

ALLON[®] OPERATIONAL TRAINING



SOFTWARE 6.3



ALLON[®] – INDICATION FOR USE

510K – Indication for use

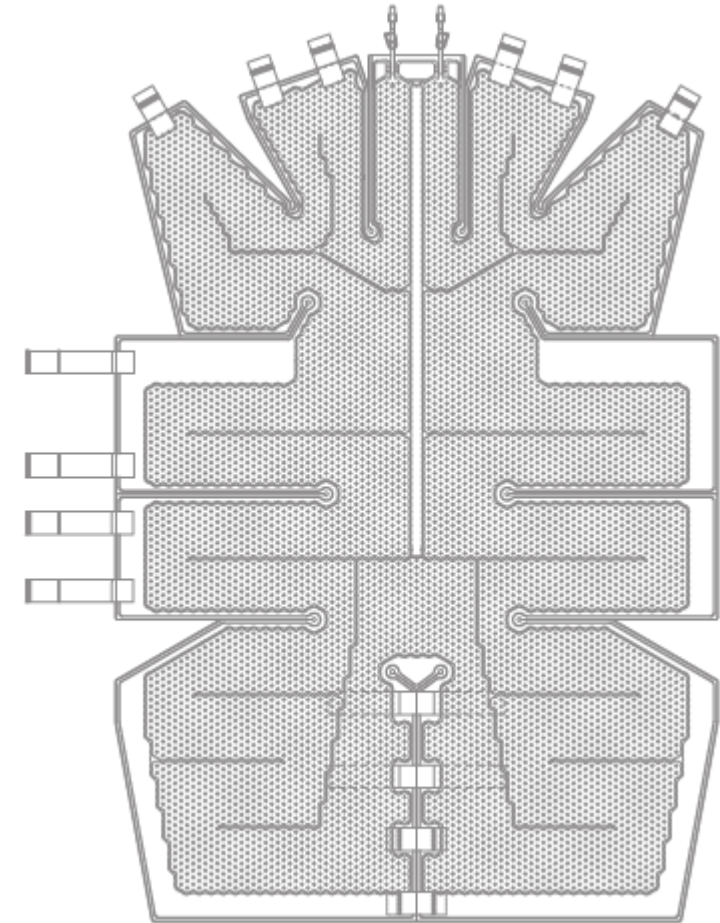
- Intended to maintain pre-set body temperature as determined by the physician
- Can also be utilized to maintain normal body temperature during surgical procedures
- Can be used with adult and pediatric patients



ALLON PRODUCT FAMILY



Allon® Control Unit



ThermoWrap® Garments

CONTROL AND MAINTAIN NORMOTHERMIA THROUGHOUT THE ENTIRE PERIOPERATIVE CONTINUUM



PRE-OPERATIVE

Initiate patient warming
before the procedure



INTRA-OPERATIVE

Manage patient temperature
during the procedure

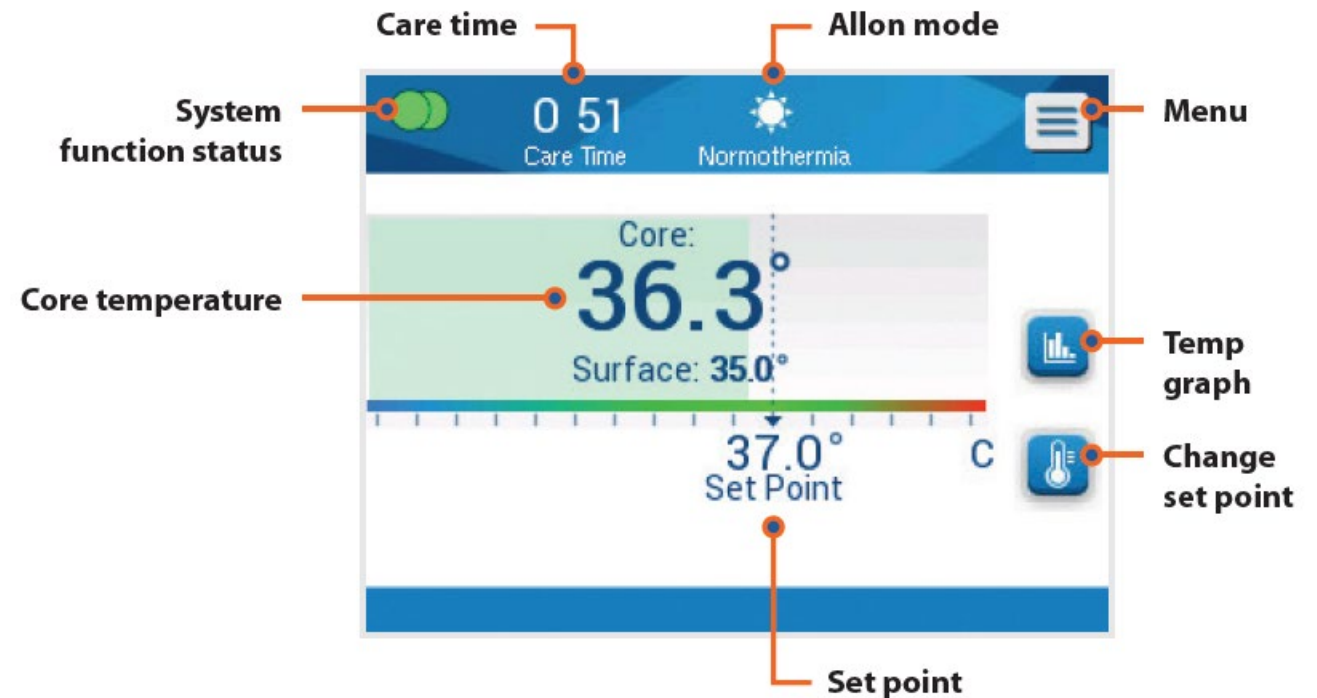


POST-OPERATIVE

Maintain patient body
temperature in the
recovery room

BENEFITS FOR YOU AND YOUR TEAM

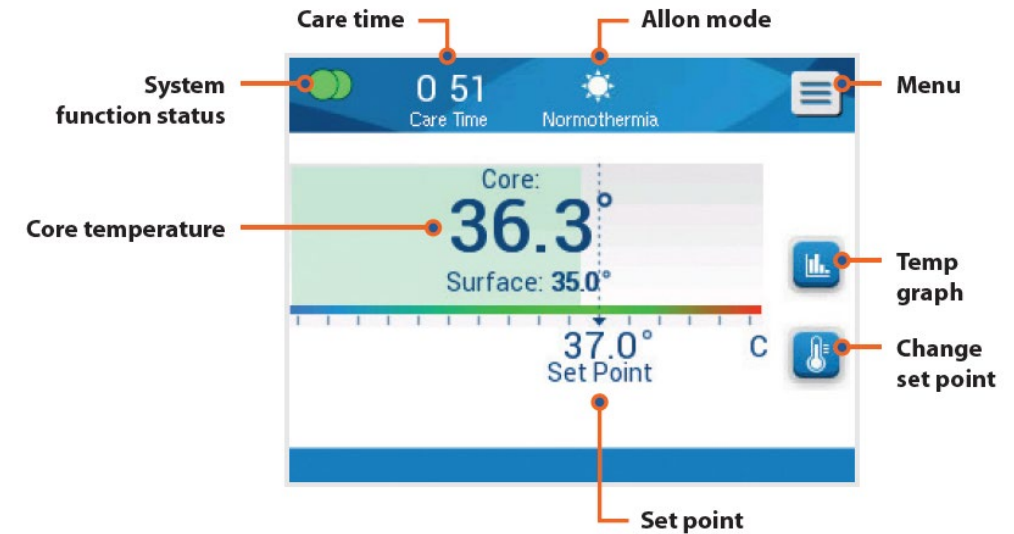
- Safe, simple, and effective
- Quick to set up
- Start warming upon patient arrival
- Warms the patient without blowing air around the room
- Multiple configurations for the positioning and access you need
- Track and externally access procedure data using the CliniLogger™



ALLON'S UNIQUE TECHNOLOGY

ENERGY EXCHANGE CONTROLLER

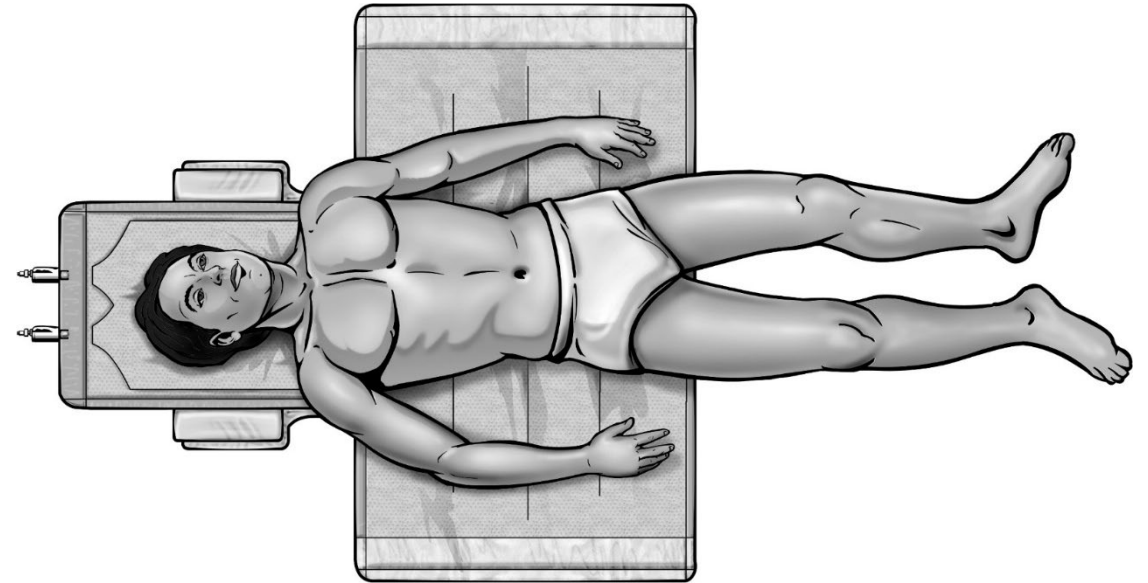
- Effective energy transfer
- Quiet, compact, reliable control
- Precise heating/cooling capabilities
- Intuitive user interface approach



ALLON'S UNIQUE TECHNOLOGY

PATIENT ENERGY EXCHANGER

- Optimal heat transfer garments
- Specialized materials
- Maximum heat transfer with minimum interference to surgical field



DESIGNED WITH YOUR PATIENT IN MIND

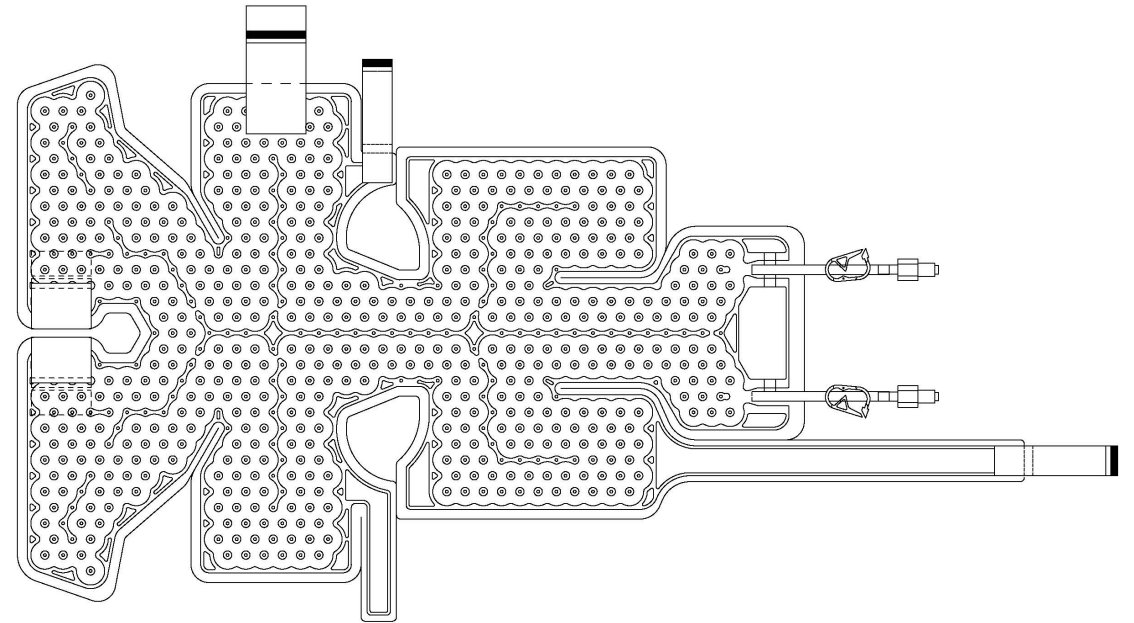
- Range of sizes to accommodate your patient's anatomy
- Pressure relief algorithm
- Up to 80% body surface area coverage
- Soft mesh that is easy to wrap and secure
- Clutter-free with only one pair of connecting tubes
- Go from pre-op to post-op with a single ThermoWrap*

*ThermoWrap can be used for up to 28 hours unless soiled.



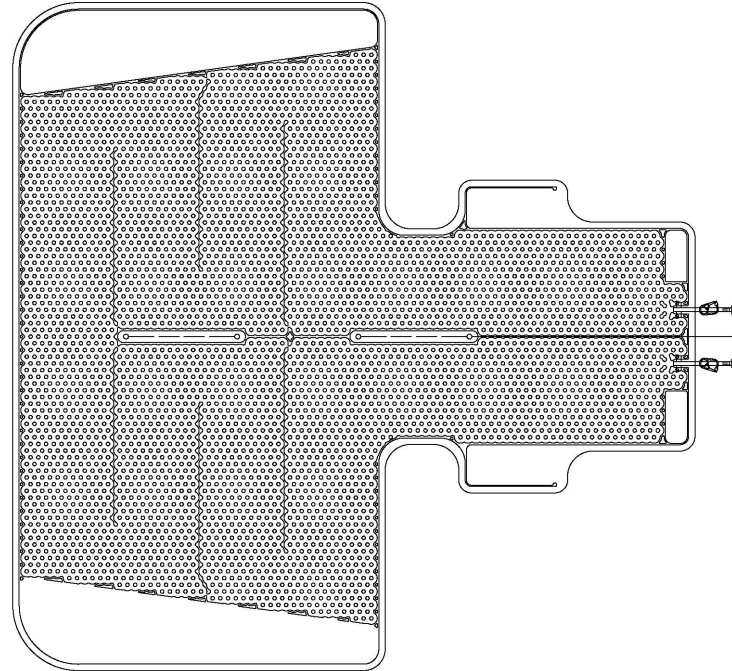


INFANT THERMOWRAP®



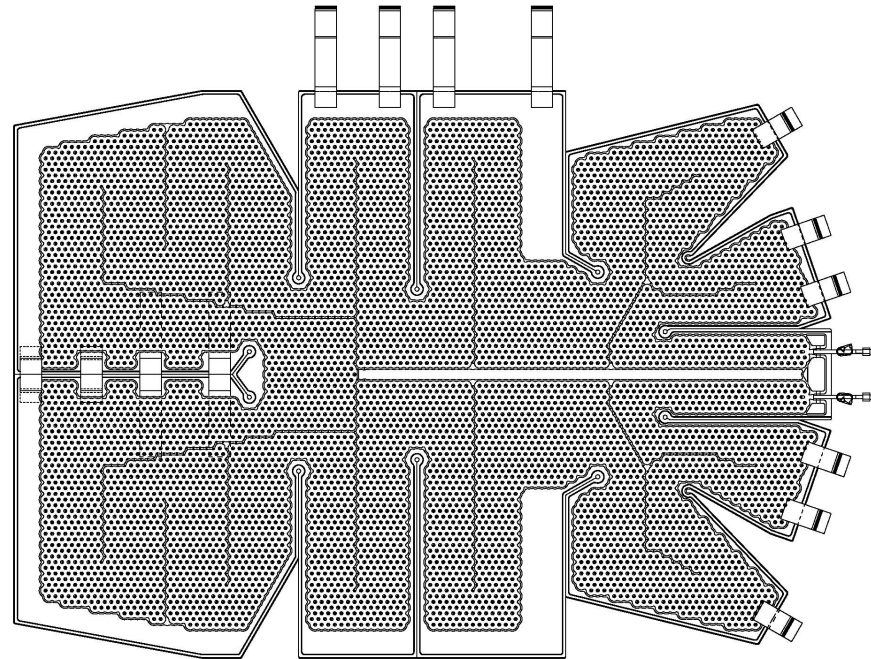


CARDIAC THERMOWRAP®



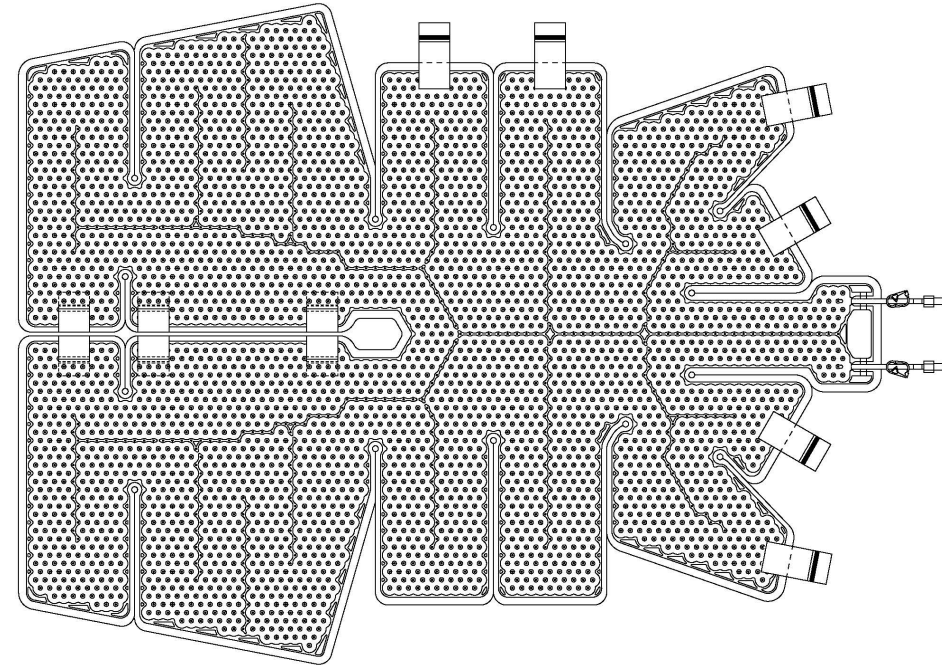


UNIVERSAL THERMOWRAP®





PEDIATRIC THERMOWRAP®



THERMOWRAP

FLEXIBILITY WHERE YOU NEED IT

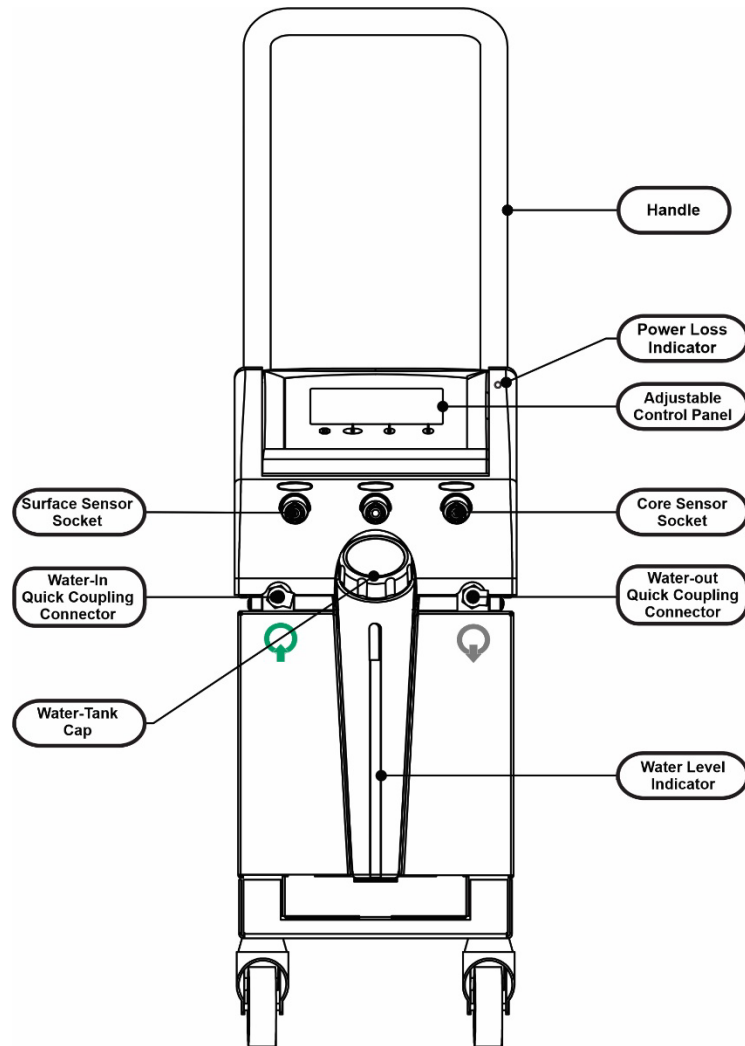


THERMOWRAP CONFIGURATIONS

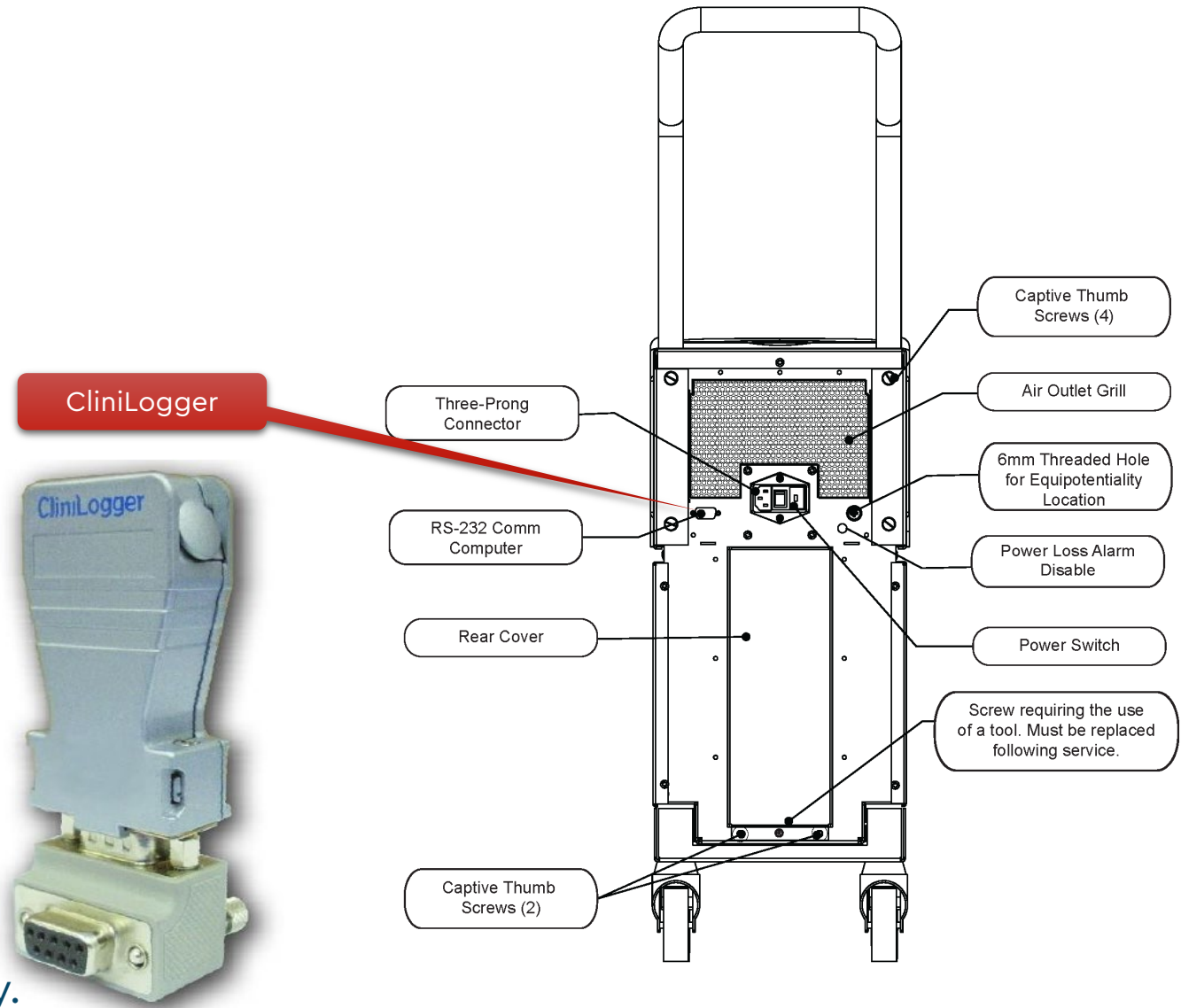
Wrap Type	Part Number	Quantity Per Box	Patient Height/ Weight	Wrap Length/ Width (m)
Cardiac	512-03363	12	165-182 cm Fits all adults	1.348 / 1.319
Adult/ Universal	512-03166	12	168-180 cm (over 66")	1.904 / 1.321
	512-03160	12	152-168 cm (60-66")	1.934 / 1.295
	512-03153	12	135-152 cm (53-60")	1.744 / 1.212
Pediatric	512-03148	12	122-135 cm (48-53")	1.582 / 1.193
	512-03141	12	104-122 cm (41-48")	1.398 / 1.068
	512-03136	12	91-104 cm (36-41")	1.225 / 0.841
	512-03131	12	79-91 cm (31-36")	1.118 / 0.739
Infant	524-03125	24	7-11 kg (15.5-24.3 lb)	0.983 / 0.629
	524-03121	24	4-7 kg (8.8-15.5 lb)	0.698 / 0.604
	524-03118	24	2.5 to 4 kg (5.5-8.8 lb)	0.660 / 0.465



ALLON – FRONT VIEW



ALLON CONTROL UNIT: REAR VIEW



Note: CliniLogger™ is an optional accessory.



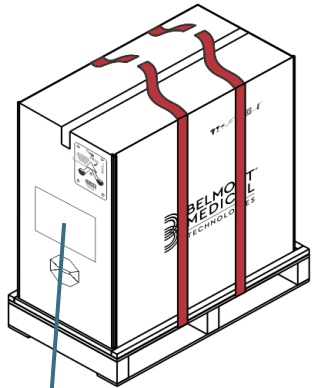
SETTING UP ALLON

UNPACKING ALLON

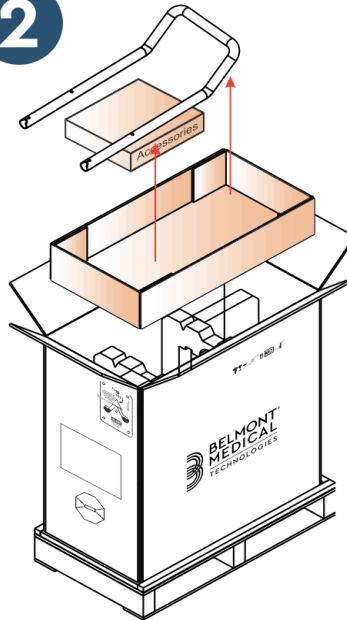
Upon arrival, check the **SHOCKWATCH®** and **TIP-N-TELL®** indicators.

If either has been activated, immediately open the package and check for external damage. If the device has been damaged, photograph the damage and immediately notify the shipping carrier and/or Belmont Medical Technologies at techservice@belmontmedtech.com, being sure to provide all relevant information, including evidence of the damage.

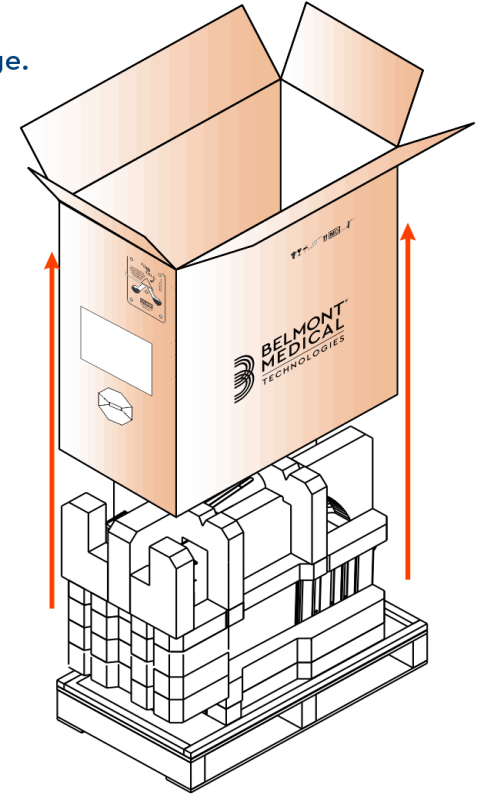
1



2



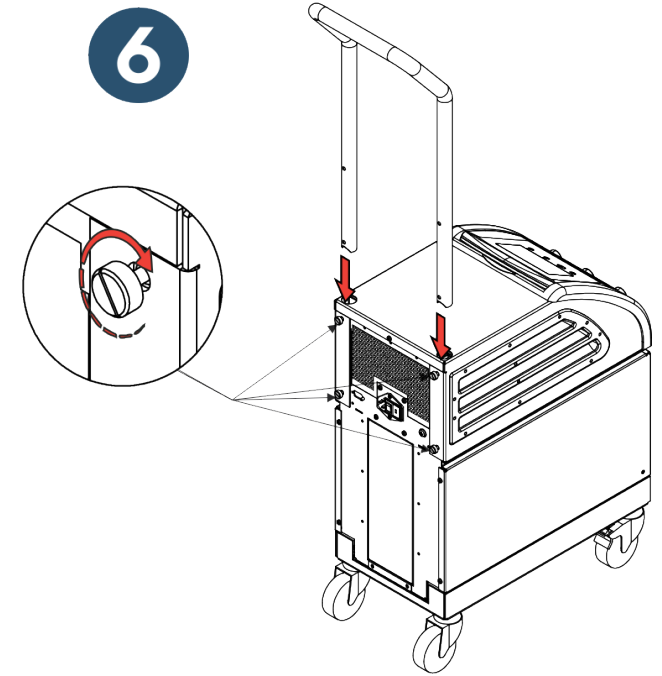
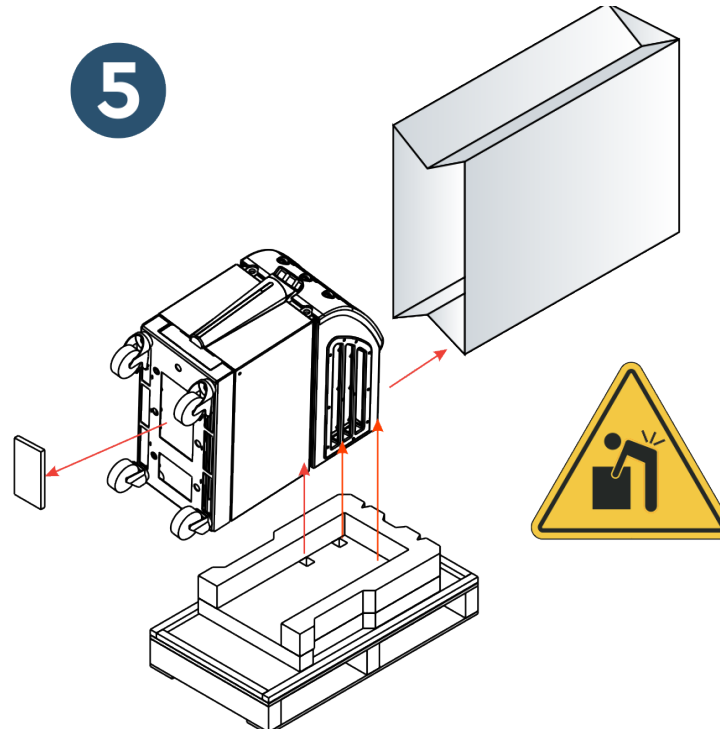
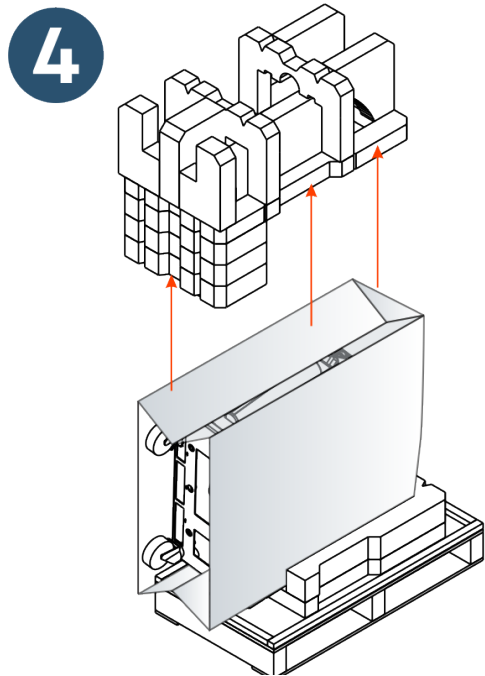
3



Unpacking instructions are affixed to the box.
Please refer to instructions on the box.

Keep the original box

UNPACKING ALLON



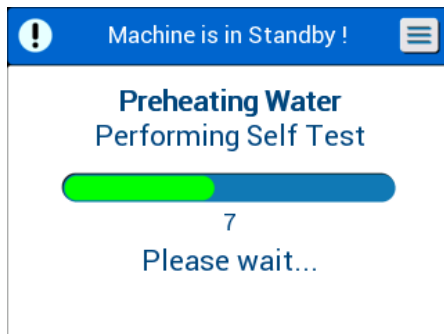
SETTING UP ALLON

1. Place the Allon unit near the bed and lock the front wheels
2. Fill tank with sterile water or 0.22 micron filtered water to the red line (6.0L)



SETTING UP ALLON – POWER ON

1. Turn the Allon device ON
2. An initial Self-Test is performed
3. Pre-heating of the water and continuation of Self Test begins automatically. Once water is preheated and everything is connected, the system will automatically start flowing warm water to the ThermoWrap
 - Allon can prewarm the wrap from 23°C to 37°C in less than 5 minutes.
 - Preheating water & continuation of self test can take up to 15 minutes.

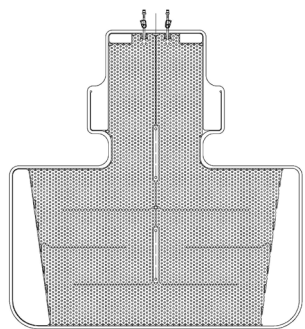


NOTE: Allon warms the water once powered on. If the intention is to lower a patient's temperature, connect hoses, wrap, and probes before powering on, and ensure set point is appropriate.

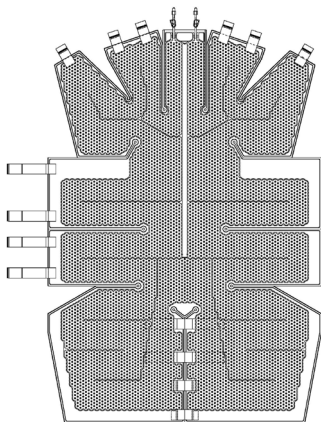


Power switch in the back

STEP BY STEP – SELECT A THERMOWRAP



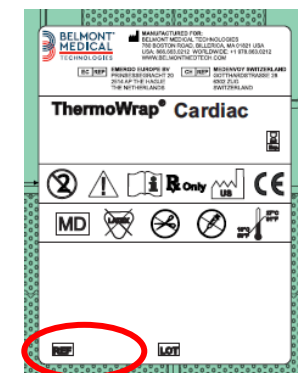
- Cardiac ThermoWrap
 - Provides full access to the torso and legs
 - Allows for wrapping arms
 - Cardiac and transplant procedures, among others



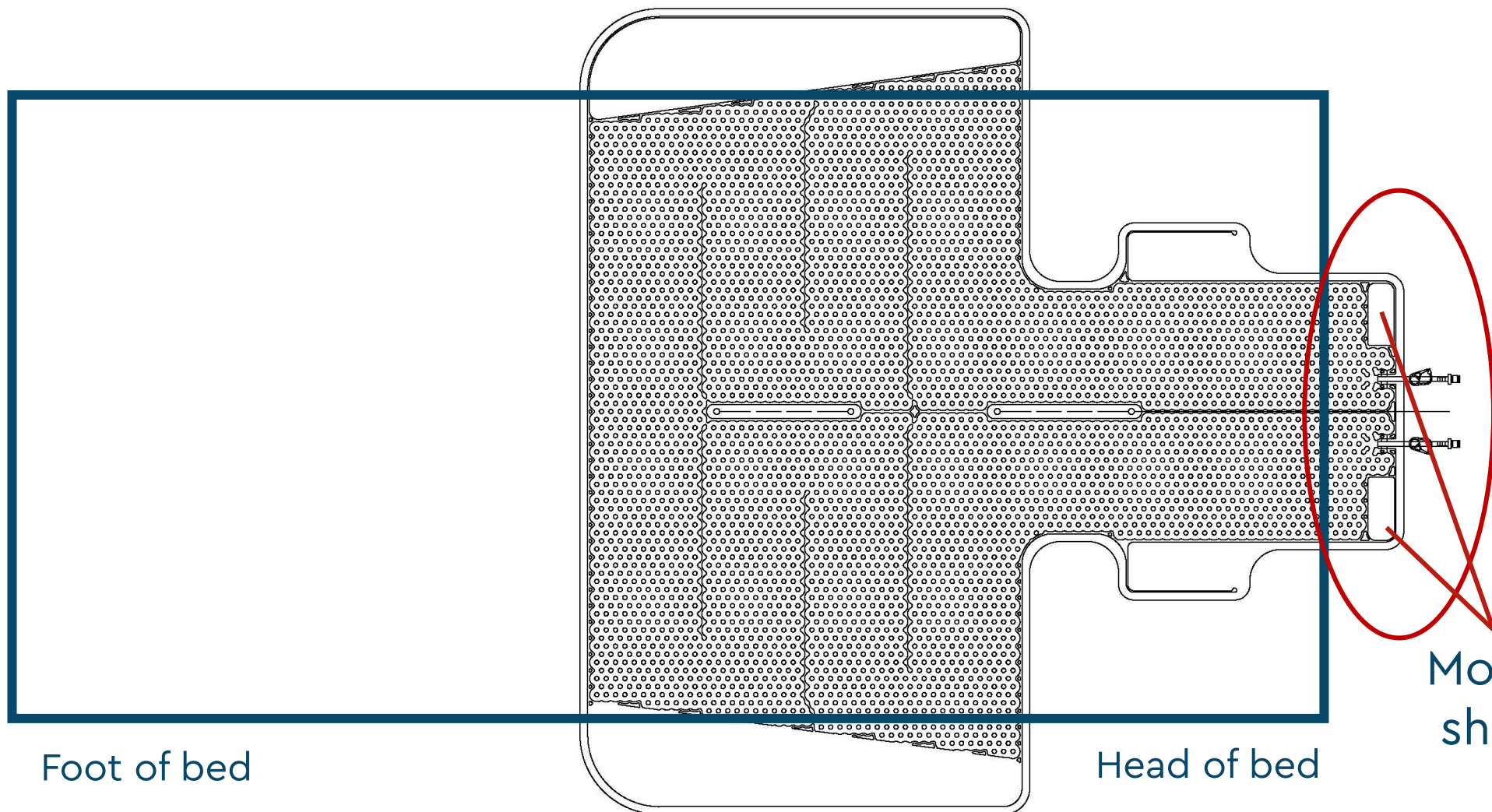
- Universal ThermoWrap
 - Allows for wrapping as much of the body as possible, while still providing access where needed
 - Patients with less insulation
 - Procedures where gravity could be an issue for CardiacWrap
 - Thoracic procedures or any surgery where more coverage is desirable

Type	Part Number	Patient Height / Weight	Wrap Length / Width (m)
Infant Universal	500-03118	2.5 to 4 kg (5.5 to 8.8 lb)	0.660/0.465
	500-03121	4-7 kg (8.8-15.5 lb)	0.698/0.604
	500-03125	7-11 kg (15.5-24.3 lb)	0.983/0.629
Pediatric Universal	500-03131	79-91 cm (31-36")	1.118/0.739
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	500-03160	152-168 cm (60-66")	1.934/1.295
	500-03166	168-180 cm (over 66")	1.904/1.321
Cardiac	500-03363	165-182 cm Fits all adults	1.348 / 1.319

NOTE: Part Numbers shown in table above and circled below to the right are for single wraps. ThermoWrap is sold in boxes of 12 or 24; see [ThermoWrap Configurations](#).



LAY THERMOWRAP ON OPERATING TABLE



See ThermoWrap Instructions For Use

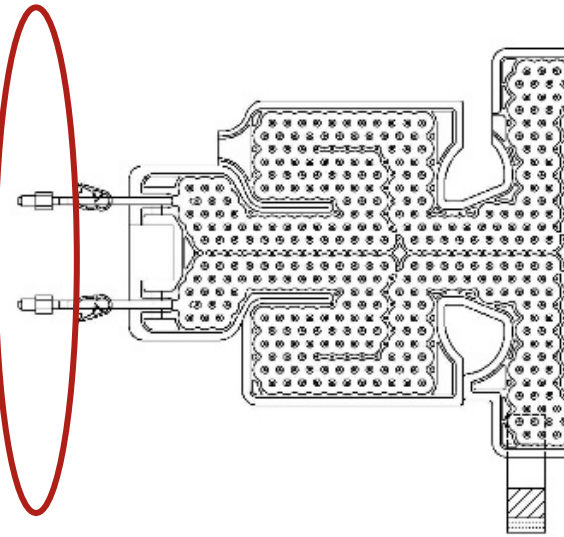
SETTING UP ALLON – CONNECT HOSES

- Connect metal fittings on blue hose to metal fittings on the front of Allon
- Listen for the "click"
- Tug slightly to ensure securely inserted



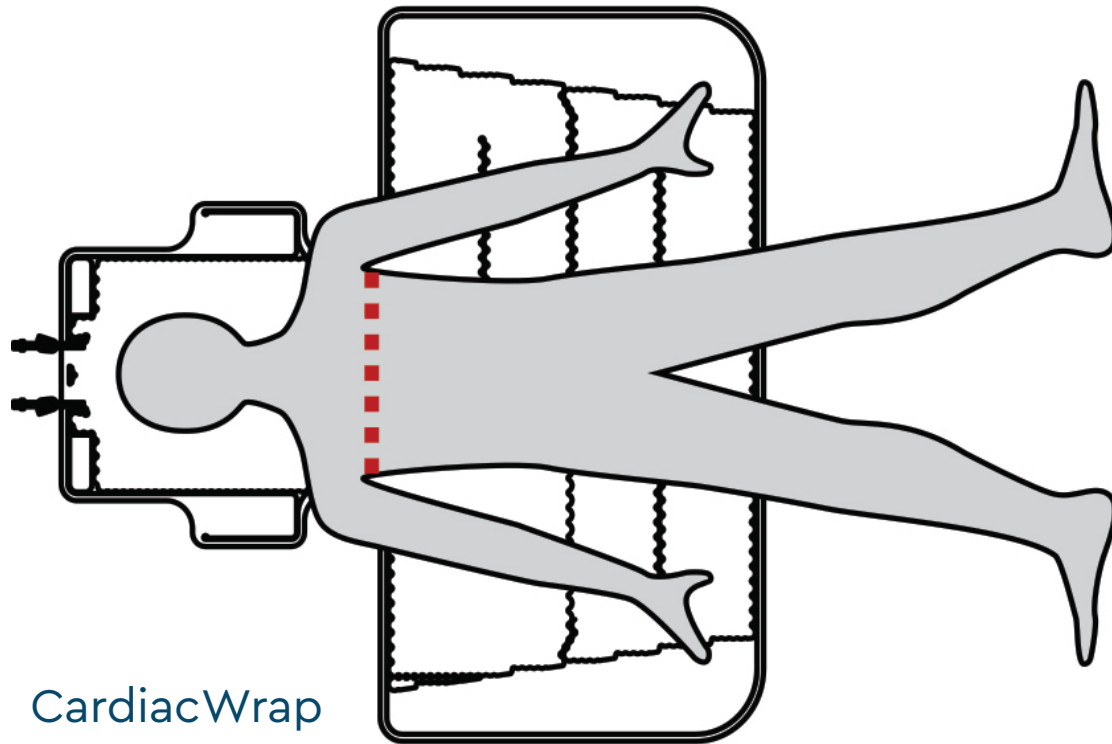
SETTING UP ALLON – CONNECT THERMOWRAP

- Connect plastic ends of blue connecting water hoses to wrap
 - Ensure clamps are OPEN
 - Listen for the “click”

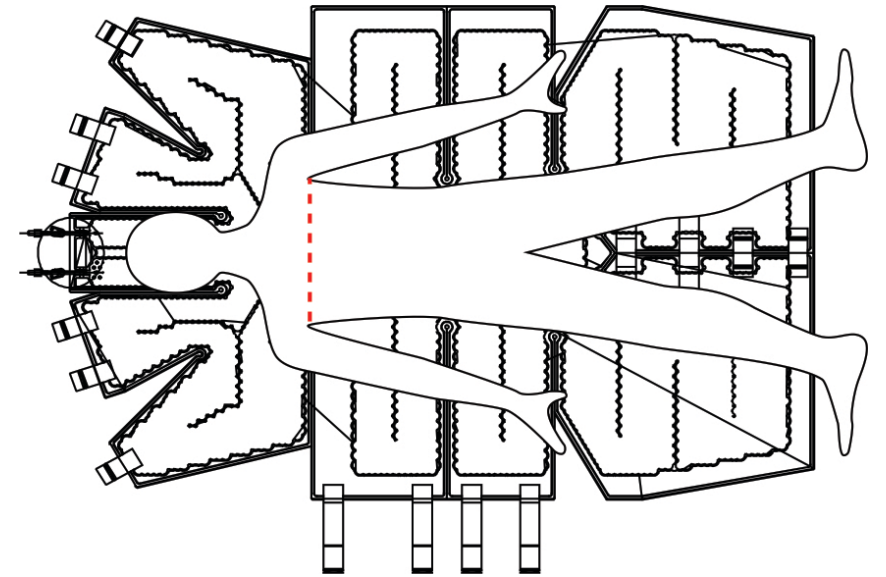


POSITION THE PATIENT

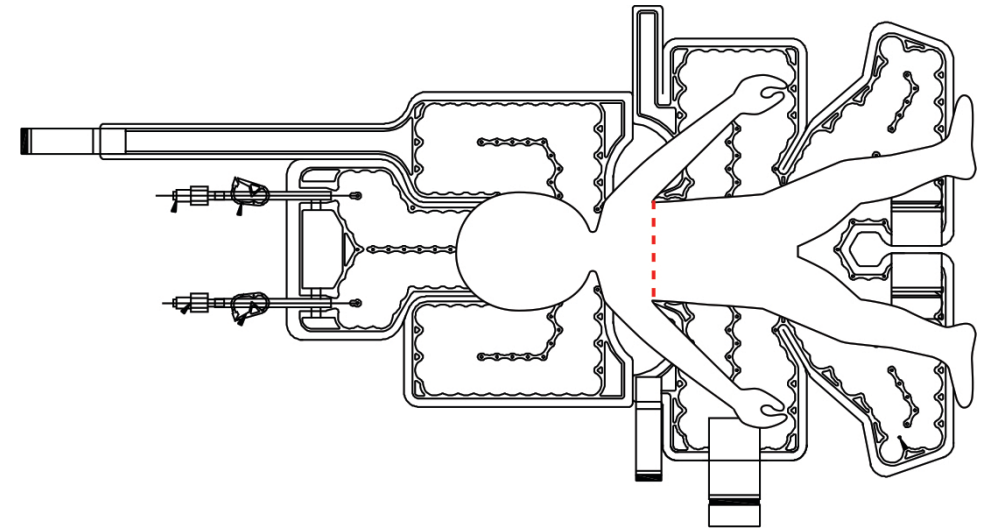
- After the wrap has filled with water, position the patient on the ThermoWrap. See ThermoWrap instructions for use.
- Note positioning of the patient's shoulders.



CardiacWrap



Adult Universal ThermoWrap



Infant Universal ThermoWrap

SELECT TEMPERATURE PROBE TYPE

Core

Reusable
Temperature Probes
(only select markets)

PN# 014-00005



Infant 10FR

PN# 014-00020



Adult 12FR

OR

Surface

PN# 014-00021



Disposable
Temperature Probes
(United States – select markets)

PN# 014-00035

PN# 014-00038

PN# 014-00036

PN# 014-00220



Disposable

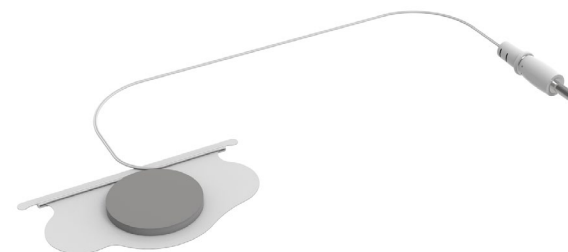
AND

PN# 014-00028



Adapter Cable

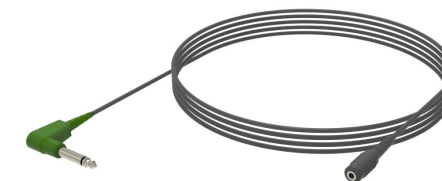
PN# 014-00323



Disposable

AND

PN# 014-00324



Adapter Cable



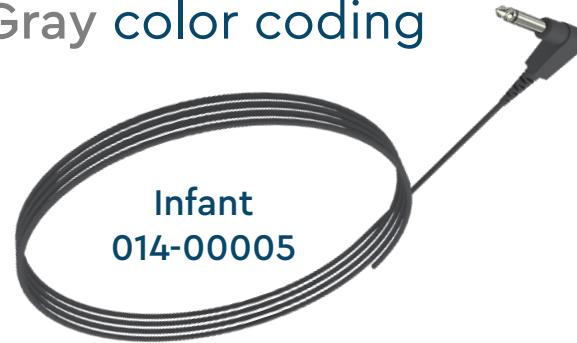
REUSABLE PROBES – SET UP

- Connect **Core** probe to the **Core** socket and **Surface** probe to the **Surface** socket

SURFACE on left
Green color coding



CORE on right
Gray color coding



OR



DISPOSABLE PROBES – ADAPTER CABLE SET UP

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

SURFACE on left
Green color coding

014-00324

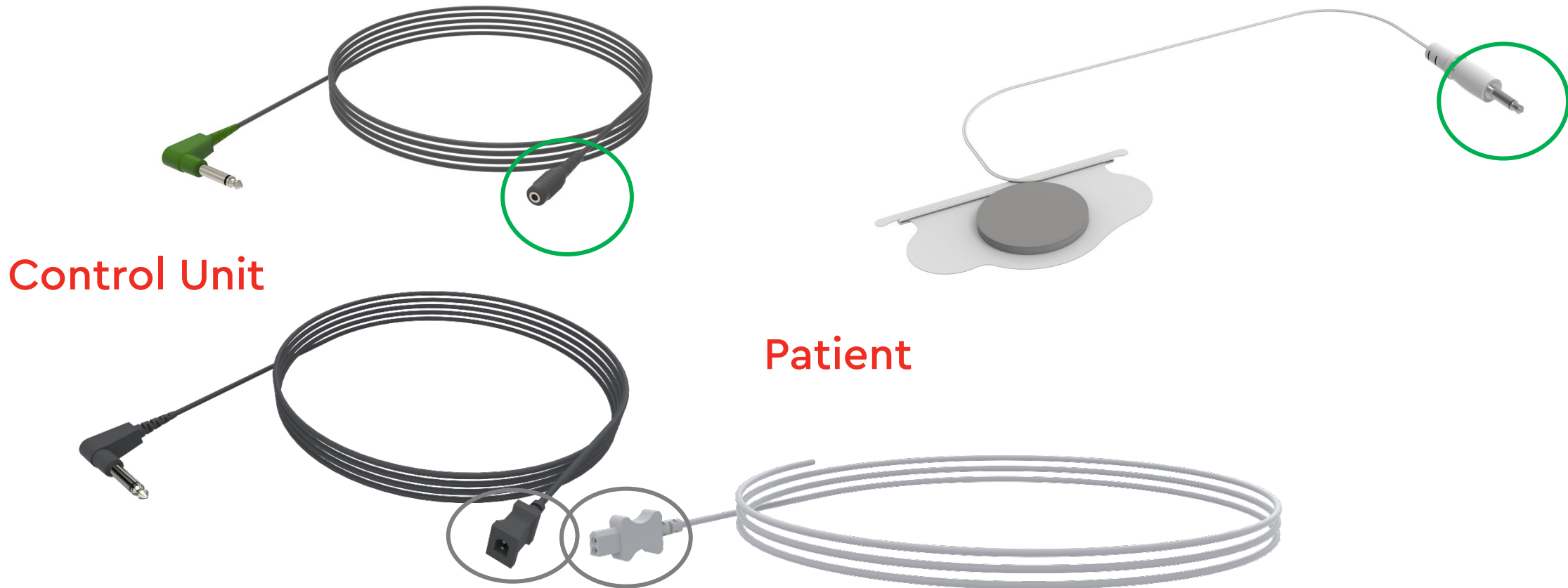
CORE on right
Gray color coding

014-00028



DISPOSABLE PROBES – PROBE SET UP

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



TEMPERATURE PROBES – PATIENT SET UP

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

- **Core Probe Placement:**

- Rectal/esophageal
- PN# 014-00035, 014-00038, 014-00036 or 014-00220

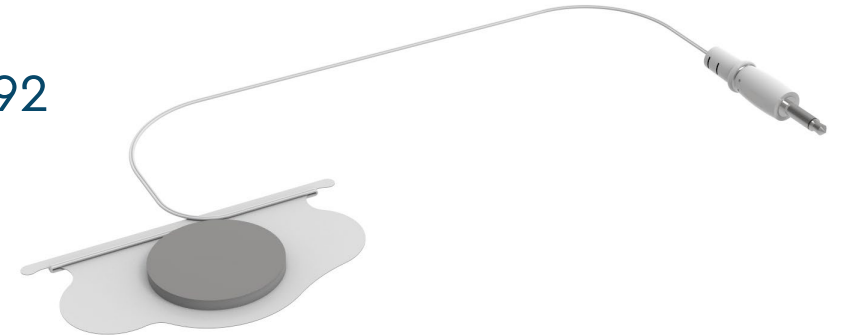


- **Surface Probe Placement:**

- Do not place skin sensor under ThermoWrap
- PN# 014-00323

Please review all indications and contraindications for each probe prior to use.

Refer to Probe Sales Eligibility by Market 701-00491, 701-00492 and 701-00565 to determine where items may be sold.

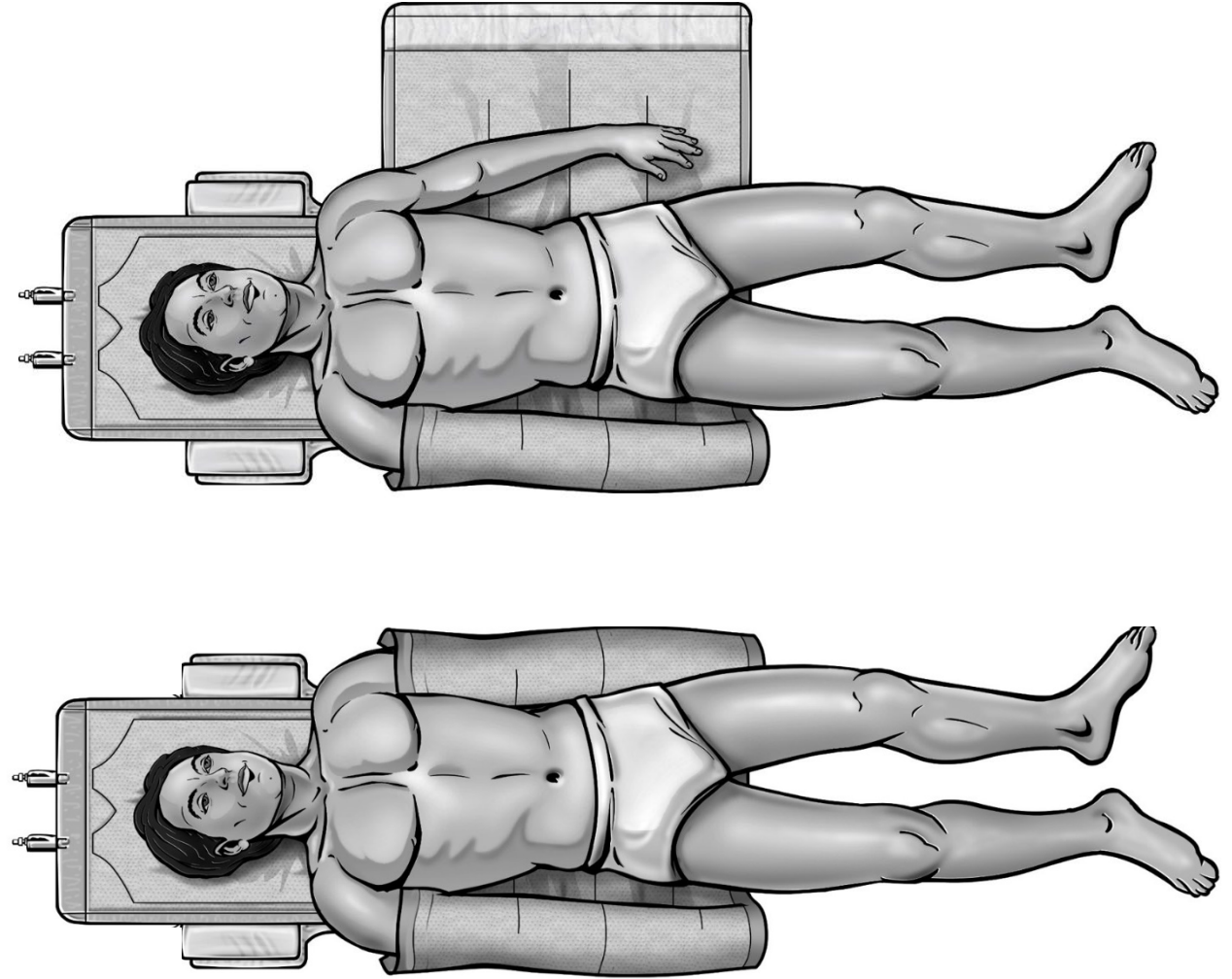
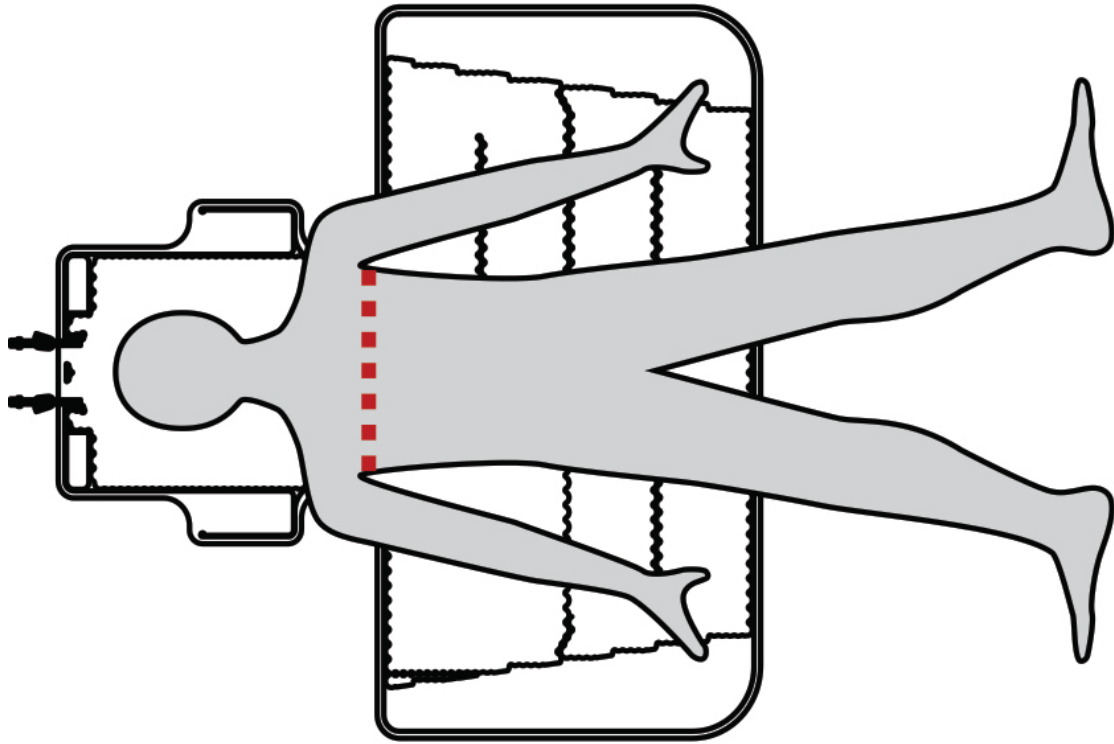


WRAPPING THE PATIENT FOR SURGERY

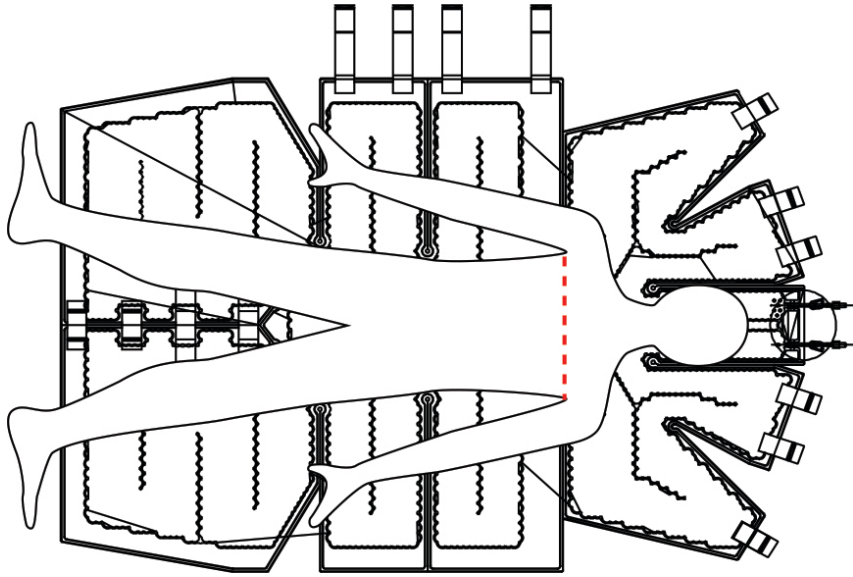
- Secure ThermoWrap on the patient
- See ThermoWrap instructions for use



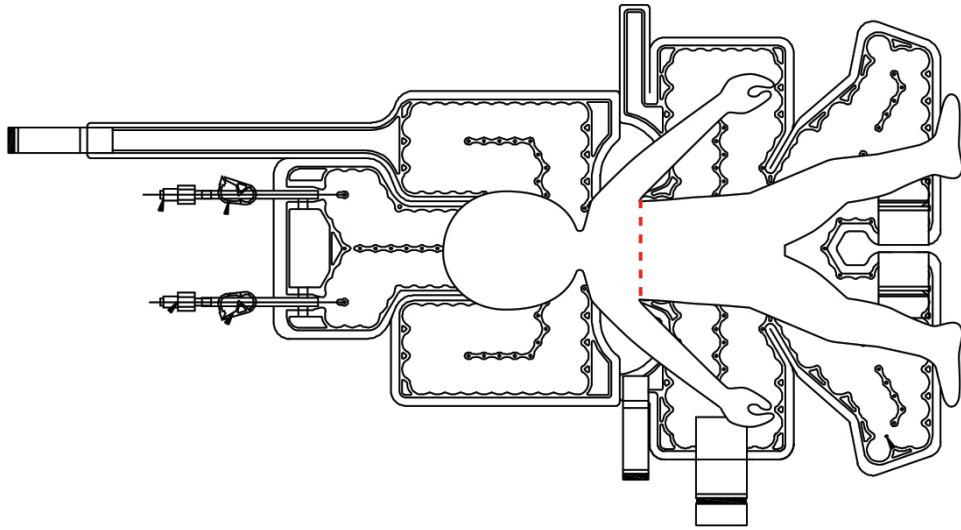
CARDIACWRAP – SECURING ON PATIENT



UNIVERSAL THERMOWRAP – SECURING ON PATIENT



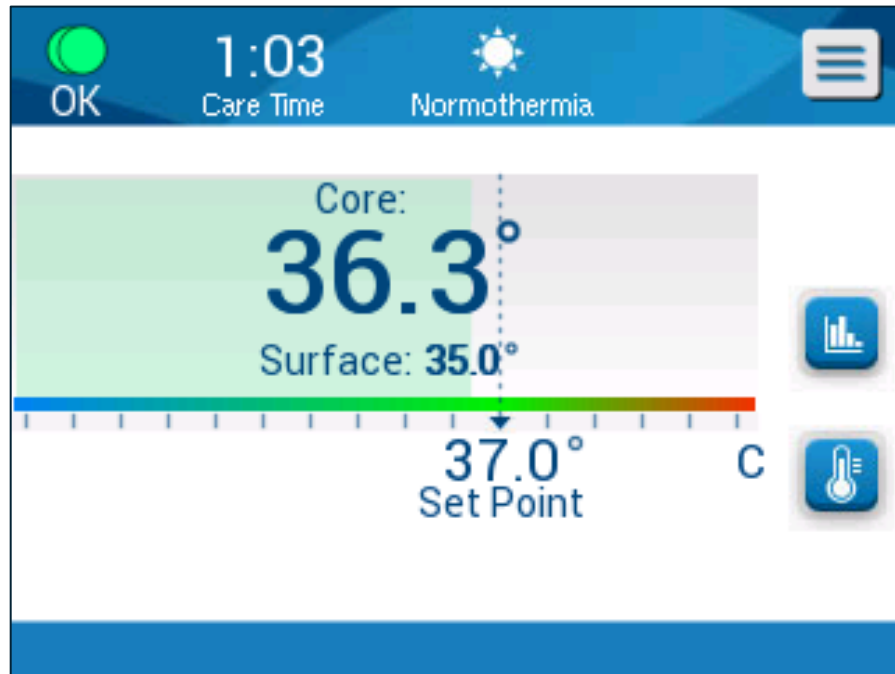
INFANT UNIVERSAL THERMOWRAP – SECURING ON PATIENT



ALLON IS NOW FULLY SET UP

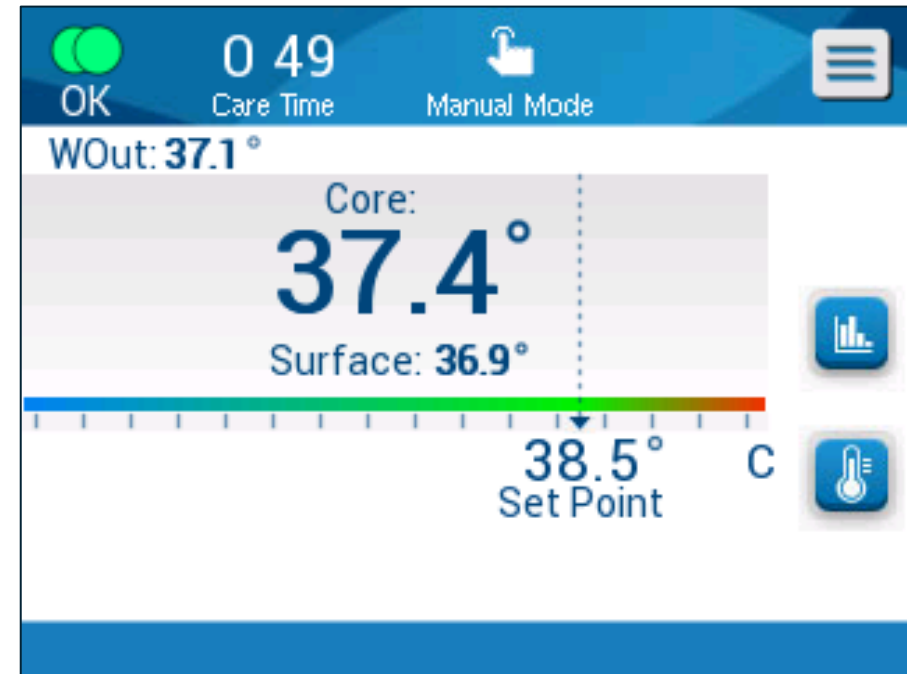
In **Normothermia Mode**, the patient's temperature is now regulated by Allon as set by the physician.

- Normothermia Mode initiates automatically



In **Manual Mode**, the water temperature is now regulated by Allon as set by the physician.

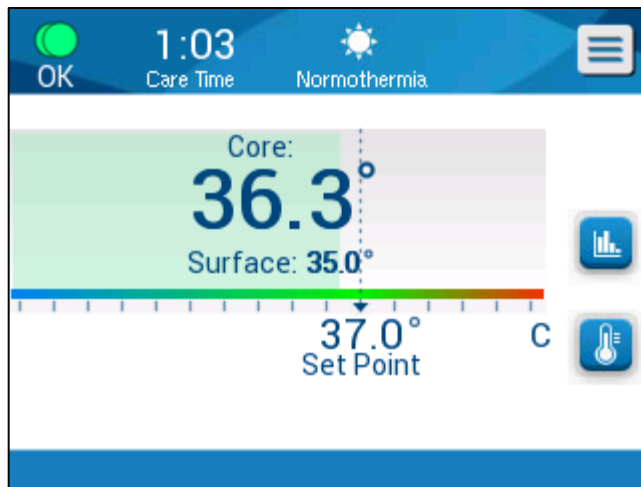
- Accessed by Mode Select screen



ADJUSTING THE SET POINT

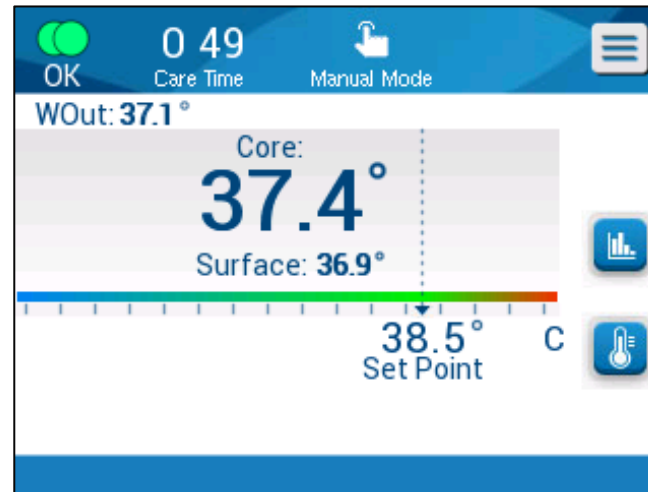
- Normothermia Mode is the default mode
- Always confirm and/or adjust the set point when initiating a mode.

The Default Patient Set Point
Temperature = 37.0°C in
Normothermia Mode



Normothermia Mode

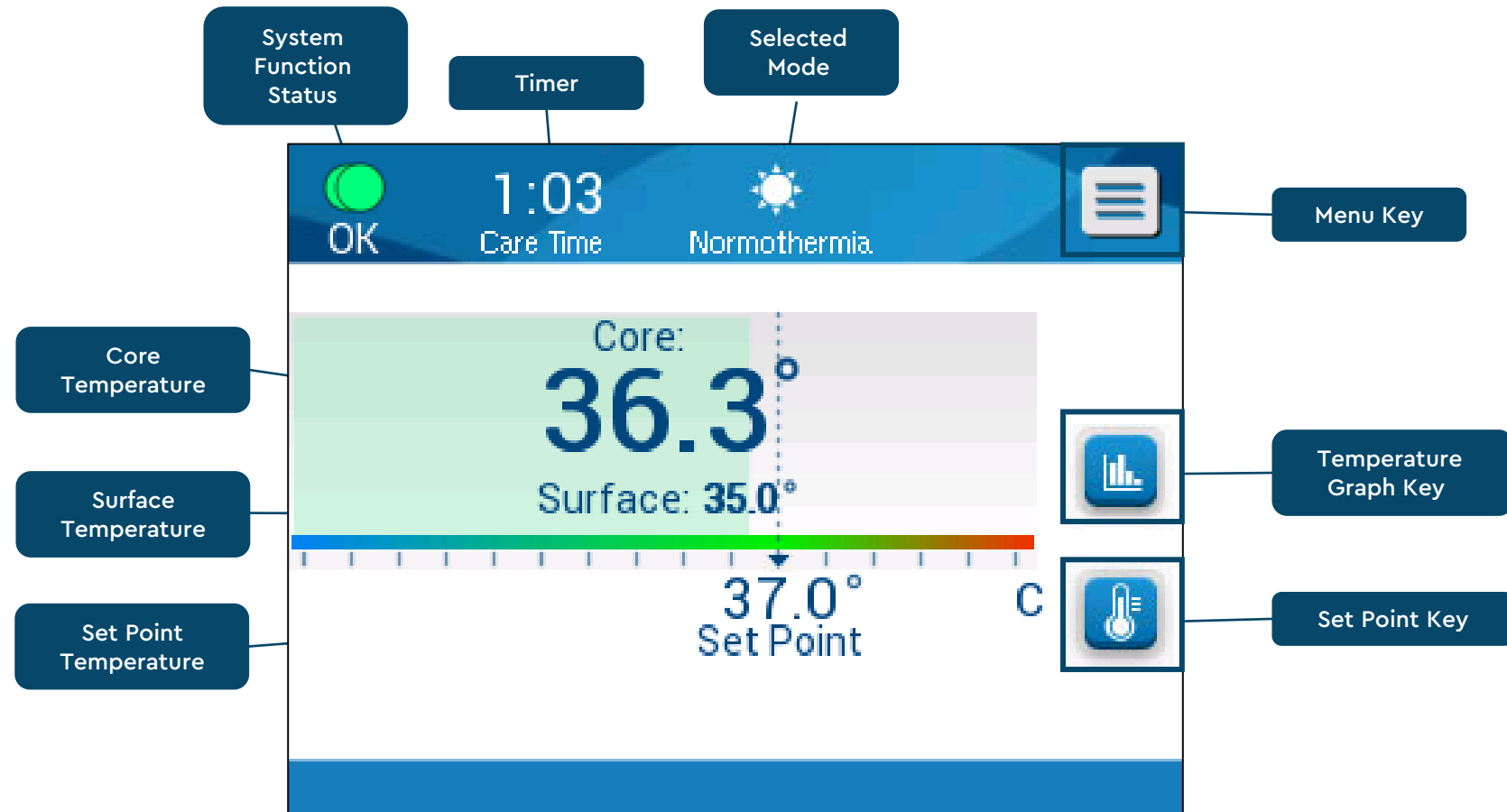
The Default Water Set Point
Temperature = 38.5°C in
Manual Mode



Manual Mode

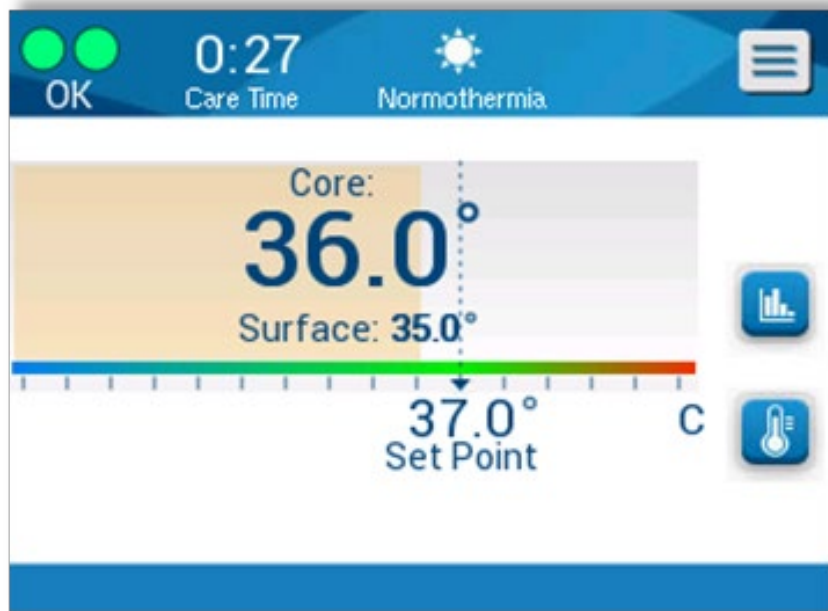
To change Set Point

MAIN OPERATION SCREEN



ALLON 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:

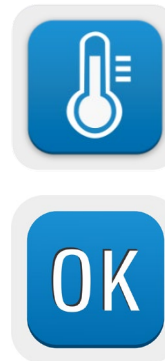


Once the Menu drop down ESC icon appears, touch it to return to previous screen

SELECT SET POINT TEMPERATURE: NORMOTHERMIA MODE

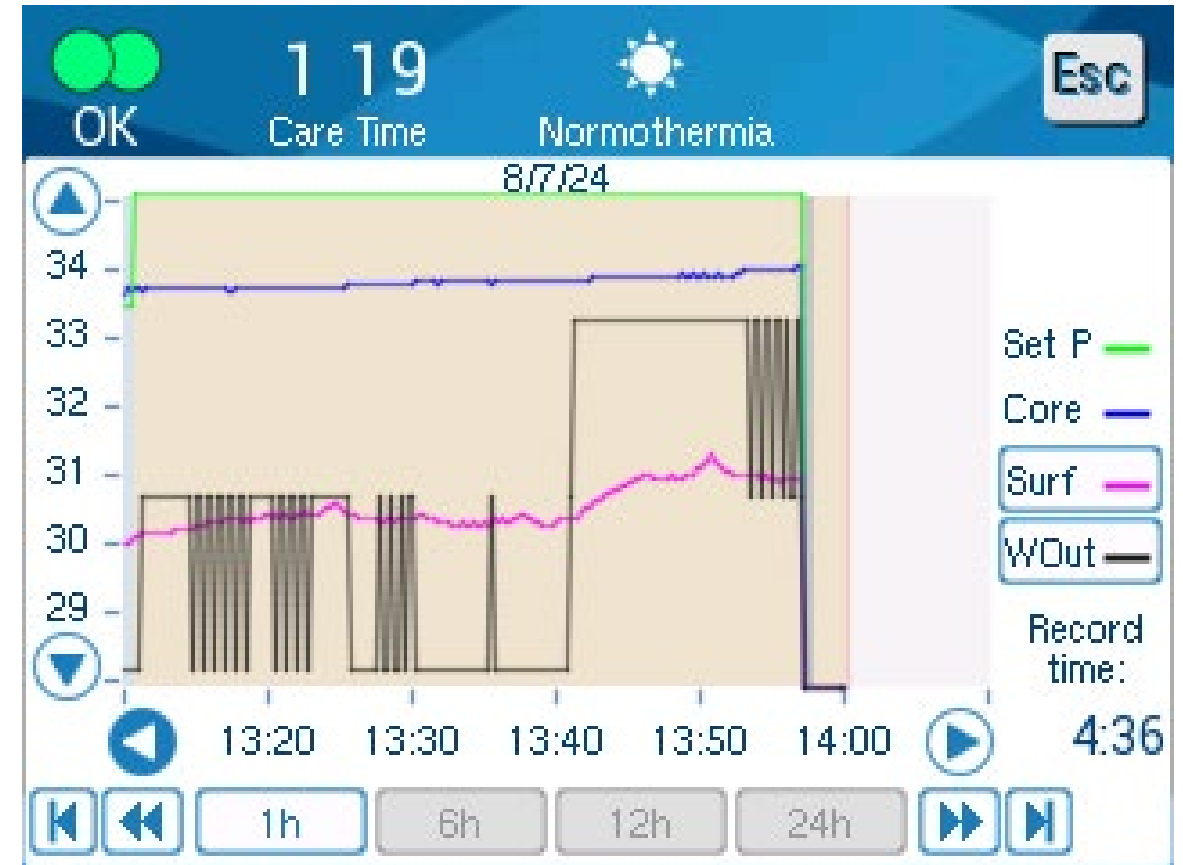
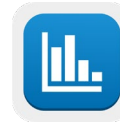
Set Point = Patient's Target Temperature

- The Allon warms/cool the patient to reach and maintain the preset **Set Point**
- When initiating a mode, always confirm the set point temperature is appropriate and adjust as needed.
- **Default Set point = Patient's Core Temperature**
 - **37.0°C** for Normothermia 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
- Allon displays the current case temperature data
 - Set P (Set Point Temperature)
 - Core (Core Temperature)
 - Surf (Surface Temperature)
 - WOut (Water Out Temperature)
- 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



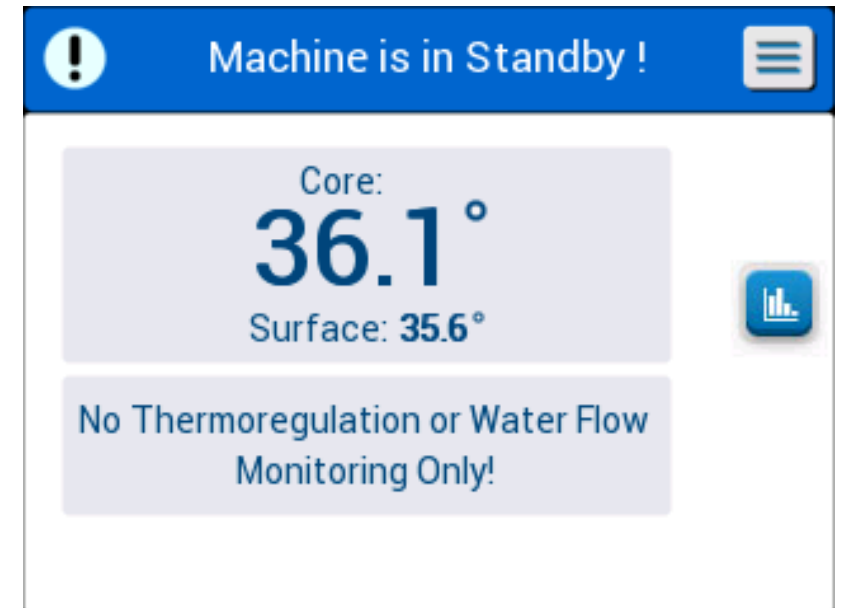
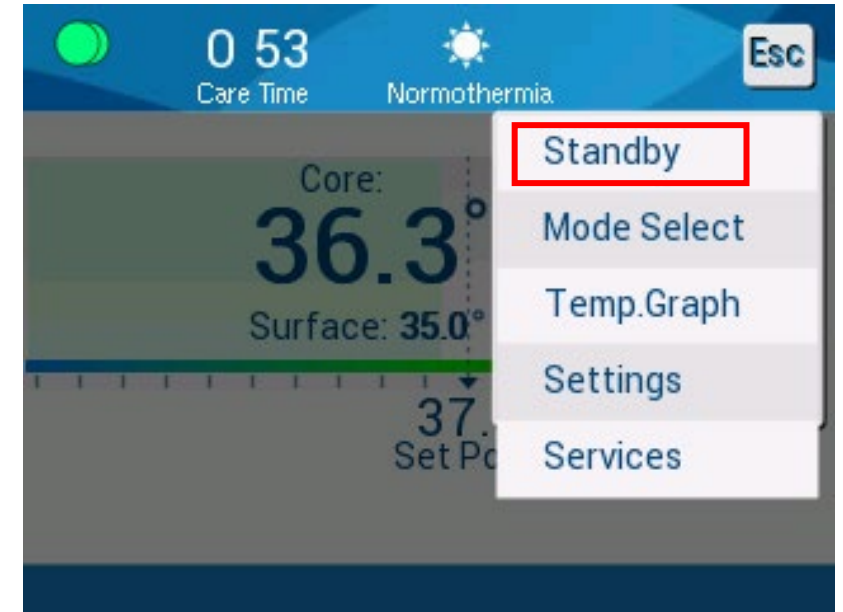
STANDBY MODE

To turn on Standby mode:

1. Touch **MENU** icon/button
2. Select **Standby**
 - Water flow to the ThermoWrap will stop
 - ThermoWrap will deflate
 - Allon will continue to monitor patient's temperature

To resume thermoregulation:

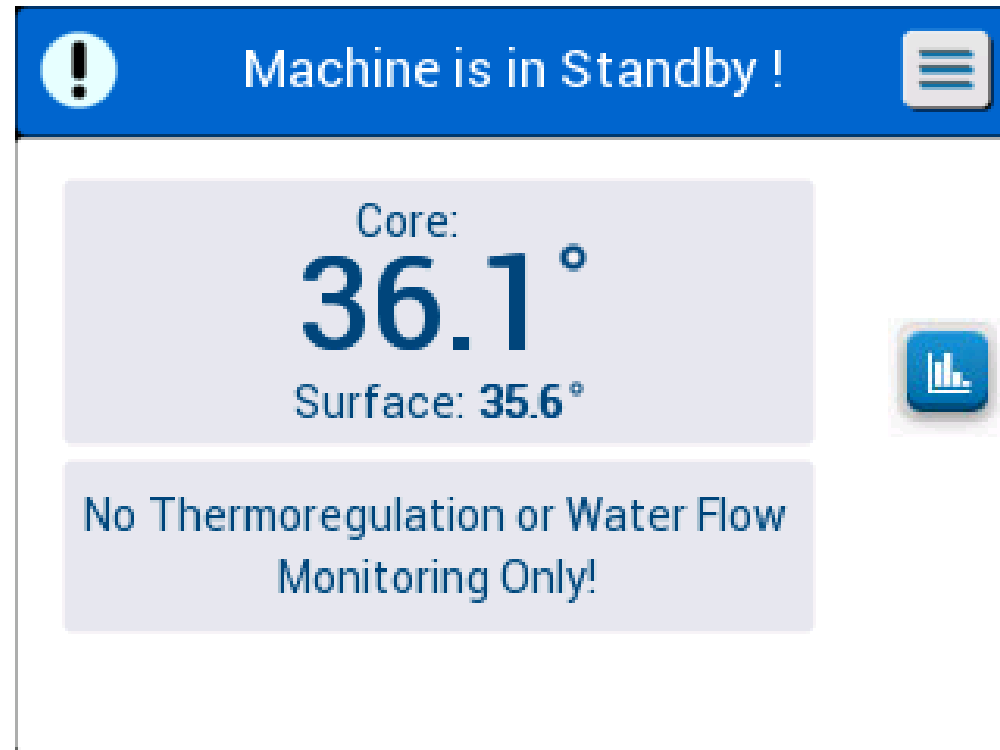
1. Touch **MENU** icon/button
2. Select **OPERATE**



USING STANDBY MODE

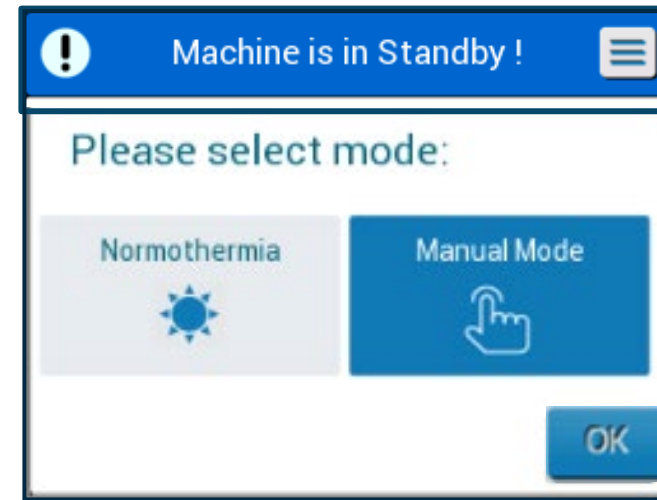
- Turn on Standby mode to stop the water flow to the wrap:
 - Every time that mild or deep hypothermia is in use during the surgery
 - End of therapy, before disconnecting ThermoWrap

Note: While in Standby Mode, the water is circulating internally and being warmed to 38.5°C.



SELECTING MANUAL MODE

- To select Manual Mode:
 - Touch the **MENU** icon/button
 - Select **MODE SELECT**
 - Touch on the **Manual Mode** icon
 - Touch **OK** to confirm



- Use this mode to select the water temperature inside ThermoWrap

SELECT SET POINT TEMPERATURE: MANUAL MODE

Set Point = Target Water Temperature

- The Allon warms/cools the water to reach and maintain the preset Set Point
- Default Set Point = **38.5°C** for Manual Mode
- Range: **36.0°C – 40.0°C**
- Steps: **0.5°C**
- 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



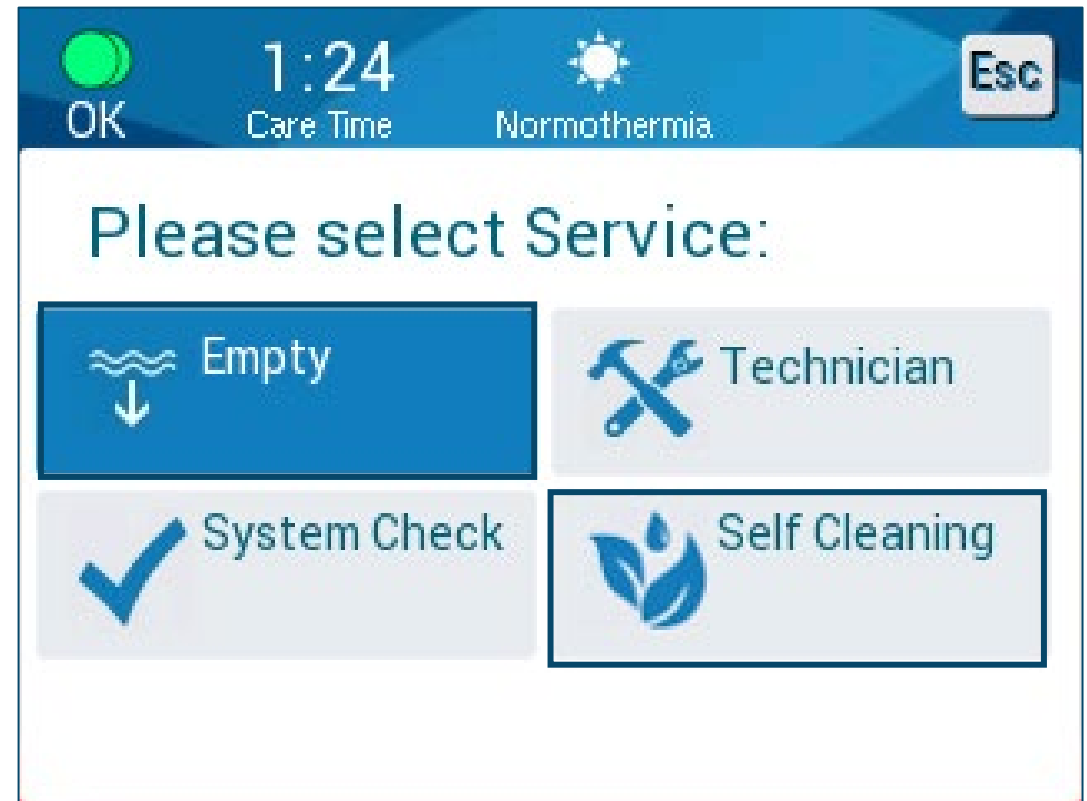


MAINTENANCE

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.



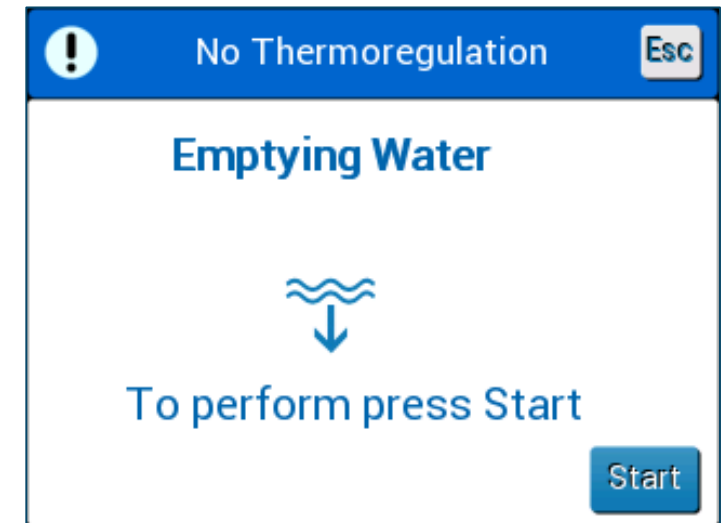
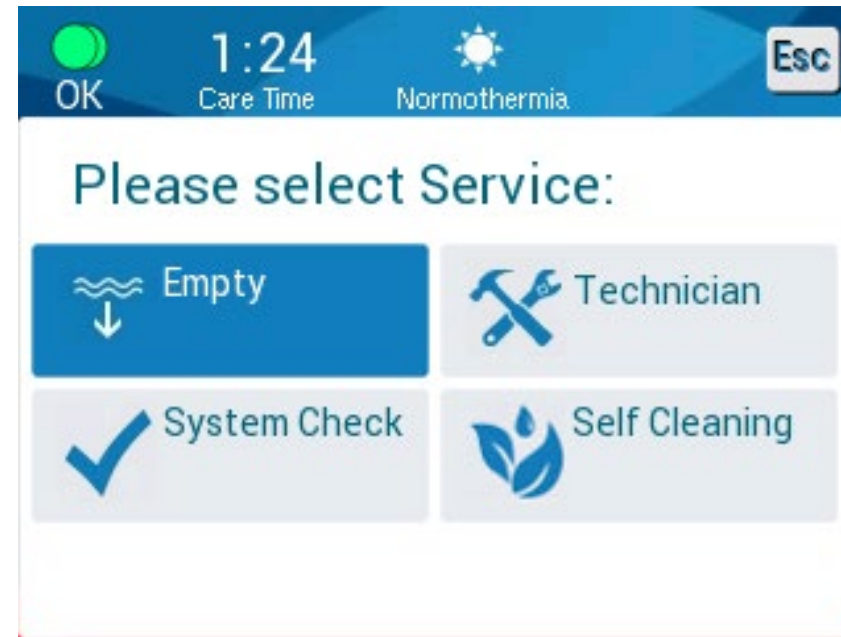
EMPTYING

- 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"*

Drain water from water tank (refer to the operator's manual for detailed instructions):

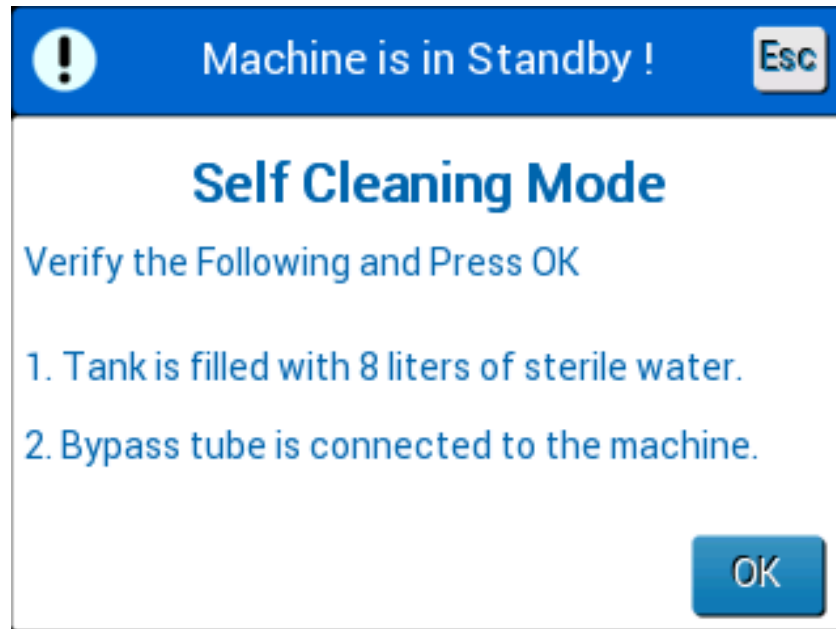
For Frequent Use (3-4 times a week): Drain the water once a week

For Infrequent Use: Drain the water after each use



THERMAL DISINFECTION

- Thermal Disinfection is Password Protected
 - Can only be accessed by a Belmont-trained Biomedical Technician
 - Thermal disinfection cycle recommended as part of the annual periodic maintenance
 - Fill with up to 8L of sterile water



ROUTINE MAINTENANCE

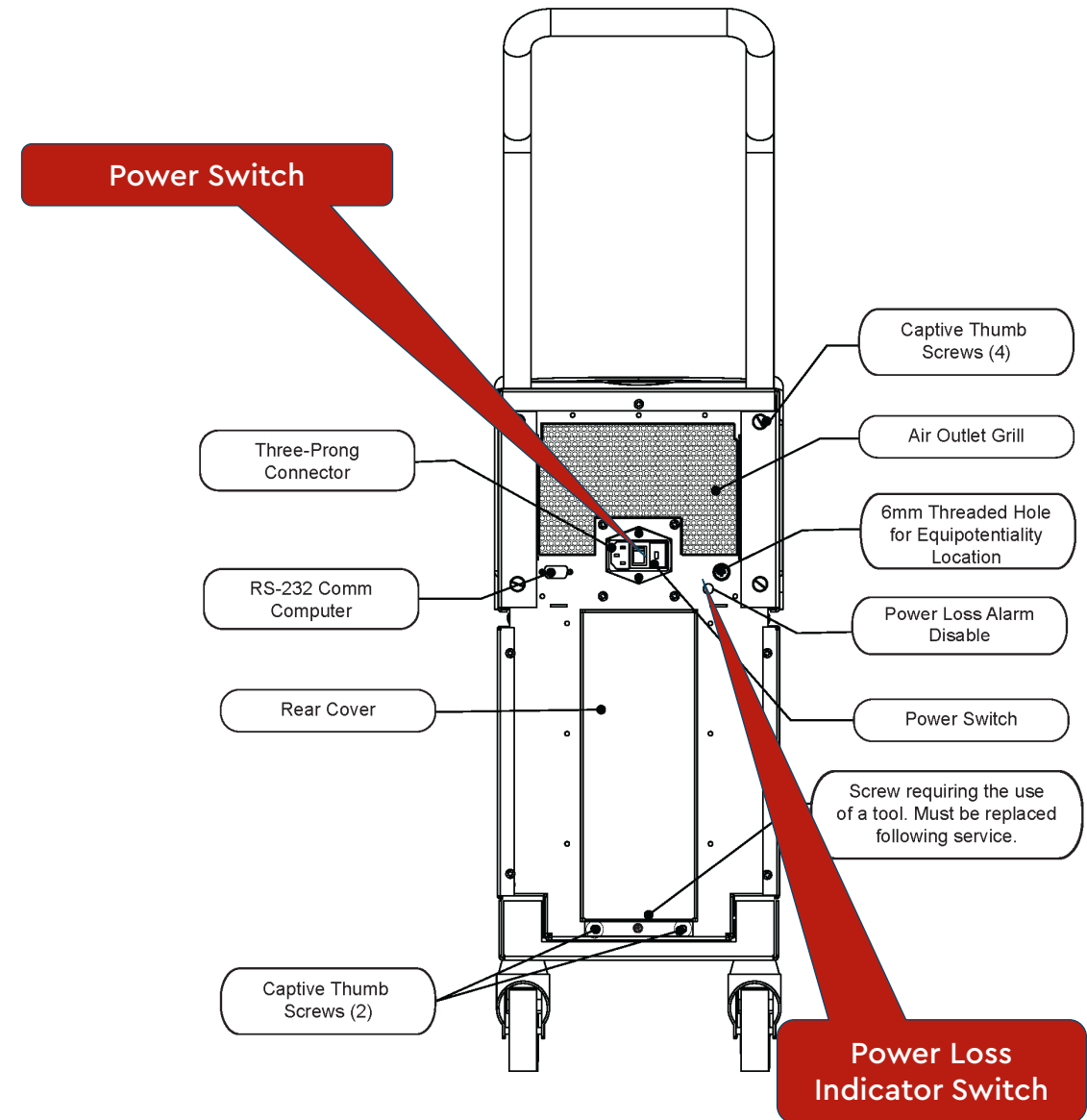
- After each use or between cases, drop sodium dichloroisocyanurate (NaDCC) tablets or powder into the 6.0 liter (1.6 gallon) water tank as per the NaDCC manufacturer's instructions and run the machine for 30 minutes.
 - NaDCC is sold by many manufacturers
 - US market: Brulin BruTab, Thermo Fisher Scientific and Millipore Sigma Aldrich
- Empty Allon®:
 - **For Frequent Use (3-4 times a week):** Once a week
 - **For Infrequent Use:** After each use
- Once a year, perform periodic maintenance by a Belmont Medical Technologies or authorized trained technician only. As part of the annual periodic maintenance, a thermal disinfection cycle will be performed.

<i>Frequency</i>	<i>Inspection/Service</i>	<i>Performed By</i>
Before each treatment	• Clean connecting tubes and Quick Coupling Connectors with a wet cloth. • Perform a visual inspection for any mechanical failure in sensors, connecting tubes, and power cable. • Perform a visual inspection of the exterior of the Allon® Device. • Circulate NaDCC per manufacturer's instructions through Allon® Device for 30 minutes.	Staff
As required by hospital/clinic protocol	• Routine external cleaning and disinfecting. • Empty Allon: – For Frequent Use (3-4 times a week): drain once a week – For Infrequent Use: drain after each use • Replace Connecting Water Hoses (PN #200-00109) periodically	Staff
Annually	• Thermal disinfection • Replace filter * • Preventive maintenance	Belmont Medical Technologies' authorized technician



POWERING OFF ALLON

- Turn off power switch in rear of device
- LED power loss indicator light on front of unit will flash for ten minutes then shut off automatically
- Optional:
 - Turn off LED power loss indicator light by pressing LED power loss indicator button next to power switch in rear of unit



AFTER USE CLEANING

After each operation:

1. Make sure that the system is turned off. If you wish to turn off the flashing light, press the power light indicator switch.
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:
 - 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.
 - Sterilization: Probes can be sterilized with Ethylene oxide. Do not autoclave.
5. Drop sodium dichloroisocyanurate (NaDCC) tablets or powder into the 1.2 liter (0.317 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 exterior of the hoses with Ready To Use wipes 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 wetted with 70% 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.



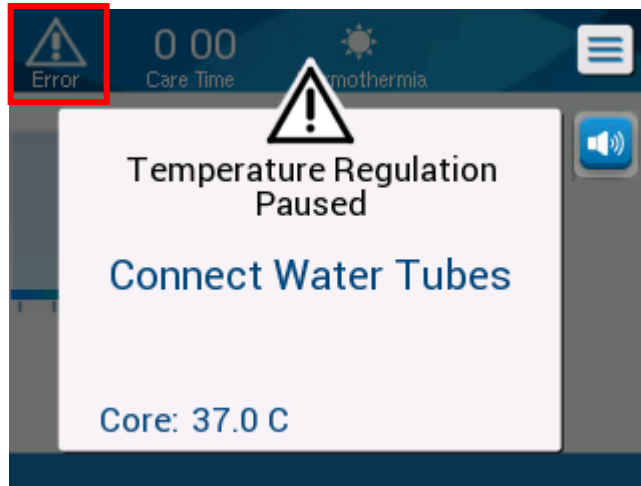


ALLON SETTINGS AND ALARMS

MESSAGES & TROUBLESHOOTING

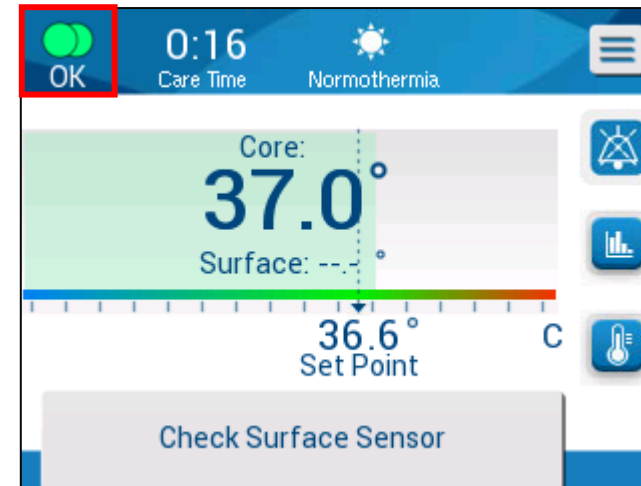
Allon uses two types of messages:

Error Message



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

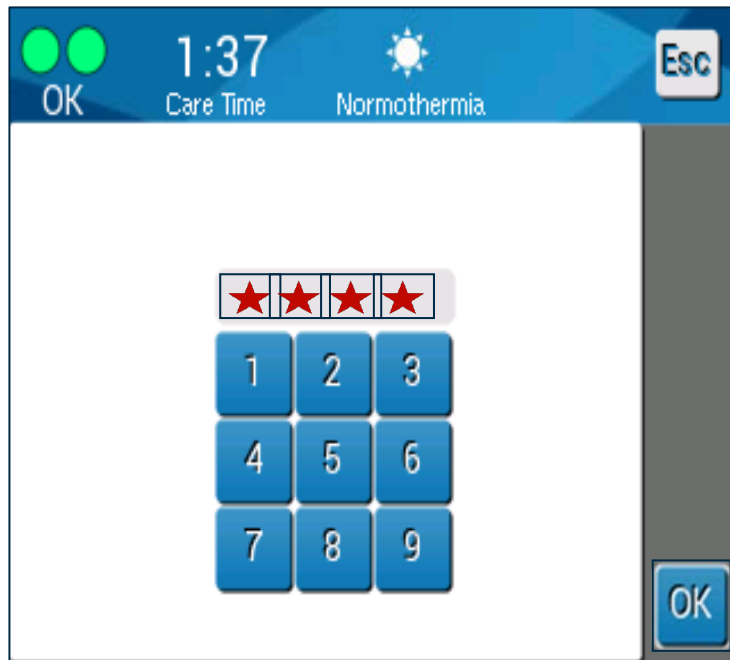
Informative Message



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

SETTINGS SCREEN – PASSWORD PROTECTED

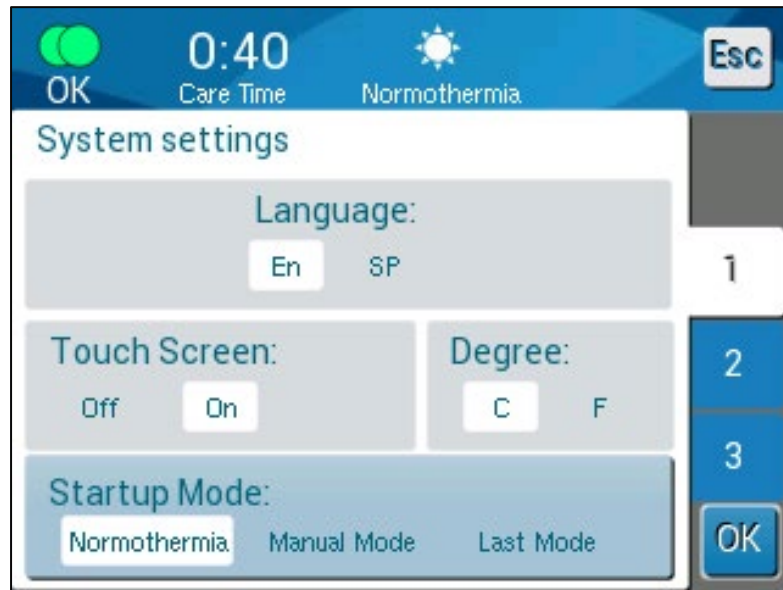
- Password for the Settings Screen: 6873



SETTINGS SCREEN – PASSWORD PROTECTED

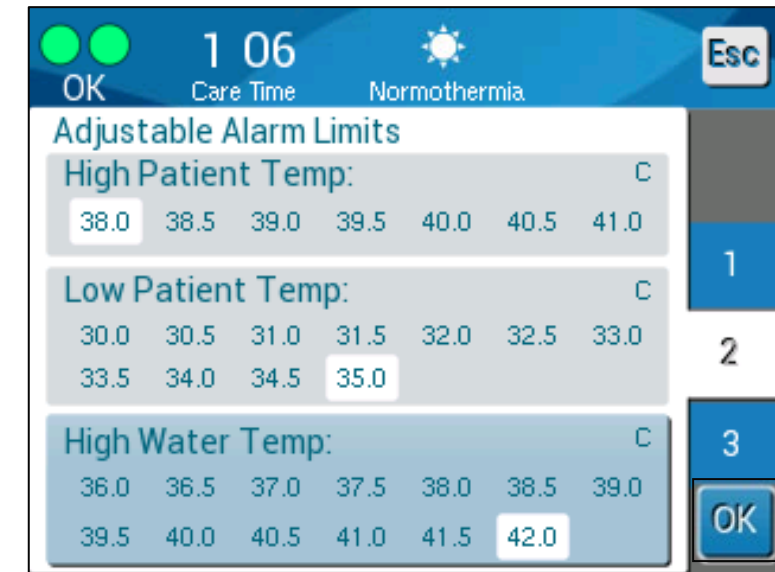
- There are **Three** Screens in the Settings mode
- Push **OK** to confirm and return to main screen
- Allon keeps the last setting to the next power up – default/last selection is highlighted

Screen #1 – General Settings



Screen #1 - General Settings interface. The top bar shows 'OK', '0:40 Care Time', 'Normothermia', and 'Esc'. The main content area is titled 'System settings' and contains three sections: 'Language:' with 'En' and 'SP' options, 'Touch Screen:' with 'Off' and 'On' options, and 'Degree:' with 'C' and 'F' options. Below these is 'Startup Mode:' with 'Normothermia', 'Manual Mode', and 'Last Mode' options. A vertical navigation bar on the right has buttons '1', '2', '3', and 'OK'.

Screen #2 – Setting Alarm Limits

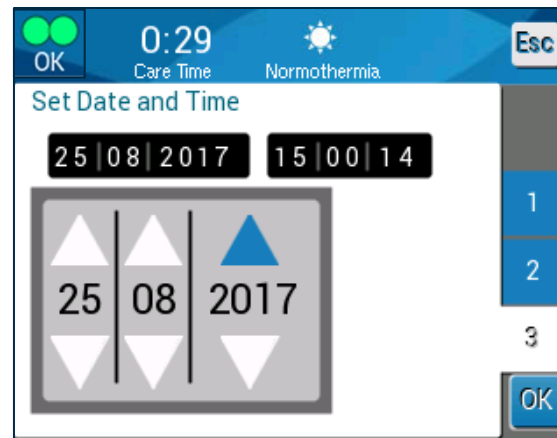
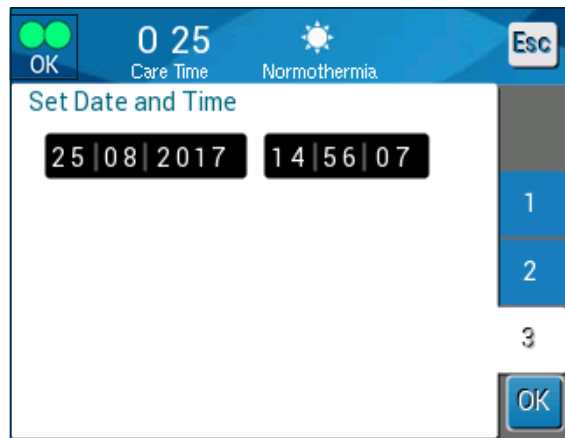


Screen #2 - Setting Alarm Limits interface. The top bar shows 'OK', '1 06 Care Time', 'Normothermia', and 'Esc'. The main content area is titled 'Adjustable Alarm Limits' and contains three sections: 'High Patient Temp:' with a grid of temperature values (38.0 to 41.0) and 'C' unit, 'Low Patient Temp:' with a grid of temperature values (30.0 to 35.0) and 'C' unit, and 'High Water Temp:' with a grid of temperature values (36.0 to 42.0) and 'C' unit. A vertical navigation bar on the right has buttons '1', '2', '3', and 'OK'.

SETTINGS SCREEN – PASSWORD PROTECTED

- Touch the Date / Time to open a selection window
- Use the arrows to modify Date / Time
 - If Celsius has been selected in Setting Screen #1, date format will be in DD/MM/YYYY
 - If Fahrenheit has been selected in Setting Screen #1, date format will be MM/DD/YYYY
- Touch **OK** to confirm your selection and return to the main screen

Screen #3 – Date and Time Setting



WATER TEMPERATURE SETTINGS

- Water Temperature Range:
 - 13°C – 40.8°C
- Alarms when water temperature is >42°C or <10°C
 - Default high water temp alarm is 42°C
 - Keep it there
- Automatically stops flowing into wrap if water temperature >42°C
- If water temperature >43°C (no water flow), the pump stops, the thermoelectric coolers (TECs) are automatically turned off and the unit shuts off with Halt 3.

The screenshot shows the 'Adjustable Alarm Limits' menu on a device. The top status bar includes two green indicator lights, the text 'OK', '1 06' (likely time), 'Care Time', a sun icon, 'Normothermia', and an 'Esc' button. The menu is divided into three sections: 'High Patient Temp', 'Low Patient Temp', and 'High Water Temp'. Each section has a grid of temperature values in degrees Celsius. In the 'High Patient Temp' section, 38.0 is highlighted. In the 'Low Patient Temp' section, 35.0 is highlighted. In the 'High Water Temp' section, 42.0 is highlighted. On the right side of the screen, there are three large buttons labeled '1', '2', and '3', and an 'OK' button at the bottom right.

Adjustable Alarm Limits							
High Patient Temp: °C							
38.0	38.5	39.0	39.5	40.0	40.5	41.0	
Low Patient Temp: °C							
30.0	30.5	31.0	31.5	32.0	32.5	33.0	
33.5	34.0	34.5	35.0				
High Water Temp: °C							
36.0	36.5	37.0	37.5	38.0	38.5	39.0	
39.5	40.0	40.5	41.0	41.5	42.0		

PRESSURE RELIEF ALGORITHM

Normothermia Mode

- Initial Phase of Regulation:
 - 12 minutes of water flowing
 - 1 minute of no water flow
- Steady State (Once 90 minutes have passed and patient has reached the set point):
 - 12 minutes of water flowing
 - 12 minutes of no water flow
- At Any Point:
 - Difference of $>0.3^{\circ}\text{C}$ between Set Point and Core Temperature will cause water to flow back into the wrap

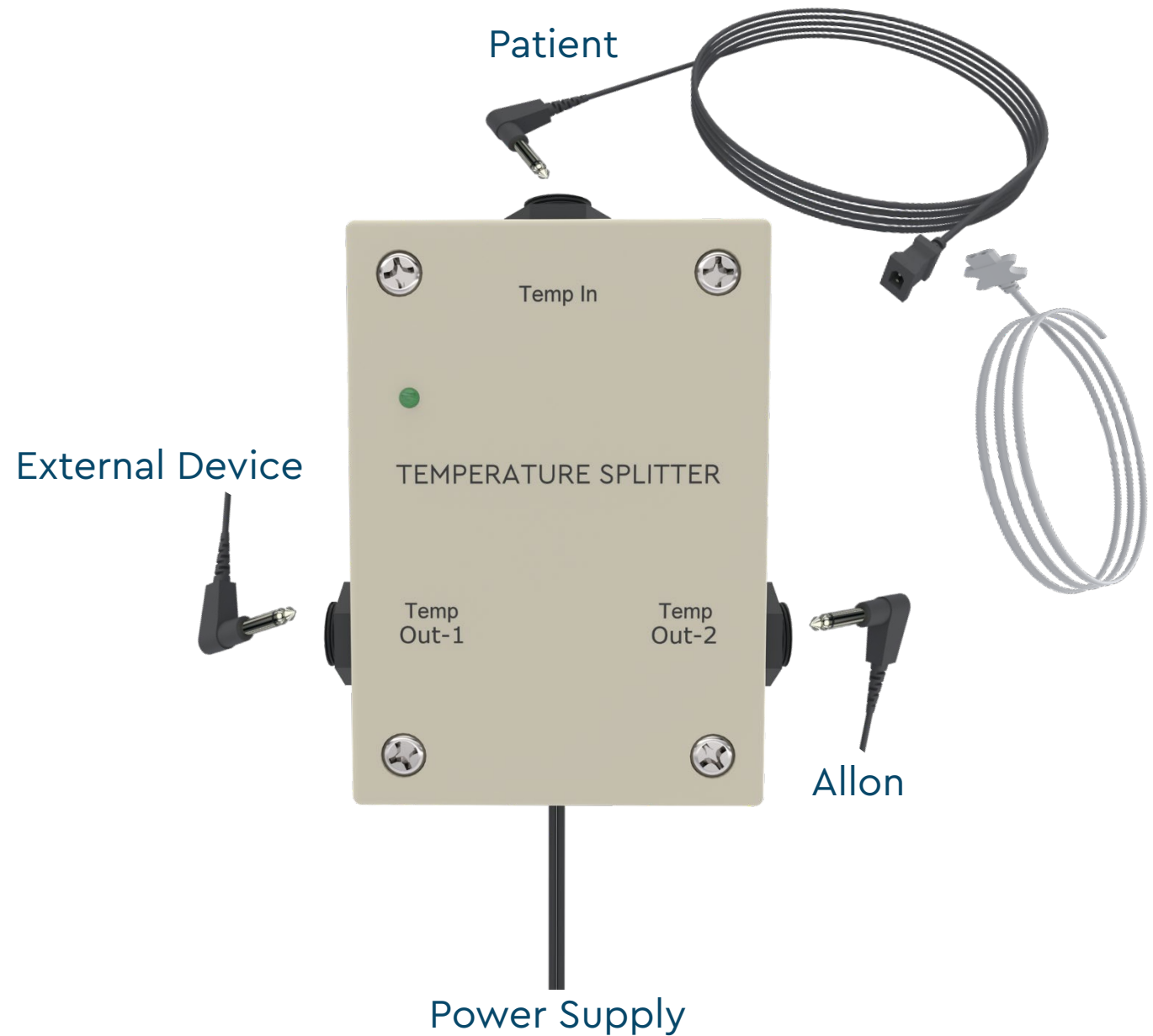
Manual Mode

- At all times:
 - 12 minutes of water flowing
 - 1 minute of no water flow



TEMPERATURE SPLITTER

- Optional accessory
- Shares patient core temperature with an external device



POWER INTERRUPTS

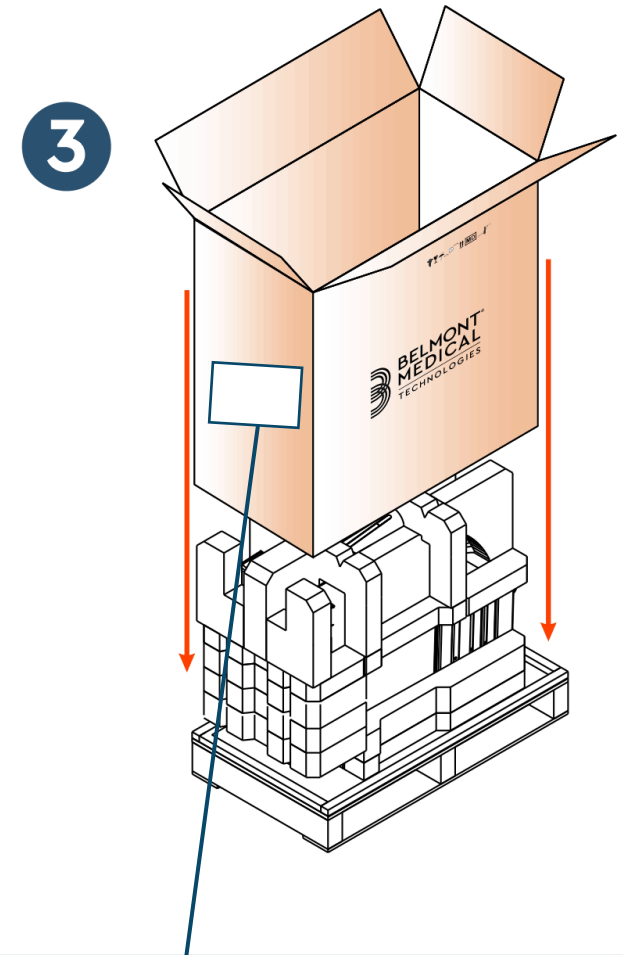
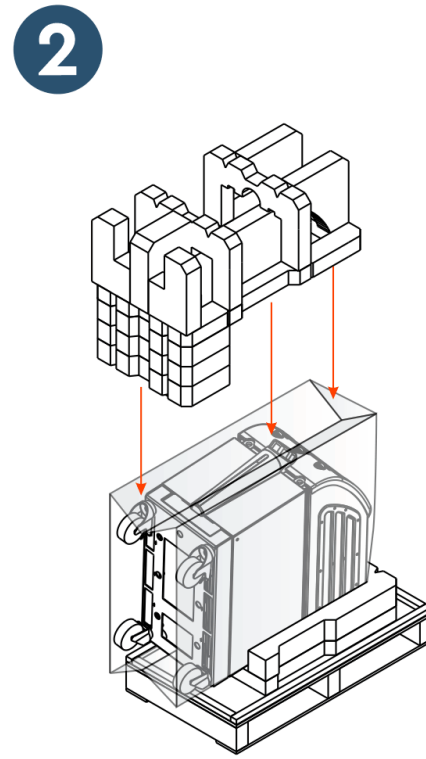
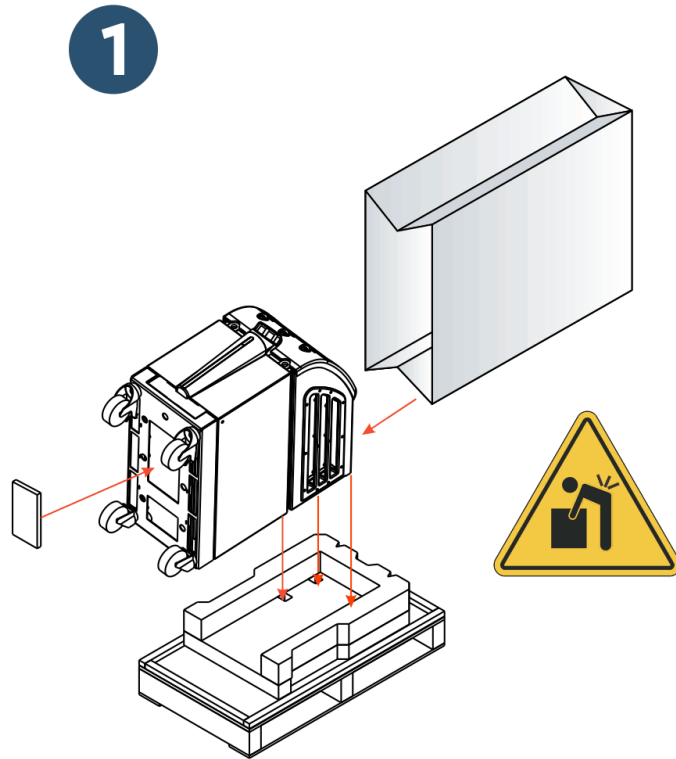
CAUTION!

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

- Interruptions longer than 10 minutes return the machine to the Start-up Screen. An alarm will sound when the power is returned to indicate that the machine has returned to the Startup screen.
- Interruptions shorter than 10 minutes return the machine to the mode that was operating before the interruption, but a warning will appear.



PACKING ALLON FOR SHIPMENT

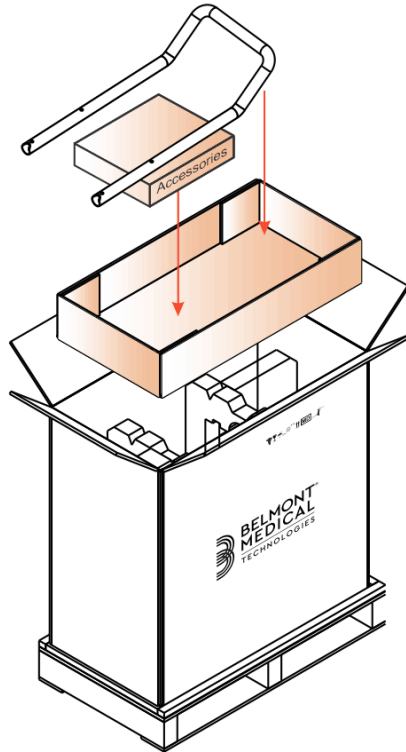


Note: Allon must always ship in the Belmont box!

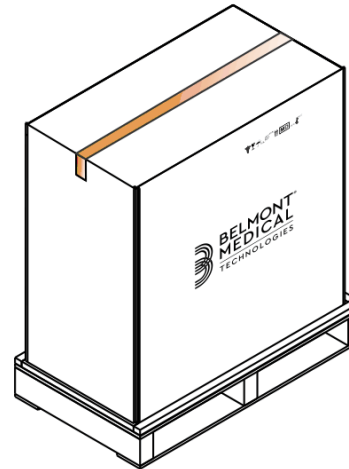
Packing instructions are affixed to the box.
Please refer to instructions on the box.

PACKING ALLON FOR SHIPMENT

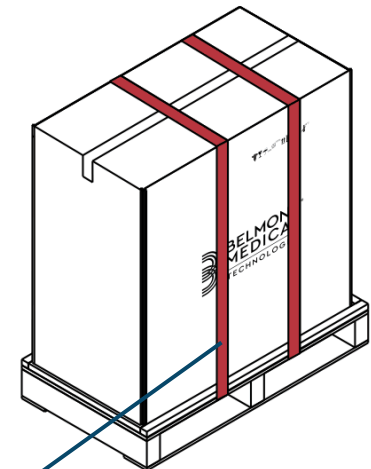
4



5



6



General purpose straps are needed for shipping and are not included with the shipment.

IMPORTANT POINTS

- Use sterile water or 0.22 micron filtered water only.
- Both core and surface temperature probes must be plugged into the Allon device when operated in Normothermia mode.
- ThermoWrap should be filled with water prior to wrapping and securing on patient.
- ThermoWrap should stay one finger loose on the patient.
- Do not use ThermoWrap to lift the patient.
- Avoid handling ThermoWrap with sharp objects.
- Common practice guidelines to prevent pressure sores should be followed.
- Avoid accumulation of fluids between skin and ThermoWrap.





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MEDICAL

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THANK YOU

