

Version 6.3

TARGETED TEMPERATURE MANAGEMENT: CritiCool® Infant Step-by-Step Indication for use: CritiCool is a thermal regulating system, indicated for monitoring and controlling patient temperature Fill the water tank with sterile water / 0.22 micron filtered water 1. CRITICOOI 2. Place the CritiCool unit at the desired location and lock the front wheels Power ON the system. After a short Self-Test, a "Select Mode" screen 3. appears. The water inside CritiCool will begin to cool. Select and place the appropriate CureWrap® on the bed or underneath patient (see CureWrap Instructions for Use) 4. • Ensure the CureWrap clamps are OPEN • Do not secure the wrap on the patient yet! Connect Core cable to the Core socket on the right and Surface cable to the Surface socket on the left of the system, matching colors, gray to gray and 5. green to green, and then plug the temperature probes into the appropriate adapter cables. Attach the Core and Surface temperature probes to the patient 6. • Do not place Surface temperature probe underneath the CureWrap • CritiCool cannot thermoregulate without a Core readout 34:11 鱳 Connect water hoses to the wrap and to the CritiCool device 7. • Water automatically starts to flow into the wrap Core 33.5° Return to the touch screen. TTM is the default mode and is already 8. highlighted. Touch **OK** to select TTM. <u>L.</u> Surface: 32.9° The default Set Point (SP) Temperature is 33.5°C. If required, change 33.5° Set Point 9. the Set Point by using the Set Point key: Wait until the CureWrap is filled with water - When filling is complete, 10. secure the CureWrap to the patient (see CureWrap Instructions for Use) Thermoregulation with CritiCool has now begun.

Note: It is normal to see slight fluctuations in the patient's temperature as a physiological response.

CONTROLLED REWARMING

The patient's temperature is gradually increased every hour by a pre-set step.				
1.	Choose Select Mode from the drop-down menu on the upper right side of the screen	Machine is in Standby ! Esc		
2.	Select Controlled Rewarming mode and touch OK to confirm	Please select mode:		
3.	 "Switching to AutoRewarm Mode" message appears As long as this message appears, the Rewarming has not started yet! 	TTM Tropted Temp. Hemagement		
4.	Confirm that the Core temperature readout is valid, touch OK and start the rewarming	ок		
The patient's temperature will now begin to rise gradually to the required Target Temperature. • The CritiCool rewarming Target Temperature default is 36.5°C		Coro 55 34 M Acoust		

- The CritiCool rewarming Target Temperature default is 36.5°C
- The user can select Target Temperature between 30°C and 40°C using the Target Temperature Key (See user manual instructions)
- A Rewarming step (per hour) should be pre-set according to the clinical protocol

CritiCool uses a default Rewarming step of 0.2°C/hour



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OK

Paused

Switching to AutoRewarm Mode

Confirm Core in place and press OK

ore: 31.2 C



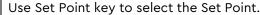
CRITICOOL® Infant Step-By-Step Guide

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MANUAL REWARMING

The user can manually increase the patient's temperature gradually.

1. The user increases the Set Point temperature manually, as per the rewarming protocol, until the target temperature is achieved.



• Note: It is recommended to raise the Set Point temperature in steps of 0.2°C-0.3°C per hour



MESSAGES

2.

"Core Readout too Low"					
Trigger:	Core reading is at least >2.0°C below Set Point				
Indicates:	This message may indicate wrong placement of the Core temperature probe				
Impact:	The system will stop the water flow to the CureWrap and halt thermoregulation!				
If the message appears:	 Check that the core temperature probe is correctly inserted into the patient and that the temperature reading is valid Reposition the Core temperature probe if needed Then touch OK to confirm Core temperature reading In Controlled Rewarming, it is especially important to ensure the core temperature reading is correct BEFORE pressing the OK button. If the OK button is pressed before confirming the core temperature is correct, thermal regulation algorithms may be affected. Thermoregulation will continue and the screen will return to TTM mode. Note: If the system continues to measure low Core temperature, this message will be repeated every 30 minutes. 				

MESSAGES

"Low Core Temperature. Thermoregulation is Continuing"					
Trigger:	If the difference between the patient's Core temperature and the Set Point is >0.8°C but <2.0°C	● 0.29 *			
Indicates:	This message may indicate wrong placement of the Core temperature probe	31.9°			
Impact:	Thermoregulation continues	Surface: 33.5°			
If the message appears:	 Check that the core temperature probe is correctly inserted into the patient. Keep following the patient's temperature. 	33.5° C C Low Care Temperature Thermoregulation is Continuing			

AFTER USE CARE: Before storage, or at least once a week

 Change the system mode to Standby. After waiting a few seconds, close the clamps on the CureWrap and detach the CureWrap and probes from the patient. Drop NaDCC into the water tank per NaDCC manufacturer recommendations and run for 30 minutes in Standby Mode.
 Empty the water tank: Select Empty from the Services menu (see User Manual for instructions). CritiCool will alert you when the tank has emptied.
 Clean and disinfect CritiCool according to hospital routine care.

*This document does not replace the requirement to read the entire CritiCool 6.3 user manual.



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