BD Arctic Sun™ Stat

Temperature Management System

OPERATOR'S MANUAL

Medivance®

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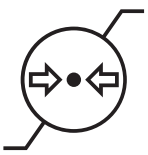
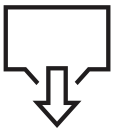
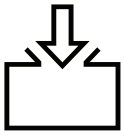
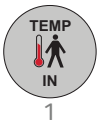
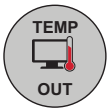
I. SYMBOLS

The Arctic Sun™ Temperature Management System and its packaging bear the following symbols:

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1 Reference no. 5.1.1	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Reference no. 5.1.3	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Reference no. 5.1.4	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Reference no. 5.1.5	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Reference no. 5.1.6	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Reference no. 5.1.7	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1 Reference no. 5.3.7	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Reference no. 5.3.8	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1 Reference no. 5.3.9	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1 Reference no. 5.4.2	Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	IEC TR 60878 Reference ISO 7010-M002	Graphical Symbols for Electrical Equipment in Medical Practice	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read.
	IEC TR 60878 Reference no. 6050	Graphical Symbols for Electrical Equipment in Medical Practice	Model number	To identify the model number or type number of a product. In the application of this symbol, the model number or type number of the product should be accompanied with this symbol.
	IEC TR 60878 Reference no.5334	Graphical Symbols for Electrical Equipment in Medical Practice	Defibrillation-proof type BF applied part	To identify a defibrillation-proof type BF applied part complying with IEC 60601-1.
	IEC TR 60878 Reference no. 5041	Graphical Symbols for Electrical Equipment in Medical Practice	Caution, hot surface	To indicate that the marked item can be hot and should not be touched without taking care.
	IEC TR 60878 Reference no. 0029	Graphical Symbols for Electrical Equipment in Medical Practice	Draining; emptying	To indicate the emptying of any vessel, or container of liquid or produce, for example draining of oil tanks, draining ink reservoirs, or emptying grain hoppers.
	IEC TR 60878 Reference no. 0028	Graphical Symbols for Electrical Equipment in Medical Practice	Filling	To indicate the filling of a vessel or container by any type of liquid or produce, for example filling of oil tanks, filling ink reservoirs, filling grain hoppers.
	IEC TR 60878 Reference ISO 7010-W012	Graphical Symbols for Electrical Equipment in Medical Practice	Warning; Electricity	To warn of electricity.
	IEC TR 60878 Reference 7010-P017	Graphical Symbols for Electrical Equipment in Medical Practice	No pushing	To prohibit pushing against an object.
	IEC TR 60878 Reference 7010-W001	Graphical Symbols for Electrical Equipment in Medical Practice	General Warning Sign	To signify a general warning.
	IEC TR 60878 Reference no. 5007 & 5008	Graphical Symbols for Electrical Equipment in Medical Practice	Power On/Off	Indicates power on/off switch

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	IEC TR 60878 Reference no. 5021	Graphical Symbols for Electrical Equipment in Medical Practice	Equipotentiality	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
	IEC TR 60878 Reference no. 2794	Graphical Symbols for Electrical Equipment in Medical Practice	Packaging Unit	To indicate the number of pieces in the package.
	IEC TR 60878 Reference no. 0623	Graphical Symbols for Electrical Equipment in Medical Practice	This way up	On transport packaging. To indicate the correct upright position.
	IEC TR 60878 Reference no. 0621	Graphical Symbols for Electrical Equipment in Medical Practice	Fragile; handle with care	On transport packaging. To indicate the content of the package is fragile and that the package must be handled with care.
	IEC TR 60878 Reference no. 0626	Graphical Symbols for Electrical Equipment in Medical Practice	Keep away from rain	Indicates a medical device that needs to be protected from moisture.
	Directive 2002/96/EC (WEEE)	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	Waste Stream Disposal Status	Do not dispose of electronic products in the general waste stream
	21CFR801.15	Labeling; Prescription devices	Prescription Use Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
	AAMI ES 60601-1 IEC 60601-1-8 IEC 60601-10 IEC 806012-35 CSA C22.2 No. 6060101	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance	ETL Monogram	Per ETL Intertek, models of the ARCTIC SUN™ Temperature Management System that bear the ETL Monogram confirm to AAMI ES60601-1, IEC 60601-1-8, IEC 60601-10, IEC 80601-2-35 and are certified to CSA C22.2 No. 60601-1.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 7000 Reference no. 3650	Graphical symbols for use on equipment	Universal Serial Bus (USB), port/plug	To identify a port or plug as meeting the generic requirements of the Universal Serial Bus (USB). To indicate that the device is plugged into a USB port or is compatible with a USB port.
	IEC 60417 Reference no. 5850	Graphical symbols for use on equipment	Serial interface	To identify a connector for a serial data connection
	N/A	N/A	N/A	Indicates that only sterile water should be used when filling the ARCTIC SUN™ Temperature Management System Control Module.
	N/A	N/A	N/A	Identifies Patient Temperature 1, the patient temperature probe input for monitoring and control.
	N/A	N/A	N/A	Identifies Patient Temperature 2, the patient temperature probe input for monitoring.
	N/A	N/A	N/A	Identifies Patient Temperature Out, the patient temperature output to an external hospital monitor.
	N/A	N/A	N/A	Identifies mechanical hazard
	N/A	N/A	N/A	Do Not Discard
	N/A	N/A	N/A	To identify the number to call for urgent clinical support. The number shall be placed adjacent to the symbol.
	N/A	N/A	N/A	Plug Type

II. WARNINGS AND CAUTIONS DEFINITION

WARNINGS and **CAUTIONS** throughout the manual should be carefully reviewed before and during use of the device.

WARNING — Informs the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

CAUTION — Informs the reader about a situation which, if not avoided, could result in minor or moderate injury to the user or patient of damage the device or other property. This includes special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

III. SAFETY PRECAUTIONS

⚠ WARNINGS

- Do not use the Arctic Sun™ Temperature Management System in the presence of flammable agents because an explosion and/or fire may result.
- Do not use high frequency surgical instruments or endocardial catheters while the Arctic Sun™ Temperature Management System is in use.
- There is a risk of electrical shock and hazardous moving parts. There are no user serviceable parts inside. Do not remove covers. Refer servicing to qualified personnel.
- Power cord has a hospital grade plug. Grounding reliability can only be achieved when connected to an equivalent receptacle marked “hospital use” or “hospital grade.”
- When using the Arctic Sun™ Temperature Management System, note that all other thermal conductive systems, such as water blankets, water gels, and patient coverings in use while warming, cooling, or not delivering therapy with the Arctic Sun™ Temperature Management System may actually alter or interfere with patient temperature control.
- Do not place ArcticGel™ pads over transdermal medication patches as temperature can impact drug delivery rate, resulting in possible harm to the patient.
- The Arctic Sun™ Temperature Management System is not intended for use in the operating room environment.
- Protection of mechanical equipment against the effects of the discharge of cardiac defibrillators is dependent upon the use of appropriate cables. Use of temperature cables listed in the System Components section of the Operator’s Manual is recommended.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Arctic Sun™ Temperature Management System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- BD supplies temperature simulators (fixed value resistors) for testing, training and demonstration purposes. Never use this device, or other method, to circumvent the normal patient temperature feedback control when the system is connected to the patient. Doing so exposes the patient to the hazards associated with severe hypo- or hyperthermia.

⚠ CAUTIONS

- This product is to be used by or under the supervision of trained, qualified medical personnel.
- Federal law (USA) restricts this device to sale, by or on the order of a physician.
- Use only sterile water. The use of other fluids will damage the Arctic Sun™ Temperature Management System.
- When moving the Arctic Sun™ Temperature Management System always use the handle to lift the controller over an obstacle to avoid over balancing.
- The patient’s bed surface should be located between 30 and 60 inches (75 cm and 150 cm) above the floor to ensure proper flow and minimize risk of leaks.
- The clinician and/or operator is responsible to determine the appropriateness of custom parameters. When the system is Powered Off, all changes to parameters will revert to the default unless the new settings have been saved as new defaults in the Advanced Setup screen. For small patients (≤30 kg) it is recommended to use the following settings: Water Temperature High Limit ≤40°C (104°F); Water Temperature Low Limit ≥10°C (50°F); Control Strategy = 2. It is recommended to use the Patient Temperature High and Patient Temperature Low alarm settings.
- Manual Control is not recommended for patient temperature management. The operator is advised to use the automatic therapy modes (e.g. Control Patient, Cooling, Rewarming) for automatic patient temperature monitoring and control.
- The Arctic Sun™ Temperature Management System will monitor and control patient core temperature based on the temperature probe attached to the system. The clinician is responsible for correctly placing the temperature probe and verifying the accuracy and placement of the patient probe at the start of the procedure.
- It is recommended to measure patient temperature from a second site to verify patient temperature. BD recommends the use of a second patient temperature probe connected to Arctic Sun™ Temperature Management System Temp In 2 input as it provides continuous monitoring and safety alarm features. Alternatively, patient temperature may be verified periodically with independent instrumentation.
- The displayed temperature graph is for general information purposes only and is not intended to replace standard medical record documentation for use in therapy decisions.
- Patient temperature will not be controlled and alarms are not enabled in Stop Mode. Patient temperature may increase or decrease with the Arctic Sun™ Temperature Management System in Stop Mode.
- Carefully observe the system for air leaks before and during use. If the pads fail to prime or a significant continuous air leak is observed in the pad return line, check connections. If needed, replace the leaking pad. Leakage may result in lower flow rates and potentially decrease the performance of the system.
- The Arctic Sun™ Temperature Management System is for use only with the ArcticGel™ pads.
- The ArcticGel™ pads are only for use with the Arctic Sun™ Temperature Management System.
- The ArcticGel™ pads are non-sterile for single patient use. Do not reprocess or sterilize. If used in a sterile environment, pads should be placed according to the physician’s request, either prior to the sterile preparation or sterile draping. ArcticGel™ pads should not be placed on a sterile field.

⚠ CAUTIONS (Continued)

- Use pads immediately after opening. Do not store pads once the kit has been opened.
- Do not place ArcticGel™ pads on skin that has signs of ulceration, burns, hives, or rash.
- While there are no known allergies to hydrogel materials, caution should be exercised with any patient who has a history of skin allergies or sensitivities.
- Do not allow circulating water to contaminate a sterile field when patient lines are disconnected.
- The water content of the hydrogel affects the pad's adhesion to the skin and conductivity, and therefore, the efficiency of controlling patient temperature. Periodically check that pads remain moist and adherent. Replace pads when the hydrogel no longer uniformly adheres to the skin. Replacing pads at least every 5 days is recommended.
- Do not puncture the ArcticGel™ pads with sharp objects. Punctures will result in air entering the fluid pathway and may reduce performance.
- If accessible, examine the patient's skin under the ArcticGel™ pads often, especially those at higher risk of skin injury. Skin injury may occur as a cumulative result of pressure, time and temperature. Possible skin injuries include bruising, tearing, skin ulcerations, blistering, and necrosis. Do not place bean bag or other firm positioning devices under the ArcticGel™ pads. Do not place positioning devices under the pad manifolds or patient lines.
- 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 diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy. If warranted, use pressure relieving or pressure reducing devices under the patient to protect from skin injury.
- 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. Ensure that pad sizing/ coverage and custom parameter settings are correct for the patient and treatment goals, and the patient temperature probe is in the correct place. For patient cooling, ensure environmental factors such as excessively hot rooms, heat lamps, and heated nebulizers are eliminated and patient shivering is controlled. Otherwise, consider increasing minimum water temperature, modifying target temperature to an attainable setting or discontinuing treatment. For patient warming, consider decreasing maximum water temperature, modifying target temperature to an attainable setting or discontinuing treatment.
- 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 loss of pad adhesion. Replace pads immediately if these fluids come into contact with the hydrogel.
- Do not place ArcticGel™ pads over an electrosurgical grounding pad. The combination of heat sources may result in thermal injury.
- If needed, place defibrillation pads between the ArcticGel™ pads and the patient's skin.
- Carefully remove ArcticGel™ pads from the patient's skin at the completion of use. Discard used ArcticGel™ pads in accordance with hospital procedures for medical waste.
- The USB data port is to be used only with a standalone USB flash drive. Do not connect to another mains powered device during patient treatment.
- Users should not use cleaning or decontamination methods different from those recommended by the manufacturer without first checking with the manufacturer that the proposed methods will not damage the equipment. Do not use bleach (sodium hypochlorite) as it may damage the system.
- BD will not be responsible for patient safety or equipment performance if the procedures to operate, maintain, modify or service the Arctic Sun™ Temperature Management System are other than those specified by BD. Anyone performing the procedures must be appropriately trained and qualified.
- The clinician and/or operator is responsible for clinical decisions based on Arctic Sun Work to Cool data provided by the system. The displayed graphics are for general information purposes only and are not intended to replace standard medical record documentation for use in therapy decisions. Anyone interpreting the Arctic Sun Work to Cool data to make clinical decisions must be appropriately trained and qualified.

COMPLICATIONS

- Targeted Temperature Management can trigger pathophysiological side-effects on the body such as but not limited to: cardiac dysrhythmia, electrolyte and pH balance, metabolic changes, hemodynamic changes, blood-glucose balance, infection, shivering, and can affect the coagulation, respiratory, renal and neurological systems. The controlling of patient temperature should only be performed under the supervision of a qualified healthcare professional.

IV. INTRODUCTION

TECHNICAL DESCRIPTION

The Arctic Sun™ Temperature Management System is a thermoregulatory device that monitors and controls patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F).

A patient temperature probe connected to the Control Module provides patient temperature feedback to an internal control algorithm which automatically increases or decreases the circulating water temperature to achieve a pre-set patient target temperature determined by the clinician.

The Arctic Sun™ Temperature Management System pulls temperature-controlled water ranging between 4°C and 40°C (39.2°F and 104°F) through the ArcticGel™ pads. This results in heat exchange between the water and the patient.

The Arctic Sun™ Temperature Management System Control Module is a Class I mobile device (Type BF, IPX0 and Mode of Operation – Continuous) per classification scheme of IEC 60601-1.

The Arctic Sun™ Temperature Management System Control Module meets both the electromagnetic interference and susceptibility requirements of IEC 60601-1, and is compatible with other equipment that also conforms to that standard. There is no known failure mode in the Arctic Sun™ Temperature Management System Control Module associated with electromagnetic interference from other devices. See Appendix A for the full declaration regarding electromagnetic compatibility.

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.

SPECIFICATIONS

Environmental Conditions
At operating temperatures higher than 27°C (80.6°F), the refrigeration system's cooling capacity and therefore its ability to cool a patient is compromised.

If the Control Module is to be exposed to subfreezing temperatures, perform the Total Drain process. See section **VI. Operation Guide–Advanced Setup–Total Drain** for further instructions.

Disposal
Upon end of life, dispose of in accordance with local WEEE regulations or contact your local BD Supplier or Distributor to arrange for disposal.

Parameter	Specification
Therapy Modes	Normothermia: Control Patient, Rewarming Hypothermia: Cooling, Rewarming
Heater Maximum Power	814 Watts
Circulating Fluid	Sterile Water with Cleaning Solution
Average Reservoir Capacity	3.5 liters
Patient Probe Type	YSI 400 Series compatible
Patient Temperature Inputs	Temp In 1: control, monitor, alarm Temp In 2: monitor, alarm
Patient Temperature Display Range	10°C to 44°C/50°F to 111.2°F 0.1°C/°F increments
Patient Temperature Measurement Accuracy	±0.4°C (10°C to 32°C/50°F to 89.6°F) ±0.2°C (32°C to 38°C/89.6°F to 100.4°F) ±0.4°C (38°C to 44°C/100.4°F to 111.2°F) Excludes external probe
Responses of the PCLCS (Physiologic Closed-Loop Control System)	Settling Time: ~4.5 hours Relative Overshoot: <0.5°C Command Overshoot: <0.5°C Warming (max) Response Time: 32°C to 37°C/89.6°F to 98.6°F: ~8.5 hours Cooling Response Time: 37°C to 33°C/98.6°F to 91.4°F: ~2 hours Steady State Deviation: 0 Tracking Error: 0 Note: All values derived from testing in simulated use
Patient Temperature Control Range	32°C to 38.5°C/89.6°F to 101.3°F 0.1°C/°F increments
Water Temperature Display Range	3°C to 45°C/37.4°F to 113.0°F 0.1°C /°F increments
Water Temperature Control Range (Manual)	4°C to 40°C 1°C increments
High Water Temperature Limit	36°C to 40°C 1°C increments
Low Water Temperature Limit	4°C to 25°C 1°C increments
Time to heat water from 25°C to 40°C	<15 minutes
Time to lower water temperature from 25°C to 7°C	<15 minutes
Sound Pressure	Low Priority Alarm: 64-71dB at 1 meter Medium Priority Alarm: 64-71dB at 1 meter Reminder Tone: 65dB at 3 meters
Mains Input	120VAC 60Hz 11Amp
Total Patient Leakage Current (Normal Condition)	<300 µA
Operating Relative Humidity Range	5% to 70% non-condensing
Storage and Transport Relative Humidity Range	5% to 95% non-condensing
Operating Temperature Range	15.5°C to 32.2°C/59.9°F to 90.0°F
Storage and Transport Temperature Range	-30°C to 50°C/-22°F to 122°F
Atmospheric Pressure Range	60 kPa to 101 kPa
Dimensions	Height: 41 inches (104 cm) Width: 16 inches (41 cm) Depth: 20 inches (51 cm)
Weight	Filled: 55.3 kg/122 lbs

SYSTEM COMPONENTS

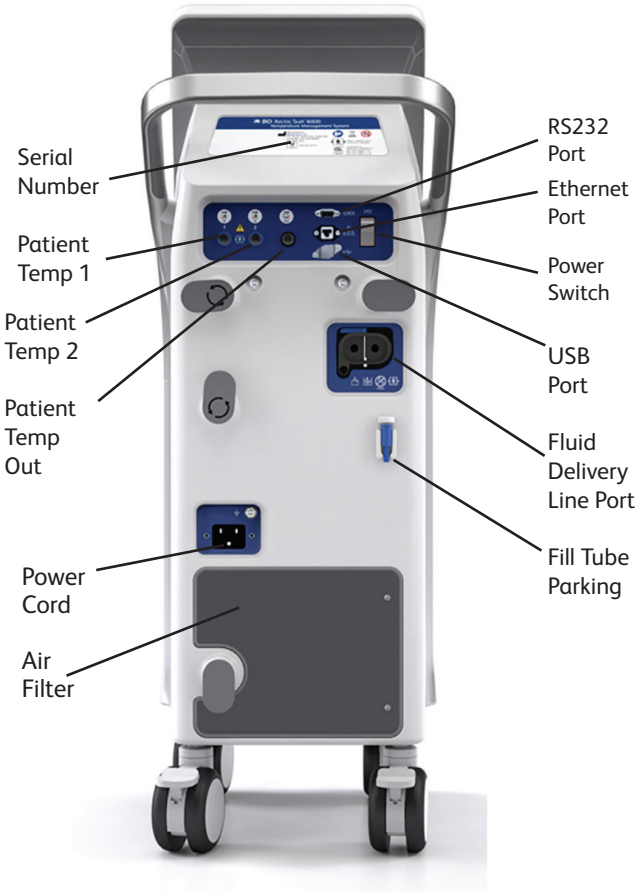


Figure IV-1. Product illustration

Control Module
The Arctic Sun™ Temperature Management System Control Module is the main component of the Arctic Sun™ Temperature Management System. It incorporates the system electronics, hydraulics, software, and the touch-screen Control Panel. The power cord, fluid delivery line, patient temperature in cables, patient temperature out cable and fill tube connect to the rear of the Control Module. The figure above identifies the main features and component connection sites. Use only BD supplied cables and accessories with Arctic Sun™ Temperature Management System Control Module. The use of accessories, transducers or cables other than those specified may result in increased electromagnetic compatibility (EMC) emissions or decreased immunity of the Arctic Sun™ Temperature Management System Control Module.

Power Cord
Hospital-grade power cords are available with several inlet connector styles to meet national/regional power requirements and wall outlet specifications.

Fluid Delivery Line
Water flows between the ArcticGel™ pads and Control Module through the Fluid Delivery Line.

Fill Tube
A Fill Tube is used to fill the Control Module water reservoir.

Arctic Sun Cleaning Solution
Arctic Sun Cleaning Solution is added when filling the Control Module with Sterile Water. This is done to suppress microorganism growth in the water reservoir and hydraulic circuit.
For information regarding safe handling, please refer to http://www.medivance.com/manuals for the Cleaning Solution SDS.

Patient Temperature Input Cables and Probes
Patient temperature control with the Arctic Sun™ Temperature Management System requires patient temperature feedback provided by an indwelling patient temperature probe connected to the Control Module via the Temp In 1 and Temp In 2 inputs. Any commercially-available Yellow Springs Instrument 400 Series (YSI 400) compatible patient temperature probe can be connected to the Arctic Sun™ Temperature Management System.

The Arctic Sun™ Temperature Management System temperature cables are available with several connector styles (e.g. Phillips, GE, Rusch, Bard, Nellcor) for compatibility with various manufacturers' temperature probes. Select the patient temperature cable with the correct connector style for your chosen temperature probe.

Figure IV-2. Temperature input cables

A temperature cable and probe connected to the Temp In 1 connector provides the patient temperature feedback required for automatic patient temperature control.

A second patient temperature probe and cable are recommended to be connected into the Temp In 2 Connector. Temp In 2 is used to provide monitoring from a second patient site for increased patient safety when patient temperature is not continuously monitored by a second device.

NOTE: Patient temperature is not controlled from the Temp In 2 connector. It is for patient temperature monitoring only.

SYSTEM COMPONENTS (Continued)

Patient Temperature Output Cables
The Arctic Sun™ Temperature Management System Control Module has the capability to output the current Temp In 1 reading to a YSI 400 compatible hospital monitor. The Arctic Sun™ Temperature Management System temperature output cables are available with several connector styles (e.g. Phillips, GE, Rusch, Bard, Nellcor) for compatibility with the various hospital monitor input cables. Select the patient temperature cable with the correct connector style for your hospital monitor.

NOTE: The temperatures displayed on the Arctic Sun™ Temperature Management System Control Panel and the hospital monitor represents the same probe reading but may not be identical due to calibration differences between the Control Module and the monitor.

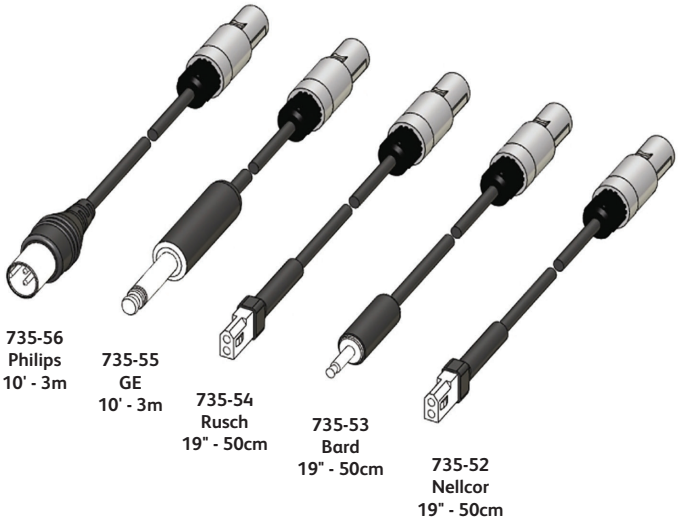


Figure IV-3. Temperature output cables

V. SETUP PROCEDURE

UNPACK

1) Unpack the Arctic Sun™ Temperature Management System Control Module and accessories.
2) Allow the Control Module to remain upright for at least two hours prior to completing the installation and setup procedure in order to allow the chiller oil to settle. Damage to the chiller compressor may result otherwise.

CONNECTIONS

1) Use only approved cables and accessories with the Arctic Sun™ Temperature Management System Control Module (Appendix B).
2) Inspect the accessories for wear, breakage, or fraying before use. Replace if necessary.
3) Connect the Fluid Delivery Line, Temp In 1 cable, Temp In 2 cable (optional), Temp Out cable and Fill Tube to the back of the Control Module.
4) Plug the Power Cord into the wall outlet. Position the Arctic Sun™ Temperature Management System so that access to the power cord is not restricted.

POWER ON

1) Power On by activating the power switch on the back of the device.
2) The patient **Therapy Selection** screen will appear on the control panel.

FILL RESERVOIR

Approximately four liters of sterile water will be required to fill the reservoir at initial installation. Fill the reservoir with sterile water only. When filling the Control Module during initial installation or when completely empty, add one vial of Arctic Sun™ Temperature Management System Arctic Sun Cleaning Solution to the sterile water. It is recommended to add the vial when filling with the second liter of sterile water.

1) From the patient **Therapy Selection** screen, select the button next to either Normothermia or Hypothermia under the New Patient heading. Select any pad type to continue.
2) From the **Hypothermia** or **Normothermia** therapy screen, press the **Fill Reservoir** button.
3) The **Fill Reservoir** screen will appear. Follow the directions on the screen.
4) The filling process will automatically stop when the reservoir is full. Continue to replace the bottles of sterile water until the filling process stops.
5) When the **Fill Reservoir** process is complete, the screen will close.
6) To stop the process early, press the **Stop** button.

   NOTE: If the filling cycle is stopped prior to completion, the reservoir will not be full and may requiring filling after fewer patient therapies have been performed.

7) Press the **Cancel** button to close the screen.

FUNCTIONAL VERIFICATION

Certificates of Conformance for calibration, performance, and electrical safety tests are included with the shipment of each Arctic Sun™ Temperature Management System. To verify the system will heat and cool properly, perform the following functional verification procedure after initial setup and installation of the Control Module.

1) Power On the Control Module.
2) From the patient **Therapy Selection** screen, press the button next to Hypothermia to display the **Hypothermia** therapy screen. Select the adult pad type to continue.
3) From the **Hypothermia** therapy screen, press the **Manual Control** button to open the **Manual Control** window. If the Manual Control button is not visible, select the **Adjust** button at the bottom of the screen and select the **More** button to access the therapy settings screen. Enable Manual Control and save your settings to close the window.
4) Use the Up and Down arrows to set the Manual Control water target temperature to 40°C and the duration to 30 minutes.
5) Press the **Start** button to initiate Manual Control. Allow at least 3 minutes for the system to stabilize.
6) Monitor the flow rate and water temperature in the **System** status area on the **Hypothermia** therapy screen.
7) Verify that the flow rate reaches at least 1.5 liters/minute.
8) Verify that the water temperature increases to at least 30°C.
9) Press the **Stop** button.
10) Set the Manual Control water target temperature to 4°C and the duration to 30 minutes.
11) Press the **Start** button to initiate **Manual Control**.
12) Monitor the flow rate and water temperature in the **System** status area of the **Hypothermia** therapy screen. Verify that the water temperature drops to 6°C or colder.
13) Press the **Stop** button to stop **Manual Control**
14) Press the **Cancel** button to close the **Manual Control** window.
15) Before placing the device into clinical use, it is recommended to disable Manual Control unless requested by clinical users. Select the **Adjust** button at the bottom of the therapy screen and select the **More** button to access the therapy settings screen. Disable Manual Control and save your settings to close the window.
16) Power Off the Control Module.

VI. OPERATION GUIDE

THERAPY PREPARATION

Place ArcticGel™ Pads

Read the Instructions for Use that accompanies the ArcticGel™ pads. Examine each pad for damage prior to placement.

Connect ArcticGel™ Pads

Water flows between the ArcticGel™ pads and Control Module via a Fluid Delivery Line. Each side of the Fluid Delivery Line can be placed by the feet or along the lower legs. There are three connectors on each side of the line for a total of six connectors. These will accommodate a full kit of four pads plus a maximum of two optional Universal pads for use in larger patients.

To connect the ArcticGel™ Pads:

1) While holding the pad line tubing, insert the clear pad line connector into the Fluid Delivery Line manifold. Do not press or squeeze the wings when connecting. The connector will click into place.
2) If the connectors are not aligned properly, the connectors will not fit or click into place.

Patient Placement

The Arctic Sun™ Temperature Management System operates under negative pressure, which helps the pads to conform to the patient's body and minimizes the risk of leaks in the event of accidental puncture of a pad or accidental disconnection of the Fluid Delivery Line. In order to ensure negative pressure on the pads at all times, the patient's bed surface should be placed 30 inches to 60 inches (75 cm to 150 cm) above the floor.

Device Placement

It is recommended to position the device near the foot of the bed during use. Use the wheel locks on the Control Module to prevent the wheels from rotating during use. Press down on the wheel locks to lock the wheels, and lift up the wheel locks to release the wheels.

Temperature Probe Placement

Refer to the manufacturer's Instructions for Use for the specific indications and temperature probe placement. Select the patient temperature cable with the correct connector style for your chosen temperature probe to measure core temperature. Insert the cable into the Temp In 1 connector port on the back of the device for monitoring patient temperature on the Arctic Sun™ Temperature Management System.

THERAPY SELECTION

Use the **Therapy Selection** screen to initiate a **New Patient**, **Continue a Current Patient**, or access the **Advanced Setup** screen.

New Patient–Normothermia

If the therapy goal is to maintain a patient temperature at a pre-defined target temperature for an indefinite period of time, press the button next to Normothermia to display the **Normothermia** therapy screen.

Pressing the **Normothermia** button will initiate a **New Patient** therapy and will reset the **Normothermia** therapy screen to the saved system default settings. Any active, current patient therapy settings and patient data will no longer be available.

New Patient–Hypothermia

If the therapy goal is to reduce and maintain a patient temperature at a set target temperature for a defined period of time then slowly rewarm the patient at a controlled rewarming rate, press the button next to Hypothermia to display the **Hypothermia** therapy screen.

Pressing the **Hypothermia** button will initiate a new patient therapy and will reset the **Hypothermia** therapy screen to the saved system default settings. Any active, current patient therapy settings and data will no longer be available.

Additional Protocol Option

Two additional protocols (**Hypothermia** or **Normothermia**) may be visible on the **Therapy Selection** screen. See **VI. Operation Guide–Advanced Setup–Save Settings as Default** for instructions on how to add custom protocols on the **Therapy Selection** screen.

Confirm New Patient

The therapy selected will override the active, current patient therapy. To continue a current case, press **Continue**. To begin a new therapy, press **New**.

Current Patient

The **Continue Current Patient** button and the date and time that the current therapy was paused will display on the **Therapy Selection** screen if a patient therapy was paused within the past 6 hours.

Press the **Continue** button to resume a paused patient therapy. Selecting the **Continue** button will display the appropriate therapy screen. The therapy screen will retain and display the previously set therapy settings and patient data.

NOTE: Continuation of a current patient therapy will be available whether the Control Module was Powered On or Off in the preceding 6 hours.

PATIENT PAD SELECTION

Once the therapy has been selected, the user will be prompted with the **Pad Selection** screen. Select the appropriate pad type based on the pads placed on the patient.

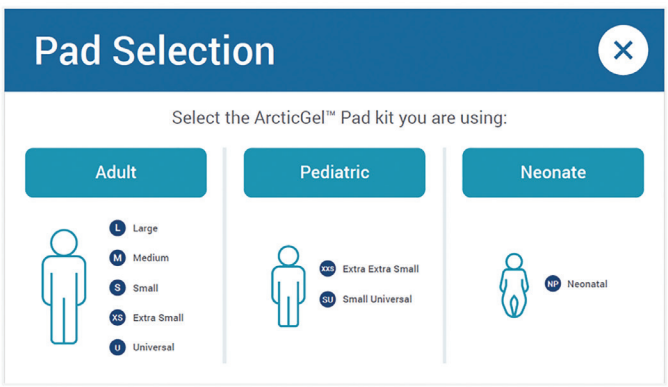


Figure VI-1. Pad selection screen

THERAPY SCREENS

The following information is displayed and functions are available from the **Normothermia** and **Hypothermia** therapy screen.

1. **Therapy Selection (or Screen Lock)**
2. **System Access**
3. **Notification**
4. **Temperature Units (if enabled)**
5. **Patient Status**
   - A. Patient Temperature
   - B. Patient Temperature 2 (if enabled)
6. **System Status**
   - C. Water Temperature
   - D. Flow Rate
7. **Therapy Graph**
   - E. Patient Temperature
   - F. Water Temperature
   - G. Date and Time
   - H. Progress Bar
8. **Empty Pads**
9. **Fill Reservoir**
10. **Monitor Mode**
11. **Arctic Sun Work to Cool Trend**
12. **Control (Normothermia Screen)**
    Cooling (Hypothermia Screen)
13. **Start/Stop**
14. **Adjust**
15. **WiFi Connected (if enabled)**
16. **Rewarming (Hypothermia Screen)**

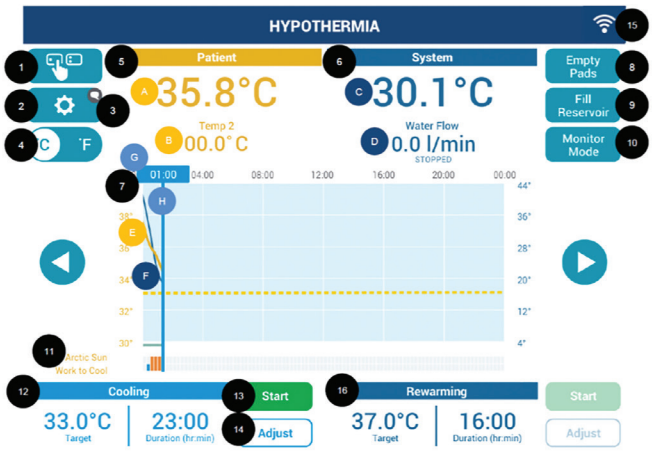


Figure VI-2. Hypothermia therapy screen when using adult ArcticGel™ pads

The following information is displayed and functions are available from the **Normothermia** and **Hypothermia** therapy screen.

1. **Therapy Selection (or Screen Lock)**
2. **System Access**
3. **Notification**
4. **Temperature Units (if enabled)**
5. **Patient Status**
   - A. Patient Temperature
   - B. Patient Temperature 2 (if enabled)
6. **System Status**
   - C. Water Temperature
   - D. Flow Rate
7. **Therapy Graph**
   - E. Patient Temperature
   - F. Water Temperature
   - G. Date and Time
   - H. Progress Bar
8. **Empty Pads**
9. **Fill Reservoir**
10. **Monitor Mode**
11. **Arctic Sun Work to Cool Trend**
12. **Control (Normothermia Screen)**
    Cooling (Hypothermia Screen)
13. **Start/Stop**
14. **Adjust**
15. **WiFi Disconnected (if enabled)**

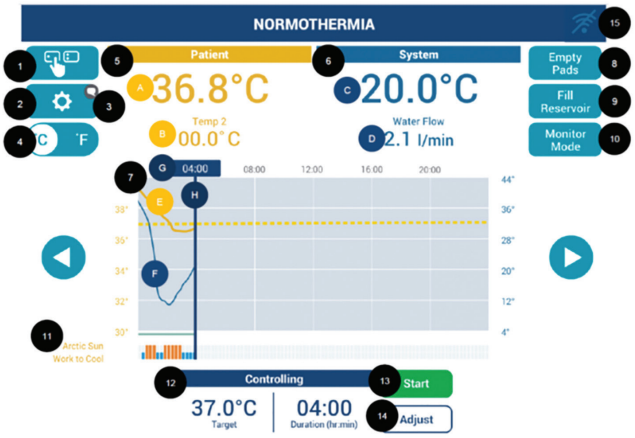


Figure VI-3. Normothermia therapy screen when using adult ArcticGel™ pads

THERAPY SCREENS (Continued)

1. ***Therapy Selection***
If the therapy has not started or is not currently running, pressing the therapy selection button ( ) will return the user to the **Therapy Selection** screen.

Screen Lock
When an active therapy is running, the therapy selection button will change to the screen lock button ( ). Press the screen lock button to manually display the therapy status screen. By default, after approximately 2 minutes of inactivity, the screen will lock to prevent inadvertently changing parameters during patient therapy.

The therapy status screen will appear over the therapy screen when the screen is locked. The status screen displays the Patient Temperature, Water Temperature, Arctic Sun Work to Cool, and the current therapy phase target temperature. Press the button on the top right of the status screen to return to the therapy screen.

See section **VIII. Troubleshooting–Screen–Screen Locked** if there is a problem with screen lock.

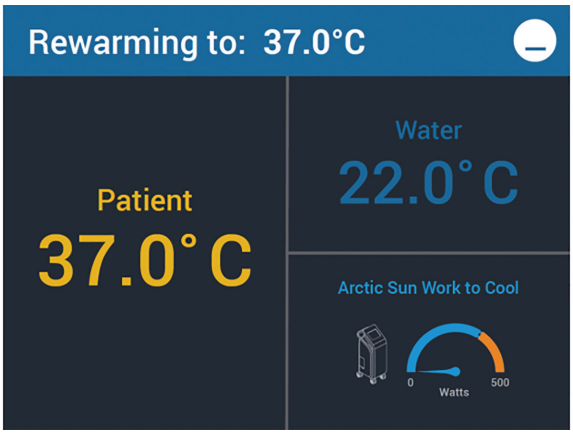


Figure VI-4. Status Screen

2. ***System Access***
The System Access screen allows the user to view diagnostic information and a log of events during the last 10 cases.

Diagnostics
Selecting the Diagnostics button on the **System Access** screen allows the user to view the flow, pressure, patient temperature and individual water temperature sensor readings. This information is valuable during the troubleshooting process.

Event Log
Selecting the Event Log button on the System Access Screen will display a record of non-recoverable system alarms and recoverable alarms from the last 10 cases. After 10 cases, the event log will overwrite the data in a first in, first out format when new cases are initiated.

The Event Log is still maintained when the system is powered down or if the system experiences a complete loss of power. Time of power down is not captured in the Event Log.

3. ***Notification***
Notifications are active when attention to the system is required (e.g. preventative maintenance).

When a notification is active, a small icon ( ) will appear next to the **System Access** button. Press the **System Access** button to read the notification.

4. ***Temperature Units (if enabled)***
From the **Normothermia** therapy screen or the **Hypothermia** therapy screen, press the **˚C/˚F** button to toggle the displayed patient and water temperatures between ˚C and ˚F.

NOTES: The **˚C/˚F** button is not visible when the **Temperature Units Adjust** parameter in **Normothermia Settings** or **Hypothermia Settings** is disabled. Set the **Temperature Units Adjust** parameter to enabled in order for the **˚C/˚F** button to display.

See section **VI. Operation Guide–Therapy Settings–Temperature Units Adjust** for further instructions on enabling/disabling this feature.

5. ***Patient Status***
The following **Patient** status information is displayed in the upper left side of the therapy screen.

A. Patient Temperature
- Displays the temperature input from the **Temp In 1** connector.
- **Temp In 1** is the patient temperature input utilized by the device for automatic patient temperature control.

Range:	10°C to 44°C 50°F to 111.2°F
Increments:	0.1°C/°F

- If a patient temperature probe is not connected into the **Temp In 1** connector, or the temperature is out of the display range, then the patient temperature will display dashes (--.-).
- If a patient temperature probe is not connected into the **Temp In 1** connector when you attempt to Start therapy, an alarm will occur.

B. Patient Temperature 2 (if enabled)
- Displays the temperature input to the **Temp In 2** connector.
- **Temp In 2** is for additional patient temperature monitoring only. It is not utilized by the device for automatic patient temperature control.

Range:	10°C to 44°C 50°F to 111.2°F
Increments:	0.1°C/°F

- If a patient temperature probe is not connected into the **Temp In** connector, or the temperature is out of the display range, then the patient temperature will display dashes (--.-).

THERAPY SCREENS (Continued)

- **Patient Temperature 2** must be enabled in the **Normothermia Settings** or **Hypothermia Settings** for Patient Temperature 2 to display.

  NOTE: See section **VI. Operation Guide–Therapy Settings–Patient Temperature 2** for instructions on enabling/disabling Patient Temperature 2.

6. System Status

The following **System** status information is displayed in the upper right side of the therapy screen.

C. Water Temperature

- Displays the temperature of the circulating water.
- If the current water temperature is at the pre-set "high water temperature" or "low water temperature" limit, then the word "Limit" will appear on the screen, next to the displayed water temperature.

D. Flow Rate

Displays the water flow rate in liters per minute.

7. Therapy Graph

The temperature graph displays the patient temperature history, patient target temperature, water temperature history, and Monitor Mode thresholds (if enabled) over time on the therapy screen.

E. Patient Temperature

- The patient temperature scale displays in yellow on the left side of the graph.
- The patient temperature is represented on the graph by a solid thick yellow line. (If **Patient Temperature 2** is enabled it is represented by a thin yellow line.)
- The patient target temperature is represented on the graph by a dotted yellow line.

F. Water Temperature

- The water temperature scale displays in blue on the right side of the graph.
- The water temperature is represented on the graph by a solid blue line.

G. Date and Time

- The temperature graph is divided into 5 segments denoted by time markers 00:00, 04:00, 08:00, 12:00, 16:00, and 20:00.
- During Hypothermia therapy, the graph background is color coded to represent the current time remaining in both the Cool and Rewarm therapies.
- A vertical time line displays to signify the current system time.
- Use the arrows on either side of the graph to scroll the graph backward or forward in time. Each press of the scroll arrow will advance the screen 15 minutes.

H. Progress Bar

- A progress bar displays on the bottom of the temperature graph to signify the operating modes active throughout the therapy.
- A green line denotes Control Patient, Cooling or Rewarming.
- A blue line denotes Manual Control.
- A red line denotes Stop mode.
- No line represents time when system was Powered Off or when the current case was not active.

8. Empty Pads

The Empty Pads feature empties water from the ArcticGel™ pads and fluid delivery lines into the Control Module reservoir.

To Empty Pads:

1) From the **Normothermia** therapy screen or the **Hypothermia** therapy screen, press the **Empty Pads** button.
2) The **Empty Pads** window will appear. Follow the directions on the screen.
3) Press the **Empty** button to begin to automatically empty the pads.
4) The **Emptying Pads** screen will appear and animate during the emptying process.
5) The emptying process will automatically stop when the pads are empty.
6) To stop the process early, press the **Stop** button.
7) Press the **Cancel** button to close the screen.

NOTE: The **Empty Pads** button is not visible and the feature disabled when the **Control**, **Cooling, Rewarming** or **Manual Control** functions are active. The system must be in Stop mode for the **Empty Pads** button to be visible and functional.

9. Fill Reservoir

See section **V. Setup Procedure–Fill Reservoir**.

THERAPY SCREENS (Continued)

10. Monitor Mode

The Monitor Mode feature delivers active therapy when user-defined thresholds are crossed. This feature is useful for temperature surveillance of the patient.

The **Monitor Mode** button appears on the therapy screen when Monitor Mode is enabled as *Automatic* or *Manual* in the therapy settings.

Press the **Monitor Mode** button to display the **Monitor Mode–Adjust** window. Use the Up and Down arrows to adjust the Upper limit, Lower limit, and Duration limits.

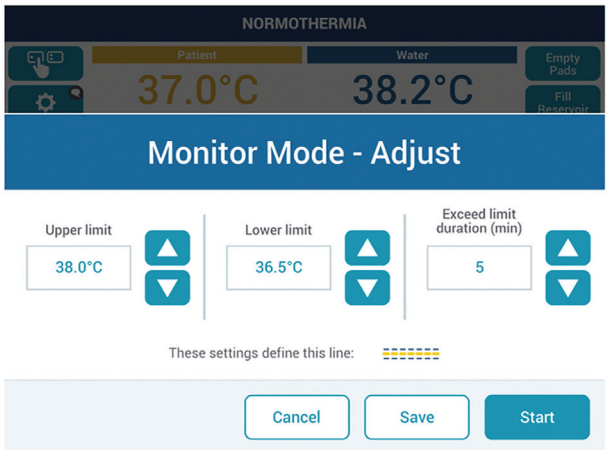


Figure VI-5. Monitor Mode Adjust Screen

When activated, the Monitor Mode temperature limits will be displayed as dotted lines above and below the target temperature on the therapy screen. When active, the flow rate status will indicate "Monitoring" and the "Monitoring" message will be animated on the status screen. To stop Monitor Mode, press **Stop** on the main therapy screen. See **VI. Operation Guide–Therapy Settings–Monitor Mode** to activate Monitor Mode and change the Monitor Mode setting to Automatic, Disabled, or Manual.

In Monitor Mode set to *Automatic*, the system will resume control of patient temperature to the configured target temperature when the patient temperature has been outside of the user-defined limits for greater than the user-defined duration limit. Return to patient temperature will occur as quickly as possible without ramp.

In Monitor Mode set to *Manual*, an alert will appear on the screen after the patient temperature has been outside of the user-defined limits for greater than the user-defined duration limit. The alert will recur every 15 minutes if the temperature remains outside the limit bands. The user must then manually start therapy if desired from the **Normothermia** or **Hypothermia** therapy screen.

Upper limit

Control Strategy	1,2	3
Range:	33.5°C to 38.5°C	32.5°C to 38.5°C
	92.3°F to 101.3°F	90.5°F to 101.3°F
Increments:	0.1°C/°F	0.1°C/°F

Lower limit

Control Strategy	1,2	3
Range:	33.0°C to 38.0°C	32.0°C to 38.0°C
	91.4°F to 100.4°F	89.6°F to 100.4°F
Increments:	0.1°C/°F	0.1°C/°F

Duration Limit

Range:	0 to 1 hr.
Increments:	0, 5, 10, 15, 30, 45, 60 min

NOTE: Monitor Mode is inaccessible during active cooling. When Monitor Mode is active, Arctic Sun Work to Cool will not be displayed, water temperature will be dashed, and flow rate will be zero in the therapy graph and status screen.

NOTE: Monitor Mode only applies to the normothermia phase or the rewarming phase when the rate is set to **Maximum**. To start Monitor Mode, the difference between the patient temperature and target temperature must be within 0.5°C (0.9°F) and the patient temperature must be within the selected upper/lower limits.

11. Arctic Sun Work to Cool

The Arctic Sun Work to Cool feature will monitor the heat removed by the Arctic Sun Temperature Management System during active Normothermia or Hypothermia therapy when using Adult ArcticGel™ Pads.

This feature measures changes in water temperature between the pads and the system in order to calculate average heat transfer to the Arctic Sun temperature management system. Arctic Sun Work to Cool levels are displayed on the Arctic Sun Work to Cool graph under the therapy graph and on an Arctic Sun Work to Cool gauge displayed on the status screen.

The Arctic Sun Work to Cool graph will begin to display once patient therapy has been started. Each bar represents the average heat removed during Hypothermia or Normothermia over the last 15 minutes.

Arctic Sun Work to Cool is displayed in either blue or orange corresponding to changes in heat transfer to the Arctic Sun Temperature Management System during therapy. The threshold for the change in color from blue to orange can be adjusted in Therapy Settings, but will be set at a default of 250 W.

THERAPY SCREENS (Continued)

Color	Level (W)	Display
Blue	<250	Baseline
Orange	>250	High

When the heat transfer continues to increase above the established threshold, orange bars will appear on the Arctic Sun Work to Cool graph. Likewise, the Arctic Sun Work to Cool gauge on the status screen will appear orange.

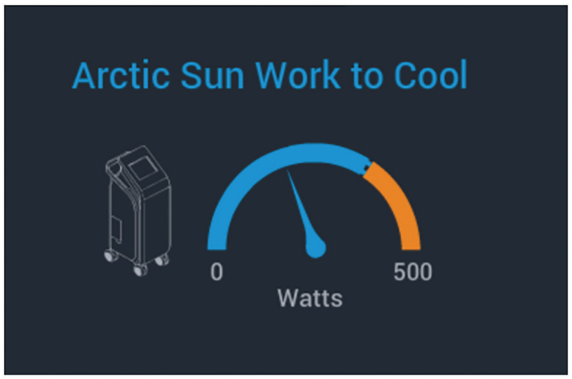


Figure VI-6. Arctic Sun Work to Cool gauge displaying as blue

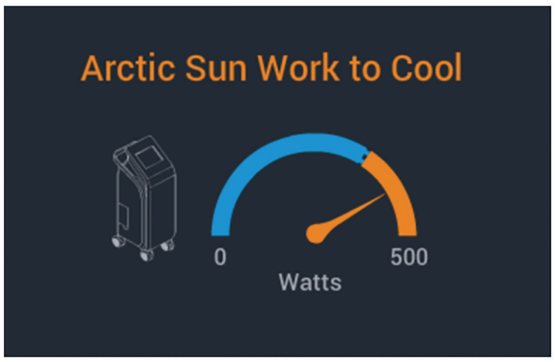


Figure VI-7. Arctic Sun Work to Cool gauge displaying as orange

When the Arctic Sun Work to Cool is displaying as blue, it is an indication that the Arctic Sun is not working hard to cool and the patient should be monitored as normal. When the Arctic Sun Work to Cool is displaying as orange, it is an indication that the Arctic Sun is working hard to cool and that the patient should be assessed for: shivering, seizure, fever, internal bleeding, or other causes of heat generation.

See **VI. Operation Guide–Therapy Settings–Work to Cool Threshold** to change the temperature thresholds for Arctic Sun Work to Cool.

NOTE: Bars will not be graphed when therapy is stopped by the user or when therapy is stopped due to a medium priority alarm.

NOTE: If the Arctic Sun™ Temperature Management System was previously in stop mode, or if the target temperature has been changed, the Arctic Sun Work to Cool Trend graph will be greyed, and the icon will display a grey hour glass for a period of 15 minutes.

12. Control Settings (Normothermia Screen)

- The default patient target temperature will display in the **Control** window.
- To modify the patient target temperature, press the **Adjust** button to display the **Control–Adjust** window.
- **Control to**: Use the Up and Down arrows to set the desired patient target temperature to control the patient.

  Range: 32.0°C to 38.5°C
  89.6°F to 101.3°F
  Increments: 0.1°C/°F

- **Rewarm at a Rate of**: Use the Up and Down arrows on the right of the screen to set the rewarming rate.

  Range: 0.01 to 0.50°C/hour
  0.02 to 0.90°F/hour
  Increments: 0.01 and 0.05°C/hour

Cooling Settings (Hypothermia Screen)

The **Cooling** window displays the cooling phase patient target temperature and the length of time remaining in the cooling phase of the Hypothermia Therapy.

- The default patient target temperature and duration will display in the **Cooling** window.
- To modify the patient target temperature and duration, press the **Adjust** button to display the **Cooling–Adjust** window.
- **Cool To:** Use the Up and Down arrows on the left side to set the desired patient target temperature to cool the patient.

  Range: 32.0°C to 38.5°C
  89.6°F to 101.3°F
  Increments: 0.1°C/°F

- **Cool For:** Use the Up and Down arrows on the right side to set the duration (hours and minutes) to cool the patient before rewarming begins.

  Range: 15 minutes to 99 hours
  Increments: 15 minutes (0-8 hours)
  1 hour (8-99 hours)

THERAPY SCREENS (Continued)

13. ***Start or Stop***

Start Therapy

From the **Normothermia** therapy screen or the **Hypothermia** therapy screen, press the **Start** button to start therapy and begin the flow of water to the ArcticGel™ pads. You will hear a tone and then a voice stating "Therapy Started."

Stop Therapy

From the **Normothermia** therapy screen or the **Hypothermia** therapy screen, press the **Stop** button to stop therapy and halt the flow of water to the ArcticGel™ pads. You will hear a tone and then a voice stating "Therapy Stopped."

14. ***Adjust***

Select the **Adjust** button on the therapy screen to change Control, Cooling, or Rewarming settings. Select **More** on the **Adjust** screen in order to display the therapy settings screen. Use the **Hypothermia Settings** or **Normothermia Settings** screen to view the current settings and modify the settings.

See **VI. Operation Guide–Therapy Settings** for details on each setting parameter.

15. ***WiFi Connection***

Once the Arctic Sun™ Temperature Management System is initially connected to WiFi, there will be an indicator in the upper right corner of the therapy screen that displays the connection status. If the WiFi icon is white, the device is connected. If the WiFi icon is blue with a slash through it, the device is disconnected.

16. ***Rewarming (Hypothermia Therapy Screen)***

The **Rewarming** window displays the rewarming phase patient target temperature and the length of time remaining in the rewarming phase of the **Hypothermia** therapy.

- The default patient target temperature and duration will display in the **Rewarming** window.
- To change the rewarming phase patient target temperature and rewarming rate, press the **Adjust** button in the **Rewarming** window to display the **Rewarming–Adjust** screen. Use the Up and Down arrows on the left side to set the desired final patient target temperature.
- **Rewarm To:** Use the Up and Down arrows on the right side to set the desired final patient target temperature.

  Range: 32.0°C to 38.5°C
  89.6°F to 101.3°F
  Increments: 0.1°C/°F

  NOTE: The low end of the range is limited by the current target temperature.

- **Rewarm at a Rate of**: Use the Up and Down arrows in the center of the screen to set the rewarming rate.

  Range: 0.01°C/hour to 0.50°C/hour
  0.02°F/hour to 0.90°F/hour
  Increments: 0.01°C/hour (0.01-0.35°C/hour)
  0.05°C/hour (0.35-0.50°C/hour)
  0.02°F/hour (0.02-0.58°F/hour)
  0.09°F/hour (0.59-0.90°F/hour)

- **Rewarm From:** When cooling a patient, adjustment of the Rewarm From setting on the left side of the screen is disabled and defaults to the Cooling target temperature.
- When rewarming a patient, the Rewarm From adjustment is enabled and the value can be modified. The Rewarm From setting is the temperature to which the system is currently controlling the patient. The Rewarm From temperature will automatically increase as the rewarming process continues. This feature allows the rewarming procedure to be optimized by allowing complete control of the rewarming ramp.
- Using the Rewarm From temperature, the Rewarm To temperature and the rewarming rate settings, the system will calculate and display the rewarming duration and the date/time at which the patient will reach the final rewarming target temperature.

  NOTE: If the rewarming rate is set to Maximum, then the Rewarm From temperature will automatically set to the Rewarm To final target temperature and the rewarming duration will display as 0.

17. ***Patient Temperature Trend Indicator***

The Patient Temperature Trend Indicator reflects the rate of change in the patient's temperature over the previous 5 minutes. The number of yellow arrows represents different rates of temperature change. Up arrows indicate the patient temperature is increasing; down arrows indicate that the patient temperature is decreasing.

When assessing a patient, the practitioner may refer to the Patient Trend Indicator for insight into patient heat generation which may be indicative of shivering or fever generation.

Trend Indicator	***Patient Temperature Trend***
	No trend established or no patient temperature input
	No change or less than 0.25°C (0.45°F) change per hour
	0.25°C to 0.50°C (0.45°F to 0.90°F) change per hour
	0.50°C to 0.75°C (0.90°F to 1.35°F) change per hour
	0.75°C to 2.0°C (1.35°F to 3.6°F) change per hour
	Greater than 2.0°C (3.6°F) change per hour

THERAPY SCREENS (Continued)

18. Manual Control

Use the Manual Control feature to circulate water at a set temperature through the ArcticGel™ pads for a set duration of time. Manual Control is not recommended for patient temperature management. The operator is advised to use the automatic therapy modes (e.g. Control Patient, Cooling, Rewarming) for automatic patient temperature monitoring and control.

NOTE: The system patient temperature limit alarms will not automatically stop Manual Control but will only alarm the user to an over limit condition.

Manual Control can be disabled or set to the default Manual Control water temperature and maximum time duration in the **Normothermia Settings** or **Hypothermia Settings** screen. If the Manual Control feature is disabled, the **Manual Control** button is not visible on the therapy screen. When activating Manual Control from the therapy screen, the user will have the option to select the Manual Control time duration. The Manual Control time duration range that is selectable will be limited by the maximum time duration set in Manual Control settings. See **VI. Operation Guide–Therapy Settings–Manual Control**.

INITIATE THERAPY

Initiate Normothermia (Control Patient)
Normothermia therapy is initiated and managed, and patient temperature is automatically controlled to a set target temperature from the **Control Patient** window in the **Normothermia** therapy screen. The **Control Patient** window displays the patient target temperature and the duration since the initiation of normothermia therapy.

To initiate Normothermia therapy:

1) From the patient **Therapy Selection** screen, press the button next to Normothermia to display the **Normothermia** therapy screen.
2) The default patient target temperature will display in the **Control** window towards the bottom of the screen.
3) To modify the patient target temperature, press the **Adjust** button to display the **Control Patient–Adjust** window.
4) **Control Patient** to: Use the Up and Down arrows to set the desired target temperature to control the patient.
5) **Rewarm at a Rate** of: Use the Up and Down arrows on the right of the screen to set the rewarming rate.
6) Press the **Save** button to save the new settings and close the **Control Patient–Adjust** window.
7) Press **Start**, in the **Control** window to initiate therapy. You will hear a tone and then a voice stating "Therapy Started".

NOTE: For patient target temperature between 32°C and 32.9°C (89.6°F to 91.2°F) to be available for selection, Control Strategy 3 must be chosen in **Normothermia Settings**. See **VI. Operation Guide–Therapy Settings– Control Strategy** for further instructions on setting the control strategy.

Initiate Hypothermia (Cooling and Rewarming)
Hypothermia therapy is initiated and managed, and patient temperature is automatically controlled to a set target temperature from the **Cooling** and **Rewarming** windows in the **Hypothermia** therapy screen.

The **Cooling** window displays the cooling phase patient target temperature and the length of time remaining in the cooling phase of the Hypothermia therapy.

The **Rewarming** window displays the rewarming phase patient target temperature and the length of time remaining in the rewarming phase of the Hypothermia therapy.

To initiate Hypothermia therapy:
From the patient **Therapy Selection** screen, press the button next to Hypothermia to display the **Hypothermia** therapy screen.

1) **Cooling Settings**

- Press the **Adjust** button on the **Cooling** window to display the **Cooling–Adjust** window. Use the Up and Down arrows to set the desired patient target temperature and the desired cooling duration to cool the patient before rewarming begins.
- Press the **Save** button to save the new settings and close the **Cooling–Adjust** window.
- Press the **Cancel** button to close the **Cooling–Adjust** window without saving the new settings.

NOTE: For patient target temperature between 32.0°C and 32.9°C (89.6°F to 91.2°F) to be available for selection, control strategy 3 must be chosen in **Hypothermia Settings**. See **VI. Operation Guide–Therapy Settings–Control Strategy** for further instructions on setting the control strategy.

2) **Rewarming Settings**

- Press the **Adjust** button on the **Rewarming** window to display the **Rewarming–Adjust** screen. Use the Up and Down arrows to set the desired final patient target temperature and the desired rewarming rate.
- Press the **Save** button to save the new settings and close the **Rewarming–Adjust** window.
- Press the **Cancel** button to close the **Rewarming–Adjust** window without saving the new settings.

3) **Initiate Patient Cooling**
Press **Start**, in the **Cooling** window to initiate therapy. You will hear a tone and then a voice stating "Therapy Started."

INITIATE THERAPY (Continued)

4) **Initiate Patient Rewarming**

- Upon completion of the cooling phase, there are two options for initiation of patient rewarming, either Automatically or Manually, depending on the **Rewarming Begins** setting in **Hypothermia Settings**.
- If **Rewarming Begins** is set to **Automatically**, the rewarming process starts automatically when the **Cooling** phase is complete and the duration reaches zero.
- If **Rewarming Begins** is set to **Manually**, the rewarming process starts when the **Start** button is pressed in the **Rewarming** window. The cooling process will continue until the **Rewarming Start** button is pressed. A **Low Priority Alarm** will occur when the **Cooling** duration reaches zero. When the **Rewarming** duration timer reaches zero, the system will continue to control the patient to the target temperature until the **Stop** button is pressed. Once in **Normothermia**, the timer will reset and begin tracking the duration of **Normothermia** therapy.

  NOTE: See **VI. Operation Guide–Therapy Settings–Rewarming Begins** for further instructions on selecting the **Rewarming Begins** setting.

INTERRUPT THERAPY FOR PATIENT TRANSPORT

1) From the **Normothermia** therapy or **Hypothermia** therapy screen, press the **Stop** button to terminate water circulation to the pads.
2) Press the **Empty Pads** button, and follow the instructions on the screen to purge the pads of water.
3) Disconnect the pads from the Fluid Delivery Line as follows:
   - Pinch the two wings on the pad line connector.
   - Push the connector toward the fluid delivery line manifold to release the catches on both sides.
   - Pull apart.
4) Leave the pads on the patient.
5) Disconnect patient temperature probes from the Patient Temperature Cables.
6) Turn Off the Control Module. Disconnect the power cord from the wall.
7) Transport the patient and the Control Module.
8) Temperature management can be re-initiated when the patient reaches the transport destination.
9) Plug the Control Module power cord into the wall.
10) Power On.
11) Connect the patient temperature probes to the Patient Temperature Cables.
12) Connect pads to the Fluid Delivery Line.
13) From the patient **Therapy Selection** screen, press the **Continue Current Patient** button.

    The date and time that the current patient therapy was paused appears below the Continue Current Patient button. This feature is available for up to 6 hours after pausing therapy.

    NOTE: Do not press the **New Patient** Normothermia or Hypothermia buttons if continuing the paused therapy is desired. Doing so will delete all previous patient therapy data and settings.

14) The **Normothermia** therapy or **Hypothermia** therapy screen from the therapy session will appear, and the therapy settings will be active.
15) Press the **Start** button in the appropriate window (e.g. **Control**, **Cooling**) at the bottom of the therapy screen.

END THERAPY

1) From the **Normothermia** therapy or **Hypothermia** therapy screen, press the **Stop** button to terminate water circulation to the pads. You will hear a tone and then a voice stating “Therapy Stopped”.
2) Press the **Empty Pads** button, and follow the instructions on the screen to purge the pads of water.
3) Disconnect the pads from the Fluid Delivery Line.
   - Pinch the two wings on the pad line connector.
   - Push the connector toward the fluid delivery line manifold to release the catches on both sides.
   - Pull apart.
4) Slowly and carefully remove pads from the patient skin. Do not pull pads. Avoid aggressive removal of the pad adhesive. Cold temperature increases the adhesiveness of the hydrogel. For ease of removal, leave pads on the patient for approximately 15 minutes to allow the hydrogel to warm.
5) Discard the used pads in accordance with hospital procedures for medical waste.
6) Power Off the device.

   NOTE: If power is lost while the power switch is in the On position, an audible alarm will be issued until it is switched Off. This alarms the user that the treatment may have been accidentally stopped.

THERAPY SETTINGS

Use the **Hypothermia Settings** or **Normothermia Settings** screen to view the current settings and modify the settings for the following parameters. To modify any parameter setting, press the button to the right of the parameter.

To access the **Hypothermia Settings** or **Normothermia Settings** screen press the **Adjust** button on the **Hypothermia** or **Normothermia** therapy screen and then press the **More** button.

Therapy Settings
1. Cooling Begins (Hypothermia Setting)
2. Rewarming Begins (Hypothermia Setting)

Water Temperature Settings
3. Pre-Condition Water
4. Manual Control
5. High Water Limit
6. Low Water Limit

Patient Temperature Settings
7. High Patient Alarm
8. Low Patient Alarm
9. Control Strategy
10. Monitor Mode
11. Work to Cool Threshold

Display Settings
12. Temperature Units
13. Temperature Units Adjust
14. Patient Temperature 2

Volume
15. Speaker Volume

1. Cooling Begins

Use the **Cooling Begins** parameter to set the event that triggers when the cooling duration timer starts. The options are to start the timer immediately after pressing the Start button in the Cooling window, or when the patient approaches within 0.5°C or 1°F of the Cooling target temperature.

- From the **Hypothermia Settings** screen, press the button to the right of the Cooling Begins parameter.
- Select the point that the therapy timer begins.

  Range: Immediately; At Target

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

2. Rewarming Begins

Use the **Rewarming Begins** parameter to set the method by which patient rewarming begins. The two options to initiate rewarming are:

Manually	Initiates the rewarming process when the **Start** button is pressed by the user in the **Rewarming** window. An Alarm will be displayed when the cooling period has expired. Cooling will continue until Rewarming is manually started.
Automatically	Initiates the rewarming process automatically when the Cooling therapy is complete and the duration timer reaches zero.

- From the **Hypothermia Settings** screen, press the button to the right of the Rewarming Begins parameter.
- Use the Up and Down arrows to select the point that the therapy duration timer begins.

  Range: Manually; Automatically

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

NOTE: Though the **Normothermia Settings** and **Hypothermia Settings** screens and are very similar, the Normothermia Settings and Hypothermia Settings are saved independently. This allows for different default settings for each therapy type.

THERAPY SETTINGS (Continued)

3. ***Pre-Condition Water***
The **Pre-Condition Water** feature cools or warms the water to a set temperature prior to starting patient therapy.

Use the Pre-Condition Water parameter to either disable the Pre-Condition Water feature or set the pre-conditioned water to a selected temperature. If a Pre-Condition Water temperature is selected, then water pre-conditioning will automatically start after entering the therapy screen.

Preconditioning will automatically end when the system detects a valid patient temperature or that a pad has been attached. This feature is useful to reduce the time needed to cool or rewarm a patient.

- From the **Normothermia Settings** screen or the **Hypothermia Settings** screen, press the button to the right of the Pre-Condition Water parameter.
- Use the Up and Down arrows to either disable the feature or select the pre-condition water temperature.

Range:	Disable; 4°C to 40°C 39.2°F to 104°F
Increments:	1°C/°F

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

4. Manual Control

- From the **Normothermia Settings** screen or the **Hypothermia Settings** screen Press the button to the right of the Manual Control Settings parameter.

Adjust to the desired temperature

- Use the Up and Down arrows to either disable the feature or select the Manual Control default temperature. The selected temperature will be the default temperature displayed in the Manual Control pop-up window.

Range:	Disable; 4°C to 40°C 39.2°F to 104.0°F
Increments:	1°C/°F

Adjust the desired time

- Use the Up and Down arrows to select the Manual Control maximum time duration. The selected time will be the default time displayed in the Manual Control pop-up window.

Range:	15 minutes to 99 hours
Increments:	15 minutes (from 0 to 8 hours) 1 hour (from 8 to 99 hours)

- Press the **Start** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

5. ***High Water Limit***
Use the **High Water Limit** to set the maximum water temperature delivered to the pads during therapy. Reducing the high water temperature limit may be appropriate for patients with fragile skin or other medical conditions.

- From the **Normothermia Settings** screen or the **Hypothermia Settings** screen, press the button to the right of the High Water Limit parameter.
- Use the Up and Down arrows to select the maximum water temperature.

Range:	36°C to 40°C 97°F to 104°F
Increments:	1°C/°F

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

NOTE: The **High Water Limit** setting does not affect the **Manual Control** water temperature.

6. Low Water Limit
Use the **Low Water Limit** to set the minimum water temperature delivered to the pads during therapy. Increasing the low water temperature limit may be appropriate for patients with fragile skin or other medical conditions.

- From the **Normothermia Settings** screen or the **Hypothermia Settings** screen, press the button to the right of the Low Water Limit parameter.
- Use the Up and Down arrows to select the minimum water temperature.

Range:	4°C to 25°C 39°F to 77°F
Increments:	1°C/°F

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

NOTE: The **Low Water Limit** setting does not affect the **Manual Control** water temperature.

THERAPY SETTINGS (Continued)

7. High Patient Alarm

Use the **High Patient Alarm** to select a patient temperature at which the system will issue an alarm if the patient temperature exceeds this limit during therapy.

- From the **Normothermia Settings** screen or the **Hypothermia Settings** screen, press the button to the right of the High Patient Alarm parameter.
- Use the Up and Down arrows to select the patient temperature high alarm setting.

Range:	10.1°C to 44.0°C
	50.2°F to 111.2°F
Increments:	0.1°C/°F

NOTE: The minimum value of the range is limited to 0.1°C/°F above the **Low Patient Alarm** setting

- Press the **Save** button to save the new setting and close the window. Press the **Cancel** button to close the window without saving the new settings.

8. Low Patient Alarm

Use the **Low Patient Alarm** to select a patient temperature at which the system will issue an alarm if the patient temperature goes below this limit during therapy.

- From the **Normothermia Settings** screen or the **Hypothermia Settings** screen, press the button to the right of the Low Patient Alarm parameter.
- Use the Up and Down arrows to select the patient temperature low alarm setting.

Range:	10.0°C to 43.9°C
	50.0°F to 111.0°F
Increments:	0.1°C/°F

NOTE: The maximum value of the range is limited to 0.1°C/°F below the **High Patient Alarm** setting

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

9. Control Strategy

Use the **Control Strategy** setting to select the control algorithm parameters employed during therapy based upon the specific patient population and/or treatment goal:

Strategy 1: Awake patients
Strategy 2: Patients receiving anesthesia or neuromuscular blockade
Strategy 3: Patients receiving anesthesia or neuromuscular blockade, and target temperature is set to less than 33°C (91.4°F).

- From the **Hypothermia Settings** screen or the **Normothermia Settings** screen, press the button to the right of the Control Strategy parameter.
- Use the Up and Down arrows to select the control strategy setting.

  Range: 1; 2; 3
- Press the **Save** button to save the new setting and close the window. Press the **Cancel** button to close the window without saving the new settings.

  NOTE: Changing control strategy from 3 to either 1 or 2 will automatically adjust the patient target temperature to a minimum of 33°C (91.4°F). Check the patient target temperature after adjusting the control strategy. For patient target temperature between 32°C and 32.9°C (89.6°F to 91.2°F) to be available for selection, control strategy 3 must be chosen.

10. Monitor Mode

From the **Hypothermia Settings** screen or the **Normothermia Settings** screen, press the button to the right of the Monitor Mode parameter.

Monitor Mode can be set to *Manual, Automatic, or Disabled* using the Up and Down arrows.

Manual

An alert will be generated after the patient temperature is consistently outside the limit bands for a period longer than the user-defined limit duration. Arctic Sun™ Temperature Management System therapy delivery must be manually started.

Automatic

The Arctic Sun™ Temperature Management System will resume therapy delivery and control to the patient target temperature after the patient temperature is consistently outside the limit bands for a period longer than the user-defined limit duration. Once the machine begins delivering active therapy, the purple bands will disappear.

Disabled

Monitor Mode is disabled. The **Monitor Mode** button is not displayed on the therapy screen. Selecting "Disabled" and pressing "Save" when Monitor mode is active in the therapy will cause the therapy to enter stop mode.

Use the Up and Down arrows to set the desired Monitor Mode setting and press **Save**. Press **Cancel** to close the Monitor Mode settings window without saving.

11. Work to Cool Threshold

From the **Hypothermia Settings** screen or the **Normothermia Settings** screen, press the button to the right of the Work to Cool Threshold parameter.

The Work to Cool Threshold parameter accompanies the Arctic Sun Work to Cool functionality of the system.

Use the Up and Down arrows to adjust the threshold at which the Arctic Sun Work to Cool icon will display as orange.

Range:	0 W to 500 W
Increments:	10 W

THERAPY SETTINGS (Continued)

12. Temperature Units

Use the **Temperature Units** to select to have either °C or °F as the default temperature units displayed on the therapy screen.

NOTE: If both units may be useful, enable the **Temperature Units Adjust** feature so that the temperature units are selectable from the therapy screen.

- From the **Hypothermia Settings** screen or the **Normothermia Settings** screen, press the button to the right of the Temperature Units parameter.
- Use the Up and Down arrows to select the temperature units setting.

  Range: °C; °F

- Press the **Save** button to save the new setting and close the window. Press the **Cancel** button to close the window without saving the new settings.

13. Temperature Units Adjust

Use the **Temperature Units Adjust** to enable or disable the **˚C/˚F** button on the therapy screen. The **˚C/˚F** button allows the user to toggle the displayed patient and water temperatures between Celsius (°C) and Fahrenheit (°F). If the Temperature Units Adjust is enabled, the **˚C/˚F** button is visible and functional. If the Temperature Units Adjust is disabled, the **˚C/˚F** button is not visible and the function disabled.

- From the **Normothermia Settings** screen or the **Hypothermia Settings** screen, press the button to the right of the Temperature Units Adjust parameter.
- Use the Up and Down arrows to select the temperature units setting.

  Range: Enable; Disable

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

14. Patient Temperature 2

Use the **Patient Temperature 2** setting to enable or disable the Patient Temperature 2 display on the therapy screen. This safety feature allows independent patient temperature alarms and alarms.

If the Patient Temperature 2 is enabled, the Patient Temperature 2 reading is displayed. If the Patient Temperature 2 is disabled, the Patient Temperature 2 reading is not displayed.

- From the **Hypothermia Settings** screen or the **Normothermia Settings** screen, press the button to the right of the Patient Temperature 2 setting.
- Use the Up and Down arrows to select the Patient Temperature 2 display setting.

  Range: Enable; Disable

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new settings.

15. Speaker Volume

Use the **Speaker Volume** setting to select the level of audio tones (e.g. Alarms) issued by the unit. The allowable settings are 1 to 5, with 1 being the lowest volume, and 5 being the highest volume.

- The volume of certain critical safety alarms is not affected by the Speaker Volume setting.
- From the **Hypothermia Settings** screen or the **Normothermia Settings** screen, press the button to the right of the Speaker Volume parameter.
- Use the Up and Down arrows to select the speaker volume setting.

  Range: 1; 2; 3; 4; 5

- Press the **Save** button to save the new setting and close the window. The unit will issue an audio tone of the selected volume level.
- Press the **Cancel** button to close the window without saving the new settings.

ADVANCED SETUP

Use the **Advanced Setup** screen to view the current settings and modify the settings for the following parameters. To modify any parameter setting, press the button to the right of the parameter.

To access the Advanced Setup screen:

1) Press **Advanced Setup** button on the patient **Therapy Selection** screen.
2) The Advanced Setup screen will be displayed.

NOTE: The **Advanced Setup** button on the Patient Therapy screen will be available when the unit is Powered On. The **Advanced Setup** button will not be available once patient therapy has been started. The **Advanced Setup** button can only be redisplayed after cycling the power.

Functions

1. Download Patient Data
2. Connectivity Settings
3. Calibration
4. Total Drain
5. Save All Settings As Default

Location / Time Settings

6. Number Format
7. Current Time
8. Date Format
9. Current Date

Information

10. Software Versions
11. Last Calibration Date
12. Next Calibration Due

1. Download Patient Data

The data for the 10 most recent patient therapies is stored on the Arctic Sun™ Temperature Management System Control Module internal storage. The data may be downloaded through the USB port to a flash drive. This data is maintained when the Arctic Sun™ Temperature Management System is Powered Off, or in the event of a total loss of power.

To download patient data:

- Insert a flash drive into the USB port on the back of the Control Module.
- From the **Advanced Setup** screen, press the Start button to display the **Download Patient Data** window.
- Use the Up and Down arrows to select the patient data file for download. Each patient data file is identified by the date and time that the patient therapy ended.
- Press the **Save** button to initiate the download process. The download process will indicate when the process is complete by changing the color of the patient data file text to gray.
- Remove the flash drive from the USB port.
- The data is saved as a text file to the flash drive's main directory. The file will be named according to the following convention: *Arctic Sun-Date-Time.csv*
- See the following table for the contents of the data file. During therapy, the values for each parameter are saved every minute.
- Press the **Cancel** button to close the window.

NOTES:
The USB data port is to be used only with a standalone USB flash drive. Do not connect to another mains powered device during patient treatment.

Patient Data Fields	
Parameter	**Units**
Date	MM/DD/YY
Time	HH:MM
Sequence starter indicator	$
Sequence serial number	Sequential integer beginning with 1 (initializing at Power On)
Patient Temperature 1	°C, 0 if probe not attached
Patient Temperature 2	°C, 0 if probe not attached
Patient Target Temperature	°C
Operating Mode	0 = initialization 1 = Stop 2 = Patient Control 3 = Manual Control 4 = Empty Pads 5 = Fill Reservoir 6 = Monitor Mode (RS232) 8 = Monitor Mode
Diagnostic Mode	0 = Normal 1 = Diagnostic
Outlet Water Temperature (T1)	°C
Outlet Water Temperature (T2)	°C
Inlet Water Temperature (T3)	°C
Chiller Water Temperature (T4)	°C
Water Outlet Target Temperature	°C
Temperature Display Units	0 =°C 1 =°F
Communications Output Mode	Seconds
Current Alarm Number	Integer
Flow Rate	Liters/Minute
Reservoir Level Last Measured	0 = Empty 1 = Low 2 = ½ 3 = ¾ 4 = Full 5 = Full
Inlet Pressure	Psi
Heater Power	0 – 32
Mixing Pump Power	0 – 200
Flow Pump Power	0 - 235
Control Power Mode	1, 2, 3
Software Version	x.y (major revision)
Device Identifier*	Globally unique ID
Arctic Sun Work to Cool*	Watts
Bypass*	0 = Not engaged (closed) 1 – Engaged (open)
Vent*	0 = Not engaged (closed) 1 – Engaged (open)
Pump Hours*	Hours
System Hours*	Hours
Facility ID*	Unique string identifying facility
Arctic Sun Work to Cool Threshold*	Watts
Upper Temp Threshold for Monitor Mode*	°C
Lower Temp Threshold for Monitor Mode*	°C
ArcticGel Pad Size*	Adult Pediatric Neonate

* Indicates data is included in wifi data only

ADVANCED SETUP (Continued)

2. Connectivity Settings

Use Connectivity Settings to connect the Arctic Sun™ Temperature Management System to the hospital network connection. This optional feature allows therapy data from the Arctic Sun™ Temperature Management System to be sent wirelessly

To connect:

- From the **Advanced Setup** screen, press the Start button to display the **Connectivity Settings** window.
- From the **Device** tab, select **Configure**.
- Select **Edit** under the Device ID tab and enter the serial number, located on the back of the device.
- Press the **Continue** button once the Device ID has been entered.
- Re-enter the Device ID and press the **Continue** button to confirm.
- Select **Edit** under the Facility ID tab and enter the name of the facility where the device is located.
- Press the **Continue** button once the Facility ID has been entered.
- Close the **Device Configuration** screen.
- From the **Network** tab, press the **Connect** button
- Select the desired Network to connect with from the list.
- Enter network password and select **Continue**
- From the **Server** tab, select **Edit.**
- Select **Edit** under the Server Address tab and enter the account Server Address and press **Continue**.
- Select **Configure** under the Server Port Number tab and enter the account Server Address Number and press **Continue**.
- Select **Start** under the Test Connection tab to verify if the connection to the server is successful
- Select **Edit** under the Encryption Password tab to enter an encryption passphrase.
- Enter the passphrase and press **Continue**.

NOTE: If wireless connectivity is lost, therapy will continue uninterrupted. Any therapy data generated while wireless connectivity is lost will automatically be sent upon reconnection unless a new therapy is started or the device is powered off for more than six hours before connection is reestablished. Therapy data that is not transmitted can be retrieved via USB.

Maximum network latency: 500 ms
Hourly data throughput: ~18 kb
Integrity of data in transit: TCP/IP protocol
Wireless security protocol: WPA2 Personal

3. Calibration

Calibration is recommended after 2,000 hours of operation or 250 uses, whichever occurs first as indicated on the display screen. See the Arctic Sun™ Temperature Management System Service Manual for calibration requirements and instructions. Calibration should be done only by trained service personnel.

4. Total Drain

The Arctic Sun™ Temperature Management System needs to be totally drained of water prior to shipping or exposure to subfreezing temperatures to prevent damage.

- Turn Control Module Power Off.
- Attach the drain line connectors to the two drain ports on the back of the Control Module. The water will passively drain into the bag.
- Perform the following steps to run the device pumps and further expel water from the system.
- Plug in the Control Module and Power On.
- From the **Advanced Setup** screen, press the **Start** button next to **Total Drain**. The **Total Drain** pop up window will display.
- Press the **Drain** button on the window to initiate the drain cycle. The text in the window will change to notify the user that the pumps are running and draining the device.
- The drain cycle should complete in approximately 30 seconds.
- Press the **Cancel** button to exit the screen when the process is complete.

5. Save Settings as Default

The **Save all Settings as Default** option will save all of the **Advanced Setup** settings. The system default is Normothermia and Hypothermia. Two additional settings can be added.

- From the **Advanced Setup** screen, press the **Start** button next to **Save All Settings as Default**.
- The device allows for two additional default settings of **Normothermia** or **Hypothermia**.
- The additional default settings may be added by pressing the appropriately labeled button. Once selected, you will automatically be taken back to the **Advanced Setup Screen**. Press **Close** and return to the patient **Therapy Selection** screen.
- Select the recently added default on the patient **Therapy Selection** screen. The settings will automatically be the same as the standard defaults. Adjust settings as desired.
- Return to the patient **Therapy Selection** Screen and press **Advanced Setup**.
- Select **Save All Settings as Default**.
- Press **Save** to store new default on the Arctic Sun™ Temperature Management System.
- To remove default from the Arctic Sun™ Temperature Management System, press the trash icon.
- **Close** the **Advanced Setup** Screen.

NOTE: Selecting the **Close** button without saving will retain the previous default configuration.

ADVANCED SETUP (Continued)

6. Number Format

To set the number format to the local requirements:

- From the **Advanced Setup** screen, press the button the right of the Number Format parameter.
- Use the Up and Down arrows to select the number format.

  Range: 1,234.5
  1.234,5

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new setting.

7. Current Time

To set the current local time in 24-hour notation:

- From the **Advanced Setup** screen, press the button to the right of the Current Time parameter.
- Use the Up and Down arrows to set the hours.

  Range: 00 to 23

- Use the Up and Down arrows to set the minutes.

  Range: 00 to 59

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new setting.

  NOTE: Making changes to the date or time during an active patient therapy will automatically stop the therapy. Wait until the current patient therapy has ended before making any adjustments to this feature.

8. Date Format

- To set the date format to the local requirements:
- From the **Advanced Setup** screen, press the button to the right of the Date Format parameter.
- Use the Up and Down arrows to select the date format.

  Range: MM/DD/YY
  DD/MM/YY
  DD/MM/YYYY

- Press the **Save** button to save the new setting and close the window. Press the **Cancel** button to close the window without saving the new setting.

9. Current Date

To set the current local date:

- From the **Advanced Setup** screen, press the button to the right of the Current Date parameter.
- Use the Up and Down arrows to set the Day.

  Range: 01 to 31 (depending on month)

- Use the Up and Down arrows to set the Month.

  Range: 01 to 12

- Use the Up and Down arrows to set the Year.

  Range: 2018 to 2099

- Press the **Save** button to save the new setting and close the window.
- Press the **Cancel** button to close the window without saving the new setting.

  NOTE: Making changes to the date or time during an active patient therapy will automatically stop the therapy. Wait until the current patient therapy has ended before making any adjustments to this feature.

10. Software Versions

The current controller and graphics software versions installed on the device are displayed.

11. Last Calibration Date

The last calibration date of the device is displayed.

12. Next Calibration Due

The next calibration date of the device is displayed in number of uses and hours.

VII. ALARMS

The Arctic Sun™ Temperature Management System safety system continually monitors the state of the device and the patient, and issues alarms to notify the user of conditions that may interfere with patient safety or system performance.

Main Safety Alarms

While there are multiple alarms and safety features in the Arctic Sun™ Temperature Management System, there are five main safety alarms that will place the device into Stop mode until the condition is addressed.

Alarm	Specification
High Patient Temperature	39.5°C (103.1°F)
Low Patient Temperature	31.0°C (87.8°F)
High Water Temperature	42.5°C / 44°C (108.5°F / 111.2°F)
Low Water Temperature	3.0°C / 3.5°C (37.4°F / 38.3°F)
System Self-Test Failure	At device Power On

Each time the Arctic Sun™ Temperature Management System is Powered On, a system self-test for the independent safety alarm is automatically run. This test simulates a "water high temperature" fault situation on both the primary and secondary water temperature sensors. Both the primary and secondary safety systems must respond to the fault and be verified by the opposing safety system. If either safety systems do not respond appropriately either an alarm 80 or 81 will be issued. Contact BD Customer Support. If power is unexpectedly lost, the device will beep to notify the user. Upon restoration of power, the device will issue alarm 45.

There are two types of conditions: **Medium Priority Alarms** and **Low Priority Alarms**.

A **Medium Priority Alarm** notifies the user a condition that may potentially pose discomfort or reversible injury to the patient requires operator response. Failure to respond may result in irreversible injury or death.
Note: The system and any ongoing therapy will be placed in Stop mode.

MEDIUM PRIORITY ALARMS

A Medium Priority Alarm is denoted by an audio signal that repeats every 10 to 15 seconds until the Alarm is cleared. The yellow Alarm screen will appear that displays the alarm number, alarm title, a description of the problem or conditions that triggered the alarm, and solutions and instructions for troubleshooting and resolving the alarm condition. If certain Alarm conditions are not acknowledged by the operator within 2 minutes, a Reminder tone will sound. All Alarm settings are maintained in the event of a power interruption.

Non-Recoverable Alarms

If an Alarm condition occurs that prevents proper use of the device or proper patient treatment (such as the five main safety alarms discussed above), the system is placed into Stop mode and will not allow therapy to continue. This type of Alarm is known as Non-Recoverable. If this situation occurs, cycle the device power (turn device Off then On). If the alarm recurs contact BD Customer Support.

Recoverable Alarms

Other Alarms that temporarily Stop the device until the user is able to correct the cause and clear the Alarm are classified as Recoverable. If the condition that initiated the alarm is not addressed and problem persists, the Alarm will recur.

If a Recoverable Alarm occurs:

- When an alarm is issued the device is placed into Stop mode.
- Read the displayed instructions.
- Note the Alarm number.
- Press the Close button to clear the alarm.
- Follow the instructions to correct the alarm condition. Perform the actions in the order listed until the alarm condition is resolved.
- Once you have cleared the alarm, press the Start button in the therapy window to restart therapy. You will hear a tone and a voice stating "Therapy Started".

If the condition does not resolve, contact BD Customer Support.

A **Low Priority Alarm** notifies the user a condition that may potentially pose discomfort or reversible injury to the patient requires operator response.

LOW PRIORITY ALARMS

A Low Priority Alarm is denoted by an audio signal that repeats every 25 to 30 seconds. The blue Alarm screen will appear that displays the alarm number, alarm title, a description of the problem that triggered the alarm, and solutions and instructions for troubleshooting and resolving the alarm condition.

If a Low Priority Alarm occurs:

- Read the displayed instructions.
- Note the Alarm number.
- Press the Close button to clear the alarm.
- Follow the instructions to correct the alarm condition. Perform the actions in the order listed until the alarm condition is resolved. If the condition does not resolve, contact BD Customer Support.

NOTES: Refer to **Appendix B–Alarm Information** for more information on the Alarm number.

If the condition that initiated the alarm is not addressed and the problem persists, the Alarm will recur and/or escalate.

To view alarms, the operator should stand in front of the Arctic Sun™ Temperature Management System display screen.

VIII. TROUBLESHOOTING

WATER

Water Not Cooling

- Confirm the patient is cooling properly. If not, see **VIII. Troubleshooting–Patient Temperature–Patient Not Controlling** for instructions.
- Confirm the water temperature is not limited by a user setting. See **VI. Operation Guide—Therapy Settings–Water–High Water Limit** or **Low Water Limit** for instructions on adjusting the water temperature setting.
- Confirm the water flow rate is adequate. Low flow will limit the system's ability to cool. If water flow is low, see **VIII. Troubleshooting–Water–Low Water Flow** for instructions.
- Confirm the air filter is not occluded with dust. If dust is present, wipe surface with clean cloth. See section I**X. Cleaning** and **X. Maintenance and Service** for instructions.
- Operate the system in Manual Control mode with the water temperature target set at 6˚C (43˚F). Confirm that the water temperature approaches the target over a period of 10 minutes. If so, the system is operating properly. If not, contact BD Customer Support.

Water Not Warming

- Confirm the patient is warming properly. If not, see **VIII. Troubleshooting–Patient Temperature–Patient Not Controlling** for instructions.
- Confirm the water temperature is not limited by a user setting. See **VI. Operation Guide—Therapy Settings–High Water Limit** or **Low Water Limit** for instructions on adjusting the water temperature setting.
- Confirm the water flow rate is adequate. Low flow will limit the system's ability to warm. If water flow is low, see **VIII. Troubleshooting–Water–Low Water Flow** for instructions.
- Confirm the air filter is not occluded with dust. If dust is present, wipe surface with clean cloth. See section I**X. Cleaning** and **X. Maintenance and Service** for instructions.
- Operate the system in Manual Control mode with the water temperature set at 40˚C (104˚F). Confirm that the water temperature rises above room temperature over a period of 10 minutes. If so, system is performing properly. If not, contact BD Customer Support.

Extended Cold Water Exposure

Exposure of the skin to low or high water temperatures for an extended period of time may increase the risk for skin injury. The clinician should monitor the patient and water temperatures displayed on the Arctic Sun™ Temperature Management System therapy graph to properly assess the progress of the temperature management therapy. Additionally, the Arctic Sun™ Temperature Management System incorporates an extended cold water exposure alarm. If the water temperature remains below 10°C (50°F) for 8 of the previous 10 hours, the device will issue a low priority alarm. The alarm will recur every 1 hour if the condition continues. After the device has issued 11 extended cold water exposure alarms, it will issue a prolonged cold water exposure If a patient has been cooled continuously for over 4 hours and has NOT reached target temperature, the water temperature has been below 10°C (50°F) for greater than 8 continuous hours, or extended cold water exposure alarm has been issued it is important to assess the patient's skin underneath the ArcticGel™ pads and consider and address the potential causes following the steps outlined below.

- Verify the Custom Parameters
  - Patient target is set to the correct temperature. See **VI. Operation Guide–Therapy Settings** on setting patient target temperature.
  - One of the automatic patient control modes (e.g. Control Patient, Cooling or Rewarming) is activated. (The system is not in Manual Control mode.)
  - The high water temperature limit and low water temperature limits are set correctly. See **VI. Operation Guide–Therapy Settings**.
- Verify Pad Sizing and Coverage
  - A full set of four ArcticGel™ pads of the appropriate size for the patient applied to the patient.
  - For patients > 100 kg (220 lbs), 1 or 2 Universal pads are added as required for adequate coverage.
- Verify System Performance
  - Water flow rate should be greater than the minimum flow rate requirements specified in the ArcticGel™ pads IFU at least 1 hour continuous use. See **VIII. Troubleshooting–Water–Low Water Flow** for troubleshooting instructions.
  - Water temperature is responding appropriately to control patient temperature towards the target. If not see **VIII. Troubleshooting–Water–Water Not Warming**.
- Verify Shivering Control
  - If the device settings, pad sizing and system performance is correct and patient target temperature is still not reached and/or water temperature remains below 10˚C (50˚F), then the patient is generating excessive heat, most likely from shivering which may or may not be visible.
  - Consider administration of additional medication for shivering control, adequate for the patient weight and magnitude of shivering.
  - Evaluate patient response to medication.

WATER (Continued)

- Make Clinical Decision
  - If all of the above considerations have been addressed and the patient still has not reached target temperature the physician and nursing staff make a clinical decision to limit the cold water exposure:
  - Increase low water temperature limit. See **VI. Operation Guide–Therapy Settings Hypothermia Settings–Low Water Limit** or **Normothermia Settings–Low Water Limit.**
  - Set the patient target temperature to the lowest patient temperature achieved. See **VI. Operation Guide–Therapy Settings** on setting patient target temperature.
  - Discontinue cooling therapy.

Extended Warm Water Exposure

Exposure of the skin to low or high water temperatures for an extended period of time may increase the risk for skin injury. The clinician should monitor the patient and water temperatures displayed on the Arctic Sun™ Temperature Management System therapy graph to properly assess the progress of the temperature management therapy. Additionally, the Arctic Sun™ Temperature Management System incorporates an extended warm water exposure alarm. If the water temperature remains between 38°C (100.4°F) and 40°C (104°F) for an extended period of time, the device will issue an alarm. The alarm will recur if the condition continues. If an extended warm water exposure alarm has been issued it is important to assess the patient's skin underneath the ArcticGel™ pads and consider and address the potential causes following the steps outlined below.

- Verify the Custom Parameters
  - Patient target is set to the correct temperature. See **VI. Operation Guide–Therapy Settings** on setting patient target temperature.
  - One of the automatic patient control modes (e.g. Control Patient, Cooling or Rewarming) is activated. (The system is not in Manual Control mode.)
  - The high water temperature limit and low water temperature limits are set correctly. Consider reducing the maximum water temperature setting. See **VI. Operation Guide–Therapy Settings**.
- Verify Pad Sizing and Coverage
  - A full set of four ArcticGel™ pads of the appropriate size for the patient applied to the patient.
  - For patients > 100 kg (220 lbs), 1 or 2 Universal pads are added as required for adequate coverage.
- Verify System Performance
  - Water flow rate should be greater than the minimum flow rate requirements specified in the ArcticGel™ pads IFU at least 1 hour continuous use. See **VIII. Troubleshooting–Water–Low Water Flow** for troubleshooting instructions.
  - Water temperature is responding appropriately to control patient temperature towards the target. If not see **VIII. Troubleshooting–Water–Water Not Cooling**.
- Make Clinical Decision
  - If all of the above considerations have been addressed and the patient still has not reached target temperature the physician and nursing staff make a clinical decision to limit the warm water exposure:
  - Decrease high water temperature limit. See **VI. Operation Guide–Therapy Settings Hypothermia Settings–High Water Limit** or **Normothermia Settings–High Water Limit.**
  - Set the patient target temperature to the highest patient temperature achieved. See **VI. Operation Guide–Therapy Settings** on setting patient target temperature.
  - Discontinue warming therapy.

Low Water Flow

- Confirm that all of the pad connectors are fully seated in the fluid delivery line manifolds.
  If not fully seated, reseat connectors.
- Check the pads for foam-to-foam folds or buckles created during placement.
  If folds or buckles, smooth out and reapply pads.
- Check the pad lines for kinks or occlusions.
  If kinks or occlusions, straighten lines to remove.
  BD recommends use of fluid delivery line straps to keep lines from kinking.
- Check the pad connectors for a continuous stream of air bubbles.
  If air bubbles are observed, disconnect one pad at a time and wait one minute. If flow increases during pad disconnect, the pad is damaged. Replace the damaged pad with a Universal pad.

PATIENT TEMPERATURE

Patient Not Controlling

A patient's temperature may not always be controlled as precisely as expected. This can lead to conditions where the patient temperature overshoots the target temperature high or low, the patient fails to cool, rewarms too quickly, or is unstable at the target temperature. In each case the following steps can be taken to improve the level of control:

- Verify Pad Sizing and Coverage
  - A full set of four ArcticGel™ pads of the appropriate size for the patient applied to the patient.
  - For patients > 100 kg (220 lbs), 1 or 2 Universal pads are added to the standard kit as required for adequate coverage.
  - The pads are well-adhered to the patient.
- Verify System Performance
  - Water flow rate should be greater than the minimum flow rate requirements specified in the ArcticGel™ pads IFU at least 1 hour continuous use. See **VIII. Troubleshooting–Water–Low Water Flow** for troubleshooting instructions.
  - Water temperature is responding appropriately to control patient temperature towards the target. If not see **VIII. Troubleshooting–Water–Water Not Cooling**.

PATIENT TEMPERATURE (Continued)

- Verify Patient Temperature
  - The patient temperature probe is properly placed and providing an accurate and stable temperature.
  - Confirm patient's temperature with a second device to ensure accuracy.
- Verify the Custom Parameters.
  - Patient target is set to the correct temperature. See **VI. Operation Guide–Therapy Settings** on setting patient target temperature.
  - One of the automatic patient control modes (e.g. Control Patient, Cooling or Rewarming) is activated. (The system is not in Manual Control mode.)
  - The high water temperature limit and low water temperature limits are set correctly. See **VI. Operation Guide–Therapy Settings**.
- Verify Medications / Shivering Control
  - If not sufficiently sedated, a patient may generate significant heat from shivering, which will interfere with patient temperature control. Consider administration of additional medication for shivering control, adequate for the patient weight and magnitude of shivering and evaluate patient response to medication.
  - Has the patiently received a sedatives or other vasoactive drugs? These drugs may cause vasodilation, resulting in cold or warm peripheral blood returning quickly to the core. This may lead to a rapid change in core temperature that the system is unable to counteract immediately.

No Patient Temperature Display

- Confirm that the patient temperature probe is properly placed in the patient.
- Confirm that the patient temperature probe is connected to the Temp In 1 cable / connector on the back of the Control Module.
- Confirm that the connection between the temperature probe and cable is secure.
- Confirm that the connection between the temperature cable and Control Module is secure.
- Confirm that none of the connections are wet.
- If using a Foley temperature probe, check for adequate urine flow.

SCREEN

Screen Locked

After approximately 2 minutes of inactivity, the screen will lock to prevent inadvertently changing parameters during patient therapy.

A therapy status screen will appear over the **Therapy** screen when the screen is locked.

1. To unlock the therapy status screen and return to the **Hypothermia or Normothermia Therapy** screen, press the button.
2. To manually lock the screen when treating a patient, press the **Screen Lock** button ( ).

Note: The **Screen lock** button is not available when the device is in **Stop** mode.

WIRELESS CONNECTION

Wireless Connection Lost

- Confirm the connectivity icon is dark blue with a slash through it as shown in **Figure VI-3**
- See **VI. Operation Guide–Advanced Setup** on Connectivity Settings for instructions.
- If network is not connecting, confirm that network name and password are correct
- To test the server, select **Start** under the Test Connection tab

IX. CLEANING AND DISINFECTION

SURFACE CLEANING

After use, the external surfaces of the Arctic Sun™ Temperature Management System may be a potential biohazard. The Arctic Sun™ Temperature Management System external surfaces should be manually cleaned, disinfected and visually examined per the instructions below.

Prior to cleaning:

1) Use appropriate personal protective equipment (e.g. gloves, eyewear, face mask or shields) per manufacturer's guidelines for the enzymatic spray to protect user from exposure to both chemicals and microorganisms.
2) Apply the castor brakes on the Arctic Sun™ Temperature Management System.
3) Unplug the power cable from the wall outlet.
4) Straighten the power cable.
5) Disconnect all other cables and hoses from the Arctic Sun™ Temperature Management System and straighten them.

Manual Cleaning:

- Timing
  Clean the Arctic Sun™ Temperature Management System external surfaces as soon as practical after use (e.g. at the point of use).
- Cleaning Materials
  Required: Neutral-pH Enzymatic spray cleaner; clean, dry cloths
  Validated: Medline Bio-Zolve Instrument Presoak Spray
- Cleaning
  1) Saturate a clean, dry cloth with the Enzymatic cleaner and remove all heavy soil loads from the external surfaces of the Arctic Sun™ Temperature Management System.
  2) Saturate a second clean, dry cloth with the Enzymatic cleaner and thoroughly wipe all external surfaces of the device.
     a) Ensure that all surfaces are dampened, including seams of the device.
     b) Use as many additional clean cloths saturated with the Enzymatic cleaner as necessary to ensure device is completely dampened.
     c) Thoroughly wipe the following with additional clean cloths saturated with the Enzymatic cleaner – fluid delivery line, power cable, temperature cables, USB cable, RS232 cable.
  3) Allow surfaces to remain treated for a minimum of two (2) minutes.
  4) Use a clean, dry cloth to remove remaining cleaning solution.

SURFACE DISINFECTION

Disinfect the Arctic Sun™ Temperature Management System immediately following cleaning. Follow all manufacturers' guidelines for the pre-saturated germicidal wipes, including wearing gloves and other personal protective equipment when dispensing and using the wipes.

Manual Disinfection:

- Disinfection Materials:
  Required: Pre-saturated germicidal wipes (active ingredient – alcohol)
  Validated: Super Sani-Cloth Germicidal Disposable Wipe
- Disinfection
  1) Using pre-saturated germicidal wipes, disinfect all external surfaces of the Arctic Sun™ Temperature Management System.
     a) Ensure that all surfaces are dampened, including all seams of the device.
     b) Use as many clean towelettes as necessary to ensure device is completely dampened with disinfectant.
     c) Thoroughly wipe the following with additional clean towelettes – fluid delivery line, power cable, temperature cables, USB cable, RS232 cable.
  2) Allow the treated surfaces to remain wet for the manufacturer's specified contact time.
  3) Wipe each surface of the device with a lint-free cloth premoistened with sterile water.
  4) Let air dry.
  5) Reattach cables and hoses.

VISUAL INSPECTION AND RETURN TO USE

1) After cleaning and disinfecting the device per the instruction provided, examine the device for cleanliness. If visible soil remains, repeat manual cleaning instructions.
2) Inspect cables and hoses for signs of damage.
3) Inspect external shell for discoloration or cracking.
4) Inspect labels for legibility.
5) Do not use the device if it has failed visual inspection for soil after multiple cleaning attempts, or if there is visible damage. Contact BD Customer Support for additional recommendations.
6) Store the device in a dry and clean environment when not in use.

NOTE: The device has been validated for exterior surface cleaning and disinfection per the instructions provided. Any deviation from the recommended parameters must be validated by the user. Interior surfaces of the device (including deep crevices) are not addressed as part of this cleaning and disinfection protocol.

To prevent possible discoloration, do not use iodine-based solutions, such as Betadine, on any part of the machine.

For questions on device cleaning and disinfection of external surfaces contact BD Customer Support.

X. MAINTENANCE AND SERVICE

Routine maintenance and service should be performed on the Arctic Sun™ Temperature Management System Control Module every 6 months at a minimum. This consists of cleaning the external surfaces, accessories and chiller condenser, inspecting the device, and replenishing the internal Arctic Sun Cleaning Solution that suppresses microorganism growth in the water reservoir and hydraulic circuit. See the Arctic Sun™ Temperature Management System Service Manual for additional information.

Procedure	Interval
Clean and disinfect external surfaces	After each use
Inspect Connectors and Cables	6 months
Clean the Condenser	6 months
Replenish Arctic Sun Cleaning Solution	6 months
Inspect Screen Protector	6 months
Inspect Fluid Delivery Line	6 months
Inspect Manifold O-ring	6 months
Calibration	Every 2000 hours or 250 uses, whichever occurs first, as indicated by system display

INSPECT CONNECTORS AND CABLES

Inspect the patient temperature cable(s) and power cord for integrity. Ensure temperature cables are properly strain relieved. Ensure power cord bracket is secure.

CONDENSER

- A dirty chiller condenser will significantly reduce the cooling capacity of the Control Module.
- To clean the condenser, wipe the dust from the exterior grill using a soft cloth. Depending on the quality of your institution's air, periodically remove the back cover and vacuum or brush the condenser fins. At a minimum the condenser fins should be cleaned annually. Maintenance activities should be performed by qualified personnel.

DEVICE INSPECTION

- Periodically inspect the external areas of the device for damaged, loose or missing parts, and frayed or twisted power cords and cables.
- Discontinue using the device displaying one or more of the above conditions until the problem is corrected and has been verified to be operating correctly.

REPLENISH INTERNAL SOLUTION

Contact Customer Service to order internal Arctic Sun Cleaning Solution.

To replenish the internal Arctic Sun Cleaning Solution:

1) Drain the reservoir.
   - Turn Control Module Power Off.
   - Attach the drain line to the two drain ports on the back of the Control Module. Place the end of the drain line into a container. The water will passively drain into the container.

2) Refill the reservoir.
   - Connect the fill tube.
   - From the Hypothermia therapy screen or the Normothermia therapy screen, press the Fill Reservoir button.
   - The Fill Reservoir screen will appear. Follow the directions on the screen.
   - Add one vial of Arctic Sun™ Temperature Management System cleaning solution to the second liter of sterile water.
   - The filling process will automatically stop when the reservoir is full. Continue to replace the bottles of sterile water until the filling process stops.
   - When the Fill Reservoir process is complete, the screen will close.

NOTE: The reservoir level sensor requires a conductive fluid to operate properly. Filling the reservoir without using the Arctic Sun Cleaning Solution may result in overfilling the reservoir.

Do not use Cleaning Solution that has passed the use by date listed on the bottle.

The Cleaning Solution must be stored inside the UV resistant pouch provided.

INSPECT SCREEN PROTECTOR

The Control Panel's touchscreen is supplied with a disposable screen protector. If it becomes damaged, it can be removed by lifting the edge and carefully peeling it from the screen. To ensure dust and particulates are removed, clean the touchscreen using isopropyl alcohol. Remove the blue liner from the screen protector. Then carefully apply the protector to the screen with the liner side down.

INSPECT FLUID DELIVERY LINE

1) Power On the system
2) From the patient **Therapy Selection** screen press the Hypothermia button to display the Hypothermia therapy screen.
3) From the Hypothermia therapy screen, press the Manual Control button to open the Manual Control window.
4) Set the Manual Control water target temperature to 28°C and the duration to 30 minutes.
5) Connect a shunt to a set of fluid delivery line ports.
6) Press the **System Access** button on the Therapy screen then press the **Diagnostics** button. Verify that inlet pressure is -7 ± 0.2 Psi.
7) Repeat on all valves. If inlet pressure is out of range, replace the two valves that the shunt is connected to.
8) Ensure that the shunt is removed before device is put back in service.

MAINTENANCE AND SERVICE (Continued)

INSPECT MANIFOLD O-RING
Inspect the O-rings in the manifold. Ensure no cuts or tears are present and that the rings make an intact seal with the Fluid Delivery Line.

SYSTEM DIAGNOSTICS
Select the **System Access** button on the **Normothermia** therapy or **Hypothermia** therapy screen to access **System Diagnostics** in order to verify pressures and flow rates through the system.

SERVICE
Contact BD Customer Support for technical support and customer service instructions to enable appropriately qualified technical personnel to repair those parts of the equipment that BD considers repairable.

CALIBRATION
See Arctic Sun™ Temperature Management System Service Manual for calibration requirements and instructions. Calibration is recommended after 2,000 hours of operation, or 250 uses, whichever occurs first as indicated by the system display.

XI. PREVENTATIVE MAINTENANCE

Use of the Arctic Sun™ Temperature Management System in excess of 2,000 hours without conducting preventative maintenance, may result in failure of certain system components and failure of the system to function as intended. To maintain system performance, the Arctic Sun™ Temperature Management System requires periodic service and/or replacement of key components.

The operator will be informed of preventative maintenance through the notification icon on the therapy screen. See section **VI. Operation Guide–Therapy Screens–Notification** for additional detail.

For additional information, please refer to http://www.medivance.com/manuals, call 1-844-823-5433 or contact your local BD representative.

XII. CUSTOMER SUPPORT

Manufacturer
Medivance, Inc.
321 South Taylor Avenue, Suite 200
Louisville, Colorado 80027 USA
303.926.1917 Phone
844.823.5433 Toll Free
866.840.9776 Urgent Clinical Help*
lou.customerservice@bd.com

** The 24/7 Helpline is intended to assist healthcare professionals with technical questions they may have regarding the use of the* Arctic Sun™ Temperature Management System*. While the Helpline may be staffed by licensed critical care nurses, they are not able to provide medical or nursing advice to prescribe treatment.*

APPENDIX A: ELECTROMAGNETIC COMPATIBILITY

Medical electrical equipment needs special precautions regarding electromagnetic compatibility. Ensure that the Arctic Sun™ Temperature Management System is installed and used according to the electromagnetic compatibility information provided. The following are guidance and manufacturer's declarations regarding electromagnetic compatibility for the Arctic Sun™ Temperature Management System.

- The use of accessories or cables other than those specified or sold by BD (shown below) is not recommended. Use of unapproved accessories or cables may result in increased emissions or in decreased immunity of the Arctic Sun™ Temperature Management System.
- If the Arctic Sun™ Temperature Management System is used directly adjacent to or stacked with other equipment, the user should periodically observe the Arctic Sun™ Temperature Management System device to verify it operates normally in that environment.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Accessories and cables approved by BD for use with the Arctic Sun™ Temperature Management System	Part #
Temperature In-Cable - Nellcor	735-02
Temperature In-Cable - Bard	735-03
Temperature In-Cable - Rusch	735-04
Temperature In-Cable - GE	735-05
Temperature In-Cable - Philips	735-06
Temperature Out-Cable - Nellcor	735-52
Temperature Out-Cable - Bard	735-53
Temperature Out-Cable - Rusch	735-54
Temperature Out-Cable - GE	735-55
Temperature Out-Cable - Philips	735-56
Power Cord, US, Canada, Mexico	733-00

1.1 EN/IEC 60601-1-2 Table 1		
Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Arctic Sun™ Temperature Management System is intended for use in the electromagnetic environment specified below. The customer or the end user of the Arctic Sun™ Temperature Management System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Arctic Sun™ Temperature Management System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Arctic Sun™ Temperature Management System unit is suitable for use in all establishments other than domestic, establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

1.2 EN/IEC 60601-1-2 Table 2			
Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The EUT is intended for use in the electromagnetic environment specified below. The customer or user of the EUT should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	Contact + air ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV Air only ±15 kV	Contact + air ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV Air only ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	AC Power: ±2 kV SIP/SOP: ±1 kV 100 kHz repetition frequency	AC Power: ±2 kV SIP/SOP: ±1 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ± 2 kV Line-to-ground	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25 cycles Single phase: at 0° 0 % UT; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that they find a suitable uninterruptible power supply.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30A/M 60 Hz	30A/M 60 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

1.3 EN/IEC 60601-1-2: Table 3:			
Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Arctic Sun™ Temperature Management System unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the Arctic Sun™ Temperature Management System should assure it is used in such an environment.			
Immunity Test	IEC60601 test level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 6Vrms (In ISM Bands) 150 kHz to 80 MHz	3Vrms 6Vrms (In ISM Bands) 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Arctic Sun™ Temperature Management System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80MHz to 2.7GHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Recommended separation distance d = 1,2√P d = 1,2√P d = 2,3√P where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Even if other equipment complies with CISPR8 emission requirements, interference may occur in the vicinity of equipment marked with the following symbol: 

1.3 EN/IEC 60601-1-2: Table 9:						
Test freq. (MHz)	Band (MHz)	Service	Modulation	Max Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse mod. 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460 FRS 460	FM +-5 kHz deviation 1kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse mod. 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CMDA 850, LTE band 5	Pulse mod. 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25 UMts	Pulse mod. 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450 LTE band 7	Pulse mod. 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse mod. 217 Hz	0.2	0.3	9

1.4 EN/IEC 60601-1-2:2007 Sub-clause 5.2.2.2 Table 6:			
Recommended separation distances between portable and mobile RF communications equipment and the Arctic Sun™ Temperature Management System unit			
RF communications equipment can affect medical electrical equipment. The Arctic Sun™ Temperature Management System unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Arctic Sun™ Temperature Management System unit can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the Arctic Sun™ Temperature Management System unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150kHz to 80MHz d = 1.2√P	80MHz to 800MHz d = 1.2√P	800MHz to 2.5GHz d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

APPENDIX B: ALARMS

Medium Priority Warning
Low Priority Warning

Alarm	Problem	Solution
00 Communications Failure Medium Priority Alarm	Communications to control panel have failed upon power up	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
01 Patient Line Open Low Priority Alarm	The system is detecting that the fluid delivery line or patient line is open to air or has significant air in the line. The fluid pump is working at the expected speed but the flow rate is less than 1 liter per minute and the fluid pressure is less than -6 psi.	1. Check that patient line connectors are fully seated in the fluid delivery line manifold. If indicated, reseat connectors. 2. Check patient line connectors for damage that prevents connector from properly seating / sealing with manifold. If connector damage found, replace pad. 3. Check pads for leaks. Disconnect one pad at a time from the manifold to determine if one pad is contributing to the air leak or low flow. Wait a minimum of 45 seconds for the air to clear the line and then check to see if the flow has increased. If faulty pad found, replace faulty pad. 4. To check whether a valve is leaking, reinstall the pad into a different location on the fluid delivery line manifold and wait a minimum of 45 seconds again.
02 Low Flow Low Priority Alarm	The flow rate is less than 50% of the maximum flow rate measured since the last Power On or Empty Pads, or the flow rate is less than 300 ml/minute.	1. Check that patient line connectors are fully seated in the fluid delivery line manifold. If indicated, reseat connectors. 2. Check patient line connectors for damage that prevents connector from properly seating / sealing with manifold. If connector damage found, replace pad. 3. Check that pad lines are not kinked. 4. Check pads for leaks. Disconnect one pad at a time from the manifold to determine if one pad is contributing to the air leak or low flow. Wait a minimum of 45 seconds for the air to clear the line and then check to see if the flow has increased. If faulty pad found, replace faulty pad. 5. To check whether a valve is leaking, reinstall the pad into a different location on the fluid delivery line manifold and wait a minimum of 45 seconds again.
03 Water Reservoir Low Low Priority Alarm	At Power On or the end of the Empty Pads cycle or the Fill Reservoir cycle, the system fluid level sensors are detecting that the water reservoir is low. There is only enough water in the reservoir to run one patient therapy.	1. Pads may not have been emptied prior to powering down. Empty pads to reestablish the volume of water in the system. See **VI. Operation Guide-Therapy Screens-Empty Pads** for instructions. 2. Fill the water reservoir. See **VI. Operation Guide-Therapy Screens-Fill Reservoir** for instructions.
04 Water Reservoir Below Minimum Medium Priority Alarm	At the end of the Empty Pads cycle, the system fluid level sensors are detecting that the water reservoir is empty or below the minimum level required to operate the system.	1. Pads may not have been emptied prior to powering down. Empty pads to reestablish the volume of water in the system. See **VI. Operation Guide-Therapy Screens-Empty Pads** for instructions. 2. Fill the water reservoir. See **VI. Operation Guide-Therapy Screens-Fill Reservoir** for instructions.
05 Water Reservoir Empty Medium Priority Alarm	At Power On or the end of the Empty Pads cycle, the system fluid level sensors are detecting that the water reservoir is empty or below the minimum level required to operate the system.	Fill the water reservoir. See **VI. Operation Guide-Therapy Screens-Fill Reservoir** for instructions.
07 Empty Pads Not Complete Low Priority Alarm	A significant amount of water was still being returned from the pads at the end of the Empty Pads cycle.	1. The pads may still contain a significant amount of water. Use caution when disconnecting pads to avoid spilling water. The system can continue to be used without further action. 2. Check reservoir level. Reservoir may have been overfilled. If reservoir level full: a. Power Off system. b. Drain approximately 1 liter of water from the drain port. c. Power On system. d. Repeat Empty Pads. 3. Contact BD Customer Support if problem persists.

Alarm	Problem	Solution
08 Patient Temperature 1 High Medium Priority Alarm	The Patient Temperature 1 reading is above 39.5°C (103.1°F), and the water temperature is above 39.5°C (103.1°F), and the system is continuing to warm the patient when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. **Verify Patient Temperature Accuracy** ▪ Confirm patient temperature using a secondary site. ▪ Confirm that the primary temperature probe is properly placed and registering an accurate temperature. 2. **Verify Patient / Water Temperature Control** ▪ Observe patient temperature Is the patient temperature decreasing? ▪ Observe water temperature. Is the water temperature <39.5°C (103.1°F)? Is the water temperature decreasing? If the water and/or patient temperatures are beginning to decrease, the system is working correctly. Continue to monitor patient temperature. 3. **Verify Water Temperature Limits** ▪ In **Normothermia Settings** or **Hypothermia Settings**, confirm that the water temperature low limit is set ≤10°C (50°F). ▪ If necessary, set water temperature low limit ≤10°C (50°F). ▪ Resume therapy. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are beginning to decrease, the system is working correctly. Continue to monitor patient temperature. 4. **Verify Water Cooling – External Factors** ▪ Check environmental conditions that may affect cooling. • Are the machine vents blocked? • Is the room temperature too high? • Is the oxygen heated? • Are there hot lights or heating blankets on the patient? ▪ Remove any impediments. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are beginning to decrease, the system is working correctly. Continue to monitor patient temperature. 5. **Verify Water Control – System Performance** ▪ Place unit in Manual mode, with water temperature set < 38°C (100.4°F). ▪ Monitor water temperature and patient temperature. ▪ If the water temperature is <u>not</u> decreasing to the commanded temperature, the water cooling system is not working. Call BD Customer Support. ▪ If the water temperature decreases to the commanded temperature, the water cooling system is working. 6. **Verify Patient Control – System Performance** ▪ Place system back into the patient control mode. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are continuing to decrease, the system is working correctly. Continue to monitor patient temperature. ▪ If the water temperature and/or patient temperatures are not decreasing, call BD Customer Support.
09 Patient Temperature 1 Above High Patient Low Priority Alarm	In Normothermia Therapy: The Patient Temperature 1 reading is above the High Patient Alarm setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 1 reading is above the High Patient Alarm setting in Hypothermia Settings.	If desired, adjust the **High Patient Alarm** setting in **Normothermia Settings** or **Hypothermia Settings.**

Alarm	Problem	Solution
10 Patient Temperature 1 Low Medium Priority Alarm	The Patient Temperature 1 reading is below 31°C (87.8°F), and the water temperature is below 31°C (87.8°F), and the system is continuing to cool the patient when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. **Verify Patient Temperature Accuracy** ▪ Confirm patient temperature using a secondary site. ▪ Confirm that the primary temperature probe is properly placed and registering an accurate temperature. 2. **Verify Patient / Water Temperature Control** ▪ Observe patient temperature. Is the patient temperature increasing? ▪ Observe water temperature. Is the water temperature >31°C (87.8°F)? Is the water temperature increasing? ▪ If the water and/or patient temperatures are beginning to increase, the system is working correctly. Continue to monitor patient temperature. 3. **Verify Water Temperature Limits** ▪ In **Normothermia Settings** or **Hypothermia Settings**, confirm that the water temperature high limit is set ≥36°C (96.8°F). ▪ If necessary, set water temperature high limit ≥36°C (96.8°F). ▪ Resume therapy. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are beginning to increase, the system is working correctly. Continue to monitor patient temperature. 4. **Verify Water Control – System Performance** ▪ Place unit in Manual mode, with water temperature set > 38°C (100.4°F). ▪ Monitor water temperature and patient temperature. ▪ If the water temperature is not increasing to the commanded temperature, the water heating system is not working. Call BD Customer Support. ▪ If the water temperature increases to the commanded temperature, the water heating system is working. 5. **Verify Patient Control – System Performance** ▪ Place system back into the patient control mode. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are continuing to increase, the system is working correctly. Continue to monitor patient temperature. ▪ If the water temperature and/or patient temperatures are not increasing, call BD Customer Support.
11 Patient Temperature 1 Below Low Patient Low Priority Alarm	In Normothermia Therapy: The Patient Temperature 1 reading is below the Low Patient Alarm setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 1 reading is below the Low Patient Alarm setting in Hypothermia Settings.	If desired, adjust the **Low Patient Alarm** setting in **Normothermia Settings** or **Hypothermia Settings.**
12 Patient Temperature 1 High Low Priority Alarm	The Patient Temperature 1 reading is above 39.5°C (103.1°F), and the water temperature is above 39.5°C (103.1°F) when the system is in Manual Control mode. Patient temperature is not automatically controlled while in Manual Control mode	Decrease Manual Mode water target temperature to a setting that is ≤ 38.5°C (101.3°F). See **VI. Operation Guide–Therapy Settings–Manual Control** for further instructions.
13 Patient Temperature 1 Low Low Priority Alarm	The Patient Temperature 1 reading is below 31°C (87.8°F), and the water temperature is below 31°C (87.8°F) when the system is in Manual Control mode. Patient temperature is not automatically controlled while in Manual Control mode	Increase Manual Mode water target temperature to a setting that is ≥ 32°C (89.6°F). See **VI. Operation Guide–Therapy Settings–Manual Control** for further instructions.

Alarm	Problem	Solution
14 Patient Temperature 1 Probe Out of Range Medium Priority Alarm	Temp In 1 probe is not detected, or the temperature reading is below the lower limits of the display range (10°C/50°F) when the system is in a patient control mode (e.g. Control, Cooling or Rewarming).	1. Check that the Temp In 1 probe is properly placed in the patient and has not dislodged. 2. Check that the Temp In 1 probe is connected to the Temp In 1 cable / connector on the back of the Control Module. 3. Check that the connection between the temperature probe and temperature cable is secure. 4. Check that the connection between the temperature cable and the Temp In 1 connector is secure. 5. Check the integrity of the temperature cable. Flex the cable to check for an intermittent fault. If damaged, replace cable. 6. Replace the patient temperature probe.
15 Unable to Obtain a Stable Patient Temperature Medium Priority Alarm	Patient temperature discontinuity. There has been a significant change in the patient temperature reading for more than 10 minutes when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. Check that the Temp In 1 probe is properly placed in the patient and has not dislodged. 2. Check that the Temp In 1 probe is connected to the Temp In 1 cable / connector on the back of the Control Module. 3. Check that the connection between the temperature probe and temperature cable is secure. 4. Check that the connection between the temperature cable and the Temp In 1 connector is secure. 5. Check the integrity of the temperature cable. Flex the cable to check for an intermittent fault. If damaged, replace cable. 6. Replace the patient temperature probe. 7. Confirm the patient temperature is accurate with a secondary monitor. If it is confirmed to be accurate, return the unit to a patient control mode and monitor patient temperature closely.
16 Patient Temperature 1 Probe Out of Range Medium Priority Alarm	Temp In 1 probe is not detected, or the temperature reading is above the upper limit of the display range (44°C/111.2°F) when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. Check that the Temp In 1 probe is properly placed in the patient and has not dislodged. 2. Check that the Temp In 1 probe is connected to the Temp In 1 cable / connector on the back of the Control Module. 3. Check that the connection between the temperature probe and temperature cable is secure. 4. Check that the connection between the temperature cable and the Temp In 1connector is secure. 5. Check the integrity of the temperature cable. Flex the cable to check for an intermittent fault. If damaged, replace cable. 6. Replace the patient temperature probe. 7. Confirm the patient temperature is accurate with a secondary monitor. If it is confirmed to be above 44°C (111.2°F), place the unit in Manual mode at 10°C and monitor patient temperature closely until the patient's temperature has dropped below 44°C.
17 Patient Temperature 1 Calibration Error Medium Priority Alarm	The system is unable to internally check the calibration of the Temp In 1 channel within ± 1.0°C when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate a patient control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration. The system may be operated in Manual Control, but patient temperature will not be displayed.
18 Patient Temperature 1 Calibration Error Low Priority Alarm	The system is unable to internally check the calibration of the Temp In 1 channel within ± 1.0°C when the system is in Manual Control mode.	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate Manual Control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration. The system may be operated in Manual Control, but patient temperature will not be displayed.
19 Patient Temperature 1 Calibration Error Medium Priority Alarm	The system is unable to calibrate the Temp In 1 channel within ± 1.0°C when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate a patient control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration. The system may be operated in Manual Control, but patient temperature will not be displayed.
20 Patient Temperature 1 Calibration Error Low Priority Alarm	The system is unable to calibrate the Temp In 1 channel within ± 1.0°C when the system is in Manual Control mode.	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate Manual Control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration. The system may be operated in Manual Control, but patient temperature will not be displayed.

Alarm	Problem	Solution
21 Patient Temperature 2 High Medium Priority Alarm	The Patient Temperature 2 reading is above 39.5°C (103.1°F), and the water temperature is above 39.5°C (103.1°F), and the system is continuing to warm the patient when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. **Verify Patient Temperature Accuracy** ▪ Compare to Temp In 1 reading. ▪ Confirm patient temperature using a secondary site. ▪ Confirm that the secondary temperature probe is properly placed and registering an accurate temperature. 2. **Verify Patient / Water Temperature Control** ▪ Observe patient temperature. Is the patient temperature decreasing? ▪ Observe water temperature. Is the water temperature <39.5°C (103.1°F)? Is the water temperature decreasing? ▪ If the water and/or patient temperatures are beginning to decrease, the system is working correctly. Continue to monitor patient temperature. 3. **Verify Water Temperature Limits** ▪ In **Hypothermia Settings** or **Normothermia Settings**, confirm that the water temperature low limit is set ≤10°C (50°F). ▪ If necessary, set water temperature low limit ≤10°C (50°F). ▪ Resume therapy. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are beginning to decrease, the system is working correctly. Continue to monitor patient temperature. 4. **Verify Water Cooling – External Factors** ▪ Check environmental conditions that may affect cooling. • Are the machine vents blocked? • Is the room temperature too high? • Is the oxygen heated? • Are there hot lights or heating blankets on the patient? ▪ Remove any impediments. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are beginning to decrease, the system is working correctly. Continue to monitor patient temperature. 5. **Verify Water Control – System Performance** ▪ Place unit in Manual mode, with water temperature set < 38°C (100.4°F). ▪ Monitor water temperature and patient temperature. ▪ If the water temperature is <u>not</u> decreasing to the commanded temperature, the water cooling system is not working. Call BD Customer Support. ▪ If the water temperature decreases to the commanded temperature, the water cooling system is working. Go to Solution 6 to check the patient control performance. 6. **Verify Patient Control – System Performance** ▪ Place system back into the patient control mode. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are continuing to decrease, the system is working correctly. Continue to monitor patient temperature. ▪ If the water temperature and/or patient temperatures are not decreasing, call BD Customer Support.
22 Patient Temperature 2 Above High Patient Low Priority Alarm	In Normothermia Therapy: The Patient Temperature 2 reading is above the High Patient Alarm setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 2 reading is above the High Patient Alarm setting in Hypothermia Settings.	If desired, adjust the **High Patient Alarm** setting in **Normothermia Settings** or **Hypothermia Settings.**

Alarm	Problem	Solution
23 Patient Temperature 2 Low Medium Priority Alarm	The Patient Temperature 2 reading is below 31°C (87.8°F), and the water temperature is below 31°C (87.8°F), and the system is continuing to cool the patient when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming).	1. **Verify Patient Temperature Accuracy** ▪ Compare to Temp In 1. ▪ Confirm patient temperature using a secondary site. ▪ Confirm that the primary temperature probe is properly placed and registering an accurate temperature. 2. **Verify Patient / Water Temperature Control** ▪ Observe patient temperature. Is the patient temperature increasing? ▪ Observe water temperature. Is the water temperature >31°C (87.8°F)? Is the water temperature increasing? ▪ If the water and/or patient temperatures are beginning to increase, the system is working correctly. Continue to monitor patient temperature. 3. **Verify Water Temperature Limits** ▪ In **Hypothermia Settings** or **Normothermia Settings**, confirm that the water temperature high limit is set ≥36°C (96.8°F). ▪ If necessary, set water temperature high limit ≥36°C (96.8°F). ▪ Resume therapy. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are beginning to increase, the system is working correctly. Continue to monitor patient temperature. 4. **Verify Water Control – System Performance** ▪ Place unit in Manual mode, with water temperature set > 38°C (100.4°F). ▪ Monitor water temperature and patient temperature. ▪ If the water temperature is not increasing to the commanded temperature, the water heating system is not working. Call BD Customer Support. ▪ If the water temperature increases to the commanded temperature, the water heating system is working. 5. **Verify Patient Control – System Performance** ▪ Place system back into the patient control mode. ▪ Monitor water temperature and patient temperature. ▪ If the water and/or patient temperatures are continuing to increase, the system is working correctly. Continue to monitor patient temperature. ▪ If the water temperature and/or patient temperatures are not increasing, call BD Customer Support.
24 Patient Temperature 2 Below Low Patient Low Priority Alarm	In Normothermia Therapy: The Patient Temperature 2 reading is below the Low Patient Alarm setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 2 reading is below the Low Patient Alarm setting in Hypothermia Settings.	If desired, adjust the **Low Patient Alarm** setting in **Normothermia Settings** or **Hypothermia Settings.**
25 Patient Temperature 2 High Low Priority Alarm	The Patient Temperature 2 reading is above 39.5°C (103.1°F), and the water temperature is above 39.5°C (103.1°F) when the system is in Manual Control mode. Patient temperature is not automatically controlled in Manual Control mode.	Decrease Manual Mode water target temperature to a setting that is ≤ 38.5°C (101.3°F). See **VI. Operation Guide- Therapy Settings–Manual Control** for further instructions.
26 Patient Temperature 2 Low Low Priority Alarm	The Patient Temperature 2 reading is below 31°C (87.8°F), and the water temperature is below 31°C (87.8°F) when the system is in Manual Control mode. Patient temperature is not automatically controlled in Manual Control mode.	Increase Manual Mode water target temperature to a setting that is ≥ 32°C (89.6°F). See **VI. Operation Guide- Therapy Settings–Manual Control** for further instructions.

Alarm	Problem	Solution
27 Patient Temperature 2 Probe Out of Range Medium Priority Alarm	Patient Temperature 2 probe is not detected, or the temperature reading is below the lower display range (10°C /50°F).	1. Check that the Patient Temperature 2 probe is properly placed in the patient and has not dislodged. 2. Check that the Patient Temperature 2 probe is connected to the Patient Temperature 2 cable / connector on the back of the Control Module. 3. Check that the connection between the temperature probe and temperature cable is secure. 4. Check that the connection between the temperature cable and the Patient Temperature 2 connector is secure. 5. Check the integrity of the temperature cable. Flex the cable to check for an intermittent fault. If damaged, replace cable. 6. Replace the patient temperature probe.
28 Patient Temperature 2 Probe Out of Range Medium Priority Alarm	Patient Temperature 2 probe is not detected, or the temperature reading is above the upper limits of the display range (44°C/ 111.2°F).	1. Check that the Patient Temperature 2 probe is properly placed in the patient and has not dislodged. 2. Check that the Patient Temperature 2 probe is connected to the Patient Temperature 2 cable / connector on the back of the Control Module. 3. Check that the connection between the temperature probe and temperature cable is secure. 4. Check that the connection between the temperature cable and the Patient Temperature 2 connector is secure. 5. Check the integrity of the temperature cable. Flex the cable to check for an intermittent fault. If damaged, replace cable. 6. Replace the patient temperature probe.
29 Patient Temperature 2 Calibration Error Low Priority Alarm	The system is unable to internally check the calibration of the Patient Temperature 2 channel within ± 1.0°C when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming). Patient Temperature 2 channel is made inactive.	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate a patient control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration.
30 Patient Temperature 2 Calibration Error Low Priority Alarm	The system is unable to internally check the calibration of the Patient Temperature 2 channel within ± 1.0°C when the system is in Manual Control mode. Patient Temperature 2 channel is made inactive.	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate Manual Control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration.
31 Patient Temperature 2 Calibration Error Low Priority Alarm	The system is unable to calibrate the Patient Temperature 2 channel within ± 1.0°C when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming). Patient Temperature 2 channel is made inactive	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate a patient control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration.
32 Patient Temperature 2 Calibration Error Low Priority Alarm	The system is unable to calibrate the Patient Temperature 2 channel within ± 1.0°C when in Manual Control mode. Patient Temperature 2 channel is made inactive.	1. Power system Off. Wait 30 seconds. Power system On. 2. Initiate Manual Control mode. 3. If the alarm recurs, contact your hospital clinical engineering department or BD Customer Support to verify the system calibration.
33 Water Temperature High Medium Priority Alarm	The primary outlet water temperature is above 44°C (111.2°F).	1. Check flow rate. A low flow rate or fluctuating flow rate may cause the water to overheat. If the flow rate is low, see **VIII. Troubleshooting-Water-Low Water Flow** for troubleshooting assistance. 2. Allow the water to cool. Restart the previous control mode and monitor water temperature. 3. If the problem persists, contact BD Customer Support.
34 Water Temperature High Medium Priority Alarm	The primary outlet water temperature is above 42.5°C (108.5°F).	1. Check flow rate. A low flow rate or fluctuating flow rate may cause the water to overheat. If the flow rate is low, see **VIII. Troubleshooting-Water-Low Water Flow** for troubleshooting assistance. 2. Allow the water to cool. Restart the previous control mode and monitor water temperature. 3. If the problem persists, contact BD Customer Support.
35 Water Temperature Low Medium Priority Alarm	The primary outlet water temperature is below 3.5°C (38.3°F).	1. Allow the water to warm. Restart the previous control mode and monitor water temperature. 2. If the problem persists, contact BD Customer Support.

Alarm	Problem	Solution
36 Water Temperature High Medium Priority Alarm	The secondary outlet water temperature is above 44°C (111.2°F).	1. Check flow rate. A low flow rate or fluctuating flow rate may cause the water to overheat. If the flow rate is low, **VIII. Troubleshooting-Water-Low Water Flow** for troubleshooting assistance. 2. Allow the water to cool. Restart the previous control mode and monitor water temperature. 3. If the problem persists, contact BD Customer Support.
37 Water Temperature High Medium Priority Alarm	The secondary outlet water temperature is above 43°C (109.4°F).	1. Check flow rate. A low flow rate or fluctuating flow rate may cause the water to overheat. If the flow rate is low, see **VIII. Troubleshooting-Water-Low Water Flow** for troubleshooting assistance. 2. Allow the water to cool. Restart the previous control mode and monitor water temperature. 3. If the problem persists, contact BD Customer Support.
38 Water Temperature Low Medium Priority Alarm	The secondary outlet water temperature is below 3.0°C (37.4°F).	1. Allow the water to warm. Restart the previous control mode and monitor water temperature. 2. If the problem persists, contact BD Customer Support.
40 Unable to Maintain Stable Water Temperature Medium Priority Alarm	In Manual Control mode, the system is unable to control the water temperature within 1.0°C/°F of the water target temperature after 25 minutes in the current mode or since the last change to the water target temperature.	1. Contact your hospital clinical engineering department to perform calibration check on the device. 2. Contact BD Customer Support.
41 Low Internal Flow Low Priority Alarm	Insufficient internal flow during system priming or pre-conditioning.	1. This problem does not represent a patient treatment issue. Check flow once the system has stabilized for several minutes with water flowing through the pads. If satisfactory, treatment can continue. 2. Contact BD Customer Support if the situation persists.
43 User Settings Not Saved Low Priority Alarm	The user settings are invalid and are unable to be saved. The saved system default settings are restored	1. Check all patient target, water temperature and alarm settings before resuming patient therapy. Save settings. 2. If problem persists, contact BD Customer Support.
44 Invalid System Log Entry Low Priority Alarm	One or more of the entries into the system event log is invalid. The system event log is used by clinical engineering personnel for product service. This issue does not affect the performance of the system to deliver patient therapy.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If the problem persists, contact BD Customer Support.
45 AC Power Lost Low Priority Alarm	The AC power was lost while the power switch was in the On position.	This alarm is to make you aware that the AC power may have been lost and therapy interrupted. Press Continue Current Patient to resume the patient therapy with the previously established parameters. Check that all settings are correct before initiating patient therapy.
46 Control Panel Communication Medium Priority Alarm	The control panel is not communicating with the system.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If the problem persists, contact BD Customer Support.
47 Control Panel Communication Medium Priority Alarm	The control panel is not communicating with the system.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If the problem persists, contact BD Customer Support.
48 Patient Temperature Out Invalid Medium Priority Alarm	The Patient Temperature Out calibration data in non-volatile memory is invalid.	1. Turn the Control Module Off. Wait 30 seconds and turn the Control Module On. 2. This problem does not affect patient treatment. The Patient Temperature Out feature will not be available and should not be used. 3. If the issue persists, contact BD Customer Support.
50 Patient Temperature 1 Erratic Low Priority Alarm	Patient Temperature 1 discontinuity. There has been a significant change in patient temperature over the past 8 minutes.	1. Check that the Temp In 1 probe is properly placed in the patient and has not dislodged. 2. Check that the Temp In 1 probe is connected to the Temp In 1 cable / connector on the back of the Control Module. 3. Check that the connection between the temperature probe and temperature cable is secure. 4. Check that the connection between the temperature cable and the Temp In 1 connector is secure. 5. Check the integrity of the temperature cable. Flex the cable to check for an intermittent fault. If damaged, replace cable. 6. Replace the patient temperature probe. 7. Confirm the patient temperature is accurate with a secondary monitor. If it is confirmed to be accurate, return the unit to a patient control mode and monitor patient temperature closely.

Alarm	Problem	Solution
51 Patient Temperature 1 Below Control Range Low Priority Alarm	Patient Temperature 1 is less than 31°C (87.8°F) while in a patient control mode (e.g. Control Patient, Cooling, or Rewarming).	1. Verify patient temperature from a secondary site. If patient temperature is less than 31°C (87.8°F), use Manual Control to raise patient temperature above 32°C (89.6°F) then resume using the previous control mode. 2. Check that the Temp In 1 probe is properly placed in the patient and has not dislodged. 3. Check that the Temp In 1 probe is connected to the Temp In 1 cable / connector on the back of the Control Module. 4. Check that the connection between the temperature probe and temperature cable is secure. 5. Check that the connection between the temperature cable and the Temp In 1 connector is secure. 6. Check the integrity of the temperature cable. Flex the cable to check for an intermittent fault. If damaged, replace cable. 7. Replace the patient temperature probe.
52 Extended Period of Cold Water Low Priority Alarm	The circulating water temperature has been below 10°C (50°F) for 8 of the previous 10 hours. The alarm will recur after 1 hour if the condition continues. After the device has issued 11 extended cold water exposure alarms, it will issue a prolonged cold water exposure alarm. Extended periods of cold water delivery may increase the risk for skin injury. Assess patient's skin underneath the ArcticGel™ pads.	1. **Verify the Custom Parameters.** ▪ Patient target is set to the correct temperature. See **VI. Operation Guide–Therapy Screen–Control Patient Settings** for instructions on setting patient target temperature. ▪ One of the automatic patient control modes (e.g. Control Patient or Cooling) is activated. (The system is not in Manual Control mode.) ▪ The high water temperature limit and low water temperature limits are set correctly. See **VI. Operation Guide–Therapy Settings–High Water Limit** or **Low Water Limit**. 2. **Verify Pad Sizing and Coverage** ▪ A full set of four ArcticGel™ pads of the appropriate size for the patient applied to the patient. ▪ For patients > 100 kg (220 lbs), 1 or 2 Universal pads are added as required for adequate coverage. ▪ The pads are well-adhered to the patient. 3. **Verify System Performance** ▪ Water flow rate should be greater than the minimum flow rate requirements specified in the ArcticGel™ pads IFU at least 1 hour continuous use. See **VIII. Troubleshooting-Water-Low Water Flow** for troubleshooting instructions. ▪ The patient temperature probe is properly placed and providing an accurate and stable temperature. 4. **Verify Shivering Control** ▪ If the device settings, pad sizing and system performance is correct and patient target temperature is still not reached and/or water temperature remains below 10°C (50°F), then the patient is generating excessive heat, most likely from shivering which may or may not be visible. ▪ Consider administration of additional medication for shivering control, adequate for the patient weight and magnitude of shivering: follow physician orders, institutional TTM protocol and current medical guidelines. ▪ Evaluate patient response to medication. 5. **Make Clinical Decision** ▪ If all of the above considerations have been addressed and the patient still has not reached target temperature the physician and nursing staff make a clinical decision to limit the cold water exposure: ▪ Increase low water temperature limit. See **VI. Operation Guide–Therapy Settings–Low Water Limit**. ▪ Set the patient target temperature to the lowest patient temperature achieved. See **VI. Operation Guide–Therapy Screen–Hypothermia Therapy–Cooling** or **Normothermia Therapy–Control Patient** for instructions on setting patient target temperature. ▪ Discontinue cooling therapy.

Alarm	Problem	Solution
53 Prolonged Cold Water Exposure Medium Priority Alarm	The circulating water temperature has been below 10°C (50°F) for a prolonged period of time. The extended period of cold water alarm has been issued 11 times. The alarm was first issued after the system sensed that the water temperature was below 10°C (50°F) for 8 of 10 hours. The alarm was then issued an additional 10 times every 1 hour because the situation was not resolved. Prolonged cold water exposure may increase the risk for skin injury. Assess patient's skin underneath the ArcticGel™ pads.	1. **Verify the Custom Parameters.** ▪ Patient target is set to the correct temperature. See **VI. Operation Guide–Therapy Screen–Hypothermia Therapy–Cooling** or **Normothermia Therapy – Control Patient** for instructions on setting patient target temperature. ▪ One of the automatic patient control modes (e.g. Control Patient or Cooling) is activated. (The system is not in Manual Control mode.) ▪ The high water temperature limit and low water temperature limits are set correctly. See **VI. Operation Guide–Therapy Settings–High Water Limit** or **Low Water Limit**. 2. **Verify Pad Sizing and Coverage** ▪ A full set of four ArcticGel™ pads of the appropriate size for the patient applied to the patient. ▪ For patients > 100 kg (220 lbs), 1 or 2 Universal pads are added as required for adequate coverage. ▪ The pads are well-adhered to the patient. 3. **Verify System Performance** ▪ Water flow rate should be greater than the minimum flow rate requirements specified in the ArcticGel™ pads IFU at least 1 hour continuous use. See **VIII. Troubleshooting-Water–Low Water Flow** for troubleshooting instructions. ▪ The patient temperature probe is properly placed and providing an accurate and stable temperature. 4. **Verify Shivering Control** ▪ If the device settings, pad sizing and system performance is correct and patient target temperature is still not reached and/or water temperature remains below 10°C (50°F), then the patient is generating excessive heat, most likely from shivering which may or may not be visible. ▪ Consider administration of additional medication for shivering control, adequate for the patient weight and magnitude of shivering: follow physician orders, institutional TTM protocol and current medical guidelines. ▪ Evaluate patient response to medication. 5. **Make Clinical Decision** ▪ If all of the above considerations have been addressed and the patient still has not reached target temperature the physician and nursing staff make a clinical decision to limit the cold water exposure: ▪ Increase low water temperature limit. See **VI. Operation Guide–Therapy Settings–Low Water Limit**. ▪ Set the patient target temperature to the lowest patient temperature achieved. See **VI. Operation Guide–Therapy Screen–Hypothermia Therapy–Cooling** or **Normothermia Therapy – Control Patient** for instructions on setting patient target temperature. ▪ Discontinue cooling therapy.
60 Non-Recoverable System Error Medium Priority Alarm	Control processor and Monitor processor start up synchronization fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
61 Non-Recoverable System Error Medium Priority Alarm	Control processor parameter memory fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
62 Non-Recoverable System Error Medium Priority Alarm	Monitor processor parameter memory fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
64 Non-Recoverable System Error Medium Priority Alarm	Unable to enable pump power (Control processor).	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
65 Non-Recoverable System Error Medium Priority Alarm	Unable to enable pump power (Monitor processor).	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.

Alarm	Problem	Solution
66 Non-Recoverable System Error Medium Priority Alarm	Unable to disable pump power (Control processor).	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
67 Non-Recoverable System Error Medium Priority Alarm	Unable to disable pump power (Monitor processor).	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
71 Non-Recoverable System Error Medium Priority Alarm	Primary outlet water temperature sensor out of range – high resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
72 Non-Recoverable System Error Medium Priority Alarm	Primary outlet water temperature sensor out of range – low resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
73 Non-Recoverable System Error Medium Priority Alarm	Secondary outlet water temperature sensor out of range – high resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
74 Non-Recoverable System Error Medium Priority Alarm	Secondary outlet water temperature sensor out of range – low resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
75 Non-Recoverable System Error Medium Priority Alarm	Inlet water temperature sensor out of range – high resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
76 Non-Recoverable System Error Medium Priority Alarm	Inlet water temperature sensor out of range – low resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
77 Non-Recoverable System Error Medium Priority Alarm	Chiller water temperature sensor out of range – high resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
78 Non-Recoverable System Error Medium Priority Alarm	Chiller water temperature sensor out of range – low resistance.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
79 Non-Recoverable System Error Medium Priority Alarm	Primary and secondary outlet water temperature sensors differ by greater than 1°C.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
80 Non-Recoverable System Error Medium Priority Alarm	The control processor failed to detect a simulated water temperature fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
81 Non-Recoverable System Error Medium Priority Alarm	The monitor processor failed to detect a simulated water temperature fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
82 Non-Recoverable System Error Medium Priority Alarm	Processor fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
83 Non-Recoverable System Error Medium Priority Alarm	Monitor processor communications fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
84 Non-Recoverable System Error Medium Priority Alarm	Control processor communications fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
86 Non-Recoverable System Error Medium Priority Alarm	Power supply voltage fault.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.

Alarm	Problem	Solution
99 Non-Recoverable System Error Medium Priority Alarm	Program unexpectedly aborted.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
101 No USB Drive Found During Save Low Priority Alarm	When attempting to Download Patient Data, no flash drive was found in the USB port.	Insert a solid state flash drive into the USB port on the back of the Control Module. Press the Save button in the Download Patient Data window. See **VI. Operation Guide–Advanced Setup–Download Patient Data** for further instructions.
103 Unable to Communicate Settings Low Priority Alarm	There was an error communicating Hypothermia Settings, Normothermia Settings or Advanced Setup settings to the system.	1. Re-enter setting that was just attempted. 2. If the alarm persists, discontinue use and contact BD Customer Support.
104 Manual Control End Low Priority Alarm	The Manual Control has reached the end of its set duration. The system has been placed in **Stop** mode.	1. Reset Manual Control duration timer. See **VI. Operation Guide–Therapy Settings–Manual Control** for further instructions. 2. Initiate therapy using one of the patient control modes (e.g. Control Patient, Cooling or Rewarming. See **VI. Operation Guide–Therapy Screen–Hypothermia Therapy–Cooling** or **Normothermia Therapy–Control Patient** for further instructions.
105 Cooling End Low Priority Alarm	**Cooling** timer has reached the end of its set duration and **Rewarming Begins** in **Hypothermia Settings** is set to **Manually**. See **VI. Operation Guide–Therapy Settings–Rewarming Begins** for more information.	Press the Start button in the Rewarming window to initiate patient rewarming. See **VI. Operation Guide–Therapy Screen–Hypothermia Therapy–Rewarming** for further instructions.
106 Non-Recoverable System Error Medium Priority Alarm	Graphic user interface communications lost with Control Module control processor.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
107 Non-Recoverable System Error Medium Priority Alarm	Graphic user interface communications lost with Control Module monitor processor.	1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
108 Operating Mode Incorrect Medium Priority Alarm	The Control Module has not entered the commanded therapy mode.	1. Press the Start button to initiate therapy. 2. If alarm persists, contact BD Customer Support
109 Esophageal Probe Recommended Low Priority Alarm	Control Strategy 3 has been chosen which allows the Patient Target temperature to be set between 32.0°C and 32.9°C (89.6°F to 91.2°F). For patient target temperatures between 32°C to 32.9°C (89.6°F to 91.2°F) an esophageal temperature probe should be used. During the hypothermia induction phase, the esophageal temperature tracks real-time core temperature changes more closely than bladder or rectal temperature. Due to this lag time when using bladder or rectal temperature sites, actual patient core temperatures may be lower than measured. Therefore, the use of esophageal temperature is recommended for patient temperature control below 33°C.	BD recommends the use of an esophageal temperature probe when patient target temperature control below 33°C is set. Place esophageal temperature probe in patient and connect to the Temp In 1 cable on the back of the Control Module.
110 Data File Not Readable Low Priority Alarm	The data file which contains the system default settings has been corrupted. The system has automatically reset the system to the factory defaults.	All user defined settings in Advanced Setup, Normothermia Settings and Hypothermia Settings should be reset by the user prior to the next patient treatment. **Note:** The Continue Current Case option will not be available in this situation.

Alarm	Problem	Solution
112 Confirm Return to Cooling Phase Low Priority Alarm	Treatment is currently programmed to be in the Rewarming phase, but the **Start** button in the **Cooling** window was pressed.	1. If you intended to return to the cooling phase, press the green **Start** button in the **Cooling** window to confirm. 2. If you intended to remain in the rewarming phase, press the green **Start** button in the **Rewarming** window. **Note**: The "Rewarming from" setting in the **Rewarming–Adjust** window will revert automatically to the current cooling phase target temperature to assure a smooth transition from cooling to rewarming
113 Reduced Water Temperature Control Low Priority Alarm	The system has detected that the water temperature has not been controlled as accurately as expected in the last 30 minutes. This situation may be temporary due to sudden patient temperature changes, interruption in water flow, or blockage of air flow by an obstruction or dirty filter.	1. Confirm that water flow is adequate. 2. Confirm that air vents are not obstructed. Clean filter if dirty. 3. Confirm that patient temperature control is stable. 4. If this alarm recurs or patient temperature is not adequately controlled, consider replacing the device or discontinuing treatment. 5. Contact BD Customer Support for troubleshooting assistance.
114 Treatment Stopped Low Priority Alarm	Treatment has been stopped for the last ten (10) minutes.	Press the green **Start** button to continue treatment
115 Prolonged Warm Water Exposure Medium Priority Alarm	The circulating water temperature has been between 38°C (100.4°F) and 40°C (104.0°F) for a prolonged period of time. Prolonged warm water exposure may increase the risk for skin injury. Assess patient's skin underneath the ArcticGel™ pads.	1. **Verify the Custom Parameters.** ▪ Patient target is set to the correct temperature. See **VI. Operation Guide–Therapy Screen-**topics **Hypothermia Therapy–Rewarming** or **Normothermia Therapy–Control Patient** for instructions on setting patient target temperature. ▪ One of the automatic patient control modes (e.g. Control Patient or Rewarming) is activated. (The system is not in Manual Control mode.) ▪ The high water temperature limit is set correctly. Consider reducing the maximum water temperature setting to 38°C (100°F) or lower. See **VI. Operation Guide–Therapy Settings–High Water Limit**. 2. **Verify Pad Sizing and Coverage** ▪ A full set of four ArcticGel™ pads of the appropriate size for the patient applied to the patient. ▪ For patients > 100 kg (220 lbs), 1 or 2 Universal pads are added as required for adequate coverage. ▪ The pads are well-adhered to the patient. 3. **Verify System Performance** ▪ Water flow rate should be greater than the minimum flow rate requirements specified in the ArcticGel™ pads IFU for at least 1 hour continuous use. See **VIII. Troubleshooting–Water–Low Water Flow** for troubleshooting instructions. ▪ The patient temperature probe is properly placed and providing an accurate and stable temperature. **4. Make Clinical Decision** ▪ If all of the above considerations have been addressed and the patient still has not reached target temperature the physician and nursing staff make a clinical decision to limit the warm water exposure: ▪ Decrease high water temperature limit. See **VI. Operation Guide–Therapy Settings–High Water Limit** ▪ Set the patient target temperature to the highest patient temperature achieved. See **VI. Operation Guide–Therapy Screen–Hypothermia Therapy–Rewarming** or **Normothermia Therapy–Control Patient** for instructions on setting patient target temperature. ▪ Discontinue warming therapy.
116 Patient Temperature 1 Change Not Detected Low Priority Alarm	Patient Temperature 1 has not changed by more than 0.15°C for an extended period of time.	1. Verify that the Temp In 1 probe is correctly positioned and correctly connected to the system. 2. Verify patient temperature by an independent measurement. 3. Verify that the rate of temperature change is intentionally set to a low value.
117 Patient Temperature 1 Change Not Detected Medium Priority Alarm	Patient Temperature 1 has not changed by more than 0.15°C for an extended period of time.	1. Verify that the Temp In 1 probe is correctly positioned and correctly connected to the system. 2. Verify patient temperature by an independent measurement. 3. Verify that the rate of temperature change is intentionally set to a low value.

Alarm	Problem	Solution
119 Patient Temperature 1 Outside of Monitor Mode Limits Low Priority Alarm	Patient Temperature 1 has exceeded the Monitor Mode Limits and is set to **Manually**. See **VI. Operation Guide–Therapy Settings–Manual Mode** for more information.	Press the Start button in the therapy screen to initiate patient treatment. See **VI. Operation Guide–Therapy Screen–Hypothermia Therapy–Rewarming** for further instructions.

Appendix C- Warranty

Limited Warranty

Bard Medical Division, C. R. Bard, Inc. ("Bard") warrants to the original customer that each Arctic Sun™ Control Module ("Equipment") and ArcticGel Pad ("Disposable") will be free of defects in workmanship and materials for the period set forth in the labeling and if no such period is set forth, then one year from the date of purchase. If the Equipment or a Disposable proves to be so defective, such Equipment or Disposable may be repaired, replaced, refunded or credited, at Bard's option. A comprehensive post warranty service plan for Equipment is available for purchase. The warranty covers all parts and labor associated with defects in material and workmanship of the Equipment and Disposable. Bard will, at its discretion, determine if the Equipment or a Disposable is to be repaired on site, or at the Bard service center. If Equipment or a Disposable is to be returned for service, Bard will supply packaging materials and pay for ground shipping. However, it is the customer's responsibility to prepare and package the Equipment or Disposable for shipment at its own cost. Any expedited shipment request will be at the customer's expense. Any unauthorized Equipment or Disposable repair performed during the warranty period will void the warranty. All returns must be authorized in advance by Bard. The liability of Bard under this product warranty does not extend to any abuse, accidental damage, misuse, improper storage, alteration, further manufacture, packaging or processing, accidental damage or damage from misuse of Equipment, damage caused by using tap water rather than distilled water, routine maintenance, recalibration, or its repair by any person or entity not authorized by a Bard representative.

Disclaimers.

I. THE LIMITED WARRANTY PROVIDED ABOVE IS THE ONLY WARRANTY PROVIDED BY BARD AND IS IN LIEU OF ANY OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING title, non-infringement, non-interference, interoperability, quality or condition, accuracy, completeness, merchantability, fitness for a particular purpose, or the absence of any defects, whether latent or patent.

II. CUSTOMER IS RESPONSIBLE FOR THE PERFORMANCE OF ITS RESEARCH AND THE CARE OF ITS PATIENTS, AND DETERMINING THE APPROPRIATENESS OF THE EQUIPMENT AND DISPOSABLES FOR ITS USE; CUSTOMER ACKNOWLEDGES THAT Bard is not responsible for the delivery of medical care or medical services to customer's patients or any other person. The Equipment and Disposables are a tool to be used by customer but do not replace professional skill or judgment. By providing the Equipment and Disposables to customer, neither Bard nor any employee of Bard is engaged in the practice of medicine. Customer is responsible for verifying the accuracy, completeness, and pertinence of any medical, patient, legal or other results, data or information entered in, received by, processed by, stored in, transmitted by, produced by, displayed by, or used in connection with the Equipment and Disposables. Customer assumes all risks and liabilities associated with the use of such information, whether such information is used alone or in combination with other information. Bard is not responsible for the performance, support, or any other aspect of customer's technology environment.

III. CUSTOMER ACKNOWLEDGES THAT COMPUTER AND TELECOMMUNICATIONS SYSTEMS ARE NOT FAULT-FREE AND OCCASIONAL PERIODS OF DOWNTIME OCCUR. BARD DOES NOT GUARANTEE THE USE OF THE EQUIPMENT AND ITS CONNECTIVITY FEATURES WILL BE UNINTERRUPTED, TIMELY, SECURE, OR ERROR-FREE OR THAT CONTENT LOSS WON'T OCCUR, NOR DOES BARD GUARANTEE ANY CONNECTION TO OR TRANSMISSION FROM THE CUSTOMER TECHNOLOGY ENVIRONMENT.

IV. **Exclusions**. The foregoing warranties will not apply to failure of any Equipment or Disposable caused by (i) customer's abuse, neglect or misuse or resulting from any failure to comply with the customer's responsibilities; (ii) malfunction or failure of any element of customer's technology environment or use other than as expressly authorized by Bard; (iv) customer's failure to maintain the physical environment for the Equipment (including normal maintenance) specified in the relevant documentation provided by Bard; (v) malicious software not introduced by Bard; or (vi) customer's failure to permit installation of any software updates or upgrades.

THE LIABILITY AND REMEDY STATED IN THIS LIMITED WARRANTY WILL BE THE SOLE LIABILITY OF BARD AND REMEDY AVAILABLE TO CUSTOMER WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BARD WILL NOT BE LIABLE TO CUSTOMER FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF HANDLING OR USE OF BARD EQUIPMENT OR DISPOSABLES EVEN IF BARD HAS BEEN ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES. IN NO EVENT WILL BARD'S LIABILITY UNDER THIS WARRANTY EXCEED THE PURCHASE PRICE PAID TO BARD BY CUSTOMER FOR SUCH EQUIPMENT AND DISPOSABLE.

Terms of Service

If Equipment availability is critical for patient treatment, it is the customer's responsibility to purchase back-up Equipment. Although Bard will attempt to promptly repair Equipment under warranty, the timeliness of repair is not guaranteed.

The customer is responsible for maintaining the Equipment according to the schedules and instructions in the documentation supplied with each system. Bard provides remote Technical Support from 8:00AM to 5:00PM Mountain Time and 24/7 emergency phone support. Contact customer Service for all service related requests. A detailed description of the problem or service required, the unit serial number, and contact information will be required to assist in providing efficient service of the unit. The customer must provide personnel to assist Technical Support with troubleshooting.

Loaned Equipment

If Equipment under warranty is returned for service, subject to availability, loaned Equipment may be available to the customer at no charge upon request for the duration of the service. The customer is responsible for setting up the loaned Equipment and to prepare and package the Equipment for return shipment according to the documentation. The customer is also responsible for the care and maintenance of the loaned Equipment and all accessories while the Equipment is in their possession. Any loss or damage will be the sole responsibility of the customer. Loaned Equipment must be returned within 7 days upon return of the repaired Equipment or rental charges will be applied at a rate of $50 per day. Loaned equipment will be shipped ground at Bard's expense. Any expedited shipment request will be at the customer's expense.

Non-Warranty Service

Parts and service are available for a fee through customer Service for Equipment no longer under warranty. If requested, Bard can provide an estimate of the cost of factory repair. Bard will require a Purchase Order from the customer in order to initiate the repair service. If it is later determined the Equipment requires repair which exceeds the original estimate, Bard will contact the customer for authorization prior to proceeding with the repair.

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