



**BELMONT  
MEDICAL  
TECHNOLOGIES**

Saving Lives. Together.

**CRITICOOL®**

Safe, Precise, and Effective<sup>1,2</sup>

PATIENT TEMPERATURE MANAGEMENT

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TARGETED TEMPERATURE MANAGEMENT



INFANT



PEDIATRIC



ADULT

CRITICOOL®

CritiCool® is a thermal regulating system indicated for maintaining pre-set body temperature as determined by a physician. The system is composed of two elements, the CritiCool device and the CureWrap™.

The CritiCool device functions as a control unit for use with the CureWrap. The control unit reads the patient's core temperature through specific probes every 66 milliseconds and adjusts temperature as necessary in order to maintain the physician determined pre-set temperature settings.

The cooling/heating pump brings the water to the temperature set point and circulates it in a closed-loop system through the uniquely designed CureWrap.

FAST. SIMPLE. PRECISE.

- Accurate temperature control as set by the physician
- Full-color, touch-screen display
- Simple, easy to use interface with intuitive controls
- Real-time monitoring and graphical display of temperature measurements
- Quick and easy setup
- Track data using the Clinilogger™

CUREWRAP™

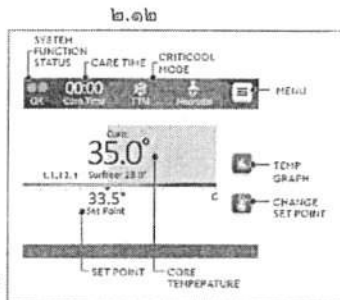
The CureWrap is a single use, one-piece flexible garment that acts in conjunction with the CritiCool control unit. The CureWrap's flexible configurations facilitate the wrapping of individual parts of the body to maximize surface coverage.

The CureWrap is designed to conveniently attach to the control unit using Quick Coupling Connectors (QCC) that allow for inflow and outflow. Integrated channels within the suit-like garment circulate water in a closed-loop system over a large surface area.

The CureWrap is secured via pressure sensitive adhesive strips which adhere to the garment, and not the patient.

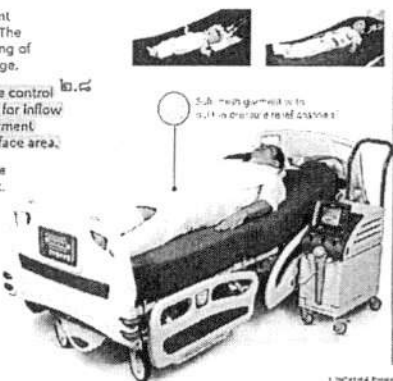
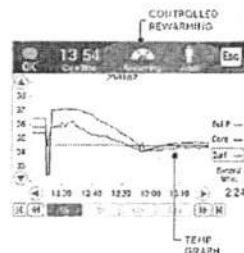
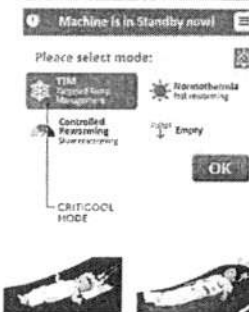
DESIGNED WITH YOUR PATIENT IN MIND

- One-piece body shaped garment with various sizes and configurations
- Up to 85% body surface area coverage
- Soft mesh that is easy to wrap and secure
- Clutter-free with only one pair of connecting tubes



TARGETED TEMPERATURE MANAGEMENT HAS NEVER BEEN EASIER

- ⊕ SET: Select the desired temperature set point
- Ⓜ WRAP: Apply the CureWrap garment
- ❄️ COOL: Initiate fast cooling
- ☀️ REWARM: Manage controlled rewarming



The CureWrap is available in a range of sizes and designs to accommodate your patient's anatomy.

WRAP TYPE	PACK TYPE	PART NUMBER	QUANTITY PER BOX	PATIENT HEIGHT/WEIGHT	WRAP LENGTH/WIDTH (IN)
Infant	Single Size	508-0318	8	23-41 kg (51-91 lb)	0.658 / 0.643
		508-0321	8	6-7 kg (13.8-15.4 lb)	0.618 / 0.603
Pediatric (Small)		PEU14002	8	(41) 23-41 kg (51-91 lb) (42) 5-7 kg (11-15.4 lb)	0.612 / 0.648 0.618 / 0.633
Pediatric (Medium)		PEU14005	4	(41) 7-11 kg (15.4-24.3 lb) (42) 7-11 kg (15.4-35 lb)	0.511 / 0.620 0.518 / 0.700
Pediatric (Large)		PEU14008	8	(41) 11-16 kg (24-35 lb) (42) 12-12 kg (26-27 lb)	1.225 / 0.851 1.370 / 1.014
Pediatric (XL Large)		PEU20008	8	(41) 12-15 kg (26-33 lb) (42) 12-15 kg (26-33 lb)	1.532 / 1.113 2.030 / 1.334
Adult	Single Size	201-03500	8	151-188 cm (5'-11" - 6'-2") 65-100 kg (143-220 lb)	2.030 / 1.334

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## ORDERING INFORMATION

### CONTROL UNIT

CritiCool® (115V)	Part #100-00003
CritiCool® (230V)	Part #100-00004
CritiCool® (100V)	Part #100-00007

### CRITICOOL ACCESSORY KIT (Select one only for each CritiCool unit)

INFANT KIT FOR DISPOSABLE TEMPERATURE SENSORS Part #200-00330

The Infant Kit contains:

- Core Adapter Cable Part #014-00028
- Surface Adapter Cable Part #014-00129
- Connecting Water Tubes (2 by 2 way) Part #200-00109

ADULT KIT FOR DISPOSABLE TEMPERATURE SENSORS Part #200-00310

The Adult Kit contains:

- Core Adapter Cable Part #014-00028
- Surface Adapter Cable Part #014-00129
- Connecting Water Tubes (2 by 3 way) Part #200-00147

Note: Disposable Temperature Probes must be ordered separately.

### REUSABLE KITS:

(NOT AVAILABLE IN THE UNITED STATES AND SELECT MARKETS)

INFANT REUSABLE KIT Part #200-00320

The Infant Kit contains:

- Reusable Core Temperature Probe, Infant Part #014-00005
- Reusable Surface Temperature Probe Part #014-00021
- Filter unit Part #200-R0130
- Connecting Water Tubes (2 by 2 way) Part #200-00109

ADULT REUSABLE KIT Part #200-00300

The Adult Kit contains:

- Reusable Core Temperature Probe, Adult Part #014-00020
- Reusable Surface Temperature Probe Part #014-00021
- Filter unit Part #200-R0130
- Connecting Water Tubes (2 by 3 way) Part #200-00147

### ACCESSORIES

Disposable Core Temperature Probe	Part #014-00322
Disposable Surface Temperature Probe	Part #014-00321
CliniLogger™	Part #017-00250

Note: Connecting Water Tubes (2 by 3 way) (Part #200-00147) is required for Pediatric X-Large CureWrap (Part #PED-XL008) and for Adult CureWrap (Part #508-03500).

## HARDWARE SPECIFICATIONS

### HEAT EXCHANGERS

Peltier Technology (TECs)

### WATER TANK

Sterile or 0.22 micron filtered tap water  
Tank Capacity: 6 liters (1.6 gal.)

### WATER TEMPERATURE

Water Temperature Accuracy:  $\pm 0.3^{\circ}\text{C}$  ( $0.5^{\circ}\text{F}$ )  
Water Temperature (outflow):  $13\text{--}40.8^{\circ}\text{C}$  ( $55.4\text{--}105.4^{\circ}\text{F}$ )

### PUMP

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

### PATIENT TEMPERATURE CHANNELS

2 Channels: Core, Surface  
Sensor Temperature Range:  $15^{\circ}\text{C}$  to  $44^{\circ}\text{C}$  ( $59^{\circ}\text{F}$  to  $111.2^{\circ}\text{F}$ )  
Sensor Temperature Accuracy:  $\pm 0.3^{\circ}\text{C}$  ( $0.45^{\circ}\text{F}$ )

### TEMPERATURE AND PRESSURE SENSORS

System Sensors:

- 3 Internal Temperature Sensors: Water in, Water out, Thermostat
- 2 Pressure sensors

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

### INPUT POWER

115VAC 5.7 A 50/60 HZ  
230VAC 2.9 A 50/60 HZ  
100VAC 6.6 A 50/60 HZ

### LCD DISPLAY

Size: 5.7" color display  
Resolution: 320x240

### CUREWRAP™

Single Patient Use



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For more information about the products we offer,  
contact us at [sales@belmontmedtech.com](mailto:sales@belmontmedtech.com).



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WARMING



PATIENT  
COOLING



FLUID  
MANAGEMENT



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NEW MEDICAL

New Medical

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Belmont Instrument LLC  
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File Number: A18173

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## CritiCool® System

The CritiCool® system consists of the following elements:

- CritiCool® device
- Wrap
- Accessories

## CritiCool® Device

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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 flow in the wrap is regulated by timed pauses of the flow during clinical operation.

In TTM and Normothermia modes - during the initial phase of regulation the flow cycle is 12 minutes ON and 1 minute OFF.

In steady state (when the Core Temp is within the Set Point range) the cycle is 12 minutes ON and 12 minutes OFF.

The CritiCool® device is equipped with a handle for easy transport.



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# CritiCool®

## Technical Specification



The CritiCool®, one of Belmont Medical Technologies Temperature Regulating systems, induces, maintains, and reverses hypothermia in an effective and precise manner. The desired patient 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 CritiCool® device, and the CureWrap™.

The CritiCool® device functions as a control unit constantly monitoring the Patients' core temperature and as a cooling/heating device 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

- Sterile/ 0.22 micron filtered tap water usage
- Tank Capacity: 6 liters (1.6 gal.)

#### Water Temperature

- Water Temperature Accuracy  $\pm 0.3^{\circ}\text{C}$  (0.54°F)
- Water Temperature (outflow) 13-40.8°C (55.4-105.4°F)

#### Pump

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

#### Patient Temperature Channels

- 2 Channels: Core, Surface
- Sensor Temperature Range: 15°C to 44°C (59°F to 111.2°F)
- Sensor Temperature Accuracy  $\pm 0.3^{\circ}\text{C}$  (0.54°F) ๒.๖

#### Temperature and Pressure Sensors

- System Sensors:
  - ◊ 3 Internal Temperature Sensors: Water In, Waterout, Thermostat
  - ◊ 2 Pressure sensors
- Safety measures:
  - ◊ Over pressure protection and alarm
  - ◊ High water temperature protection and alarm

#### Physical Dimensions

- Mobile Unit with 4 wheels and 2 brakes
- 280 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 (Switchable) with isolation transformer 50/60Hz
- 100VAC with isolation transformer 50/60Hz

#### Maximum Current

- 230 VAC 2.5A-3A
- 115 VAC 4.8A-5A
- 100 VAC 6A-6.6A

#### Environmental Operating Conditions

- Temperature: 5°C to +40°C (41°F to 104°F)
- Humidity: 10 to 93%, non-condensing
- Should not be used in an atmosphere with flammable anesthetic mixtures.

#### Environmental Storage Conditions

- Ambient temperature range of -15°C to (+68)°C (5°F to 154°F)
- Humidity: 10 to 93%, non-condensing

#### External Ports

- 1 X Isolated Serial Port

#### LCD Display

- Size: 5.7" color display
- Resolution: 320x240

#### Touch Screen

- Multi Capacitive Touch screen

### SOFTWARE

#### Displayed Information

- Mode of operation
- Set point temperature (Range: 30°C - 40°C) ๒.๘
- Target temperature (Range: 32°C - 38°C)
- Core Temperature
- Surface temperature
- System status and alarms
- Technician mode display
- Temperature graph

#### Operating Modes

- Target Temperature Management (TTM): ๒.๘
- Controlled Re-Warming
- Normothermia
- Stand-By

#### Languages

- |           |              |           |
|-----------|--------------|-----------|
| • German  | • Dutch      | • Russian |
| • English | • Spanish    | • Czech   |
| • French  | • Portuguese | • Polish  |
| • Finnish | • Swedish    |           |
| • Turkish | • Norwegian  |           |
| • Italian | • Danish     |           |

#### User Interface (GUI)

- 5 soft push buttons

### ACCESSORIES

#### Temperature Sensors

- YSI 400 Series Probes
- Reusable core\*
- Reusable surface\*
- Disposable core
- Disposable adapter core
- Disposable surface
- Disposable adapter surface

\*Not applicable for US market

#### CureWraps™/ThermoWraps®

- Sizes range from 44 cm-200 cm
- Wrap Storage Span: 5 years
- Storage Conditions:
  - ◊ Temperature: 10°C to 27°C
  - ◊ Humidity: 10-90%
- Transport Conditions:
  - ◊ Temperature: -20°C to +60°C
  - ◊ Humidity: 20%-95%
- Duration of use:
  - ◊ CureWraps™: up to 5 days
  - ◊ ThermoWraps®: up to 28 hours of use

#### External Water Tubes

- Dual/Triple connector to wrap



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## Settings Screen 1

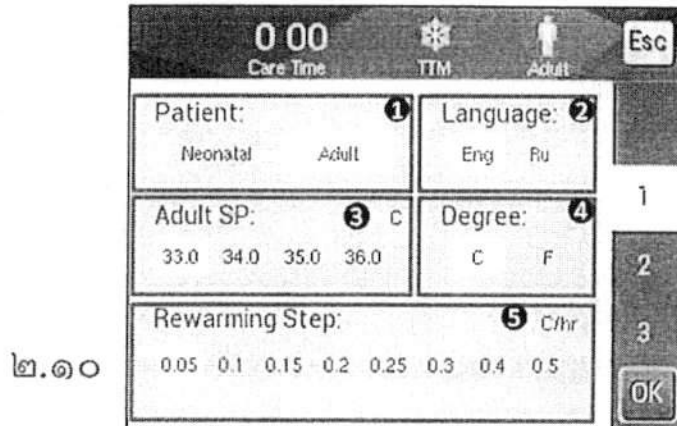


Figure 4-9: Settings Screen 1.

Settings Screen 1 includes:

- Selecting the type of patient: Adult or Neonatal ①
- Language ②
- Default Set Point Temperature ③
- Temperature Scales (Celsius/ Fahrenheit) ④
- Rewarming Step for the Controlled Rewarming mode ⑤

## Settings Screen 2

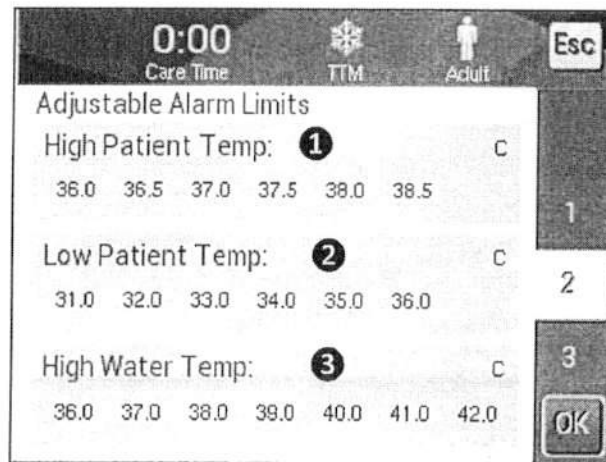


Figure 4-10: Settings Screen 2.

Settings Screen 2 includes adjustable alarm limits, for:

- High Patient temperature ①
- Low Patient temperature ②
- High Water temperature ③



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The following messages should be checked and confirmed:

- Low Core temperature thermoregulation is continuing...
- Core Readout too Low
- Out of Normothermia Range
- Patient Temperature above XX.X°C (\*)
- Patient Temperature below YY.Y °C (\*)
- Water Temp Too High (\*)

**NOTE:** Only authorized users can change the range of the alarms marked by (\*) in the Settings screen. The user needs to insert a password to enter the Settings panel and change the alarm limit.

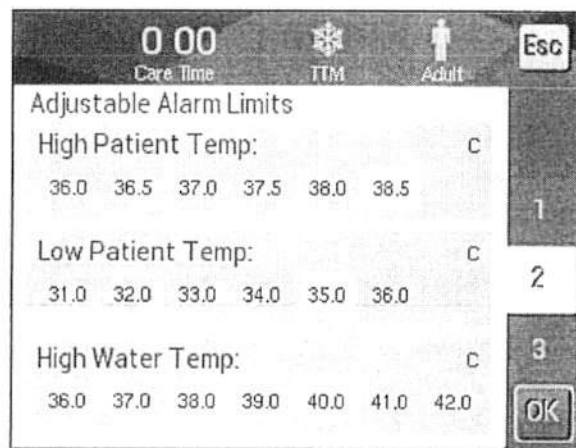


Figure 4-24: Adjustable Alarm Limits.

## Constant Alarms

Constant alarms occur in the following states:


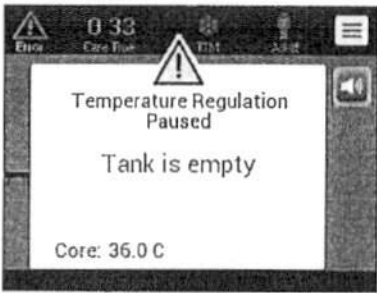
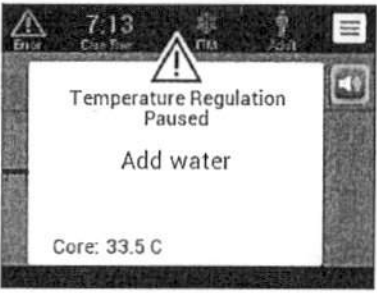
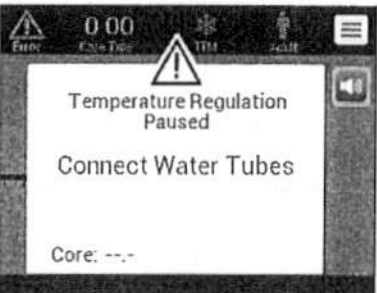
- ๒.๑๓
- Halt condition
  - Select Mode screen



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Table 7-3: CritiCool® System Messages Troubleshooting Guide

Message	Cause of Problem	Action to be taken	Comments
 Indicates that an alarm is activated			
Tank is empty 	No water in the tank. Water tank float is jammed	Refill water tank to maximum level. Open water tank cap and insert a long object to release the float.	
Add Water 	Water level is too low	Refill water tank to maximum	The alarm can be muted for an unlimited time.
Connect Water Tubes 	Connecting tubes are not connected.	Connect connecting tubes. Check for snarls, folds, or objects that obstruct the water flow in the wrap. Check clamps.	* Pressing Alarm Mute silences the buzzer for 30 minutes.

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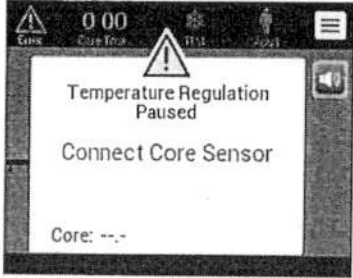
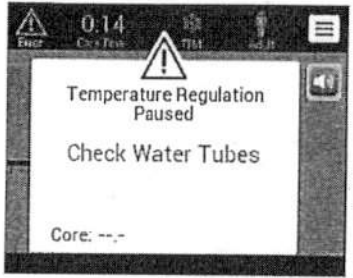
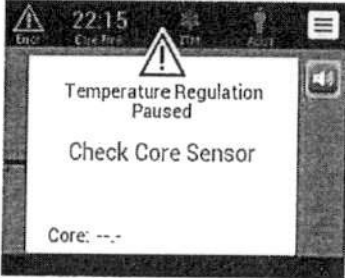


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Table 7-3: CritiCool® System Messages Troubleshooting Guide

Message	Cause of Problem	Action to be taken	Comments
<p>Connect Core temperature probe</p> 	No core temperature probe is inserted in its socket.	Connect core temperature probe	* Pressing Alarm Mute silences the buzzer for 30 minutes.
<p>Check Water Tubes</p> 	Wrap is blocked due to improper wrapping. Wrap clamps are closed.	Check for snarls, folds, or objects that obstruct the water flow in the wrap. Check clamps	* Pressing Alarm Mute silences the buzzer for 30 minutes.
<p>Check Core temperature probe</p> 	Misplacement of core temperature probe in core socket. Core temperature probe's adapter is connected to the CritiCool® without the temperature probe.	Connect the core temperature probe to the appropriate socket. Connect disposable temperature probe	This alarm cannot be muted.

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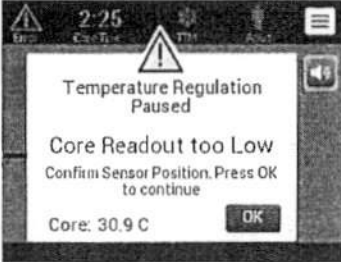


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Table 7-3: CritiCool® System Messages Troubleshooting Guide

Message	Cause of Problem	Action to be taken	Comments
<p>Core Readout too Low</p> 	<p>This message appears when Core Temp. is at least 2°C lower than Set Point or: When the Core Temperature is below 31°C, which ever first.</p>	<p>Once the operator confirmed the location of the core temperature probe, he must touch OK to continue</p>	<p>An alarm issues and thermoregulation stops. The alarm can be muted for 5 minutes NOTE: If you disregard the message and do not touch OK for over 30 minutes, the alarm cannot be silenced until the OK button is touched. When OK is touched, the screen returns to the Main Screen and a message appears for 5 seconds indicating that thermoregulation has resumed.</p>
<p>Switching to AutoRewarm Mode</p> 	<p>The systems ask for confirmation of the patient's core temperature before changing to Controlled Rewarming mode</p>	<p>The operator must confirm the patient's temperature before switching to Rewarming mode. Once confirmed, he must touch OK to continue.</p>	<p>This alarm Cannot be muted</p>
<p>Water temp. too low</p> 	<p>When the water temperature in the system is less than 10°C (50°F)</p>	<p>Thermoregulation stops. Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool® and contact your local service representative.</p>	<p>The alarm can be muted for unlimited time.</p>

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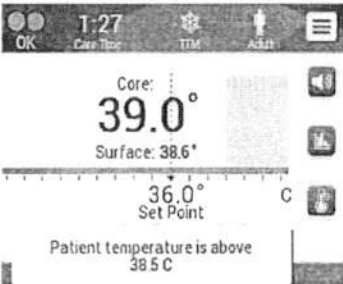

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Table 7-3: CritiCool® System Messages Troubleshooting Guide

Message	Cause of Problem	Action to be taken	Comments
<p>Water temp. too High</p> 	<p>When the water temperature in the system is more than 42°C(107.6°F)</p>	<p>Thermoregulation stops until the water cools or the system halts. Turn OFF the system for 3 seconds and then turn it ON again. If the problem persists, turn OFF the CritiCool® and contact your local service representative.</p>	<p>The alarm can be muted for an unlimited time.</p>
<p>Patient's temperature is above XX.X°C</p> 	<p>The alarm for High patient's temperature can be configured in "settings". The alarm and message are issued according to the selected alarm limit. The available values are:36°C,36.5°C, 37°C, 37.5°C,38°C,38.5°C</p>	<p>Check Core temperature probe is in place and follow the patient's temperature. Inform the physician.</p>	<p>Thermoregulation continues. The alarm can be muted for 30 minutes.</p>
<p>Low Core Temperature Thermoregulation is continuing.</p> 	<p>This message appears: 1. When Core temp. is Less than 0.8°C less below the Set Point 2.According to alarm settings.</p>	<p>Check core temperature probe is in place and keep following the patient's temperature No action is required. If Rewarming manually: Do not attempt to increase more than 0.8°C above actual core temperature.</p>	<p>For this message, an alarm issues but thermoregulation continues. The alarm can be muted for 30 minutes.</p>

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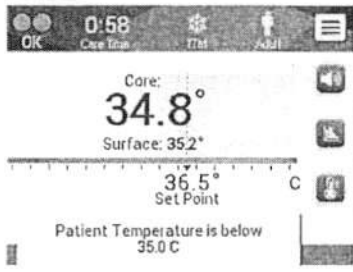
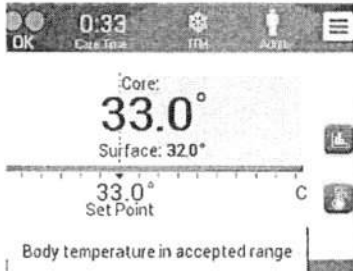
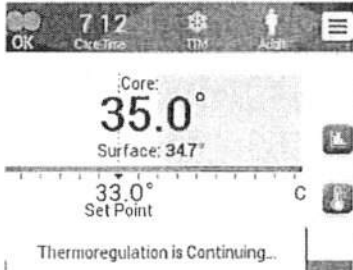



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Table 7-3: CritiCool® System Messages Troubleshooting Guide

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Message	Cause of Problem	Action to be taken	Comments
<p>Patient's temperature is below XX.X°C</p> 	<p>The message appears with an alarm when Core temperature is below the alarm limit preconfigured in the Settings panel. The alarm and message are issued according to the selected alarm limit. The available values are: 31°C, 32°C, 33°C, 34°C, 35°C, 36°C</p>	<p>Check Core temperature probe is in place and follow the patient's temperature. Inform the physician.</p>	<p>Thermoregulation continues. The alarm can be muted for 30 minutes</p>
<p>Body temperature in accepted range</p> 	<p>This appears once core temperature reaches an acceptable core temperature</p>		<p>No alarm. The message appears for 5 seconds.</p>
<p>Thermoregulation is Continuing.</p> 	<p>This appears after confirming low core temperature.</p>		<p>No alarm. The message appears for 5 seconds.</p>
<p>Out of Normothermia Range</p> 	<p>This appears when the operator chooses Set Point temperature for Normothermia &lt;32°C and &gt;38.0°C. For this message, thermoregulation continues.</p>	<p>Touching OK confirms the new Set Point temperature and eliminates the message.</p>	<p>No alarm</p>



EARTH LINE CO.,LTD.  
บริษัท เอิร์ธไลน์ จำกัด

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N. S. S.

EARTH LINE CO.,LTD.  
บริษัท เอิร์ธไลน์ จำกัด

Date: August 29, 2016

To Whom It May Concern

1. Our exclusive representative-distributor in Thailand, **Earthline Company Ltd.**, is fully authorized by us to offer, sale, deliver, install and service our products, in Thailand.
  2. We will accept and execute every order from **Earthline Company Ltd.**
- We will provide **Earthline Company Ltd.**, with spare parts for the offered medical equipment for Ten (10) years and we will continue to provide spare parts to the user, even if **Earthline Company Ltd.**, ceases to be our exclusive representative in Thailand or if **Earthline Company Ltd.**, terminates conducting business in Thailand.



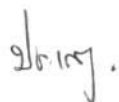
Ms. Miri Maza  
Sales Manager-Asia Pacific  
Belmont Medical Ltd.



รับรองสำเนาถูกต้อง



EARTH LINE CO.,LTD.  
บริษัท เอิร์ธไลน์ จำกัด



Technical Certificate

Date: August 31, 2016  
To: Whom It May Concern

This is to certify that Product Specialist Passawat Chansomboon from the company Earth Line has successfully completed the user, technical training for the following

- CritiCool
- CritiCool Pro
- CritiCool Mini
- Allon

The training held in Bangkok in March 2016.

Sinceirly,



Ms. Miri Maza  
Sales Manager-Asia Pacific  
Belmont Medical Ltd.

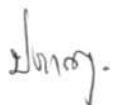
รับรองสำเนาถูกต้อง



EARTH LINE CO.,LTD.  
บริษัท เอิร์ธไลน์ จำกัด



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บริษัท เอิร์ธไลน์ จำกัด







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# CERTIFICATE OF REGISTRATION

## Belmont Medical Technologies

780 Boston Road  
Billerica, Massachusetts 01821 UNITED STATES

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

**ISO 13485:2016**  
**EN ISO 13485:2016**

Design, development, manufacture, and servicing of rapid infuser fluid management system (pump and sterile disposable kit), hyperthermia pump (pump and sterile disposal kit), blood/fluid warmers (hardware and sterile disposable kit) and thermoregulation devices (hardware and related wraps) for the area of general medicine.



Authorized by  
*Paul Hilgeman*

**Paul Hilgeman**  
Director & Global Industry Leader, Medical  
CMIT – Medical Regulatory



Check Certificate  
Status: [here](#)

File Number A18173  
Certificate Number 1030.220709  
Initial Issue Date April 27, 2017

Cycle Start July 9, 2022  
Effective Date July 9, 2022  
Expiry Date July 8, 2025

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

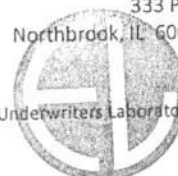


Form-ULID-000724 Issue 3.0



**EARTH LINE CO.,LTD.**  
บริษัท เอิร์ธไลน์ จำกัด

UL LLC  
333 Pflugsten Road  
Northbrook, IL 60062-2096 USA



**EARTH LINE CO.,LTD.**  
บริษัท เอิร์ธไลน์ จำกัด

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*Long*



**U.S. FOOD & DRUG  
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

หน้า 16

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

Certificate No. 3882-1-2021

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Manufacturer

MT. OLIVE MFG., CO.  
3304 Hancel Cir  
Mooreville, IN USA 46158

Manufacturer

R.H. ELECTRONICS LTD.  
5 HATZOREF ST.  
P.O. BOX 740  
NAZARETH ILLIT, Tel-Aviv ISRAEL 17000

Name of Manufacturer/Distributor

Legal Manufacturer

BELMONT MEDICAL TECHNOLOGIES  
780 Boston Rd  
BILLERICA, MA USA 01821

---END OF MANUFACTURER/DISTRIBUTOR LIST---

รับฝากคั่ง

*N. H.*



EARTH LINE CO., LTD.  
บริษัท เอิร์ธ ไลน์ จำกัด



EARTH LINE CO., LTD.  
บริษัท เอิร์ธ ไลน์ จำกัด

*Long*



**FDA U.S. FOOD & DRUG ADMINISTRATION**  
 CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

Manufacturer

R.H. ELECTRONICS LTD.  
 5 HATZOREF ST.  
 P.O.BOX 740  
 NAZARETH ILLIT, Tel-Aviv ISRAEL 17000

Name of Product(s)

200-00063 Allon® 230V  
 200-00263 Allon® 115V  
 200-01263 Allon® 100V  
 200-00036 CritiCool® 230V  
 200-00236 CritiCool® 115V  
 200-01236 CritiCool® 100V

Name of Manufacturer

Manufacturer

MT. OLIVE MFG., CO.  
 3304 Hancel Cir  
 Mooresville, IN USA 46158

Name of Product(s)

524-03118 Infant ThermoWrap (2.5-4Kg)  
 524-03121 Infant ThermoWrap (4-7Kg)  
 524-03125 Infant ThermoWrap (7-11Kg)  
 512-03131 Pediatric ThermoWrap (79-91cm)  
 512-03136 Pediatric ThermoWrap (91-104cm)  
 512-03141 Pediatric ThermoWrap (104-122cm)  
 512-03148 Pediatric ThermoWrap (122-135cm)  
 512-03153 Universal ThermoWrap (135-152cm)  
 512-03160 Universal ThermoWrap (152-168cm)  
 512-03166 Universal ThermoWrap (168-180cm)  
 512-03363 Cardiac ThermoWrap (165-182cm)  
 508-03500 Adult CureWrap (168-180cm)  
 508-03518 Infant CureWrap (2.5-4Kg)  
 508-03521 Infant CureWrap (4-7Kg)  
 508-03525 Infant CureWrap (7-11Kg)  
 508-03531 Pediatric CureWrap (79-91cm)  
 508-03536 Pediatric CureWrap (91-104cm)  
 508-03541 Pediatric CureWrap (104-122cm)  
 508-03548 Pediatric CureWrap (122-135cm)  
 PED-SM008 Pediatric CureWrap (Small)  
 PED-MD008 Pediatric CureWrap (Medium)  
 PED-LA008 Pediatric CureWrap (Large)  
 PED-XL008 Pediatric CureWrap (X-Large)

END OF PRODUCT LIST

รับรองสำเนาถูกต้อง

*(Handwritten signature)*



**EARTH LINE CO.,LTD.**  
 บริษัท เอิร์ธไลน์ จำกัด



**EARTH LINE CO.,LTD.**  
 บริษัท เอิร์ธไลน์ จำกัด

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# CERTIFICATE

**EC No 1434-MDD-483/2019**  
**Full Quality Assurance System**

**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**Belmont Medical Technologies**  
**780 Boston Road**  
**Billerica, Massachusetts 01821 UNITED STATES**

for the design, manufacture and final inspection of medical devices, class: Class IIb

**Products list in attachments: 1**

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)  
implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 09.10.2019 to 08.07.2024

The date of issue of the Certificate: 09.10.2019

The date of the first issue of the Certificate: 26.04.2019

**CE 1434**

Application No: 816/2019  
Module H2/3/4/5



**EARTH LINE CO.,LTD.**  
บริษัท เอิร์ธไลน์ จำกัด

*Signature*

*Signature*

*Signature*

Michał Pachowski, Ph.D.  
President



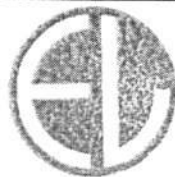
**EARTH LINE CO.,LTD.**  
บริษัท เอิร์ธไลน์ จำกัด




**ANNEX 1 TO CERTIFICATE**  
**VALID ONLY WITH CERTIFICATE**  
**No 1434-MDD-483/2019**

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type
Fluid management systems - 2530	The Belmont Rapid Infuser	The Belmont® Rapid Infuser RI-2
Fluid warmers - 2530	The Belmont buddy	The Belmont® buddy lite™ Blood/Fluid Warmer
		The Belmont® buddy lite AC™ Blood/Fluid Warmer
	The Belmont Hyperthermia Pump	The Belmont® Hyperthermia Pump
Hyperthermia Pump Disposable Set	Dual Reservoir Y-Set Kit	REF 902-00005
	Heat Exchanger Set	REF 902-00006
	Hyperthermia Pump Procedure Kit	REF 902-00045
	Single Reservoir Straight Inflow/Bifurcated Outflow Patient Line Kit	REF 902-00008
	Single Reservoir Straight Inflow/Outflow Patient Line Kit	REF 902-00007
	Straight Inflow/Bifurcated Outflow Patient Line Kit	REF 902-00038
	Straight Inflow/Outflow Patient Line Kit	REF 902-00037
Rapid Infuser Disposable Set	3.0 Liter Reservoir with Heat Exchanger Patient Line	REF 903-00032
	3-Spike Disposable Set (Qty. 12)	REF 903-00006
	3-Spike Disposable Set (Qty. 6)	REF 903-00106
Thermoregulation Devices	Allon 2001	200-00063, 200-00263 and 200-01263
	CritiCool	200-00036, 200-0236 and 200-01236
	CritiCool Mini	200-00336



EARTH LINE CO., LTD.  
บริษัท เอิร์ธไลน์ จำกัด

  
Michal Pachowski, Ph.D.  
President

สาขาธนบุรี 1 รามอินทรา กย.8 (0057)

6,8,10 ซอยนวมินทร์ 98

เขตดินนาพยา กรุงเทพมหานคร 10230 0002621

รอบรายการบัญชี/Statement Period  
01/01/2019. - 31/01/2019

เรียน บจ. เอิร์ธ ไลน์  
129/196 ซอยนวมินทร์ 163  
นวมินทร์ บึงกุ่ม  
กรุงเทพมหานคร 10230

วันที่ออกรายงาน/Statement Date  
01/02/2019

หน้า/Page 001/005

ตั้งแต่วันที่ 1 กุมภาพันธ์ 2562 เป็นต้นไป เชื่อกันว่าการแก้ไขข้อมูล  
โปรดให้ผู้ส่งจ่ายเปลี่ยนเช็คใหม่ หรือมาใช้เงินที่ธนาคารเจ้าของเช็ค

รายการเคลื่อนไหวบัญชีเงินฝากกระแสรายวัน  
บัญชี/Account No. 057-301403-2

THB

Current Account Transaction Record  
บจ. เอิร์ธ ไลน์

 **รับรองสำเนาถูกต้อง**  
**EARTH LINE CO.,LTD.**  
บริษัท เอิร์ธ ไลน์ จำกัด

 **EARTH LINE CO.,LTD.**  
บริษัท เอิร์ธ ไลน์ จำกัด

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