



CritiCool Pro™

Thermoregulation System

USER MANUAL



DDT-136-007 Rev. A
January 2010



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

Manufacturer's Name:

Mennen Medical 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

Publication No. DDT-136-007 Rev. A

Revision: January 2010

Copyright 2010 by MTRE. All RIGHTS RESERVED
Registered trademarks are the intellectual property of their respective holders.

Important Notice

This document is delivered subject to the following conditions and restrictions:

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 Ltd..

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

Trademarks

CritiCool Pro is a trademark of MTRE Ltd.

Other company and brand, product and service names are for identification purposes only and may be trademarks or registered trademarks of their respective holders. Data is subject to change without notice.

Responsibility of Manufacturer

MTRE Ltd. considers itself responsible for the effects on safety, reliability, and performance of the equipment only if:

Repairs are carried out by authorized MTRE personnel only.

Electrical installation of the room in which the system is installed complies with all aspects of the relevant internationally-recognized electrical safety standards, as well as specific hospital requirements.

The equipment is used in accordance with instructions for use.

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

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

The information provided in this manual is not intended to replace regular medical training procedures.

This manual should always accompany the system. All qualified personnel operating the system should know the location of the manual. For additional copies of this manual, please contact your MTRE representative

TABLE OF CONTENTS

Chapter 1:

Safety Precautions 1-1

Definitions	1-1
Intended Use	1-1
Warnings	1-1
Precautions	1-2
Improper Use	1-3
Labels	1-4
CritiCool Pro Device Labels	1-4

Chapter 2:

System Description 2-1

General Description	2-1
CritiCool Pro System	2-1
CritiCool Pro Device	2-2
External Features 2-2	
Front View 2-2	
Side View 2-3	
Rear Panel	2-4
Garment	2-4
Accessories	2-7

Chapter 3:

Installation 3-1

Pre-installation Requirements	3-1
Space and Environmental Requirements	3-1
Electrical Requirements	3-1
Unpacking and Inspection	3-1
Assembling the Handle	3-1
Equipment List	3-2
Moving the Unit	3-3
Preparation:	3-3
Locking and Unlocking the Trolley Wheels	3-3
Storage Conditions and Transport	3-3
Storage	3-3

Chapter 4:	
Operating Instructions	4-1
General	4-1
Controls, Indicators and Connections	4-1
Main Power Switch	4-1
QCC—Quick Coupling Connector	4-1
Sensor Sockets	4-2
Preparing the System for Operation	4-2
Turning on the System	4-2
System Setup	4-2
Turning on the System	4-4
Self-Test	4-5
Cooling Therapy Control Panel	4-5
Selecting Modes	4-6
Set-Point Setting	4-7
Target Temperature Setting	4-9
Re-Warm Setup	4-10
Getting Started	4-11
Inserting and Attaching Human Sensors	4-11
Attaching Surface Sensor	4-11
Fastening Garment to Patient	4-12
Replacing the Garment	4-12
Cooling Mode	4-12
Warming Mode	4-13
Normothermia Management	4-14
Re-Warming Mode	4-14
STAND-BY Mode	4-16
Empty Mode	4-16
Turning Off the System	4-17
Chapter 5:	
Ordering Information	5-1
Equipment and Accessories - Ordering Information	5-1
Equipment and Accessories - Inventory	5-1
Available Garments	5-1
Chapter 6:	
Maintenance	6-1
Introduction	6-1
Service Information	6-1
Routine Maintenance	6-1
Sterilization of Reusable Sensors and Disposable Sensor Adapters	6-1
Cleaning and Disinfecting Procedures for Reusable Sensors	6-2
Cleaning	6-2
Disinfecting	6-2
Filter Replacement	6-2

Chapter 7:

Troubleshooting 7-1

General	7-1
Trouble-shooting Guide	7-1

Chapter 8:

Specifications 8-1

Physical	8-1
Control System	8-1
Auxiliary Systems	8-1
Warranty	8-2
Operation	8-2
Storage and Transport without Water	8-2
Electricity	8-2
Safety	8-2
Accessories	8-3

Chapter 9:

MTRE Customer Service Representative A-1

LIST OF FIGURES

Figure 1-1 Label Placement for the CritiCool Pro Device	1-4
Figure 2-1: Front View	2-2
Figure 2-2: Side View	2-3
Figure 2-3: Rear View	2-4
Figure 2-4: Measurements	2-6
Figure 3-1: Handle Assembly	3-2
Figure 4-1 CritiCool Setup in VitaLogik	4-3
Figure 4-2 Full Screen monitor display	4-4
Figure 4-3 : Thermoregulation Control Panel	4-5
Figure 4-4 CritiCool Pro Mode selection panel	4-7
Figure 4-5 Set-Point Setting Panel	4-8
Figure 4-6 Target Temperature Setting Panel	4-9
Figure 4-7 Re-warm Mode	4-10
Figure 4-8 Re-Warm Setup Panel	4-10
Figure 4-9 Alarm Message "Core too low"	4-13
Figure 6-1: Filter Orientation.....	6-3
Figure 6-2 Filter Assembly	6-3
Figure 7-1: ThermoWrap Connecting Tubes and Special Male Connector	7-3
Figure 7-2: CureWrap Connecting Tubes and Special Male Connector	7-4

LIST OF TABLES

Table 5-1 CureWrap Sizes	5-1
Table 5-2 Accessories Inventory	5-2
Table 6-1 Inspection and Maintenance Schedule	6-4
Table 7-1 CritiCool Pro System Undisplayed Malfunction Troubleshooting Guide	7-2
Table 7-2 CritiCool Pro System Undisplayed Malfunction Troubleshooting Guide (cont.)	7-3
Table 7-3 CritiCool Pro System Message Troubleshooting Guide	7-4
Table 7-4 CritiCool Pro System Message Troubleshooting Guide (cont.)	7-5
Table 7-5 CritiCool Pro System Message Troubleshooting Guide (cont.)	7-6
Table 7-6 CritiCool Pro System Message Troubleshooting Guide (cont.)	7-7

CHAPTER 1: SAFETY 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 CritiCool Pro system is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Warnings

- 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.
- The patient should be constantly attended by a physician.
- The misuse of the temperature regulation equipment can be potentially harmful to the patient.
- Do not plug wet PL plugs of the human sensors into the sensor sockets of the CritiCool Pro device.
- The user should verify that no fluids are present at the skin/Garment interface during the treatment. 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.
- In procedures 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 CritiCool Pro system does not prevent this occurrence.

- Before initiating maintenance procedures as described in Chapter 6, disconnect the power cord from the power source.
- The default setting is intended to induce hypothermia. The system provides the physician with the option of selecting a body temperature in the range of 30°C to 40°C (86°F-104°F).
- Do not lift or move the patient by means of the Garment. This may cause tearing and water leakage.
- Use reusable core sensors or disposable sensor adapters supplied by MTRE or YSI series 400 compatible sensors.
- 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 CritiCool Pro system is mandatory.
- The repair, calibration, and servicing of the CritiCool Pro system should be performed only by MTRE Advanced Technologies LTD or authorized agents trained by 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 CritiCool Pro system. All hospital personnel using the CritiCool Pro system must complete the CritiCool Pro training program.
- The repair and servicing of the CritiCool Pro 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 CritiCool Pro device, disconnect the power cable from its power source, and correct the problem before proceeding.
- The desired set-point temperature should be fixed only as prescribed by and under the order of a physician.
- If the device sounds an alarm and/or presents a display other than the standard MTRE display, the operator should proceed according to the display message

and/or the troubleshooting instructions
(see Chapter 7 Troubleshooting).

- Avoid folds in the Garment—these may obstruct water flow.
- Do not block the CritiCool Pro device ventilation grilles. Air must be able to flow freely in and out in order to keep the device cool.
- Do not use de-ionized or distilled water. Use tap water only.
- When X-ray imaging is performed on a patient wearing a Garment, shadows from the Garment may appear on the X-ray film.
- Avoid inserting any sharp object between the patient and the Garment.

Improper Use

Improper use of the CritiCool Pro system can lead to skin lesions, electrical hazards, and severe changes in body temperature.

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

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

Labels

CritiCool Pro Device Labels

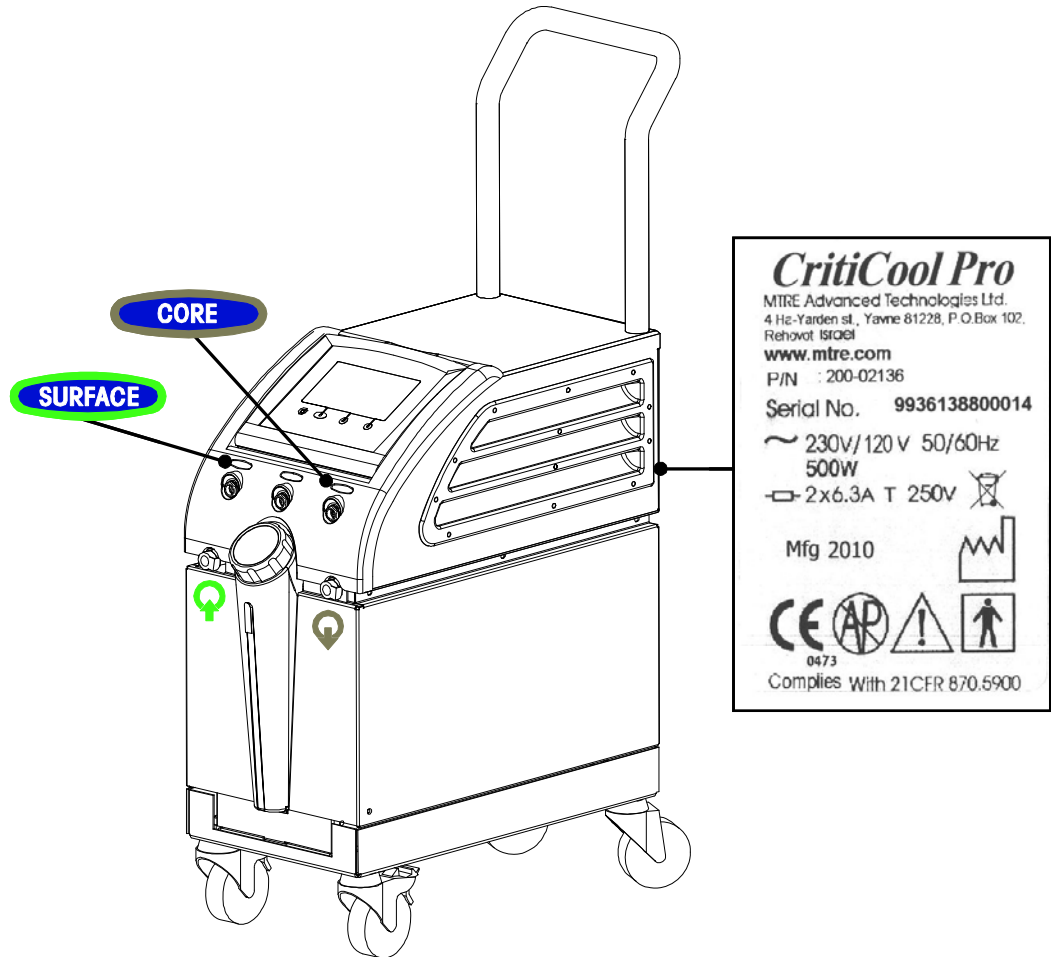













Figure 1-1 Label Placement for the CritiCool Pro Device

Table 1-1 Key to Label Symbols

	<p>Location of core sensor socket</p>
	<p>Location of surface sensor socket</p>
	<p>AC Voltage</p>
	<p>Fuse</p>
	<p>CE mark of conformity indicates that the product has received the European approval for MDD 93/42/EEC.</p>
	<p>Equipment not suitable in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.</p>
	<p>Refer to user manual</p>
	<p>Type BF equipment</p>
	<p>Recycle</p>

<p>Mfg 2007 </p>	<p>Date of manufacture</p>
<p> C US</p>	<p>CSA symbol indicates that the product has received the approval of the Canadian Standards Association.</p>
<p>xx - yyyy</p>	<p>Machine Version - Machine serial number</p>

CHAPTER 2: SYSTEM DESCRIPTION

General Description

A growing number of cases require a solution for controlling patient temperature in various hospital settings. Inducing hypothermia or simply controlling fever is beneficial and sometimes vital.

The CritiCool Pro™ systems combines the thermal regulation capabilities of its predecessor the CritiCool® with the well known VitaLogik patient monitoring.

It provides integrated data storage of the thermal regulation and the clinical condition of the patient under going treatment.

The patient monitoring waveforms and numeric vital sign can be viewed on Mennen Medical Central Nurse Station the Ensemble and the Enguard if the CritiCool Pro™ is connected to the MennenNet.

The CritiCool Pro 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 Hypothermia to Normothermia.

CritiCool Pro is member of MTRE's product family of body temperature control systems: Allon 2001, CritiCool and CritiCool Pro including ThermoWraps CureWraps and accessories.

The system is composed of two elements, the CritiCool Pro device, and the CureWrap garment. The CritiCool Pro 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 CureWrap.

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 contact area of the body, thus allowing optimization of energy transfer.

CritiCool Pro System

The CritiCool Pro system consists of the following elements:

- CritiCool Pro device

- Garment
- Accessories
- VitaLogik monitor

CritiCool Pro Device

The CritiCool Pro device has a microprocessor that controls the water temperature flowing into 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 CritiCool Pro device is equipped with a handle for easy transport.

External Features

Front View

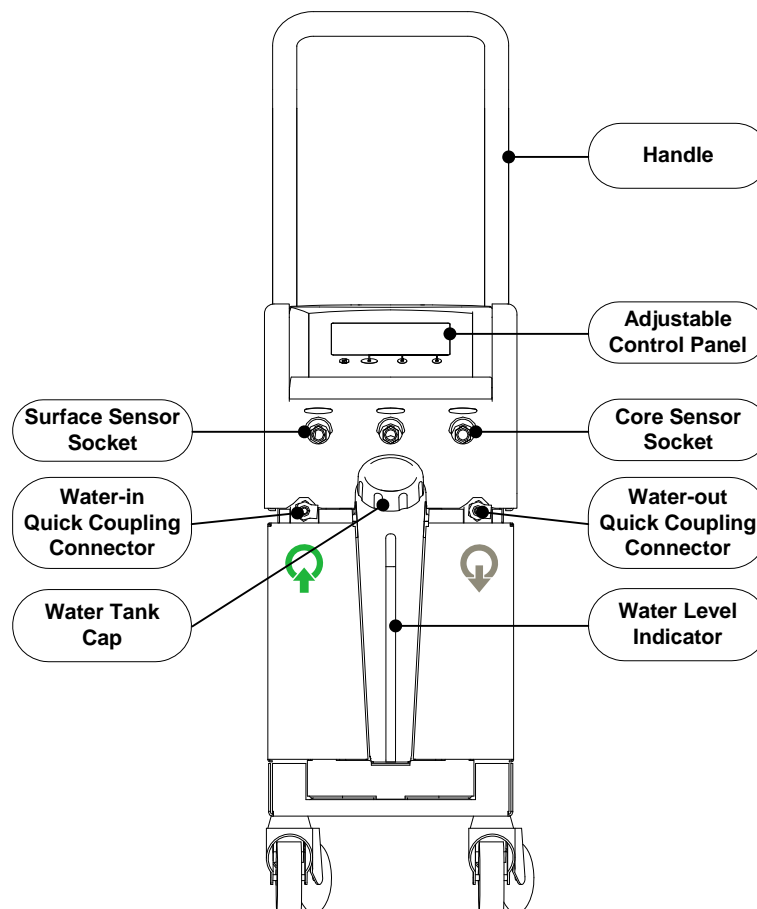


Figure 2-1: Front View

Side View

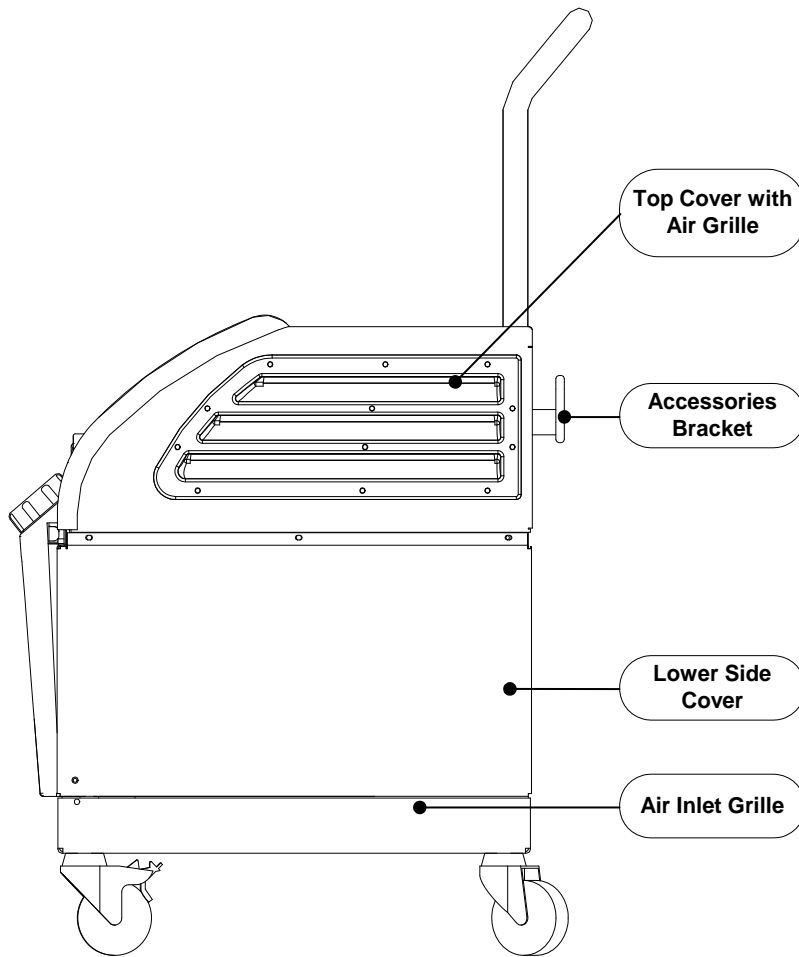


Figure 2-2: Side View

Rear Panel

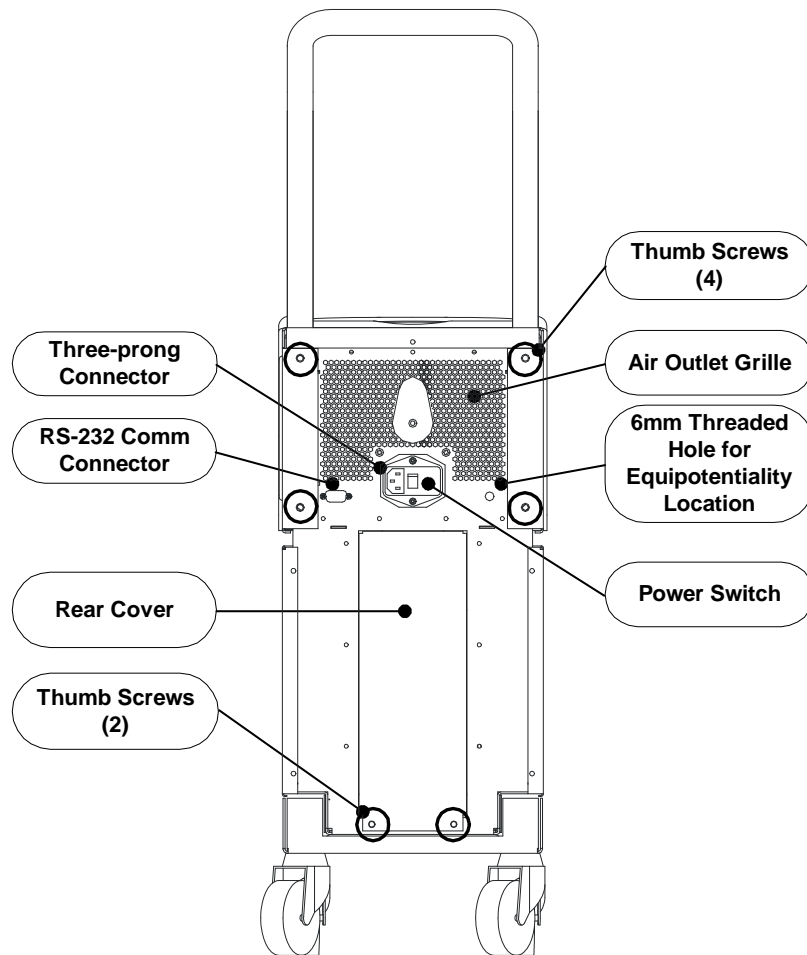


Figure 2-3: Rear View

Garment

General

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

Description and Intended Use

The Garment is:

- Disposable
- Biocompatible
- Latex free

- Antistatic
- Inflatable
- Adjustable

Each section of the Garment is separately wrapped around the appropriate area of the patient (e.g. chest, arms and thighs) to ensure maximum body surface coverage.

The water's exit and entrance points are short sections of tubing integrated with a Quick Coupling Connector (QCC) and welded to convenient locations on the edges of the Garment.

The Garment design allows the physician user to cover a maximum surface area as needed.

The Garment is secured to the patient via hook and loop strips or pressure sensitive adhesive strips.

Selected Garment Design

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

CureWrap

- **Material**
 - Patient side: Non-Woven PP (Avgol Ltd.)
 - Water Barrier Film - Appelon MPE Grade #S6606
 - Exterior side: Frontal Tape FT 600
- **Usage duration – 72 hours**
- **Fastening method – Velcro (unlimited repeated use)**

CAUTION! *Select the garment according to the patient's size*

XXX-XXXcm
 x'x"-x'xx"



Figure 2-4: Measurements

Table 2-1: CureWrap

Table of CureWrap Sizes					
Part No.	Height - Meter	Width - Meter	Garment Area, sq. m	Patient Height In Inches	Patient weight
Part No. 3500	2.030	1.354	2.324	All adults sizes	
Part No. 3548	1.582	1.193	1.399	48"-53"	
Part No. 3541	1.390	1.054	1.089	41"-48"	
Part No. 3536	1.225	0.841	0.763	36"-41"	
Part No. 3531	1.118	0.740	0.637	31"-36"	
Part No. 3525	0.981	0.628	0.425	25"-31"	7-11 kg
Part No. 3521	0.698	0.602	0.347	21"-25"	4-7 kg
Part No. 3518*	0.659	0.448	0.219	18" - 21"	< 4 Kg

* For use only out of USA.

Accessories

The following accessories are needed in order to operate the CritiCool Pro system the :

Human Temperature Sensors

a. Reusable Sensors

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

b. Disposable Sensors

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

Sensors and adapters are guaranteed for one year.

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

Reusable Core Sensor (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 CritiCool Pro 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 CritiCool Pro 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 CritiCool Pro 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 CritiCool Pro device. The other end is attached with adhesives to the patient's skin.

Disposable Surface Sensor Adapter (Part No. 014-00029):

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 CritiCool Pro device. The sensor is attached with adhesives to the patient's skin and measures surface body temperature.

Table 2-2: Sensor and Data Provider Input Specifications

Part 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

Detachable Electric Power Cable & Plug

See Table 5-2, “Accessories Inventory,” on page 5-2.

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

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

Connecting Tubes (Part No. 200-00109)

Two flexible 2.5m long connecting tubes connect the ThermoWrap with the CritiCool Pro 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 CritiCool Pro device end and with two female Quick Coupling Connectors at the ThermoWrap end.

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

Refer to Table 7-1, “CritiCool Pro System Undisplayed Malfunction Troubleshooting Guide,” on page 7-1.

Spare Water Filter (Part No. 200-00130)

For annual filter replacement - packed in the accessory box

Handle (Part No. 007-00365)

Interface cable between CritiCool Pro and the VitaLogik monitor (Part number 641-345-090).

CHAPTER 3: INSTALLATION

Pre-installation Requirements

Space and Environmental Requirements

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

The following dimensions should be considered when placing the CritiCool Pro device:

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

Electrical Requirements

230/115VAC 500W

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

Unpacking and Inspection

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

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

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

Assembling the Handle

- *To assemble the handle:*
 1. Release the four thumb screws by hand.

2. Slide the two ends of the handle into the holes in the top cover (pay attention to the direction of the curve in the handle) until the handle is inserted all the way in (see Handle Assembly3-1).
3. Press in and screw the four thumb screws by hand (do not use force when screwing) to secure the handle and the top cover.

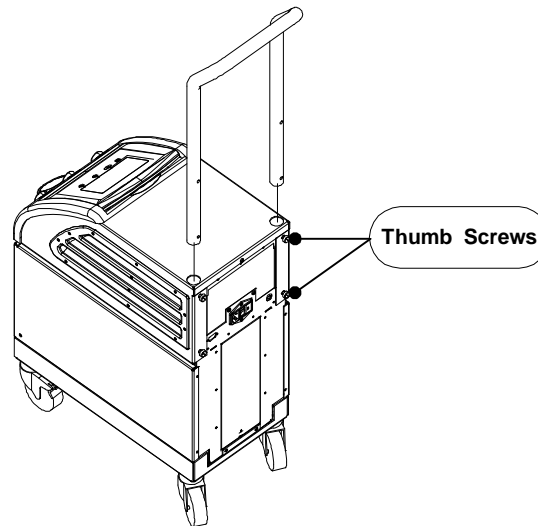


Figure 3-1: Handle Assembly

Equipment List

The CritiCool Pro system includes the following:

- CritiCool Pro device
- Connecting tubes for ThermoWrap
- Connecting tubes for CureWrap
- Special connector for draining the water tank
- Reusable core sensor (for 230V system)
- Reusable surface sensor (for 230V system)
- Reusable infant core sensor (ordered separately) (for 230V system)
- Disposable core sensor adapter (for 120V system)
- Disposable surface sensor adapter (for 120V system)
- Handle
- Spare Filter

- Power cable
- VitaLogik 4000/4500 monitor
- User's manual
- Quick Reference Guide

Moving the Unit

Preparation:

Before moving the unit:

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

Locking and Unlocking the Trolley Wheels

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

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

Storage Conditions and Transport

Storage

CAUTION! Use protective means to avoid excessive vibration during device transport.

Store the CritiCool Pro 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%
- An atmospheric pressure range of 500 hPa to 1060 hPa.

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

CHAPTER 4: OPERATING INSTRUCTIONS

General

This chapter contains:

- A description of the controls, indicators and connections for the CritiCool Pro device.
- Detailed operating instructions for the CritiCool Pro system for the different mode of operation.

Controls, Indicators and Connections

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

- Main power switch
- QCC—Quick Coupling Connectors
- Sensor sockets

The following functions of the CritiCool Pro device are described:

- Cooling
- Warming
- Re-Warming
- Standby
- Empty

Main Power Switch

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

QCC—Quick Coupling Connector

The Quick Coupling Connectors are located at the front of the CritiCool Pro device, and are connected to the Garment by means of the connecting tubes.

- ***To connect the Connecting Tubes:***
 1. Lock the connecting tubes by pressing them against the connectors; When locked, a clicking sound is produced.
 2. Verify that the tubes have been locked by lightly tugging them towards you.
- ***disconnect the Connecting Tubes:***
 1. Press the metal flange and pull out the connecting tubes.

Sensor Sockets

There are two sensor sockets located in the front of the CritiCool Pro device.

- ***To connect the Sensors:***
 1. Insert the appropriate reusable sensor or disposable sensor adapter into the designated socket.
- ***To disconnect the Sensors:***
 1. Pull the appropriate reusable sensor or disposable adapter out of its socket.

Preparing the System for Operation

- ***To prepare the system for operation:***
 1. Place the unit in the desired position according to “Space and Environmental Requirements” on page 3-1.
 2. Press the brake pedals and lock the wheels to secure the CritiCool Pro device.
 3. Remove the water tank feeder cover, and pour in ***tap water*** until the maximum allowable level is reached. Observe the water-level indicator to prevent overfilling the water tank. Close the water tank feeder cover. In case of overfilling, see Table 7-1.
 4. Connect the CritiCool Pro device and the VitaLogik monitor to the power source.

Turning on the System

System Setup

Before turning on the CritiCool Pro system you need to set up the system using the VitaLogik monitor.

Note: Refer to the VitaLogik User Manual for accessing the System Setup options.

➤ **To setup CritiCool Pro:**

On the VitaLogik monitor:

1. Discharge the patient.
2. Open the **Main** menu.
3. Select **Setup**.
4. Select **System Setup**.

Note: Use of System Setup is password protected.

From the **System Setup** menu, select **Vital Signs Setup**. The Vital Signs menu is displayed.

2. From the **VS Setup** menu, select **CritiCool Setup**. The CritiCool Setup dialog panel is displayed.

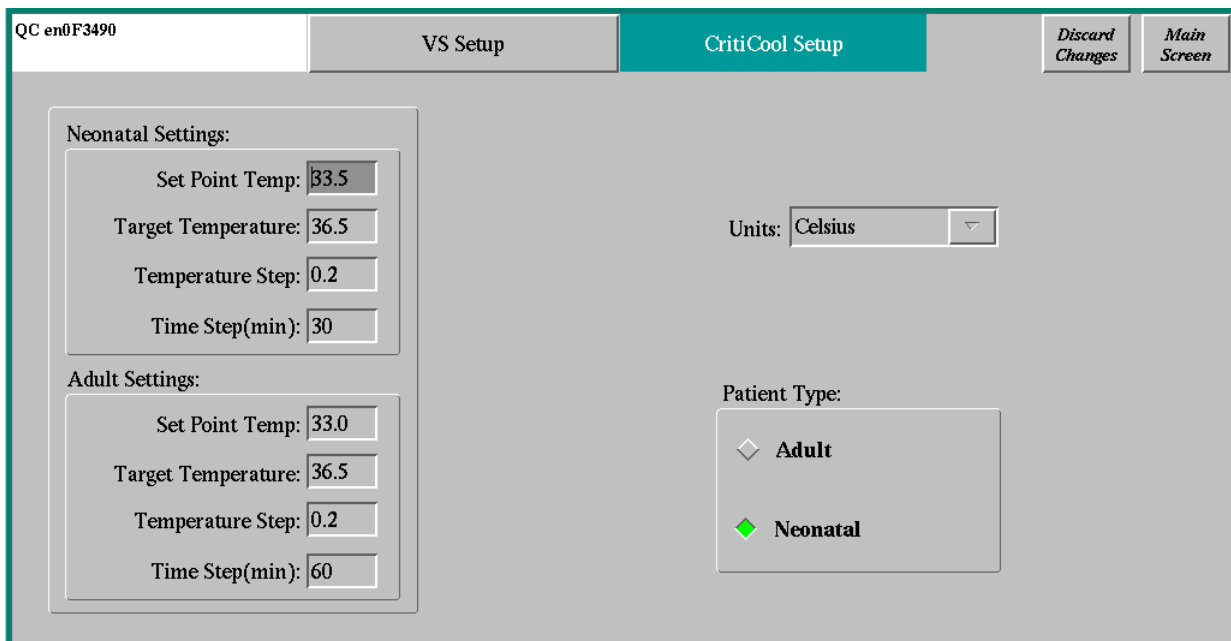


Figure 4-1 CritiCool Setup in VitaLogik

5. From the **Units** drop-down list, select the temperature readout unit. You can select control panel units to be either Centigrade or Fahrenheit.
6. Select the **Patient Type: Adult** or **Neonatal**.
7. Select default Settings values for **Set Point Temp**, and **Target Temperature** and default values for automatic Re-Warming mode (according to the Patient Type).

Turning on the System

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

➤ **To turn on the system:**

1. Turn the main switch, on the CritiCool Pro system, located in the rear of the unit, upwards to the ON position.
2. Turn on the VitaLogikPatient monitor.

The patient information is displayed on the monitor

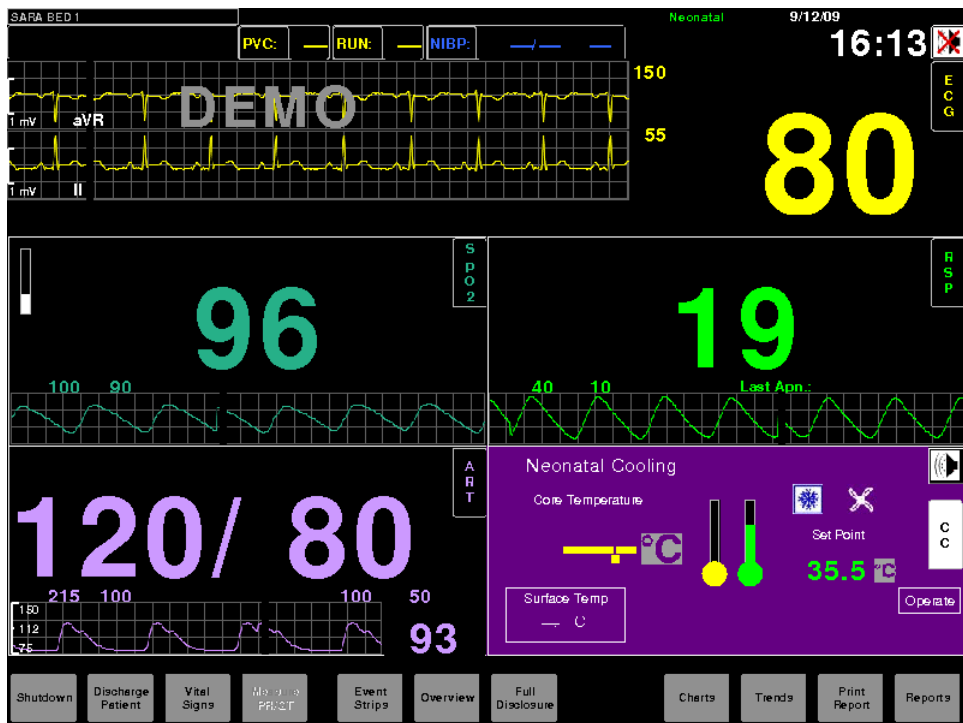


Figure 4-2 Full Screen monitor display

Self-Test

Once power is supplied to the CritiCool Pro device, the unit performs a self-test. During the self test the control panel presents the message "CritiCool Pro NO COM"

Cooling Therapy Control Panel

After completion of the Self- Test, the Cooling Therapy Control Panel appears.

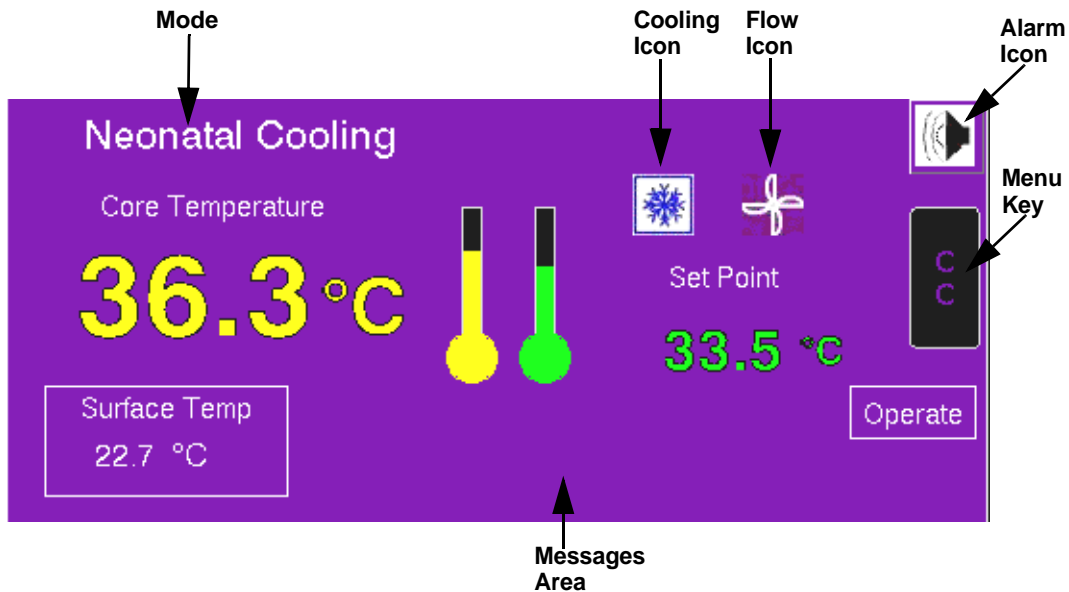




Figure 4-3 : Thermoregulation Control Panel

The Control panel shows the patients Core and Surface temperatures, the Set Point temperature, a **Cooling**  icon that indicates that the system is cooling the water, and a moving **Flow**  icon that indicates that water is flowing through the Garment.

Note: Use the **Alarm**  icon to mute the audible alarm.

Alarm and warning messages are displayed at the lower part of the panel.

Use the Quickey or Touch Screen (Optional) to reach the control panels and keys.

Use the CC (Menu) key to open the thermoregulation menu.

The menu consists of the following:

- **Set Mode:** Select the operating mode

- **Set-Point Setting:** Set the temperature to which the thermoregulation system is cooling or warming the patient's body.
- **Target Temperature Setting:** Set the target temperature for rewarm mode.
- **Re-Warm Setup:** Setup the warm-up procedure.
- **Activate:**

Selecting Modes

The following modes are available:

- Warming
- Cooling
- Re-Warm
- Standby
- Empty

Warming

In this mode the system warms the water, to prepare the system for patient warming. The set point is selected and the temperature control is activated to warm the patient and prevent hypothermia. Set point is limited to maximum 2°C above Core temperature.

Cooling

In this mode the system cools the water, to prepare the system for patient cooling in attempt to achieve mild hypothermia.

Re-Warming

Re-Warming after therapeutic hypothermia must be gradual. This mode provides controlled gradual warming. Each step of the procedure increases the set point temperature by a fixed, small step for a predefined period. The step is always related to the Core temperature reached at the end of the previous stage. The user has to set only the final, Target, temperature.

Standby

During Standby mode, the system measures patient temperatures without water flowing through the Garments and/or temperature regulation.

Empty

Use this mode to empty the system from water, prior of storage of the CritiCool Pro.

➤ **To select a mode:**

1. Press the CC (Menu) key.
2. Select the **Set Mode** option to display the **Set Mode** panel.

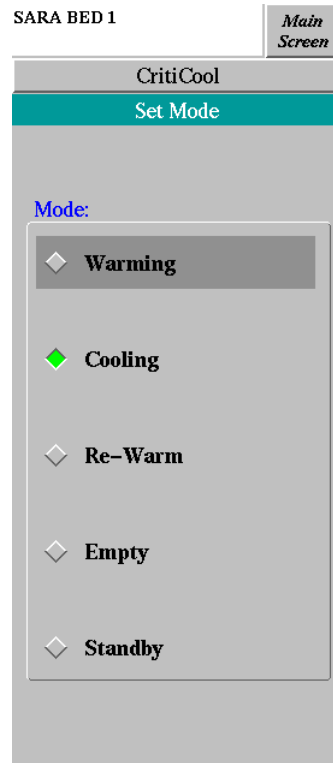


Figure 4-4 CritiCool Pro Mode selection panel

3. Use the Quickey to select the required mode.
The selected mode is marked by a green dot.
4. Click **Main Screen** to activate the mode.

Note: The selected mode is show on the top of the control panel (see Figure 4-3).

Set-Point Setting

The Set-Point is the temperature to which the thermoregulation system is cooling or warming the patient's body.

The set-point default for cooling is 33.5°C (92.3°F) for neonates and 33.0°C (91.4°F) for adult

➤ **To change the set point temperature**

1. Use the CC (**Menu**) key to open the **Set Point Setting** panel (Figure 4-5)

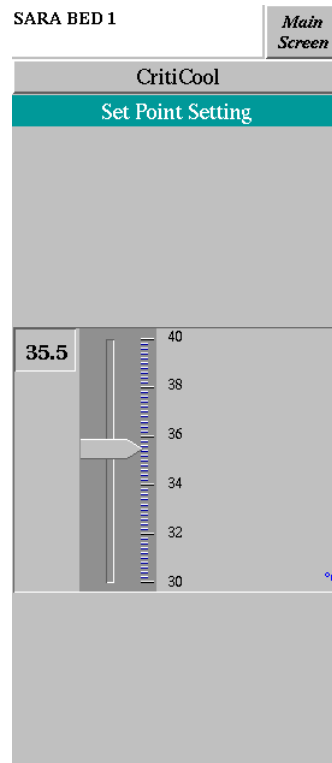


Figure 4-5 Set-Point Setting Panel

2. Use the Qickey or touch (optional) to select the required set-point
3. Click **Main Screen** to accept.

Target Temperature Setting

The Target Temperature Setting option enables selecting the re-warming target temperature and is available only in Re-Warm mode.

The default Target Temperature for Re-Warm is 36.5°C (97.7°F).

➤ ***To change the Target temperature***

1. Use the CC (**Menu**) key to open the Set point panel.

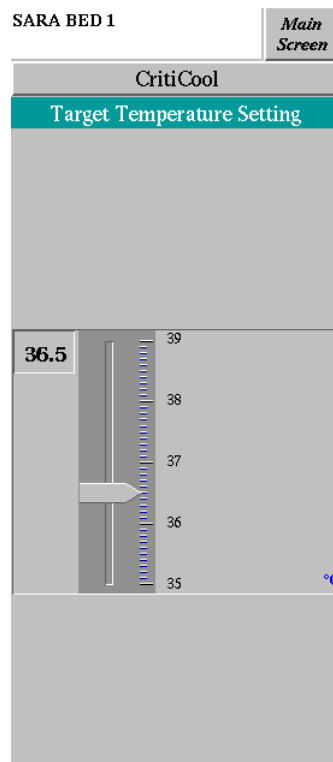


Figure 4-6 Target Temperature Setting Panel

2. Use the Quickey or touch (optional) to select the required target temperature.
3. Click **Main Screen** to accept.

Re-Warm Setup

The Re-Warm Setup panel provides control over the temperature steps during re-warming and the duration of each step.

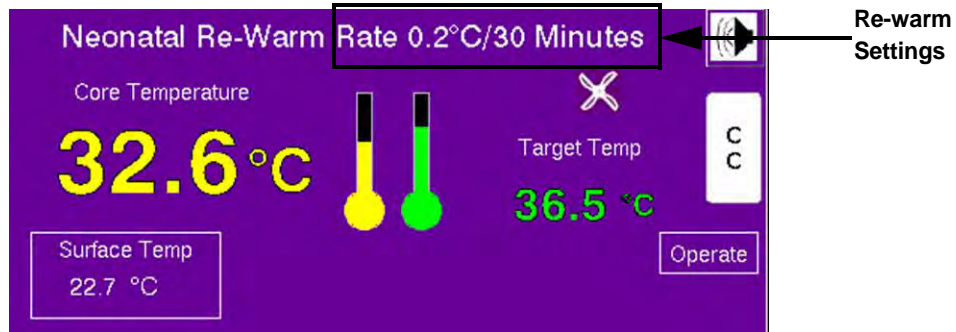


Figure 4-7 Re-warm Mode

The default step and duration for Neonate is 0.2°C and 30 seconds and for Adult 0.2°C and 60 seconds.

Note: This panel is accessible only in Re-Warm mode.

➤ **To change the Re-Warm settings**

1. Use the CC (Menu) key to open the **Re-Warm Setup** panel.

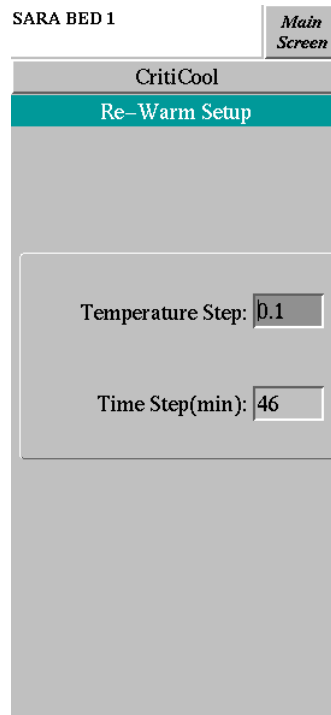


Figure 4-8 Re-Warm Setup Panel

2. Rotate the Quickey to change the Temperature Step, then click to select.
3. Rotate the Quickey to change the Time Step (in minutes), then click to select.
4. Click **Main Screen** to accept.

Getting Started

➤ *To get started:*

1. Place the appropriate Garment on the bed or underneath the patient (see the **Instructions for Use** leaflet).
2. Connect the connecting tubes to the CritiCool Pro device and to the Garment.

Note: Select the corresponding connecting tubes according to the Garment in use.

3. Insert the reusable core and surface sensors or the disposable core and surface adapters into the CritiCool Pro device sockets as described in section “Accessories ” on page 2-7.

Note: The CritiCool Pro device does not initiate thermoregulation if the core sensor is not properly inserted into the patient. Ensure that direct patient feedback is monitored at all times.

Inserting and Attaching Human Sensors

CAUTION! For proper use of the CritiCool Pro device, the core sensor must be inserted and the surface sensor must be attached.

Insert the Core Sensor into the Patient. Insert the reusable core sensor or the disposable core sensor or connect the disposable core sensor to its adapter as soon as possible into the patient prior to fastening the Garment.

Attaching Surface Sensor

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

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

Fastening Garment to Patient

Refer to the Instructions for Use leaflet supplied with each Garment.

CAUTION! *If treatment exceeds the allowed lifetime as indicated in the leaflet, replace the garment.*

Sustaining treatment for extended periods may result in skin wetting.

Replacing the Garment

➤ ***To replace the Garment:***

1. Use the CC (Main) menu to open the mode panel.
2. Select STAND-BY mode.
3. Close garment clamps to avoid water spill.
4. Disconnect the connecting tubes from Garment.
5. Remove the used Garment and dispose according to hospital regulations.
6. Place the new Garment (follow the **Instructions for Use** leaflet supplied with each Garment).
7. Fill the Water Tank with tap water to required level.
8. Reconnect the connecting tubes to the new Garment.
9. Fill the new Garment by water.
10. The system is ready for treatment.

Cooling Mode

After completing the self-test, the CritiCool Pro device shifts into the operation mode, the default mode is Cooling.

The default temperature is 33.5°C (92.3°F) for neonates and 33.0°C (91.4°F) for adult. You can change the set point temperature for cooling. See “Set-Point Setting” on page 4-7.

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

For example, if the Core temperature is 34°C (93.2°F) and the set-point temperature is 33°C (91.4°F), decreasing the set-point temperature will not accelerate the cooling of the water in the CritiCool Pro system. The CritiCool Pro device automatically operates at the optimal level to obtain the desired set-point temperature.

WARNING!!!: *The default setting is intended to maintain mild hypothermia.*

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

Note: *The system provides the physician with the option of selecting a body temperature in the range of 30°C to 40°C (86°F-104°F).*

After setting the set-point temperature, follow the on-screen instructions and operate as instructed.

Example: Figure 4-9 shows a screen with the "Core too Low, Check Core & Operate" (18) message.

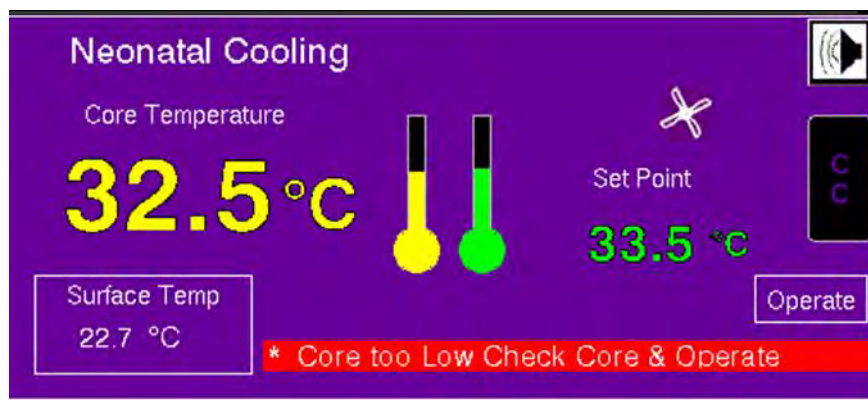


Figure 4-9 Alarm Message "Core too low"

The sensor reads the room temperature until it is inserted into the patient. This message indicates that the core temperature is 2° C below the desired set point (see Warning in Section Changing the Set Point Temperature). When the core sensor is inserted into the patient, the sensors read the patient's body temperature and the message clears.

Warming Mode

Use the Warming mode for warming a patient in order to reach Normothermia following accidental hypothermia, or to manually re-warm the patient at the end of hypothermia treatment period.

Note: *The CritiCool Pro device is automatically pre-set for Cooling therapy. The device can be set to operate in Warming mode (see "Selecting Modes" on page 4-6).*

To manually, re-warm the patient, select a set point that is slightly above the core temperature (see "Set-Point Setting" on page 4-7) and wait until Core temperature

reaches the new set point, increase the set point another step and wait for the core temperature to reach the next step.

Repeat the procedure until the patient reaches normal temperature.

The set point step and the duration at each step, depend on the hospital treatment policy.

WARNING!!! *When warming the patient, always choose a setpoint temperature that is no more than 2°C (3.6°F) above the core temperature. Otherwise the CritiCool Pro device ignores the set point and continues cooling.*

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

Normothermia Management

To achieve Normothermia use Warming mode. Set the temperature Set-Point to the desired temperature.

The CritiCool Pro device automatically operates at the optimal level to obtain the desired set-point temperature so that, when in Warming mode, the difference between the set point temperature and the core temperature does not affect the heating rate. A further increase in the set point temperature will not affect the water temperature in the Garment.

For example, if the core temperature is 36°C (96.8°F) and the set-point temperature is 37°C (98.6°F), raising the set-point temperature will not accelerate the heating of the water in the CritiCool Pro system.

Exceeding the Normothermia Range

If the desired set point temperature is set to be out of Normothermia range (36°C-38°C / 96.8°F-100.4°F), the message "Core too High check Core and Operate" appears.

Re-Warming Mode

This mode is used for automatic Re-warming at the end of hypothermia treatment period.

In Re-Warming mode the CritiCool Pro increases the set-point automatically in small steps with a pre-selected duration for each step.

The default temperature steps and their duration are defined in the System Setup (password protected) (see "Re-Warm Setup" on page 4-10)..

The default for neonatal is $\Delta T = 0.2$ °C and $t = 30$ minutes .

The default for adults is $\Delta T = 0.2$ °C and $t = 60$ minutes.

The Automatic Re-Warm Process.

The Re-Warm process starts with the hypothermia temperature -

for example 33.5 °C, the first step of the process is to increase the virtual Set-Point by 0.2°C: $33.5 + 0.2 = 33.7^{\circ}\text{C}$ for a period of 30 minutes.

Assuming that at the end of the 30 minutes period, the Core temperature has reached ,for example, 33.6°C, the Re-Warm algorithm adds 0.2°C to the current Core temperature and the new virtual set point is now $33.6 + 0.2 = 33.8^{\circ}\text{C}$ for an additional 30 minutes, and so on, until the Core temperatures reaches the Target temperature. At this point the process stops and the system changes the mode to "Cooling" mode with the Set Point equal to the Target temperature.

Note that the step delta temperature of the virtual set point, is from the Core temperature that was achieve at the end of the step period, and not from the last virtual set point.

➤ *To Start Automatic Re-Warm:*

1. Use CC (Menu) key to open the **Set Mode** panel and change the mode from "Cooling" to "Re - Warm" (see "Selecting Modes" on page 4-6).

Note: *In the automatic "Re-Warm" mode the set point display changes to "Target Temperature" with a default of 36.5 °C*

2. Use the "Target Temperature Setting" panel (see "Target Temperature Setting" on page 4-9) if you need to change the default target temperature.

Note: *The "Target" temperature is the temperature at which the automatic Re-Warm process will end.*

3. Click **Operate** to start Re-Warming.



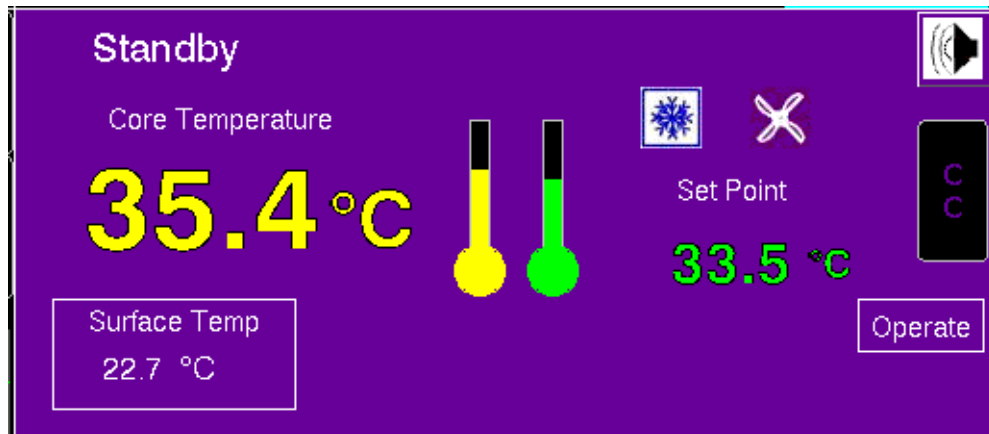
The CritiCool Pro heats the water, and starts circulation - The flow icon starts to rotate.

The system proceeds to increase the virtual set point until the Target temperature is reached. When Core temperature reaches the Target temperature, the mode automatically changes to "Cooling" with the set point equal to the Target Temperature and the

CritiCool Pro stabilizes the body temperature at the normothermia.

STAND-BY Mode

STAND-BY mode is used only to monitor body temperature. The CritiCool Pro Device circulates the water internally and maintains the water temperature at the appropriate level to be ready when returning to Cooling or Warming mode



Note: Note: During STAND-BY mode there is no temperature regulation. Use this mode when replacing a Garment.

Empty Mode

Before storing the system you have to empty the water from the CritiCool Pro.

- **To empty the water.**
 1. Disconnect the garment.
 2. Connect an emptying tube to the "water out" of the CritiCool Pro and direct the tube to a bucket for water collection.
 3. Change the mode to **Empty**.
 4. Wait for all the water to come out of the system.

The CritiCool Pro is now ready for storage until next procedure.

Turning Off the System

➤ ***To turn off the system:***

1. At the end of treatment, turn off the CritiCool Pro device by pressing the ON / OFF switch downwards to the OFF position and disconnecting the power cord from the power source.
2. Close the clamps on the connecting tubes to avoid returning water overflow.
3. Disconnect the connecting tubes from the CritiCool Pro device and from the Garment.
4. Disconnect the core and surface sensors from the CritiCool Pro device.
5. Remove the Garment and the sensors from the patient.
6. Dispose of the Garment in accordance with national regulations governing non-toxic plastic waste discharge.
7. Disinfect the surface of the connecting tubes and the exterior of the CritiCool Pro device with a wet cloth soaked in 70% alcohol.
8. Dispose of disposable sensors or disinfect the reusable sensors and disposable sensor adapters as required by hospital/clinic protocol.
9. Empty the water from the CritiCool Pro using the Empty procedure.
10. Press the brake pedals and lock the wheels to secure the CritiCool Pro device.
11. Store the CritiCool Pro device and its accessories in a safe place.

CHAPTER 5: ORDERING INFORMATION

This section outlines information for ordering, shipping and replacing parts of the CritiCool Pro system.

Equipment and Accessories - Ordering Information

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

Equipment and Accessories - Inventory

Available Garments

Models for various garments are available. Refer to Table 5-1.

Table 5-1 CureWrap Sizes

Table of CureWrap Sizes					
Part Number	Height Meter	Width Meter	Garment Area, sq. m.	Patient Height In Inches	Patient Height
3500	2.030	1.354	2.324	All adults sizes	
3548	1.582	1.193	1.399	48"-53"	
3541	1.390	1.054	1.089	41"-48"	
3536	1.225	0.841	0.763	36"-41"	
3531	1.118	0.740	0.637	31"-36"	
3525	0.981	0.628	0.425	25"-31"	7-11 kg
3521	0.698	0.602	0.347	21"-25"	4-7 kg
3518*	0.659	0.448	0.219	18" - 21"	< 4 Kg

* For use only outside the USA.

Table 5-2 Accessories Inventory

Part No.	Description
007-00365	Handle
200-00147	CureWrap Connecting tubes
200-00109	Connecting tubes
002-00069	Male connector for draining water tank
200-00130	Spare water filter
014-00020	Core sensor—Gray
014-00021	Surface sensor—Green
014-00028	Core sensor adapter—Gray
014-00029	Surface sensor adapter—Green
014-00005	Infant Core sensor—Gray
014-00017	Power cord (European Standard)
014-00016	Power Cord (USA Standard-Hospital Grade)
641-345-090	Interface cable CritiCool to VitaLogik
024-00010	CritiCool Pro User manual (English)

CHAPTER 6: MAINTENANCE

Introduction

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

WARNING!!! *The repair, and servicing of the CritiCool Pro system should be performed only by MTRE Advanced Technologies LTD or authorized agents of MTRE Advanced Technologies LTD.*

Service Information

When communicating with authorized MTRE representatives regarding the CritiCool Pro system, always state the model and serial numbers on the identification label located on the rear panel of the CritiCool Pro device (see Figure 1-1)

When communicating regarding Garments, refer to the label on the Garment package for lot number details.

Routine Maintenance

The CritiCool Pro device should be periodically inspected and maintained to make sure that it remains in optimum condition.

A recommended routine inspection and maintenance schedule is provided in Table 6-1

System Calibration is performed monthly by the hospital Biomed engineer.

Refer to CritiCool Pro Service manual section (((XXX))) for calibration procedure

Sterilization of Reusable Sensors and Disposable Sensor Adapters

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

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

Cleaning and Disinfecting Procedures for Reusable Sensors

Cleaning

Probes should be cleaned with a mild detergent and water to remove excess bio-burden and improve the effectiveness of disinfecting and sterilization.

Disinfecting

- For low-level cleaning use Cidex / glutaraldehyde
- For high-level cleaning use Cidex / glutaraldehyde dilute bleach, 70% isopropyl alcohol

Filter Replacement

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

The filter must be replaced every twelve months.

- ***To replacement the filter (by the hospital personnel):***
1. Drain the water tank (see Table 7-1, on page 7-2).
 2. Remove the rear cover:
 3. Unscrew the thumb captive screws at the bottom of the cover.
 4. Pull the bottom part of the cover towards you and then down to release the lip from the chassis.
 5. Unscrew the filter clamp screw and remove the filter clamp (see Figure 6-2).
 6. 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.
 7. Dispose of the old filter.

➤ **To replace the filter assembly:**

CAUTION! The filter is marked with an arrow indicating the direction of water flow (see Figure 6-1:).

You must assemble the filter in the manner indicated.

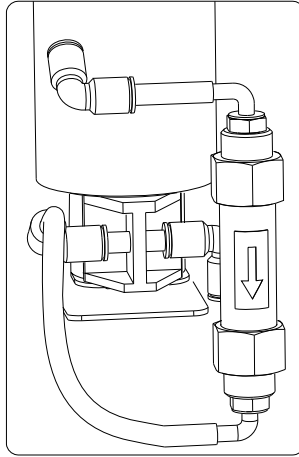


Figure 6-1: Filter Orientation

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

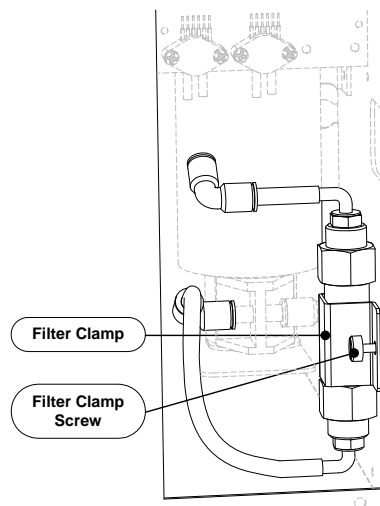


Figure 6-2 Filter Assembly

3. Close the rear cover and tighten the thumb captive screws by hand.

Table 6-1 Inspection and Maintenance Schedule

Frequency	Inspection/Service	Performed By
Before each treatment	<ul style="list-style-type: none"> • Clean connecting tubes and Quick Coupling Connector with a wet cloth. • Perform a visual inspection for any mechanical failure in sensors, connecting tubes, and power cable. • Perform a visual inspection of the exterior of the CritiCool Pro Device. 	Staff
As required by hospital/clinic protocol	Routine external cleaning and disinfecting.	Staff
Monthly	System Calibration Check	BMD
* Semi-annually/Annually	Thermal verification	BMD
	Replace filter	BMD
* Perform Thermal Verification according to hospital policy		

Note: The Garment contains chlorine tablets (Cl) that prevent contamination of the hydraulic system of the CritiCool Pro system.

CHAPTER 7: TROUBLESHOOTING

General

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

Trouble-shooting Guide

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

provides a list of fault messages that appear on the CritiCool Pro device screen.

WARNING!!! *The repair and servicing of the CritiCool Pro system should be performed only by MTRE Advanced Technologies Ltd or authorized agents of MTRE Advanced Technologies Ltd.*

Table 7-1 CritiCool Pro System Undisplayed Malfunction Troubleshooting Guide

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

Table 7-2 CritiCool Pro System Undisplayed Malfunction Troubleshooting Guide (cont.)

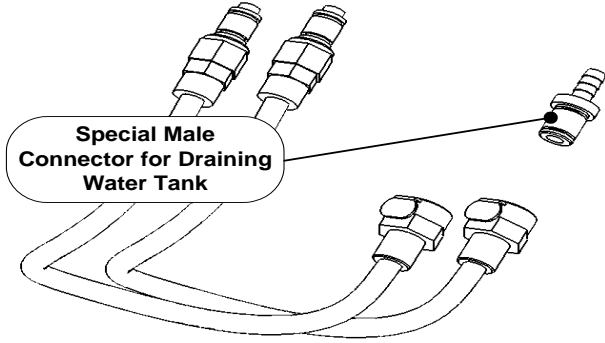
Observation	Action to be Taken
<p>Water tank overfilled.</p>	<p>If it is necessary to drain the water tank because of overfilling, proceed as follows:</p> <ol style="list-style-type: none"> 1 Connect one end of the ThermoWrap connecting tube to the right Quick Coupling Connector (under the Core Sensor socket). or, Connect the gray-coded end of the CureWrap connecting tube to the right Quick Coupling Connector (under the Core Sensor socket). 2 Connect the special male connector to the connecting tube: For ThermoWrap, see ThermoWrap Connecting Tubes and Special Male Connector7-1. or, For CureWrap, see 7-CureWrap Connecting Tubes and Special Male Connector2. 3 Turn the CritiCool Pro device ON. 4 Change into Operation mode. 5 Allow the excess water to drain into a receptacle, pail or sink. 6 When the desired water level has been reached, turn the CritiCool Pro device OFF. <div style="text-align: center;">  <p>The diagram illustrates the components for draining the water tank. It shows two ThermoWrap connecting tubes with quick coupling connectors at one end. A separate 'Special Male Connector for Draining Water Tank' is shown with a small black dot on its side, which is used to attach to the tubes. A callout box with a pointer identifies this connector.</p> </div> <p style="text-align: center;"><i>Figure 7-1: ThermoWrap Connecting Tubes and Special Male Connector</i></p>

Table 7-2 CritiCool Pro System Undisplayed Malfunction Troubleshooting Guide (cont.)

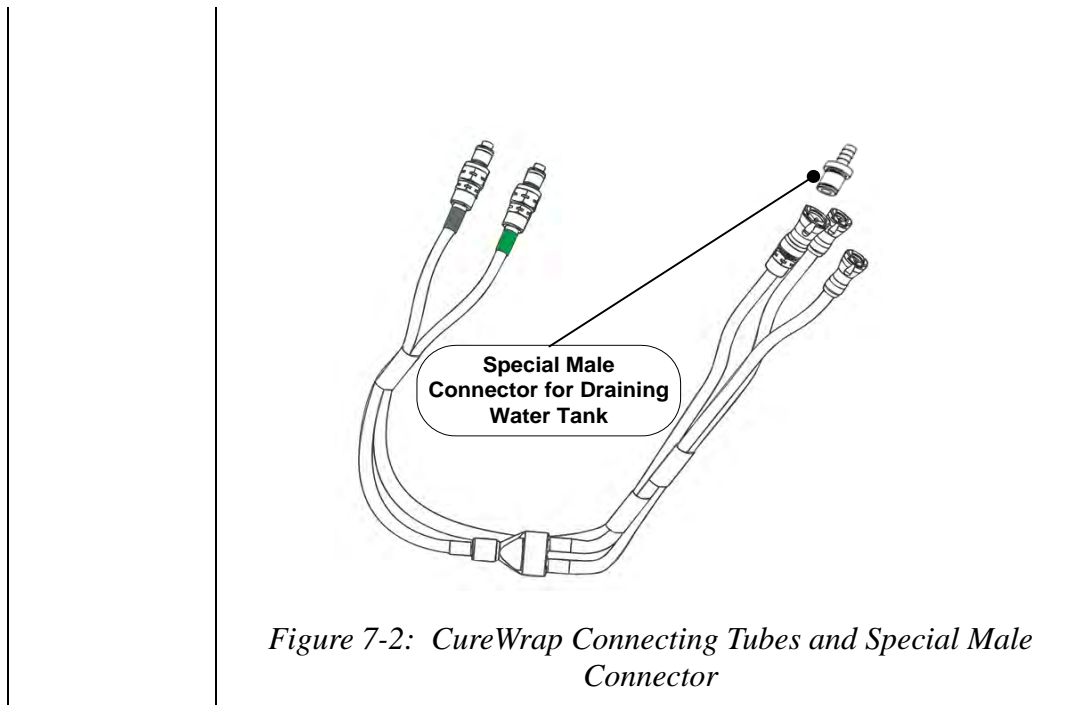


Figure 7-2: CureWrap Connecting Tubes and Special Male Connector

Note: A muted alarm is activated when a subsequent message appears.

Note: The Halt – Please Restart message indicates an error that can have numerous causes.
You must restart the CritiCool Pro device.

Table 7-3 CritiCool Pro System Message Troubleshooting Guide



Message	Probable Cause	Action to be Taken
HALT - PLEASE RESTART  XX	Error during normal function	Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool Pro device and contact your local service representative. Note the number that appears on the screen (1–16).
ATTENTION NO WATER – PLEASE ADD WATER 	No water in tank	Refill water to maximum level.
	Water tank float is jammed	Open water tank cap and insert a long object to release the float.

Table 7-3 CritiCool Pro System Message Troubleshooting Guide


<p>ATTENTION OUT OF NORMOTHERMIA PRESS OK TO CONFIRM</p>	<p>For Cooling Therapy: Desired set-point is set to exceed 38°C</p> <p>For Normothermia Mode: Desired set-point is set to be out of 36°C–38°C</p>	<p>Approve the action. Disapprove the action.</p>
<p> - Indicates alarm activated</p>		

Table 7-4 CritiCool Pro System Message Troubleshooting Guide (cont.)



Message	Probable Cause	Action to be Taken
<p>ATTENTION WATER CONNECTIONS</p>	<p>For Normothermia Mode: While self test was performed no water connection were attached</p>	<p>Connect water connection to system and garment.</p>
<p>ATTENTION CHECK WATER CONNECTIONS</p> <p> 10</p>	<p>Connecting tubes are not connected.</p>	<p>Connect connecting tubes.</p>
	<p>Garment is blocked due to improper wrapping</p>	<p>Check for snarls, folds, or objects that obstruct the water flow in the Garment.</p>
	<p>Garment clamps are closed</p>	<p>Check clamps</p>
<p>ATTENTION CHECK CORE SENSOR</p> <p> 11</p>	<p>Misplacement of sensor in core socket</p>	<p>Connect the core sensor to the appropriate socket.</p>
	<p>Core adapter is connected to the CritiCool Pro device without the disposable temperature sensor.</p>	<p>Connect disposable sensor</p>
<p>ATTENTION CHECK SURFACE SENSOR</p> <p>12</p>	<p>Misplacement of sensor in surface socket</p>	<p>Connect the appropriate surface sensor to its socket.</p>
	<p>Surface adapter is connected to the CritiCool Pro device without the disposable temperature sensor.</p>	<p>Connect disposable sensor</p>

Table 7-4 CritiCool Pro System Message Troubleshooting Guide (cont.)



<p>ATTENTION CONNECT CORE SENSOR*</p> 	<p>No core sensor inserted in its socket.</p>	<p>Connect core sensor.</p>
<p> - Indicates alarm activated</p>		
<p>* The alarm is activated again after 30 minutes if no action is taken.</p>		

Table 7-5 CritiCool Pro System Message Troubleshooting Guide (cont.)







Message	Probable Cause	Action to be Taken
<p>ATTENTION WATER TEMP TOO LOW</p>  16	<p>Water Temperature < 10°C</p>	<p>Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool Pro device and contact your local service representative.</p>
<p>ATTENTION WATER TEMP TOO HIGH</p>  17	<p>Water Temperature > 42°</p>	<p>Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool Pro device and contact your local service representative.</p>
<p>ATTENTION CORE READOUT TOO LOW</p>  18	<p>For Cooling Therapy: Core temperature is more than 2°C below set point</p>	<p>Re-warming: Do not attempt to increase more than 2 ° C above actual core temperature</p>
	<p>For Normothermia Mode: Core temperature is less than 27.0°C (80.6°F)</p>	<p>Insert the core sensor into patient.</p>
<p>PATIENT TEMP ABOVE 38.5°C (101.3°F)**</p> 	<p>Core temperature reading above 38.5°C (101.3°F).</p>	<p>Inform the physician.</p>

Table 7-5 CritiCool Pro System Message Troubleshooting Guide (cont.)

Patient temp BELOW 35.5°C (95.9°F) * 	27.0°C (80.6°F) < Temp. < 35.5°C (95.9°F)	Inform the physician.
 - Indicates alarm activated		

* In Normothermia Mode.

** Pressing Alarm Mute silences the buzzer for this present condition and any reoccurrence of this condition for thirty minutes.

Table 7-6 CritiCool Pro System Message Troubleshooting Guide (cont.)

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

CHAPTER 8: SPECIFICATIONS

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

Control System

Micro-controller

Operating icons

Set point switch and mode switch

Displays:

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

Controller range:

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

Sensors accuracy:

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

Water accuracy:

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

Auxiliary Systems

Water tank—Maximum Volume:

6 liters (1.6 gal.)

Warranty

One year

Operation

Ambient Temperature:

10°C–40°C (50°F–104°F)

Storage and Transport without Water

Control CritiCool Pro Device:

- Maximum storage time 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%_n
- An atmospheric pressure range of 500 hPa to 1060 hPa.

Electricity

Input power:

230/115 VAC with isolation transformer 50/60 Hz


Maximum Current

230/115 VAC 6.3 amp


Transformer:

Medical multiple isolation transformer: 230/115 VAC

Safety

Warning displays: () *indicates audible alarm*

SYSTEM HALT ()

ATTENTION NO WATER - PLEASE ADD WATER ()

ATTENTION OUT OF NORMOTHERMIA RANGE! PRESS OK TO CONFIRM

ATTENTION CHECK WATER CONNECTIONS ()

ATTENTION CHECK CORE SENSOR ()

ATTENTION CHECK SURFACE SENSOR

ATTENTION CONNECT CORE SENSOR ()

ATTENTION WATER TEMP TOO LOW (🔊)

ATTENTION WATER TEMP TOO HIGH (🔊)

ATTENTION CORE READOUT TOO LOW (🔊)

ATTENTION PATIENT TEMPERATURE ABOVE 38.5°C (101.3°F) (🔊)

ATTENTION PATIENT TEMPERATURE BELOW 35.5°C (95.9°F) (🔊)*

ATTENTION ELECTROMAGNETIC INTERFERENCE

ATTENTION CONNECT SURFACE SENSOR

* In Warming Mode

Protection against electric shock:

Type BF

Degree of protection against electric shock:

Class 1

Special mechanism

Prevents extremely high pressure and temperature

Quick coupling connectors

Prevent leakage

Anti-current overload system:

6.3 amp fuse

CritiCool Pro device shutdown mechanism

Software failure

Accessories

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

Sensors - 1/4" PL Stereo Phone Plug:

- "Reusable core
- "Reusable surface

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

Garment:

- "Various Garment types
- "Sizes range from 40 cm-196 cm (1'4"-6'5")

APPENDIX A

MTRE CUSTOMER SERVICE REPRESENTATIVE

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

Representative Name:	
Company Name:	
Address:	
Telephone No:	
Fax:	
E-mail:	

