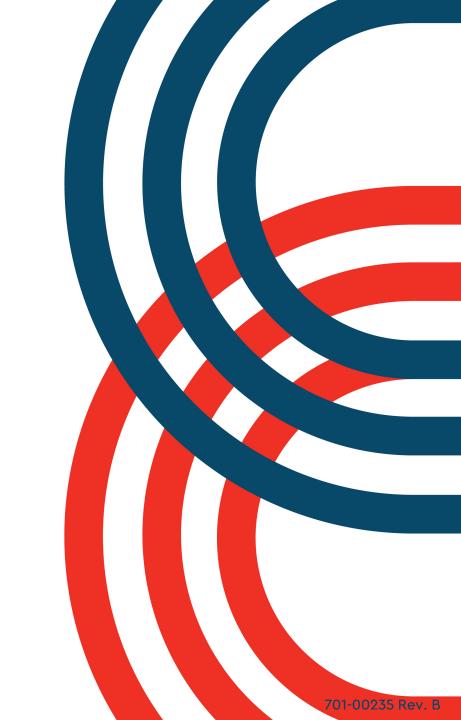
# CRITICOOL 6.3 OPERATIONAL TRAINING

# **UPDATED MAY 2020**







# INTRODUCTION

701-00235 Rev. B

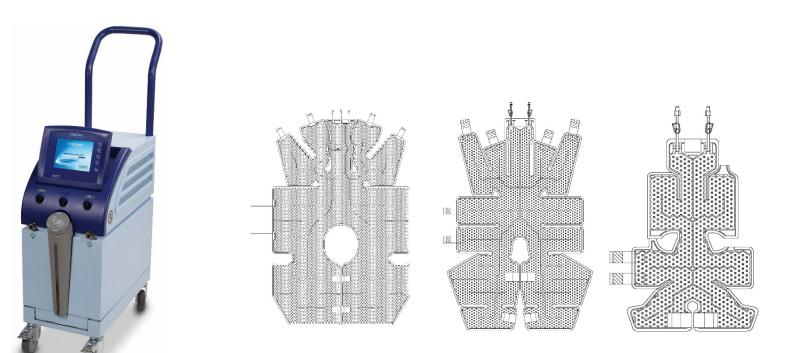
### **CRITICOOL® INDICATION FOR USE**



#### Indication for Use

 CritiCool is a thermal regulating system, indicated for monitoring and controlling patient temperature

#### **CRITICOOL PRODUCT FAMILY**



CritiCool<sup>®</sup> Control Unit

#### CureWrap<sup>™</sup> Garments

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### SIMPLE. PRECISE. EFFECTIVE.

#### TARGETED TEMPERATURE MANAGEMENT HAS NEVER BEEN EASIER



Select the desired temperature set point



WRAP Apply the CureWrap garment



COOL Initiate fast cooling



**REWARM** Manage controlled rewarming



### SIMPLE. PRECISE. EFFECTIVE.

#### Every 133 milliseconds

The control unit reads the patient's core temperature through specific probes every 133 milliseconds and adjusts temperature as necessary in order to maintain the physician determined pre-set temperature settings.

# Every 0.133 seconds

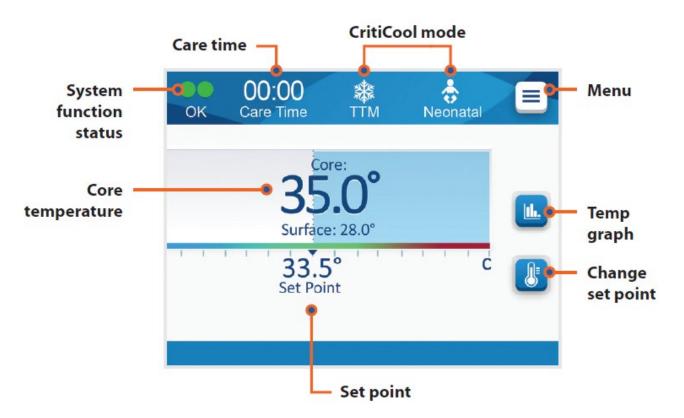


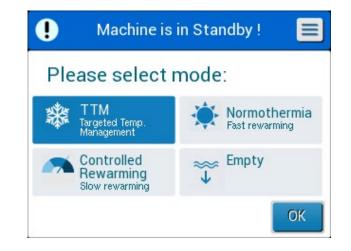
# Safe, Precise, and Effective ADVANCED TEMPERATURE MANAGEMENT

- Precise 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 set up
- Track data using the CliniLogger™



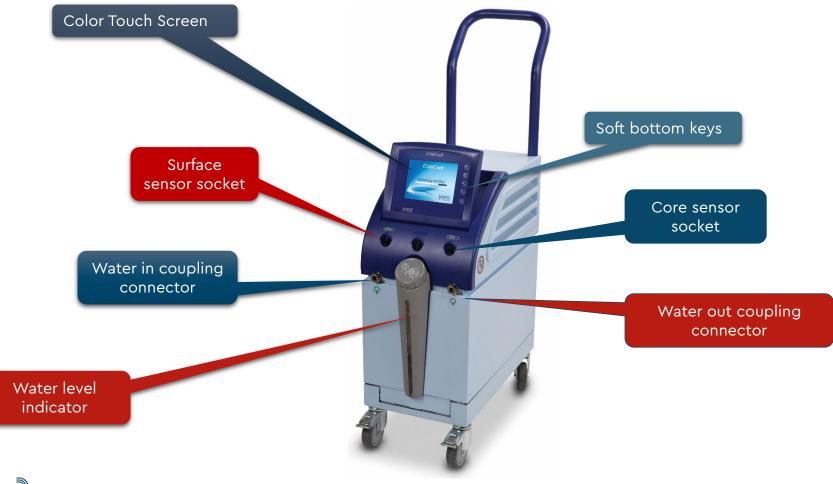
#### SIMPLE, EASY TO USE INTERFACE







#### **CRITICOOL CONTROL UNIT: FRONT VIEW**



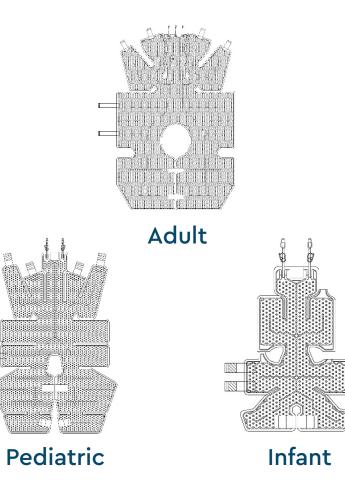
#### **CRITICOOL CONTROL UNIT: REAR VIEW**



10

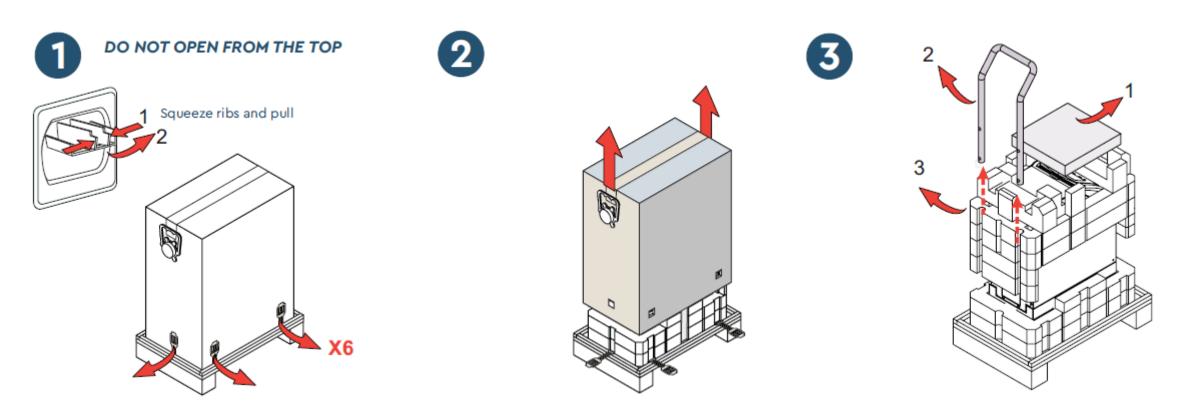
#### **CUREWRAP – SELECTING THE WRAP**

		Туре	Part Number	Number of Wraps per Package		Patient Height / Weight	Wrap Length / Width (m)
ize		Adult	508-03500	8		168-180 cm (Over 66")	2.030/1.354
	Single Size	Infant	508-03518	8		2.5 to 4 kg (5.5 to 8.8 lb)	0.659/0.448
Sin			508-03521	8		4-7 kg (8.815.5 lb)	0.698/0.602
	Pediatric Assortments	<b>Pediatric</b> (Small)	PEDSM008	8 (multi-size)	(x4) (x4)	2.5 to 4 kg (5.5 to 8.8 lb) 4-7 kg (8.815.5 lb)	0.659/0.448 0.698/0.602
, tric		<b>Pediatric</b> (Medium)	PEDMD008	8 (multi-size)	(x4) (x4)	7-11 kg (15.ք24.3 lb) 79-91 cm (3136")	0.981/0.628 1.118/0.740
Pedia		<b>Pediatric</b> (Large)	PEDLA008	8 (multi-size)	(x4) (x4)	91-104 cm (3641") 104-122 cm (4148")	1.225/ 0.841 1.390/1.054
		<b>Pediatric</b> (X-Large)	PEDXL008	8 (multi-size)	(x4) (x4)	122-135 cm (4853") Over 135 cm (Over 53")	1.582/1.119 2.030 /1.354



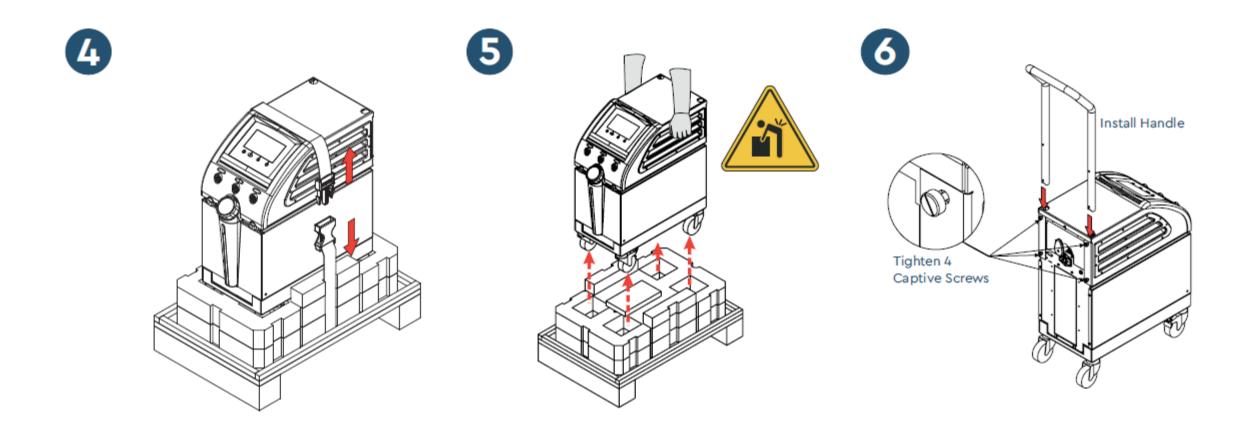
# SETTING UP CRITICOOL

#### UNPACKING CRITICOOL



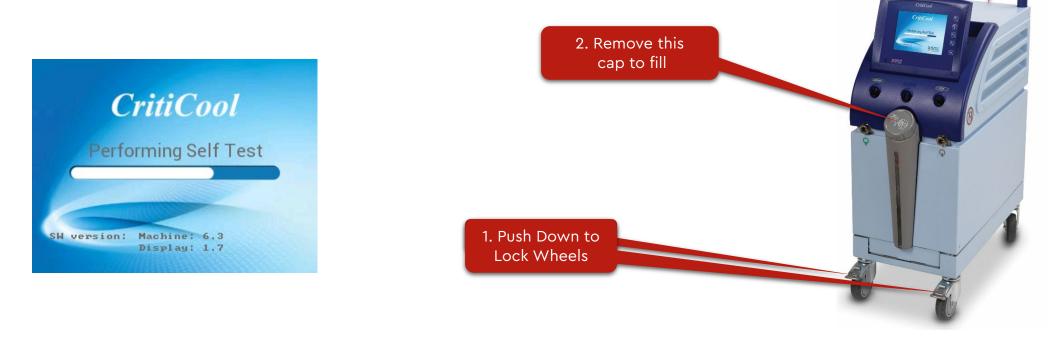
Keep the original box

#### UNPACKING CRITICOOL



### **STEP BY STEP: TTM – SETTING UP CRITICOOL**

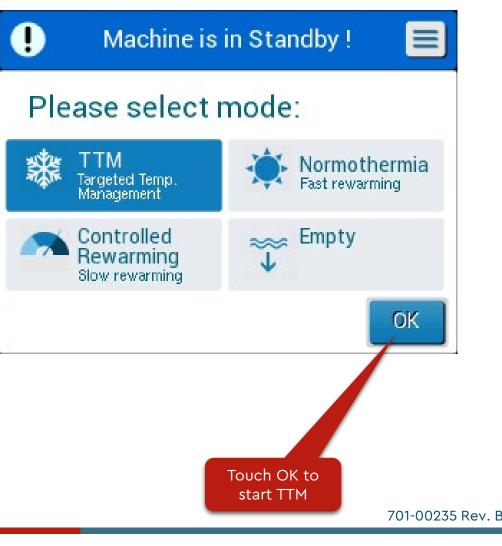
- 1. Place the CritiCool unit near the bed and lock the front wheels
- 2. Fill tank with sterile water or 0.22 micron filtered water (6.0L)
- 3. Power ON switch after a short Self Test, Mode Select screen appears



3. Power switch in the back

### **STEP BY STEP: TTM – SETTING UP CRITICOOL**

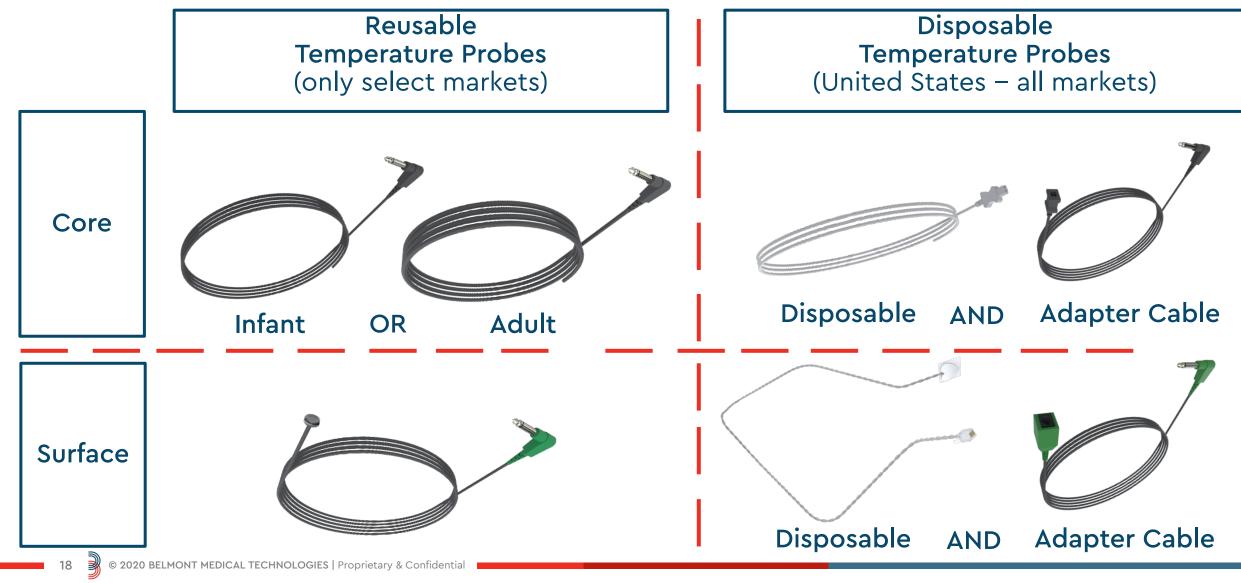
- 1. After self test is complete, the start up Mode Select screen appears.
- 2. Push **OK** to select **TTM** mode (default Mode)
- 3. CritiCool is now cooling and circulating the water internally



### **STEP BY STEP – SETTING UP CUREWRAP**

- 1. Place the appropriate CureWrap on the
  - bed or underneath patient
    - See CureWrap Instructions For Use

#### CHOICE OF TEMPERATURE PROBE TYPE



#### **STEP-BY-STEP: SETTING UP CRITICOOL**

#### For use with Disposable Probes:

• Connect **Core** cable to the **Core** socket and **Surface** cable to the **Surface** socket

SURFACE on left Green color coding

CORE on right Gray color coding

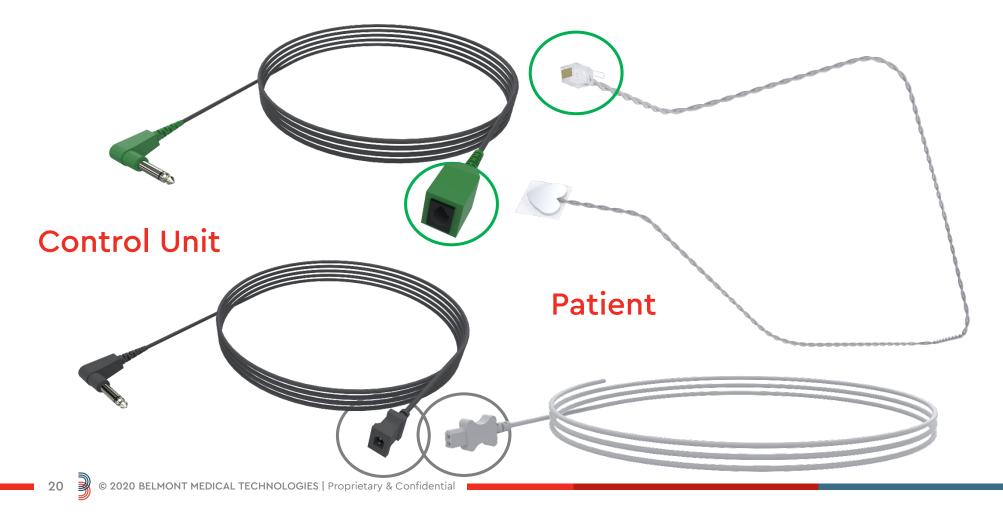




Cables shown above are representative only.

#### **STEP-BY-STEP: SETTING UP THE PATIENT**

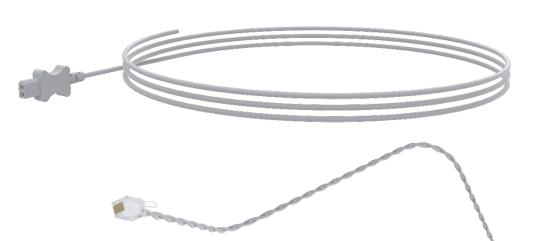
• Connect Core sensor to the Core Adapter Cable and the Surface sensor to the Surface Adapter Cable



# **STEP-BY-STEP: SETTING UP THE PATIENT**

Insert Core sensors into the patient and position the Surface sensor on the patient skin

- Core Probe Placement:
  - Rectal/esophageal
  - 014-00322 or 014-00220
- Surface Probe Placement:
  - Do not place skin sensor under the CureWrap
  - Neonates: often by clavicle
  - 014-00321



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# **STEP-BY-STEP: SETTING UP THE PATIENT**

- CritiCool cannot thermoregulate without a valid Core readout
  - Therefore, water will not flow into CureWrap until the core probe is connected to CritiCool and the core probe is attached to the patient.





#### **STEP-BY-STEP: SETTING UP CUREWRAP**

• Connect metal fittings on blue hose to metal fittings on the front of CritiCool

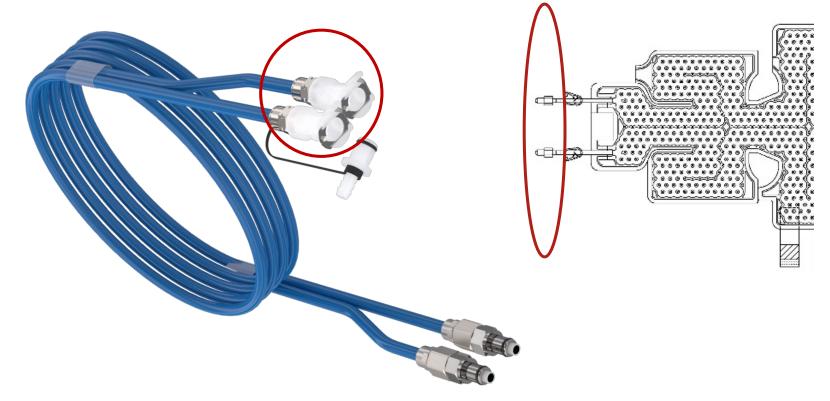




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#### **STEP-BY-STEP: SETTING UP CUREWRAP**

- Connect plastic ends of blue connecting water hoses to wrap.
  - Wrap should be filled with water prior to wrapping patient
  - Ensure clamps are OPEN



#### HOSES NEEDED FOR EACH CUREWRAP

	Туре	Part Number	Number of Wraps per Package	Patient Height / Weight	Wrap Length / Width (m)
Size	Adult	508-03500	8	168-180 cm (Over 66")	2.030/1.354
Pediatric Assortments	Infant	508-03518	8	2.5 to 4 kg (5.5 to 8.8 lb)	0.659/0.448
		508-03521	8	4-7 kg (8.815.5 lb)	0.698/0.602
	Pediatric (Small)	PEDSM008	8 (x4) (multi-size) (x4)	2.5 to 4 kg (5.5 to 8.8 lb) 4-7 kg (8.815.5 lb)	0.659/0.448 0.698/0.602
	Pediatric (Medium)	PEDMD008	9 (y4)	7-11 kg (15.524.3 lb) 79-91 cm (3136")	0.981/0.628 1.118/0.740
	Pediatric (Large)	PEDLA008	<b>e</b> (y4)	91-104 cm (3641") 104-122 cm (4448")	1.225/ 0.841 1.390/1.054
<	Pediatric	PEDXL008	8 (x4)	122-135 cm (4853")	1.582/1.119
	(X-Large)	FEBALUUO	(multi-size) (x4)	Over 135 cm (Over 53")	2.030 /1.354

# IF USING CUREWRAP 500-03500 (ADULT/PEDIATRIC XL):

#### Use the 2x3 Way Water Connecting Tubes

- The 2x3 way Connecting Water Hoses (200-00147) are needed for 500-03500
- 500-03500 is sold in two different boxes of CureWraps:
  - 508-03500 (includes eight 500-03500 CureWraps)
  - PED-XL008 (includes four 500-03500 and four 500-03548 CureWraps)
- 500-03500 has 3 connectors to the CureWrap.
- The 2x3 Way Hoses are included in all Adult Accessory Kits or can be ordered separately.



# IF USING A CUREWRAP OTHER THAN 500-03500:

Use the 2x2 Way Water Connecting Tubes

- The 2x2 way Connecting Water Hoses (200-00109) are needed for all wraps other than 500-03500.
- All wraps except 500-03500 have 2 connectors to the CureWrap.
- The 2x2 Way hoses are included in all Infant Accessory Kits or can be ordered separately.



#### **STEP-BY-STEP: TTM**

- The default Set Point (SP) Temperature is 33.0°C in Adult Mode
  - The Default Set Point temperature for Adult Mode can be adjusted in Settings
- The default Set Point (SP) Temperature is 33.5°C in Neonatal Mode

• If required, change the SP temperature by using the Set Point soft key on the screen



# SECURING THE CUREWRAP AROUND THE PATIENT

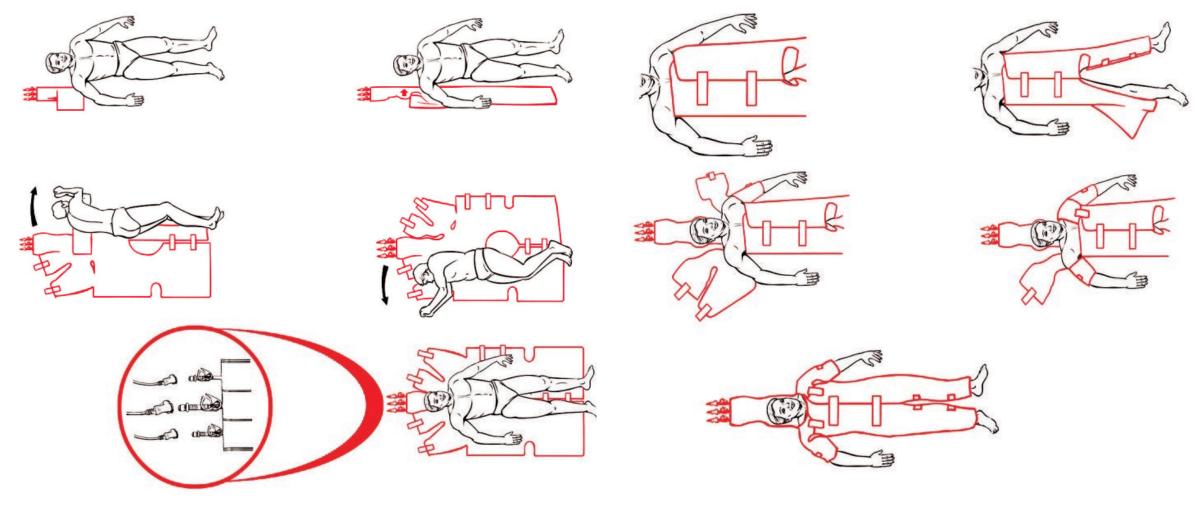
- 1. Confirm that CureWrap is filled with water
- 2. Secure CureWrap on the patient (see CureWrap Instructions For Use)

#### Note:

- Ensure clamps to the wrap are open
- Ensure CureWrap fits loosely; there should be a finger's width space
- Do not use the CureWrap to lift the patient
- Avoid handling the CureWrap with sharp objects
- Constant clicking sound may indicate water obstruction
  - Check to ensure the clamps are open and water is allowed to flow to CureWrap and that water is flowing



#### SECURING THE CUREWRAP AROUND THE PATIENT

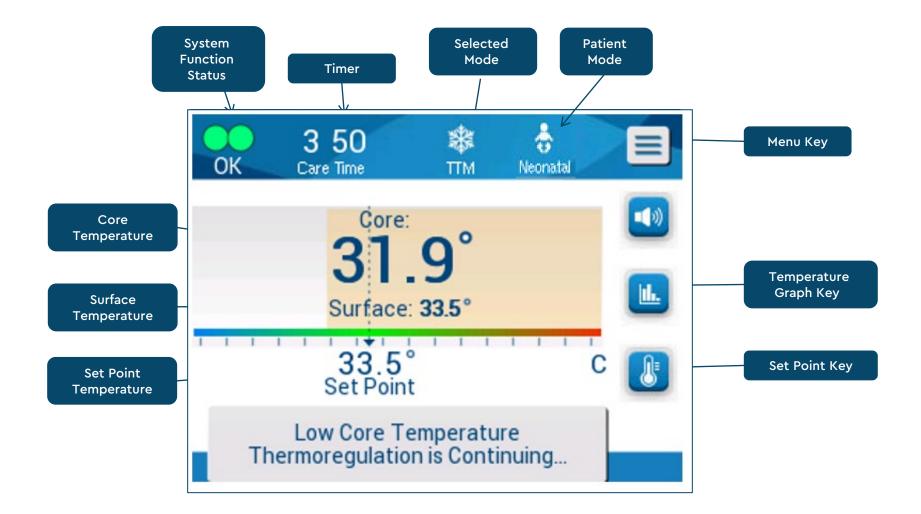


Model 500-03500 CureWrap shown

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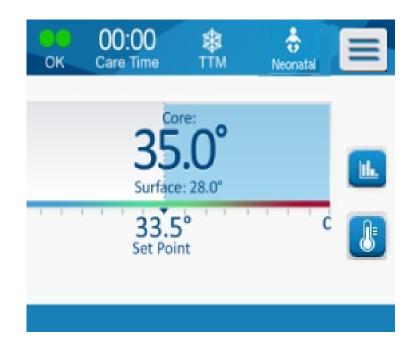
30

#### MAIN OPERATION SCREEN



#### **CRITICOOL TOUCHSCREEN**

#### **Touch Keys**



- 5.7" large operational touch-screen
- 5 soft keys
- Power soft key

#### Soft Button Keys



Main Menu / Escape



Alarm tone ON/OFF



Show graph / Up Arrow



Open Settings panel / Down Arrow



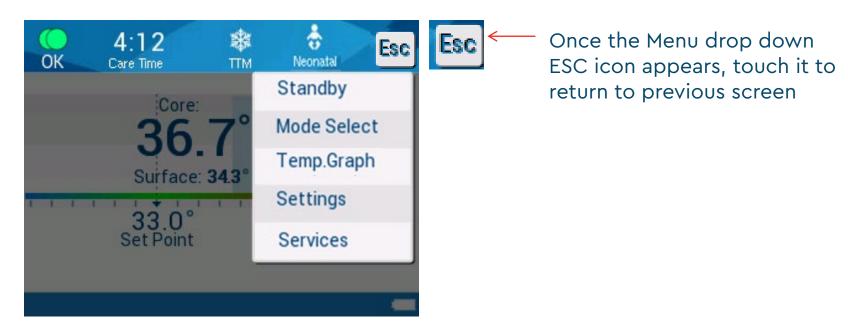
Accept changes

#### **MENU OPTIONS**

#### Touch the Menu Icon / Soft Button Key



Drop Menu will appear with the following options:



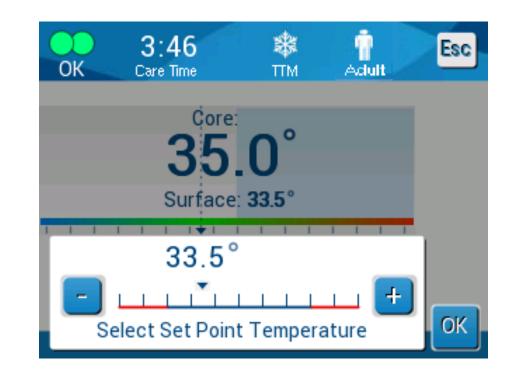
# SELECT SET POINT TEMPERATURE

#### Set Point = Patient's Target Temperature

- The CritiCool cools/warms the patient to reach and maintain the preset Set Point
- TTM default set-point:
  - 33.0°C for Adult Mode
  - 33.5°C for Neonatal Mode
- To change the Set Point:
  - 1. Touch the Set Point Icon/button
  - 2. Use +/- to select the desired Set Point
  - 3. Press OK to confirm





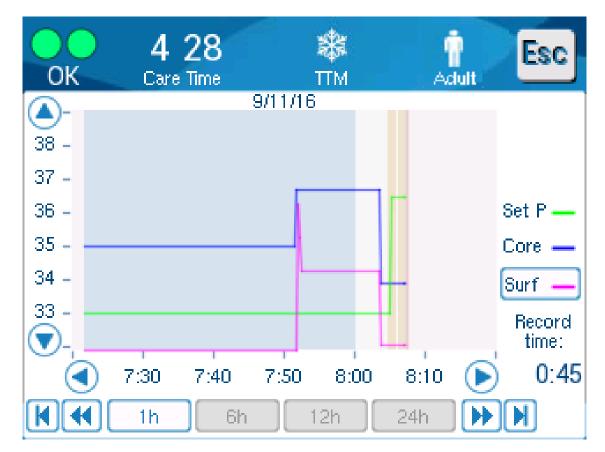


### TEMPERATURE GRAPH

- Use the Temp Graph icon / soft key to enter a Graphic Display of the current or last case temperature data
- CritiCool displays the current case temperature data
- 1 hour, 6 hours, 12 hours and 24 hours displays are available
- Last case data is saved until next patient is connected
- Press ESC to return to main screen

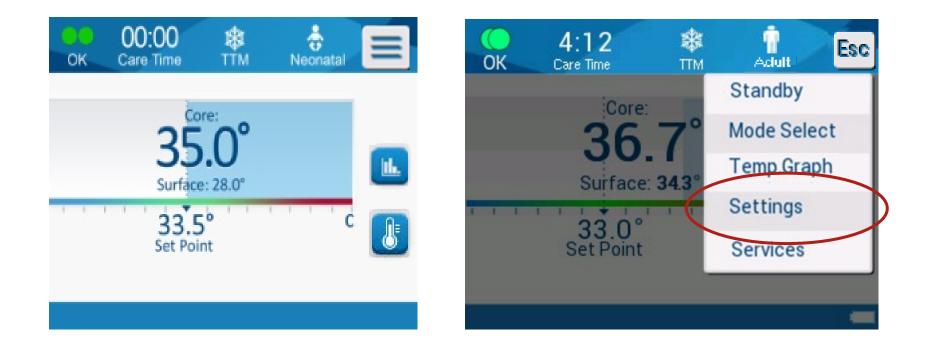






#### SETTINGS SCREEN – PASSWORD PROTECTED

• Password for the Settings Screen: \_\_\_\_ (Enter once trained; See slide 38)



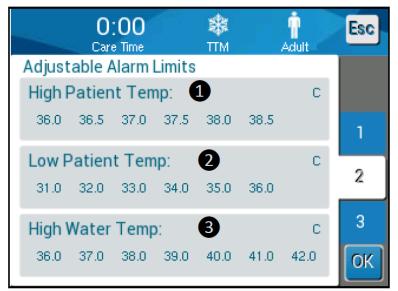
# SETTINGS SCREEN – PASSWORD PROTECTED

- There are Four Screens in the Settings mode
- Push OK to confirm and return to main screen
- The CritiCool keeps the last setting to the next power up
  - The default/last selection is highlighted

#### Screen #1 – General Settings



#### Screen #2 - Setting Alarm Limits

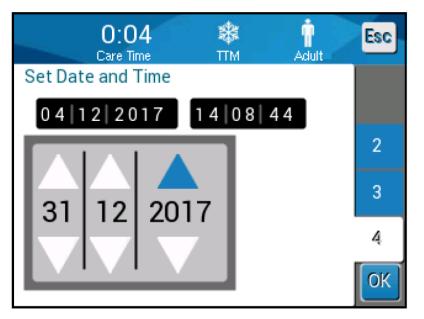


## SETTINGS SCREEN – PASSWORD PROTECTED

#### Screen #3 – Touch Screen ON/OFF



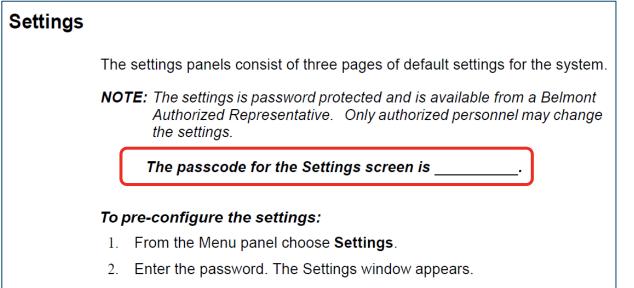
#### Screen #4 – Set Date and Time



# PASSCODE FOR SETTINGS SCREEN

### • Enter into:

- Settings section 4-18 in CritiCool User Manual
- Appendix A at the end of the CritiCool User Manual



3. Touch the page numbers to move between the pages.

#### APPENDIX A: Belmont Medical Technologies CUSTOMER SERVICE REPRESENTATIVE

WARNING!!! The following details are necessary to contact your Belmont Medical Technologies representative. Keep this form with the User Manual for ease in case your CritiCool<sup>®</sup> device is in need of service.

Representative Name:	
Company Name:	
Address:	
Telephone No:	
Fax:	
E-mail:	
CritiCool® Passcode	for the Settings Screen:

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# **STANDBY MODE**

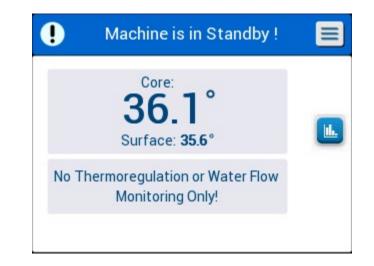
### To turn on Standby mode:

- 1. Touch **MENU** icon/button
- 2. Select Standby
  - $\circ~$  Water flow to the CureWrap will stop
  - CureWrap will deflate
  - CritiCool will continue to monitor patient's temperature (as long as core temperature probe in place)

### To resume thermoregulation:

- 1. Touch **MENU** icon/button
- 2. Select **OPERATE**
- Turn on Standby mode to stop the water flow to the wrap:
  - End of therapy, before disconnecting the CureWrap





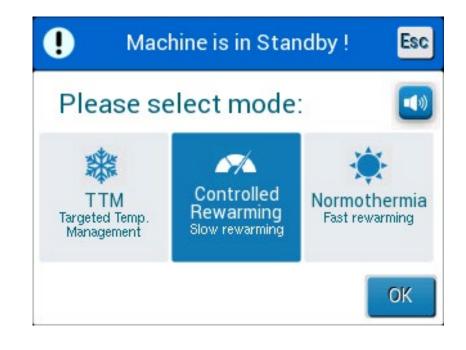
# **SELECT MODE**

### Mode Selection:

- **TARGETED TEMPERATURE MANAGEMENT (TTM)** The default mode for body thermoregulation
- **CONTROLLED REWARMING** Use this mode for slow re-warming
- NORMOTHERMIA Use this mode for fast warming and Normothermia Management

### To select/change a mode:

- 1. Touch the MENU icon/button
- 2. Select MODE SELECT
- 3. Touch the desired mode
- 4. Touch OK to confirm



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# TARGETED TEMPERATURE MANAGEMENT

### TTM – The default mode

- Use this mode:
  - To reach a preset set point
  - To maintain patient temperature
  - For manual re-warming

OK	3:42 Care Time	<b>ж</b> ПМ	
	Core <b>35</b> Surface	.0°	
1 1 1	33.5 Set Poin	t	C

# **CONTROLLED REWARMING**

An automatic patient re-warming mode with steps per hour that are preset according to the hospital protocol in the Settings screen

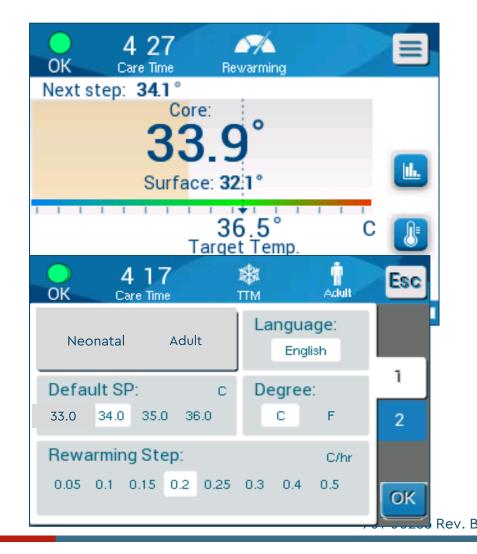
- 1. Select Controlled Rewarming and push OK to confirm
  - "Temperature Regulation Paused"
  - "Switching to AutoRewarm Mode" messages appear
  - While these messages appear, the Rewarming has not started yet!
- 2. Push OK to confirm Core temperature probe is in place and start the rewarming process





# **CONTROLLED REWARMING - CONTINUED**

- The CritiCool will reach the *Target Temp.* gradually by raising patient temperature according to the rewarming step per hour chosen in Settings
- Rewarming step per hour can be preset in the SETTING screen
- Rewarming step default: 0.2°C/hour
- Rewarming step range: 0.05-0.5°C/hour
- Target Temperature default: 36.5°C
- Target Temperature range: 30°C to 40°C
- Use the Target Temperature Touch/Soft Key to select a different target



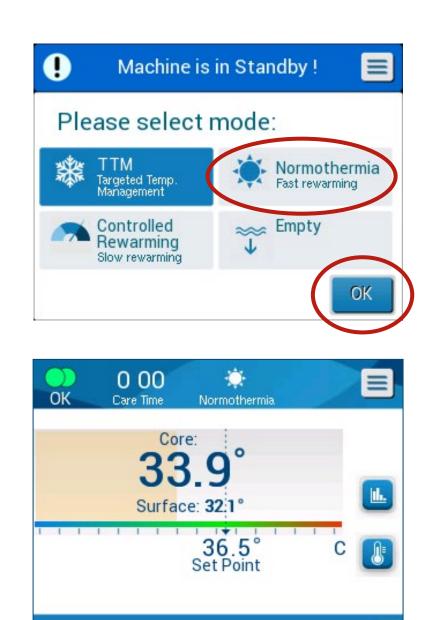
# NORMOTHERMIA MODE

• Select Normothermia for fast rewarming

#### Note:

- This mode is used for fast rewarming
- It has no rewarming steps
- Algorithm aims to bring patient to the target temperature as quickly as possible

 The CritiCool warms the patient to reach and maintain the selected *Set Point*

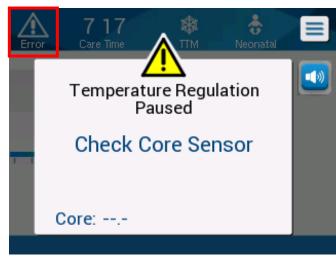


# MESSAGES AND TROUBLESHOOTING

# **MESSAGES & TROUBLESHOOTING**

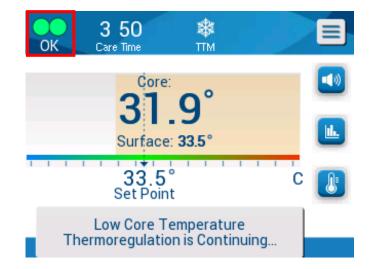
### The CritiCool uses two types of messages:

### **Error Message**



- o Alarm sound
- Error Message screen
- Troubleshooting guidelines
- Error icon is on

### **Informative Message**

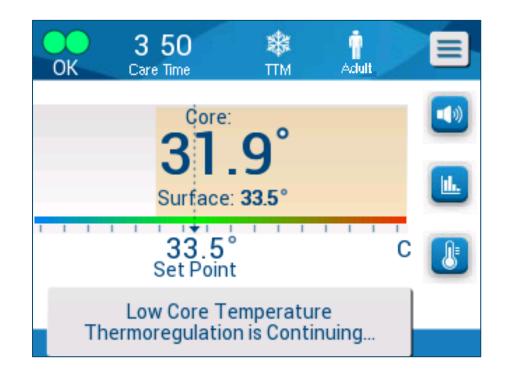


- o Alarm sound
- Operation screen
- Thermoregulation continues
- $\circ$  System function status is on  $\mathbb{R}$

# ALARM MESSAGE #1 (INFORMATIVE MESSAGE)

### Core temperature is 0.8°C to 2°C lower than Set Point

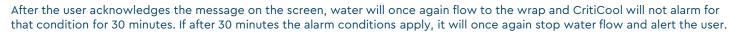
- Staff awareness to patient's core temperature is needed
- No other action is needed
  - $\circ$  Alarm sound
  - Operation screen
  - Thermoregulation continues
  - $\circ~$  System function status is on

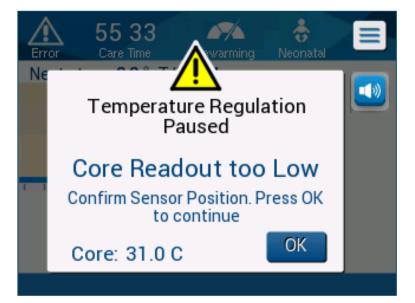


# ALARM MESSAGE #2 (ERROR MESSAGE)

Core Temperature is at least 2°C lower than Set Point or below 31°C, whichever happens first

- Thermoregulation Paused!
- Adult Mode:
  - Water flow only stops if Core Temp <31°C
- Neonatal Mode:
  - Water flow to CureWrap stops
- Check Core temp sensor position and fix if necessary
- Touch or to confirm Core temp. and resume thermoregulation





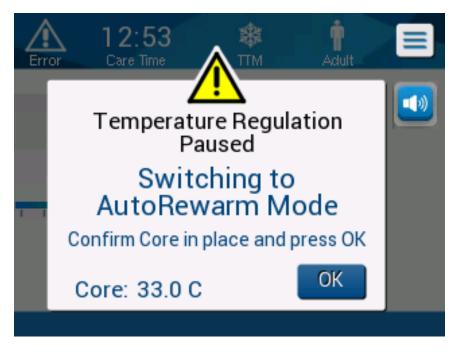
- o Alarm sound
- o Error Message screen
- Troubleshooting guidelines
- Error icon is on



# ALARM MESSAGE #3: THERMOREGULATION PAUSED

When Switching to Controlled Re-warming Mode Patient's Core temperature probe position should be confirmed to initiate the automatic process

- Check Core temp sensor position and fix if necessary
- Touch or to confirm Core temp. and Start Re-warming



- o Alarm sound
- Error Message screen
- Troubleshooting guidelines

• Error icon is on



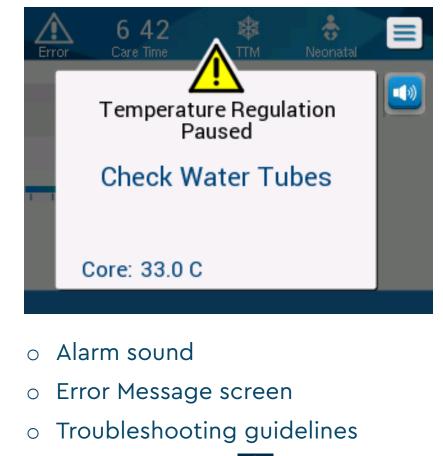
# **ALARM MESSAGE #4: CHECK WATER TUBES**

### Water flow to the CureWrap is interrupted

- Check the blue hoses are not kinked/bent
- Check that the blue hoses are flat near the CureWrap connections
- Check if the CureWrap is folded







• Error icon is on



# PRESSURE RELIEF ALGORITHM

- Initial Phase of Regulation: (when patient has yet to reach the target temperature)
  - 12 minutes of water flowing
  - 1 minute of no water flow
- Steady State: (begins when patient reaches the set point temperature)
  - 12 minutes of water flowing
  - 12 minutes of no water flow
- At Any Point:
  - Difference of >0.3°C between Set Point and Core Temperature will cause water to flow back into the wrap



#### CritiCool<sup>®</sup> Device

The CritiCool<sup>®</sup> device has a microprocessor that controls the water temperature flowing into the wrap 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 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.

# DIFFERENCES BETWEEN PATIENT MODES

	Adult Mode	Neonatal Mode	
Default Set Point	33.0°C	33.5°C	
Adjustable Default	Yes (in Settings Screen 1)	No	
Adjustable Default Options	33.0°C, 34.0°C, 35.0°C, 36.0°C	n/a	
>2.0°C between Set Point and Core Temperature stops water flow to the wrap	Only if patient core temp <31.0°C	Yes, always*	
Patient temp drops below 31.0°C	No water flow to the wrap	No water flow to the wrap	



\*After the user acknowledges the message on the screen, water will once again flow to the wrap and CritiCool will not alarm for that condition for 30 minutes. If after 30 minutes the alarm conditions apply, it will once again stop water flow and alert the user.

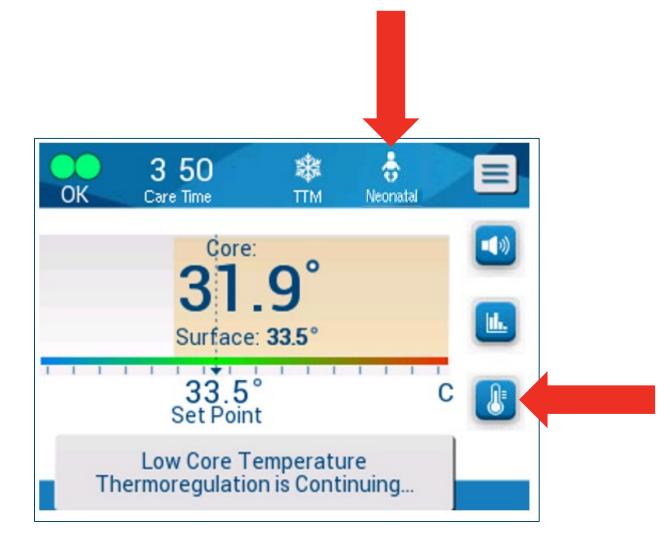
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# NEONATAL PATIENT MODE

- Default Set Point: 33.5°C (Set point temperature range: 30-40°C)
- To change the set point:
  - Press the thermometer key
  - Choose the desired temperature





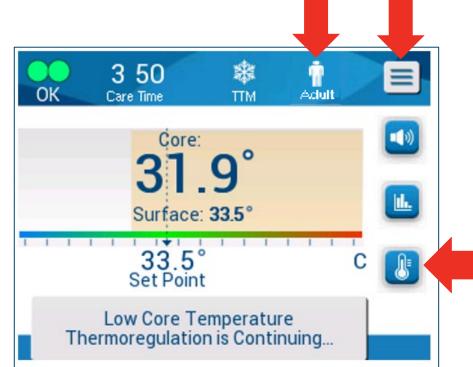
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# **ADULT PATIENT MODE**

- Default Set Point: 33.0°C
- To change the set point:
  - Press the thermometer key
  - Choose the desired temperature
  - Select OK

(Selection will not be default)





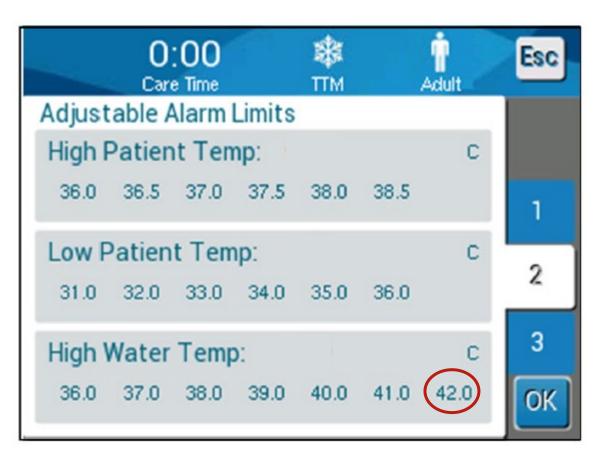
- To change the default set point:
  - Press the MENU button
  - Press Settings
  - Adjust Adult SP by choosing among: 33.0, 34.0, 35.0 or 36.0 (see #3 at right)
  - Select OK

(Selection will be default in future)



# WATER TEMPERATURE SETTINGS

- Water Temperature Range:
  - 13°C 40.8°C
- Alarms when water temperature is >42°C or <10°C</li>
  - Default high water temp alarm is 42°C
    - Keep it there
- Automatically stops flowing into wrap if water temperature >42°C
  - CritiCool turns off thermoelectric coolers (TECs) if water temperature >43°C (no water flow)
  - CritiCool shuts off if water temperature reaches 44°C with Halt 3 (no water flow)



# SOFTWARE V 6.3 PRODUCT UPDATES

- Alarm sound
- Muting alarms
- Icon for muted alarm
- Colors
- Power loss



To:





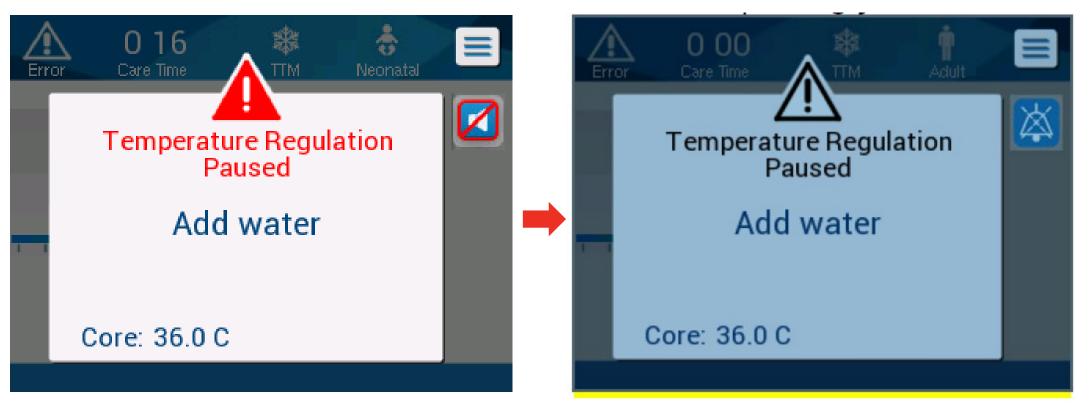
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#### 701-00235 Rev. B

Internal Use Only

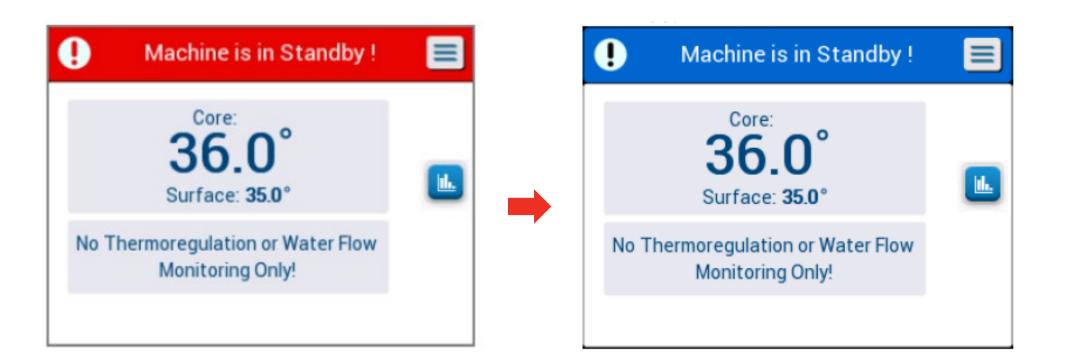
# SOFTWARE V 6.3 PRODUCT UPDATES

- Muted alarm icon
- Colors
- Power loss



# SOFTWARE V 6.3 PRODUCT UPDATES

- Muted alarm icon
- Colors
- Power loss



# **POWER INTERRUPTS**

CritiCool Versions
 6.2 and earlier:

CAUTION! Power interrupts affect the functionality of the system, depending on the mode of operation

Interrupts longer than 10 seconds return the machine to the Start-up Screen. A beep is heard when the power is returned to indicate that the machine has returned to the StartUp screen.
Interrupts shorter than 10 seconds return the machine to the mode that was operating before the interruption, but a warning will appear.

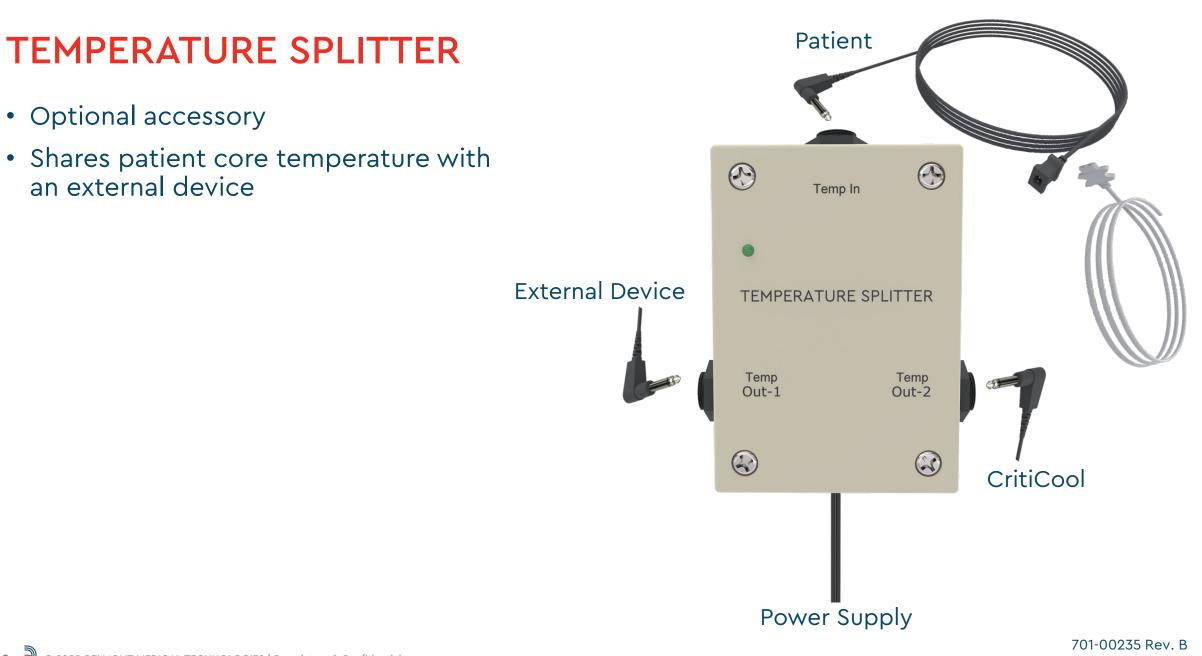
*IMPORTANT!* Make sure to read the messages in order to ensure correct reactivation of the machine.



 CritiCool Version 6.3 / After July 2020:

### CAUTION!

Power interruptions shorter than 10 minutes return the machine to the mode that was operating before the interruption with a 3 beep alarm.

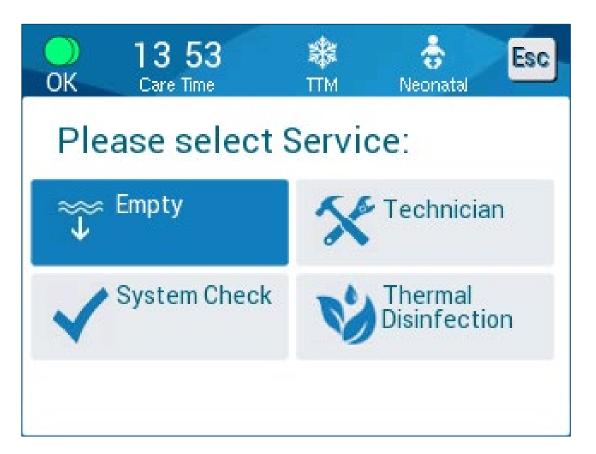


# MAINTENANCE

# **SERVICE SCREEN**

- Empty:
  - Use this mode to drain the water
- System Check:
  - An automatic system check (takes about 10 minutes)
- Technician:
  - A password protected screen for certified technicians
- Thermal Disinfection:
  - A password protected screen for certified technicians

# Reference the Service Manual for further instructions.

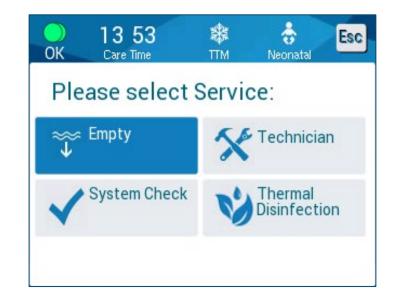


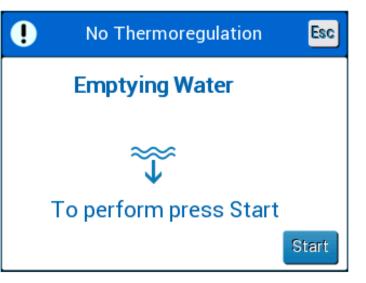
# **EMPTYING CRITICOOL**

- Select *Service* from the *MENU*
- Select *Empty* and touch *OK* to confirm
- Connect water hoses and make sure the draining plug is connected
- Place water out hose with inserted drain plug into a sink or water receptacle
- Touch *Start* and wait for the message:
   *"water tank is empty"*
- Clean and disinfect the machine and accessories as per the hospital protocol

Drain Plug







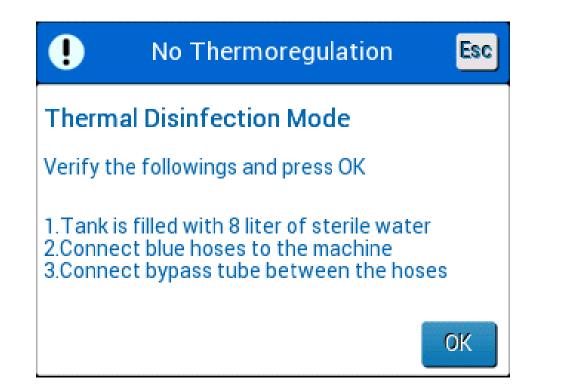
See user manual for complete instructions.

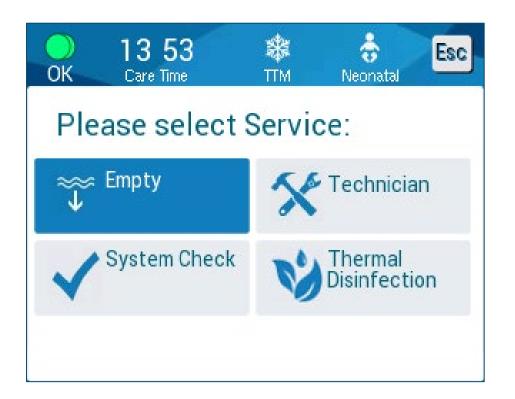
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# THERMAL DISINFECTION

### Thermal Disinfection is Password Protected

- Can only be accessed by a Belmont-trained Biomedical Technician





Internal Use Only

# CARE INSTRUCTIONS:

- Use only 0.22 micron filtered tap water or sterile water
- Before each use, clean surface of device according to instructions in the operator's manual
- After each use or between cases, drop sodium dichloroisocyanurate (NaDCC) tablets into the 6.0 liter (1.6 gallon) water tank as per the NaDCC manufacturer's instructions and run the machine for 30 minutes.
  - NaDCC is sold by many manufacturers
    - US market: Thermofisher Scientific and Sigma Millipore Aldrich
- Perform periodic maintenance once a year by a Belmont Medical Technologies or authorized trained technician only. As part of the annual periodic maintenance, a thermal disinfection cycle will be performed.

# AFTER USE CLEANING

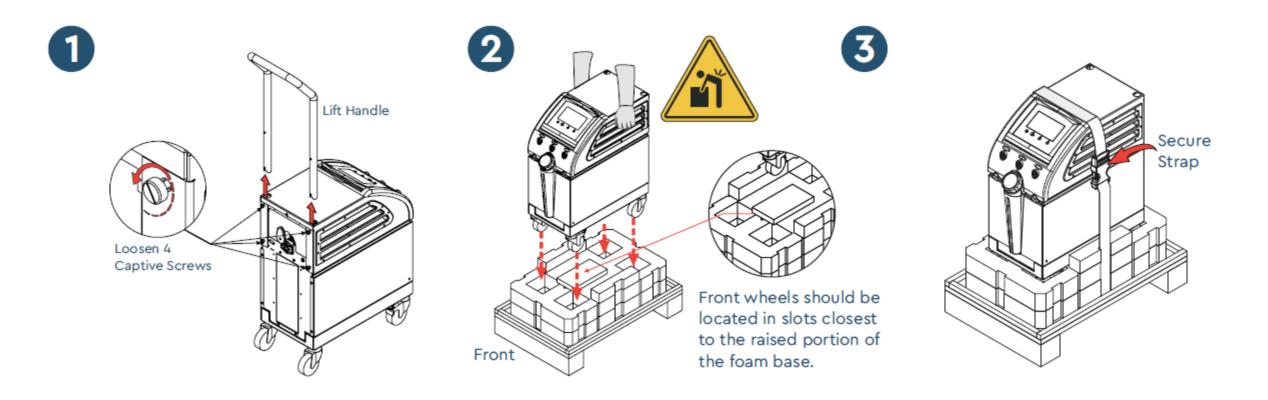
#### After each operation:

- 1. Make sure that the system is turned off.
- 2. Close the clamps on the garment.
- 3. Remove the garment from patient and disconnect from machine. Dispose the garment.
- 4. Disconnect the temperature sensors from patient and machine:
  - If they are Disposable Sensors: Dispose of the sensors.
  - If they are Reusable Sensors: They should be cleaned and disinfected/sterilized:
    - $\circ$   $\,$  Cleaning: Clean the probes with a mild detergent and water.
    - Disinfection: Probes can be disinfected with Alcohol 70% or activated dialdehyde.
    - After cleaning and/or disinfection: the probes should be thoroughly rinsed with water.
    - $\circ$   $\;$  Sterilization: Probes can be sterilized with Ethylene oxide. Do not autoclave.
- 5. Drop sodium dichloroisocyanurate (NaDCC) tablets or powder into the 6.0 liter (1.6 gallon) water tank as per the NaDCC manufacturer's instructions and run the machine for 30 minutes.
- 6. Drain water from water tank (refer to the operator's manual for detailed instructions)
- 7. Disconnect the Hoses from the machine.

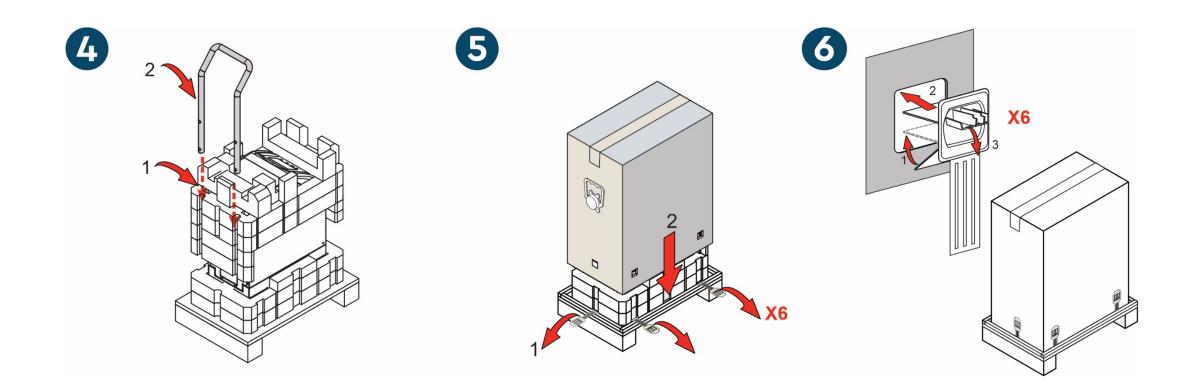
8. Clean the hoses with Ready To Use wipe with Alcohol/ Quaternary Ammonium Compounds (QAC) and store them in a cool and dry place.

- 9. Clean the external surfaces of the machine:
  - Remove any soil or hard dirt with a dry cloth.
  - Gently clean with a Ready To Use wipe or a cloth soaked in alcohol/ Quaternary Ammonium Compounds (QAC) over the machine.
  - Gently wipe the screen. Do not put physical pressure on the screen.
  - After cleaning let the system dry for 10 minutes.

## PACKING CRITICOOL FOR SHIPMENT



## PACKING CRITICOOL FOR SHIPMENT



# **IMPORTANT POINTS**

- Use sterile water or 0.22 micron filtered water only
- The CritiCool cannot thermoregulate without a valid Core readout
- CureWrap should be filled with water prior to wrapping and securing on patient
- CureWrap should stay one finger loose on the patient
- Do not use the CureWrap to lift the patient
- Avoid handling the CureWrap with sharp objects





#### **TECHNICAL SUPPORT**

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# THANK YOU



