


A decorative graphic consisting of a blue line that curves around a red circle with a grey center, resembling a stylized 'C' or a medical symbol.

# Introduction

Florida Neonatal Neurologic Network Conference  
August 4, 2018

# About Belmont



*“ I am very proud of our products and the lives they have been able to save, and of the highly skilled and motivated employees who have joined u from around the world to design, develop, and manufacture life saving medical devices. ”*

– Brian Ellacott, CEO

Founded in 1980, **Belmont Instrument, LLC** is a leading provider of fluid resuscitation and patient temperature management solutions for use worldwide in medical facilities, military combat fields, and EMS settings.

By focusing on patient safety, Belmont has been able to develop some of the most reliable and effective fluid management devices on the market.

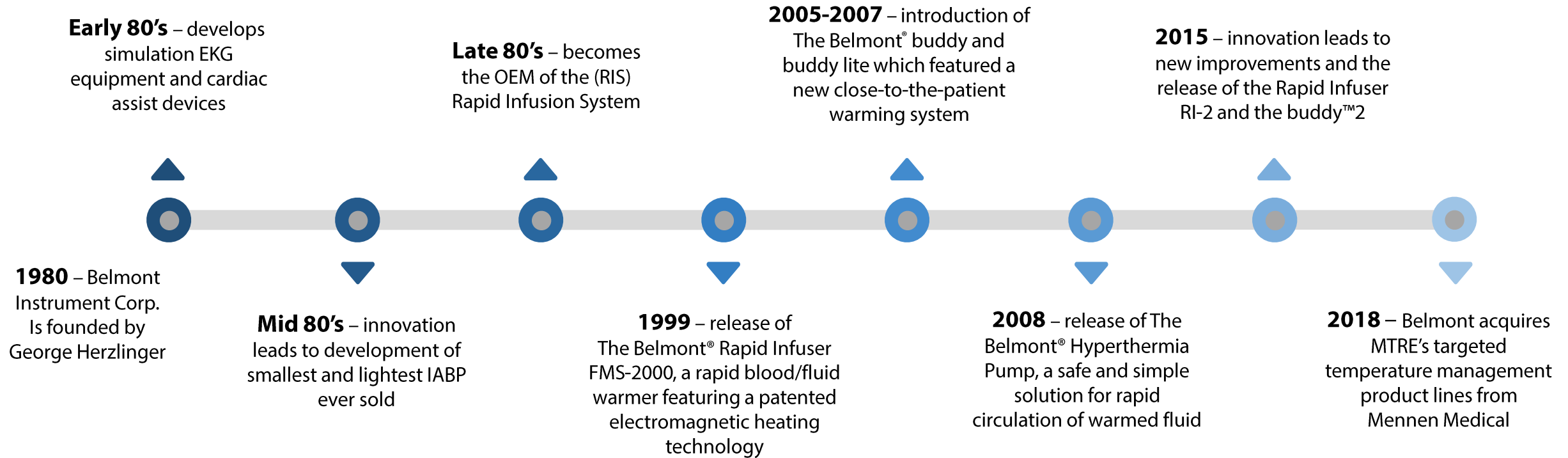


# Belmont's Mission

Belmont Instrument is committed to saving lives by working together with healthcare providers to develop patient safety-focused medical technologies.

*Together, Saving Lives.*

# Our History





# The Belmont Family Grows

- On June 20<sup>th</sup>, 2018 Belmont announced the acquisition of MTRE Advanced Technologies Ltd., an advanced developer and manufacturer of non-invasive solutions for body temperature management
- Belmont's acquisition of MTRE extends its portfolio to include non-invasive body temperature management solutions and advances Belmont's strategy to invest in technologies that leverage the company's existing product portfolio and sales channels





*Together, Saving Lives.*

# CritiCool® Operational Training Infant

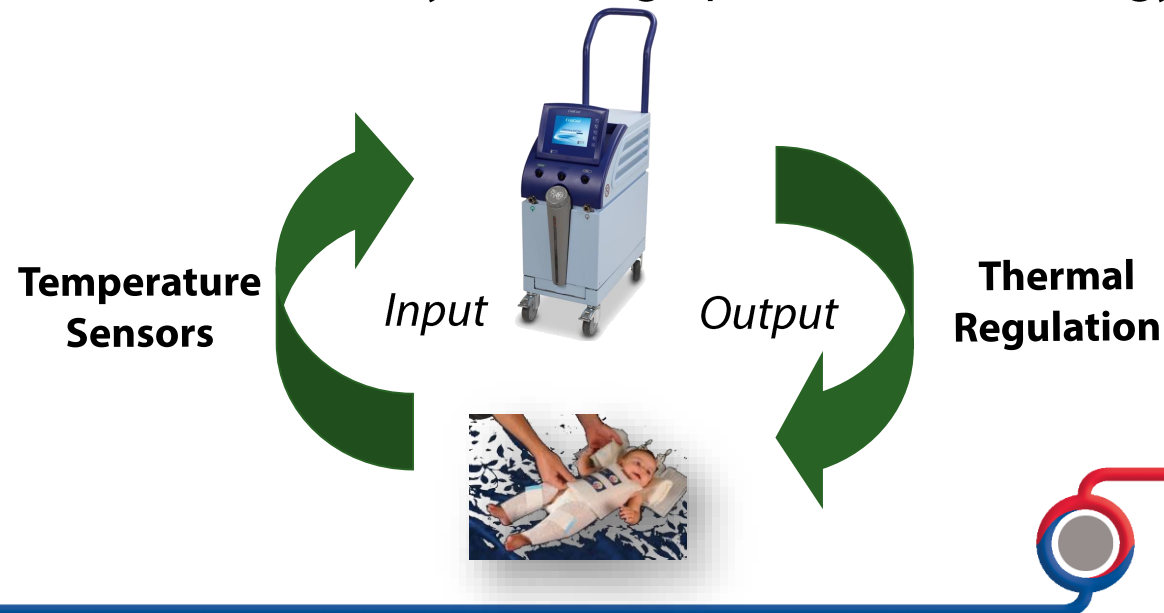
**This information is not intended to be a replacement of the User Manual. Please refer to User Manual for comprehensive information about how to operate CritiCool.**



# Thermoregulation Process

The system is composed of 2 elements:

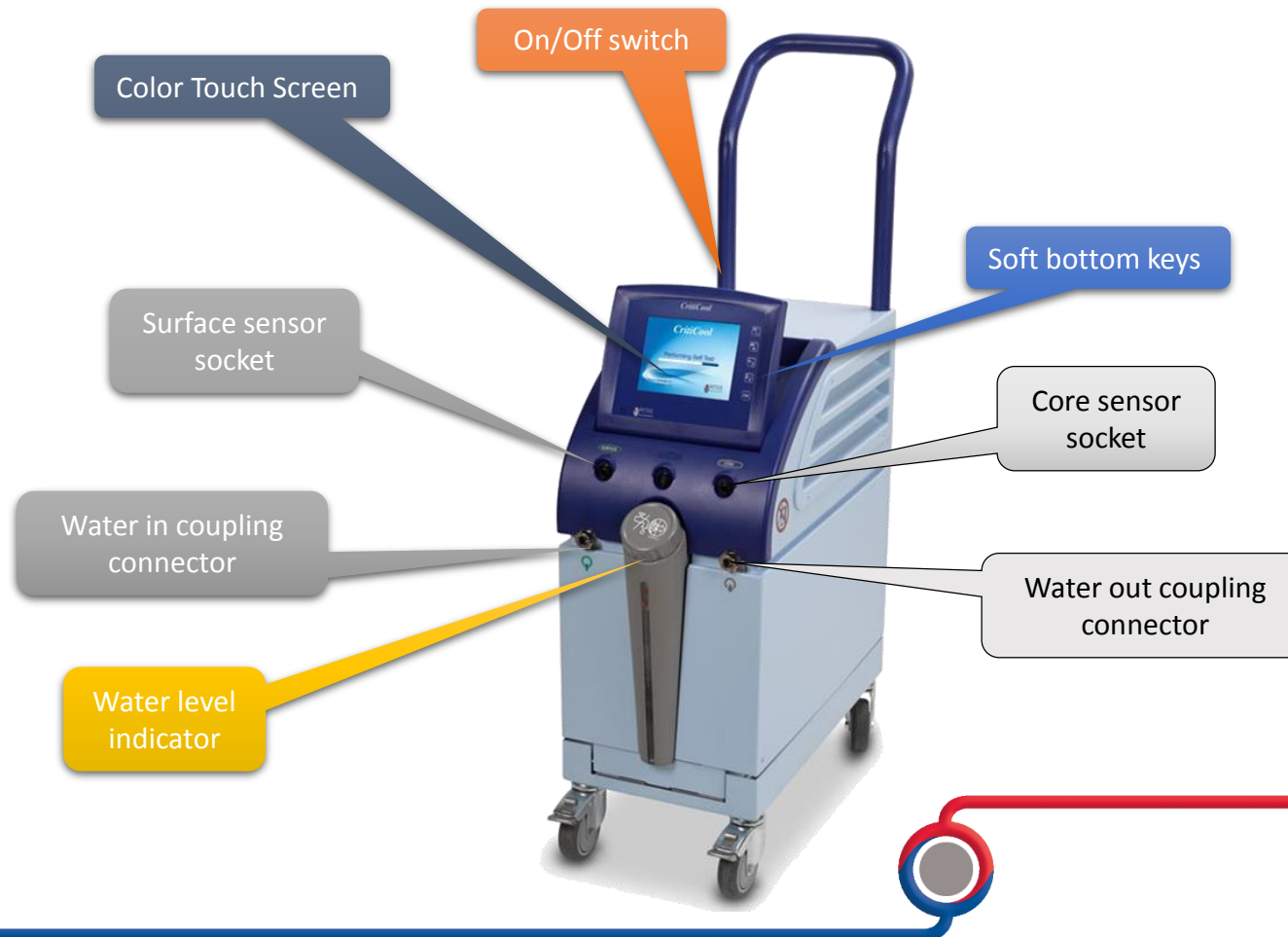
- CritiCool®
  - The control unit is an algorithm driven thermoelectric-based heat/cool pump
- CureWrap™
  - A flexible 3D single piece body wrap is designed to be in close contact with a large surface area of the body, allowing optimization of energy transfer



# CritiCool

## Indication of Use:

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

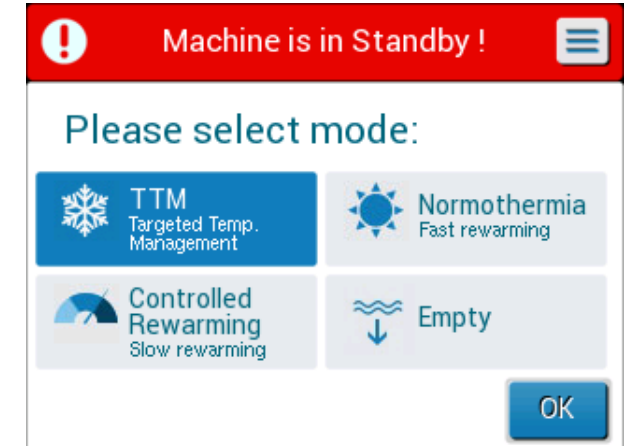




# Targeted Temperature Management Step By Step Operation

## Set Up CritiCool

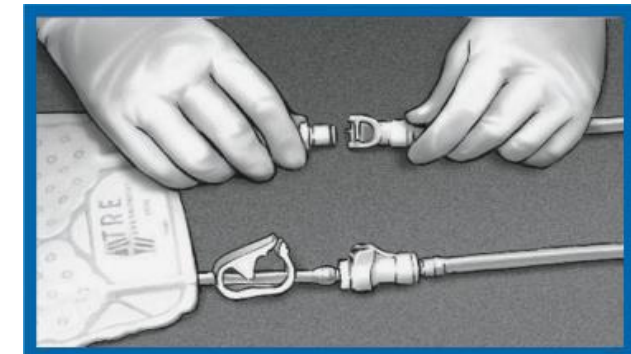
1. **Place** the CritiCool unit near the bed and lock the front wheels
2. **Fill** tank with sterile water or 0.22 micron filtered water (6.0L)
3. Power **ON** switch - after a short *Self Test*, Mode Select screen appears
4. Push **OK** to select **TTM** mode (default Mode)
5. The CritiCool is now cooling and circulating the water internally



# Targeted Temperature Management Step By Step Operation


## Set Up CureWrap

1. **Place** the appropriate CureWrap on the bed or underneath patient (see CureWrap Instructions For Use)
2. **Connect** **Core** cable to the **Core** socket and **Surface** cable to the **Surface** socket
3. **Insert** **Core** sensors into the patient and position the **Surface** sensor on the patient skin (Do not place Skin sensor under the CureWrap) **The CritiCool cannot thermoregulate without a valid Core readout**
4. **Connect** metal fittings on blue hose to metal fittings on front of the CritiCool
5. **Connect** plastic end of blue hose to wrap
6. Wrap should be filled with water prior to wrapping patient (Ensure clamps are OPEN)



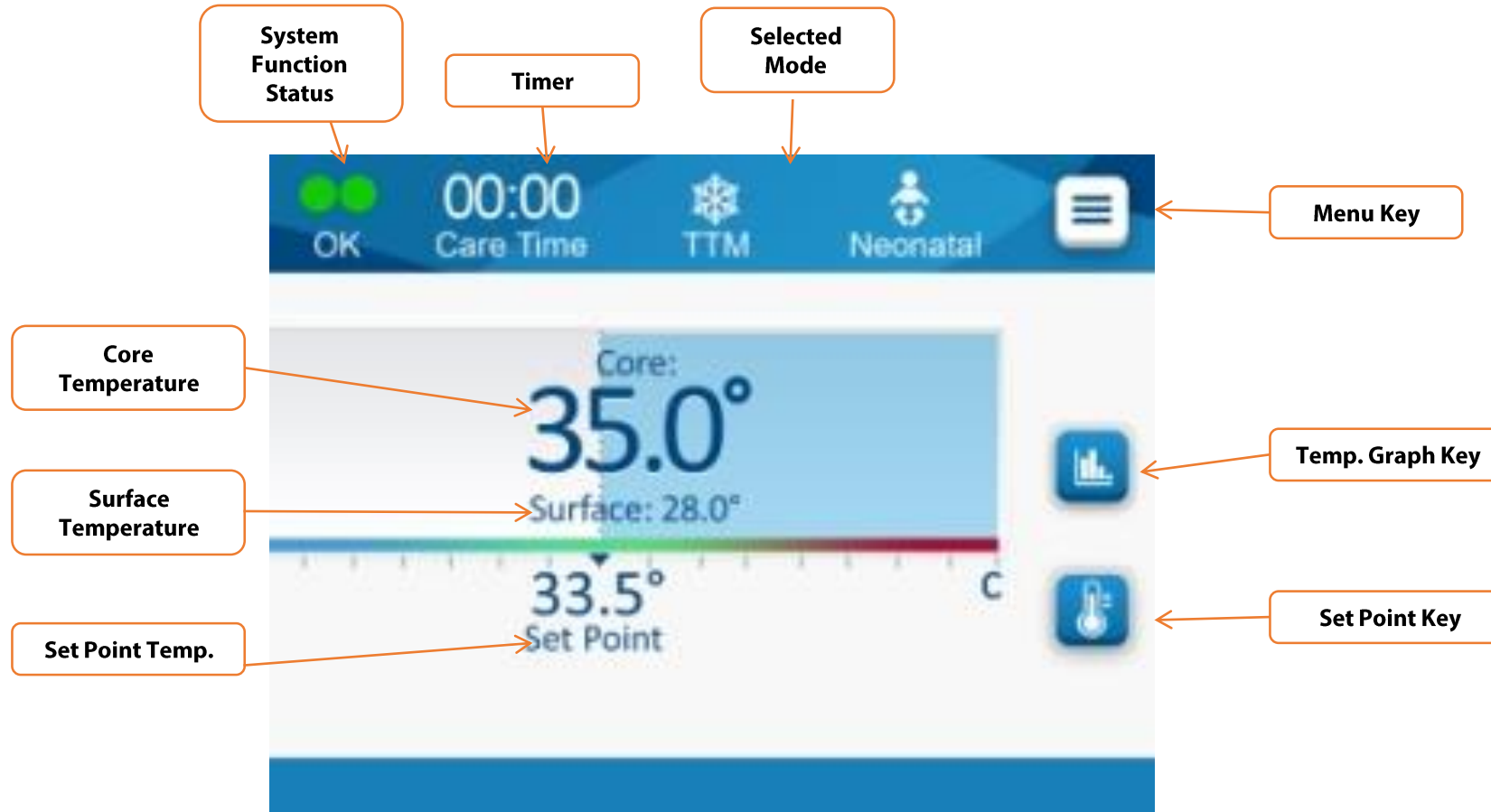
# Targeted Temperature Management

Step By Step cont.

1. The default Set Point (SP) Temperature is 33.5°C. If required, change the SP temperature by using the Set Point soft key on the screen 
2. **Wait until the CureWrap is filled with water**
3. **Secure the CureWrap on patient** (see CureWrap Instructions For Use)
  - **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**
  - **Constant clicking sound may indicate water obstruction – check to ensure the clamps are open and water flow inside the CureWrap is not kinked**



# Main Operation Screen



# CritiCool Touch Screen

## 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 Setting panel / Down Arrow



Accept changes

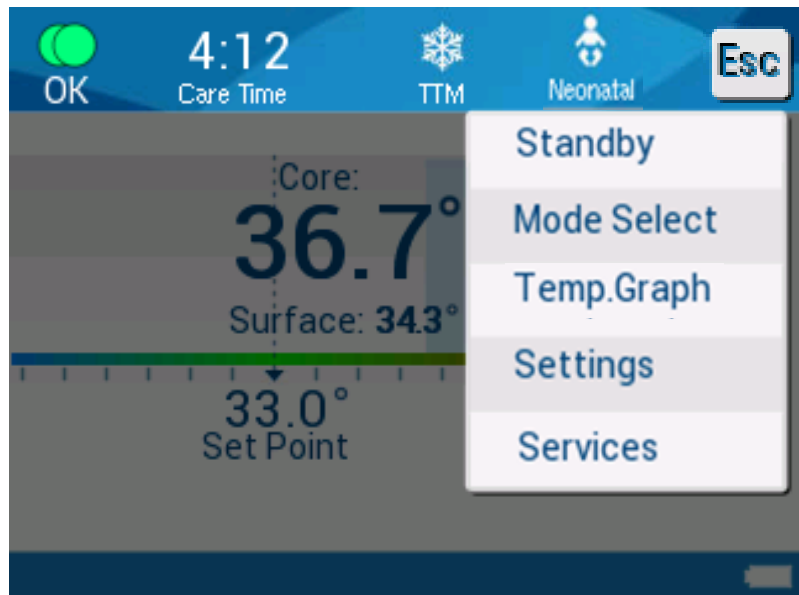


# Menu Options

Touch the **Menu icon / soft button key**



Drop Menu will appear with the following options:

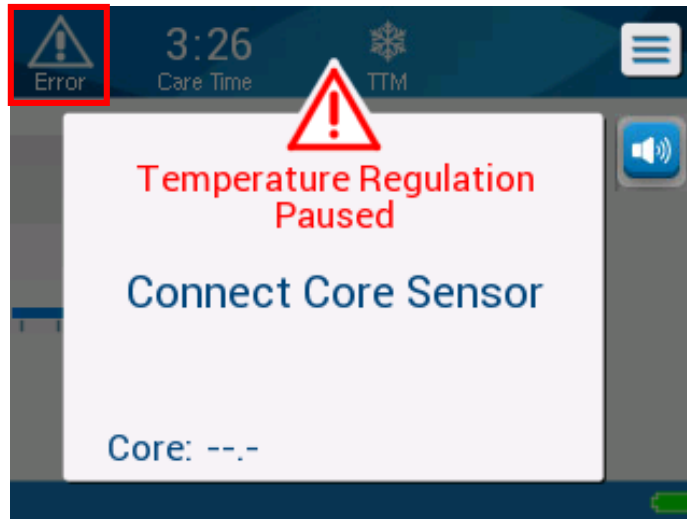



Once the Menu drop down ESC icon appears, touch it to return to previous screen

# Messages & Troubleshooting

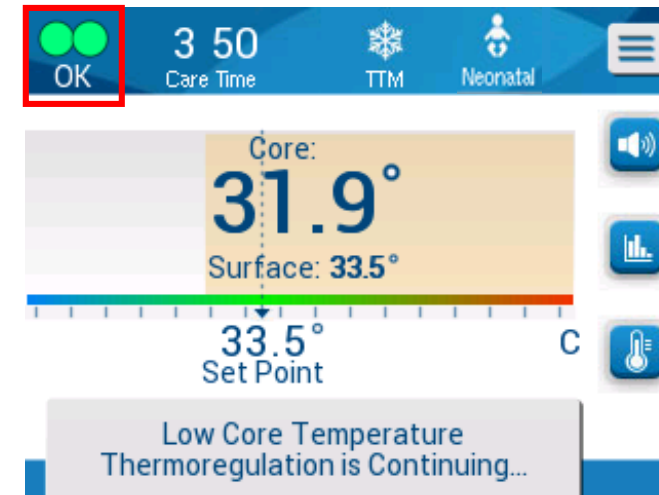
The CritiCool uses Two types of messages


## Error Message



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

## Informative Message




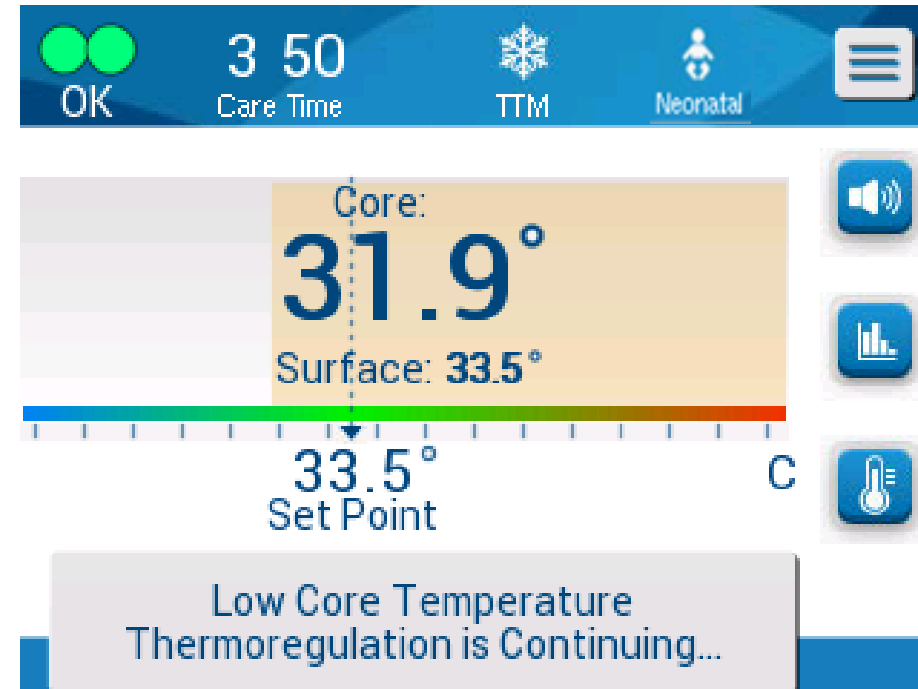
- Alarm sound
- Operation screen
- Thermoregulation continues
- System function status is on 

# Alarm Message #1 (informative message)

Core temperature is **0.8°C - 2°C** lower than Set Point

Staff awareness to patient's core temperature is needed


- Alarm sound
- Operation screen
- Thermoregulation continues
- System function status is on 



## Alarm Messages #2 (Error Message)

**Core Temperature Is at least 2°C lower than Set Point or below 31°C, whichever first**  
**Thermoregulation Paused!**

- Check Core temp sensor position and fix if necessary
- Touch **OK** to confirm Core temp. and resume thermoregulation

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




# Alarm Messages #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 **OK** to confirm Core temp. and Start Re-warming

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






# Alarm Messages #4: Check Water Tubes

## Water flow to the CureWrap is interrupted

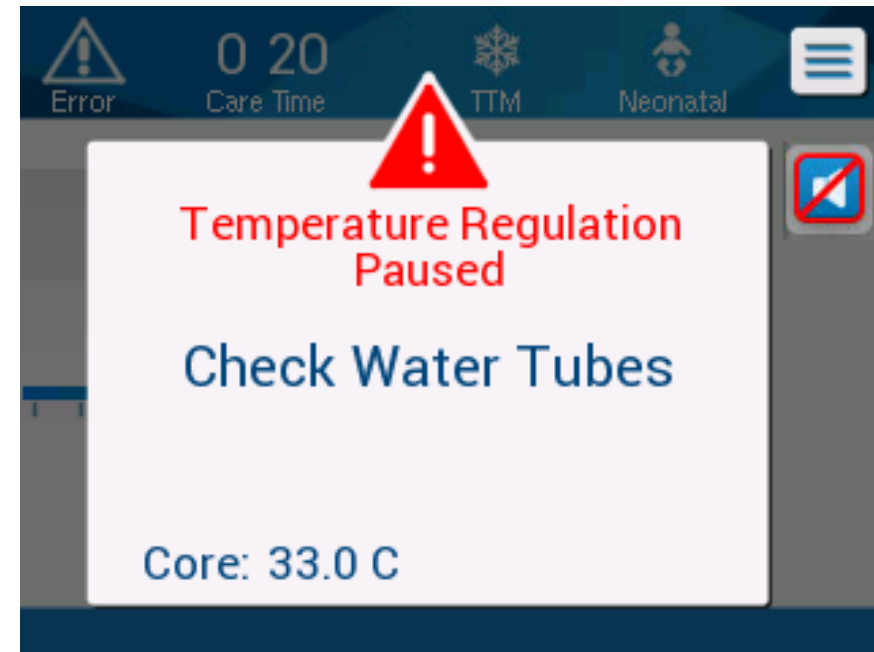
Check the blue hose are not kinked

Check that the blue hoses are flat near the CureWrap connections

Check if the CureWrap is folded

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

Solve the problem and the message will disappear

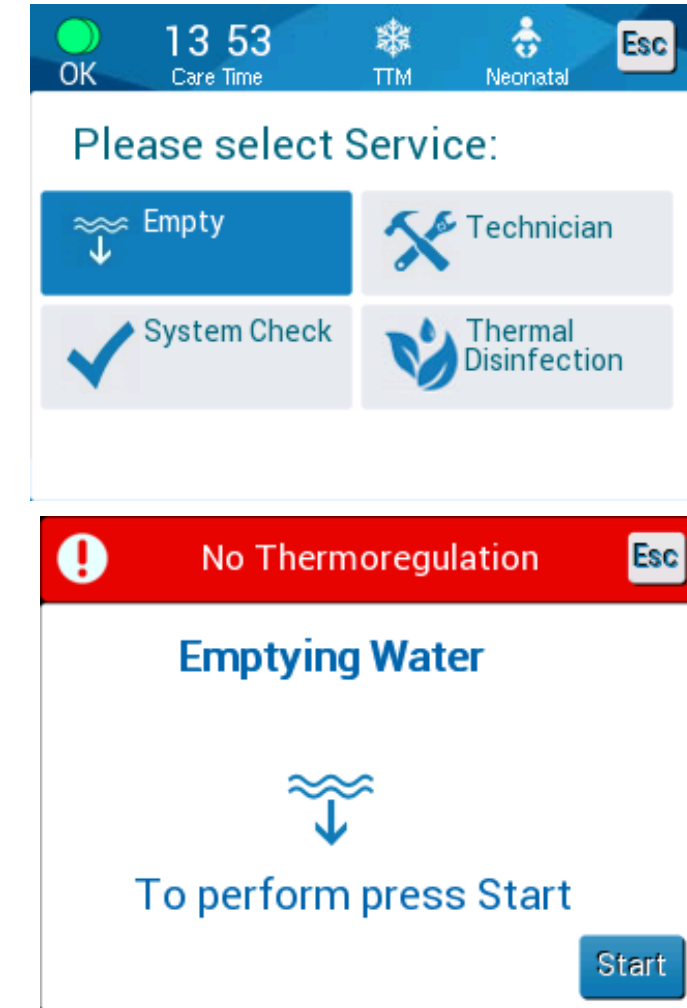


# After Care Use

## *Empty the water from the tank prior to storage*

After the therapy is completed:

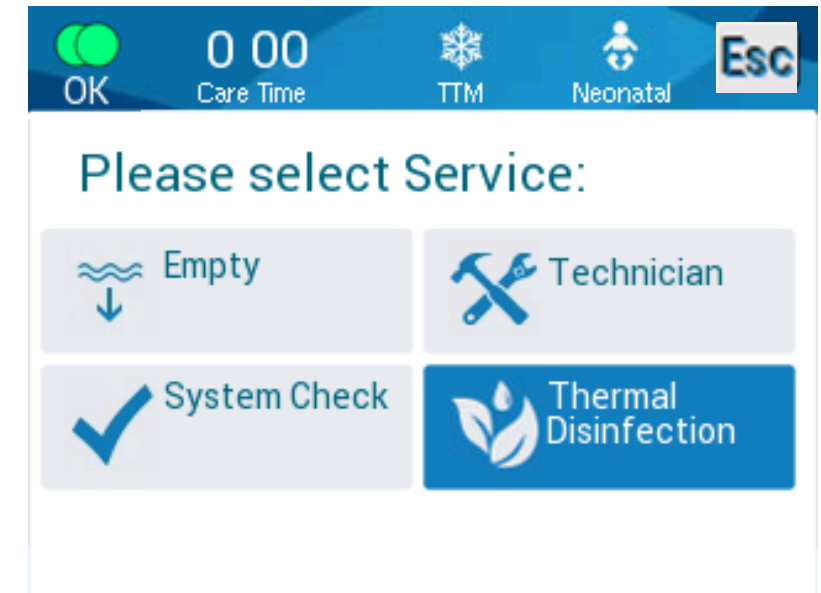
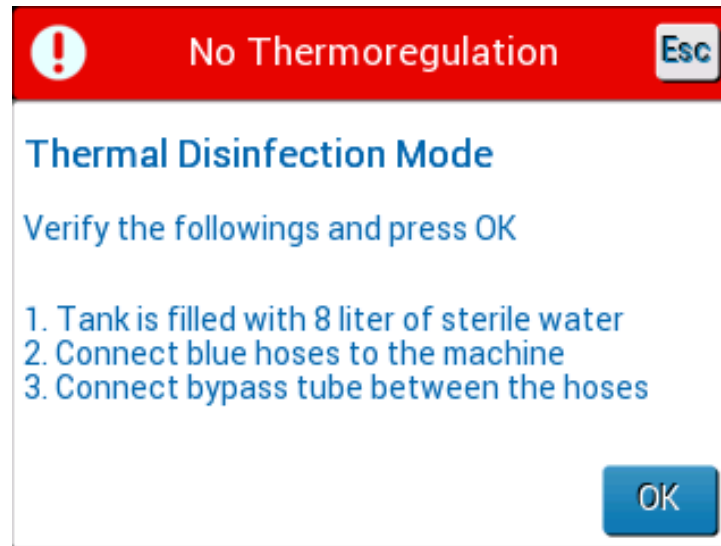
1. Switch to Standby
2. Shut the clamps of the CureWrap
3. Disconnect and remove the CureWrap
4. Disconnect and remove the sensors
5. *Add 2 AQUATAB tablets into the water tank*
6. *Run the system in Standby mode 60 minutes*
7. *Drain the water:*
  - Select **Service** from the **MENU**
  - Select **Empty** and touch **OK** to confirm
  - Connect water hoses and make sure the draining plug is connected
  - Touch **Start** and wait for the message: "**water tank is empty**"
8. Clean and disinfect the machine and accessories as per the hospital protocol



# Thermal Disinfection

Thermal Disinfection is Password Protected

- Can only be used by trained Biomedical Technicians



# 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



A decorative graphic consisting of a red horizontal line that curves down into a circular shape with a blue outline and a grey center, then continues as a blue horizontal line to the left.

**Thank you!**