
Thermoregulation Systems

S E R V I C E M A N U A L



Catalog No. FDT-200-000

Rev: C

Revised December 2013

For CritiCool machines with 10



0473

Conformity according to the Council Directive 93/42/EEC concerning Medical Devices as amended by 2007/47/EC.

Manufacturer's Name  :

MTRE Advanced Technologies Ltd.
4 Hayarden Street, Yavne, 81228
P.O. Box 102, Rehovot, 76100, Israel
Tel.: +972-8-9323333
Fax: +972-8-9328510

European Representative  :

Charter-Kontron Limited
Unit 18 Avant Business Centre
21 Denbigh Road
Milton Keynes
MK1 1DT England
Tel.: 01908 646070
Fax: 01908 646030

US Representative:

Mennen Medical Corp.
290 Andrews Road
Feasterville-Trevoise, PA 19053-3480
Phone 215 259-1020
Fax 215 357-2010

C a t a l o g N o . FDT-200-000 Rev C

Revised December 2013

(For 100-OPT99)

Copyright © MTRE Advanced Technologies Ltd. 2013 All RIGHTS RESERVED

Registered trademarks are the intellectual property of their respective holders.

Copyright ♥ 2013 by MTRE

All rights reserved. No part of this manual may be reproduced or copied in any form by any graphic, electronic or mechanical means – including photocopying, scanning, typing or information retrieval systems – without advanced written permission from MTRE.

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 Thermoregulation 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; or
- 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 Garment in each procedure while operating the system.

Note that all Garments 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 MTRE Thermoregulation system described in this manual has been designed to meet international safety and performance standards. Only qualified personnel may service the system, and these field engineers 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 service the system. It is important that you read this manual and familiarize yourself thoroughly with its contents before you attempt to service 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.

Field Repairs Statement

Repair of MTRE. Equipment in the field will be performed by service engineers, authorized by MTRE. Repair will be performed on a board level **only**.

The list of replaceable component and boards is available in the spare part list.(Appendix B)

System testing will be performed using the test form available in the Service manual.

Training and Qualification

MTRE or its authorized distributor will provide training for technicians and sales personal as per the Intended use of the device or system.

The scope of the training is part of the agreement between MTRE or its authorized distributor and/or the end user.

Servicing of MTRE equipment is allowed only to persons that were trained and qualified to service the equipment efficiently and safely.

Warning!!!

No modification of this equipment is allowed. Software update must be performed by service engineer authorized by MTRE.

TABLE OF CONTENTS

Chapter 1:

About This Manual

Applicable Systems	1-1
Garments	1-1
Essential Performance	1-1

Chapter 2:

Warnings and Precautions

Definitions	2-1
Intended Use	2-1
Warnings	2-1
Precautions	2-2
Labels	2-4
Thermoregulation Device Labels	2-4
.....	2-4

Chapter 3:

System Description

General Description	3-1
Thermoregulation Device	3-1
External Features	3-2
Front View	3-2
Side View	3-3
Rear Panel	3-4
Accessories	3-4

Chapter 4:

Installation

Pre-installation Requirements	4-1
Space and Environmental Requirements	4-1
Electrical Requirements	4-1
Unpacking and Inspection	4-1
Assembling the Handle	4-1
Accessory Kits	4-3
Moving the Unit	4-5
Preparation	4-5
Locking and Unlocking the Trolley Wheels	4-6
Storage Conditions and Transport	4-6
Storage Environment	4-6

Chapter 5:

Panels and Covers

Introduction	5-1
Removal of the Trolley	5-8

Chapter 6:**Electrical System**

Introduction	6-1
Release of PCB Spacer Supports	6-2
Slide Lock Connector	6-2
Power Supply Assembly	6-2
Controller Board	6-4
Controller Board Fuses	6-7
Removal of Controller Board	6-7
TEC Control (Thermo-Electric Components) Board	6-8
Human Sensors (HS) Board	6-12
MMI (Man-Machine Interface)	6-15
FP Board	6-16
HCU (Heating Cooling Unit)	6-18
Z Heat Exchanger	6-19
Thermal Exchange Components (Peltier)	6-20
Heat Sink	6-20
Fan	6-20
Pump	6-22
Solenoid Bypass Valve	6-22
Thermistors	6-23
Water-out and Thermostat Thermistor Replacement	6-23
Water-in Thermistor Replacement	6-24
Float	6-25

Chapter 7:**Hydraulic System**

Introduction	7-1
Water Tank Assembly	7-3
Water Tank Top Cover Assembly	7-4
Filter	7-5
.....	7-5
Replacing the Filter	7-5
Removing the Filter	7-5
Installing the New Filter	7-6
Pump	7-7
Removing the Pump	7-7
Pump Block Diagram	7-9
Solenoid Bypass Valve	7-9
Water-In and Water-Out Connectors	7-10

Chapter 8:**Software**

Overview	8-1
Self-Test	8-1
Safety Algorithm	8-1
Halt Conditions	8-2
Technician Mode Error Messages	8-3
Explanation of Error Messages	8-3

Chapter 9:

Periodic Maintenance

Overview of the Periodic Maintenance Procedures	9-1
Removing the Cover	9-2
Replacing the Water Filter	9-2
Activating the CritiCool Machine	9-2
Human Sensors Verification	9-2
Water Temperature Sensors Verification	9-4
Thermostat Verification	9-6
Pressure Verification	9-8
TEC Current Test	9-9
Check for Water Leakage	9-11
Self-test	9-11
Replacing Controller Board Fuses	9-11

Chapter 10:

Troubleshooting

Halt Messages	10-1
Text Messages	10-3

Chapter 11:

Special Equipment and Tools

Calibration Toolset: Verification and Calibration Units	11-1
MTRE Temperature Calibration Unit P/N: 017-00184	11-2
MTRE Temperature Calibration Unit - Controls	11-2
Analog Flow and Pressure Calibration Unit P/N 017-00190	11-4
Digital Pressure Gauge P/N 017-00290	11-4
TEC Current Verification Unit	11-6
Calibration Cables	11-7
Core Calibration Cable	11-7
Surface Calibration Cable	11-7
Standard Tools	11-8
Calibration Test for the MTRE Temperature Calibration Unit	11-8
Thermostat Verification Tool	11-9
PCB Extraction Tool	11-9

Chapter 12:

Specifications

Appendix A:

Technician Mode

Technician Mode	A-1
Technician Mode Screen	A-1
Technician Mode Screen—Details	A-2
Entering Technician Mode	A-4

Appendix B:

Spare Parts List

Disclaimer	B-1
CritiCool™ – Cooling Control Unit	B-1
CritiCool™ – Spare Parts List	B-2

Allon 2001™ – Warming Control Unit, Version-05	B-17
Allon 2001™ – Spare Parts List For, Version-05	B-17
Upgrade Package for Allon 2001™ Warming Control Unit	B-17

Appendix C:

Service Form

Appendix D:

Periodic Maintenance

For Stimulator: TP-400 FOGG	D-1
For Stimulator MTRE Temperature Calibration Unit	D-5

Appendix E:

Downloading Updated CritiCool Software

CHAPTER 1: ABOUT THIS MANUAL

Applicable Systems

This Service Manual covers all Normothermia management and Cooling Therapy systems produced by MTRE Advance Technology Ltd. To avoid confusion, all systems will be referred to in this manual as the *Thermoregulation System*.

Information (component descriptions or procedures) specific to any particular system will be noted within the manual in the relevant section.

Garments

The Thermoregulation System is designed to function with both the ThermoWrap and the CureWrap systems. Both ThermoWrap and CureWrap will be referred to in this manual as the *Garment*.

Information specific to any one of these Garments will be noted within the manual in the relevant section.

Essential Performance

The following functions are considered by the manufacturer as essential:

- Water temperature control
- Unexpected core temperature alarm

WARNING!!! *The system will HALT if any of these elements of the control mechanism fail.*

CHAPTER 2: WARNINGS AND PRECAUTIONS

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.

Intended Use

The Thermoregulation System is designed to regulate body temperature as determined by the physician.

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. Mishandling 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 Thermoregulation device.
5. The user should verify that no fluids are present at the skin/Garment interface during the operation. Failure to do so can cause lesions on the patient's skin.

Following the procedure, a pattern resembling the Garment 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

Thermoregulation system does not prevent this occurrence. It is therefore recommended to use pressure sores protective means between the operating table and the Garment.

7. Before initiating maintenance procedures as described in Chapter 9, disconnect the power cable 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 to 104°F).

9. Do not lift or move the patient by means of the Garment. 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 Thermoregulation system is mandatory.

12. Repair, and servicing of the Thermoregulation System should be performed only by MTRE Advanced Technologies LTD or authorized agents of MTRE Advanced Technologies LTD.

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 Thermoregulation System. All hospital personnel using the Thermoregulation system must complete the Thermoregulation training program.

The repair, and servicing of the Thermoregulation 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 Garment, turn off the Thermoregulation 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 Thermoregulation 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 10: Troubleshooting).

Avoid folds in the Garment—these may obstruct water flow.

Do not block the Thermoregulation device ventilation grills. Air must be able to flow freely in and out in order to 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 Garment, shadows from the Garment may appear on the X-ray film.

Avoid inserting any sharp object between the patient and the Garment.

WARNING!!! *Improper use of the Thermoregulation systems, may lead to skin burns, electrical hazards, and several changes in body temperature.*

CAUTION! *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 Thermoregulation system is mandatory*

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

Labels

Thermoregulation Device Labels

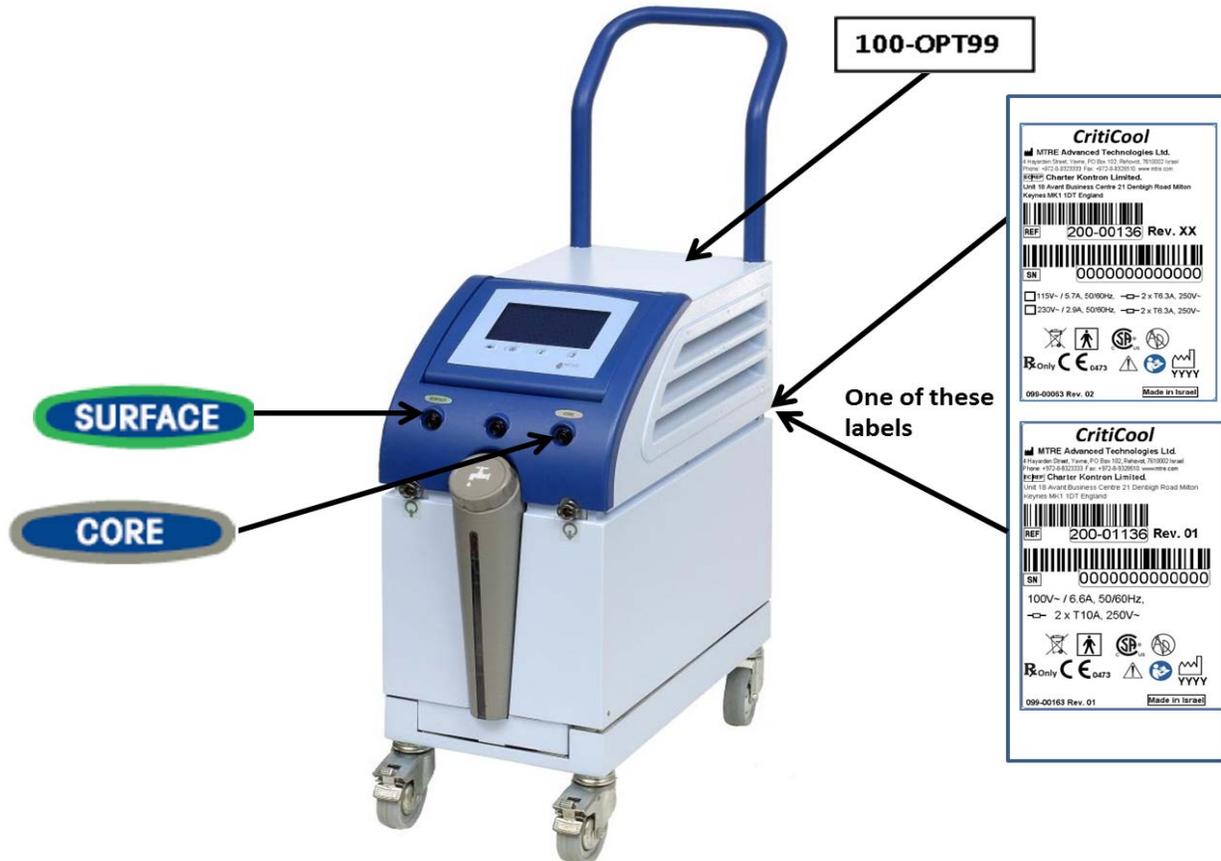


Figure 2-1: Label Placement for the CritiCool Thermoregulation Device



Figure 2-2: Label Placement for the Allon Thermoregulation Device

Table 2-1: Key for Label Symbols

Symbol	Description
	Location of core sensor socket
	Location of surface sensor socket
	AC Voltage
	Fuse
	The 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.
	See User Manual
	Type BT equipment
	Date of manufacture
	The CSA symbol indicates that the product has received the approval of the Canadian Standards Association.
	Machine Version - Machine serial number
	Water-in connector indicator
	Water-out connector indicator
	No Pushing

CHAPTER 3: SYSTEM DESCRIPTION

General Description

MTRE's Thermoregulation system induces, maintains, and reverses hypothermia in an effective and precise manner. The desired temperature is preset by the physician with a possible range of target temperature from Mild Hypothermia to Normothermia.

The system is composed of two elements, the Thermoregulation device and the Garment. The Thermoregulation device functions as a control unit and a cooling/heating pump which circulates water. The control unit constantly monitors the patients' core temperature through specific sensors, and, using its on-board body temperature control algorithm, delivers the optimum water temperature to reach the desired set point temperature. The cooling/heating pump brings the water to the required temperature and the pump circulates it through the specially designed Garment.

The Garment is a flexible 3D single piece design, through which the water circulates. It is designed to be in close contact with a large contact area of the body, thus allowing optimization of energy transfer. . The MTRE garment is proprietary to MTRE and this is the only garment authorized to be used with the Thermoregulation Device.

Thermoregulation Device

The Thermoregulation device has a microprocessor that controls the water temperature to the Garment 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 Garment is regulated by timed pauses of the flow during clinical operation.

The Thermoregulation device is equipped with a handle for easy transport.

CAUTION! *Never place the Thermoregulation device on its rear or side.*

External Features

Front View

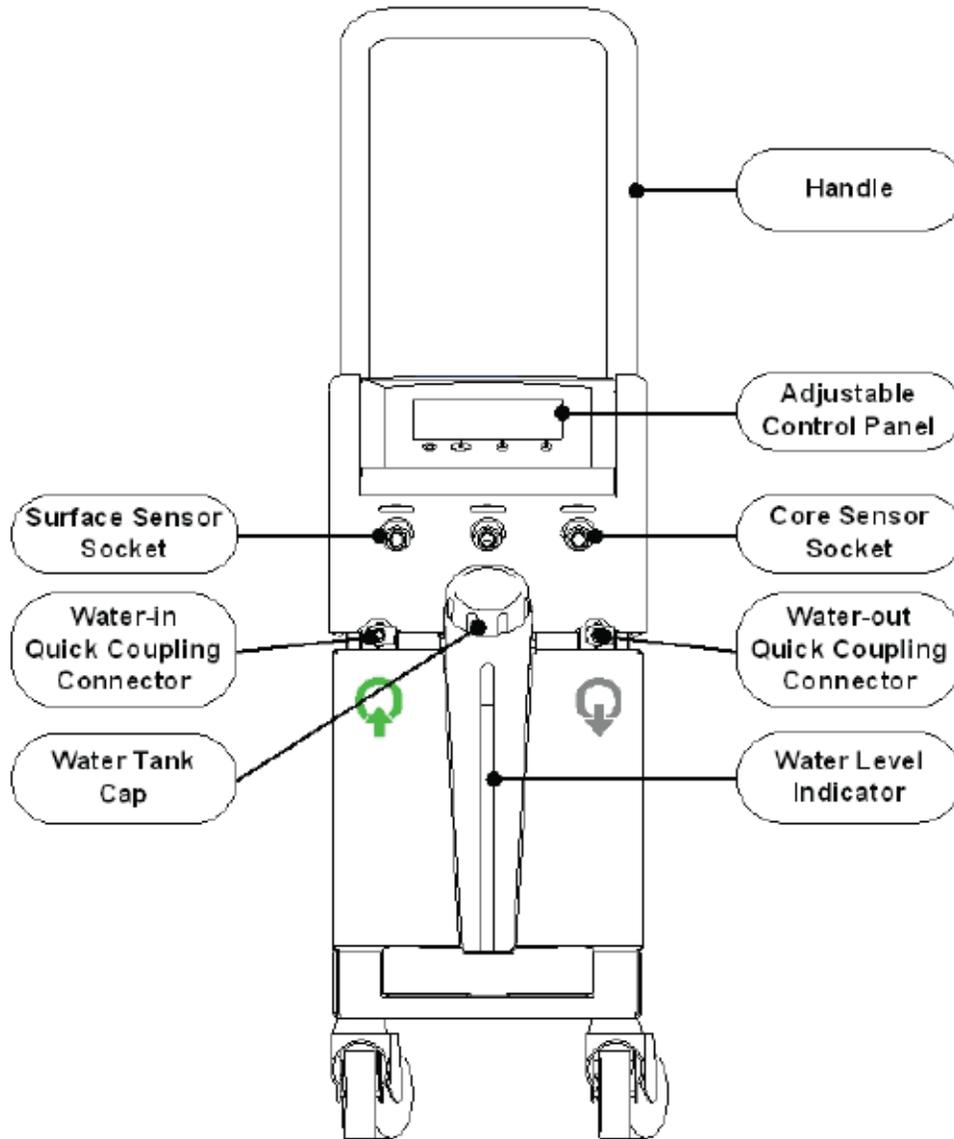


Figure 3-1: Front View

Side View

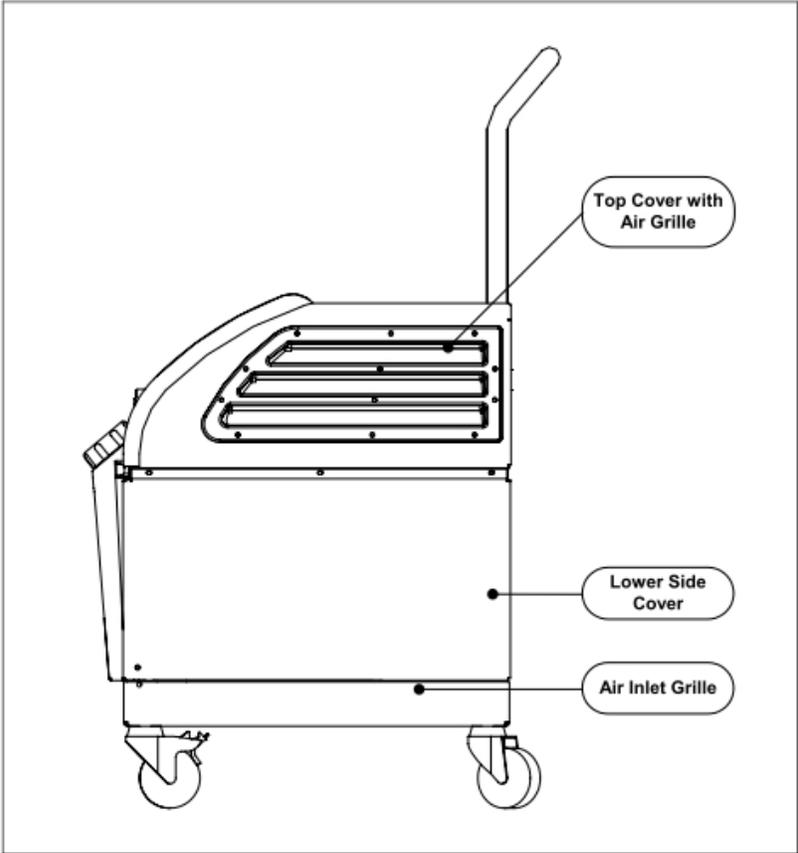


Figure 3-2: Side View

Rear Panel

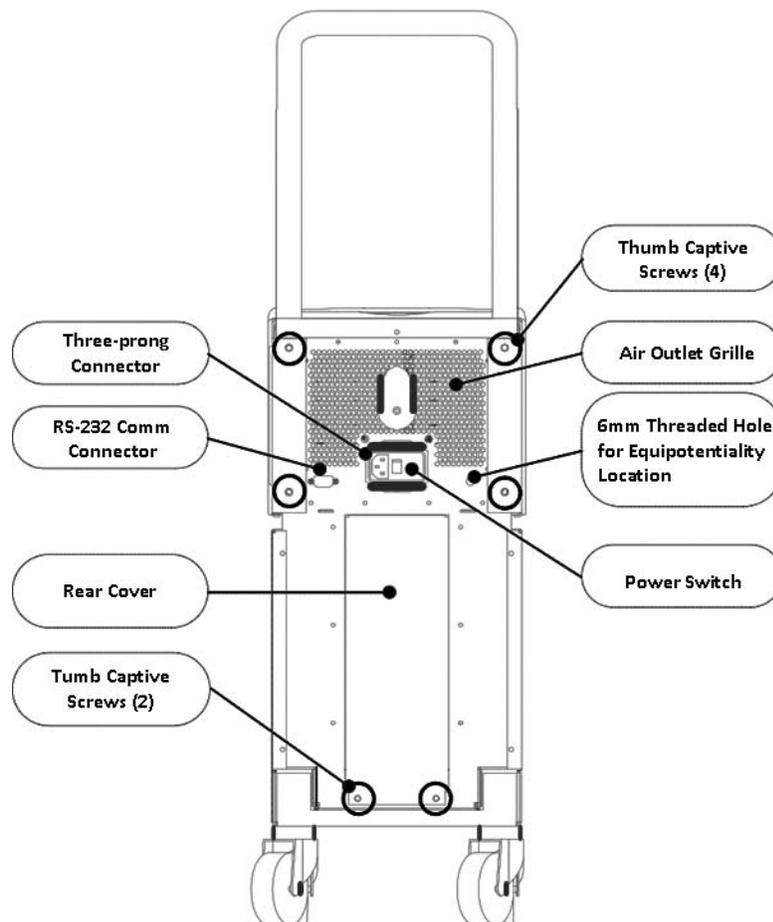


Figure 3-3: Rear View

Accessories

To operate the Thermoregulation system, the following accessories are needed:

1. Human Temperature Sensors

- 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 device. The core sensor must be inserted into the patient's body and the surface sensor must be attached to the patient's skin for the device to function properly.

- Disposable Sensors

Disposable sensors are attached to two color-coded adapters: gray (Core) and green (Surface). The core sensor must be inserted into the patient's body and the surface sensor must be attached to the patient's skin 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.
Use reusable surface sensors or disposable surface sensor adapters supplied by MTRE only.

- Reusable Core Sensor (Part No. 014-00020):

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 Thermoregulation device.

The other end is inserted into the patient and measures core body temperature.

- Disposable Core Sensor Adapter (Part No. 014-00028):

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 Thermoregulation Device. The sensor is inserted into the patient and measures core body temperature.

- Reusable Infant Core Sensor (Part No. 014-00005):

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 Thermoregulation device. The other end is inserted into the patient and measures core body temperature.

- Reusable Surface Sensor (Part No. 014-00021):

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 Thermoregulation device. The other end is attached with adhesives to the patient’s skin.

- Disposable Surface Sensor Adapter (Part No. 014-00129):

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 Thermoregulation device. The sensor is attached with adhesives to the patient’s skin and measures surface body temperature.

Table 3-1: Sensors and Data Provider Input Specification

Model No.	Name	Description	Accuracy	Resolution	Type
014-00020	Core	Inner body temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor
014-00021	Surface	Skin temp	± 0.3°C	± 0.1°C	Medical Grade Thermistor
014-00005	Core Infant	Infant Inner body temp.	± 0.3°C	± 0.1°C	Medical Grade Thermistor

2. Detachable Electric Power Cable and Plug

- Power cord (European Standard) (Part No. 014-00017)
- Power Cord (USA Standard-Hospital Grade) (Part No. 014-00016)

3. Connecting Tubes for CureWrap (Part No. 200-00147)

Two flexible 2.5 m long, color-coded connecting tubes, connect a CureWrap with the Thermoregulation 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 Thermoregulation device end and with three female Quick Coupling Connectors at the CureWrap end.

4. Connecting Tubes for ThermoWrap or CureWrap Garments (Part No. 200-00109)

Two flexible 2.5m long connecting tubes connect the Garment with the Thermoregulation 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 Thermoregulation device end and with two female Quick Coupling Connectors at the Garments end.

5. Male Connector for Draining Water Tank (Part No. 002-00069)

Refer to Section "Draining the Water Tank" in Chapter 9.

6. Spare Water Filter (Part No. 200-00130)

For annual filter replacement - packed in the accessory box

7. Handle

- Allon Model (Part No. 007-00333)
- CritiCool Model (Part No. 007-00365)

CHAPTER 4: INSTALLATION

Pre-installation Requirements

Space and Environmental Requirements

The Thermoregulation device is supplied on a trolley as a mobile unit for user convenience. Locate the Thermoregulation device not less than 5 cm (2") from other objects to avoid impairing its ventilation.

The following dimensions should be considered when placing the Thermoregulation device:

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

Electrical Requirements

230/120 VAC 500W

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

Unpacking and Inspection

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

The device 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 device 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.

Assembling the Handle

➤ To assemble the handle:

1. Release the four thumb captive screws from the handle.

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 4-1).
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.

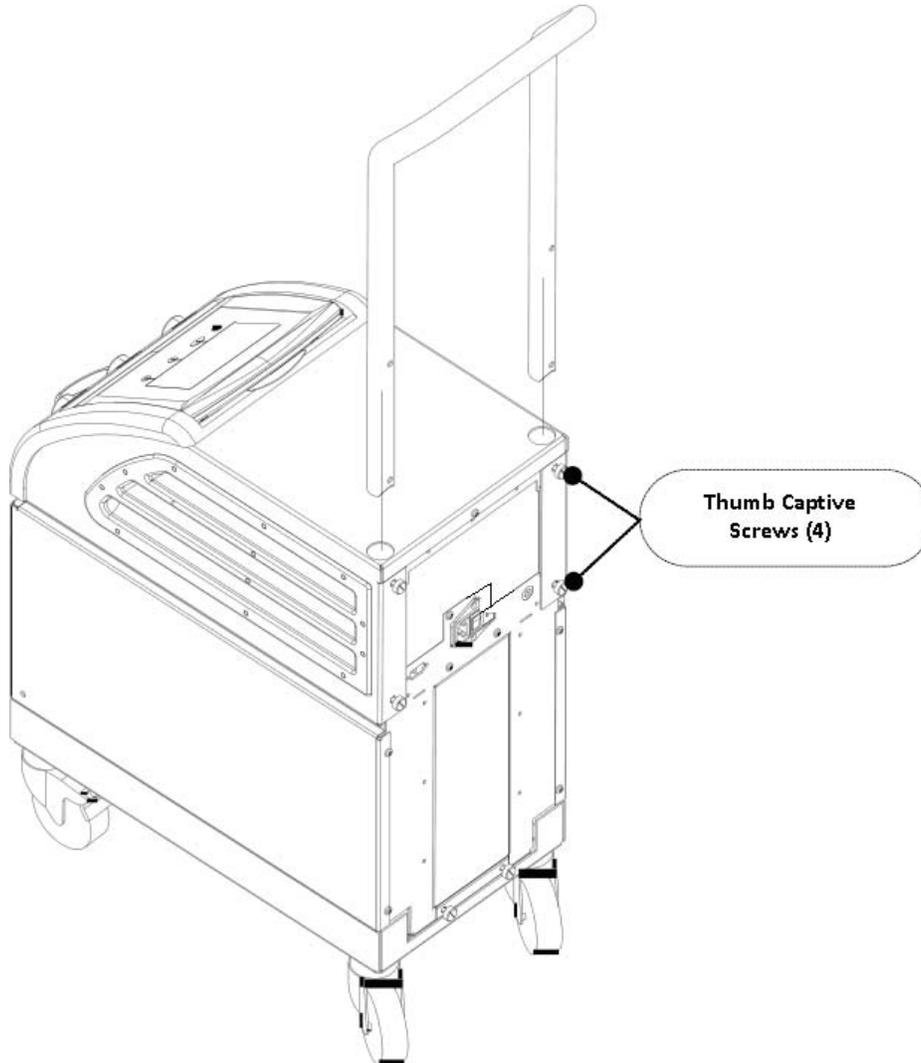


Figure 4-1: Handle Assembly

Accessory Kits

Note: Refer to User's Manual for the equipment list specific to the Thermoregulation model.

The Thermoregulation system includes one of the following accessories kits:

Allon 2001™ Accessory Kits

Table 4-1: Acc. Kit for Adult with Reusable Temperature Sensors - 200-00400

QTY	Description	Part Number
1	Connector 1/4' with hose barb	002-00069
1	Adult Eso / Rectal Core Sensor	014-00020
1	SURF Sensor, YSI B-C, GREEN	014-00021
1	Accessories Box	015-00035
1	ThermoWrap Connecting Tube	200-00109
1	Filter Assembly	200-00130
1	Quick Reference Guide, English	014-00058
1	Label Set, Multilanguage	200-00091

Table 4-2: Acc. Kit for Adult with Interface Cables Only for Disposable Sensors - 200-00410

QTY	Description	Part Number
1	Connector 1/4' with hose barb	002-00069
1	Interface Cable for Disp. Core Sensor	014-00028
1	Interface Cable for Disp. SURF Sensor	014-00029
1	Accessories Box	015-00035
1	ThermoWrap Connecting Tube	200-00109
1	Filter Assy	200-00130
1	Quick Reference Guide, English	014-00058
1	Label Set, Multilanguage	200-00091

Table 4-3: Acc. Kit for Infant with Reusable Temperature Sensors - 200-00420

QTY	Description	Part Number
1	Connector 1/4' with hose barb	002-00069
1	Infant Eso / Rectal Core Sensor	014-00005
1	SURF Sensor, YSI B-C, GREEN	014-00021
1	Accessories Box	015-00035
1	ThermoWrap Connecting Tube	200-00109
1	Filter Assy	200-00130
1	Quick Reference Guide, English	014-00058
1	Label Set, Multilanguage	200-00091

CritiCool™ Accessory Kits

Table 4-4: Acc. Kit for Adult with Reusable Temperature Sensors -200-00300

QTY	Description	Part Number:
1	Connector 1/4' with hose barb	002-00069
1	Adult Eso / Rectal Core Sensor	014-00020
1	SURF Sensor, YSI B-C, GREEN	014-00021
1	Accessories Box	015-00035
1	Filter Assy	200-00130
1	CureWrap Connecting Tubes	200-00147
1	Quick Reference Guide, English	014-00082
1	Label Set, Multilanguage	200-00142

Table 4-5: Acc. Kit for Infant with Reusable Temperature Sensors - 200-00320

QTY	Description	Part Number:
1	Connector 1/4' with hose barb	002-00069

Table 4-5: Acc. Kit for Infant with Reusable Temperature Sensors - 200-00320

1	Interface Cable for Disp. Core Sensor	014-00028
1	Interface Cable for Disp. SURF Sensor	014-00029
1	Accessories Box	015-00035
1	Filter Assy	200-00130
1	CureWrap Connecting Tubes	200-00147
1	Quick Reference Guide, English	014-00082
1	Label Set, Multilanguage	200-00142

Table 4-6: Acc. Kit for Infant with Interface Cables Only for Disposable Sensors - 200-00330

QTY	Description	Part Number:
1	Connector 1/4' with hose barb	002-00069
1	Interface Cable for Disp. Core Sensor	014-00028
1	Interface Cable for Disp. SURF Sensor	014-00029
1	Accessories Box	015-00035
1	ThermoWrap Connecting Tube	200-00109
1	Filter Assy	200-00130
1	Quick Reference Guide, English	014-00082
1	Label Set, Multilanguage	200-00142

Moving the Unit

Preparation

Prior to moving the unit:

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

Locking and Unlocking the Trolley Wheels

The Thermoregulation device trolley has four wheels. The front wheels are fitted with a brake. The brake lever is located over the wheel. To lock, firmly depress the lever. To release, lift the lever. When the unit is stationary, the brakes must be in the locked position. Release the brakes only when transporting the unit.

Storage Conditions and Transport

Storage Environment

Store the Thermoregulation device in a clean and dry area with:

- An ambient temperature of -40°C to +70°C (-40°F to +158°F)
- A relative humidity range of 10% to 100%, including condensation
- An atmospheric pressure range of 500 hPa to 1060 hPa

Note: Disconnect connecting tubes and sensors when the device not in use.

Drain the water and keep the water tank top open.

CHAPTER 5: PANELS AND COVERS

Introduction

This chapter contains a description of:

- Which element of the Thermoregulation device can be accessed by each cover
- The instructions for removal and re-assembly of each cover

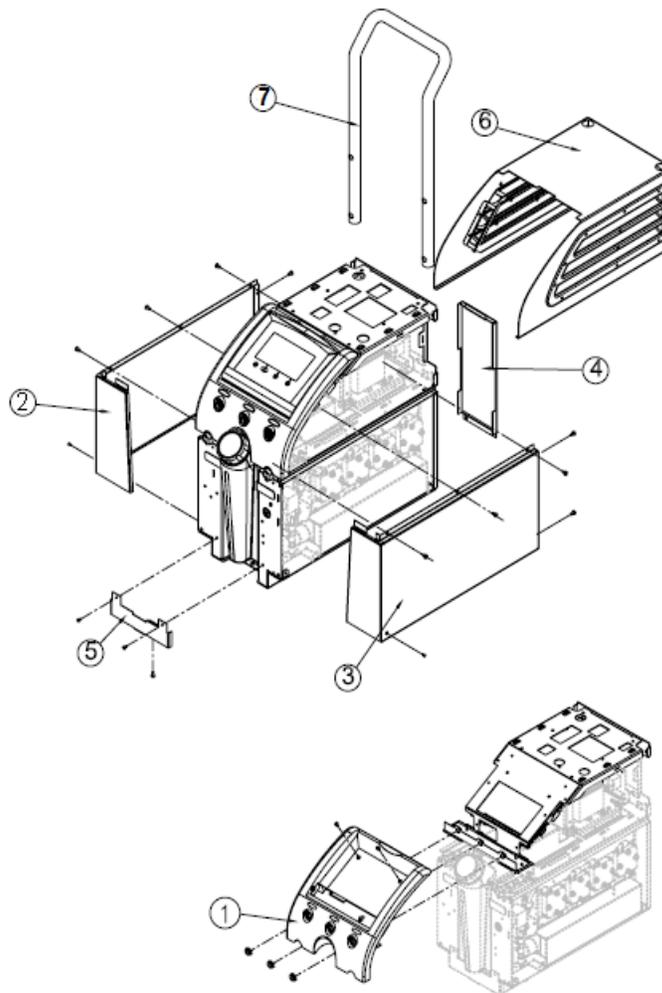


Figure 5-1: Covers Assembly

Table 5-1: Thermoregulation Device Elements and Removal Instructions

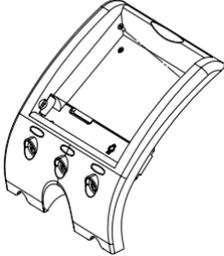
Element	Item Number in Figure 5-1:	Removal and re-assembly
<p>MMI Cover</p> 	1	<p>The MMI cover provides access to the human sensors board. It is attached with two M4x8 socket-head Allen screws and three hexagon nuts screwed to the Human Sensor temperature sockets.</p> <p>The MMI is connected to:</p> <ul style="list-style-type: none"> • The main controller with a ribbon cable • A drainage tube by means of a gutter that drains any fluids spilled on the MMI. The fluid flows down through the drainage tube and exits at the bottom of the unit. <p>➤ To remove the MMI:</p> <ol style="list-style-type: none"> 1. Unscrew the two Allen head screws located behind the moving panel. 2. Open the three nuts screwed on the human sensor jacks. 3. Disconnect the connector of the ribbon cable from the controller board (J4) and slide the ribbon cable through the chassis. <p>➤ To re-assemble the cover:</p> <ol style="list-style-type: none"> 1. Connect the connector of the ribbon cable to the controller board (J4) and slide the ribbon cable through the chassis. 2. Close the three hexagonal nuts, and tighten with a torque of 80–90 Ncm. 3. Screw the two Allen head screws located behind the moving panel <p><i>Caution: Do not stretch the ribbon cable when removing the MMI cover.</i></p>

Table 5-1: Thermoregulation Device Elements and Removal Instructions

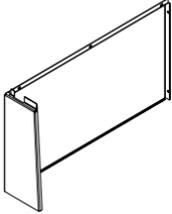
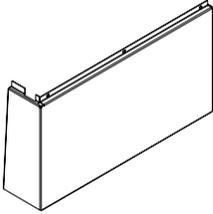
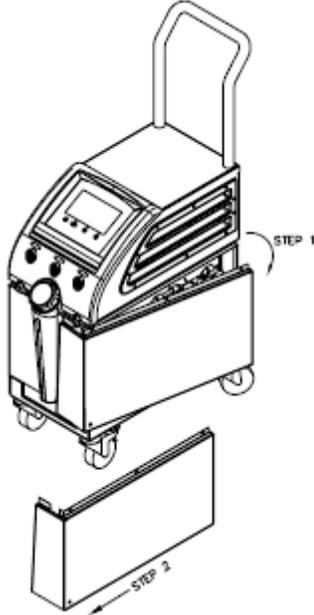
Element	Item Number in Figure 5-1:	Removal and re-assembly
<p>Left Side Cover</p> 	<p>2</p>	<p>The left side cover provides access to the following components:</p> <ul style="list-style-type: none"> • HCU (Heating Cooling Unit) No. 1 • Water-in temperature sensor <p>The right side cover provides access to the following components:</p> <ul style="list-style-type: none"> • HCU (Heating Cooling Unit) No. 2 • Water-out temperature and thermostat sensors • Solenoid by-pass valve
<p>Right Side Cover</p> 	<p>3</p>	<p>➤ To remove the Side Covers (see Figure 5-1)</p> <ol style="list-style-type: none"> 1. Unscrew the three M4x8 Philips-head screws on the top lip and the two screws in the back of the cover. 2. Slightly release the cover from the back and rotate the front end of the cover so that it clears the Quick Coupling Connector. 3. Release the two 2mm Allen screws at the bottom side of the cover. 

Figure 5-2: Side Cover Removal

Table 5-1: Thermoregulation Device Elements and Removal Instructions

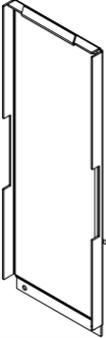
<i>Element</i>	<i>Item Number in Figure 5-1:</i>	<i>Removal and re-assembly</i>
		<p>➤ To re-assemble the side covers:</p> <ol style="list-style-type: none"> 1. Position the slot in the front to fit around the Quick Coupling Connectors. 2. Align the back end. 3. Tighten all screws.
<p>Rear Cover</p> 	<p>4</p>	<p>The rear cover provides access to the following:</p> <ul style="list-style-type: none"> • FP circuit board • Pressure tubes • Pressurestat tube • Pump <p>The top of the cover is inserted into a slot in the frame of the unit and the bottom is attached with two Thumb Captive screws.</p> <p>➤ To remove of the Rear Cover</p> <ol style="list-style-type: none"> 1. Unscrew the two thumb-captive screws at the bottom of the cover. 2. Pull the bottom part of the cover towards you and then down to release the lip from the chassis. <p>➤ To re-assemble the rear cover:</p> <ol style="list-style-type: none"> 1. Insert the lip at the top of the cover into the unit. 2. Tighten the two screws at the bottom of the cover.

Table 5-1: Thermoregulation Device Elements and Removal Instructions

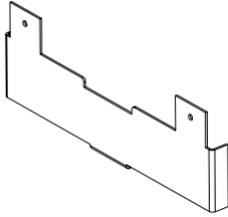
<i>Element</i>	<i>Item Number in Figure 5-1:</i>	<i>Removal and re-assembly</i>
<p>Bottom Front Cover</p> 	<p>5</p>	<p>The bottom cover provides access to the water-in and water-out tubes leading from the bottom of the water tank. To remove the water tank, it is necessary to remove the bottom front cover.</p> <p>➤ To remove the Bottom Front Cover:</p> <ol style="list-style-type: none"> 1. Remove the handle. 2. Remove the top cover. 3. Remove the right and left side covers (see page 5-2) to expose the two M4x8 Philips-head screws that secure the bottom front cover. 4. Unscrew the two M4x8 Philips-head screws, one on each side of the cover. 5. Carefully place the Thermoregulation device on its side. 6. Unscrew the 2mm Allen screw (located at the bottom front edge of the trolley). <p>➤ To re-assemble the cover:</p> <ol style="list-style-type: none"> 1. Return the cover and tighten the 2mm Allen screw and the two Philips-head screws. 2. Re-assemble the right and left side covers.

Table 5-1: Thermoregulation Device Elements and Removal Instructions

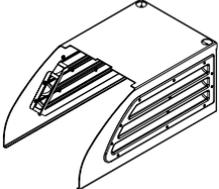
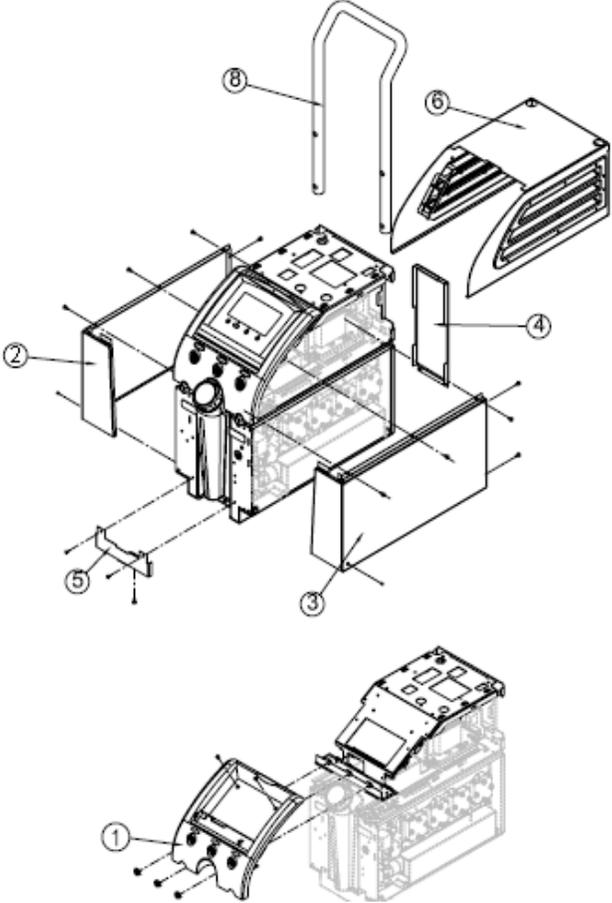
<i>Element</i>	<i>Item Number in Figure 5-1:</i>	<i>Removal and re-assembly</i>
<p>Top Cover</p> 	<p>6</p>	<p>The top cover provides access to the following elements:</p> <ul style="list-style-type: none"> • Main controller • Power supply unit • TEC controller • Water-in, water-out, thermostat temperature sensor connectors <p>The top cover is attached by means of four thumb captive screws and one M4x8 Philips-head screw in the back of the unit. To remove the top cover, the handle must also be removed.</p> <p>➤ To remove the top cover:</p> <ol style="list-style-type: none"> 1. Unscrew the four screws by hand. 2. Pull out the handle. 3. Slide the cover out from the back of the unit. <p>➤ To re-assemble the cover:</p> <ol style="list-style-type: none"> 1. Slide the back cover, and replace the handle. 2. 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.

Table 5-1: Thermoregulation Device Elements and Removal Instructions

<i>Element</i>	<i>Item Number in Figure 5-1:</i>	<i>Removal and re-assembly</i>
<p>Handle</p> 	<p>7</p>	<p>The handle allows easy transport of the Thermoregulation device. It must be removed to enable removal of the top cover.</p> <p>➤ To remove of the Handle:</p> <ol style="list-style-type: none"> 1. Release the four thumb captive screws by hand. 2. Pull up the handle. <p>➤ To re-assemble the handle:</p> <ol style="list-style-type: none"> 1. 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. 2. 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.  <p style="text-align: center;"><i>Figure 5-3: Cover Assembly</i></p>

Removal of the Trolley

➤ To remove the trolley:

1. Empty the water tank.
2. Place the Thermoregulation device on its **side**.
3. Unscrew the six Phillips-head screws and washers that secure the trolley to the main chassis.

To re-assemble the trolley, follow the above procedure in reverse order. Make sure that you tighten the screws with the washers.

Note: Assemble the trolley with the braked wheels in front.

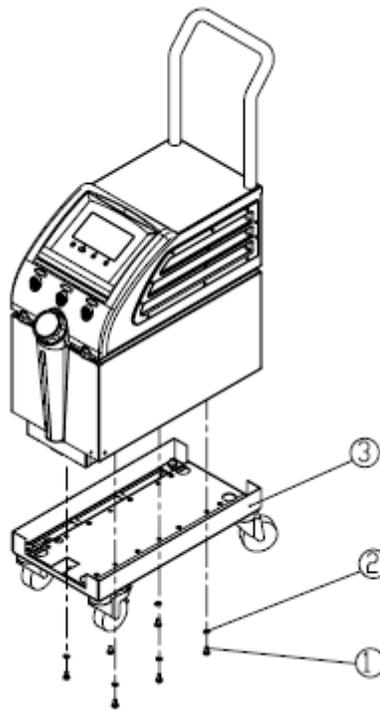


Figure 5-4: Trolley Assembly

Table 5-2: Trolley Parts

Item No.	Qty.	Part No.	Description
1	6	009-00034	Screw M6x12 Pan Philips s.s
2	6	010-00025	Spring Washer M5 s.s
3	1	200-00067	Allon Trolley
		200-00141	CritiCool Trolley

CHAPTER 6: ELECTRICAL SYSTEM

This section outlines the electric and electronic systems that control the functioning of the Thermoregulation system.

WARNING!!! *Detach the power cable before you do any maintenance or replacement procedures. Failure to do so could result in severe personal injury.*

CAUTION! *Before performing any procedure in this chapter, use an ESD (Electrical-Static Discharge) wrist-strap to connect yourself to the chassis of the device. Failure to do so can cause irreparable damage to the electrical components.*

Introduction

This chapter describes the electrical system of the Thermoregulation device.

The electrical system consists of the following elements:

- Power Supply Assembly on paragraph 6-4
- Controller Board on paragraph 6-5
- TEC Control (Thermo-Electric Components) Board on paragraph 6-6
- Human Sensors Board on paragraph 6-7
- MMI (Man-Machine Interface) on paragraph 6-8
- FP Board on paragraph 6-9
- HCU (Heating Cooling Unit) on paragraph 6-10
- Pump on paragraph 6-11
- Solenoid Bypass Valve on paragraph 6-12
- Thermistors on paragraph 6-13
- Float on paragraph 6-14

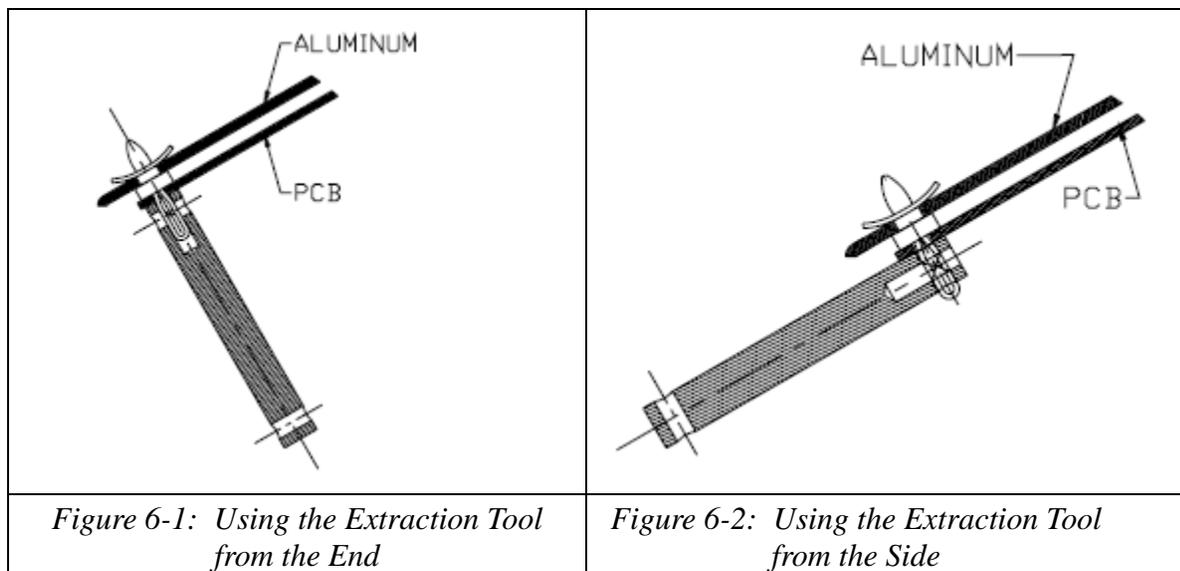
Release of PCB Spacer Supports

PCB spacer support release is accomplished by means of the PCB Extraction tool (see Chapter 11 "Special Equipment and Tools").

The extraction tool enables the release of the PCB spacer supports by insertion:

- To the hole at the end of the extraction tool where there is enough clearance (see Figure 6-1).
- To the hole on the side of the tool where there is not enough clearance (see Figure 6-2).

Inserting the spacer support into the extraction tool collapses the pinch head so that the PCB can be released (see Figure 6-1 and Figure 6-2).



Slide Lock Connector

Connectors on the PCB are equipped with a slide lock assembly. The slide lock assembly consists of a sliding bracket fitted on the PCB connector and corresponding lock posts that fit into the mounting holes of the mating connector.

After attaching the flat cable connector to the PCB, slide the bracket to lock the connectors together. To release the connectors, slide the bracket in the opposite direction.

Power Supply Assembly

The Power Supply Assembly consists of the following:

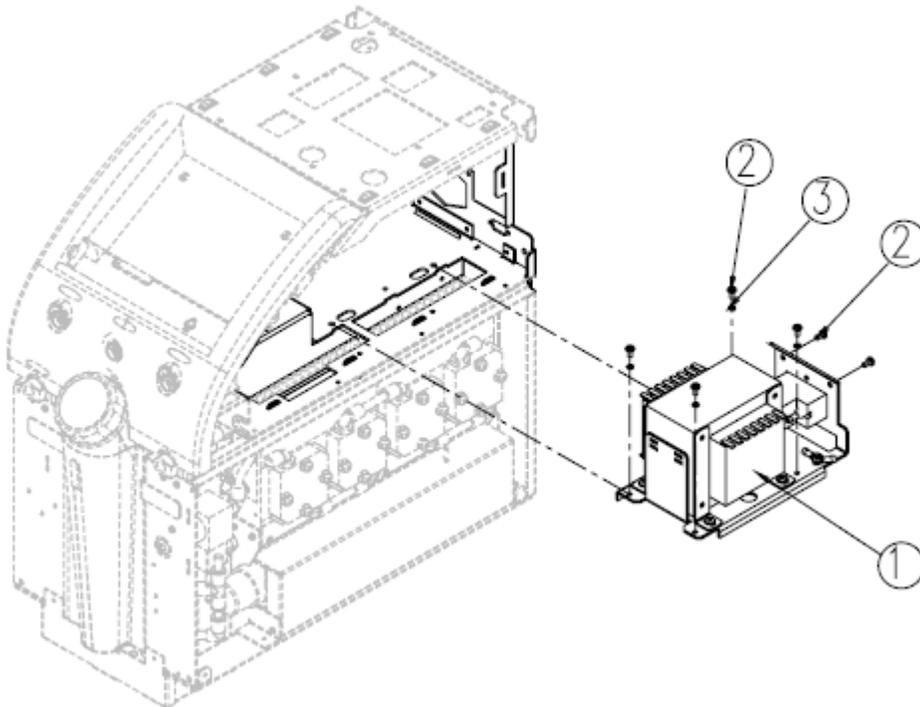
- External electrical connection by means of a hospital-grade power cable, switchable 230/120 VAC with two 6.3 amp fuses

- On/Off switch
- Medical isolation transformer 230/120V 500W
- Two current harnesses to the TEC Control board
- One current harness to the controller board
- Current ground harness

➤ **To remove the Power Supply Assembly:**

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Remove the two Philips-head screws from the ON/OFF switch panel in the rear of the Thermoregulation device.
3. Remove the controller board (see "Removal of the Controller Board ", paragraph 6.5.2)
4. Remove the four Philips-head screws and washers.
5. Release all cables leading from the controller board and both halves of the TEC Control board.

Note: To re-assemble the Power Supply Assembly, follow the above procedure in reverse order.



*Figure 6-3: Power Supply Assembly***Table 6-1: Power Supply Parts**

Item No.	Qty.	Part No.	Description
1	1	200-00059	Power Supply Assembly
2	6	009-00006	Screw M4x8 Pan Philips s.s
3	4	010-00013	Spring Washer M4 s.s

Controller Board

The controller board monitors all system functions, performs all the internal algorithms, and converts analog signal received from the sensors to digital input.

The controller board contains the following components:

- controller 87C552
- RAM /ROM
- Flash Memory
- Address and data components
- Voltage regulators
- Very Fast-Acting type fuses
- Rectifiers
- LEDs
- RS-232 Communication Port
- Audible alarm

The controller board receives input from the:

- Human Sensors
- Water Temperature sensors
- FP board
- Power Supply Assembly
- Water level sensor
- MMI
- RS-232 Communication Port

It controls output to the:

- TECs
- MMI—the display
- Solenoid bypass valve
- Pump
- Fans
- RS-232 Communication Port

The controller board incorporates the power distribution circuit. Power from the transformer is rectified and supplied to the:

- Controller board
- MMI
- FP Board
- Human Sensors Board

The TEC control has its own power-rectifying circuit.

The following table lists all main power distribution components on the controller board.

Table 6-2: Controller Board—Power ON LEDs on the Controller

LED Identifier	LED Indication	Remarks
LED 6	Vent 1	Vent voltage
LED 3	Vent 2	Vent voltage
LED 30	Com cable	Indicates RS 232 cable connector
LED 26	Com 5v	
LED 9	VCC	
LED 29	LCD	-12V
LED 4	X3	Over pressure pump
LED 27	X1	Communication
LED 28	X2	Communication
LED 5	AUX	Not in use
LED 15	- 12V	Voltage indication
LED 13	+ 12V	Voltage indication
LED 10	Pump	Pump voltage

Table 6-2: Controller Board—Power ON LEDs on the Controller

LED 7	Sol 2	Solenoid voltage
D2	Fan Voltage type (Allon & CritiCool)	D2

Table 6-3: Controller Board—Connectors

Identifier	Type	Description
J4	DB37 socket	MMI connector
J6, J8	DB15 socket	TEC board control (right and left)
J9	DB15 socket	FP board connector
J10	DB15 socket	Human Sensors board connector
P1	DB9 socket	RS-232 connector
J1	Header	Left side FAN and pump
J3	Header	Right side FAN, solenoid, and water level float position
J2	Header	Power Supply Assembly connector

Controller Board Fuses

Controller board fuses of the Thermoregulation device are soldered to the board.

In case a fuse blows, MTRE allows the service engineer the option of soldering a replacement fuse instead of replacing the controller board. Fuses are purchased directly from the manufacturer (Littelfuse, Inc.) according to the catalog number listed in Table 6-3..

See Chapter 9 "Periodic Maintenance" for fuse replacement procedure.

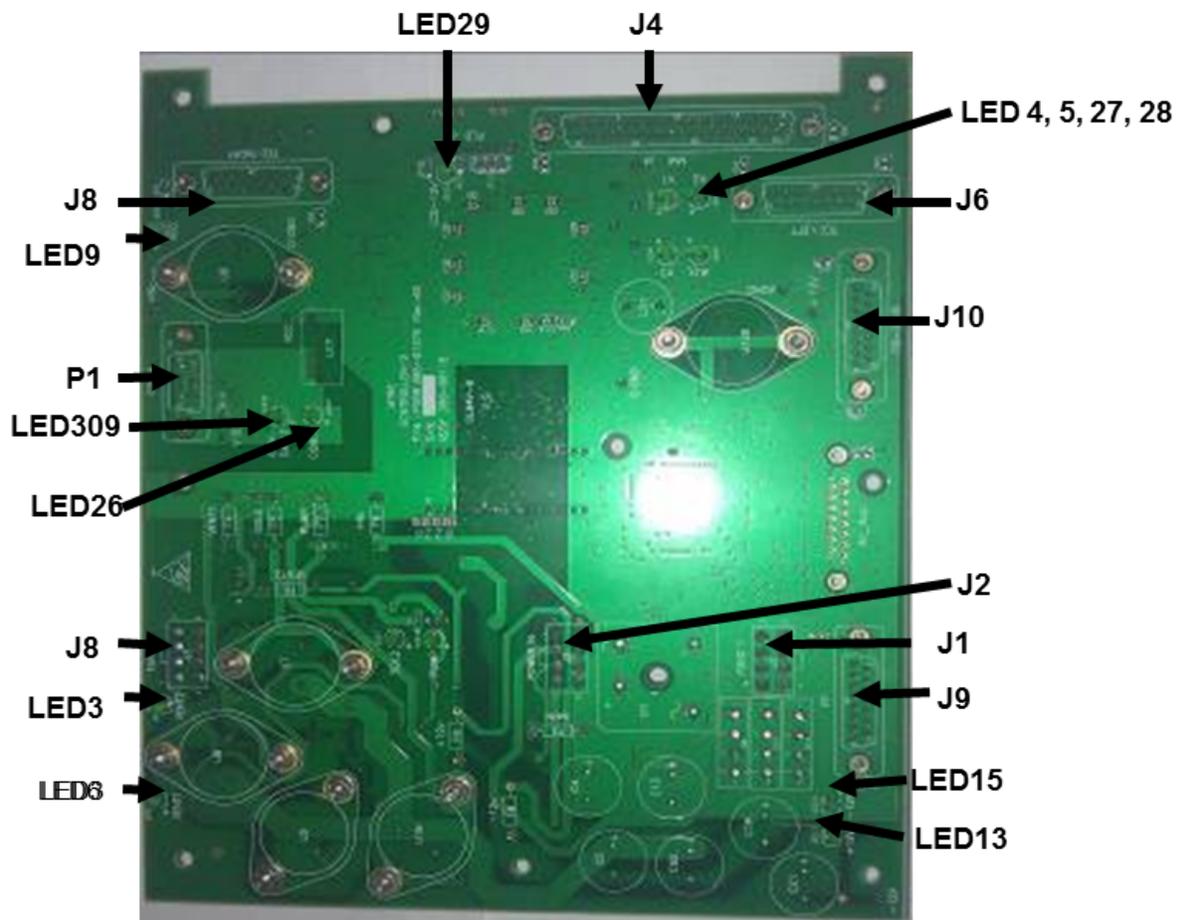


Figure 6-4: Controller Board Component Placement—Print Side

Removal of Controller Board

➤ To remove the Controller Board:

(see Figure 6-5)

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Detach all the ribbon cables from the underside of the controller board by pressing the slide lock brackets.

3. With the extraction tool, release all seven PCB spacer supports.
4. To remove the controller board, slide it out from the side.

Note: To re-assemble the controller board, follow the above procedure in reverse order.

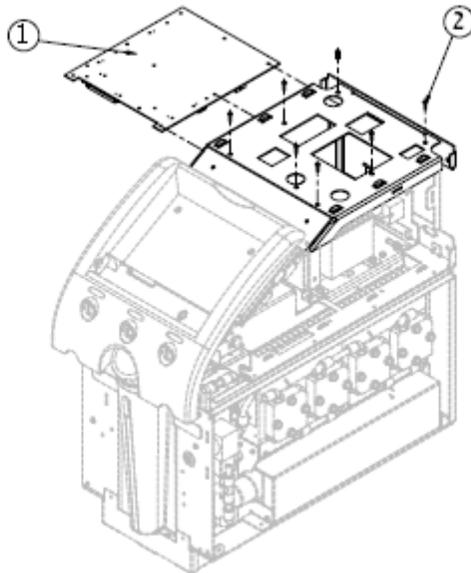


Figure 6-5: Controller Board Assembly

Table 6-4: Controller Board Parts

Item No.	Qty.	Part No.	Description
1	1	300-00114/300-00118	Controller 2 Assembly
2	7	004-00029	PCB Spacer Support SCC-15

TEC Control (Thermo-Electric Components) Board

The TEC Control board is located under the MMI. It has two identical halves that operate independently. Both halves of the TEC Control board receive power supply directly from the transformer, rectify it, and distribute power to the TECs via digitally-controlled current switches. The internal system algorithm on the controller board calculates the human and temperature sensors' values, and determines the quantity of TEC pairs actuated by the TEC control boards.

Digital signals from the main control board are processed by the local MSP controller on the TEC control board. The MSP controller controls pairs of P and N MOSFET transistors that drive the TEC units. Each

pair of transistors can, depending on the command, drive the TEC unit in forward or reverse current to heat or cool the water.

MSP controller also measure the output voltage of each power bridge and provide status indication by dedicated color (Reg/Green or orange)

Table 6-5: TEC Control Board—Fuse List

Identifier	Value	Size	Type	Voltage to:
F3	25A	6.3mmx32mm	Slow Blow	D8
F4	25A	6.3mmx32mm	Slow Blow	D9
F1L	25A	6.3mmx32mm	Slow Blow	D6L
F2L	25A	6.3mmx32mm	Slow Blow	D5L

Table 6-6: TEC Control Board—Connectors

Identifier	Type	Description
J3	Header 16	Control signals from controller board
J4L	Header 16	Control signals from controller board
J1	Header 8	Power to TECs
J2L	Header 8	Power to TECs
J6	Header 4	AC power from transformer
J5L	Header 4	AC power from transformer
J19	Molex 9 pin	Controller JTAG Right Side
J20	Molex 9 pin	Controller JTAG Left Side

Table 6-7: TEC Control Board—Led indicators

Identifier	Meaning	Note
CR5	Right Side TEC NUM 1	Cooling = Green, Heating = Red
CR6	Right Side TEC NUM 2	Cooling = Green, Heating = Red
CR7	Right Side TEC NUM 3	Cooling = Green, Heating = Red
CR8	Right Side TEC NUM 4	Cooling = Green, Heating = Red

Table 6-7: TEC Control Board—Led indicators

CR9	Left Side TEC NUM 1	Cooling = Green, Heating = Red
CR10	Left Side TEC NUM 2	Cooling = Green, Heating = Red
CR11	Left Side TEC NUM 3	Cooling = Green, Heating = Red
CR12	Left Side TEC NUM 4	Cooling = Green, Heating = Red
CR3	Left Side Bridge1 Voltage Indication	Green/Orange = OK OFF = Fault
CR4	Left Side Bridge2 Voltage Indication	Green/Orange = OK OFF = Fault
CR1	Right Side Bridge1 Voltage Indication	Green/Orange = OK OFF = Fault
CR2	Right Side Bridge2 Voltage Indication	Green/Orange = OK OFF = Fault

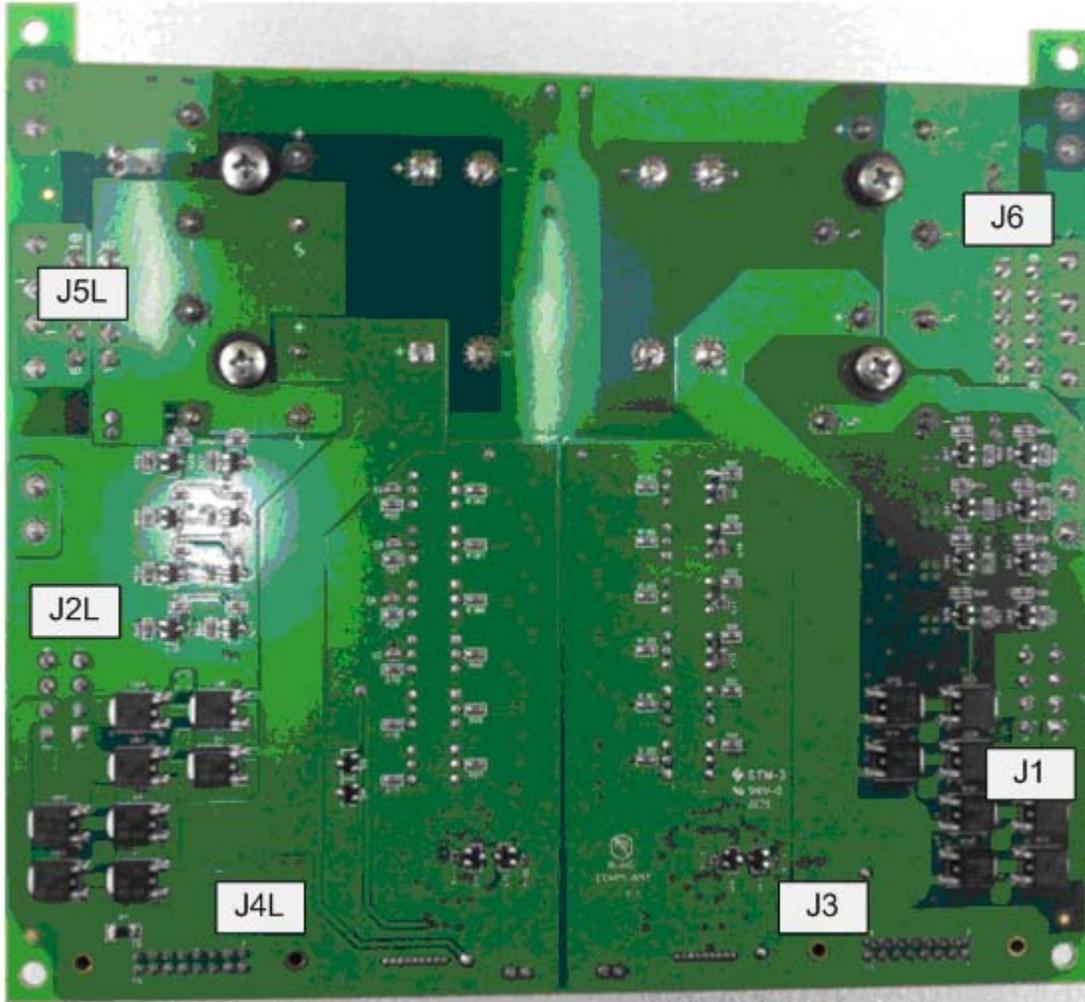


Figure 6-6: TEC Control Board - Component Placement

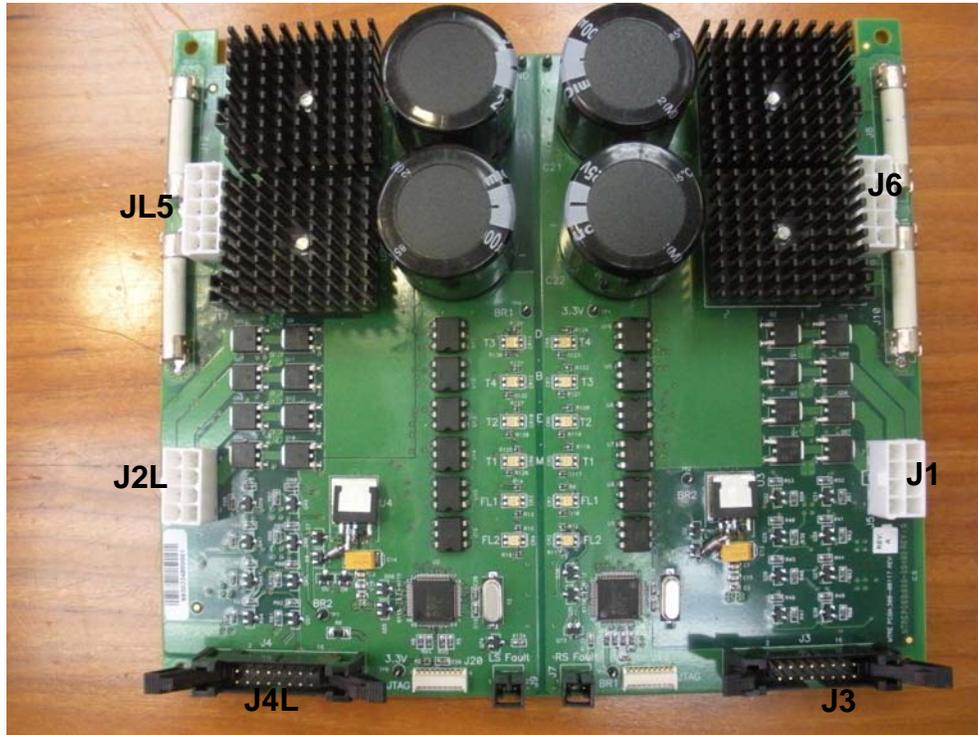


Figure 6-7: TEC Control Board—Component Placement

➤ **To remove the TEC Control Board:**

(See Figure 6-8)

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Detach the three cables (voltage in, voltage out, control) from each side of the TEC control board.
3. With the extraction tool, release all four PCB spacer supports.
4. Slide out the TEC control board from the side.

Note: To re-assemble the TEC control board, follow the above directions in reverse order.

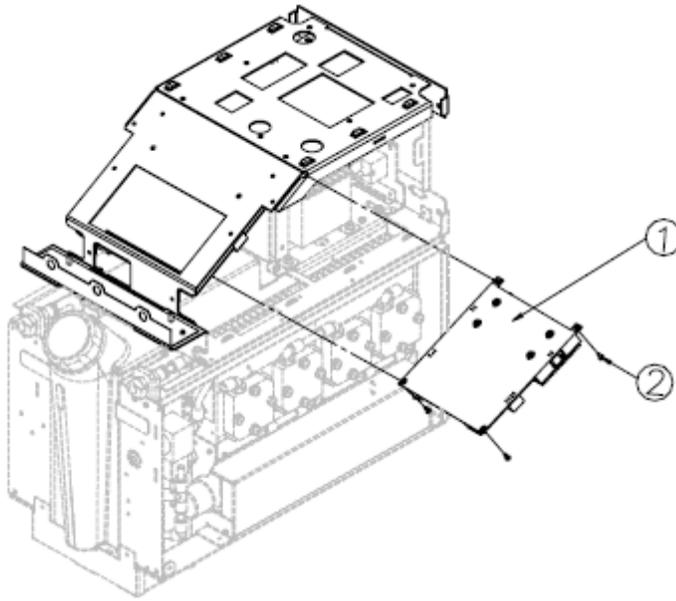


Figure 6-8: TEC Controller Assembly

Table 6-8: TEC Controller Components

Item No.	Qty.	Part No.	Description
1	1	300-00117	TEC Controller Assembly
2	4	004-00030	PCB Spacer Support ECC-5

Human Sensors (HS) Board

The Human Sensors board receives input from the:

- Human temperature sensors
- Water-in and water-out temperature sensors
- Thermostat sensor

The Human Sensors board relays voltage back to the controller board. The controller board converts the analog signal from analog to digital and makes the temperature adjustments according to the system calibration.

All Human Sensor inputs are from thermistor temperature sensors.

Table 6-9: Human Sensor Board—Input Signal

Sensor	Input Type	Measurement
Core	Thermistor	Continuous
Surface	Thermistor	Continuous
Water-in	Thermistor	Continuous
Water-out	Thermistor	Continuous
Thermostat	Thermistor	ON/OFF*

Note: *The Thermostat input signal passes through a comparator on the Human Sensor board; the comparator output (Logic 0 or 1) activates the “ATTENTION HALT - PLEASE RESTART (3)” warning.*

Table 6-10: Human Sensor Board—Connectors

Identifier	Type	Description
J10	DB15	Power supply from controller board, output signals to controller board
J1	0.25" stereo socket	CORE input signal
J5	0.25" stereo socket	SURFACE input signal
J4	Header 2	Water-out temperature input signal
J6	Header 2	Water-in temperature input signal
J7	Header 2	Thermostat input signal

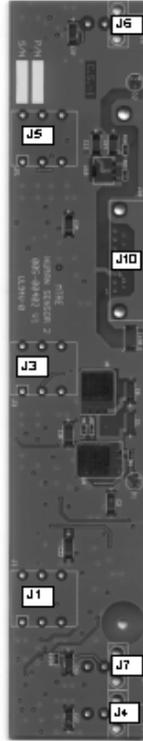


Figure 6-9: Human Sensors Board—Component Placement

➤ **To remove the Human Sensors Board:**

(see Figure 6-10)

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Remove the MMI Cover (see Chapter 5 "Panels and Covers").
3. Remove the two Philips-head screws and washers that connect the Human Sensors board to the bracket.
4. Detach the ribbon cable to the controller board by pressing the slide lock bracket.
5. Detach the Water-in, Water-out, and thermostat connectors.

Note: *To re-assemble the Human Sensors board, follow the above directions in reverse order. Tighten the three hexagonal nuts to a torque of 80–90 Ncm with a 5/8" socket wrench*

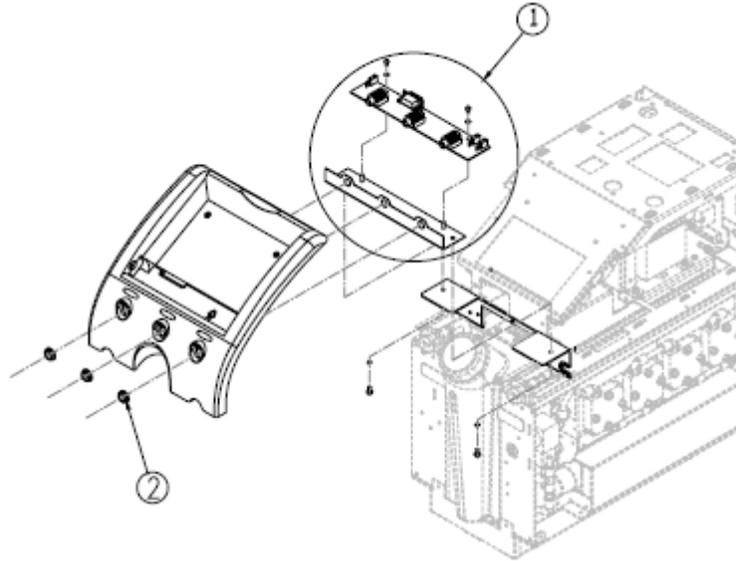


Figure 6-10: Human Sensors Board Assembly

Table 6-11: Human Sensor Board Parts

Item No.	Qty.	Part No.	Description
1	1	300-00016	Human Sensor Board
2	3		Nut Sensor Socket

MMI (Man-Machine Interface)

The MMI receives:

- Input from the user via the soft touch buttons.
- Output from the controller board and displays it on the interface screen.

The data is relayed via a ribbon cable to the controller board. The connector of the ribbon cable is inside the MMI and cannot be disconnected without the removal of the back cover.

For removal of the MMI see Chapter 5 "Panels and Covers".

Table 6-12: MMI Parts

Item No.	Qty.	Part No.	Description
1	1	200-00062	Top Panel Assembly (display and cover)

FP Board

The FP board reads the measurement of pressure coming from the pump. It receives power from the controller board power supply, rectifies it and activates the piezoelectric transducers.

Table 6-13: FP Board Connector

Identifier	Type	Description
J1	Header 16	Power input from controller board, output signals to controller board

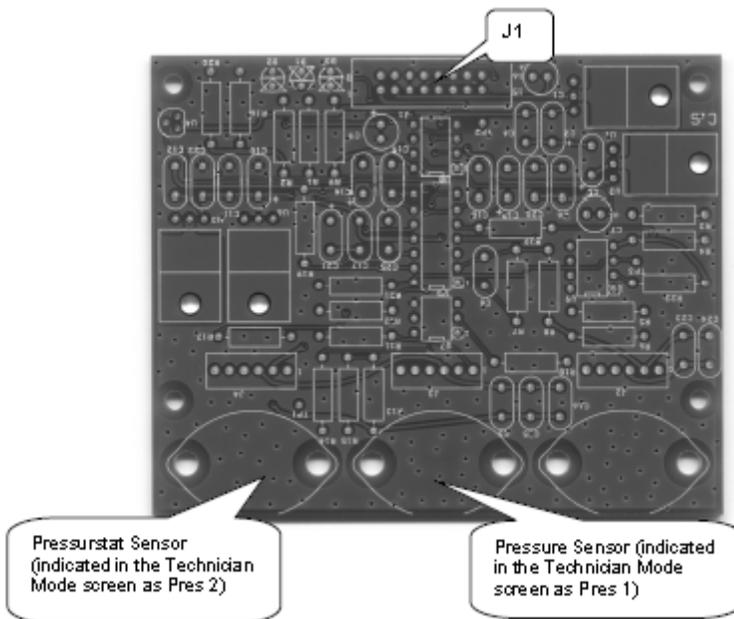


Figure 6-11: FP Board Component Placement

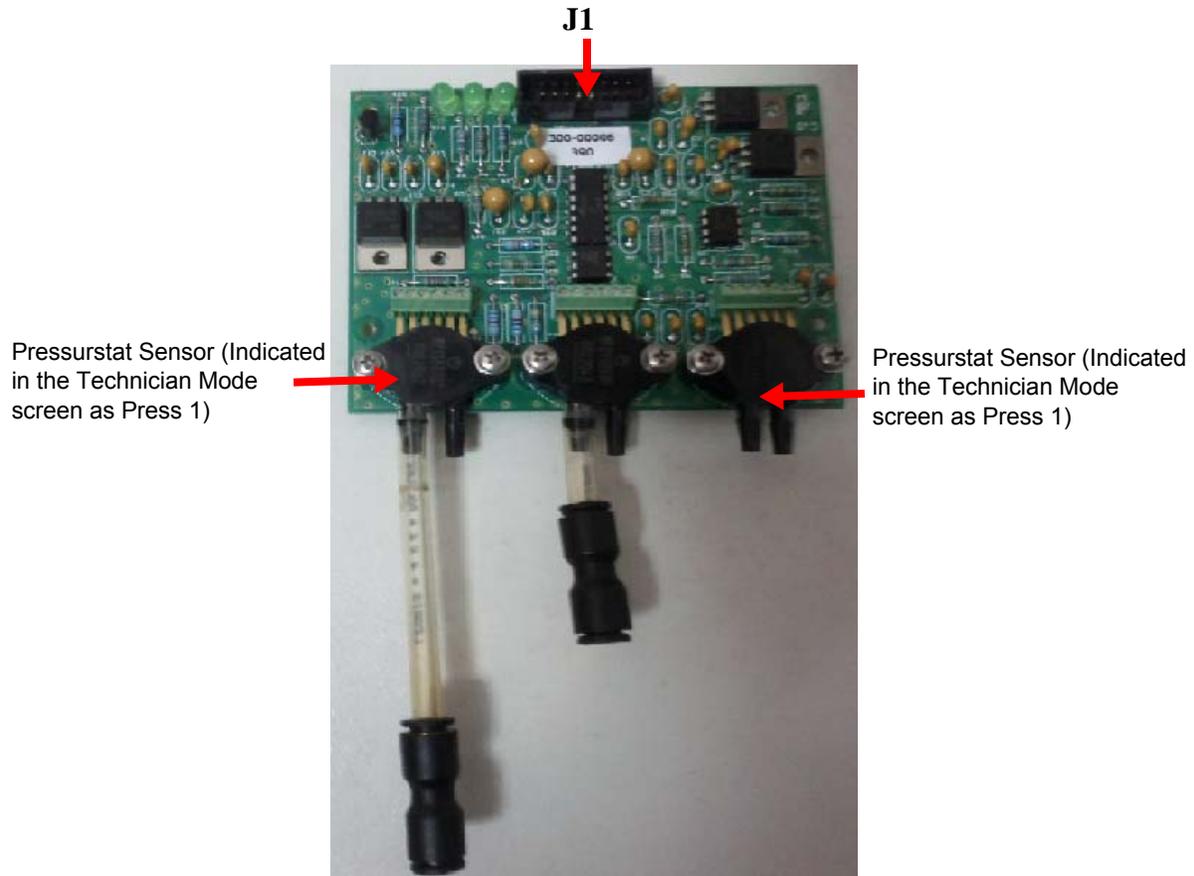


Figure 6-12: FP Board

➤ **To remove the FP board:**

(See Figure 6-13)

1. Remove the rear cover (see Chapter 5 "Panels and Covers").
2. Detach the ribbon cable by pressing the slide lock bracket.
3. With the extraction tool, release all four PCB spacer supports — two on each side of the board.
4. Detach the two tubes connected to the piezoelectric transducers by pressing the release ring of each fitting and pulling out the tubes.

Note: To re-assemble the FP board, follow the above directions in reverse order.

Note: Label the tubes before you remove the FP board.

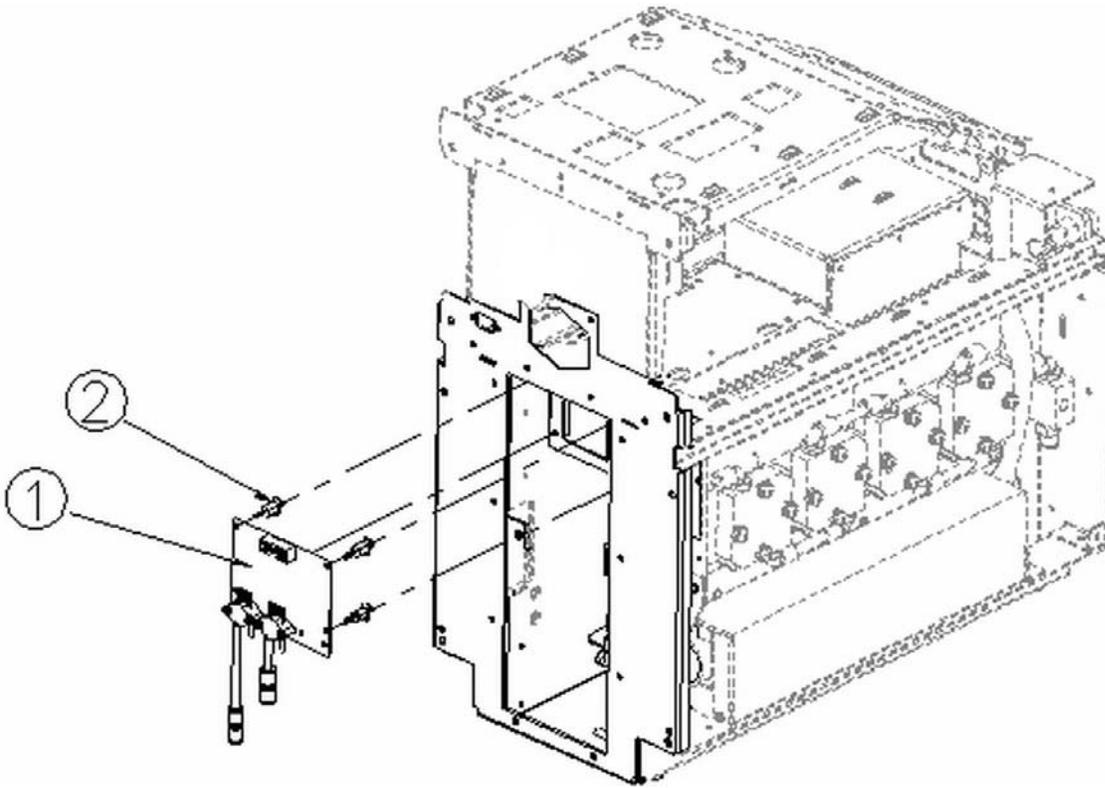


Figure 6-13: FP Board Assembly

Table 6-14: FP Board Parts

Item No.	Qty.	Part No.	Description
1	1	300-00015	FP Board
2	4	004-00031	PCB Spacer Support LCC-10

HCU (Heating Cooling Unit)

The HCU is the element that exchanges energy with the water as it flows through the system. It is comprised of the following components:

- Z heat exchanger—used for dispersing energy (heat) from the Thermal Exchange Components to the water
- Thermal Exchange Components (Peltier)
- Heat sink—used for dispersing energy (heat or cold) from the Thermal exchange elements
- Fan

Note: The HCU is an integrated unit. If any of the components listed above is faulty, replacement of the entire HCU is necessary.

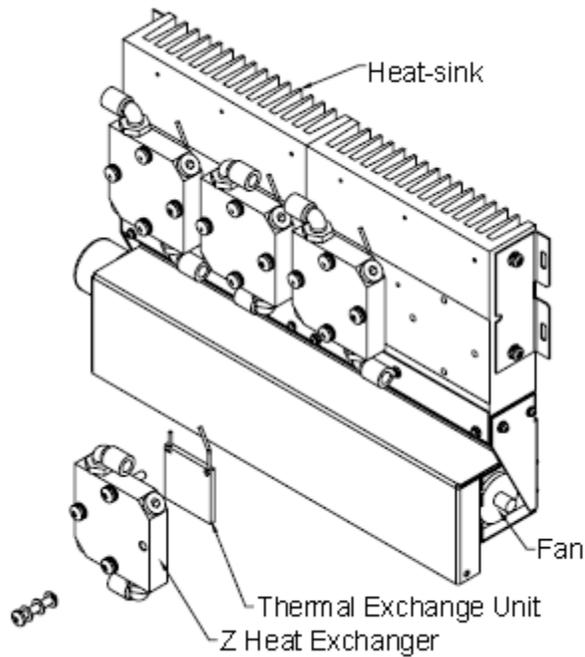


Figure 6-14: 6-14 HCU Assembly

Item No.	Qty.	Part No.	Description
1	1	200-00054	HCU Assembly

Z Heat Exchanger

There are four Z heat exchangers on each side of the Thermoregulation device. Water flows from the water tank, through the filter, through the pump, and through each set of the Z heat exchangers. The water is either heated or cooled in the Z heat exchanger by the thermal exchange units according to the demands of the system.

Figure 6-15 displays the water flow represented by the geometric cross hatch.

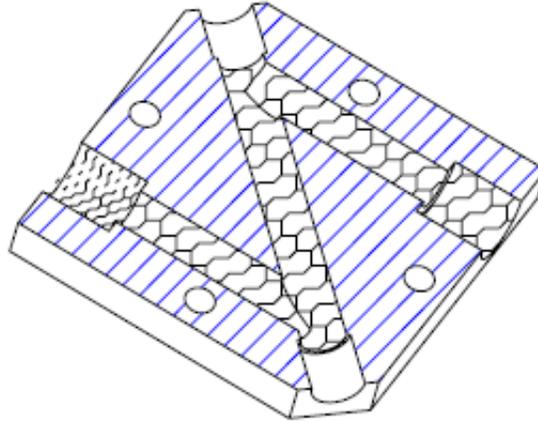


Figure 6-15: Z Heat Exchanger—Cross-section

Thermal Exchange Components (Peltier)

The TEC components are solid-state modules (no moving parts) that convert electrical energy into a temperature gradient, known as the "Peltier effect". They are composed of two similar alloys that have different free electron densities at the same temperature.

One is composed of material having a deficiency of electrons while the other has an excess of electrons. As current flows up and down through the module it attempts to establish a new equilibrium within the materials. The analog signal treats the first material as a hot junction needing to be cooled and the second material as a cold junction needing to be heated. Since the material is actually at the same temperature, the result is that the hot side becomes hotter while the cold side becomes colder. The direction of the analog signal determines if a particular side will cool down or heat up. In short, reversing the polarity will switch the hot and cold sides.

Heat Sink

The purpose of the heat sinks is to dissipate the heat or cold created by the thermal exchange elements as quickly as possible. The capability of the TEC to either heat or cool depends on the level of temperature on the side of the heat sink. If it is very cold on that side, its ability to heat is diminished. The faster the heat or cold are dissipated, the faster the Thermoregulation device reaches the required water temperature.

Fan

The fans remove the heated or cooled air dissipated through the heat sinks. The air is drawn in from the bottom grille and expelled through the grilles in the top cover and in the rear of the Thermoregulation device. The fans receive power directly from the controller board.

➤ *To remove the HCU:*

(See Figure 6-16).

Note: Before you start, place a cloth on a flat surface. Turn the Thermoregulation device on its side on the cloth to prevent damage.

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Open the appropriate side cover.
3. Release the electric connector by unscrewing the two flat screws on top of the connector. Firmly grasp the electric connector and pull up to release.
4. Release the Water-in tube and the Water-out tube from the HCU by pressing the release ring of each fitting and pulling out the tubes.
5. Remove four nuts (with a 7mm socket) and washers—two on each side of the HCU.
6. Unscrew two Philips screws on the bottom sides of the HCU. Access the screws through holes in the frames of the Thermoregulation device.
7. Grasp the two sides of the HCU and carefully slide it out of the Thermoregulation device.
8. Place the HCU on a flat surface.

CAUTION: The heavy heat sinks can deform the unit if it is not placed on a flat surface.

Note: To re-assemble the HCU follow the above procedure in a reverse order. Note that there are oblong holes in the bracket of the HCU. Before completely tightening the nuts, lift the HCU.

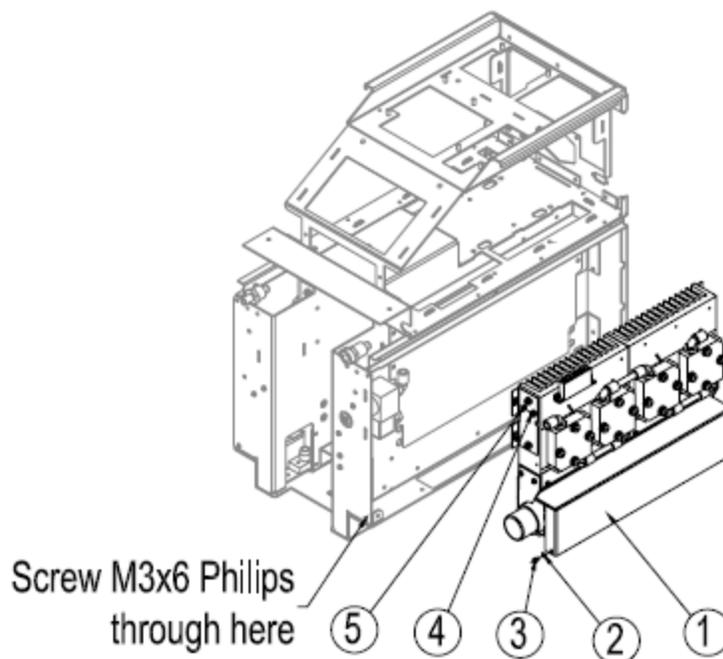


Figure 6-16: HCU Removal

Table 6-15: HCU Parts

Item No.	Qty.	Part No.	Description
1	1	200-00054	HCU Assembly
2	2	010-00001	Spring Washer M3 s.s
3	2	009-00005	Screw M3x6 Pan Philips s.s
4	4	011-00001	Nuylock Nut M4 s.s Blue
5	4	010-00008	Flat Washer M4 s.s

Pump

The pump circulates water through the system at rates of 0.8-1.2 liters per minute. The pump is a positive displacement type; it builds up unlimited pressure at the pump output. This pressure is limited in two stages:

- Pres 1 - at 0.9bar
- Pres 2 - at 1.8 bar (safety)

The controller board controls the pump power supply by digital control (ON/OFF). There is a "Fast Acting" fuse and a LED for the pump. The pump works on 12V (Machine Version 04, 05) and 10V (Machine Version 03). The pump operates at 1.8 bar for two minutes before being stopped at system halt.

For removal of the pump, see Chapter 7 "Hydraulic System".

Solenoid Bypass Valve

The solenoid bypass valve directs the flow of water to the Garment or back to the water tank. It is activated by the control signal from the controller board.

➤ To remove the Solenoid Valve:

(see Figure 6-17)

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Open the right side cover.
3. Disconnect the 8 mm flow tube to the water-out assembly by pressing the release ring on the fitting.
4. Disconnect the 8mm flow tube to the water tank.

5. Disconnect the 8mm tube to the HCU.
6. Disconnect the electrical control connection from the lower part of the solenoid with a bulldog Philips screwdriver.
7. Unscrew the two Philips screws that secure the Solenoid Valve Bracket from the front of the Thermoregulation device.

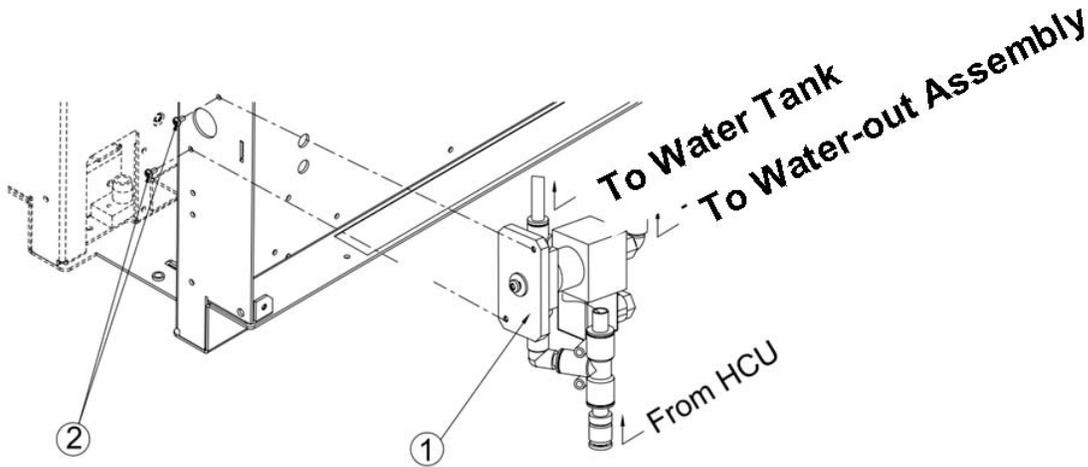


Figure 6-17: Solenoid Valve Removal

Table 6-16: Solenoid Parts

Item No.	Qty.	Part No.	Description
1	1	200-00078	Solenoid Valve Assembly
2	2	009-00024	Ejot Screws 35x12

Thermistors

The thermistor used for water-out and thermostat is a double thermistor unit assembly containing two thermistors in one jacket. In case of damage in one of the thermistors, replace the complete component.

The thermistor used for Water-in is a single thermistor unit assembly

Water-out and Thermostat Thermistor Replacement

➤ To remove the Water-out and Thermostat Thermistor

1. Drain the water tank (see Chapter 7 "Hydraulic System").

2. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
3. Open the right side cover.
4. Disconnect the water-out and thermostat two pin Molex connectors from the Human Sensors board (see Figure 6-18).

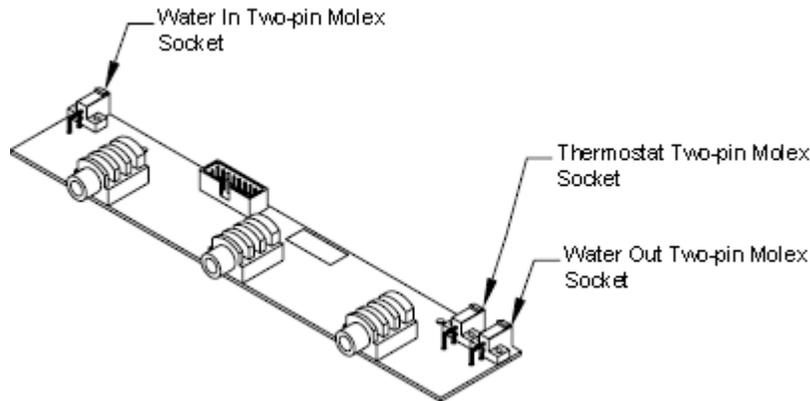


Figure 6-18: Socket Location

5. Follow the cable to the other end and remove the thermistor by pressing the release ring from the water connector.

➤ ***To re-assemble the new water-out and thermostat thermistor:***

1. Perform the same procedure in reverse order.
2. Fill the water tank and check for water leakage.
3. Replace the right side cover.

Water-in Thermistor Replacement

➤ ***To remove the Water-in Thermistor:***

1. Drain the water tank (see Chapter 7: Hydraulic System).
2. Remove the handle and the top cover (see Chapter 5: Panels and Covers).
3. Open the left side cover.
4. Disconnect the Water-in pin Molex connectors from the Human Sensors board (see Figure 6-18).
5. Follow the cable to the other end and remove the thermistor by pressing the release ring from the water connector.

➤ ***To re-assemble the new thermistor:***

1. Perform the same procedure in reverse order.
2. Fill the water tank and check for water leakage.

3. Replace the left side cover.

Float

The float contains a bottom switch that monitors the presence of water in the tank. The non-activation of the switches sends a signal to the controller board. The system notifies the user with the following message:

Allon:

1. During selftest: “ADD WATER”
2. In other cases: “ATTENTION NO WATER – PLEASE ADD WATER”

CritiCool:

1. During selftest :”TANK IS EMPTY”
2. In other cases: “ADD WATER”

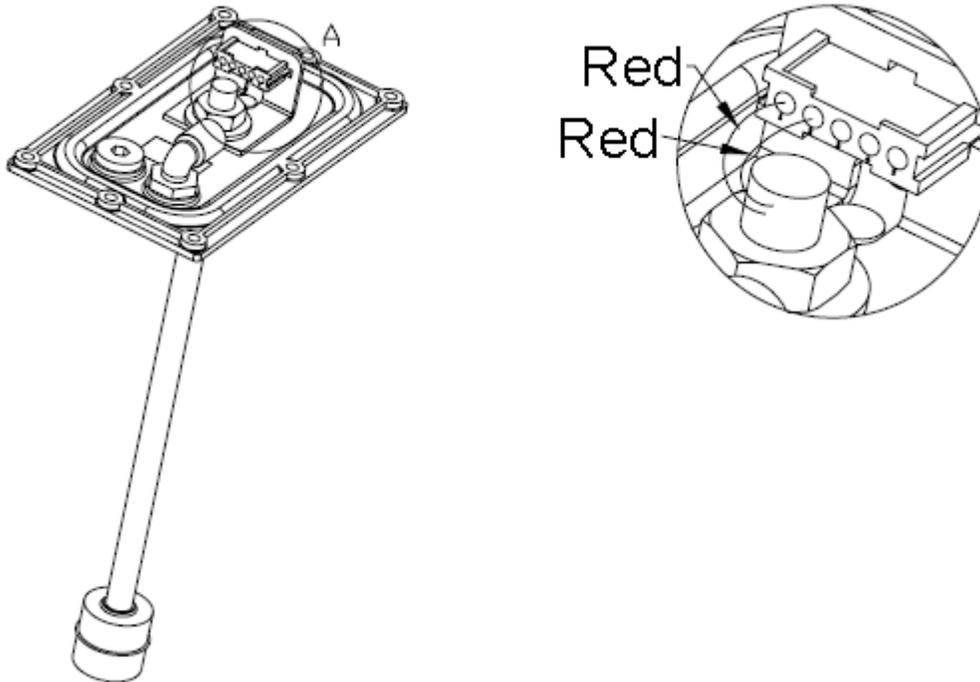


Figure 6-19: Floats—Electrical Connections

CHAPTER 7: HYDRAULIC SYSTEM

***WARNING!!!**The repair, calibration, and servicing of the Thermoregulation System should be performed only by MTRE Advanced Technology Ltd or authorized agents of MTRE Advanced Technology Ltd.*

***WARNING!!!**Detach the power cable before you do any maintenance or replacement procedures. Failure to do so could result in severe personal injury.*

Introduction

This chapter describes the hydraulic system of the Thermoregulation device. The hydraulic system circulates water from the water tank through a filter, pump, heating/cooling elements, solenoid bypass valve, Garment, and back to the water tank.

Water flows through the internal connecting tubes in 2 circular loops:

- Through the Garment
- Through a solenoid valve to by-pass the Garment directly into the water tank

The hydraulic system consists of the following elements:

- Water Tank Assembly
- Filter
- Pump
- Solenoid Bypass Valve
- Water-In and Water-Out Connectors

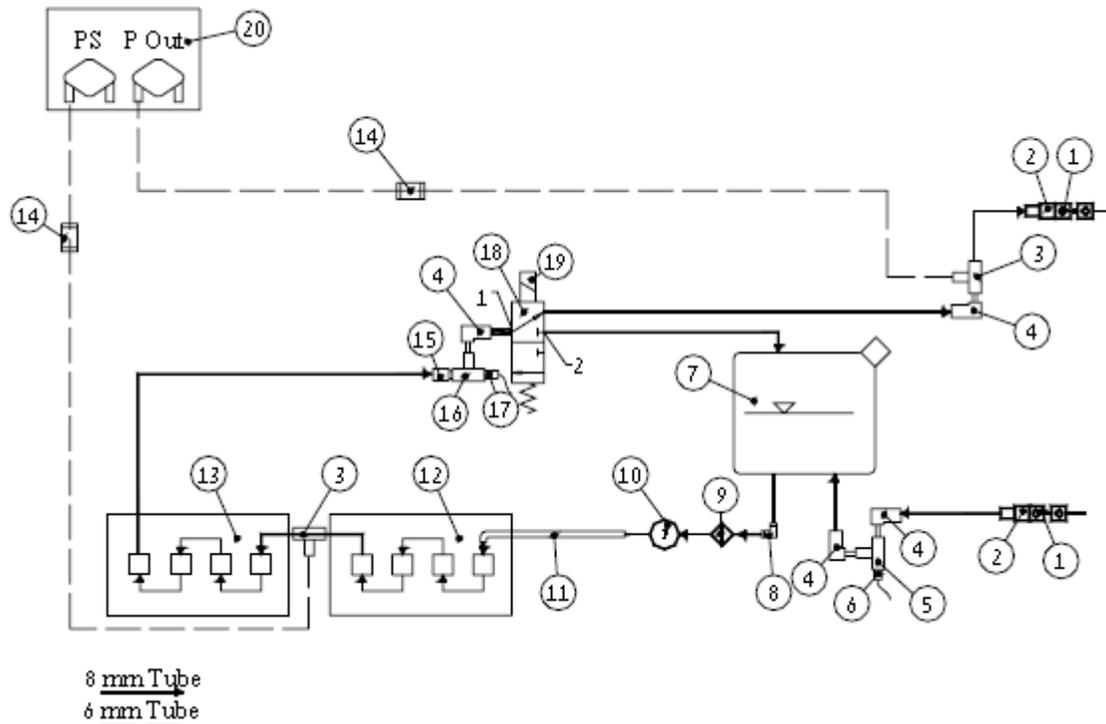


Figure 7-1: Hydraulic Block Diagram

Table 7-1: Hydraulic Block Diagram Elements

Item No.	Qty.	Part No.	Description
1	2	002-00147	QCC Brass, fem, 1/4BSPT, Viton
2	2	002-00148	Quick fitting 8mm BSPT fem str
3	2	002-00019	Quick Connector T 8mm/6mm
4	4	002-00158	Connector Plug-in 8mm elbow 8mm
5	1	002-00176	Connector T to 8mm Tube
6	1	200-00128	S. S. Thermistor Housing
7	1	200-00104	Water Tank Main Assy
8	1	002-00027	Quick Connector Elbow 8mm Tube
9	1	200-00130	Qosina Filter Assy
10	1	200-00115	RD5 Pump Assy
11	1	200-00069	Buffer Tube Assy

Table 7-1: Hydraulic Block Diagram Elements

Item No.	Qty.	Part No.	Description
12	1	200-00054	HCU Right
13	1	200-00054	HCU Left
14	2	002-00007	Quick Connector Straight 6mm
15	1	002-00178	Fitting Quick Reducer 10-8
16	1	002-00179	Quick Connector T 10-8
17	1	200-00131	Double Sensor Thermistor
18	1	003-00001	Solenoid Valve 3/2 Orif 3.5mm
19	1	003-00012	Solenoid Plug
20	1	300-00015	FP Assy

Water Tank Assembly

The water tank assembly consists of the following parts:

- Water tank—made of ABS. It contains up to 6.2 liters of water.
- Water tank top cover assembly—made of ABS. The water tank holds the float water level sensors, tube connectors, and float electrical connector.
- Cap—made of molded plastic
- Lower water connectors—Water-in And water-out
- Bracket
- Water level indicator

Before removing the water tank you need to drain it.

➤ *To drain the water tank – Allon 2001*

1. Connect one male connector of the connecting tubes to the water outlet under the Core socket.
2. Turn the Thermoregulation device ON.
3. Switch to Operation mode.
4. Connect the special male connector Model No. 002-00069 to the female connector of the tube that is connected under the Core socket (see Figure 7-2).
5. Allow the excess water to drain into a receptacle, pail or sink.
6. When the water finishes draining, turn the Thermoregulation device OFF.

➤ **To drain the water tank – CritiCool**

1. Turn the Thermoregulation device ON.
2. Select Empty Mode.
3. Connect one male connector of the connecting tubes to the water outlet under the Core socket.
4. Connect the special male connector Model No. 002-00069 to the female connector of the tube that is connected under the Core socket (see Figure 7-2).
5. Allow the excess water to drain into a receptacle, pail or sink.
6. When the water finishes draining, turn the Thermoregulation device OFF.

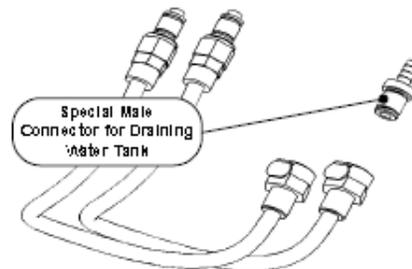


Figure 7-2: Connecting Tubes and Special Male Connector

➤ **To remove the Water Tank**

1. Drain the water tank (see procedure above).
2. Remove the two side covers, and the lower front cover (see Chapter 5 "Panels and Covers").
3. Disconnect the two bottom tubes: Water-out on the right side, and Water-in on the left side.
4. Open two self-locking 7 mm nuts and washers—one on each side of the tank.
5. Partially slide the water tank out and, from the top of the tank, disconnect the float electrical connector and the water bypass tube coming from the solenoid.
6. Slide out the water tank.

Note: To re-assemble the new water tank, follow the same procedure in reverse order.

Water Tank Top Cover Assembly

The water tank top cover assembly performs the following functions:

- Seals the top of the water tank to prevent leakage
- Secures the float rod and contains the float electrical connector
- Allows the flow of water to the tank by means of the by-pass connector

Filter

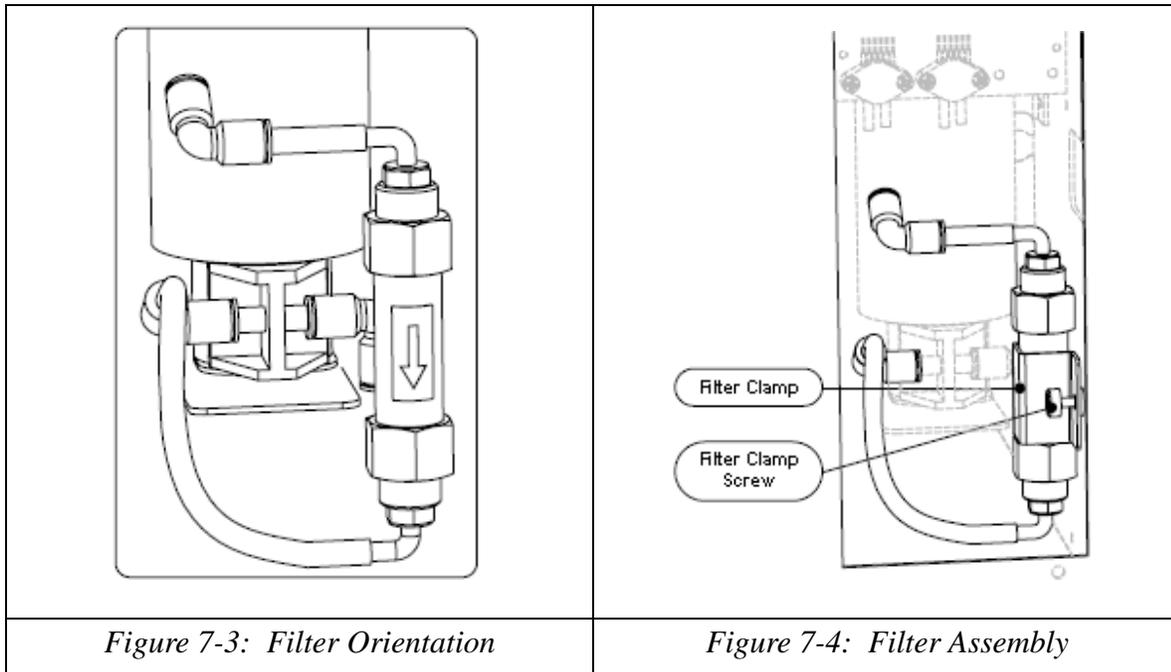


Figure 7-3: Filter Orientation

Figure 7-4: Filter Assembly

Replacing the Filter

Filter replacement must be performed every twelve months and is performed by the hospital personnel.

Note: An additional filter is supplied in the accessory box.

Removing the Filter

► To remove the filter:

1. Drain the water tank (see To drain the water tank – Allon 2001 or To drain the water tank – CritiCool 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 7-3, 7-4 on page 7-7).
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.

Installing the New Filter

➤ *To install the new filter assembly:*

CAUTION : The filter is marked with an arrow indicating the direction of water flow (see Figure 7-3 and Figure 7-4).

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 7-5).
3. Close the rear cover and tighten the thumb captive screws by hand.

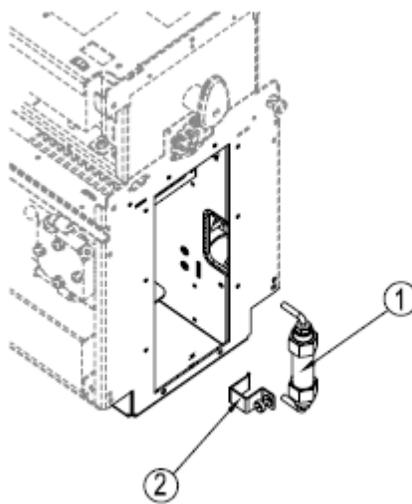


Figure 7-5: Filter Assembly Overview

Table 7-2: Filter Parts

Item No.	Qty.	Part No.	Description
1	1	200-00130	Qosina Filter Assembly
2	1	007-00334	Qosina Filter Bracket

Pump

The pump circulates water through the system at rates of 0.8-1.2 liters per minute.

The pump is a positive displacement type so it builds up pressure at the pump output.

This pressure is limited in two stages:

- Pres 1 at 0.9bar
- Pres 2 at 1.8 bar (safety)

The pump is digitally controlled from the controller board and is powered by 12VDC.

Removing the Pump

WARNING!!! You must drain the water tank before removing the pump.

➤ To remove the pump:

(see Figure 7-6):

1. Drain the water tank (see "Drain the tank" on page 7-6).
2. Open the rear cover (see Chapter 5 "Panels and Covers").
3. Disconnect the pump power connector.
4. Disconnect the water-in tube on the bottom of the pump coming from the water filter and the water-out tube from the pump leading to the HCU connector of the pressurestat. Press the release ring of each fitting and pull out the tubes.
5. Loosen the four pump screws leaving them in their rubber washers. These rubber washers are shock absorbers for the pump.
6. Slide the pump out of the Thermoregulation device.

Note: To re-assemble the new pump, follow the same procedure in reverse order.

CAUTION: Do not over-tighten the four pump screws. Over tightening may cancel the effect of the shock absorbers.

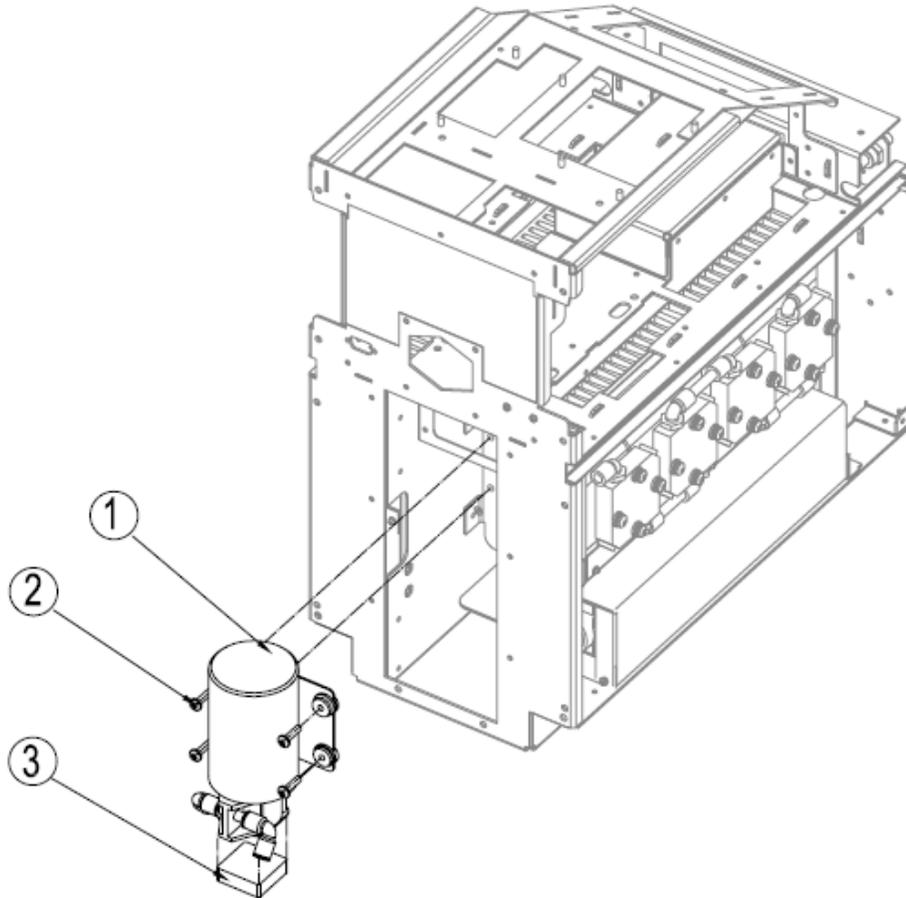


Figure 7-6: Pump Removal

Table 7-3: Pump Parts

Item No.	Qty.	Part No.	Description
1	1	200-00115	Pump Assembly
2	4	009-00009	Screw M4x16 Pan Philips s.s.
3	1	007-00232	Pump Shock Absorber

Pump Block Diagram

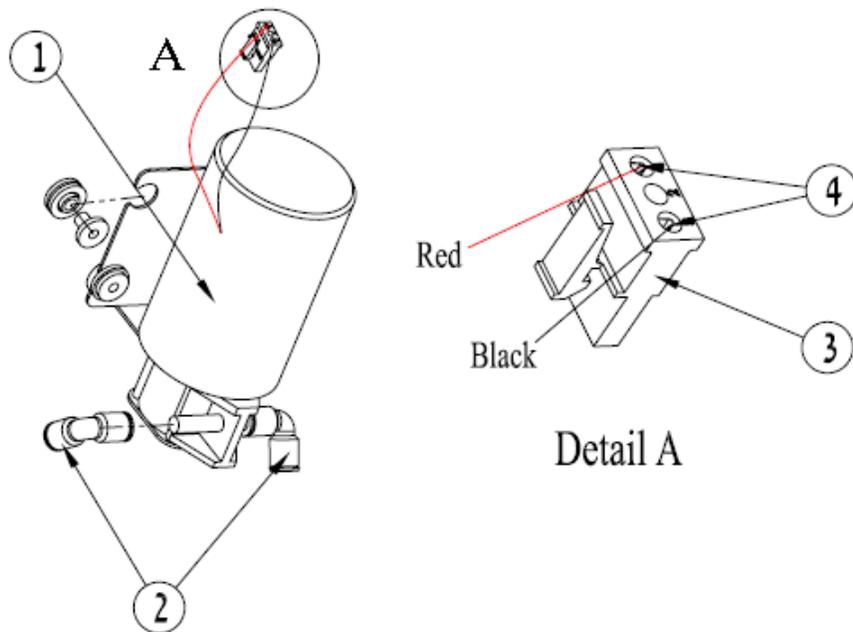


Figure 7-7: Pump Block Diagram

Table 7-4: Pump Block Parts

Item No.	Qty.	Part No.	Description
1	1	200-00115	RD5 Pump Assembly
2	2	002-00027	Quick Angle Connector for Tube 8mm
3	1	005-00156	Connector Male 3-pin Crimp Panel Mount
4	2	005-00159	Pin Female Crimp 16 AWG

Solenoid Bypass Valve

Refer to Section "Solenoid Bypass Valve" in "Chapter 6: Electrical System".

Water-In and Water-Out Connectors

➤ To remove the Water-out Assembly:

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Remove the right side cover.
3. Disconnect the 6mm pressure tube.
4. Disconnect the 8mm flow tube.
5. Unscrew the two Philips screws from the water bracket.

Note: To re-assemble the new Water-out assembly, follow the same procedure in reverse order.

➤ To remove the Water-in Assembly

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Remove the left side cover.
3. Disconnect the 8mm flow tube.
4. Unscrew the two Philips screws from the water bracket.

Note: To re-assemble the new Water-in assembly, follow the same procedure in reverse order.

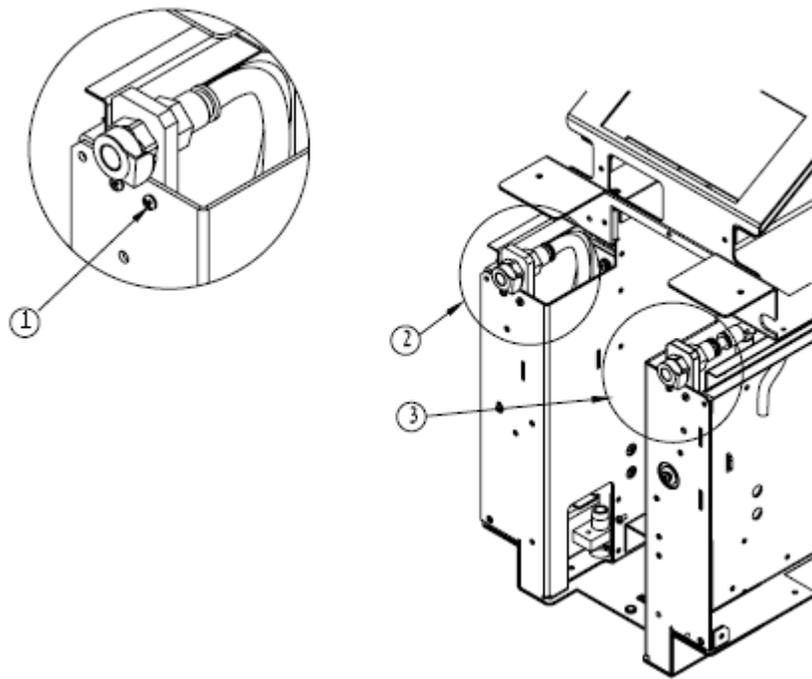


Figure 7-8: Water-in and Water-out Connectors

Table 7-5: Water Connectors Parts

Item No.	Qty.	Part No.	Description
1	4	009-00006	Screw M4x8 Pan Philips s.s.
2	1	200-00097	Water-in Female Assembly
3	1	200-00097	Water-out Female Assembly

CHAPTER 8: SOFTWARE

Overview

The software handles all system inputs and outputs. It is downloaded through the RS-232 communication port to the ROM or Flash and initialized each time the system is turned on.

Self-Test

On system restart, the software executes a self-test. The self-test verifies the correct functioning of the Thermoregulation device:

- Screen and buzzer test
- Flow test
- CRC test
- Cooling and heating capability test
- Water preheating - Allon
- Normal operation test

Note: For details regarding Self Test, refer to the User Manual.

Safety Algorithm

The purpose of the Safety algorithm is to prevent device malfunction and risk to the patient by detecting one or more of a set of safety conditions and then taking one or more of the following actions:

- Displaying a message
- Activating a buzzer
- Activating Bypass
- Turning off the TECs
- Disabling the keyboard

Some safety conditions are recoverable by operator action and are called **Messages**.

If the Safety algorithm detects a **HALT** condition, it disables the Thermoregulation device by turning OFF the pump, turning OFF the TECs, activating the bypass, and turning ON the buzzer. In this condition the soft-touch keys are disabled!

If the Safety algorithm activates the buzzer for a Message condition, the operator can mute the buzzer by pressing the **Alarm Mute** button.

Halt Conditions

Several conditions require you to disable the Thermoregulation device to prevent possible hazard to the patient or to the operator.

These conditions are called HALT CONDITIONS and are listed in Table 8-1:

Table 8-1: Halt Conditions

Message	Possible problem
No power	Power switch OFF Power cord connected insecurely Power in wall connector Main Fuses 6.3A blown Faulty AV voltage from transformer secondary
Halt 1 or 4 HALT 2 Halt 3 Halt 5 Halt 6 or 7 Halt 8 Halt 13 Halt 17 (CritiCool only) Halt 18 (CritiCool only) Halt 19 (CritiCool only)	System detected a flow problem Set point error. Test of the memory. Halt occurs when current Set point is not equal to the Set point previously saved to memory(memory corruption). System detected thermostat tripped, indicating a likely overheating condition System indicating a likely program memory Self test detected a problem with Heating/Cooling unit Self test detected no reading in Water in sensor System detected overpressure Battery is bad. Software error (patient not Adult and not Neonatal) System shut down. When we get command "Shut down" from Monitor . End case.

Technician Mode Error Messages

An error message displayed in Operation mode is a *single* error of the highest severity. The message displayed in Technician mode is a coded error that simultaneously provides all the errors (see Section "Technician Mode Screen in Appendix A "Technician Mode") present in the system.

The errors messages in technician mode are read from right to left in order of severity. Each character in the error message is a hexadecimal number and represents a group of errors (see Table 8-2).

To view the error messages, enter Technician mode (see Appendix A "Technician Mode").

Explanation of Error Messages

In the following example, the third number from the right (C) represents Error Group 3 (errors 9–12). When translated into binary code (see Table 8-3) it yields a four digit number read from right to left. Each “1”, in conversion to binary, represents an activation of an error message.

Table 8-2: Error Messages

Error Group	Description	Error Number
00000001	Core readout too low	1
00000002	HALT SetPoint	
00000004	Patient temperature less then 35.5°C - (95.9°F)	
00000008	Patient temperature high then 38.500C - (101.3°F)	
00000010	Water out temperature is less than 10.000C - (50°F)	2
00000020	Water out temperature is higher than 42.000C - (107.6°F)	
00000040	Water level in water tank is too low	
00000080	Internal pressure (pressure too low or too high)	
00000100	Available for future use	3
00000200	Check ThermoWrap (pressure is higher then 0.8 bar)	
00000400	Connect core sensor to the Thermoregulation device	
00000800	Wrong core sensor is inserted to the Thermoregulation device socket	
00001000	Connect surface sensor to the Thermoregulation device	4
00002000	Wrong surface sensor is inserted to the Thermoregulation device socket	
00004000	Available for future use	
00008000	Available for future use	

Table 8-2: Error Messages

Error Group	Description	Error Number
00010000	Set point temperature is out of NormoThermia range	5
00020000	HALT Overpressure	
00040000	HALT Thermostat	
00080000	General electromagnetic interference in the sensor signal reading	
00100000	Electromagnetic interference in the core sensor signal reading	6
00200000	Available for future use	
00400000	Electromagnetic interference in the surface sensor signal reading	
00800000	Electromagnetic interference in the water in sensor signal reading	
01000000	Electromagnetic interference in the water out sensor signal reading	7
02000000	Core less than 30 C	
04000000	Difference between SetPoint and Core more then 2C	
08000000	Difference between SetPoint and Core more then 0.8C	
10000000	Available for future use	8
20000000	Available for future use	
40000000	Available for future use	
80000000	Available for future use	

Group 8	Group 7	Group 6	Group 5	Group 4	Group 3	Group 2	Group 1
0	0	0	0	2	C	0	1



Error Number	8	4	2	1
Hexadecimal	1	1	0	0

Table 8-3: Hexadecimal to Binary Translation

Hexadecimal	Binary	Decimal
1	0001	1
2	0010	2
3	0011	3

Table 8-3: Hexadecimal to Binary Translation

Hexadecimal	Binary	Decimal
4	0100	4
5	0101	5
6	0110	6
7	0111	7
8	1000	8
9	1001	9
A	1010	10
B	1011	11
C	1100	12
D	1101	13
E	1110	14
F	1111	15

CHAPTER 9: PERIODIC MAINTENANCE

WARNING!!! *The repair and servicing of the Thermoregulation System should be performed only by MTRE Advanced Technology Ltd or authorized agents of MTRE Advanced Technology Ltd.*

WARNING!!! *Follow all safety guidelines as described in Chapter 2: Warnings and Precautions. Failure to do so can cause serious personal injury.*

Note: *At the end of any maintenance procedure, connect a tube to bypass the Garment and conduct a complete self-test.
This is to guarantee that the system is operational.*

Overview of the Periodic Maintenance Procedures

This chapter describes the periodic maintenance procedures performed on the Thermoregulation device. Periodic maintenance should be performed every twelve months.

The following steps outline the routine procedures in periodic maintenance:

1. Entering Technician Mode (see "Entering Technician Mode" on page A-4)
2. Draining Water Tank (see "Water Tank Assembly" on page 7-3) .
3. Removing the Cover (see "Removing the Cover" on page 9-20).
4. Replacing the Water Filter (see "Replacing the Water Filter" on page 9-2).
5. Activating the CritiCool Machine (see "Activating the CritiCool Machine" on page 9-2)
6. Verification
 - a. Human Sensors Verification (see "Activating the CritiCool Machine" on page 9-2).
 - b. Water Temperature Sensors (see "Water Temperature Sensors Verification" on page 9-4).
 - c. Thermostat Verification (see "Thermostat Verification" on page 9-6).
 - d. Pressure Verification (see "Pressure Verification " on page 9-8
 - e. TEC Current Test "TEC Current Test" on page 9-9
7. Checking for Water Leakage (see "Check for Water Leakage" on page 9-11).
8. Self-test (see "Self-test " on page 9-11

Removing the Cover

Remove the following:

- Handle
- Top cover
- Rear cover

For instructions on panel removal, see Chapter 5: Panels and Covers.

Replacing the Water Filter

Replace the water filter. Follow the instructions in Chapter 7: Hydraulic System.

Activating the CritiCool Machine

➤ *To Activate the Criticool Machine:*

Activate Technician Mode: Turn on the Thermoregulation system and immediately, press simultaneously the left (SILENCE) and right (UP) buttons. The Main Menu screen appears.

Human Sensors Verification

Your calibration tool kit may include either

- MTRE Temperature Calibration Unit (P/N 017-00184) or
- TP-400 FOGG Temperature Calibration unit (P/N 017-00284)

The verification procedure depends on the type of your calibration device.

➤ *To test the proper functioning of the Human Sensors board using MTRE Temperature Calibration Unit (P/N 017-00184):*

1. Enter Technician mode.
2. Connect the **Core** sensors calibration cable to the **Output** socket in the MTRE Temperature Calibration Unit. Use the **RED** plug.
3. Connect the **BLACK** plug of the cable to the **Core** sensor socket on the Thermoregulation device.

Note: *The plugs on both sides of the cable are not identical. Be sure to connect the proper plug into the correct socket.*

4. Toggle the Calibration/Verification switch to "Verification" (017-00184).
5. Turn the **Human Sensor Verification** knob counter-clockwise to the number "42.9" (017-00184). Record the value that appears on the display for "Core" in the "Physical" column in the Verification form.
6. Turn the **Human Sensor Verification** knob clockwise to the next increment (37.5) and record the new value that appears on the display.
7. Repeat the procedure for all the remaining increments according to 8.
8. At the end of verification, remove the cable from the **Core** sensor socket.
9. Connect the **Surface** sensor calibration cable to the "Output" socket in the MTRE Temperature Calibration Unit. Use the **RED** plug.
10. Connect the **SILVER** plug of the cable to the **Surface** sensor socket on the Thermoregulation device.
11. Turn the "Human Sensor Verification" knob counter-clockwise to the number "42.9". Record the value that appears on the display for "Surface" in the "Physical" column in the Verification form. See Table 9-1 for sample.
12. Repeat the procedure for all the remaining increments.
13. When all the increments have been recorded, Human Sensor verification is complete. Remove the Surface sensor calibration cable.

Table 9-1: Verification Form—Human Sensors- using MTRE Temperature Calibration Unit 017-00184

Temp. [C]	Max	Min	Surface [C]	Core [C]	Accept/Failed
42.90	43.10	42.70			
37.50	37.70	37.30			
36.20	36.40	36.00			
33.30	33.50	33.10			
27.10	27.30	26.90			
22.90	23.10	22.70			
18.50	18.70	18.30			

You have completed the Human Sensors verification procedure. Summarize the verification results and check to see that they are within the tolerance.

If either of the sensors is out of tolerance, refer to [CHAPTER 10: Troubleshooting](#) for the solution to this problem.

➤ **To test the proper functioning of the Human Sensors board using TP-400 FOGG Temperature Calibration unit (P/N 017-00284):**

1. Turn the machine ON.
2. Core measurement; connect Core cable between temperature simulators to the tested sensor socket.
3. Change the temperature value on the simulator according to Table 9-2.
4. Surface measurement; connect **Surface** cable between temperature simulators to the tested sensor socket.
5. Change the temperature value on the simulator according to Table 9-2.

Table 9-2: Verification Form—Human Sensors- using Temp Probe Simulator TP400017-00284

Temp. [C]	Max	Min	Surface [C]	Core [C]	Accept/Failed
20	20.30	19.70			
25	25.30	24.70			
30	30.30	29.70			
35	35.30	34.70			
36	36.30	35.70			
38	38.30	37.70			
40	40.30	39.70			

Water Temperature Sensors Verification

The Water Temperature and Thermostat connectors are located on the Human sensors board.

Note: *Perform this test in one shift. If the maximum water temperature measurements exceed the allowed tolerance (+/-1.0), refill the water tank with fresh water!*

➤ **To perform the Water Temperature sensors verification test:**

1. Add 1.5 liter of tap water to the water tank.
2. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
3. Turn the ON Thermoregulation device.

4. Scroll down to **Operation Mode** and press the **Mode** key to enter.
5. Change the set-point temperature with the arrow keys to 40°C.
6. Press **Mode**. Scroll down to **Technician Mode** and press the **Mode** key to enter.
7. Connect the Temperature Calibration Unit (P/N 017-00184 or P/N 017-00284) with the Core Calibration cable P/N 300-00093 (red and black jacks) to the Thermoregulation device.
8. Toggle the Calibration/Verification switch to "Calibration" (on P/N 017-00184).
9. Turn the Human Sensor Calibration switch to 36.7°C. For the CritiCool system, toggle the Calibration/Verification switch to 39.8°C. with P/N 017-00284 pick 38.0° as the Core temperature.

This state is intended to simulate the patient temperature of 36.7°C or 39.8° (or 38.0° with P/N 017-00284) on the CritiCool system with the desired set point of 40°C. In this state the Thermoregulation device heats at its full capacity.

***Note:** Make sure that the Thermoregulation device is in Technician mode.*

10. Connect the external bypass tube with the Thermocouple (200-00096) to the Water-out connector under core socket and to the Water-in.
11. Connect the External Temperature meter P/N 017-00238 to the Thermocouple and turn it ON.
12. Observe the Water Out line displayed on the Technician Mode screen. Wait a few minutes until the temperature reaches its maximum.
13. Observe the maximum temperature of Water-out on the Technician screen and max temperature on external Thermometer. Write down the values on report A-B and then press the right button on the display to turn off the Heating/Cooling elements.
14. Observe the Water Out temperature displayed on the Technician Mode screen and list the maximum temperature reading in the attached **Maintenance Verification / Calibration Report** under **Wout (B)**. At the same time, observe the maximum temperature readout on the External Temperature meter and list it in the report under **Max Temp (A)**.
15. Perform the calculation listed in the report ($\Delta = A - B$). In the event that the result is inside the listed tolerance (± 1.0), proceed as follows:
 - a. In the Technician mode screen, **press the bottom right button to toggle the TECs on and off.**
 - b. Observe the decrease in temperature on the External Temperature meter.

For each increment listed in the report (38.00, 37.00, etc.), write down the corresponding temperature reading from the Technician Mode screen in the **Wout** and **Win** columns in the report. See Table 9-2" for sample.

16. Turn the Thermoregulation device OFF.

You have completed the Water Temperature sensors verification tests. Summarize the verification results and check to see that they are within the tolerance.

If the verification tests pass, proceed to "Thermostat Verification" on page 9-6".

If the verification tests fail, replace the faulty thermistor. Refer to Section "Thermistors" on page 6-23" in Chapter 6: Electrical System for thermistor replacement procedure.

Table 9-3: Verification Form— Water Temperature Sensors

Max Temp.[C] A	W out [C] B	Δ=A-B		Accept/Failed
		Measured	Accepted	
			±1.0	

Temp. [C]	Max	Min	Surface [C]	Core [C]	Accept/Failed	Temp. [C]
38	39	37				
37	38	36				
36	37	35				
35	36	34				
34	35	33				
33	34	32				

Thermostat Verification

➤ **To check the thermostat:**

1. Remove the handle and the top cover (see Chapter 5 "Panels and Covers").
2. Detach the thermostat sensor cable next to the water-out sensor socket on the right side of the unit by pressing the latch.
3. Connect the two-pin Molex connector marked with the label "GO" on the Thermostat Verification Tool to the Thermostat socket on the Human Sensors board (see Figure 9-1).

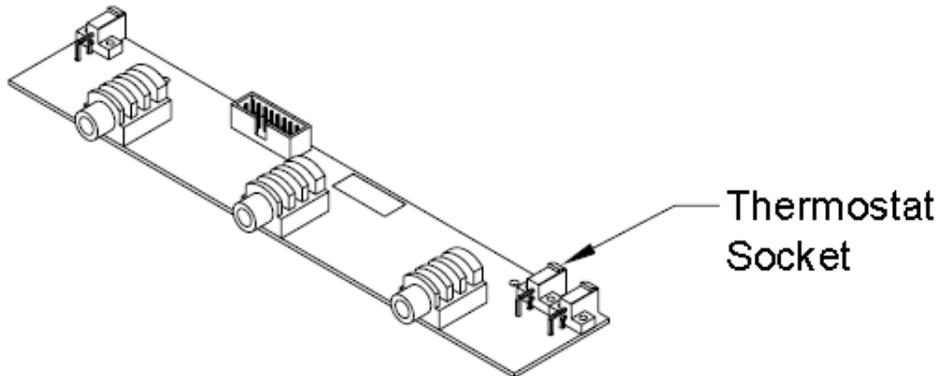


Figure 9-1: Thermostat Socket on Human Sensors Board

4. If the Thermoregulation device remains in normal operation in this position after 10 seconds, disconnect the Thermostat Verification Tool (see Figure 9-2) from the Human Sensors board.
5. Connect the two-pin Molex connector marked with the label "NO GO" on the Thermostat Verification Tool to the Thermostat socket on the Human Sensors board.
6. After 10 seconds in this position, the machine activates the buzzer and the following message appears on the display: **HALT PLEASE RESTART (3)**. This indicates that the thermostat is within operating range.

If the buzzer is not activated and if the message does not appear on the display check the following:

1. Check the resistance of the Thermostat Verification Tool with a Multi-meter.
 - On the "GO" side the resistance should be $\sim 1100(\Omega)$.
 - On the "NO GO" side the resistance should be $\sim 1020(\Omega)$.
2. If the Thermostat Verification Tool is OK, replace the Human Sensors board (see Chapter 6: Electrical System) and start the test again.



Figure 9-2: Thermostat Verification Tool

Pressure Verification

Perform the pressure verification test with the Analog Flow and Pressure Calibration Unit or the Digital Pressure Calibration Unit Assembly.

➤ **To perform pressure verification:**

1. Remove the handle and the top cover (see Chapter 5: Panels and Covers).
2. Open the valve before connecting the tubes.
3. Connect the connecting tubes from the Pressure Calibration Unit to the Thermoregulation device.
4. Enter **Technician Mode** (refer to Appendix A: Technician Mode).
5. Slowly close the valve until the pressure on the pressure gauge registers at 0.5 bar.

Record the value for 0.5 bar that appears on the Technician Mode display for "Pres1" (water-out pressure) in the "Physical" column in the Verification form. See Appendix C: Service Form for sample.

Note: *Do not close the tap too quickly. This will lead to improper measurement of the pressure due to the reaction time of the system.
Perform this test fast after disconnecting connector J3.*

6. Remove the cable connected to connector J3 (FUNK 2) on the Controller board located to the right of the RS-232 cable when facing the right side of the Thermoregulation device (refer to the Controller Board Component Placement figure in Chapter 6 "Electrical System").
7. Gradually close the valve and raise the pressure to 1.1 bar. Record the value for 1.1 bar that appears on the display for "Pres" (Pressure) in the "Physical" column in the Verification form.
8. At the end of the test, open the valve.

Note: *When performing this test on a CritiCool with Neonatal configuration use a simulate core temperature (use Core temperature simulators P/N: 017-00184/017-00284.*

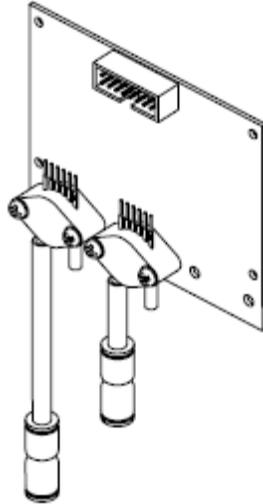


Figure 9-3: FP Pressure Gauge

Table 9-4: Verification Form— Pressure

Pressure Verification		
Pressure Setup (bar)	Range (bar)	Result (bar)
0.5	0.40-0.60	
1.1	1.0-1.2	

You have completed the Pressure verification tests. Summarize the verification results and check to see that they are within the tolerances listed in the Verification form.

Note: If either Pressure is out of tolerance, you must replace the FP board.

If the verification tests passed, proceed to "TEC Current Test" on paragraph 9-12.

TEC Current Test

The TEC Current Test checks the current sent to each TEC from the TEC control board. Both sides of the TEC control board must be checked.

The Tec Current Test is executed with both the TEC Current Verification Unit (Figure 9-4) and with the MTRE Temperature Calibration Unit.

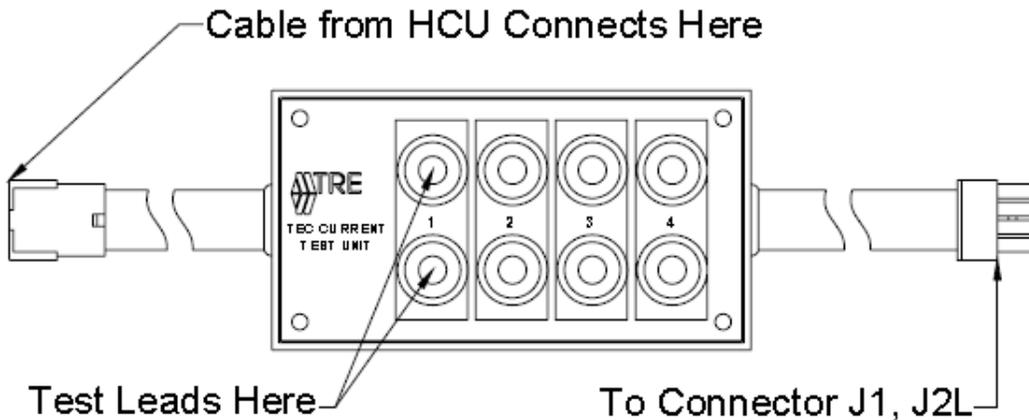


Figure 9-4: MTRE TEC Current Verification Unit

WARNING!!! Turn the Thermoregulation device OFF before connecting cables to the TEC control board. Failure to do so can cause severe shock.

➤ **To check the TEC current:**

1. Turn the device OFF.
2. Remove the top cover.
3. Detach the cable leading from connector J1 on the TEC control board to the HCU (refer to the TEC Control Board Figure 6-6 in Chapter 6: Electrical System).
4. Insert the plug of the cable leading from the HCU (detached from the TEC control board in Step 3) to the TEC Current Verification Unit cable with the connector (female).
5. Insert the plug of the TEC Current Verification Unit cable to connector J1 on the TEC control board.
6. Turn the device ON and enter Operation mode.
7. Connect the Human sensors calibration cable to the Core sensor socket on the Thermoregulation device and to the Output socket on the MTRE Temperature Calibration Unit.
8. Toggle the Calibration/Verification switch to "Verification". Set the "Human Sensor Verification" knob to "36.2".
9. Adjust the set-point temperature to 37⁰C. The system heats up to 40.8⁰C Water-out.
10. Use a multi-meter set to DC current with the pair of test cables from the MTRE Temperature Calibration Unit. Insert the probes of the cables to the pair (labeled "1") of sockets in the TEC Current Verification Unit.
11. Measure the current and note the results.

12. Repeat the procedure for every pair of sockets on the TEC Current Verification Unit.
13. Lower the set-point temperature to 34⁰C; the system cools.
14. Repeat the measurement for all four TECs.

Note: *The average current of all four pairs should be a minimum of 3 Amps.*

If any of the TECs are found to be out of tolerance, check the TECs and the TEC control board:

➤ ***To verify the fault of the TECs or of the TEC control board:***

1. Turn the Thermoregulation device OFF.
2. Remove the TEC Current Verification Unit cable from connector J1. Leave the cable leading from the HCU connected to the TEC Current Verification Unit cable with the connector.
3. Detach the cable leading from connector J2I on the TEC control board to the HCU.
4. Insert the plug of the TEC Current Verification Unit cable J2L on the TEC control board.
5. Turn the Thermoregulation device ON.
6. Measure the current in all four pairs of sockets as performed previously.

If any of the TECs are still found to be out of tolerance, replace the HCU.

If all the TECs are within tolerance, replace the TEC control board.

7. Turn the device OFF.
8. Repeat the **entire** procedure for connector J2I on the other side of the TEC control board.

Check for Water Leakage

Dry the area around the Thermoregulation device. While running the system at high pressure, check all tubes for water leakage.

Return all covers.

Self-test

At the completion of the routine maintenance procedure, activate the Thermoregulation device and run a complete self-test.

Replacing Controller Board Fuses

To replace a blown fuse on the controller board, it is not necessary to remove the board from the chassis. Replacement fuses (refer to Table 6-5, “TEC Control Board—Fuse List,” on page 6-9 in

Chapter 6: Electrical System) can be soldered to the **print side** of the controller board to the specific fuse contact point.

➤ **To replace a blown fuse on the controller board:**

1. Remove the handle
2. Open the top cover.
3. Locate the blown fuse.
4. Solder the replacement fuse to the proper contact point (contact points are shown in Figure 9-5).
5. Return the top cover and handle.

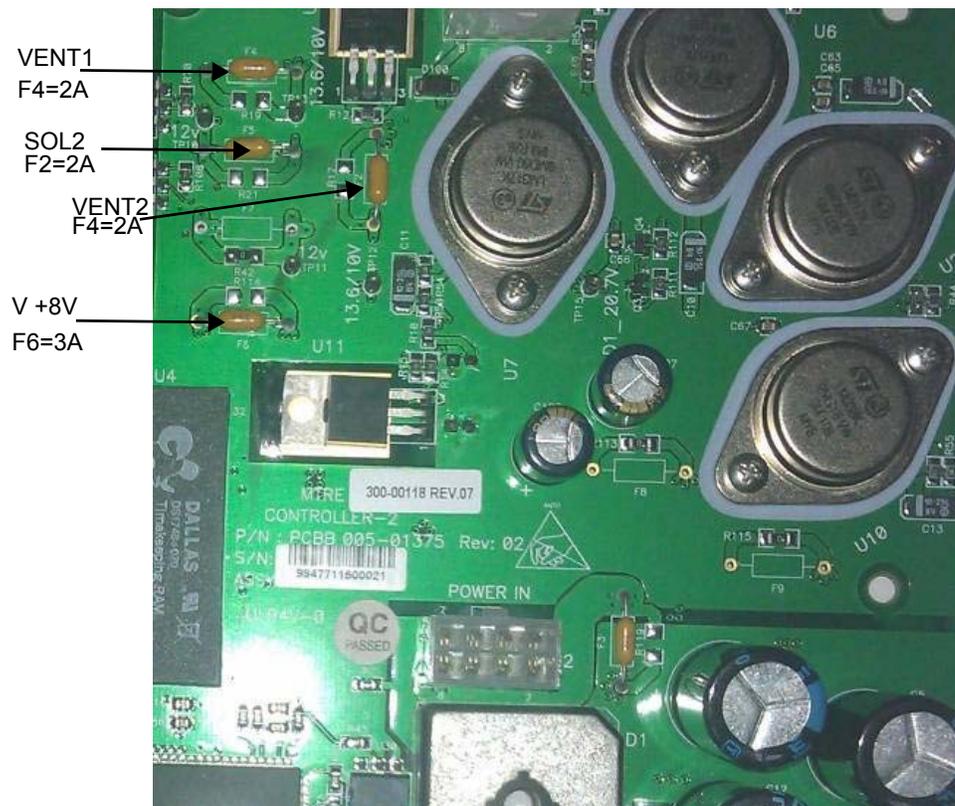


Figure 9-5: Controller Board Fuse Location

CHAPTER 10: TROUBLESHOOTING

WARNING!!! The repair, calibration, and servicing of the Thermoregulation System should be performed only by MTRE Advanced Technology Ltd or authorized agents of MTRE Advanced Technology Ltd.

Halt Messages

Halt messages provide information in cases of problems that cause the system to shutdown.

Note: The Report Section columns in Table 10-1 indicate the relevant sections for reporting the action item in the Maintenance Verification / Calibration or Service Reports.

Table 10-1: Halt messages – System Shutdown

Message	Possible Problem	Action to be taken	Report Sec.
No power	Power switch OFF	Turn power switch to ON position	
	Power cord connected insecurely	Secure power cord	
	No Power in wall connector	Use another wall connector	
	Main Fuses 6.3A blown	Replace faulty fuses	
	Faulty AV voltage from transformer secondary	Replace transformer assembly	Service report
Halt 1 or 4	System detected a flow problem	Replace the filter	
		Check FP harness connector	Pressure
		Check /Replace the pump	Pressure
		Check/replace FP board	Pressure
		Replace controller board	Complete

Table 10-1: Halt messages – System Shutdown

Message	Possible Problem	Action to be taken	Report Sec.
Halt 3	System detected thermostat tripped, indicating a likely over-heating condition	Check hardware thermostat with calibration/verification tool. If failed the GO / NO GO replace Human Sensor (HS) board	Thermostat or HS
		Check HS harness	HS
		Check/Replace Thermistor	Thermostat
		Replace controller board	Complete
Halt 5	System indicating a likely program memory	Perform re-download	Complete
		Replace controller board	Complete
Halt 6 or 7	Self test detected a problem with Heating/Cooling unit	Perform self test again	
		Check Tec's consumption	
		Replace TEC control board	TEC Current test
		Replace TEC-Transformer harnesses	
Halt 8	Self test detected no reading in Water in sensor	Perform self test again	
		Check Water in connector	
		Replace water in connector	
		Replace Water in thermistor	Water sensor
		Replace HS board	Verification
		Replace Controller board	Complete
Halt 13	System detected overpressure	Check for tubes kinked	
		Check pressure verification points	Pressure
		Check FP harness	Pressure
		Check/Replace FP board Check the Solenoid Valve	Pressure Pressure
		Replace controller board	Complete

Text Messages

Note: The Report Section columns in Table 10-2 indicate the relevant sections for reporting the action item in the Maintenance Verification / Calibration or Service Reports.

Table 10-2: Text Messages

Message / Problem	Possible Problem	Action to be Taken	Report Sec.
Add Water	Bottom float sensor in the water tank is not activated	Refill water	
		Check float movement freely	
		Check signal on float switch on J3 (pins 5 & 3). If there is no signal, replace water tank assembly	
		Replace 300-00091 Level sensor harness	
CHECK WATER CONNECTION	Pressure at Water-out exceeds 0.9 bar	Connect ThermoWrap	
		Check fuse F5 (solenoid valve)	
		Check fuse F8 (+12V)	Pressure
		Check FP board and cable to controller board	Complete
CHECK CORE SENSOR	Wrong decoding of sensor plug	Connect proper sensor	
		Replace core sensor with the one supplied with the system	HS
		Use a new core sensor	
		Check HS board and harness	HS

Table 10-2: Text Messages

Message / Problem	Possible Problem	Action to be Taken	Report Sec.
CHECK SURFACE SENSOR	Wrong decoding of sensor plug	Connect proper sensor	
		Replace surface sensor with the one supplied with the system	HS
		Use a new surface sensor	
		Check HS board and harness	HS
CONNECT CORE SENSOR	No core sensor detected	Replace core sensor	
		Check HS board and harness	HS
CONNECT SURFACE SENSOR	No surface sensor detected	Replace surface sensor	HS
		Check HS board and harness	HS
WATER TEMP TOO LOW	Water temperature below 10°C	If water temperature is not below 10°C, check HS board and harness	HS
WATER TEMP TOO HIGH	Water temperature above 42°C	If water temperature is not above 42°C, check HS board and harness	HS
PATIENT TEMP ABOVE 38.5°C (101.3°F)	Core temperature above 38.5°C	No action needed	
PATIENT TEMP BELOW 35.5°C (95.9°F)	Core temperature bellow 35.5°C	No action needed	
CORE READOUT TOO LOW	Core temperature reading below 30°C or 0.8C below Set Point	If message appears when actual core reading is adequate , check HS board and harness	HS
CORE READOUT TOO LOW CHECK CORE AND OPERATE	Core temperature reading is 2C below Set Point/Target Temp	Select operation from the menu or fix the core temperature probe, If message appears when actual core reading is adequate , check HS board and harness	HS
No display	Faulty controller board	Replace controller board (see chapter 6 Electrical System)	
	Faulty MMI	Replace MMI (see chapter 6 Electrical System)	
	Faulty controller board-MMI flat cable		

Table 10-2: Text Messages

Message / Problem	Possible Problem	Action to be Taken	Report Sec.
No display upon startup	Faulty FP board	Check fuse F6 on controller board	
	FP board and MMI, sharing the same line	Replace FP board	
		Replace MMI	Pressure

CHAPTER 11: SPECIAL EQUIPMENT AND TOOLS

This chapter describes the following:

- The special equipment supplied to perform the verification procedures described in Chapter 9 "Periodic Maintenance"
- Standard tools for normal maintenance
- The calibration test for the MTRE Temperature Calibration Unit

Calibration Toolset: Verification and Calibration Units

Verification is executed by means of the Calibration Toolset while operating in Technician mode. The Calibration Toolset consists of the components listed in Table 11-1 and are detailed in this section.

Table 11-1: Calibration Toolset Part No. 017-00210

Item No.	Part No.	Description
1	017-00184	Temperature Calibration Unit
2	017-00284	Temp Probe Simulator TP400
3	017-00190	Analog Flow Pressure Calibration Unit
4	017-00290	Digital Pressure Calibration Unit Assy.
5	017-00189	T.E.C. Current Verification Unit
6	300-00093	Core Calibration Cable
7	300-00094	Surface Calibration Cable
8	017-00203	Downloading Plug
9	900-00127	RS-323 Communication Cable
10+11	017-00260	Download Cable (With Plug)

Table 11-1: Calibration Toolset Part No. 017-00210

12	017-00211	Tool Box
13	005-00440	Red Probe for T.E.C. Verification Unit
14	005-00441	Black Probe for T.E.C. Verification Unit
15	017-00238	Mobile Thermometer Model 305
16	200-00096	Thermo couple
17	017-00229	Thermostat verification tool GO – NO GO
18	017-00236	Tool for Board Disassembly

MTRE Temperature Calibration Unit P/N: 017-00184

The MTRE Temperature Calibration Unit tests the Human temperature sensors.

The MTRE Temperature Calibration Unit consists of:

- The calibration unit
- One cable for verification of the Core Human sensors
- One cable for verification of the Surface Human sensors

MTRE Temperature Calibration Unit - Controls

The controls are as follows:

- A toggle switch for Calibration or Verification
- Human sensor switches:
 - a. Calibration
 - b. Verification
- Water Temperature switches:
 - a. Calibration
 - b. Verification
- Cable output jack for Thermoregulation calibration
- Two cable jacks for calibration check of the Temperature Calibration Unit

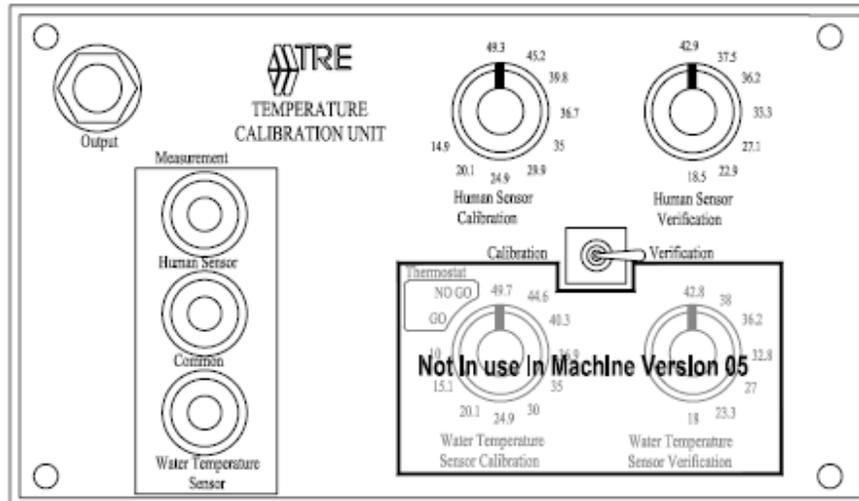


Figure 11-1: MTRE Temperature Calibration Unit (P/N 017-00184)—Front Panel

Note: The TP400 (P/N 017-00284) replaces the MTRE Temperature Calibration Unit P/N: 017-00184 (see Figure 11-10)

Analog Flow and Pressure Calibration Unit P/N 017-00190

The Flow and Pressure Calibration Unit tests the pressure of the Thermoregulation device at 0.9 bar and at 1.1 bar.

The Flow and Pressure Calibration Unit has two connecting tubes with a valve, flow meter, and pressure gauge.

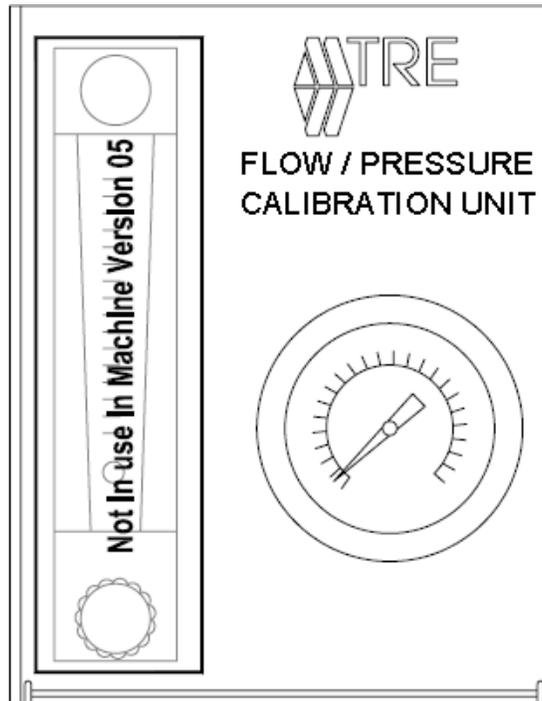


Figure 11-2: MTRE Flow and Pressure Calibration Unit

Digital Pressure Gauge P/N 017-00290



Figure 11-3: Digital Pressure Gauge P/N 017-00290

➤ **To install the digital pressure gauge:**

1. Connect **w-out** (Figure 11-4) and **w-in** (Figure 11-5) tubes to the gauge panel according to *Figure*

11-3 The labels on the panel indicate where to connect the tubes.



Figure 11-4: W-OUT



Figure 11-5: Figure 11- 5 : W-IN

The pressure gauge is connected and ready to use.



Figure 11-6: Pressure Gauge connected

WARNING!!! Do not change the setting of the gauge; the gauge is calibrated according to the transducer connected and the fixed setting as you received it.

TEC Current Verification Unit

The TEC Current Verification Unit tests the current sent to the TECs on both sides of the Thermoregulation device from the TEC control board.

The TEC Current Verification Unit has two cables. The cable with the plug is inserted to connectors J1 and J2L of the TEC current board. The cable with the connector (female) is fitted to the cable leading from the HCU.

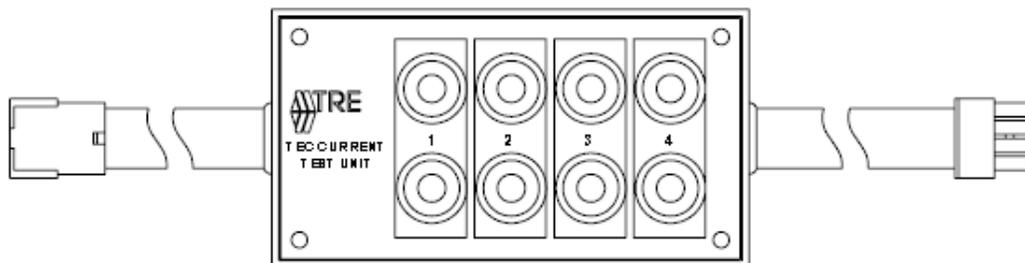


Figure 11-7: TEC Current Verification Unit

Calibration Cables

The cables needed for verification tests and calibration checks are shown below.

Core Calibration Cable

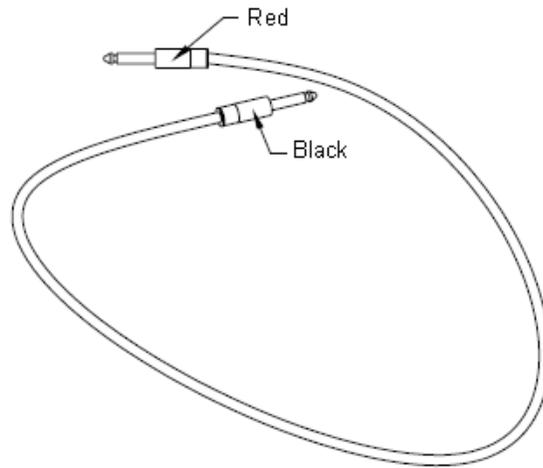


Figure 11-8: Core Calibration Cable

Surface Calibration Cable

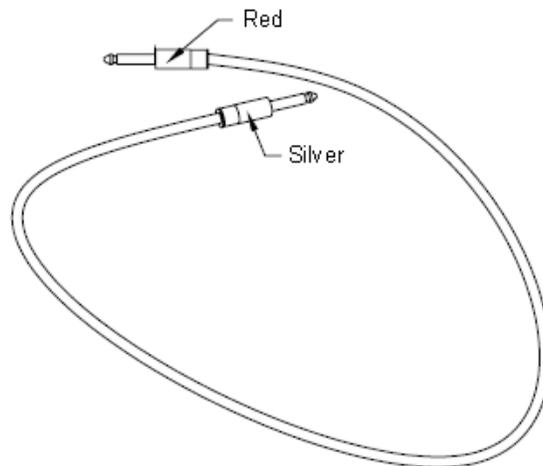


Figure 11-9: Surface Calibration Cable

Standard Tools

- Crescent wrenches:
 - 3/4"
 - 9/16"
 - 13/16"
- Large long-nosed pliers
- Small long-nosed pliers
- Scissors
- Retractable utility knife
- Cutters
- Set of Allen millimeter wrenches
- Philips-head screwdrivers
 - 2x200mm
 - 2x100mm
 - 1x80mm
 - 0x60mm
 - Bulldog 1x25mm
- Flat-head screwdriver 70mm length 4x35mm
- Flat-head bulldog screwdriver 4x20mm
- Socket extension—5/8"

Calibration Test for the MTRE Temperature Calibration Unit

The calibration test for the MTRE Temperature Calibration Unit must be performed once in 24 months with a calibrated multi-meter. Use the pair of test lead cables that are supplied with the MTRE Temperature Calibration Unit.

Note: The multi-meter must be calibrated once in twelve months.

Thermostat Verification Tool

The Thermostat Verification tool tests the tolerance of the thermostat in the Thermoregulation device.

The tool has two sides, both with two-pin Molex connector. Each side is labeled on the main wire.



Figure 11-10: Thermostat Verification Tool (P/N

PCB Extraction Tool

The PCB Extraction tool is used to release PCB spacer supports.

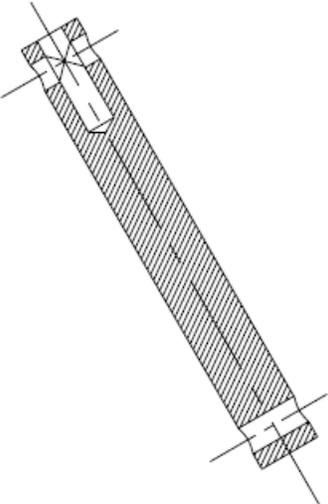


Figure 11-11: PCB Extraction Tool

CHAPTER 12: SPECIFICATIONS

The following specifications are included:

- Allon
- CritiCool
- CritiCool Pro

Thermal Regulation System - Specification

Servo controlled, Non Invasive, thermal regulation using water circulating ThermoWrap and CureWrap Garments covering up to 85% of body surface

Displays

- Mode of operation
- Set point temperature
- Core Temperature
- Surface Temperature
- Alarm displays
- Pump On/Off icon

Default mode

- Normothermia management

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 temperature accuracy

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

Water tank—Maximum Volume

- 6 liters (1.6 gal.)

Sensors

- 014-00020 Reusable core
- 014-00021 Reusable surface
- 014-00005 Reusable infant core
- 014-00028 Disposable adapter core
- 014-00129 Disposable adapter surface

Garment size

- Sizes range from 40 cm–196 cm (1'4"–6'5")

Garment Duration of use

- ThermoWrap – 28 hours
- CureWrap – 72 hours

Quick coupling connectors

- Prevent water leakage

Safety mechanism

- Prevents extremely high pressure and temperature

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

Electricity Input power

- 230/115 VAC with isolation transformer 50/60 Hz
- Medical multiple isolation transformer: 230/115 VAC

Maximum Current

- 230/115 VAC 6.3 amp

Operation Ambient Temperature

- 10°C–40°C (50°F–104°F)

Storage and Transport

- Maximum storage time without calibration is 26 weeks
- An ambient temperature range of -40°C to +70°C (-40°F to 158°F)
- A relative humidity range of 10% to 100% RH
- An atmospheric pressure range of 500 hPa to 1060 hPa.

Warranty

- One year

Protection against electric shock

- Type BF

Languages

- German
- English
- French
- Finish
- Italian
- Dutch
- Spanish
- Portuguese
- Swedish
- Norwegian

Auxiliary Systems

- CliniLogger

Regulatory

- CE 0473
- Allon 2001 FDA Clearance - K024128
- EN 60601-1
- EN 60601-1-2
- Type BF - Degree of protection against electrical shock

The **CritiCool**, one of **MTRE's** Temperature Regulating systems, induces, maintains, and reverses hypothermia in an effective and precise manner. The desired temperature is preset by the physician with a possible range of target temperature from Hypothermia to Normothermia. The system is composed of two elements, the **CritiCool** device, and the **CureWrap**. The **CritiCool** device functions as a control unit constantly monitoring the Patients' core temperature and as a cooling/heating pump which brings the circulating water to the required temperature by using its on-board body temperature control algorithm. The **CureWrap** is a flexible 3D single piece design, through which the water circulates. It is designed to be in close contact with a large area of the body, thus allowing optimization of energy transfer.

HARDWARE

Heat Exchangers

- Peltier Technology (TECs)

Water tank

- Tap water usage
- Tank Capacity: 6 liters (1.6 gal.)

Water Temperature

- Water Temperature Accuracy $\pm 0.3^{\circ}\text{C}$ (0.4°F)
- Water Temperature (outflow) $13\text{-}40.8^{\circ}\text{C}$ ($55\text{-}105.4^{\circ}\text{F}$)

Pump

- Water Circulating Pump
- Pump Rate: 1.2 L/min
- Protected by 263 micron filter

Patient Temperature Channels

- 2 Channels: Core, Surface
- YSI 400 Series Probes
- Body Temperature Range: 15°C to 44°C (59°F to 111.2°F)
- Body Temperature Accuracy $\pm 0.3^{\circ}\text{C}$ (0.4°F)

Temperature and Pressure Sensors

- System Sensors:
 - ◊ 3 Internal Temperature Sensors: Water in, Water out, Thermostat
 - ◊ 2 Pressure Detectors
- Safety measures:
 - ◊ Over pressure protection and alarm
 - ◊ High water temperature protection and alarm

Physical Dimensions

- Mobile Unit with 4 wheels and 2 brakes
- 260 mm W x 625 mm D x 940 mm H / (10.23"W x 24.6"D x 37"H)

Net Weight

- 34 kg / 75 lb

Electricity Input Power

- 230/115 VAC with isolation transformer 50/60 Hz

Maximum Current

- 230 VAC 2.5A-3A
- 115 VAC 4.8A-5A

Environmental Operating Conditions

- Temperature: $+5^{\circ}\text{C}$ to $+40^{\circ}\text{C}$ (41°F to 104°F)
- Humidity: 10 to 93 percent, non-condensing
- Ambient temperature range of -15°C to $+68^{\circ}\text{C}$ (-40°F to 158°F)

Environmental Storage Conditions

- Humidity: 10 to 93 percent, non-condensing
- Maximum storage time without calibration is 26 weeks

External Ports

- 1X Isolated Serial Port

LCD Display

- Size: 5.5"
- Resolution: 128x240

SOFTWARE

Displayed Information

- Mode of operation
- Set point temperature (Range: 30°C - 40°C)
- Core Temperature
- Surface temperature
- System status and alarms
- Technician mode display

Operating Modes

- Mild Hypothermia (Cooling):
 - ◊ Adult/Neonatal Mode
- Auto Re-Warming
- Normothermia
- Stand-By
- Emptying

Languages

- German
- English
- French
- Finnish
- Turkish
- Italian
- Dutch
- Spanish
- Portuguese
- Swedish
- Norwegian
- Danish

User Interface (GUI)

- 4 soft push buttons

ACCESSORIES

Temperature Sensors

- Reusable core (Adult, Infant)
- Reusable surface
- Disposable core (one size)
- Disposable adapter core
- Disposable surface (one size)
- Disposable adapter surface

CureWraps

- Sizes range from 40 cm–196 cm (1'4"–6'5")
- Duration of use: 72 hours
- Each garment contains a 33mg chlorine tablet

External Water Tubes

- Adult—Triple connector to garment
- Pediatric/Infant—Dual connector to garment

CliniLogger (Optional)

- Up to 240 hours of CritiCool data storage
- Connector: DB9 F Type
- CliniLogger Viewer software for PC

REGULATORY

- CE 0473
- Health Canada - 64184
- FDA Clearance - K083662
- EN 60601-1
- EN 60601-1-2
- Type BF - Degree of protection against electrical shock
- IP X0

CritiCool Pro Thermal Regulation System - Specification

Servo controlled, Non Invasive, thermal regulation using water circulating CureWraps covering up to 85% of body surface

CritiCool Pro is composed of two elements:

Thermal Regulation System – The CritiCool & the CureWraps
Patient monitor – The VitaLogik 4000/4500

Displays

- Mode of operation
- Set point temperature
- Core Temperature
- Surface Temperature
- Alarm displays
- Pump On/Off icon

Default mode

- Mild Hypothermia

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 temperature accuracy

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

Water tank—Maximum Volume

- 6 liters (1.6 gal.)

Sensors

- 014-00020 Reusable core
- 014-00021 Reusable surface
- 014-00005 Reusable infant core
- 014-00028 Disposable adapter core
- 014-00129 Disposable adapter surface

Garment size

- Sizes range from 40 cm–196 cm (1'4"–6'5")

Wrap Duration of use

- CureWrap – 72 hours

Quick coupling connectors

- Prevent water leakage

Safety mechanism

- Prevents extremely high pressure and temperature

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

Electricity Input power

- 230/115 VAC with isolation transformer 50/60 Hz
- Medical multiple isolation transformer: 230/115 VAC

Maximum Current

- 230/115 VAC 6.3 amp

Operation Ambient Temperature

- 10°C–40°C (50°F–104°F)

Storage and Transport

- Maximum storage time without calibration is 26 weeks
- An ambient temperature range of -40°C to +70°C (-40°F to 158°F)
- A relative humidity range of 10% to 100%
- An atmospheric pressure range of 500 hPa to 1060 hPa.

Warranty

- One year

Protection against electric shock

- Type BF

Languages

- German
- English
- French
- Finish
- Italian
- Dutch
- Spanish
- Portuguese
- Swedish
- Norwegian
- Danish

Auxiliary Systems

- CliniLogger

Regulatory

- CE 0473
- FDA Clearance – K102112
- EN 60601-1
- EN 60601-1-2
- Type BF - Degree of protection against electrical shock

Hardware and Parameters

VitaLogik 4000 / 4500 is a compact monitor with a built-in 12.1" display and battery back-up.

Available in two versions:

VitaLogik 4000: Non Invasive monitor

- 3/5/12 lead ECG
- Respiration
- NIBP
- SpO2 (Masimo®/ Nellcor®)
- 2 Temperatures

VitaLogik 4500: Invasive monitor

- 3/5/12 lead ECG
- Respiration
- NIBP
- SpO2 (Masimo® / Nellcor®)
- 2 Temperatures
- 2 x IBP (optional 4 IBP available)
- CO / 2 additional Temperatures

Both versions offer

- Microstream EtCO2 (optional)
- Anesthetic Gases supported via UIM Port
- 2 x Universal Input Module (UIM)
- Either 4 channels Analog output or Remote control
- Integrated 3 Channel Recorder (optional)
- External Video Output

Universal Input Module - "UIM"

- 2 x RS232 ports
- Interface to other vendor devices (A4800, EVITA, BISx, Vigilance, Matisse, Saturn Evo, IRMA, CritiCool)

CPU Details

- Via X86 Core Fusion CPU
- Sound Blaster 2W audio power / 4Ω
- Mass storage: 1 GB compact flash, optional 8 GB and 16 GB
- Operating System: QNX 4.25
- Window manager: Photon
- SW upgrades via network or memory card

Dimensions/Weight

HxWxD: 301x324x180 mm (11.9x12.8x7.1 inches)
 Weight: 5.9Kg. (13.00 lb) (for basic configuration with battery)

Power requirement

- 100-120 VAC, 2A, 50/60 Hz
- 230-240 VAC, 1A, 50 Hz

Battery

- Battery power (Basic) – Lithium Ion 14.8V / 5.2A
 Work on battery time: 3 hours, Charge time: 3 hours
- Battery power (extended) – Lithium Ion 14.8V / 10.4A
 Work on battery time: 6 hours, Charge time: 6 hours

Environmental Operating Conditions

- Temperature: +5°C to +40°C (41°F to 104°F)
- Humidity: 10 to 93 percent, non-condensing

Environmental Storage Conditions

- Temperature: -15°C to +68°C (5°F to 154°F)
- Humidity: 10 to 93 percent, non-condensing

Network

- LAN Physical: IEEE 802.3 Ethernet interface 10/100 BaseT
- Protocol: TCP/IP
- Serial Interface RS232 (optional)
- Connectivity to: Ensemble (CNS), Enguard, Enscribe (recorder) and network printer
- Wireless LAN (optional)
include:
 - ◊ Utilizes an industry-standard 802.11b/g IEEE compliant radio card
 - ◊ Dual-diversity dipole antenna
 - ◊ Signal strength indicator
 - ◊ WPA security and encryption

Display

- NEC 12.1" XGA (1024x768) LCD
- Interface to a Remote Display
- Very "Big Numbers" mode
 - ◊ One or Two Lead ECG WF, 34 mm height HR

- ◊ Three vital signs areas with 8 mm Waveform and 25 mm height numeric Vital Signs

User Controls

- 5 Fixed keys
- Quicknob
- Remote Control Keypad (optional)
- Touch Screen—ELO IT (optional)
- Keyboard and mouse

Patient Data storage

- Demographic info
- Charts - Numerical
- Trend - Graphic
- Full Disclosure All leads ECG waveform
- Overview - All Waveforms with top ECG
- Event Strips – 20 Seconds of all ECG and Vital signs waveforms (10 sec pre & post event)

Storage	Basic 1 GB	Optional 8 GB	Optional 16 GB
Tabular Chart	10 Days	80 Days	80 Days
Graphic Trends	10 Days	80 Days	80 Days
Full Disclosure	6 Hours	4 Days	30 Days
Overview	6 Hours	4 Days	30 Days
Event Strips	75	75	75
Saved Patients	3	10	10

Default Alarms

- User defined
- Fixed or calculated values
- Alarm levels:
 - ◊ Clinical levels: C1, C2, C3, C4
 - ◊ Technical levels: T1, T2.

Recorder (Optional)

- Integrated Recorder up to 3 channels

Analog Output (4 channel)

- ECG II – 1Volt/mV
- ECG V1 – 1Volt/mV
- QRS – 5 Volt
- ART – 1Volt/100 mmHg

Clinical Specifications

ECG (3 / 5 / 12 Lead)

- Leads: ECG cables for 3/5/10-lead surface ECG with defibrillation
- protection in the cable.
- Input Dynamic Range: ±5 mV peak to peak
- Input DC Offset: ±530 mV
- Baseline Correction: Automatic recovery of waveform within 100 msec
- Notch Filtering: Custom: 50Hz or 60Hz
- Frequency Response:
 - ◊ Diagnostic 0.05 to 150Hz
 - ◊ Monitoring 0.5 to 40Hz
 - ◊ ST 0.05 to 40Hz
 - ◊ Exercise 1 to 25Hz
- Sensitivity: 0.25, 0.5, 1.0, 2.0, 4.0, 8.0 mV/cm
- Common Mode Rejection: 120 dB minimum
- Noise: 30 μV
- Input Impedance: 2.5 megaΩ
- Defibrillator Pulse Protection: Yes
- Baseline Recovery: < 8 sec
- Lead Fault Sense: Based on impedance with driven lead
- Digital Sample Rate: 640Hz
- Sample Resolution: 24 bit
- Pacemaker Detection and Rejection of Pacer Artifact.
- Pacer Detection Flag inserted into ECG waveform.
- 3 Detection Modes:
 1. Fixed Threshold 2mV
 2. Adaptive 1 Threshold ½mV High Sensitivity
 3. Adaptive 2 Threshold > 2mV High Immunity
- Auto Cable Detection
- Audio Indicator: QRS Beep
- QRS Detection Range

- Height: 0.25 to 5.0 millivolt or 0.15mV, Width: 70 to 120 milliseconds
- Heart Rate Counting
- Range: 15 to 350 BPM
- 15-300 Accuracy: ± 2 BPM, 300-350 Accuracy ± 4 BPM
- **Note:** Values below 20- forced to zero
- Heart Rate Alarm Settings
- High and low rate: 20 - 350 BPM non-overlapping
- Leads analyzed for Heart Rate and Arrhythmia Configuration:
- Top two displayed
- ECG Leads:
 - ◊ I, II, III (3 Lead cable)
 - ◊ I, II, III, aVR, aVL, aVF, V (5 Lead cable)
 - ◊ I, II, III, aVR, aVL, aVF, V1-V6 (12 Lead module)
- Data Storage: Beat notification, RR Interval, Heart Rate, ST values, Arrhythmia, Alarms, Parameter settings, Cycle time and measurement time, Markers, Alarm event markers

Respiration

- Leads: RA-LA or Leads: RA-LL
- Excitation: 65 kHz, < 1 mA
- Frequency Response: 0.13 to 2.5Hz
- Impedance Range: 100 to 3000 Ω
- Input Sensitivity Range: 0.2 to 5 Ω
- Digital Sample Rate: 640 Hz
- Sample Resolution: 24 bit
- Respiration Rate Counting Range: 0 to 150 breaths/min (Less than 8 BPM is considered apnea)
- Respiration rate: Accuracy +/- 1 per minute
- Respiration Alarm Settings
 - ◊ Low rate: 0 - 150 BPM
 - ◊ High rate: 0 - 150 BPM
 - ◊ Apnea: User configurable
 - ◊ Cardiac coincidence alarm
- Data Storage:
 - ◊ Respiration rate
 - ◊ Respiration rate Alarms
 - ◊ Apnea alarms
 - ◊ Alarm event markers

Invasive Blood Pressure

- Site Labels: BPx, ART, PAP, CVP, RAP, LAP, ICP
- Input Sensitivity: 5 μ Volt/Volt/mmHg
- Dynamic Range
 - ◊ Pressure range: -50 to +350 mmHg
 - ◊ Zero range: ± 150 mmHg
 - ◊ Total dynamic range: -200 to +450 mmHg
- Transducer Excitation Voltage: +5 VDC
Separate excitation driver for each channel
- Zero Accuracy: ± 0.2 mmHg
- Zero Drift
Less than ± 0.2 mmHg in 24 hours, (at constant temperature)
- Blood Pressure Accuracy
 ± 2 mmHg or $\pm 2\%$, whichever is greater, exclusive of transducer
- Blood Pressure Linearity: within 1% across entire range
- Waveform Frequency Response: 0 - 40 Hz
- Sampling Rate: 640 Hz
- Sample Resolution: 24 bit
- Fault Detection; Transducer in/out, Cable out
- Data Storage: Systolic, Diastolic and Mean; Alarms

Pulse Oximetry (SpO2)

- Nellcor® Oximax or Masimo® SET Technology
- Plethysmograph waveform
- Saturation Range: 1% to 100% SpO2
- Extreme Alarm Capability
- SpO2 Accuracy: SpO2 % $\pm 1\%$ standard deviation
- Pulse Rate Range: 20 to 250 BPM ± 3 BPM
- Saturation alarm limits: 0% to 100%
- Data Storage: Heart rate and O2 saturation, Alarms

Integrated Thermo Dilution Cardiac Output

- Adapter and Compatibility Cables:
 - ◊ CO Set interface cable
 - ◊ Ice Bath YSI-400 cardiac output interface cable
 - ◊ Dual temperature interface cable (YSI-400)
- Temperature Range
 - ◊ Blood temperature: 27°C to 45°C (81°F to 113°F)
 - ◊ Injectate temperature: 0°C to 25°C (32°F to 77°F)
 - ◊ Body temperature: 0°C to 45°C (32°F to 113°F)
- Accuracy $\pm 0.1^\circ\text{C}$ over the entire range
- Digital Sample Rate: 160 Hz
- Sample Resolution: 24 bit
- Frequency Response: 0 to 15 Hz
- Cardiac Output Determination Range: 0 to 20 liters per minute
- Injectate Volumes: 1, 3, 5, and 10cc
- Displayed Data: Cardiac Output, Cardiac Index, Stroke Volume, Stroke Volume Index, Blood Temperature, Injectate Temperature, Trial Number
- Data Storage:

In Cardiac Output mode:

- ◊ Cardiac Output
- ◊ Hemodynamic Calculation results
- ◊ Measuring time

In Two Temp mode:

- ◊ Temperatures and Delta-Temp
- ◊ Temperature Alarms

Non-Invasive Blood Pressure

- Oscillometric Method
- Displayed Parameters: Systolic, Diastolic, Mean pressure values
- Time of last measurement, measurement interval, cuff size and heart rate
- Cuff Size: Adult, Pediatric, Infant, Neonatal
- Inflation Rate: Within 5 sec.
- Initial inflation target: 150 mmHg, Adult/Pediatric
- Initial inflation target: 100 mmHg, Neonatal
- Over pressure limit : 290 mmHg, Adult/Pediatric
- Over pressure limit : 145 mmHg, Neonatal
- Cycle Times
- Deflation time (typical): 30 sec.; BP time-out: 60 - 180 sec.
- Measurement Ranges, Adult (in mmHg)
 - Systolic: 30 to 255; Diastolic: 15 to 220; Mean: 20 to 235
- Measurement Ranges, Neonatal (in mmHg)
 - Systolic: 30 to 135; Diastolic: 15 to 110; Mean: 20-125
- Modes: Auto, Manual, STAT
- Automatic intervals 1,2,3,4,5,10,15,20,30,60,120,180,240,360, 480 minutes
- Pressure: Transducer Accuracy ± 3 mmHg or $\pm 2\%$, whichever is greater
- Heart Rate: 30 to 240 BPM, Adult/Pediatric; 40 to 240 BPM Neonatal
- Data Storage: Measurement time markers, S/D/M, Alarm even markers

Temperature

- YSI400
- Body temperature: 0°C to 45°C (32°F to 113°F) +/- 0.1 °C
- Temperature Alarm Range: 25°C to 45°C (77°F to 113°F)
- Range + / - 45 °C

Delta Temperature

- Delta temp Accuracy: +/- 0.1 °C

End Tidal CO2 Microstream (EtCO2)

- Flow rate: 50 ml/min (accuracy: -7.5ml/min + 15ml/min)
- Displayed Data:
 - ◊ Waveform labels and annotations
 - ◊ EtCO2, in CO2 and respiration rate values
- CO2 Display Range: 0-99 mmHg
- Measurement Resolution: Typical Accuracy
 - ◊ ± 2 mmHg for CO2 range of 0-38 mmHg
 - ◊ $\pm 5\%$ for CO2 range of 39-99 mmHg
 - ◊ +0.08% for every 1 mmHg above 38 mmHg
- Respiration Rate:
 - ◊ 0 to 70 bpm: ± 1 bpm,
 - ◊ 71 to 120 bpm: ± 2 bpm,
 - ◊ 121 to 150 bpm: ± 3 bpm
- Rise Time: 190 msec (10% - 90%)
- Delay Time: 2.7 Sec (10% - 90%) typical
- Start-up Time: 30 sec typical
- Automatic Compensation: At least once per hour
- Ambient Temperature: 0-65°C,
Humidity: 10-95% RH, non-condensing
- Barometric Pressure: 430-795 mmHg (-1250 to 15,000 ft. ; -380 to 5200 meter)
- Calibration required: Initially—after 1200 operating hours and then once a year or 4000 operating hours
- CO2 Alarm Limits: 0 to 100 mmHg; 0 to 10%; 0 to 15 kPa
- Respiration Rate Alarm Limits: Neonatal - 0 to 150 BMP; Adult - 0 to 50 BMP
- Data Storage: EtCO2, inCO2 and Respiration Rate values, Alarms, Apnea Alarm
- Exhaust Gas Outlet

Languages

- English, Dutch, French, Italian, Spanish, Espanol, Portuguese, Turkish, Russian, Polish.

Regulatory Approvals

- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- Degree of protection against electrical shock
 - ◊ ECG / RSP, IBP, CO and TEMP = Type CF
 - ◊ NIBP, SpO2 and EtCO2 = Type BF
- CE Mark 0473
- FDA Clearance - K073140

APPENDIX A: TECHNICIAN MODE

Technician Mode

Verification and calibration tests are done while the Thermoregulation device is in Technician mode. This mode displays the readings of the verification and calibration tests, as well as additional information as to the status of the Thermoregulation device and error codes that are necessary in the analysis and correction of failure.

Following is a detailed description of these functions.

Technician Mode Screen



Figure A-1: Technician Mode Screen

Technician Mode Screen—Details

1. Software Version Number

2. Date and Time (dd/mm/yy hh/mm/ss)

3. Functions

The following functions are listed in the Technician Mode screen:

- Core sensor (**Core**)
- Surface sensor (**Surf**)
- Water-in sensor (**Win**)
- Water-out sensor (**Wout**)
- Pressure (**Pres1**)
- Internal pressure (**Pres2**)

The "Physical" and "ADC" columns next to each function list the readings when performing the verification and calibration (see Chapter 9 "Periodic Maintenance").

The following values (-1) and (-2) are displayed in the "Physical" column for Core and Surface and they denote that the sensor is not connected/ that the wrong sensor has been inserted into the socket:

Table A-1: "Physical" Values

	Core Sensor	Surface Sensor
-1	Denotes that the sensor is not connected	Denotes that the sensor is not connected
-2	Denotes that the wrong sensor has been inserted into the socket	Denoted that the sensor is connected incorrectly in its socket

4. Error

For a detailed error list and explanation, see Chapter 8 "Software".

5. Time—value listed is in tenths of a minute

6. CRC

Software confirmation number indicating successful download

7. BAT: Good

Indication of RAM battery condition

8. SetPoint

Indicates the set-point temperature

9. DesireTmp

Indicates the desired water-out temperature

10. TECs

The number on the left side indicates how many TECs are working at the present time. For example:

0/4—no TECs are working

1/4—one pair of TECs is working, one TEC on each side of the Thermoregulation device

11. Heat/Cool

Denotes if the TECs are heating or cooling the water

12. Pump

Denotes if the pump is operating

13. ThermoWrap

ON—Thermoregulation device pumps water to the Garment

OFF—The Thermoregulation device is on by-pass

14. Use right button to toggle TECs, TECs are: ON /OFF

This function is used to switch OFF the heating/cooling elements when checking water temperature sensors.

Entering Technician Mode

Verification procedures listed Chapter 9 are performed while the Thermoregulation device is in Technician Mode.

➤ **To enter the Technician Mode:**

1. Turn the Thermoregulation device OFF for more than 10 seconds and then ON again for more than 10 seconds and then verify that self test is executed.
2. After a few seconds, simultaneously press the Alarm Mute and Arrow Up keys. This adds the Technician Mode to the menu.
3. Wait for Self Test to complete or skip to **OPERATION** by pressing the **MODE** key.
4. Press the **MODE** key to display the **MENU**.
5. Scroll down to **TECHNICIAN** and press the **ENTER** key to enter.



Figure A-2: Technician Mode Available

APPENDIX B: SPARE PARTS LIST

Disclaimer

Due to continuing product innovation, specifications in this List, as well as Typos are subject to change without notice.

Company shall not be liable for delays or for failure to manufacture and/or deliver due to causes beyond its reasonable control or due to compliance with any government regulations.

Spare Parts Prices are provided by MTRE Service Department. Always use the Service Call Form, for reporting on failures, assistance request and Price Requests.

Upon Receiving a Board for Exchange (EX), You should send back the Faulty one Freight Prepaid, to the Factory within 30 Days.

CritiCool™ – Cooling Control Unit



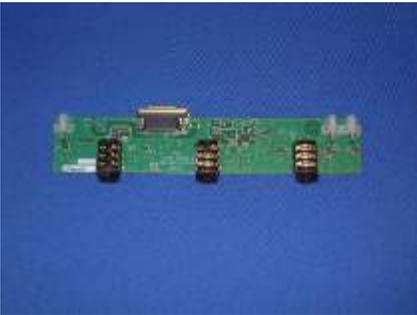
Figure B-1: CritiCool Control Unit

- Non-Invasive approach to Cooling Therapy
- Precise Temperature Control
- Maximal Energy Transfer
- Early Treatment Initiation
- Minimal Staff Labor
- Pressure relief algorithm
- Optimal Patient Surface Coverage
- Unique Heat removal Approach
- Body-Shaped 3-Dimensional CureWrap™ Garment for Intuitive use
- Latex Free CureWrap™ with Simultaneous Water Flow through Numerous Channels, Provides Superior Heat Exchange Capacity
- Biocompatible, Latex-Free and Anti-Static CureWrap™ Suits any Hospital Setting
- Includes: Control Unit, CureWrap Connecting tubes, ThermoWrap Connecting Tubes, Spare Water Filter, Core & Surface Temperature Sensors, Drain Water Tank Connector, User Manual

CritiCool™ – Spare Parts List

Note: When Ordering Boards For Exchange (EX), Fill Up a Service Call Form and return to the Factory the Faulty Board within 30 Days.

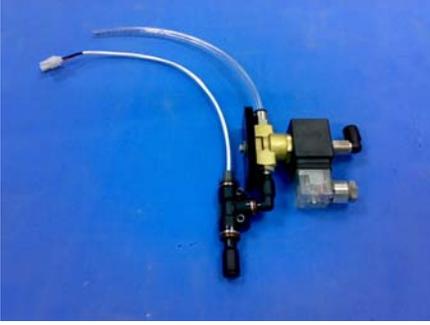
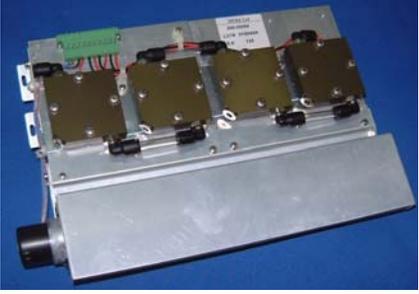
Part Number	Description
300-00118	Controller board 
300-00118EX	Exchange of Controller board
300-00117	TEC control board
300-00117EX	Exchange of TEC control board

Part Number	Description
<p>300-00016</p>	<p>Human sensor board</p>  <p>A green printed circuit board (PCB) with several electronic components, including three large black cylindrical capacitors and various integrated circuits, mounted on it.</p>
<p>300-00098</p>	<p>Controller board—TEC control board harnessx2</p>  <p>A white flat ribbon cable with a black connector at one end and a blue connector at the other.</p>
<p>300-00102</p>	<p>Transformer—TEC control board harnessx2</p>  <p>A multi-colored braided cable with a white connector at one end and a yellow connector at the other.</p>
<p>300-00100</p>	<p>Controller board—human sensor board harness</p>  <p>A black braided cable with two silver metal connectors at each end.</p>

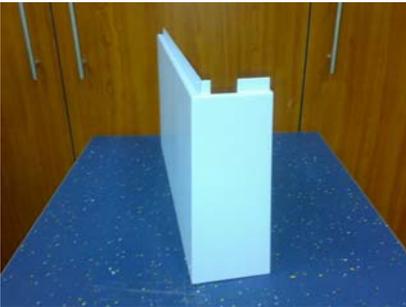
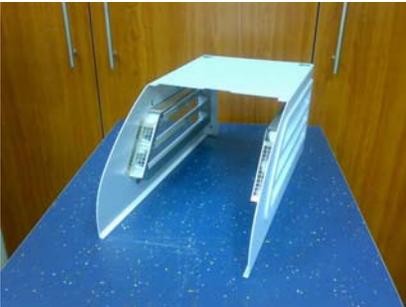
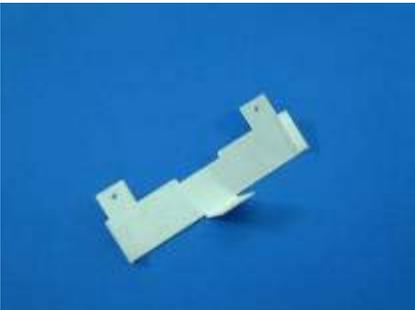
Part Number	Description
300-00099	Controller board—flow & pressure board harness 
300-00101	Controller board—RS-232 connector harness 
300-00050	Main harness right side 
300-00051	Main harness left side 

Part Number	Description
<p>300-00091</p>	<p>Level sensor harness</p>  <p>A photograph of a level sensor harness. It consists of a white plastic cable with a black braided section. The cable has two white connectors at the ends. The background is blue.</p>
<p>300-00080</p>	<p>Controller board—pump harness</p>  <p>A photograph of a controller board—pump harness. It is a white plastic cable with a black braided section. The cable has two white connectors at the ends. The background is blue.</p>
<p>200-00140</p>	<p>Top panel assembly (display & cover)</p>  <p>A photograph of a top panel assembly. It is a blue plastic component with a central display screen. The screen shows the text 'CribCool' and some icons. Below the screen are three circular buttons. The background is a light green surface.</p>

Part Number	Description
200-00130	Water filter assembly  A blue and white cylindrical water filter assembly with two metal tubes extending from the ends.
200-00115	Pump assembly  A small, cylindrical pump assembly with a red and black electrical cord attached to the side.
200-00132	Single thermistor unit assy (water in)  A single thermistor unit assembly consisting of a thin black wire with a small white sensor tip at one end and a connector at the other.
200-00131	Double thermistor unit assy(w.out +thermostat)  A double thermistor unit assembly consisting of a thin white wire with two sensor tips at one end and a connector at the other.

Part Number	Description
<p>300-00015</p>	<p>Flow & pressure board</p> 
<p>200-00078</p>	<p>Solenoid valve assembly</p> 
<p>200-00054</p>	<p>Heating & cooling unit assembly (HCU)</p> 
<p>006-00002</p>	<p>Line filter</p> 

Part Number	Description
<p>200-00059</p>	<p>Transformer assembly</p>  <p>A photograph of a transformer assembly. It consists of a metal core with windings, mounted on a metal base. Several colored wires (red, green, yellow, blue) are connected to the assembly. The transformer is set against a blue background.</p>
<p>200-00104</p>	<p>Water tank assembly</p>  <p>A photograph of a water tank assembly. It is a white, cylindrical tank with a handle on top and a spout on the side. The tank is mounted on a metal base. The background is blue.</p>
<p>200-00143</p>	<p>Right side cover</p>  <p>A photograph of a right side cover. It is a white, rectangular plastic cover with a handle on top. It is shown standing upright on a light-colored surface. The background is a wooden wall.</p>

Part Number	Description
<p>200-00144</p>	<p>LEFT SIDE COVER</p> 
<p>200-00145</p>	<p>TOP COVER</p> 
<p>007-00352</p>	<p>FRONT LOWER COVER</p> 
<p>200-00146</p>	<p>REAR COVER</p> 

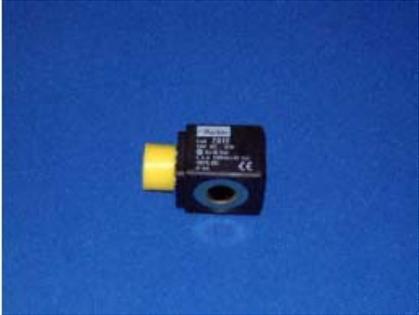
Part Number	Description
007-00365	HANDLE 
007-00334	Filter bracket 
007-00049	Trolley front wheel with lock 
007-00047	Trolley rear wheel 

Part Number	Description
<p>200-00141</p>	<p>TROLLEY ASSEMBLY</p> 
<p>200-00097</p>	<p>Water out\ in female connector</p> 
<p>200-00121</p>	<p>Service set of screws</p> 
<p>200-00119</p>	<p>Service tubing kit</p> 

Part Number	Description
200-00109	Connecting water tubes 2 by 2-way (metal connectors) 
002-00124	Female connector for connecting water tubes 
200-00147	Connecting water tubes 2 by 3-way (metal connectors) 

Part Number	Description
<p>020-00013</p>	<p>Drain Tube</p> 
<p>200-00069</p>	<p>Buffer Tube</p> <p>Image not available</p>
<p>002-00069</p>	<p>Draining Qcc</p> 
<p>002-00019</p>	<p>Qc T – 8X6X8</p> 

Part Number	Description
014-00021	Surface sensor 
014-00020	Core sensor 
014-00029	Surface sensor adaptor cable 
014-00028	Core sensor adaptor cable 

Part Number	Description
014-00005	Pediatric core sensor 
005-00483	Fuse 7A pack of 10 Image not available
014-00016	Power cord Image not available
015-00062	Reusable packaging for Allon 2001 Image not available
003-00011	SOLENOID VALVE COIL 
200-00122	SOLENOID VALVE ASSEMBLY 

<i>Part Number</i>	<i>Description</i>
<i>003-00012</i>	SOLENOID PLUG 
<i>017-00210</i>	Calibration Verification Tool Set
	Image not available
<i>017-00240</i>	Calibrating the Tool Set at the Factory (Labor Only)
	Image not available
<i>017-00290</i>	Digital Pressure Measuring Device
	Image not available

Allon 2001™ – Warming Control Unit, Version-05

- Maintains Normothermia of 36.5°C – 37.5°C
- Controls Induced Hypothermia and Provides Precise Rewarming
- Physician Presets Targeted Patient Temperature
- Real Time Dynamic Feedback Loop
- Proprietary Temperature Management Algorithms
- Supports a Wide Range of Preoperative Procedures
- Single Piece Design of ThermoWrap™ with Three Dimensional Coverage
- Maximum Available Patient Surface Coverage
- Pressure relief algorithm
- Latex Free ThermoWrap™
- Includes: Control Unit, ThermoWrap Connecting Tubes, Spare Water Filter, Core & Surface Temperature Sensors, Drain Water Tank Connector, User Manual

Allon 2001™ – Spare Parts List For, Version-05

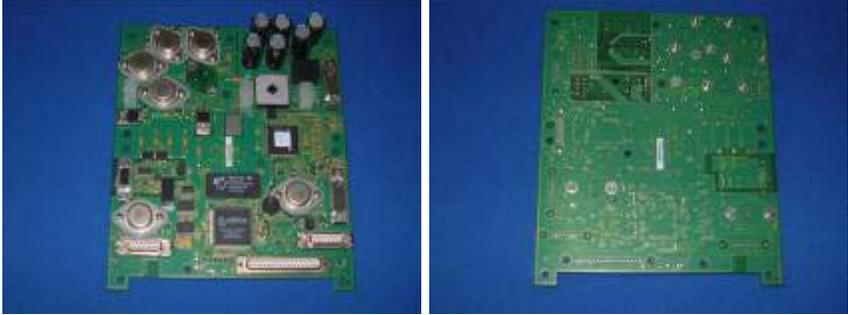
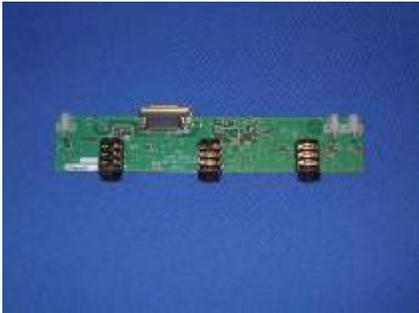
Note: When Ordering Boards for Exchange (EX), fill fp a Service Call Form and return to the Factory the Faulty Board within 30 Days.

Upgrade Package for Allon 2001™ Warming Control Unit

Upgrade Kit for Allon Version 04 Units to Allon Version 05

Table B-1: Upgrade Kit for Allon Version 04 Units to Allon Version 05

Part Number	Description
200-00002	Upgrade V4 to Allon 2001 Ver. 05, Warming Control Unit (230V)
200-00001	Upgrade V4 to Allon 2001 Ver. 05, Warming Control Unit (115V)

<i>Part Number</i>	<i>Description</i>
<i>300-00114/118</i>	Controller board
	
<i>300-00114EX</i>	Exchange of Controller board (Image not available)
<i>300-00117</i>	TEC control board
	
<i>300-00117EX</i>	Exchange of TEC control board (Image not available)
<i>300-00016</i>	Human sensor board
	
<i>300-00016EX</i>	Exchange of Human sensor board
<i>300-00015</i>	Flow & pressure board
<i>300-00015EX</i>	Exchange of Flow & pressure board

<i>Part Number</i>	<i>Description</i>
<p><i>300-00098</i></p>	<p>Controller board—TEC control board harnessx2</p> 
<p><i>300-00102</i></p>	<p>Transformer—TEC control board harnessx2</p> 
<p><i>300-00100</i></p>	<p>Controller board—human sensor board harness</p> 
<p><i>300-00099</i></p>	<p>Controller board—flow & pressure board harness</p> 

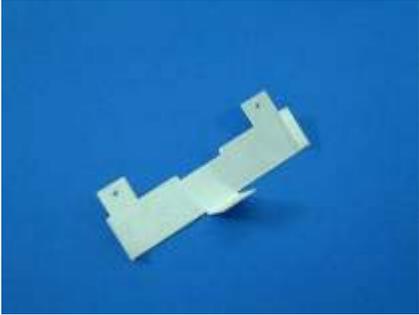
<i>Part Number</i>	<i>Description</i>
<i>300-00101</i>	Controller board—RS-232 connector harness 
<i>300-00050</i>	Main harness right side 
<i>300-00051</i>	Main harness left side 

Part Number	Description
<p>300-00091</p>	<p>Level sensor harness</p>  <p>A photograph of a level sensor harness, which is a white cable with a black section and several colored wires (red, blue, green, yellow) at the end, set against a blue background.</p>
<p>300-00080</p>	<p>Controller board—pump harness</p>  <p>A photograph of a controller board—pump harness, which is a white cable with a black section and several colored wires (red, blue, green, yellow) at the end, set against a blue background.</p>
<p>200-00062</p>	<p>Top panel assembly (display & cover)</p>  <p>A photograph of a top panel assembly, which is a light blue plastic component with a small display screen and several buttons, set against a blue background.</p>

Part Number	Description
<p>200-00130</p>	<p>Water filter assembly</p>  <p>A blue and white cylindrical water filter assembly with two metal tubes extending from the ends.</p>
<p>200-00115</p>	<p>Pump assembly</p>  <p>A cylindrical pump assembly with a white motor housing, a black base, and a red and black electrical cable.</p>
<p>200-00132</p>	<p>Single thermistor unit assy (water in)</p>  <p>A thin black cable with a white connector at one end and a metal probe at the other.</p>
<p>200-00131</p>	<p>Double thermistor unit assy(w.out +thermostat)</p>  <p>A white cable with two white connectors at one end and a metal probe at the other.</p>

<i>Part Number</i>	<i>Description</i>
<p>300-00015</p>	<p>Flow & pressure board</p> 
<p>200-00078</p>	<p>Solenoid valve assembly</p> 
<p>200-00054</p>	<p>Heating & cooling unit assembly (HCU)</p> 
<p>006-00002</p>	<p>Line filter</p> 

<i>Part Number</i>	<i>Description</i>
<p>200-00059</p>	<p>Transformer assembly</p>  <p>A photograph of a transformer assembly. It consists of a metal core with windings, mounted on a base. There are several colored wires (red, green, yellow, blue) connected to the assembly. The entire unit is set against a blue background.</p>
<p>200-00104</p>	<p>Water tank assembly</p>  <p>A photograph of a water tank assembly. It is a white, cylindrical tank with a handle on top and a small valve at the bottom. The tank is mounted on a metal base. The entire unit is set against a blue background.</p>
<p>200-00112</p>	<p>Right side cover</p>  <p>A photograph of a right side cover. It is a white, rectangular panel with a handle on the right side. The cover is set against a blue background.</p>

Part Number	Description
<p>200-00113</p>	<p>Left side cover</p> 
<p>200-00133</p>	<p>Top cover</p> 
<p>007-00243</p>	<p>Front lower cover</p> 

<i>Part Number</i>	<i>Description</i>
<i>200-00135</i>	Rear cover  A rectangular, light-colored plastic rear cover with two small gold-colored fasteners at the top edge.
<i>007-00333</i>	Handle  A white, U-shaped handle with two metal shafts extending from the ends.
<i>007-00334</i>	Filter bracket  A small, white plastic filter bracket with a circular opening and a small protrusion.

Part Number	Description
<p>007-00049</p>	<p>Trolley front wheel with lock</p> 
<p>007-00047</p>	<p>Trolley rear wheel</p> 
<p>200-00067</p>	<p>Trolley assembly</p> 
<p>200-00097</p>	<p>Water out\ in female connector</p> 

<i>Part Number</i>	<i>Description</i>
<p>200-00121</p>	<p>Service set of screws</p> 
<p>200-00119</p>	<p>Service tubing kit</p> 
<p>200-00109</p>	<p>Connecting water tubes 2 by 2-way (metal connectors)</p> 

APPENDIX C: SERVICE FORM

For technical assistance / service request fill the following form and send to neomi@mmi.co.il.



Service Call, Technical Assistance Request Form

To : Technical Support Department neomi@mmi.co.il Date : *

A - Customer Details

From :	*	E-mail :	*
Firm Name :	*	Fax # :	*

B - Technical Problem Details

	Model	Unit Part #	Description	Serial #	Software
B1 <small>Top Assembly</small>		*	*	*	*

	Parameter	Sub Unit Part #	Description	Serial #	Q'ty
B2-1 <small>Sub Assembly 1</small>		*	*	*	
B2-2 <small>Sub Assembly 2</small>					
B2-3	Fault Description: full details *				

C - Customer Request:

C1	<input type="checkbox"/> Exchange *	RMA :		Price :		Delivery :	
C2	<input type="checkbox"/> Send For Repair *	RMA :		Price :		Delivery :	
C3	<input type="checkbox"/> Buy Item *			Price :		Delivery :	
C4	<input type="checkbox"/> Information *	Customer Order Number if Exchange or Repair : *					
C5	Replacement Part # if exch.	Description			Serial #	S.W.	
	Needed						
C6	For Mennen Internal use only: MRB: <input type="checkbox"/> YES <input type="checkbox"/> NO						

D - Shipment Instructions, Customer request, after repair or exchange: *

D 1	<input type="checkbox"/> Fedex Courier	
D 2	<input type="checkbox"/> Airfreight	
D 3	<input type="checkbox"/> Other	

APPENDIX D: PERIODIC MAINTENANCE for CritiCool / Pro and Allon - P/N 200-00136/063

Period maintenance description is divided into two parts according to the type of simulator used:

- For Stimlator: TP-400 FOGG
- For Stimulator MTRE Temperature Calibration Unit

For Stimlator: TP-400 FOGG

P/N : _____ Rev: _____

Contact: MTRE SERVICE

S/N : _____

E-mail: service@mmi.co.il

Hospital: _____

Tel: 972-89328510

Country: _____

FAX: 972-89323333

CRC #: _____

Tested By: _____

1. Water Filter Assembly Maintenance

	Replaced
Replace water filter	

* **Simulator:** TP-400 FOGG Temperature Calibration unit 017-00284

2. Core & Surface Temperature Test

Temp. [C]	Max	Min	Surface [C]	Core [C]	Accept/Failed
20	20.30	19.70			
25	25.30	24.70			
30	30.30	29.70			
35	35.30	34.70			
36	36.30	35.70			
38	38.30	37.70			
40	40.30	39.70			

3. Sensors Win & Wout Test

Max Temp.[C] A	W out [C] B	$\Delta=A-B$		Accept/Failed
		Measured	Accepted	
			± 1.0	

Temp. [C]	Max	Min	Surface [C]	Core [C]	Accept/Failed	Temp. [C]
38	39	37				
37	38	36				
36	37	35				
35	36	34				
34	35	33				
33	34	32				

4. Thermostat Test

Status	Result	Pass/Failed
GO	No Halt	
NOGO	Halt 3	

5. Pressure Test

Pressure [bar] (Press 1)	Range [bar]	Measured [bar]	Accept/Failed
0.5	0.4-0.6		
1.1	1.0-1.2		

6. Tech's Current Testing.

	Range (amp)	Measured(amp)	Accept/Failed
Left side of HCU			
Tech A	3.5 – 5.0		
Tech B	3.5 – 5.0		
Tech C	3.5 – 5.0		
Tech D	3.5 – 5.0		
Right side of HCU			
Tech A	3.5 – 5.0		
Tech B	3.5 – 5.0		
Tech C	3.5 – 5.0		
Tech D	3.5 – 5.0		

7. Fan's Test

	Accept/Failed
Left side HCU	
Visual test fan is working properly	
Right side HCU	
Visual test fan is working properly	

TEST SUMMARY: PASS FAIL

Remarks: _____

Signature _____ *Date* _____

For Stimulator MTRE Temperature Calibration Unit

P/N : _____ Rev: ____ Contact: MTRE SERVICE

S/N : _____ E-mail: service@mmi.co.il

Hospital: _____ Tel: 972-89328510

Country: _____ FAX: 972-89323333

CRC #: _____ Tested By: _____

1. Water Filter Assembly Maintenance

	Replaced
Replace water filter	

* **Simulator:** Temperature Calibration unit 017-00284

2. Core & Surface Temperature Test

Temp. [C]	Max	Min	Accept/Failed	Core [C]	Surface [C]
42.90	43.20	42.60			
37.50	37.80	37.20			
36.20	36.50	35.90			
33.30	33.60	33.00			
27.10	27.40	26.80			
22.90	23.20	22.60			
18.50	18.80	18.20			

3. Sensors Win & Wout Test

W out [C] B	Max Temp.[C] A	$\Delta=A-B$		Accept/Failed
		Accepted	Measured	
			±1.0	

Temp. [C]	Max	Min	Accept/ Failed	W out [C]	W in [C]
38.00	39	37			
37.00	38	36			
36.00	37	35			
35.00	36	34			
34.00	35	33			
33.00	34	32			

4. Thermostat Test

Status	Result	Pass/Failed
GO	No Halt	
NOGO	Halt 3	

5. Pressure Test

Pressure [bar] (Press 1)	Range [bar]	Measured [bar]	Accept/Failed
0.5	0.4-0.6		
1.1	1.0-1.2		

6. Tech Current Testing.

	Range (amp)	Measured(amp)	Accept/ Failed
Left side of HCU			
Tech A	3.5 – 5.0		
Tech B	3.5 – 5.0		
Tech C	3.5 – 5.0		
Tech D	3.5 – 5.0		
Right side of HCU			
Tech A	3.5 – 5.0		
Tech B	3.5 – 5.0		
Tech C	3.5 – 5.0		
Tech D	3.5 – 5.0		

7. Fan Test

	Accept/ Failed
Left side HCU	
Visual test fan is working properly	
Right side HCU	
Visual test fan is working properly	

TEST SUMMARY: PASS FAIL

Remarks: _____

Signature _____

Date _____

APPENDIX E: DOWNLOADING UPDATED CRITICOOL SOFTWARE

➤ *To download updated CritiCool software to your PC:*

1. Turn on the PC.
2. Double-click **My Computer**.
3. In drive C, create new folder, and name it **MTRE_PC_Download**.
4. Copy the **Pc_Download.exe** file from the CD or e-Mail to the **MTRE_PC_Download** folder.
5. Copy the **CLINIC_Ver_*_xyz.BIN** file (**CLINIC_Ver_5_4B4.BIN** in the current version) from the CD or e-Mail the to the **MTRE_PC_Download** folder.

➤ *To download and install the update on CritiCool:*

1. Turn on the PC.
2. Verify that the MTRE serial cable is connected between the PC and CritiCool.
3. Browse to the **MTRE_PC_Download** folder and double-click the **Pc_Download.exe** file to open the installation program.

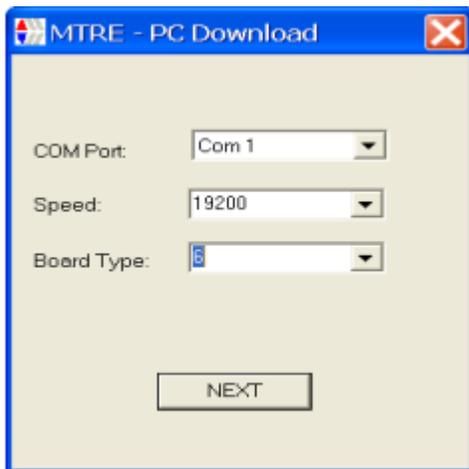


Figure E-1: MTRE - PC Download Window

4. From the **COM Port** drop-down list, select the number of the COM port you connected to the serial plug on your PC.

5. From the **Speed** drop-down list, select **19200**.
6. From the **Board Type** drop-down list, select the board type (Boards 300-00118 are type '6' the other are type '5').
7. Press **NEXT** to continue.

The **Select File** window is displayed.

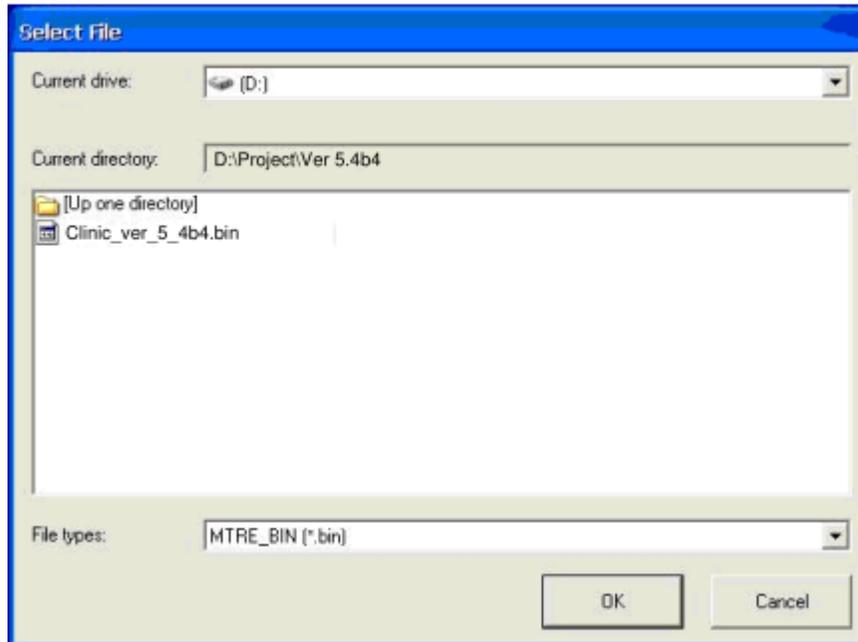


Figure E-2: Select File Window

8. From the **Current drive** drop-down list select the C: drive.
9. Double-click the **MTRE_PC_Download** folder.

Note: Make sure that the File types box displays the **MTRE_BIN(*.bin)** type.

10. Select **CLINIC_Ver_*_xyz.BIN** (for example: **CLINIC_Ver_5_4B4.BIN**) file and verify the file is highlighted.
11. Click **OK** and verify that

The **File Download** window is displayed.

12. Open the top cover of CritiCool and turn CritiCool on.
13. In the **File Download** window, click **Start** to start the download process.

During the download, a progress indicator appears on the **File Download** window and a **Program Burn** label appears, indicating the burn percentage.

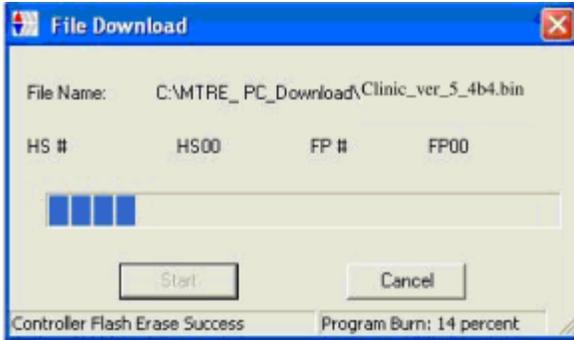


Figure E-3: File Download window

LEDs 4 and 5 on the Control Board of CritiCool flicker during the download process. At the end of the download process, both LEDs should cease to flicker and remain lit.

IMPORTANT! *Should one of them turn off, the download process is incomplete and you need to perform the download process again.*

At the end of the download process, the following message appears.



Figure E-4: Download Complete Message

14. Turn CritiCool OFF
15. Close the CritiCool cover and disconnect the MTRE serial cable from CritiCool.
16. Turn CritiCool ON.
17. Enter Technician Mode (see Appendix A - Technician Mode). Check that the new version is listed on the top of the screen and verify that the checksum (CRC) number is equal to the one in the **Download Complete** message.

```

SW. Ver 5.5 16 01 13 13 45 02 5887
Name      HWC Physical
=====
Core      1      -1
Surf     1      -1
Min      430    2074
Wout     433    2056
Pres1    59      6
Pres2    122    36
SetPoint  : 3300
DesireTmp : 1300
TECs     : 4/4
Heat/Cool : Cool
Pump     : ON
Thermolrap : ON

Error: 08001400
Time : 00000012
RF ON : 14/07/2011:27
CRC: 0x63b0
BHT: Good
OFF Max: 0604800

000006930
Use right button to
toggle TECs
TECs are:  ON  OFF

```

Figure E-5: Technician Mode Screen

If the checksum (CRC) in the **Download Complete** message (in Figure E-4:) is equal to the value displayed at Technician Mode, the software download was successful.

18. Click **Exit**.

IMPORTANT! If the checksum (CRC) does not match, turn the system OFF, and reperform Download.