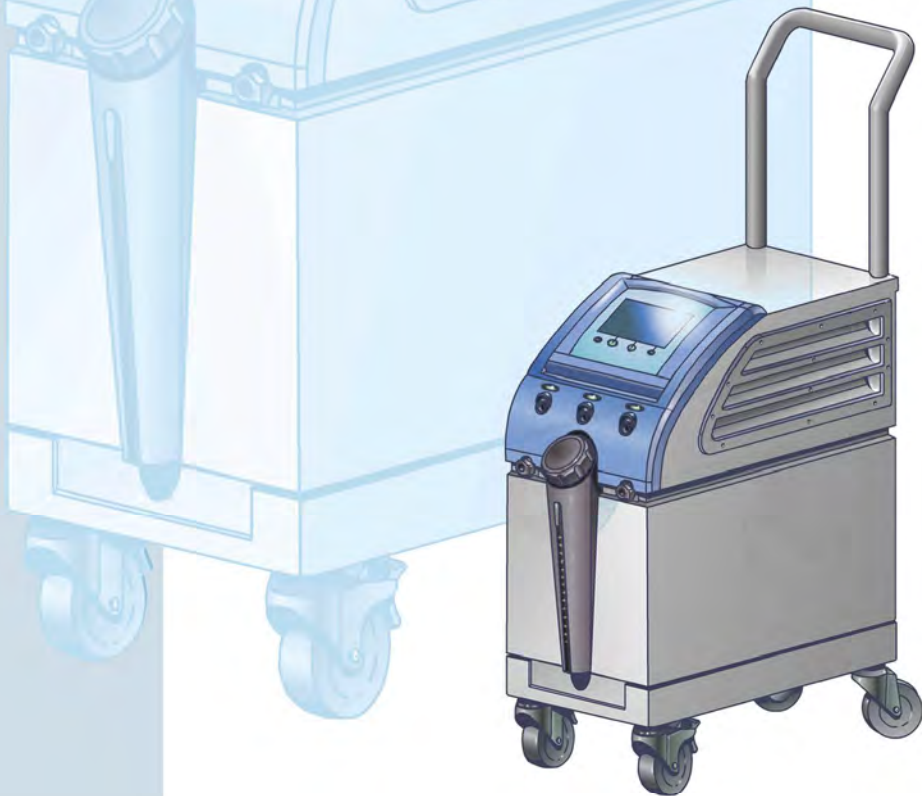

ALLON™ 2001

THERMOREGULATION SYSTEM

USER'S MANUAL



Catalog No.DDT-063-000


Rev: A

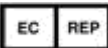
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Conformity according to the Council Directive 93/42/EEC concerning
Medical Devices

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U.S. Patent No. 6,500,200 BI

Disclaimer

MTRE is not responsible for any consequential or incidental damages or expenses of any kind, impairment of or damage to other goods or to any third party resulting from loss of use of the system caused by or due to the following:

- a. Installed, operated, maintained contrary to MTRE's instructions, notes or warnings under this manual.
- b. Misuse, unauthorized use, negligence, accident, (including fire, water, explosion, smoke, vandalism, etc.)
- c. Ignoring any of the warnings, precautions and safety measures indicated in this manual.
- d. Replace, repair or alter not by MTRE's authorized personnel.
- e. Anyone other than MTRE's authorized and certified personnel removes, casing and/or attempts to make or makes any internal changes, removals, attachments or additions to the 2001 System or components thereof;
- f. The power supplied to the System or any part thereof differs from the rated value, or any external device attached by user creates conditions exceeding the tolerance of the System;
- g. The use of accessories and other parts or equipment made by other manufacturers, whether or not warranted by such manufacturers, which have been attached or connected to the System after installation, unless such accessories and other parts have been supplied and attached or installed by the MTRE.
- h. Using the system in a contrary manner than indicated in this manual, or using the system for any purpose other than indicated in the manual.
- i. Failure to replace the ThermoWrap in each procedure while operating the system. Note that all ThermoWraps are one-use disposable materials and should not be reused.
- j. Force Majeure In no event shall MTRE be liable for loss of use, loss of profits, or other collateral, special or consequential damages.

Use of Manual:

The Allon® 2001 system described in this manual has been designed to meet international safety and performance standards. Only qualified personnel may operate the system, and these operators must first have a full understanding of the proper operation of the system.

The purpose of this manual is to help qualified personnel understand and operate the system. It is important that you read this manual and familiarize yourself thoroughly with its contents before you attempt to operate the system. If you do not understand any part of this manual, or if anything is unclear or ambiguous in any way, please contact your MTRE representative for further clarification.

The information provided in this manual is not intended to replace regular medical training procedures. This manual should always accompany the system. All qualified personnel operating the system should know the location of the manual. For additional copies of this manual, please contact your MTRE representative.

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CHAPTER 1

Safety Precautions

1.1. Definitions

WARNING—indicates a condition that may endanger the patient or the system operator

CAUTION—indicates a condition that may damage the equipment

NOTE—indicates ways in which the system's operation can be made more efficient

1.2. Intended Use

The ALLON 2001 system is designed to regulate body temperature as determined by the physician.

1.3. Warnings

1. The physician must be notified if the patient's temperature does not respond properly, does not reach the prescribed temperature, or if there is any change in the prescribed temperature range. Failure to inform the physician may result in injury to the patient.
2. The patient should be constantly attended by a physician.
3. The misuse of the temperature regulation equipment can be potentially harmful to the patient.
4. Do not plug wet PL plugs of the human sensors into the sensor sockets of the ALLON 2001 device.
5. The user should verify that no fluids are present at the skin/ThermoWrap interface during the operation. Failure to do so can cause lesions on the patient's skin. Following the procedure, a pattern resembling the ThermoWrap may appear for a short period of time on the patient's skin.
6. In operations that usually extend over two hours, pressure sores may appear or develop when soft tissue is compressed between a bony prominence and external surface. The use of the Allon 2001 system does not prevent this occurrence. It is therefore recommended to use pressure sores protective means between the operating table and the ThermoWrap.

7. Before initiating maintenance procedures as described in Chapter 6, disconnect the power cord from the power source.
8. The default setting is intended to maintain normothermia. However, the system provides the physician with the option of selecting a body temperature in the range of 30°C to 40°C (86°F-104°F).
9. Do not lift or move the patient by means of the ThermoWrap. This may cause tearing and water leakage.
10. Use reusable core sensors or disposable sensor adapters supplied by MTRE or YSI series 400 compatible sensors.
11. The technical principles, clinical applications, and risks associated with circulatory support must be thoroughly understood before using this product. Read the entire manual before attempting to activate the system. Completion of the training program prior to using the ALLON 2001 system is mandatory.
12. The repair, calibration, and servicing of the ALLON 2001 system should be performed only by MTRE Advanced Technologies LTD or authorized agents of MTRE Advanced Technologies LTD.

1.4. Precautions

- Follow the warning notes listed in the various sections of this manual.
- Only trained personnel, familiar with all system operating procedures and certified only by MTRE Advanced Technologies Ltd or authorized agents of MTRE Advanced Technologies Ltd, are allowed to use the ALLON 2001 system. All hospital personnel using the ALLON 2001 system must complete the ALLON 2001 training program.
- The repair and servicing of the ALLON 2001 device should be performed only by qualified medical equipment service technicians certified by MTRE Advanced Technologies Ltd or authorized agents of MTRE Advanced Technologies Ltd.
- If moisture or leaks are discovered in the connecting hose and/or ThermoWrap, turn off the ALLON 2001 device, disconnect the power cable from its power source, and correct the problem before proceeding.
- The desired set-point temperature should be fixed only as prescribed by and under the order of a physician.
- If the device sounds an alarm and/or presents a display other than the standard MTRE display, the operator should proceed according to the display message and/or the troubleshooting instructions (see Chapter 7 Troubleshooting).
- Avoid folds in the ThermoWrap—these may obstruct water flow.
- Do not block the ALLON 2001 device ventilation grilles. Air must be able to flow freely in and out in order to keep the device cool.
- Do not use de-ionized or distilled water. Use tap water only.
- When X-ray imaging is performed on a patient wearing a ThermoWrap, shadows from the ThermoWrap may appear on the X-ray film.
- Avoid inserting any sharp object between the patient and the ThermoWrap.

- 1.5. Improper Use** Improper use of the ALLON 2001 system may lead to skin lesions, electrical hazards, and severe changes in body temperature.

**WARNING**

The technical principles, clinical applications, and risks associated with circulatory support must be thoroughly understood before using this product. Read the entire manual before attempting to activate the system. Completion of the training program prior to using the ALLON 2001 system is mandatory.

**CAUTION**

U.S. Federal law restricts this device to sale by or on the order of a physician.

1.6. Labels

1.6.1. ALLON
2001 Device
Labels

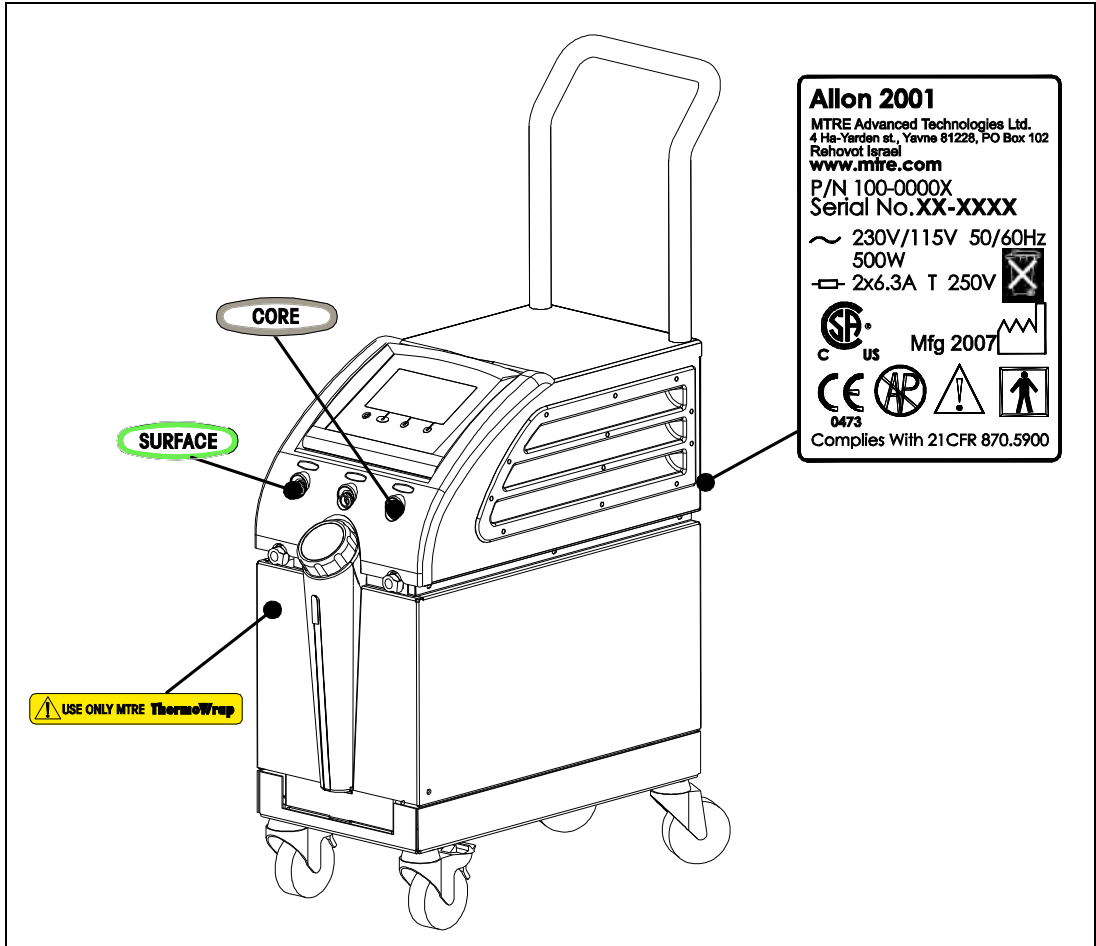













Figure 1-1 Label Placement for the ALLON 2001 Device

Table 1-1 Key to Label Symbols

Symbol	Description
	Location of core sensor socket
	Location of surface sensor socket
	AC Voltage
	Fuse
	CE mark of conformity indicates that the product has received the European approval for MDD 93/42/EEC.
	Equipment not suitable in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
	Refer to user manual
	Type BF equipment
	Recycle
<p>Mfg 2007 </p>	Date of manufacture
	CSA symbol indicates that the product has received the approval of the Canadian Standards Association.
<p>xx - yyyy</p>	Machine Version - Machine serial number

CHAPTER 2

System Description

2.1. General Description

The ALLON 2001 system maintains desired patient body temperature before, during, and after surgery. The desired patient temperature is set by the surgeon and covers the normothermia to hypothermia range. Most regular operations require normothermia. This is achieved by heating to compensate for body heat losses resulting from redistribution due to the general anesthesia and from reduced metabolic rate and exposure of body organs and skin to the cold operating theatre environment. The system is designed to maintain normothermia, induce hypothermia, and precise re-warming.

The system is composed of two elements, the ALLON 2001 device and the ThermoWrap disposable garment. The ALLON 2001 device performs the functions of heat pump, water circulating pump, and control unit. The control unit constantly monitors the patient's core temperature through specific sensors and, using its on-board body temperature control algorithm, decides on the optimum water temperature to reach the desired set point. The heat pump brings the water to the required temperature and the pump circulates it to the garment.

The ThermoWrap garment is a flexible heat exchanger through which the water circulates. It is designed to be in close contact with a large area of the body, thus effecting good heat transfer with the body. The garment, designed to be disposable, comes in a variety of styles and sizes to suit various types of operations and ages. Access to virtually any part of the body for surgical procedure without seriously interrupting heat transfer is made possible by various flaps that are built into the design.

2.2. ALLON 2001 The ALLON 2001 system consists of the following elements:

- ALLON 2001 device
- ThermoWrap
- Accessories

2.2.1. ALLON 2001 Device The ALLON 2001 device has a microprocessor that controls the water temperature flowing into the ThermoWrap worn by the patient. The decision as to the correct water temperature is based on the desired set point temperature and the actual measured patient temperature (core and surface).

Water pressure in the ThermoWrap is regulated by timed pauses of the flow during clinical operation.

The ALLON 2001 device is equipped with a handle for easy transport.

2.3. External Features

2.3.1. Front View

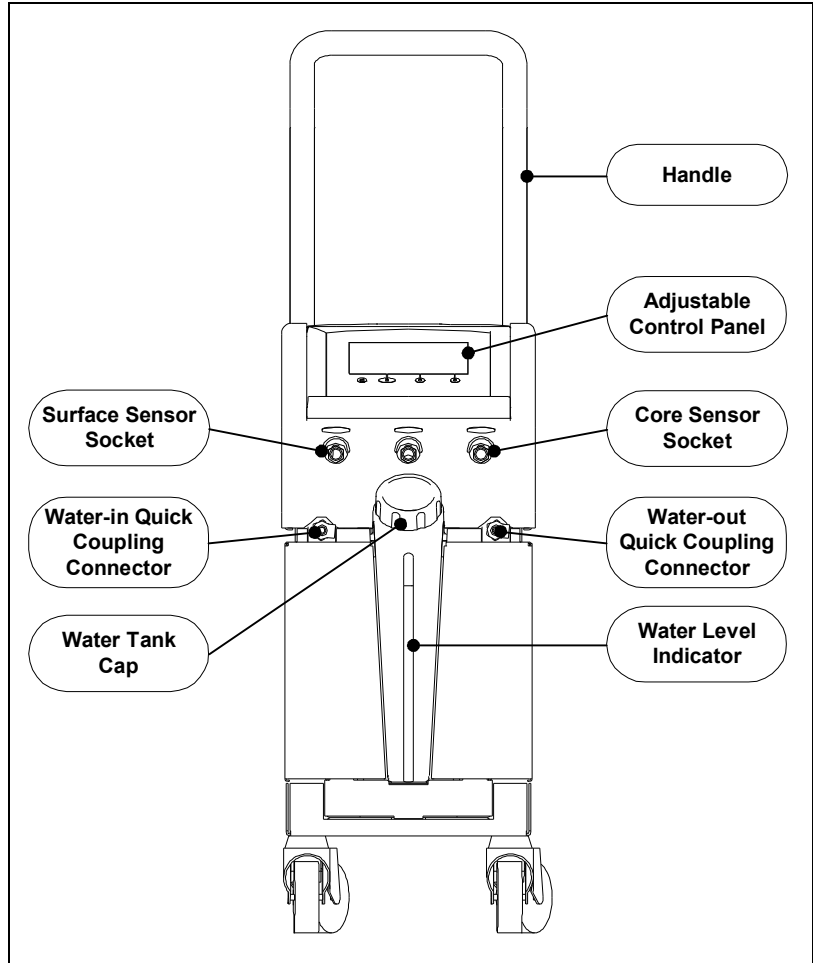


Figure 2-1 Front View

2.3.2. Side View

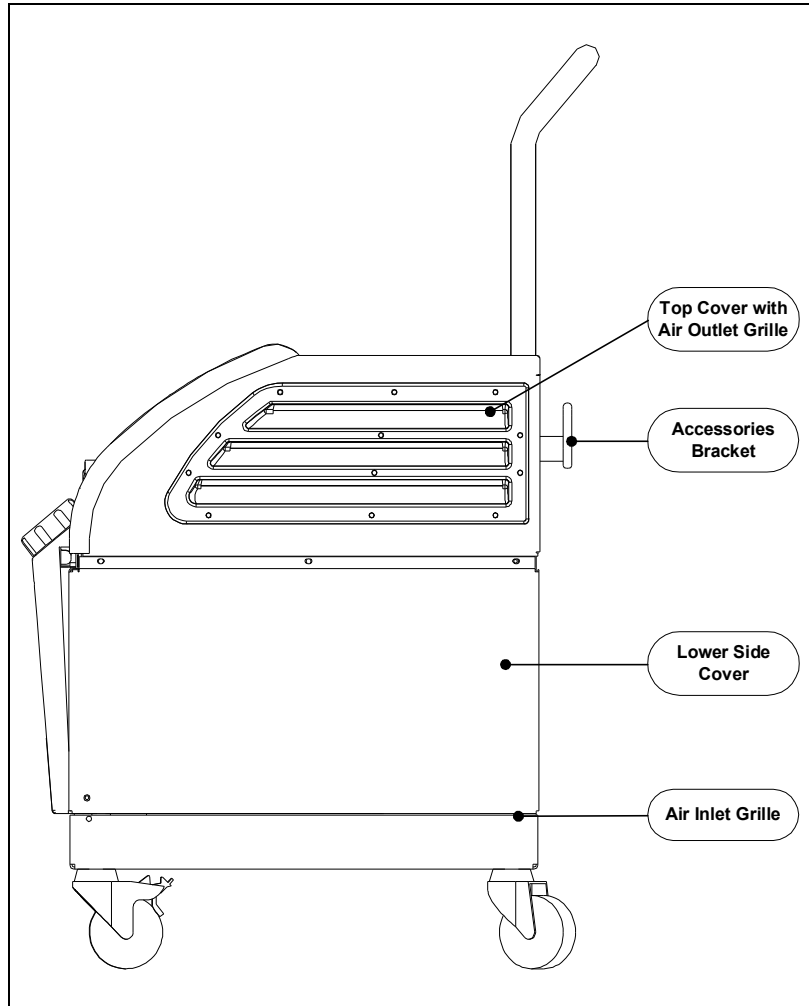


Figure 2-2 Side View

2.3.3. Rear Panel

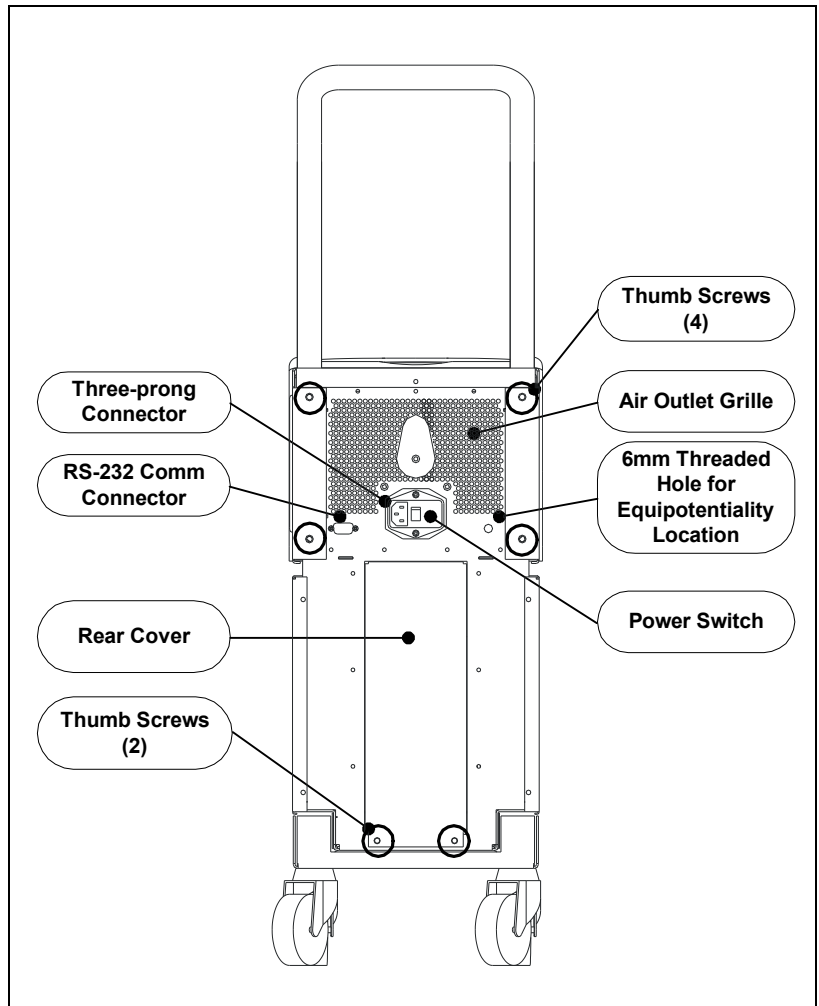


Figure 2-3 Rear View

2.3.4. *ThermoWrap*

1. General

The ThermoWrap is a one-piece garment with a one-inflow and a one-return water connection. It is designed to facilitate the wrapping of individual parts of the body (chest, arms thighs, etc) to maximize surface coverage.

2. Description and Intended Use

- The ThermoWrap is:
 - Biocompatible
 - Inflatable
 - Adjustable
 - Disposable
 - Antistatic
 - Latex free
- Each section of the ThermoWrap is separately wrapped around the appropriate area of the patient (e.g. chest, arms and thighs) to ensure maximum body surface coverage.
- The water's exit and entrance points are short sections of tubing integrated with a Quick Coupling Connector (QCC) and welded to convenient locations on the edges of the ThermoWrap.
- The ThermoWrap design allows the physician to bare different body parts as dictated by surgical procedure.
- The ThermoWrap is available in a range of sizes and designs (depending on surgery type) to optimize body coverage.
- The ThermoWrap is secured to the patient via pressure sensitive adhesive strips that adhere to the garment. The ThermoWrap can be secured to the patient's skin with medically approved peelable adhesive strips.

**WARNING**

The Garments are defined for single patient use only.
Reusing may cause cross contamination and/or irritation.

The Garments performances were validated only to defined usage time as defined in subsection 3.

3. ThermoWrap Designs

MTRE Advanced Technologies Ltd. offers disposable ThermoWraps in a wide range of sizes. There are three different ThermoWrap designs:

- Cardiac ThermoWrap—used for open-heart surgery. See Table 2-1 on page 2-5.
- Universal ThermoWrap—used for any typical surgery other than open-heart surgery. For available sizes, see Table 2-2 on page 2-5.

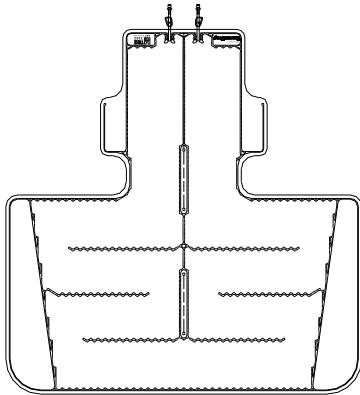


Figure 2-4 Cardiac ThermoWrap

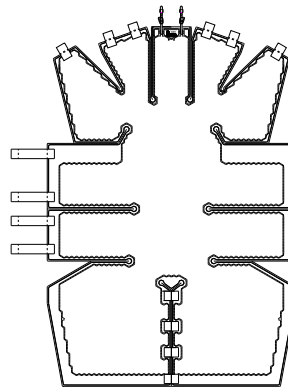


Figure 2-5 Universal ThermoWrap

- Universal / Pediatric ThermoWrap—used for pediatric surgery. For available sizes, see Table 2-2 on page 2-5.
- Infant ThermoWrap—used for infant surgery. For available sizes, see Table 2-3 on page 2-5.

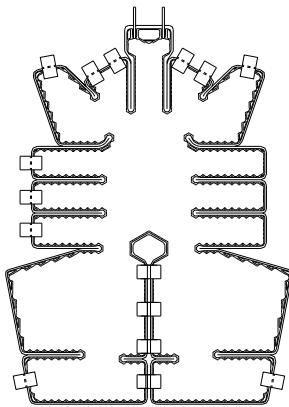


Figure 2-6 Universal/Pediatric ThermoWrap

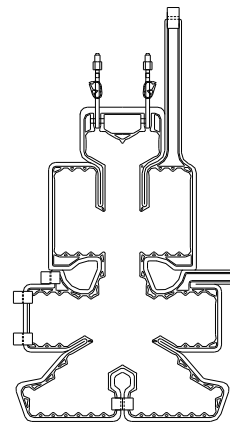


Figure 2-7 Infant ThermoWrap

To determine the most suitable type of ThermoWrap for the procedure, the following information is required:

- Adult or infant
- Adult height or infant weight (see figures below)
- For adult: type of operation to be performed (cardiac or other)

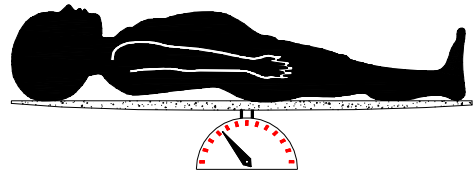
A full range (infant to adult) is available with different models. The model type, model number, and sizes are listed on the label on each package. Choose the appropriate model and size according to the parameters listed above. If the patient's overall height or overall weight matches the minimum value of a specific model, use the next smaller size.

XXX-XXXcm

x'x"-x'xx"



Adult Height



Infant Weight

Table 2-1 Cardiac ThermoWraps

Table of Cardiac ThermoWrap Sizes		
Model No.	Patient Height Range	Quantity per box
3363*	One size fits all adults	12

* Models 3365 and 3368 may still be used.

Table 2-2 Universal ThermoWraps

Table of Universal ThermoWrap Sizes			
Model No.	Height Range in Inches	Height Range in Feet & Inches	Height Range in Centimeters
3131	31"-36"	2'7"-3'0"	79-91
3136	36"-41"	3'0"-3'5"	91-104
3141	41"-48"	3'5"-4'0"	104-122
3148	48"-53"	4'0"-4'5"	122-135
3153	53"-60"	4'5"-5'0"	135-152
3160	60"-66"	5'0"-5'6"	152-168
3166	66"-71"	5'6"-5'11"	168-180

Table 2-3 Infant ThermoWraps

Table of Infant ThermoWrap Sizes		
Model No.	Weight Range in kg	Weight Range in lb
3118	2.5–4.0	5.5–8.8
3121	4.0–7.0	8.8–15.4
3125	7.0–11	15.4–24.2

2.3.5. *Accessories* To operate the ALLON 2001 system the following accessories are needed:

1. Human Temperature Sensors

a. Reusable Sensors

There are three color-coded sensors: Core (gray), Surface (green), and Infant Core (gray). Both core and surface sensors must be plugged into the ALLON 2001 device. The core sensor must be inserted and the surface sensor must be attached to the patient for the device to function properly.

b. Disposable Sensors

Disposable sensors are attached to two color-coded adapters: Core (gray) and Surface (green). The core sensor must be inserted and the surface sensor must be attached to the patient for the device to function properly.

Sensors and adapters are guaranteed for one year.



WARNING

Use reusable core sensors or disposable sensor adapters supplied by MTRE or YSI series 400 compatible sensors.

- Reusable Core Sensor (model no.4200):
The core sensor (gray) measures core body temperature when inserted into the patient's body. The PL plug of the sensor cable is plugged into the gray core sensor socket at the front of the ALLON 2001 device. The other end is inserted into the patient and measures core body temperature.
- Disposable Core Sensor Adapter (model no. 4202):
The disposable sensor is attached to the core sensor adapter (gray). The PL plug of the adapter is plugged into the gray core sensor socket at the front of the ALLON 2001 Device. The sensor is inserted into the patient and measures core body temperature.
- Reusable Infant Core Sensor (model no.4204):
The infant core sensor (gray) measures infant core body temperature when inserted into the patient's body. The PL plug of the sensor cable is plugged into the gray core sensor socket at the front of the ALLON 2001 device. The other end is inserted into the patient and measures core body temperature.



Use only reusable surface sensors or disposable surface sensor adapters supplied by MTRE.

NOTE

- Reusable Surface Sensor (model no. 4201):
The surface sensor (green) measures body surface temperature when attached to the patient's skin. The PL plug of the sensor cable is plugged into the green surface sensor socket at the front of the ALLON 2001 device. The other end is attached with adhesives to the patient's skin.

- Disposable Surface Sensor Adapter (model no. 4203):
The disposable sensor is attached to the surface sensor adapter (green). The PL plug of the adapter is plugged into the green surface sensor socket at the front of the ALLON 2001 device. The sensor is attached with adhesives to the patient's skin and measures surface body temperature.

Table 2-4 Sensor and Data Provider Input Specifications

Model No.	Name	Description	Accuracy	Resolution	Type
4200	Core	Inner body temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor
4201	Surface	Skin temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor
4204	Core Infant	Infant Inner body temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor

2. Detachable Electric Power Cable & Plug

See Table 5-4 Accessories Inventory on page 5-5.

3. Connecting Tubes (model no. 4100)

Two flexible 2.5m long connecting tubes, connect the ThermoWrap with the ALLON 2001 device to enable the flow of water between them. The tubes are supplied as a paired unit with two male Quick Coupling Connectors at the ALLON 2001 device end and with two female Quick Coupling Connectors at the ThermoWrap end.

**4. Male Connector for Draining Water Tank
(model no. 4101)**

Refer to Section Table 7-1 on page 7-5.

5. Spare Water Filter (model no. 4102)

For annual filter replacement - packed in the accessory box

6. Handle (model no. 2100)

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CHAPTER 3

Installation

3.1. Pre- installation Requirements

3.1.1. Space and Environmental Requirements

The ALLON 2001 device is supplied on a trolley as a mobile unit for user convenience. It must be located no less than 5 cm (2") from other objects to avoid impairing ventilation to the ALLON 2001 device.

The following dimensions should be considered when placing the ALLON 2001 device:

260 mm W x 625 mm D x 940 mm H /
(10.23"W x 24.6"D x 37"H)

3.1.2. Electrical Requirements

120/230 VAC 500W



CAUTION

Verify that the voltage switch is set for the local voltage.

3.1.3. *Unpacking and Inspection*

The ALLON 2001 device has undergone full quality assurance testing before shipment and should be operational upon delivery.

The unit should be unpacked, installed and tested only by MTRE's authorized personnel. No attempt should be made by the purchaser to unpack or assemble the unit alone.



NOTE

Report any container damage prior to opening the container, or any unit damage prior to unpacking, installation, or testing to your MTRE distributor.

3.1.4. *Assembling the Handle*

Assemble the handle as follows:

1. Release the four thumb captive screws by hand.
2. Slide the two ends of the handle into the holes in the top cover (pay attention to the direction of the curve in the handle) until the handle is inserted all the way in (see Figure 3-1).
3. Press in and screw the four thumb captive screws by hand (do not use force when screwing) to secure the handle and the top cover.

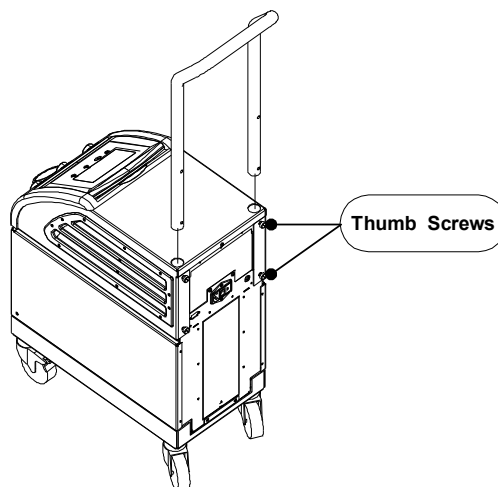


Figure 3-1 Handle Assembly

3.1.5. *Equipment List*

The ALLON 2001 system includes the following:

- Allon 2001 device
- Universal, Cardiac, Infant ThermoWraps (ordered separately)
- Connecting tubes
- Special connector for draining the water tank
- Reusable core sensor (for 230V system)
- Reusable surface sensor (for 230V system)
- Reusable infant core sensor (ordered separately) (for 230V system)
- Disposable core sensor adapter (for 120V system)
- Disposable surface sensor adapter (for 120V system)
- Handle
- Spare Filter
- Power cable
- User manual
- Quick Reference Guide

3.2. Moving the Unit

3.2.1. Preparation: Prior to moving the unit:

1. Ensure that the ALLON 2001 device is off by pressing the ON / OFF switch.
2. Ensure that all electrical connections are disconnected.

3.2.2. Locking and Unlocking the Trolley Wheels

The ALLON 2001 device trolley has four wheels. The front wheels are fitted with a brake. The brake lever is located over the wheel. To lock the wheels, firmly press the lever. To release the wheels, lift the lever.

When the unit is stationary, the brakes must be in the locked position. Release the brakes only when transporting the unit.

3.3. Storage Conditions and Transport

3.3.1. Storage



CAUTION

Use protective means to avoid excessive vibration during device transport.

Store the ALLON 2001 device in a clean and dry area with:

- a. An ambient temperature of -40°C to +70°C (-40°F to +158°F)
- b. A relative humidity range of 10% to 100%
- c. An atmospheric pressure range of 500 hPa to 1060 hPa.

The ALLON 2001 device features a utility bracket in the rear for storage of the connecting tubes and sensors when not in use.

CHAPTER 4

Operating Instructions

4.1. General

This chapter contains:

- A description of the controls, indicators and connections for the ALLON 2001 device.
- Detailed operating instructions for the ALLON 2001 system.

4.2. Controls, Indicators and Connections

Included in this section is a short description of the following:

- Main power switch
- QCC—Quick Coupling Connectors
- Sensor sockets
- Control panel
- Indicators
- Displays

4.2.1. Main Power Switch

The main power switch, located on the rear side of the unit, switches the ALLON 2001 device ON and OFF.

4.2.2. QCC—Quick Coupling Connector

The Quick Coupling Connectors are located at the front of the ALLON 2001 device, and are connected to the ThermoWrap by means of the connecting tubes.

1. Connecting the Connecting Tubes:

Lock the connecting tubes by pressing them against the connectors. When locked, a clicking sound is produced. Verify that the tubes have been locked by lightly tugging them towards you.

2. Disconnecting the Connecting Tubes:

Press the metal flange and pull out the connecting tubes.

4.2.3. *Sensor Sockets*

There are two sensor sockets located in the front of the ALLON 2001 device.

1. **Connecting the Sensors**

Insert the appropriate reusable sensor or disposable sensor adapter into the designated socket.



When using disposable adapters, you *must* connect the adapter to the disposable sensor before you insert the connector into the designated socket.

NOTE

2. **Disconnecting the Sensor**

Pull the appropriate reusable sensor or disposable adapter out of its socket.

4.3. Control Panel The adjustable control panel is located at the top of the ALLON 2001 device. Once the ALLON 2001 device is turned on, all operating functions are controlled through the control panel.

The control panel’s simple soft-touch keys and visual displays guide the user through each operational phase.

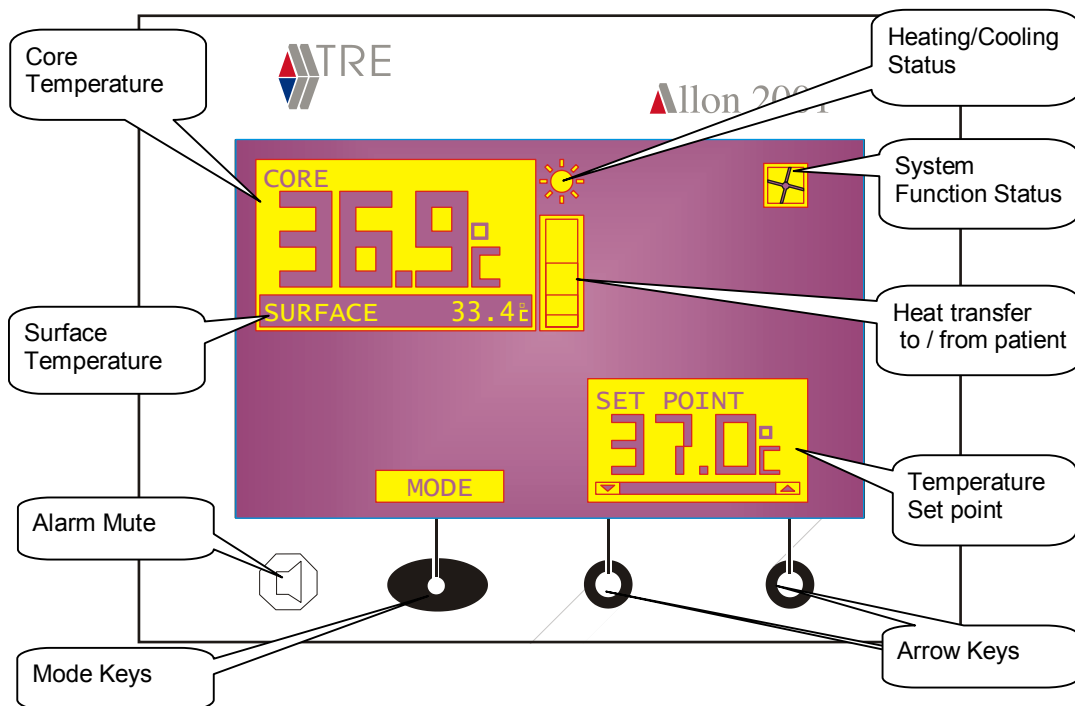


Figure 4-1 Control Panel

Table 4-1 Key to Control Panel Symbols

Symbol	Description	Explanation
	Heat transfer to / from patient	Graphical representation of the intensity of heat transferred between the patient and the Allon system
	Heating/Cooling Status	Indicates the direction of the heat transfer. <ul style="list-style-type: none"> • Sun icon - Heat transferred to the patient • Snowflake icon - Heat transferred from the patient
	System Function 'Status	Indicates the condition of the pump. If the icon is not displayed, the pump is not functioning and water does not flow to the ThermoWrap.

4.4. Preparing the System for Operation

1. Place the unit in the desired position according to section 3.1.1, Space and Environmental Requirements on page 3-5.



CAUTION

Do not place the ALLON 2001 device under the operating table or patient's bed.

2. Press the brake pedals and lock the wheels to secure the ALLON 2001 device.
3. Remove the water tank feeder cover, and pour in tap water until the maximum allowable level is reached. Observe the water-level indicator to prevent overfilling the water tank. Close the water tank feeder cover. In case of overfilling, see Table 7-1 on page 7-5.
4. Insert the reusable core and surface sensors or the disposable core and surface adapters into the ALLON 2001 device sockets as described in section 2.3.5 on page 2-5.
5. Connect the connecting tubes to the ALLON 2001 device.
6. Choose the appropriate model and size ThermoWrap as described in section ThermoWrap Designs on page 2-5. Place it on the operating table as described in the leaflet enclosed with the ThermoWrap, sections 1 and 2.
7. Make sure to lie out the ThermoWrap evenly and avoid twisting or bending the tubes.
8. Connect the ALLON 2001 device to the power source.

4.5. Procedures for Turning on the System



WARNING

The patient must be under constant supervision. The misuse of temperature regulation equipment can potentially injure a patient.

Turn the main switch, located in the rear of the unit, upwards to the ON position. Once power is supplied to the ALLON 2001 device, the unit performs a self-test (see section 4.6 Self-Test).

4.6. Self-Test

The self-test is performed in order to ensure the proper functioning of the ALLON 2001 device (see Figure 4-2 on page 4-5). A self-test is conducted every time the system is restarted. In the event of a power failure of less than 10 seconds, the self-test will not be performed and the ALLON 2001 device will remain in operation mode. During the self-test, the “PERFORMING SELFTEST PLEASE WAIT...” message appears until the system is ready (see Figure 4-2 on page 4-5).



NOTE

Whenever the Allon 2001 device is activated, a complete self-test **must** be performed. Do not interrupt the self-test, and wait until the ALLON 2001 device shifts into operation mode.

The self-test performs a complete check of the system and initiates heating. The time required for the self-test is indicated both by the progress bar and by the message on the control panel. The self-test checks the functionality of the following components:

- Screen and buzzer
- Pump
- ThermoWrap connection
- Pressure meter
- Heating and Cooling unit
- Temperature of water inflow and water outflow

Successful completion of the self-test indicates that the ALLON 2001 device is operational.



Figure 4-2 Initial Self Test Screen



Figure 4-3 Self Test Preheating Message

4.6.1. Self-test Messages

If there is a failure during the self-test, messages appear, and the ALLON 2001 device does not proceed to operation mode. See Chapter 7 “Troubleshooting” for details.



NOTE

Some of the messages will halt the ALLON 2001 device. Other messages allow the completion of the self-test but display the actions you need to take to correct the error. See Chapter 7 “Troubleshooting”.

4.7. Operating In Operation mode

After completing the self-test, the ALLON 2001 device shifts into operation mode. A buzzer is sounded, and an "ATTENTION CORE READOUT TOO LOW" message appears (see Figure 4-4 Operation Mode).

The sensors read the room temperature until you position them on the patient, and therefore the message appears. When the core sensor is inserted in the patient, the sensors read the patient's body temperature and the message clears.

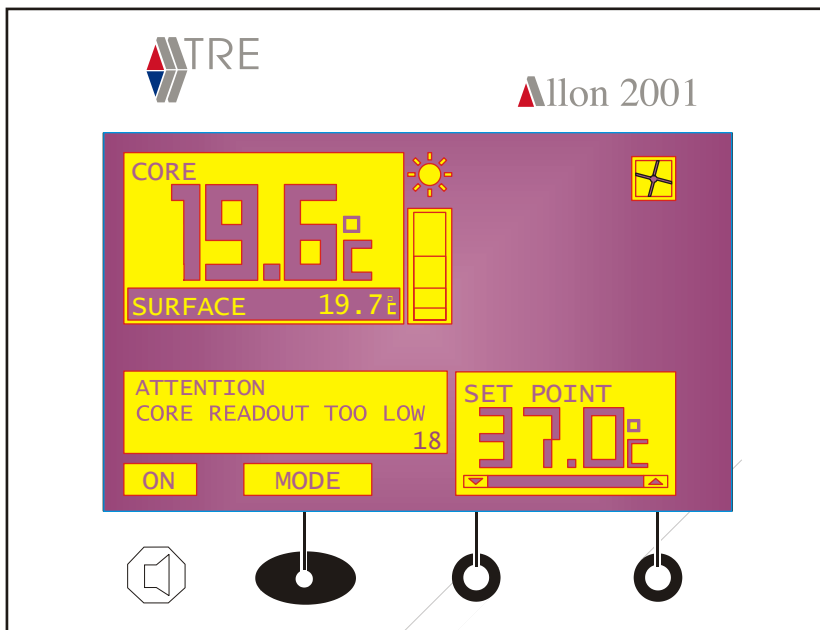


Figure 4-4 Operation Mode Screen

4.8. Changing the Set Point Temperature



WARNING

The desired set point temperature should only be set by the physician or under the order of a physician.

Press the arrow key to decrease or increase the set point temperature. The default temperature is 37°C (98.6°F).



NOTE

When there is a difference between the set point temperature and the core temperature, a further increase in the set point temperature will not affect the water temperature in the ThermoWrap.

For example, if the core temperature is 36°C (96.8°F) and the set-point temperature is 37°C (98.6°F), raising the set-point temperature will not accelerate the heating of the water in the Allon 2001 system. The Allon 2001 device automatically operates at the optimal level to obtain the desired set-point temperature.



WARNING

The default setting is intended to maintain normothermia. However, the system provides the physician with the option of selecting a body temperature in the range of 30°C to 40°C (86°F-104°F).

4.8.1. Exceeding the Normothermia Range

If the desired set point temperature is set to be out of normothermia range (36°C–38°C / 96.8°F–100.4°F), the “ATTENTION OUT OF NORMOTHERMIA! PRESS OK TO CONFIRM” message appears (see Figure 4-5).

Press **OK** to confirm.

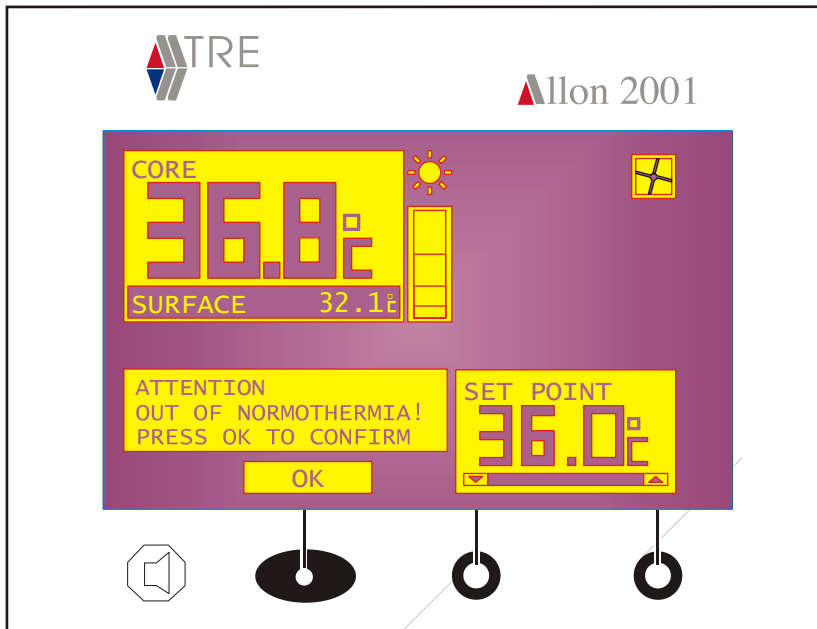


Figure 4-5 Out of Normothermia Message

4.9. Selecting Modes

1. Press the **MODE** key
2. Use the Arrow keys to select the desired mode.
3. Press the **ENTER** key to enter the desired mode.

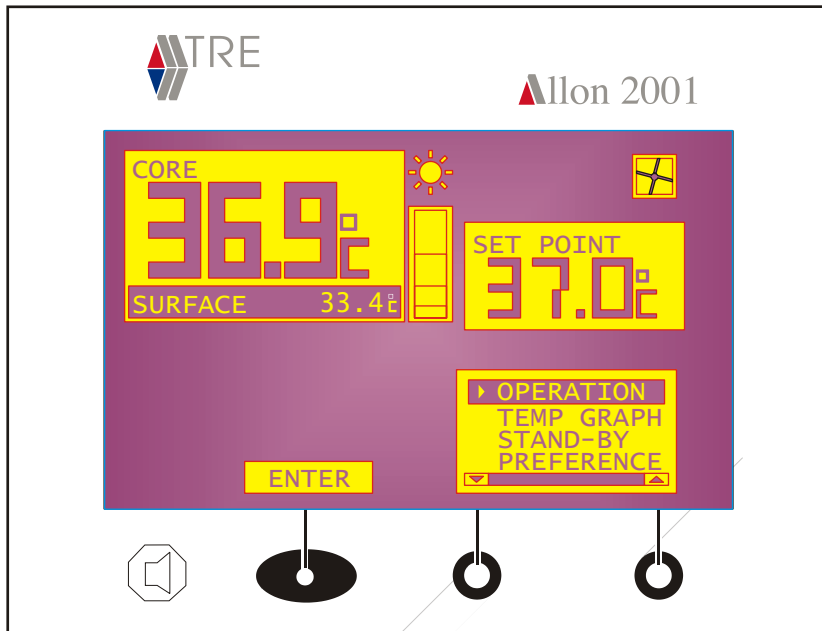


Figure 4-6 Mode Selection Screen

4.10. Modes

4.10.1. Operation Mode

OPERATION mode enables the operator to go directly to the operation mode (see Figure 4-4 on page 4-5).

4.10.2. Temp Graph Mode

TEMP GRAPH mode displays a graphic readout of the patient's Core temperature on an hourly scale (see Figure 4-7).

- Up to eleven hours are stored in memory and can be viewed by pressing the arrow keys to scroll back or forward on the graph.
- Both Core and Surface temperatures are displayed in real time at the top of the screen.
- To return to **OPERATION** mode, press **BACK**.

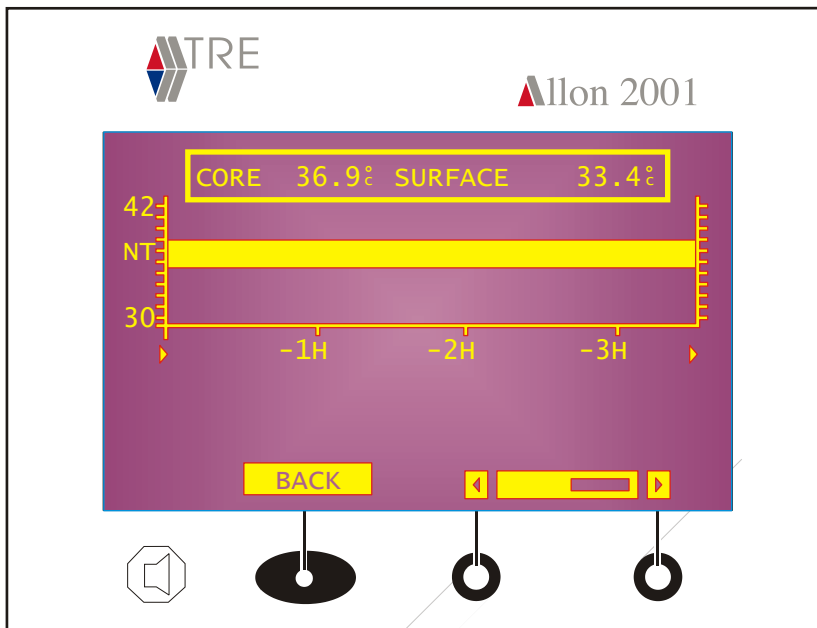


Figure 4-7 Temp Graph Mode

4.10.3. *Stand-by Mode*

STAND-BY mode is used only to monitor body temperature (see Figure 4-8). The ALLON 2001 Device circulates the water internally and maintains the water temperature at the appropriate level to be ready when returning to **OPERATION** mode.

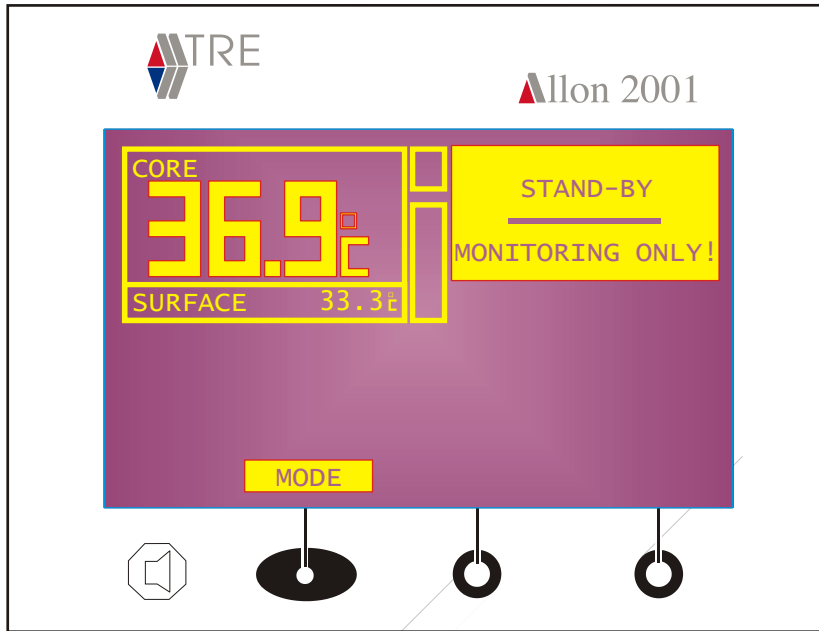




Figure 4-8 Stand-by Mode Screen



During Stand-by mode there is no temperature regulation.

NOTE



When entering Temp Graph mode from Stand-by mode, the ALLON 2001 device returns to Stand-by mode when pressing BACK. To return to Operation mode, press the MODE button again.

NOTE

4.10.4. Preference Mode

PREFERENCE mode (see Figure 4-9) enables the operator to:

- Select a language—The Language preference allows you to change the language of the control panel interface.
- Select temperature unit readout—The Degrees preference allows you to select control panel units from either Centigrade or Fahrenheit.

The active settings are indicated with a star. Selected items are highlighted.

1. Select the desired preference (language or temperature) with the Arrow down button.
2. Select the desired item with the Arrow right button. When you move from one preference to the next, the last item selected is the active setting and a star appears.
3. Press **EXIT** at any time to return to **OPERATION** mode.



Access to Thermal Verification is for MTRE authorized personnel only.

NOTE

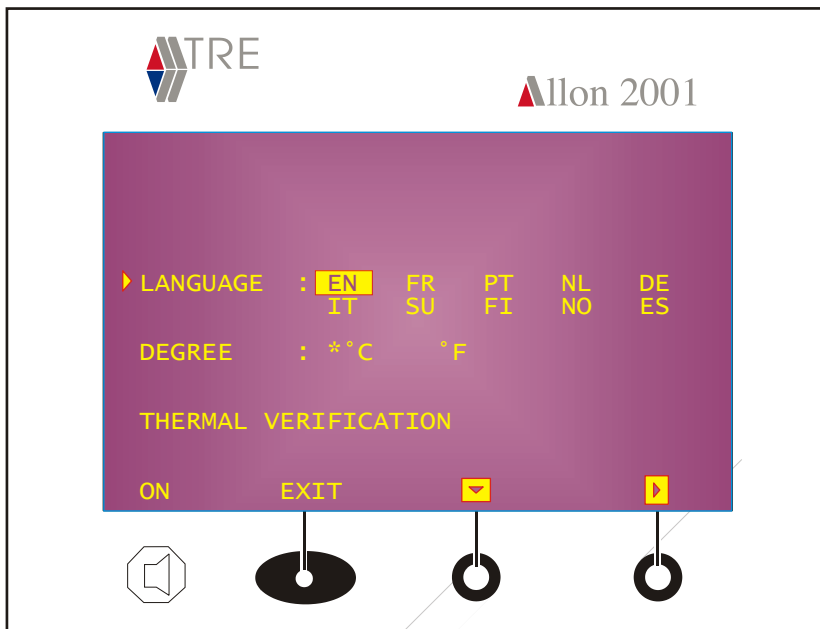


Figure 4-9 Preference Mode Screen

4.11. Inserting and Attaching Human Sensors



CAUTION

For proper use of the ALLON 2001 device, the core sensor must be inserted and the surface sensor must be attached.

4.11.1. Insert Core Sensor into Patient

Insert the reusable core sensor or the disposable core sensor as soon as possible into the patient prior to fastening the ThermoWrap. Immediately connect the disposable core sensor to its adapter.



NOTE

If core temperature reads less than 35.5°C, the "PATIENT TEMPERATURE BELOW 35.5C (95.9F)" message appears.

4.11.2. Attaching Surface Sensor

Attach the reusable surface sensor or the disposable surface sensor to an exposed area of skin with adhesive tape. Immediately connect the disposable surface sensor to its adapter.



WARNING

When using disposable sensors and adapters, make sure to connect the appropriate sensor to its adapter (note the labeling on the adapter).

***4.12. Fastening
the Universal
ThermoWrap to
Patient***

Refer to the "Instructions for Use" leaflet supplied with each ThermoWrap.

***4.13. Fastening
Cardiac
ThermoWrap to
Patient***

Refer to the "Instructions for Use" leaflet supplied with each ThermoWrap.

***4.14. Fastening
Infant
ThermoWrap to
Patient***

Refer to the "Instructions for Use" leaflet supplied with each ThermoWrap.

***4.15. Procedures
for Turning Off
the System and
Moving the
Patient to ICU
with the
ThermoWrap***

1. Turn off the ALLON 2001 device by pressing the ON / OFF switch downwards to the OFF position and disconnecting the power cord from the power source.
2. Close the clamps on the connecting tubes to avoid returning water overflow.
3. Disconnect the connecting tubes from the ALLON 2001 device and from the ThermoWrap.
4. Disconnect the core and surface sensors from the ALLON 2001 device. If the patient is not transferred to the ICU with the ALLON 2001 system, proceed to step 9.
5. Place the sensors beside the patient.
6. Upon arrival to the ICU, reconnect the sensors to the ALLON 2001 device. Reconnect the connecting tubes to the ALLON 2001 device and the ThermoWrap.
7. Turn on the ALLON 2001 device to resume treatment.
8. At the end of treatment repeat steps 1–4.
9. Remove the ThermoWrap and the sensors from the patient.
10. Dispose of the ThermoWrap in accordance with national regulations governing non-toxic plastic waste discharge.
11. Disinfect the surface of the connecting tubes and the exterior of the ALLON 2001 device with a wet cloth soaked in 70% alcohol.
12. Dispose of disposable sensors or disinfect the reusable sensors and disposable sensor adapters as required by hospital/clinic protocol.
13. Store the ALLON 2001 device and its accessories in a safe place.

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CHAPTER 5

Ordering Information

This section outlines information for ordering, shipping and replacing parts of the ALLON 2001 system.

5.1. Equipment and Accessories - Ordering Information

All equipment and accessories may be ordered directly from your local MTRE representative. When ordering parts, specify the model number as listed in this chapter as well as the serial number of your ALLON 2001 device.

5.2. Equipment and Accessories - Inventory

5.2.1. Available ThermoWraps

ThermoWraps for adult models are packed in a twelve-unit package that contains two six-unit boxes each. The minimum order for any model ThermoWrap is twelve units or any multiplication of twelve.

ThermoWraps for infant models are packed in a twenty four-unit package. The minimum order for any infant model ThermoWrap is twenty-four units or any multiplication of twenty-four.

Table 5-1 Cardiac ThermoWraps

Table of Cardiac ThermoWrap Sizes		
Model No.	Patient Height Range	Quantity per box
3363*	One size fits all adults	12

* Models 3365 and 3368 may still be used.

Table 5-2 Universal ThermoWraps

Table of Universal ThermoWrap Sizes			
Model No.	Height Range in Inches	Height Range in Feet & Inches	Height Range in Centimeters
3131	31"-36"	2'7"-3'0"	79-91
3136	36"-41"	3'0"-3'5"	91-104
3141	41"-48"	3'5"-4'0"	104-122
3148	48"-53"	4'0"-4'5"	122-135
3153	53"-60"	4'5"-5'0"	135-152
3160	60"-66"	5'0"-5'6"	152-168
3166	66"-71"	5'6"-5'11"	168-180

Table 5-3 Infant ThermoWraps

Table of Infant ThermoWrap Sizes		
Model No.	Weight Range in kg	Weight Range in lb
3118	2.5–4.0	5.5–8.8
3121	4.0–7.0	8.8–15.4
3125	7.0–11	15.4–24.2

Table 5-4 Accessories Inventory

Allon 2001 Unit	
Model No.	Description
2100	Handle
4100	Connecting tubes
4101	Male connector for draining water tank
4102	Spare water filter
4200	Core sensor—Gray
4201	Surface sensor—Green
4202	Core sensor adapter—Gray
4203	Surface sensor adapter—Green
4204	Infant Core sensor—Gray
4300	Hospital Grade Power Cable (European standard)
4301	Hospital Grade Power Cable (UK standard)
4302	Hospital Grade Power Cable (USA standard)

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CHAPTER 6

Maintenance

6.1. Introduction

This chapter outlines the maintenance instructions for the ALLON 2001 system. Qualified hospital staff may perform routine maintenance unless otherwise specified.



WARNING

The repair, and servicing of the Allon 2001 system should be performed only by MTRE Advanced Technologies LTD or authorized agents of MTRE Advanced Technologies LTD.

6.2. Service Information

When communicating with authorized MTRE representatives regarding the ALLON 2001 system, always state the model and serial numbers on the identification label located on the rear panel of the ALLON 2001 device (see Figure 1-1 Label Placement for the ALLON 2001 Device on page 1-5).

When communicating regarding ThermoWraps, refer to the label on the ThermoWrap package for lot number details.

6.3. Routine Maintenance

The ALLON 2001 device should be periodically inspected and maintained to make sure that it remains in optimum condition. A recommended routine inspection and maintenance schedule is provided in Table 6-1 Inspection and Maintenance Schedule on page 6-5.

6.4. Sterilization of Reusable Sensors and Disposable Sensor Adapters

Use the Ethylene Oxide Method (E.T.O.) to sterilize reusable sensors and disposable sensor adapters as required by hospital/clinic protocol.



CAUTION

Do not use the steam autoclave method to sterilize reusable sensors and disposable sensor adapters.

6.5. Filter Replacement



NOTE

An additional filter is supplied in the accessory box.

The filter must be replaced every twelve months. Replacement is done by the hospital personnel as follows:

1. Drain the water tank (see Table 7-1 on page 7-3).
2. Remove the rear cover:
 - a. Unscrew the thumb captive screws at the bottom of the cover.
 - b. Pull the bottom part of the cover towards you and then down to release the lip from the chassis.
3. Unscrew the filter clamp screw and remove the filter clamp (see Figure 6-2).
4. Release both the water-in and water-out tubes from the filter assembly by pressing the release ring of each end of the filter and pulling the tubes from the filter.
5. Dispose of the old filter.

To replace the filter assembly, follow the procedure listed below.

**CAUTION**

The filter is marked with an arrow indicating the direction of water flow (see Figure 6-1). You must assemble the filter in the manner indicated.

1. Connect the tubes to the new filter assembly. Insert both tubes with suitable force to ensure that they are secure.
2. Position the filter clamp in the chassis and tighten the filter clamp screw by hand (see Figure 6-2).
3. Close the rear cover and tighten the thumb captive screws by hand.

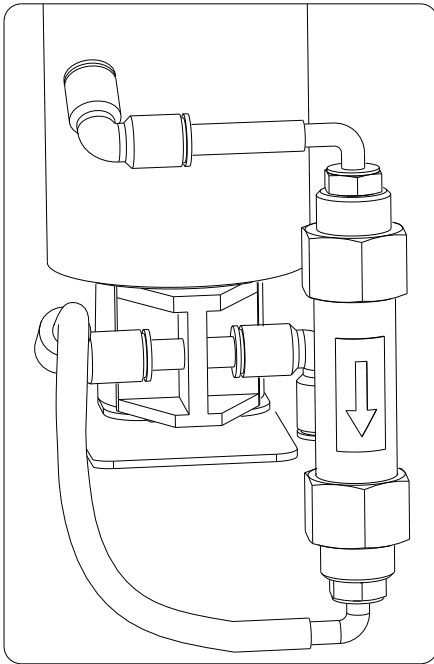


Figure 6-1 Filter Orientation

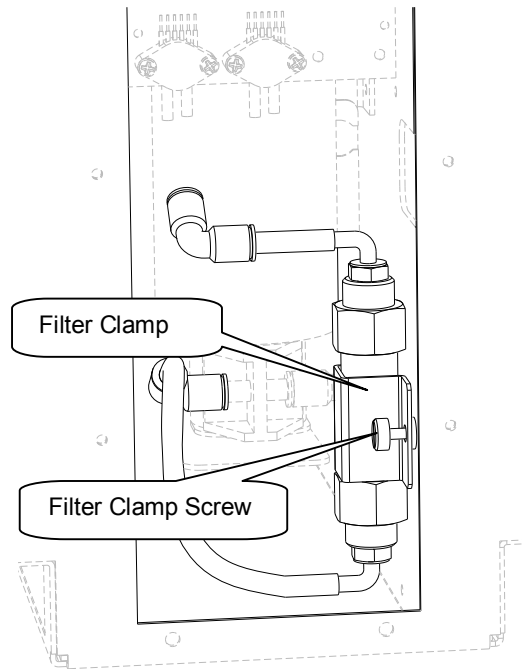


Figure 6-2 Filter Assembly

Table 6-1 Inspection and Maintenance Schedule

Frequency	Inspection/Service	Performed By
Before each treatment	<ul style="list-style-type: none"> • Clean connecting tubes and Quick Coupling Connector with a wet cloth. • Perform a visual inspection for any mechanical failure in sensors, connecting tubes, and power cable. • Perform a visual inspection of the exterior of the ALLON 2001 Device. 	Staff
As required by hospital/clinic protocol	Routine external cleaning and disinfection.	Staff
Annually	Calibration check	BMD
	Replace filter	Staff



The ThermoWrap contains chlorine tablets that prevent contamination of the hydraulic system of the Allon 2001 system.

NOTE

CHAPTER 7

Troubleshooting

7.1. General

The Allon 2001 device is equipped with self-testing routines that continuously monitor system operation. If a system fault or malfunction is detected, a fault message appears on the message display. Should a malfunction occur, consult the Troubleshooting Guide in Table 7-1 and Table 7-2 of this chapter.

7.2. Trouble-shooting Guide

Table 7-1 lists some possible symptoms that indicate malfunctions that do not appear on the message display, their cause, and recommended actions.

Table 7-2 provides a list of fault messages that appear on the ALLON 2001 device screen.



WARNING

The repair and servicing of the ALLON 2001 system should be performed only by MTRE Advanced Technologies Ltd or authorized agents of MTRE Advanced Technologies Ltd.

Table 7-1 Allon 2001 System Undisplayed Malfunction Troubleshooting Guide

Observation	Possible Problem	Action to be Taken
The power switch of the Allon 2001 device is set to "ON" but it is not activated and the control panel is blank.	ALLON 2001 device is unplugged.	Check the 120/230 VAC power cable connections.
	No line voltage	Call BMD
ThermoWrap begins to leak.	The garment was accidentally punctured during the course of the operation.	Turn off the ALLON 2001 device and allow the water to return to the reservoir. Replace the ThermoWrap if possible
Water leaks from the connector between ThermoWrap and the connecting tube.	Connecting tubes are not connected properly.	Close clamps on ThermoWrap. Disconnect connecting tubes and re-connect connecting tubes until the click sound is heard.
	Damage to connecting tubes.	Replace connecting tubes.
	Damage to Quick Coupling Connector.	Call BMD.
Water leaks between connecting tubes and the Allon 2001 device.	Connecting tubes are not connected properly.	Disconnect connecting tubes from the machine and re-connect again.
	Damage to connecting tubes.	Replace connecting tubes.
	Damage to Quick coupling connector.	Call BMD.

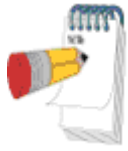
Table 7-1 Allon 2001 System Undisplayed Malfunction Troubleshooting Guide (cont.)

Observation	Action to be Taken
<p>Water tank overfilled.</p>	<p>If it is necessary to drain the water tank because of overfilling, proceed as follows:</p> <ol style="list-style-type: none"> 1. Connect one connecting tube to the right Quick Coupling Connector (under the Core Sensor socket) but not to a ThermoWrap. 2. Connect the special male connector model no. 4101 to the connecting tube (see Figure 7-1) in Step 1. 3. Turn the Allon 2001 device ON. 4. Change into Operation mode. 5. Allow the excess water to drain into a receptacle, pail or sink. 6. When the desired water level has been reached, turn the ALLON 2001 device OFF. <div data-bbox="456 836 1098 1282" style="text-align: center;"> <p>The diagram illustrates the components for draining the water tank. It shows two tubes with Quick Coupling Connectors at the top. A separate 'Special Male Connector' is shown to the right, with a callout box pointing to it. Below, two tubes with Quick Coupling Connectors are shown connected to a common base.</p> </div> <p style="text-align: center;"><i>Figure 7-1 Connecting Tubes and Special Male Connector</i></p>



NOTE

A muted alarm is activated when a subsequent message appears.



The **Halt – Please Restart** message indicates an error that can have numerous causes.

You **must** restart the ALLON 2001 device.

NOTE

Table 7-2 Allon 2001 System Message Troubleshooting Guide




Message	Probable Cause	Action to be Taken
HALT - PLEASE RESTART  XX	Error during normal function	Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the ALLON 2001 device and contact your local service representative. Note the number that appears on the screen (1–16).
ATTENTION NO WATER – PLEASE ADD WATER 	No water in tank	Refill water to maximum level.
	Water tank float is jammed	Open water tank cap and insert a long object to release the float.
ATTENTION OUT OF NORMOTHERMIA PRESS OK TO CONFIRM	Desired set-point is set to be out of 36°C–38°C	<ul style="list-style-type: none"> • Approve the action. • Disapprove the action.
 - Indicates alarm activated		

Table 7-2 Allon 2001 System Message Troubleshooting Guide (cont.)





Message	Probable Cause	Action to be Taken
ATTENTION CHECK THERMOWRAP  10	Connecting tubes are not connected.	Connect connecting tubes.
	ThermoWrap is blocked due to improper wrapping	Check for snarls, folds, or objects that obstruct the water flow in the ThermoWrap.
	ThermoWrap clamps are closed	Check clamps
ATTENTION CHECK CORE SENSOR  11	Misplacement of sensor in core socket	Connect the core sensor to the appropriate socket.
	Core adapter is connected to the Allon2001 device without the disposable temperature sensor.	Connect disposable sensor
ATTENTION CHECK SURFACE SENSOR 12	Misplacement of sensor in surface socket	Connect the appropriate surface sensor to its socket.
	Surface adapter is connected to the Allon2001 device without the disposable temperature sensor.	Connect disposable sensor
ATTENTION CONNECT CORE SENSOR* 	No core sensor inserted in its socket.	Connect core sensor. Note: In operation mode, the water temperature default setting is 38.5°C if the core sensor has not been inserted yet.
 - Indicates alarm activated		
* The alarm is activated again after 30 minutes if no action is taken.		

Table 7-2 Allon 2001 System Message Troubleshooting Guide (cont.)







Message	Probable Cause	Action to be Taken
ATTENTION WATER TEMP TOO LOW  16	Water Temperature < 10°C	Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the ALLON 2001 device and contact your local service representative.
ATTENTION WATER TEMP TOO HIGH  17	Water Temperature > 42°	Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the ALLON 2001 device and contact your local service representative.
ATTENTION CORE READOUT TOO LOW  18	<ul style="list-style-type: none"> • Core temperature is less than 27.0°C (80.6°F) if set point above 36°C (96.8°F) • Core temperature is less than 32°C (89.6°F) if set point is below 36°C (96.8°F) 	Insert the core sensor into patient.
PATIENT TEMP ABOVE 38.5°C (101.3°F)** 	Core temperature reading above 38°C (101.3°F).	Inform the physician.
PATIENT TEMP BELOW 35.5°C (95.9°F) ** 	Core temperature is higher than 27.0°C (80.6°F)	Inform the physician..
 - Indicates alarm activated		
** Pressing Alarm Mute silences the buzzer for this present condition and any recurrence of this condition for thirty minutes.		

Table 7-2 Allon 2001 System Message Troubleshooting Guide (cont.)

Message	Probable Cause	Action to be Taken
ATTENTION ELECTRO-MAGNETIC INTERFERENCE 22	The ALLON 2001 device detects an electromagnetic field greater than allowable standard.	The message will disappear after ten seconds. If the message appears for more then ten seconds, replace the core sensor.
ATTENTION CONNECT SURFACE SENSOR	No surface sensor inserted into the socket.	Connect surface sensor to its socket

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CHAPTER 8

Specifications

8.1. Physical

Dimensions:

260 mm W x 625 mm D x 940 mm H /
(10.23"W x 24.6"D x 37"H)

Net Weight:

33 kg / 77 lb

8.2. Control System

Micro-controller

Operating icons

Set point switch and mode switch

Displays:

- Surface Temperature
- Core Temperature
- Graphic display of core temperature
- Set point temperature
- Alarm displays

Controller range:

- Water Temperature (outflow) 13-40.8°C (55-105.4°F)
- Set Point Temperature 30-40°C (86-104°F)

Sensors accuracy:

Patient Temperature $\pm 0.3^{\circ}\text{C}$ (0.4°F)

Water accuracy:

Water Temperature $\pm 0.3^{\circ}\text{C}$ (0.4°F)

8.3. Auxiliary Systems***Water tank—Maximum Volume:***

6 liters (1.6 gal.)

8.4. Warranty

One year

8.5. Operation***Ambient Temperature:***

10°C – 40°C (50°F – 104°F)

8.6. Storage and Transport***Control ALLON 2001 Device:***

- Maximum storage time is 26 weeks
- An ambient temperature range of -40°C to $+70^{\circ}\text{C}$ (-40°F to 158°F)
- A relative humidity range of 10% to 100%
- An atmospheric pressure range of 500 hPa to 1060 hPa.
- Temp range without water: -40°C to 70°C (-40°F to 158°F)

8.7. Electricity***Input power:***

120/230 VAC with isolation transformer 50/60 Hz


Maximum Current











120/230 VAC 6.3 amp

Transformer:

Medical multiple isolation transformer: 120/230

8.8. Safety

Warning displays:  indicates audible alarm

- SYSTEM HALT 
- ATTENTION NO WATER – PLEASE ADD WATER 
- ATTENTION OUT OF NORMOTHERMIA RANGE!
PRESS OK TO CONFIRM
- ATTENTION CHECK THERMOWRAP 
- ATTENTION CHECK CORE SENSOR 
- ATTENTION CHECK SURFACE SENSOR
- ATTENTION CONNECT CORE SENSOR 
- ATTENTION WATER TEMP TOO LOW 
- ATTENTION WATER TEMP TOO HIGH 
- ATTENTION CORE READOUT TOO LOW 
- ATTENTION PATIENT TEMPERATURE ABOVE 38.5°C
(101.3°F) 
- ATTENTION PATIENT TEMPERATURE BELOW 35.5°C
(95.9°F) 
- ATTENTION ELECTROMAGNETIC INTERFERENCE
- ATTENTION CONNECT SURFACE SENSOR

Protection against electric shock:

Type BF

Degree of protection against electric shock:

Class 1

Special mechanism

Prevents extremely high pressure and temperature

Quick coupling connectors

Prevent leakage

Anti-current overload system:

6.3 amp fuse

ALLON 2001 device shutdown mechanism

Software failure

8.9. Accessories

- Connecting tubes
- Connector for draining the water tank
- Power cable
- Spare filter

Sensors – ¼” PL Stereo Phone Plug:

- Reusable core
- Reusable surface
- Reusable infant core
- Disposable adapter core
- Disposable adapter surface

ThermoWrap:

- Various ThermoWrap types
- Sizes range from 40 cm–196 cm (1'4"–6'5")
- Humidity level range: 10–90%
- Maximum shelf lifetime of three years

Appendix A

MTRE Customer Service Representative

Important!

The following details are necessary to contact your MTRE representative. Keep this form with the User's Manual for easy access in case your Allon 2001 device is in need of service.

Representative

Name:

Company

Name:

Address:

Telephone No:

Fax:

E-mail:
