

Guideline

Use of the CritiCool Mini for active cooling during neonatal transfer

1 Scope

For use within the Paediatric and Neonatal Decision Support and Retrieval Service (PaNDR) for the East of England.

2 Purpose

To ensure the safe and proper use of the CritiCool Mini for active cooling during transfer.

3 Definitions and abbreviations

CPAP - Continuous Positive Airway Pressure CUH – Cambridge University Hospitals
HIE – Hypoxic Ischaemic Encephalopathy NICU – Neonatal Intensive Care Unit
TTM – Targeted Temperature Management

4 Undertaken by

The guideline is to be used by members of the PaNDR team – qualified nurses, Advanced Neonatal Nurse Practitioners and doctors who have successfully completed their Criticool Mini competency.

5 Use of the CritiCool Mini

The CritiCool Mini is to be used for actively cooling neonates who have met criteria for moderate-severe HIE. Assessment and decision to commence active cooling is in consultation with the covering PaNDR Consultant.

6 Equipment List

Non-disposable components	Disposable consumables
CritiCool Mini	CureWrap mattress (2.5-4 kg or 4-7kg)
Water hoses (blue)	1L bottle sterile water
Surface temperature adaptor cable (green)	Skin temperature probe with reflective sticker
Core temperature adaptor cable (grey)	Rectal probe
	Steri-strips, Duoderm, Tegaderm

7 Filling the CritiCool Mini

The CritiCool Mini cannot complete any Self-Test without a filled water tank. Therefore, the CritiCool Mini will remain pre-filled with water to allow for Self-Test to be completed at the start of each shift. Water will be changed weekly if not used, plus after transfer of any cooling babies.

The tank capacity is 1.2L however the device will ordinarily work when filled with 1L. Fill the water tank with 1L sterile water, then close the water tank cover.

It is important to never fill the CritiCool Mini whilst the device is actively delivering therapeutic hypothermia/normothermia. If the device requires a top up of water whilst in use, it should either be off or in standby mode. If in standby mode, there should be a short period of time (one to two minutes) to allow the mattress to drain back into the water reservoir before adding water, otherwise there is a risk of overfilling the device.

8 Testing the CritiCool Mini at the start of each shift

Ensure that the CritiCool Mini is plugged in, confirmed by a solid bright green light illuminated underneath the on/off button. In addition, a solid pale green light demonstrates that the battery is fully charged, and a blinking pale green light demonstrates that the battery is charging (*see Figure 1 on next page*). Hold down the on/off button at the lower right front of the unit. The Self-Test panel is displayed, and an alarm is automatically activated. If Self-Test is successful, the main menu will appear, and the device can be turned off again until used on a transfer.

If the Self-Test discovers an issue that may impact operation, (e.g. an issue with the pump or the motherboard), a Halt Error will occur. In this case, turn off the system, wait at least ten minutes, and then power on the system again. If the Halt Error reappears upon startup, the CritiCool Mini must be removed from service, a Datix submitted with the equipment number and name of the error provided, and the device should be reviewed by Belmont.



- | | |
|-------------------------|--|
| 1. Display touch screen | 8. Surface sensor socket |
| 2. Functional buttons | 9. Core out temperature |
| 3. On/off button | 10. Water-in quick coupling connector |
| 4. Battery indicator | 11. Water-out quick coupling connector |
| 5. AC indicator | 12. Water level indicator |
| 6. Speaker | 13. Water tank cap |
| 7. Core sensor socket | |

Functional Button					
Description	Main Menu / Escape	Show Graph / Change Graph Parameters	Alarm Tone on/off	Open Setting Panel / Change Setting	Accept Change

Figure 1 – External Features of the CritiCool Mini and functional buttons

9 Setting up the CritiCool Mini prior to use

Hold down the on/off button as described previously. Following a successful Self-Test, the system automatically starts to cool the water through internal circulation. It is highly recommended to turn the CritiCool Mini on now to allow the water to cool whilst securing the remaining equipment. Do not select any mode yet until all required equipment is in place.

If the baby is being passively cooled or is receiving active cooling via a device other than a CritiCool, then the following steps must be undertaken;

- 1) Attach the disposable skin temperature probe to the baby's anterior shoulder, securing with either the reflective sticker provided or a gold teddy sticker. Insert a lubricated disposable rectal temperature probe 3-6cm into the baby's rectum, securing to the thigh with Duoderm, Steri-Strips and Tegaderm.
- 2) Two sizes of CureWrap mattress are available – 2.5-4kg or 4-7kg. Use clinical judgement to choose an appropriate size rather than focussing solely on weight, as the mattress should be a loose fit. Take the mattress out of the packaging and place it underneath the baby **textured side touching the baby with the clamps at the head end**. Secure the mattress around the

baby's abdomen and legs using the Velcro strips provided. There is no need to secure the wrap around the head. Ensure there is 2-3 fingerbreadths between the mattress and baby (*see Figure 2*), as the mattress will later fill with water. You may position the mattress in a way to ensure that any umbilical lines are visible. Note – a muslin is no longer required to be placed between the mattress and baby, as the CritiCool Mini system has an automatic pressure relief function that occurs every 12 minutes of operation.

- 3) Lock the water hoses (**blue**) into the Quick Coupling Connectors, ensuring the hose marked with tape is inserted into the Water Out connector. Verify that a clicking sound is produced on locking, lightly tug the hoses towards you to ensure they are secure, then connect the water hoses to the mattress. Insert the core temperature (**grey**) adaptor cable into the right socket labelled "Core", then connect the rectal probe to the adaptor cable. Insert the surface temperature (**green**) adaptor cable into the middle socket labelled "Surface", then connect the skin temperature probe to the adaptor cable. The left "Core Out" socket is currently not being used (it is designed to connect the CritiCool Mini to the monitor).



Figure 2 – Mattress has been secured with 2-3 fingerbreadths to allow room to fill with water, keeping umbilical lines visible.

If the baby is being actively cooled via a referring unit's own CritiCool, you may use the existing mattress, rectal and skin temperature probes. Ensure the placement of all of these is appropriate. If using a referring unit's consumables you **must** enter Standby Mode on the referring unit's device and clamp the mattress before swapping consumables over to PaNDR's device. Transferring the mattress across without clamping or entering Standby Mode will cause a large spillage of water. Further details can be found in section 14.

10 Commencing active cooling

Select "Targeted Temp Management (TTM)" from the touchscreen (see Figure 3), then select OK. The mattress will then start to fill with water. The default set point temperature during TTM is 33.5°C, there is no need to change this.

The core temperature, surface temperature and set point temperature are displayed on screen (see Figure 4). These should be documented in the Epic Flowsheets every 30 minutes in the referring/receiving unit, and every 15 minutes in the ambulance. To document the mattress temperature, press the Graph icon (circled red), click on "WOut" to activate this on the graph, and measure the black line labelled "WOut" – this is the temperature of the water being delivered to the mattress. Due to there being no numerical value to read, documentation of the water out temperature is not required during the ambulance journey.



Figure 3 – Mode Select screen post-startup.



Figure 4 – TTM Mode screen.

11 Commencing normothermia mode

If it has been decided between the clinical team, PaNDR Consultant and the baby's family that care should be redirected to palliative care, and the baby is currently being actively cooled, you may press the Menu icon (circled green, Figure 4), then select "Mode Select" followed by "Normothermia". This will accelerate the baby's rewarming process to facilitate palliative care, and the default set point temperature is 36.5°C. Do not use "Controlled Rewarming" – this is a slower process that is not to be used for transport purposes.

12 Nursing the baby in the transport incubator

If the baby is on respiratory support (ventilated, CPAP or high flow) turn the transport incubator off. If the baby is on no respiratory support, or low flow nasal cannula O₂, set the incubator to its lowest heat setting to ensure air flow is maintained through the incubator.

Ensure that the water hoses, core and surface cables are threaded underneath the incubator so that they cannot get caught, kinked or trapped during transfer.

13 Moving the CritiCool Mini from mains supply to battery power

The CritiCool Mini has a battery backup that, if fully charged, will continue operation for up to an hour when not connected to mains power. Battery use is confirmed by a solid orange light illuminated underneath the on/off button. Please ensure that the CritiCool Mini is kept plugged in in the PaNDR clinical room, neonatal units when on transfers and the ambulance to ensure there is sufficient power to continue active cooling via the battery backup when moving between these areas. If power does not return within an hour of battery backup being activated, the system will shut down. An empty battery takes six hours to recharge. The return of power after shutdown will activate the system to default settings, irrespective of the mode prior to shut down.

14 Emptying the CritiCool Mini after transfer

The wrap must be emptied of water on arrival to the receiving unit. This is to prevent spillage of water, irrespective of whether the wrap is going to continue to be used by a receiving unit or not. On arrival to the receiving unit, press the Menu icon, select "Standby" then select OK. Water will drain from the mattress back into the device via gravity when in Standby mode. After a few minutes, the mattress can be clamped. If transferring to a unit that also uses CritiCool – such as CUH – the wrap may be reconnected to the receiving unit's device, unclamped, and TTM continued.

If transferring to a unit that does not use CritiCool, once the baby has been transferred to the receiving unit's incubator, and the mattress has drained of most of the water, disconnect the wrap and dispose of as per local unit policy.

The water reservoir of the device must then be emptied of water. Connect the drainage connector to the "water out" hose marked with coloured tape. Direct the hose to an appropriately sized container. Press the Menu icon, select "Services", then select "Empty" from the Services options. Once you are ready, select "Start". Once the system has been completely emptied, a message will appear stating this is complete. You may stop the emptying process midway through if required. If you attach the drainage connector to the incorrect hose, the emptying process will not work, although water may still drain as a result of gravity. Switch the drainage connector to the correct hose.

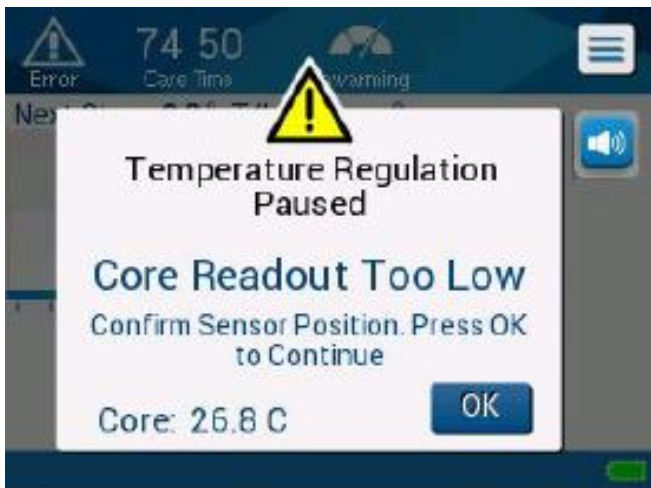
15 Cleaning the CritiCool Mini

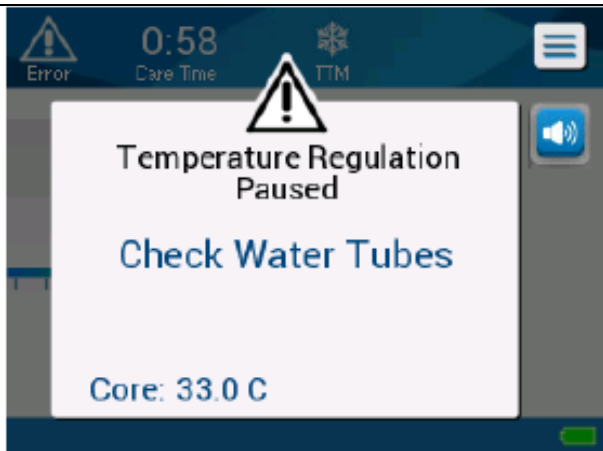
During equipment checks at the start of the shift, damp dusting of the transport incubator including the external surfaces of the CritiCool Mini should continue as per standard practice. This can be done with Clinell wipes.

After use, the CritiCool Mini external surfaces, the water hoses (**blue**), surface temperature (**green**) adaptor cable, and core temperature (**grey**) adaptor cable should be cleaned with Clinell wipes. This can be done either in the receiving unit if proceeding on to another transfer, or in the CUH NICU sluice once the team has returned to base.

Every 3 months, the CritiCool Mini should go through the disinfection and flush process outlined in Appendix 2.

16 Appendix 1 - Troubleshooting common Error messages

Message	Troubleshooting
	There are two likely scenarios when this message is displayed. The most likely is that the rectal probe has displaced. You must ensure the rectal probe is appropriately sited when this message appears. If displaced, please replace the probe and the message will automatically cancel. Do not press OK if the rectal probe has displaced, as this will cause the device to start warming the baby inappropriately. If the rectal probe has not displaced and is appropriately sited, it may be possible that the baby is/has become severely hypothermic. Press OK and the CritiCool Mini will start to rewarm the baby back to the set point temperature (33.5°C).

	The water tank requires topping up. The CritiCool Mini must be turned off or put into Standby mode before adding water otherwise the system can overflow.
	Check there are no kinks in the water hoses or the tubes connecting the hoses to the mattress.

17 Appendix 2 – Disinfection and Flush process

1. REQUIRED TOOLS FOR DISINFECTION				2. DISINFECTION FREQUENCY
A.	CritiCool® MINI Disinfection Kit (P/N 405-00021) includes:			Prior to First Use
	2-Connector Bypass Tube		P/N 200-00181	At Least Once Every 3 Months
	Temperature Simulator		P/N 017-00245	
B.	PPE (Personal Protective Equipment) per the NaDCC tablet manufacturer's instructions.			Before Long-Term Storage (>3 Months)
C.				Before Use Following Long-Term Storage (>3 Months)
Sodium Dichloroisocyanurate (NaDCC) tablets in the recommended concentration (As indicated in Table 1)				
D.	Hospital-grade disinfecting wipes			<i>NOTE: Disinfection can be performed more frequently if the hospital protocol dictates.</i> <i>NOTE: If a patient, clinician, or biomatter comes in contact with the water circuit disinfect immediately after.</i>
E.	Sterile water / 0.22µm filtered water (approximately 2 Liters total) <i>NOTE: Do not use de-ionized water or water created through reverse osmosis as it may promote corrosion of the metal components of the system.</i>			

Table 1

Tablets needed to achieve at least a 5382 ppm concentration of NaDCC		
PurTabs® (3.3g)	Klorsept® 17 (3.4g)	Aquatabs® (1.67g)
6 Tablets per 1 L of water	6 Tablets per 1 L of water	6 Tablets per 1 L of water

3. DEVICE PREPARATION AND DISINFECTION

A.		Ensure the device is powered OFF. Check the water tank level. Add room temperature sterile or 0.22µm filtered water until the water level is approximately 1.5 cm from the top of the fill indicator to ensure the machine has 1 L. <i>NOTE: Alternatively, you can prepare this disinfection solution in a separate container per the NaDCC tablet manufacturer's instructions.</i>
	B. PPE Required	Use the appropriate PPE per the NaDCC tablet manufacturer's instructions for use.

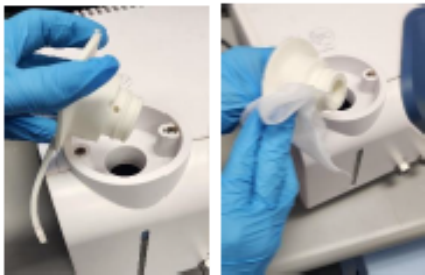
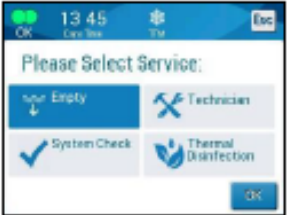
	Add NaDCC	Remove the cap from the device's water tank. Procure the appropriate NaDCC tablets and add 6 tablets to the device's water tank per <i>Table 1</i> . NOTE: Do not disinfect the water circuit near the area of care.	
C.		Allow the tablets to dissolve for 15 minutes. While tablets are dissolving, perform the remaining steps in Step C. NOTE: Do not leave the dissolved tablet solution stagnant in the device's water tank for more than 20 minutes.	
	2-Connector Bypass	 Wipe clean the cap with hospital-grade disinfecting wipes, then reattach the cap.	
	 P/N 200-00181		
D.	Plug in the device, power it ON, and allow the Self-Test to complete.		
E.		Select and operate the device in Normothermia mode. Set the patient setpoint to 37°C.	
F.		Plug the temperature simulator (P/N 017-00245) into the Core temperature socket on the front of the device and set it to 36.0°C ±0.3 by turning the dial and watching the display.	
G.		Allow the solution to circulate for 5 minutes (minimum) to 6 minutes (maximum) to disinfect the device's water circuit. Place the device into Stand-by mode once completed.	
H.	Remove the bypass tube assembly from the connected blue hose set. Drain the solution from the device's water tank following the instructions in <i>Table 2</i> . Dispose of the cleaning solution per hospital protocol.		
I.	Flush Cycle	Proceed to Section 4 "Flush Cycle" to complete the disinfection and cleaning procedure.	

Table 2		
EMPTYING THE WATER TANK		
A.	IF A WRAP IS CONNECTED: In an area away from patient care, with the system powered off, tightly clamp and then disconnect the wrap from the connecting water tubes. Dispose of the wrap.	
B.		Connect a male draining connector to the "water out" side of the connecting water tubes and direct the tube into a bucket or sink for water collection. (see image in step E in Table 2) Note: Dispose of the cleaning solution per hospital protocol. Power ON the system.
C.		Choose Empty on the main screen or navigate to Empty by touching the Menu icon  , then selecting Services, then Empty.
D.		Press OK. The following screen appears. When you are ready for the process to begin, press Start.
E.		If the "Connect Water Tubes" error message appears, it indicates that the male draining connector is connected to Water In, not Water Out.
	 The Water Out socket is indicated by the blue indicator with an arrow pointed down.	To resolve the error, press Esc on the screen. Disconnect each connecting water tube at the machine end, then reconnect in the reverse way. Now the male draining connector should be connected to the tube inserted into Water Out. When done, follow the prior steps once more to continue emptying. When the water has been emptied completely, a message appears stating that the device is now empty.

4. FLUSH CYCLE			
NOTE: Device MUST be flushed. If the device is not flushed, damage to the device's internal components may occur.			
A.		Refill the device with 1 L of sterile or 0.22µm filtered water (no NaDCC).	
B.		Reconnect the bypass tube assembly to the blue hoses still connected to the device.	
C.			Place the device back into Normothermia mode with the temperature simulator still set to 36.0°C ±0.3. Allow the water to circulate for at least 5 minutes before placing the device in Stand-by mode.
D.	Remove the bypass tube assembly from the connected blue hose set. Drain the solution from the device's water tank following the instructions per Table 2. Refill the device with 1.2 L of room temperature sterile or 0.22µm filtered water if returning to use or leave tank empty if moving to storage.		
E.	Power OFF the device, unplug it and disconnect the blue hoses. Disconnect and store the temperature simulator (P/N 017-00245).		
DEVICE IS NOW READY FOR STORAGE OR NEXT PATIENT			
NOTE: This document does not replace the requirement to read the entire device user manual. For complete operations, maintenance and cleaning instructions, please refer to the device user manual.			

18 Monitoring compliance with and the effectiveness of this document

Audit standards:

The PaNDR team will monitor compliance with this document by undertaking regular audits which will be reported back to the consultants and lead nurse.

The effectiveness of the document will be monitored by review of any reported incidents by the lead consultant and nurse for risk

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

Disclaimer

It is the responsibility of all staff to ensure they are using the latest version of a document.

Document management

Approval:	PaNDR Governance Meeting 09/06/26		
Owning department:	PaNDR		
Author(s):	Samantha Felstead		
Pharmacist:	N/A		
File name:	Use of the Criticool Mini for active cooling during neonatal transfer, June 26		
Supersedes:	N/A		
Version number:	1	Review date:	June 2029