disinfection

Bassinet

- The Otter bassinet should be disinfected, before and after the treatment of each patient. In the case that a patient undergoes treatment for more than one week then be sure to disinfect the bassinet once a week.
- If visibly soiled, clean the affected parts with soap and water using a soft cloth. Then wipe with a wet cloth and dry with a soft cloth. For difficult areas use a standard soft-bristled brush.
- To loosen heavy, dried-on soil, you may first need to saturate the spot with water.
- Only disinfect the bassinet with a solution containing at least 70% alcohol. Apply the disinfectant with a clean cloth or soft sponge. Wait for the device to dry after cleaning or disinfecting before use.
- DO NOT use alcohol to disinfect any other part of the device.
- DO NOT immerse any part of the device in water or alcohol.

 When cleaning the device disconnect the power cord.

Skin Sensor

- Clean Otter skin sensor with alcohol, or detergent or soap solution (maximum 2% in water), ensuring the manufacturer's directions for use of the cleaning agent are followed.
- Apply the cleaning solution with clean cloth or sponge, and dry all surfaces after cleaning with a clean, soft cloth or paper towel.
- DO NOT autoclave or gas sterilise the Otter skin sensor.
- DO NOT pull on the sensor cup or sensor plug during the cleaning or drying as the skin sensor may be damaged.
- Ensure the skin sensor is only removed from the controller by grasping the plug at the front panel. Ensure excessive strain is not placed on the sensor lead either during use, cleaning or inspection.

Maintenance

Caution

- Only qualified personnel should carry out service and maintenance procedures.
- To avoid the possibility of burns when performing maintenance procedures, ensure the warmer is disconnected from the power supply by removing the plug from the mains outlet and the heater element is allowed to cool for 10 minutes.
- To avoid the possibility of electric shock hazard when performing the maintenance procedures, ensure the device is disconnected from the power supply by removing the plug from the mains outlet.
- After the maintenance is completed, ensure the equipment is functioning correctly in accordance with the published performance specifications.
- Ensure only approved replacement parts are used during service and maintenance procedures.
- Contact an authorised MTTS representative for further assistance with any servicing or maintenance requirement.

Maintenance procedure

- The device should be checked at least annually to ensure reliable operation.
- Examine the bassinet, base, and display for mechanical damages.
- Check the batteries for potential leaks and damages.

Specifications

Physical Specifications

Dimensions (LxWxD)		68 cm x 36 cm x 19 cm
Total unit mass	without batteries	3 kg
	with 150 Wh batteries	5 kg
Maximum load		5 kg
Ingress Protection		IP53
Alarms	High Priority Audible	5 pulse burst, followed by 0.5 second delay, followed by 5 pulse burst, followed by 3 second delay
	High Priority Visual	Red flashing at 1.5 Hz
	Medium Priority Audible	3 pulse burst, followed by 2.5 second delay
	Medium Priority Visual	Yellow flashing at 0.5 Hz
	Alarm Volume	Adjustable

Performance Specifications

Heating element rating power		50 W
Effective surface area		48 cm x 18 cm
Surface temperature control	range	35 °C - 38 °C in steps of 0.5 °C
	uniformity	< 1 °C
	accuracy	±1 °C
Surface temperature	measurement range	15 °C - 42 °C
	accuracy	0.5 °C
	resolution	0.1 °C
Skin temperature	measurement range	10 °C - 50 °C
	accuracy	0.1 °C (in 34 °C - 37.5 °C range)
	resolution	0.1 °C

Electrical Specifications

Power supply (external)		150W, 100-240VAC, 47-63Hz Short Circuit Protection Protection Classes: Class I Safety: IEC 60601-1
Power consumption		120W maximum
Battery (internal)	Type	Li-ion
	Capacity	Optional (30/60/90/120/150 Wh)
Power Cords	North America	(part 50-07302-01)
	C.E.	(part 50-07305-01)
	U.K.	(part 50-09273-01)

Specifications

Environmental Specifications

Operating	Ambient temperature	+15°C to +35°C
	Humidity	0% to 90% RH non condensing
	Atmospheric Pressure	70-106kPa
Transport and storage	Ambient temperature	0°C to +50°C
	Humidity	0% to 90% RH non condensing
	Atmospheric Pressure	70-106kPa
Exclusions		None

Standards for Reference

EN ISO 15223-1:2021
 EN ISO 20417:2021
 EN ISO 13485:2016+A11:2021
 EN ISO 14971:2019+A11:2021
 ISO TR 24971:2020
 EN 60601-1-2:2015+A1:2021
 EN 60601-1-6:2010+A1+A2:2021
 EN 60601-1-8-2007+A1+A11+A2:2021
 EN 60601-1:2006+A1+A12+A2:2021/AC:2023
 EN IEC 60601-2-35:2021
 EN ISO 10993-1:2020
 MEDDEV. 2.7.1 Rev.4
 MEDDEV. 2.12-1 Rev. 8
 MEDDEV. 2.12-2 Rev.2
 ROHS 2015/863/EU
 WEEE 2012/19/EU

Explanation of Symbols



This statement is a warning. Not following this statement could result in injury to the patient or operator, or damage to the device.



CE Marking with Notified Body Number.



Caution: Hazard with a low level of risk, which, if not avoided, could result in minor or moderate injury



Consult instructions for use or consult the electronic instructions for use



This device contains electronic parts. Do not dispose of it with normal waste. Dispose of it according to local guidelines for disposal of electronics. Dispose according to the WEEE directive in the European Union.



Medical device



Unique device identifier



Website where a user can obtain additional information on the medical product



Model number



Catalogue number



Authorized Representative in the European Community



Device manufacturer.



Date of manufacture.



Serial number.



Keep away from sunlight.



Protected from limited dust ingress. Protected from water spray less than 60 degrees from vertical.



Country of manufacture



Temperature limit



Humidity limitation



Atmospheric pressure limitation

Warranty Policy

General Terms

This MTTs Limited Warranty gives you, the customer, express limited warranty rights from MTTs, the manufacturer for the duration specified on the Warranty Card. Please refer to the MTTs Website for an extensive description of your limited warranty entitlements. In addition, you may also have other legal rights under applicable law or special written agreement with MTTs.

MTTS MAKES NO OTHER EXPRESS WARRANTY OR CONDITION WHETHER WRITTEN OR ORAL AND MTTS EXPRESSLY DISCLAIMS ALL WARRANTIES AND CONDITIONS NOT STATED IN THIS LIMITED WARRANTY. TO THE EXTENT ALLOWED BY LOCAL LAW OF JURISDICTIONS OUTSIDE VIETNAM, MTTS DISCLAIMS ALL IMPLIED WARRANTIES OR CONDITIONS, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. FOR ALL TRANSACTIONS OCCURRING IN VIETNAM ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, SATISFACTORY QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE IS LIMITED TO THE DURATION OF THE EXPRESS WARRANTY SET FORTH ABOVE. SOME COUNTRIES DO NOT ALLOW A LIMITATION ON HOW LONG AN IMPLIED WARRANTY LASTS OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR CONSUMER PRODUCTS. IN SUCH COUNTRIES, SOME EXCLUSIONS OR LIMITATIONS OF THIS LIMITED WARRANTY MAY NOT APPLY TO YOU. FOR CONSUMER TRANSACTION, THE LIMITED WARRANTY TERMS CONTAINED IN THIS STATEMENT, EXCEPT TO THE EXTENT LAWFULLY PERMITTED, DO NOT EXCLUDE, RESTRICT, OR MODIFY BUT ARE IN ADDITION TO THE MANDATORY STATUTORY RIGHTS APPLICABLE TO THE SALE OF THIS PRODUCT TO YOU.

This Limited Warranty is applicable in all countries and may be enforced in any country or region where MTTs or its authorized service providers offer warranty service for the same product model number (subject to the terms and conditions set forth in this Limited Warranty)

Under this Limited Warranty, products purchased in one country or region may be transferred to another country or region where MTTs or its authorized service providers offer warranty service for the same product model number. Warranty terms, service availability, and service response times may vary from country or region to country or region. Standard warranty service response time is subject to change due to local parts availability. If so, your MTTs authorized service provider can provide you with details. MTTs will not alter form, fit, or function of this MTTs product to make it operate in a country for which it was never intended to function for legal or regulatory reasons. MTTs is not responsible for any tariffs or duties that may be incurred in transferring the products.

MTTS guarantees that the product that you have purchased or leased from MTTs is free from defects in materials or workmanship under normal use during Limited Warranty Period. The Limited Warranty Period starts on the date of purchase or lease from MTTs, or from the date MTTs completes installation. Your dated sales or delivery receipt, showing the date of purchase of the product, is your proof of the purchase or lease date. You may be required to provide proof of purchase or lease as a condition of receiving warranty service. You are entitled to hardware warranty service according to the terms and conditions of this document if a repair to your MTTs product is required within the Limited Warranty Period.

Unless otherwise stated, and to the extent permitted by local law, new MTTs product may be manufactured using new materials and used materials equivalent to new in performance and reliability. MTTs may repair or replace MTTs products (a) with new or previously used products or parts equivalent to new in performance and reliability, or (b) with equivalent products to an original product that has been discontinued. Replacement parts are warranted to be free from defects in material or workmanship for ninety (90) days or, for the remainder of Limited Warranty Period of the MTTs product they are replacing or in which they are installed, whichever is longer.

Warranty Policy

MTTS will, at its sole discretion, repair or replace any components or product that manifests a defect in materials or workmanship during the Limited Warranty Period. All component parts removed under this Limited Warranty become the property of MTTS. In the unlikely event that your MTTS product has recurring failures, MTTS at its sole discretion, may elect to provide you with (a) a replacement unit selected by MTTS that is the same or equivalent to your MTTS product in performance or (b) to give you a refund of your purchase price or lease payments (less interests) instead of a replacement. This is your exclusive remedy for defective products.

Exclusions

MTTS DOES NOT WARRANT THAT THE OPERATION OF THIS PRODUCT WILL BE UNINTERRUPTED OR ERROR-FREE. MTTS IS NOT RESPONSIBLE FOR DAMAGE THAT OCCURS AS RESULT OF YOUR FAILURE TO FOLLOW THE INSTRUCTIONS INTENDED FOR THE PRODUCT.

This Limited Warranty does not apply to expendable or consumable parts and does not extend to any product from which the serial number has been removed or that has been damaged or rendered defective (a) as a result of accident, misuse, abuse, contamination, improper or inadequate maintenance or calibration (if required) or other external causes; (b) by operation outside the usage parameters stated in the user documentation shipped with the product; (c) by software, interfacing, parts or supplies not supplied by MTTS; (d) improper site preparation or maintenance; (e) virus infection; (f) loss or damage in transit; or (g) by modification or service by anyone other than (i) MTTS personnel, (ii) an MTTS authorized service provider, or (iii) your own installation of end-user replaceable MTTS or MTTS approved parts if available for your MTTS product in the servicing country or region.

Limitation of Liability

IF YOUR MTTS PRODUCT FAILS TO WORK AS WARRANTED ABOVE, THE MAXIMUM LIABILITY OF MTTS UNDER THIS LIMITED WARRANTY IS EXPRESSLY LIMITED TO THE LESSER OF THE PRICE YOU HAVE PAID FOR THE PRODUCT OR THE COSTS OF REPAIR OR REPLACEMENT OF ANY HARDWARE COMPONENTS THAT MALFUNCTION IN CONDITIONS OF NORMAL USE.

EXCEPT AS INDICATED ABOVE, IN NO EVENT WILL MTTS BE LIABLE FOR ANY DAMAGES CAUSED BY THE PRODUCT OR THE FAILURE OF THE PRODUCT TO PERFORM, INCLUDING ANY LOST PROFITS OR SAVINGS OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. MTTS IS NOT LIABLE FOR ANY CLAIM MADE BY A THIRD PARTY OR MADE BY YOU FOR A THIRD PARTY.

THIS LIMITATION OF LIABILITY APPLIES WHETHER DAMAGES ARE SOUGHT, OR CLAIM MADE, UNDER THIS LIMITED WARRANTY OR AS A TORT CLAIM (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), A CONTRACT CLAIM, OR ANY OTHER CLAIM. THIS LIMITATION LIABILITY CANNOT BE WAIVED OR AMENDED BY ANY PERSON. THIS LIMITATION OF LIABILITY WILL BE EFFECTIVE EVEN IF YOU HAVE ADVISED MTTS OF THE POSSIBILITY OF ANY SUCH DAMAGES. THIS LIMITATION OF LIABILITY, HOWEVER, WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY.

THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY ALSO HAVE OTHER RIGHTS THAT MAY VARY FROM COUNTRY TO COUNTRY. YOU ARE ADVISED TO CONSULT APPLICABLE COUNTRY LAWS FOR A FULL DETERMINATION OF YOUR RIGHTS.

Warranty Policy

Limited Warranty Period

The Limited Warranty Period for this MTTS product is a specified, fixed period commencing on the date of purchase and specified on the Warranty Card. The date on your sales receipt is the date of purchase unless MTTS or your reseller informs you otherwise in writing.

Customer Responsibilities

In order to avoid the risk of charges for issues not covered by your limited warranty (issues that are not due to defects in materials and workmanship on MTTS product), you will be asked to assist MTTS as follows:

- Verify configurations, load most recent firmware, install software patches, run MTTS diagnostics and utilities;

- Implement temporary procedures or workarounds provided by MTTS while MTTS works on permanent solution;

- Cooperate with MTTS in attempting to resolve the problem using online chat, email, or telephone. This may involve performing routine diagnostic procedures, installing additional software updates or patches;

- Perform additional tasks as defined within each type of warranty service provided by MTTS and any other actions that MTTS may reasonably request in order to best perform the warranty support

CUSTOMER IS RESPONSIBLE FOR DELIVERING THE PRODUCT (AND ALL COSTS INVOLVED) FROM HIS LOCATION TO THE MTTS AUTHORIZED SERVICE POINT.

Contacting MTTS

If your MTTS product fails during the Limited Warranty Period and the suggestions in the product documentation do not solve the problem, you can receive support by doing one of the following:

- Locate and contact your nearest MTTS service provider via MTTS website:

 - <http://www.mtts-asia.com/support/>

- Call the Technical Support Center:

 - +84 43 766 6521

Before calling MTTS or an MTTS authorized service provider please have the following information available:

- Product serial number and model name
- Applicable error messages
- Detailed questions



MEDICAL TECHNOLOGY TRANSFER AND SERVICES Co., LTD
House No. 26, Alley 41, An Duong Vuong Street, Tay Ho District, Hanoi City, Vietnam
SRN: VN-MF-000036669

Tel: +84 24 3766 6521
Fax: +84 24 3718 8050



EC REP

Logic s.r.l.
Via Antonio Pigafetta 1
34147 Trieste, Italy
SRN: IT-AR-000012301

