CoreConnect™

Temperature Management Solutions

Clinical Training Workbook

ARCTIC SUN® 5000

TEMPERATURE MANAGEMENT SYSTEM

BARD | MEDICAL

Indications for Use:

The ARCTIC SUN® Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature in adult and pediatric patients of all ages.

Contraindications:

There are no known contraindications for the use of a non-invasive thermoregulatory system.

- Do not place ARCTICGEL™ Pads on skin that has signs of ulcerations, burns, hives or rash.
- Do not remove the fabric release liner of the Neonatal ARCTICGEL™ Pad and expose the hydrogel.
- Do not place ARCTICGEL™ Pads on immature (non-keratinized) skin or premature babies.
- While there are no known allergies to hydrogel materials, caution should be exercised with any patient with a history of skin allergies or sensitivities

Warnings:

When using the ARCTIC SUN® Temperature Management System, note that all other thermal conductive systems, in use while warming or cooling with this device may interfere with patient temperature control.

Cautions:

Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to edema, diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy. Examine the patient's skin under the ARCTICGEL™ Pads.

Skin injury may occur as a cumulative result of pressure, time and temperature.

- Carefully remove ARCTICGEL™ Pads from the patient's skin at the completion of use. Aggressive removal or removal of cold pads from the patient's skin may result in skin tears.
- The rate of temperature change and potentially the final achievable patient temperature is affected by many factors. Treatment application, monitoring and results are the responsibility of the attending physician. If the patient does not reach target temperature in a reasonable time or the patient is not able to be maintained at the target temperature, the skin may be exposed to low or high water temperatures for an extended period of time which may increase the risk for skin injury.

Please consult package insert for more detailed safety information and instructions for use.

Clinical Support

TARGETED TEMPERATURE MANAGEMENT has become one of the most important new advances in critical care. It is through the work of many different people, working in all facets of the hospital, that the full potential of temperature management is realized. Upon completion of The ARCTIC CIRCLE™ Clinical Resource Program, you become a leader within your field operating at the center of the circle of care.

Module Goals

- *The following information is intended to provide guidance in providing optimal care of patients treated with the ARCTIC SUN® Temperature Management System.*
- *This information is not intended to replace formal in-service training or the use and understanding of the Help Screens.*
- *Please refer to the Help Screens for complete indications, instructions, warnings and cautions pertaining to the use of the ARCTIC SUN® Temperature Management System.*

Table of Contents

1 MODULE | Electronic Inservice

www.medivance.com

To prepare for your product training workshop, you will need to complete an electronic learning module. To complete this, you will need access to the Internet.

1. Visit www.Medivance.com.
2. Click on Training/Clinical ARCTIC CIRCLE tab.
3. Select ARCTIC SUN® 5000 or ARCTIC SUN® 2000 Training Modules.
4. Enter the following username and password to access the secure zone of the website:

   Username: arcticsun
   Password: arcticcircle

   (NOTE: The training materials provided are intended for use by hospitals that have made a decision to evaluate or purchase the ARCTIC SUN® Temperature Management System)

5. Select Module 1: Computer Based Learning.
6. Read the terms, and if acceptable click that you accept and agree.
7. If you are a first-time user of the system, you will need to create your personal user account. Click on the New User link. Enter your email address (this will become your personal username) and a password of your choosing. Once you've created a user account, you will use this to complete additional modules or for retraining in the future.
8. This self-paced learning module will take approximately 15 minutes to complete.

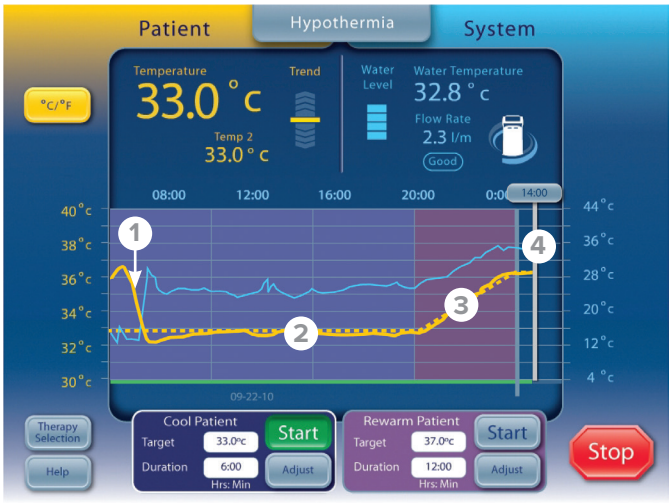
Please note: Every time you visit the training section of the website, you will be required to pass through the secure zone using the generic username and password outlined above. To access individual modules, you must use your unique username and password. If you forget your unique password, you can click the "Forgot Password" link to have an automated email sent to the address on file.

If you experience difficulty logging in, please contact your Clinical Manager.

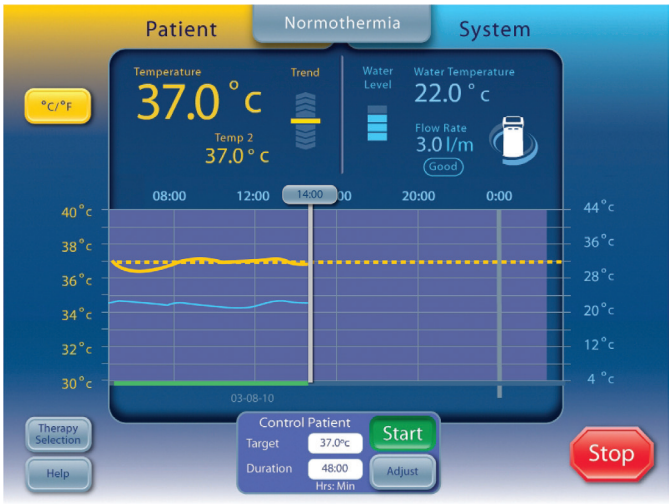
Please consult package insert for more detailed safety information and instructions for use.

2 MODULE | Advanced Patient Care

Goal Directed Automated Therapy



Hypothermia Case



Normothermia Case

4 Phases of Cooling

1. Induction
2. Maintenance
3. Rewarming
4. Normothermia

Precision Targeting

Every second during therapy, the ARCTIC SUN® Temperature Management System monitors patient temperature against your target, making micro-adjustments to the water temperature 30x/hr to ensure the therapy is delivered to your protocol.

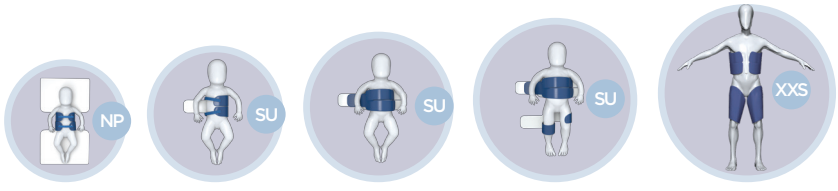
Why use hydrogel for a temperature control device?

- Hydrogel is water-based; it provides excellent surface contact and transfers energy effectively
- Hydrogel has a gentle adhesive nature
- Hydrogel absorbs transpired moisture

ARCTICGEL™ Pads

- Single Kit
  - Patients 16-100+kg (35-220+lbs)
  - Available in 5 sizes
  - Each kit contains 2 back pads and 2 thigh pads
- Universal Pad
  - Supplement coverage on larger patients
  - Each kit contains one pad
- Small Universal Pad
  - Patients 2.5-16 kg (5.5-35 lbs)
  - Each kit contains one pad
- Neonatal Pad
  - Neonates 1.8-4.5kg (4.0-9.9 lbs)
  - Each kit contains one pad

ARCTICGEL™ Pad Size Charts



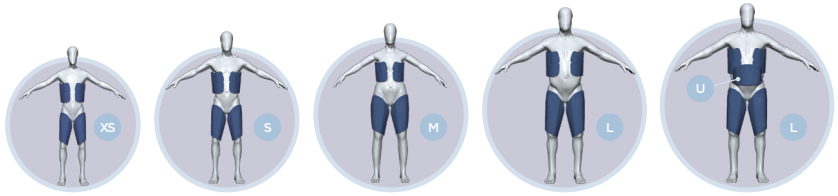
Neonatal
1.8-4.5kg
(4.0-9.9 lbs)
3180202

1 Small Universal
2.5-5kg
(5.5-10 lbs)
3180104

2 Small Universal
5-10kg
(10-22 lbs)
3180104

3 Small Universal
10-16kg
(22-35 lbs)
3180104

XX Small
16-30kg
(35-66 lbs)
31702



X Small
31-45kg
(67-98 lbs)
31703

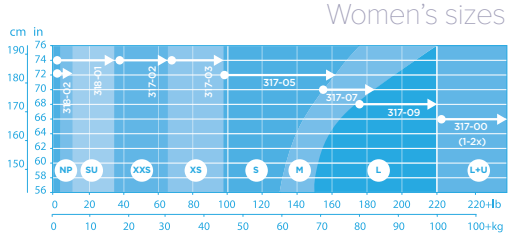
Small
46-60kg
(98-150 lbs)
31705

Medium
61-75kg
(150-180 lbs)
31707

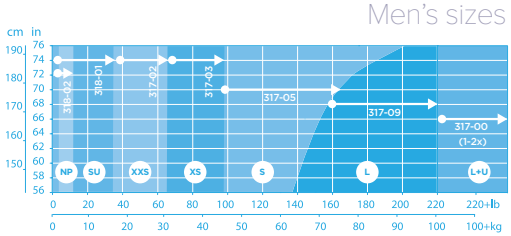
Large
76-100kg
(180-220lbs)
31709

Large + Universal
100+kg (220+lbs)
31700 (Universal)

Women's sizes

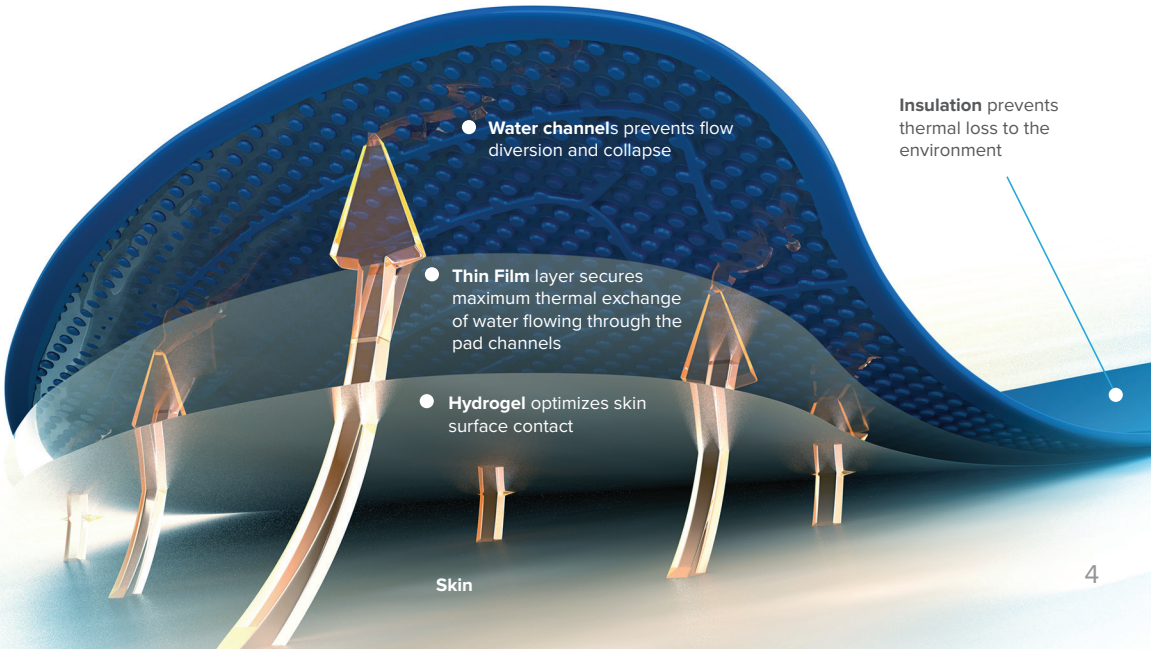


Men's sizes



ARCTICGEL™ Pad Kits
Sizing Charts

ARCTICGEL™ Pad Patented Three-Layered Construction



Applying ARCTICGEL™ Pads

- Pads must be used immediately after the package is opened
- Place on intact skin
  - Do not place ARCTICGEL™ Pads on skin that has signs of ulceration, burns, hives, or rashes
- While there are no known allergies to hydrogel materials, caution should be exercised with any patient who has a history of skin sensitivities or allergies
- ARCTICGEL™ Pads are clean, but not sterile; do not place in a sterile field
- Do not allow antibacterial agents to pool underneath the ARCTICGEL™ Pads
- Do not allow body secretions to collect underneath the Gel Pads.
- Do not place positioning devices underneath the ARCTICGEL™ Pads.
- Do not place positioning devices under the pad manifold or patient lines
- Avoid oils, lotions, and powders
- Apply to dry skin
- No need to shave, gel will not pull hair
- Avoid covering or interfering with joint motion
- Large breasts should clear the pad edges

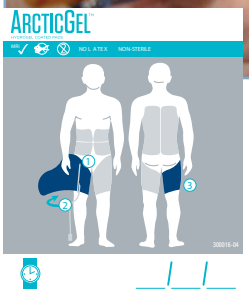
Small Universal Pad Placement

- The ARCTICGEL™ Small Universal Pads are only for use with the ARCTIC SUN® Temperature Management System. See Operators Manual for detailed instructions on system use.
- Select the proper number of pads for the patient size and clinical indication. However, the rate of temperature change and potentially the final achievable temperature is affected by pad surface area, patient size, pad placement and water temperature range. Best system performance will be achieved by using the maximum number of pads.
- The following sizing chart is provided as guidance. Modify the number of pads and locations as necessary to meet specific clinical needs.
- Place the pads on healthy, clean skin only. Locate pad edges away from articulating areas of the body to avoid irritation. Place pads to allow for full respiratory excursion.
- The pad surface must be contacting the skin for optimal energy transfer efficiency. The Small Universal Pads are provided with a cloth liner over the hydrogel. The pads may be used with the cloth liner in place or removed to expose the hydrogel adhesive. If the cloth liner is used, secure the pads with the Velcro straps to ensure good contact with the skin. The pads may be removed and reapplied if necessary.
- Due to the small patient size and the potential for rapid patient temperature change
- It is recommended to use the following settings:
  - Water Temperature High Limit: ≤40°C (104°F)
  - Water Temperature Low Limit: ≥10°C (64.4 °F)

Neonatal Pad Placement

1. Place the patient (1.8 - 4.5 kg; 4.0 - 9.9 lb) on the pad. Avoid placing the patients over the manifolds or other high pressure locations. The rate of temperature change and potentially the final achievable temperature is affected by pad surface area coverage, placement, patient size, and water temperature range.
2. The pad surface must be contacting the skin for optimal energy transfer efficiency.
   a) If desired, the center section of the pad can be wrapped around the patient's torso and secured in place using the Velcro tabs provided.
   - If this option is in use, ensure that the edges of the pad are away from articulating areas of the body to avoid irritation.
   - Place pads to allow for full respiratory excursion. e.g. ensure free movement of the chest and abdomen are guaranteed).
   - The pads may be removed and reapplied if necessary.
   - Pads should be placed on healthy, clean skin only.
3. Due to the small patient size (1.8 - 4.5 kg; 4.0 - 9.9 lb) and the potential for rapid patient temperature change, it is recommended to use the following settings to the ARCTIC SUN® Temperature Management System:
   - Water Temperature High Limit: ≤40°C (104°F)
   - Water Temperature Low Limit: ≥10°C (64.4°F)

Document the date pads applied on label



L — Appropriate size will be labeled with a dot

__/__/__ — Date pads applied

Cautions

- Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure, heat or cold
- Patients at risk include those with poor tissue perfusion or poor skin integrity due to:
  - Diabetes
  - Peripheral vascular disease
  - Poor nutritional status
  - Steroid use
  - High dose vasopressor therapy
  - Young and old age
  - Anticoagulant therapy
  - Pre-exisiting skin conditions or skin injury
- Skin injury may occur as a cumulative result of pressure, time, and temperature
  - If the patient does not reach target temperature in a reasonable period of time or is not able to be maintained at target temperature, the skin may be exposed to low or high temperatures for an extended period of time which may increase the risk for skin injury
  - If patient is not at target within 4 hours, **OR** if water temperature is below 10°C (50°F) for 8 consecutive hours, refer to ***Patient Temperature Not Controlled*** in ***Help Screens.***
- Maximum system water temperature is 42°C (107.6°F). This setting can be decreased for patients with fragile skin or other medical conditions that put them at higher risk of skin injury
- Minimum system water temperature is 4°C (39.2°F). This setting can be increased for patients with fragile skin or other medical conditions that put them at higher risk of skin injury
- Do not place electrosurgical grounding (Bovie) pads under ARCTICGEL™ Pads
  - The combination of heat sources may result in skin burns

Special Considerations

- Edematous patients
  - Avoid applying pads too tightly
  - Reposition pads as patient swells (i.e. edema) to avoid skin irritation at the edges or blistering and to provide some “give”
  - Skin integrity may be compromised and more vulnerable to mechanical injury

Use of Other Devices with the ARCTIC SUN® Temperature Management System

- Sequential compression boots
  - If indicated, are compatible with the ARCTIC SUN® Temperature Management System
- Specialty beds
  - If indicated, are compatible with the ARCTIC SUN® Temperature Management System
- Continuous passive movement devices (orthopedic patients)
  - May be used if indicated
  - Make certain there are no points of friction or pad overlap near the joint(s) being mobilized

Skin Inspection

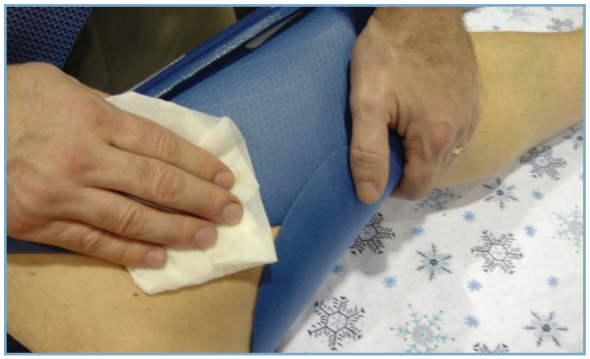
- Examine the skin under the ARCTICGEL™ Pads often, especially in patients with higher risk of skin injury
- Recommended skin inspections every 4-6 hours or per hospital guidelines
  - Light skin- observe color: red, pallor, purple
  - Darker skin- look for darker hues
  - Check for capillary refill
  - Look for abnormalities
- Inspect areas over boney prominences
- Vasoconstriction
  - Skin will be vasoconstricted during cooling

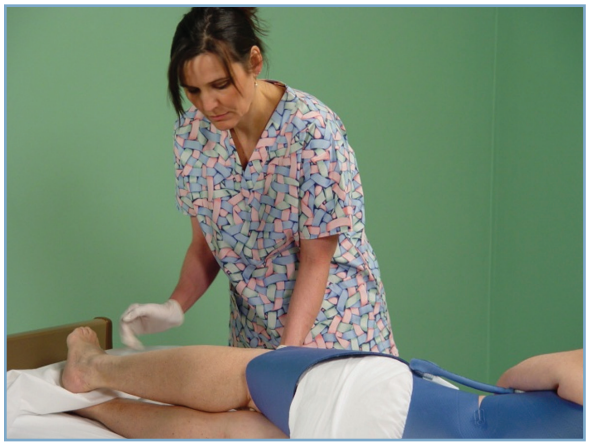
Routine Skin Care

- Replace Pads
  - When the hydrogel no longer uniformly adheres to the skin. Replacing the pads at least every 5 days is recommended
- Bathing Skin
  - Not required before application
  - Make certain skin is dry before applying
- Clean open areas after pads are in place
- Inspect under the pads
- No need to bathe under pads

Incontinence

- Soil wipes easily from outer pad (ill.)
- Clean liquid soil from skin as per hospital protocol
- For unmanageable incontinence, replace soiled pad with ARCTICGEL™ Universal pad if necessary (ill.)



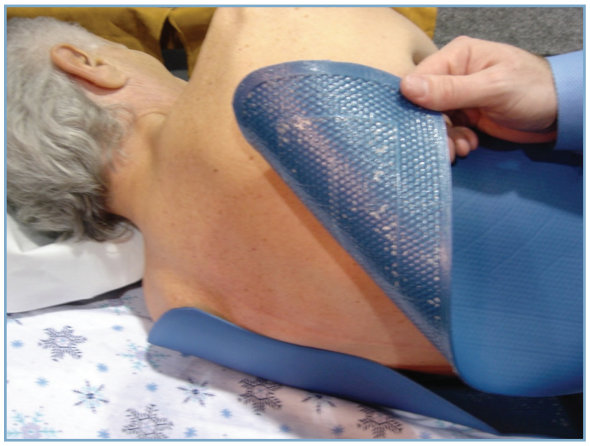


Caution

- Do not allow urine, antibacterial solutions or other agents to pool underneath the ARCTICGEL™ Pads
- Urine and antibacterial agents can absorb into the pad hydrogel and cause chemical injury and may decrease pad adhesion
- Replace pads immediately if these fluids come into contact with the hydrogel

Pad Removal

- Gently lift up the edge (ill.)
- Peel vs. pull
  - Peeling is more gentle
  - Avoid pulling
- Cold pads are stiffer and more adherent; peel cautiously and slowly



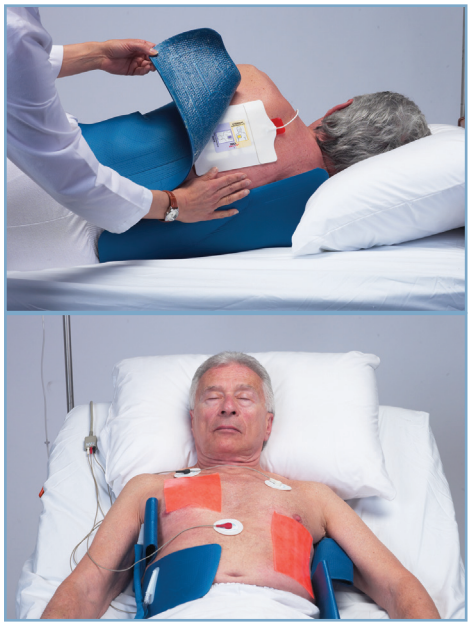
Summary

- Appropriate patient selection is essential
- Understand and adhere to cautions
- Place pads on intact skin
- Remove pads gently by peeling
- Routinely inspect skin
- Closely monitor patient response to treatment and water temperatures

ARCTIC SUN® 5000 Temperature Management System

3 MODULE | Common Questions

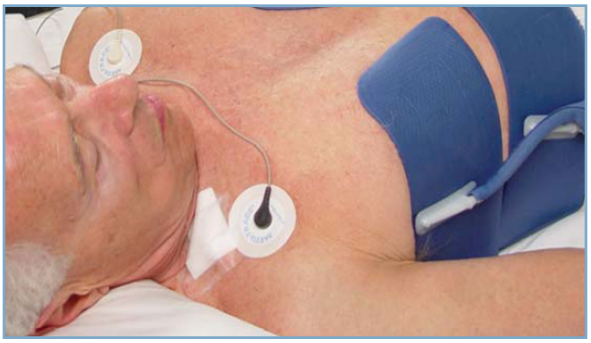
Can I defibrillate while managing a patient with the ARCTIC SUN® Temperature Management System is on?



Defibrillation Options

- Multi-purpose hands free defibrillation pad
  - Place directly on skin and under ARCTICGEL™ Pads
- Hands on conventional defibrillation
  - Apply defibrillation saline or gel pads directly on skin

How are the electrodes for telemetry monitoring placed?



EKG / Electrodes

- Chest or limb lead electrodes may be placed under the ARCTICGEL™ Pads if necessary
- Avoid placing between body structure and pad

Can microorganisms grow in the water reservoir?

Algaecide

- An algaecide (Chloramine-T) must be added to the water when the device is initially filled and each time the unit is drained and refilled
- The water must be drained and filled by the Biomedical department with the algaecide every 6 months
- Each ARCTICGEL™ Pad contains algaecide powder in the layer where the water flows so the reservoir is re-dosed every time you attach a new pad kit

How is a patient weighed with the ARCTICGEL™ Pads on?

- Weigh the patient with the full set of ARCTICGEL™ Pads on
  - Ensure the manifold and large gray hose are lifted off the weighing surface
- Use the ARCTICGEL™ Pad weight chart to deduct the specific pad weight from the total weight
  - Refer to ***Weigh Patients with ARCTICGEL™ Pads*** in ***Help Screens***
  - Pads may be empty or full for weighing procedure

How do I cool a bariatric patient?

- Use a large kit and then use supplemental Universal Pads (up to 2) as needed
- Single Kit
  - Patients 16-100+kg
  - (35-220+lbs)
  - Available in 5 sizes
- Universal Pad
  - Supplement coverage on larger patients

See Pad Sizing Chart and example placement on page 3.

What if the patient has no urine output and a urinary bladder temperature probe is being used?

Probes

- Bladder temperature probes may require urine to be present in the bladder to read accurately (check with the manufacturer to determine minimum urine output necessary)
  - For example: The BARD® Foley temperature probe measures bladder temperature even if there is no urine.
- When cooling to hypothermia, cold-induced diuresis may occur; therefore it is imperative to closely monitor input and output[1]

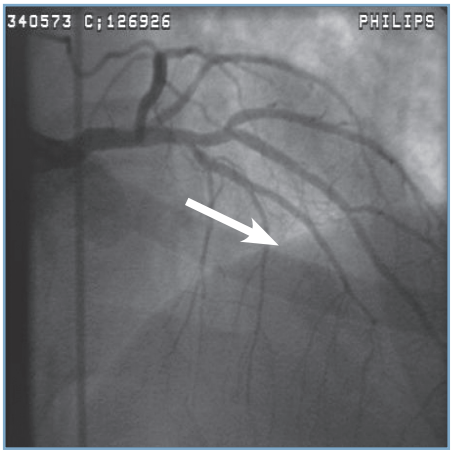
Lag Time with Temperature Probes

- Urinary bladder and rectal temperature probes may not always reflect core body temperature during hypothermia induction
  - It is not uncommon to see a lag time when comparing these probes to a pulmonary artery catheter or esophageal probe during rapid temperature shifts[1,2,3]

Why is the pulmonary artery catheter reading lower than the ARCTIC SUN® Temperature Management System?

- The use of esophageal temperature is recommended for patient core temperature control below 33°C[1,2,3]
  - Lag time is approximately 5 minutes[1,3]
  - Placement can be challenging[1]
- Once cooling becomes generalized, temperatures should correlate appropriately[1]

Do the ARCTICGEL™ Pads need to be removed for Chest X-rays?



X-ray image with ARCTICGEL™ Pad in place

- No need to remove for radiographic imaging[4]
- Even safe with water flowing[4]
- MRI up to 7.0 Tesla, CAT scan, X-ray, Cath Lab[4,5]

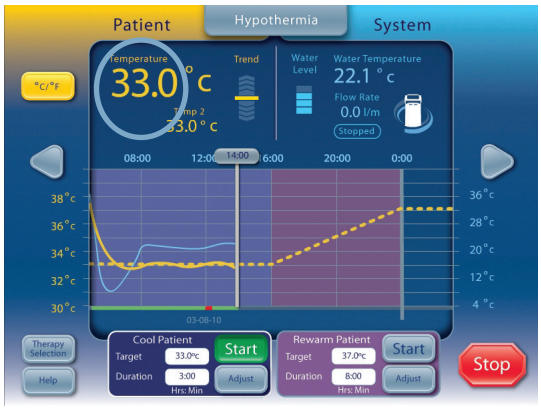
How is a patient with the ARCTIC SUN® Temperature Management System being transported?

Transport

- **Empty Pads** to avoid water spills
  - Press **EMPTY PADS** icon and follow directions on screen
  - This takes about 30 seconds
- Then pinch, push, and pull the connectors to release (ill.)
- If the ARCTIC SUN® Temperature Management System will not be transferred with the patient, leave the device on to keep the chiller running
- Reminder: The ARCTIC SUN® Temperature Management System does not have a battery; for longer procedures, bring the device with you and utilize the setting ***Continue Current Patient***

Please explain the Patient Temperature Trend Indicator

ARCTIC SUN® Temperature Management System Features which help detect Heat Generation



- The ARCTIC SUN® Temperature Management System measures temperature in 0.01°C = 0.04°F increments and can internally identify change before it shows on the display screen
- The **Patient Temperature Trend Indicator** reflects the rate of change in the patient's temperature over the previous 5 minutes
- When assessing a patient, the clinician may refer to the **Patient Temperature Trend Indicator** for insight into patient heat generation which may be indicative of shivering or fever generation

Patient Temperature Trend Indicator

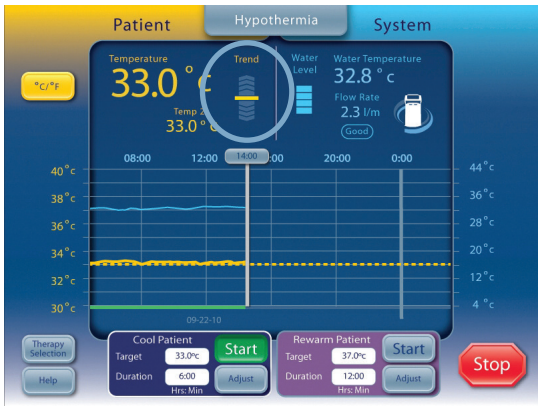
°Fahrenheit

- Center bar- no change or less than 0.45°F change per hour
- One arrow (up or down) - 0.45°F to 0.96°F change per hour
- Two arrows (up or down) - 0.96°F to 1.35°F change per hour
- Three arrows (up or down) - 1.35°F to 3.6°F change per hour
- Four arrows (up or down) - > 3.6°F change per hour

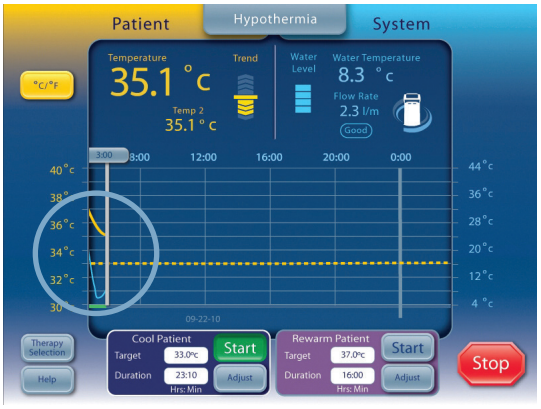
°Celsius

- Center bar- no change or less than 0.25°C change per hour
- One arrow (up or down) - 0.25°C to 0.5°C change per hour
- Two arrows (up or down) - 0.5°C to 0.75°C change per hour
- Three arrows (up or down) - 0.75°C to 2.0°C change per hour
- Four arrows (up or down) - > 2.0°C change per hour

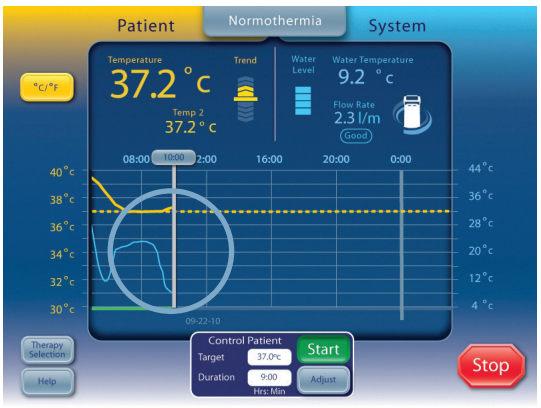
Thermoneutral
No increase or decrease in temperature



Progression of Hypothermia



Patient possibly generating heat as indicated by a drop in water temperature

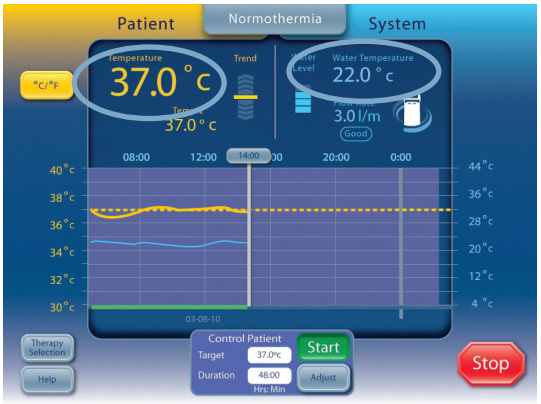


Explain the significance of water temperature changes

Changes in Water Temperature

- Circulating water temperature will stay in the range of 4°C to 42°C (39.2°F to 107.6°F)
- By selecting **Control Patient, Cool Patient** or **Rewarm Patient,** the ARCTIC SUN® Temperature Management System will modulate the water temperature through a feedback algorithm to either cool or warm the patient

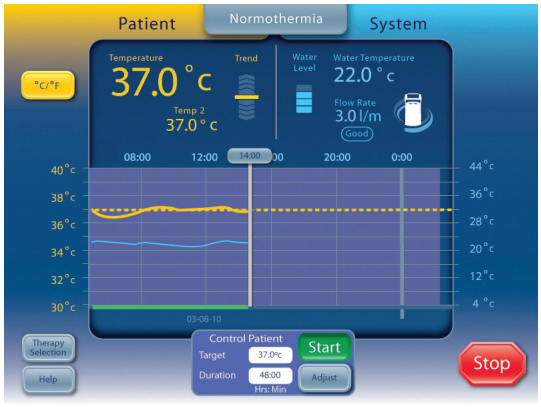
Record key parameters
According to Institutional Protocol



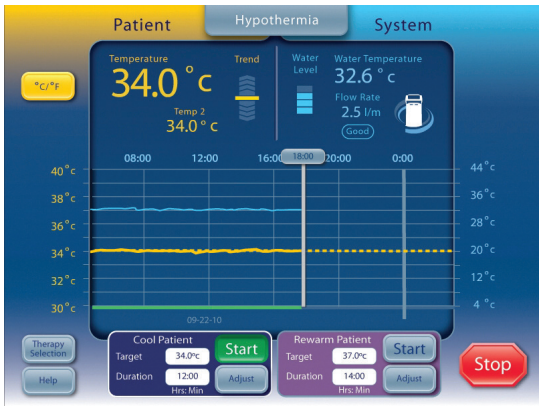
Water Temperature Stabilization

- When a patient's temperature is maintained at target temperature, the water temperature will typically be maintained in a stable range 18°C to 25°C (64.4°F to 77°F)
- However, if the patient starts to gain or lose heat, the ARCTIC SUN® Temperature Management System will change the water temperature within minutes to keep the patient at target temperature

Normothermia
Target 37°C/98.6°F, Patient Temp 37°C/98.6°F, Water Temp 22°C/71.6°F, Patient Trend Indicator in center



Hypothermia
Target 34°C/93.2°F, Patient Temp 34°/93.2°F, Water Temp 32.6°C/90.7°F, Patient Trend Indicator in center



Water Temperature and Heat Generation

- If a patient begins to generate excess heat, the water temperature of the ARCTIC SUN® Temperature Management System will decrease in order to keep the patient at target temperature
- If the water temperature drops more than 10°C from baseline during Maintenance phase and remains there (not just artifact):
  - Further assess the patient
  - Check for shivering
  - Check for other sources of heat generation
    i.e.
    - heated ventilator
    - room light
    - etc.

What should I do if the water temperature stays cold over an extended period of time?

Extended Cold Water Exposure

- The water temperature in the ARCTIC SUN® Temperature Management System will decrease when cooling a patient or when it is necessary to eliminate heat generation to maintain target temperature
- If the patient has been cooled continuously and does not reach target temperature within 4 hours OR if water temperature remains less than 10°C for 8 hours, refer to the **Patient Temperature Not Controlled** or **Extended Cold Water Exposure** in **Help Screens**
- Contact the 24/7 HelpLine for further assistance

Shivering

- Shivering must be addressed; monitor for early signs of shivering through a shivering assessment scale[13]
- Treat as directed by Physician in charge

Rationale:

- Shivering increases metabolic rate
- Shivering generates heat and raises patient's temperature[1]
- Increase in patient temperature will direct the ARCTIC SUN® Temperature Management System to deliver cool water and may increase patient exposure to cold water
- Refer to the **Patient Temperature Not Controlled** in **Help Screens** and immediately inform treating Physician, following institutional protocols

Shivering Recognition

- Look at the arrows on the **Trend Indicator**
- Look for irregularity of the baseline on your limb leads (any of the conductors connected to the electrocardiograph)[1]
- Visible shivering:
  - Mandible (masseter muscles)
  - Pectoralis muscles
  - Large or small muscle groups[6,7]
- If patient is generating heat, the ARCTIC SUN® Temperature Management System's algorithm will trigger the delivery of cold water

Rewarming

- The ARCTIC SUN® Temperature Management System can be programmed to rewarm a patient automatically or manually at a rate of 0.01-0.5°C/per hour. Max rewarm is also programmable if requested.

Troubleshooting

Alarms / Alerts

- If an alarm or alert occurs, the ARCTIC SUN® Temperature Management System will produce both an audible and visual cue
  - A screen will appear that displays: alarm or alert number, title, a description of the problem and instructions for resolving the condition
- When an alarm occurs, therapy is stopped
- Clear the alarm
  - Identify and resolve the problem
  - Press the green Start button to resume therapy

Patient is not cooled to target temperature

Determine if the ARCTIC SUN® Temperature Management System is working properly:

- Is a full kit (four pads) being used?
  - Are Pads the appropriate size?
  - Are Universal Pads being supplemented as needed for larger patients?
- Is flow rate a minimum of 2.3 L/min?
- Is the water temperature appropriately low?
  - If water temperature is too high, what is the minimum water temperature set to?
  - To view: Check under Hypothermia or Normothermia settings (press **Adjust** and then **More** to modify low water limits)
- Was the therapy stopped?
  - Stopping the device may reset the algorithm

If ARCTIC SUN® Temperature Management System is working properly, determine external conditions

- Is the patient shivering?
  - Arrows flashing upward on the Patient Temperature Trend Indicator reveals heat generation
- Was the temperature reading confirmed with a secondary source?
- What are the environmental conditions?
  - Is the room temperature too high?
    - Consider decreasing thermostat
  - Is the ventilator circuit heated?
    - Consider removing heated humidification[8]

Patient temperature falls below target

- Has the patient experienced an event or received a medication which would bring the cool blood from the periphery into the core?
  - For example, administration of vasoactive medications or change in hemodynamics[9]
- If the patient was shivering and received paralytics or sedatives, did the cessation of the heat generation cause the temperature to drop rapidly?

Patient temperature rises above target

- Is the patient generating heat through shivering or an infectious process?
  - Appropriate diagnostics and appropriate treatment may be required
- Is the patient experiencing seizures?[10,11,12]

Overshoot

- Ensure the appropriate automatic patient control modes (e.g. **Control Patient, Cool Patient** or **Rewarm Patient**) is activated
  - The appropriate patient window and the ARCTIC SUN® Temperature Management System icon will be blinking
- Is the water warming or cooling appropriately?
  - If water temperature is too high or too low, what is the maximum or minimum water temperature set to?
    - To view: In Hypothermia or Normothermia settings (press **Adjust** and then **More** to modify water limits)
- What are the arrows on the Patient Temperature Trend Indicator doing?
- Verify the patient's temperature is accurate with another source
- What is the flow rate on the ARCTIC SUN® Temperature Management System?

If the flow is below 2.3L/min

- Ensure that one full pad kit is used (Universal Pad supplementation if needed)
- Check all connections and ensure they are secure and not kinked
- Look for air bubbles to assess if a pad is damaged
  - May check for damaged pad by disconnecting one pad at a time and waiting one minute; if flow increases during disconnect, replace the damaged pad with Universal pad

The patient temperature is not displayed on the screen

- Ensure that the patient temperature probe is connected to **Temp Probe 1** outlet
- Confirm correct placement of temperature probe in patient
- If using bladder temperature probe, check for adequate urine output (if needed)
- Ensure that the connection between the temperature probe and the cable is secure
- Ensure the connection is not wet or moist
- Ensure the patient temperature probe is functional

The patient is rewarming too quickly

- Ensure **Rewarm Patient** is activated
  - The **Rewarm Patient** window will pulse and the ARCTIC SUN® Temperature Management System icon will be flashing
- Ensure warming rate is set appropriately as per Institutional protocol and/or physician's order
- Review **Patient Temperature Trend Indicator** arrows to assess heat generation
  - If identify source, treat accordingly
- Ensure water temperature is responding appropriately to patient temperature fluctuations, as evidenced on therapy graph

Case Studies

Case Study 1

A patient is admitted to the unit and the ARCTIC SUN® Temperature Management System is set to cool the patient to 33°C (91.4°F). The patient's starting temperature was 37.1°C (98.8°F), but is now 32.3°C (90.1°F) 3 hours later. The patient was medicated at the beginning of therapy with a Versed drip. The patient started to shiver at 35.6°C (96.1°F) and was given a bolus of Vecuronium (neuromuscular blockade). Nothing else has changed with the patient's drug regime- he remains on low dose Vasopressin for BP control.

What questions will you ask regarding the overshoot?

Answer:

- What is the water temperature? (It should be rising to warm the patient back to target)
- What are the **Patient Trend** Indicator arrows doing? (Remember there is a 5 minute delay but you want to see the arrows trending upward to illustrate the patient is warming)
- Did the patient experience hemodynamic changes? (This can lead to movement between compartments and the cool blood rushing to the core and leading to overshoot)

Case Study 2

A patient is admitted with a temperature of 39.8°C (103.6°F) the staff has been attempting to cool this patient for about two hours to a target temperature of 37°C (98.6°F), so far the temperature has only dropped to 38.8°C (101.8°F).

What could be the issues?

Answer:

- Not enough coverage (ensure all four pads are being used or for obese patients, Universal Pads have been added)
- Flow rate is <2.3L/min
- Patient is generating heat from shivering
- There is an issue with the chiller (ensure water temperature is < 10°C (50°F) to ensure the device is working properly)

Case Study 3

A patient in your unit is being maintained at normothermia with the ARCTIC SUN® Temperature Management System. You receive Alarm 14.

What could be the issues?

Answer:

- Alarm 14: Patient **Temperature 1** probe out of range
  - Temperature probe may be dislodged
  - Temperature probe may be in Temperature 2 port instead of Temperature 1 port
  - Connection between temperature probe and cable may be loose
  - Temperature cable may be damaged

Case Study 4

You are cooling a patient on the ARCTIC SUN® Temperature Management System to a target temperature of 33°C (91.4°F). After returning from lunch break, you find the water flow has dropped to 1.7L/min.

What could be the issues?

Answer:

- One of the pads is not connected properly to the manifold and air is leaking in
- There is a kink in the line
- There is a problem with one of the valves (you will need to contact Biomed)

Case Study 5

A patient is being cooled on the ARCTIC SUN® Temperature Management System to normothermia. The patient returns from a procedure, and as you walk by the room a half hour later, you notice the patient's temperature at 37.9°C (100.2°F).

What could be going on?

Answer:

- Continue Current Patient was not reactivated upon return to unit
  - Verify with flashing ARCTIC SUN® Temperature Management System icon and Control Patient window is pulsing

Case Study 6

One of your colleagues calls you over to her patient's bedside. She started rewarming her patient at 0.25°C/hour (0.45°F/hour) but after 2 hours, her patient has already warmed a full degree.

What could be the issue?

- The patient is generating heat from a fever or shivering
  - You will see arrows trending upward on the Patient Trend Indicator
  - You will see the water temperature drop to address the increase in heat
  - Identify the issue and treat accordingly

Trainee Name _____

Hospital _____

Bard Medical Trainer _____

Level 1: Standard User Activities:

The trainee has attended product training class and has demonstrated to the Bard Trainer the ability to perform the following activities:

Activities	Demonstrated	Comments
Identifies appropriate patients to be placed on the ARCTIC SUN® device (as per hospital protocol)		
ARCTICGEL™ Pads		
Describe essentials of pad placement and skin care		
Getting Started		
Device Set Up: Identify the fluid delivery line, temperature cable/probe, power cord, and fill tube.		
Turn device ON		
Unlock screen lock		
Interpret Display Screen		
Patient Information		
System Information		
Therapy Graph		
Normothermia Therapy		
Patient Therapy Selection: New Patient - Normothermia		
Set and verify therapy settings: Target Temperature, Duration		
Start treatment		
Hypothermia Therapy		
Patient Therapy Selection: New Patient - Hypothermia		
Set and verify therapy settings: Cool Patient: Target Temperature, Duration Rewarm Patient: Final Target Temperature, Rewarming Rate		
Start treatment		
Interrupt / Complete Therapy		
Empty Pads		
Interrupt, transport, and “Continue Current Patient”		
End patient therapy		
Fill Reservoir		
Storage of hoses and cables		
Documentation		
Water temp Q 1-2H, shivering, skin assessments, 2nd temp		
Access Help		
Help and Help Index		

Level 2: Advanced User Activities:

The advanced user attended product training, has been oriented to the Advanced Settings and has demonstrated to the Bard Trainer the ability to perform the following activities:

Activities	Demonstrated	Comments
Normothermia Settings		
Timer Begins		
Hypothermia Settings		
Cooling Begins		
Rewarming Begins		
Normothermia/Hypothermia Settings		
Condition Water		
Manual Control settings		
High/Low Water Limit		
High/Low Patient Alert		
Control Strategy		
Temperature Units/Adjust		
Patient Temperature 2		
Manual Control		
Set and verify settings: Water target temperature, duration		
Start Manual Control		
Advanced Setup		
Download Patient Data		
Date/TIme settings		
Save Settings as Default		

Training Program Assessment

Rate the training program and trainer on a scale of 1 to 5: 1= Poor, 2=Fair, 3=Good, 4=Very Good, and 5=Excellent.

Please consult product inserts and labels for any indications, contraindications, hazards, warnings, cautions and directions for use.

Therapeutic Hypothermia Supply Cart

TOP SHELF
Cart restocking list
Hypothermia protocol
Glucometer and testing supplies

DRAWER 1
Syringes
Tubes for blood draws
Needles for blood draws
ABG kits

DRAWER 2
IV insertion kit
IV tubing
Piggyback tubing
PCA tubing
Lactated Ringers
Normal Saline

DRAWER 3
Arterial line insertion kit
Pressure tubing
3-way stop-cock
Normal Saline
Pressure bag
ABG kit

DRAWER 4
Suction tubing
Oral suction tube
Pulse oximeter probe
PICC line or Central line insertion kit
Multipurpose pads (pacer/defib)

DRAWER 5
Foley
Esophageal/rectal probes
Nasogatric tube
Doppler and gel

DRAWER 6
ARCTIC SUN® backup temperature cable
ARCTICGEL™ Pads X-Small
ARCTICGEL™ Pads Small
ARCTICGEL™ Pads Medium
ARCTICGEL™ Pads Large
ARCTICGEL™ Pads Universal
ARCTICGEL™ Pad Neonatal
ARCTICGEL™ Pad Small Universal

Probe Placement

Site of Temperature Probe Placement

Site	Level of Accuracy	Average time lag between site and gold standard	Specific Advantages, problems and limitations
Pulmonary Artery (gold standard)	High	NA Cannot be used with cooling devices	Highly precise and quick temperature registration. Insertion procedure required. Needs to be removed after 72-96 hours.
Esophagus	High	5 minutes (range 3-10)	Most quick and accurate reflection of gold standard. Moderate risk of downward dislocation to stomach; leading to an increase in time lag and slight drop in registered core temperature (13°C) which is unlikely to be noticed immediately (because the deviation from the "true" core will be relatively small). Can be prevented by precise insertion to a depth of 32-38cm. Potential interference of diagnostic/therapeutic procedures (transesophageal echocardiography, gastroscopy, insertion of gastric tubes/feeding probes, etc.). Occasionally problematic probe inser- tion procedure.
Bladder	Fair/High***	20 minutes (range10-60)*	Fairly easy probe insertion procedure. Low risk of dislocation. Combination with procedure (catheter insertion) that needs to take place anyway. Long time lag. Readings affected by rate of diuresis (which may be low in some patients after cardiac arrest). Probe movement into saline-filled balloon at tip of catheter, affecting temperature readings.
Rectum	Fair/High***	15 minutes (range 10-40)**	Quick and easy probe insertion procedure. High risk of dislocation (but dislocation is likely to be noticed quickly because the difference with "true" core temperature is large). Relatively long time lag.
Tympanic Membrane	Moderate/Fair	10 minutes (range 5-20) Cannot be used with cooling devices	Quick and easy probe insertion procedure. High risk of dislocation (but dislocation is likely to be noticed quickly because the difference with "true" core temperature is large). Relatively long time lag.
Axilla, groin, other peripheral sites	Completely inaccurate	No correlation with gold standard	Should not be used to guide hypothermia treatment.

* In case of severe shock, oliguria etc.
** In case of severe shock
*** Usually high in maintenance phase when temperature is stable

Provided by Kees Polderman, M.D. Ph.D

Using the Helpline

In order to accurately provide assistance over the phone, the clinical resource will need current information relative to patient status, and ARCTIC SUN® Temperature Management System specifics (see examples below). This may require the caller to be in front of the ARCTIC SUN® Temperature Management System to respond to questions that will help with the trouble-shooting procedures. Knowing that this can be a stressful time due to the patient's condition and intense clinical scenario, we appreciate your patience. Our clinical staff take calls 24/7 for the US and Canada and are committed to providing safe, effective therapeutic temperature management.

Patient-related questions:
Current core temperature
Current or Recently Administered Medications
Protocol specifics
Hemodynamic Status

ARCTIC SUN® Device-related questions:
Type of temp probe
Target Temp, Water Temp, Flow Rate
Number & Size of ARCTICGEL™ Pads
Treatment Mode
Serial Number

Serial number found on back of ARCTIC SUN® device

Customer Service: 1800 257 232

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Conversion and Pad Weight Charts

ARCTICGEL™ Pad Weights

	3180202 Neonatal	3180104 Small Universal	31702 XXSmall	31703 XSmall	31705 Small	31707 Medium	31709 Large	31700 Universal
Empty	1.0 lbs 0.47 kg	0.2 lbs 0.11 kg	1.4 lbs 0.63 kg	1.8 lbs 0.83 kg	3.1 lbs 1.41 kg	3.2 lbs 1.45 kg	3.6 lbs 1.64 kg	0.5 lbs 0.23 kg
With water	1.5 lbs 0.68 kg	0.4 lbs 0.17 kg	1.8 lbs 0.83 kg	2.5 lbs 1.13 kg	4.6 lbs 2.09 kg	4.7 lbs 2.14 kg	5.3 lbs 2.41 kg	0.8 lbs 0.36 kg

°C to °F Conversion Table

°C	°F
42.0	107.6
41.9	107.4
41.8	107.2
41.7	107.1
41.6	106.9
41.5	106.7
41.4	106.5
41.3	106.3
41.2	106.2
41.1	106.0
41.0	105.8
40.9	105.6
40.8	105.4
40.7	105.3
40.6	105.1
40.5	104.9
40.4	104.7
40.3	104.5
40.2	104.4
40.1	104.2
40.0	104.0

°C	°F
39.9	103.8
39.8	103.6
39.7	103.5
39.6	103.3
39.5	103.1
39.4	102.9
39.3	102.7
39.2	102.6
39.1	102.4
39.0	102.2
38.9	102.0
38.8	101.8
38.7	101.7
38.6	101.5
38.5	101.3
38.4	101.1
38.3	100.9
38.2	100.8
38.1	100.6
38.0	100.4

°C	°F
37.9	100.2
37.8	100.0
37.7	99.9
37.6	99.7
37.5	99.5
37.4	99.3
37.3	99.1
37.2	99.0
37.1	98.8
37.0	98.6
36.9	98.4
36.8	98.2
36.7	98.1
36.6	97.9
36.5	97.7
36.4	97.5
36.3	97.3
36.2	97.2
36.1	97.0
36.0	96.8

°C	°F
35.9	96.6
35.8	96.4
35.7	96.3
35.6	96.1
35.5	95.9
35.4	95.7
35.3	95.5
35.2	95.4
35.1	95.2
35.0	95.0
34.9	94.8
34.8	94.6
34.7	94.5
34.6	94.3
34.5	94.1
34.4	93.9
34.3	93.7
34.2	93.6
34.1	93.4
34.0	93.2

°C	°F
33.9	93.0
33.8	92.8
33.7	92.7
33.6	92.5
33.5	92.3
33.4	92.1
33.3	91.9
33.2	91.8
33.1	91.6
33.0	91.4
32.9	91.2
32.8	91.0
32.7	90.9
32.6	90.7
32.5	90.5
32.4	90.3
32.3	90.1
32.2	90.0
32.1	89.8
32.0	89.6

C x 9/5 + 32 = °F or (°F - 32) x 5/9 = °C

Module 2 and 3 References

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Notes

Notes

CoreConnect™

Temperature Management Solutions

Clinical Training Workbook

Please consult product inserts and labels for any indications, contraindications, hazards, warnings, cautions and directions for use.

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