

 **BD Arctic Sun™ Stat**
Temperature Management System

SERVICE MANUAL



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Chapter 1 – Getting Started

Introduction

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 C for the full declaration regarding electromagnetic compatibility.

The Arctic Sun™ Temperature Management System was designed with ease of service in mind and incorporates several features that will assist clinical engineers in maintaining its performance. These features include negative pressure flow that eliminates water leaks, real-time air leak detection, and performance monitoring. It also includes access to alarm logs and past system case data, real-time diagnostic information, simplified calibration and maintenance, and modular construction allowing for simple repair if required.

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.

Warnings and Cautions



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 $\leq 40^\circ\text{C}$ (104°F); Water Temperature Low Limit $\geq 10^\circ\text{C}$ (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.

CAUTIONS (Continued)

- 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.
- 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.

⚠ CAUTIONS (Continued)

- 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.

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 E).
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.

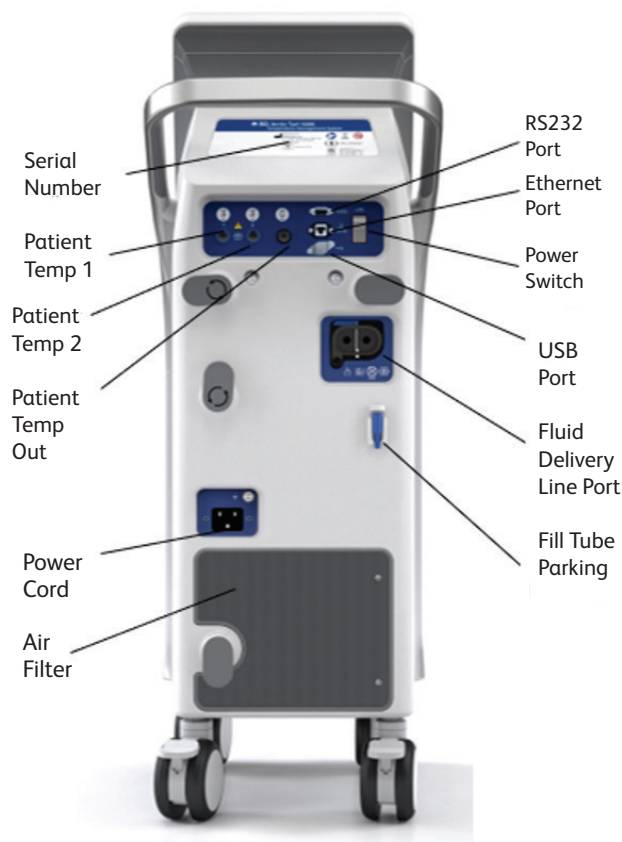


Fig 1-1 Arctic Sun™ Temperature Management System Control Module

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.

System Navigation

Therapy Selection

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



Fig 1-2 Therapy Selection Screen

Patient Pad Selection Screen

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.

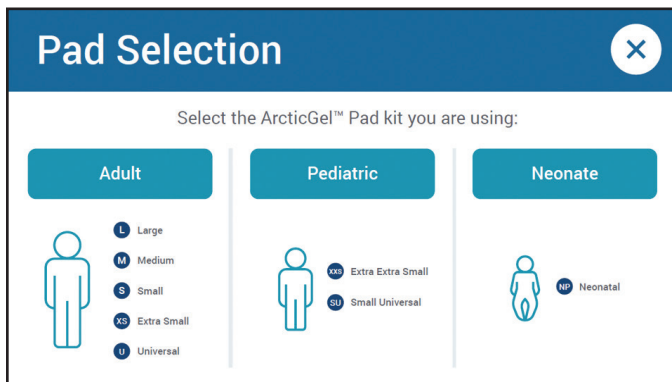


Fig 1-3 Pad Selection Screen

Therapy Screens

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

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. Wi-Fi Connected (if enabled)

16. Rewarming (Hypothermia Screen)

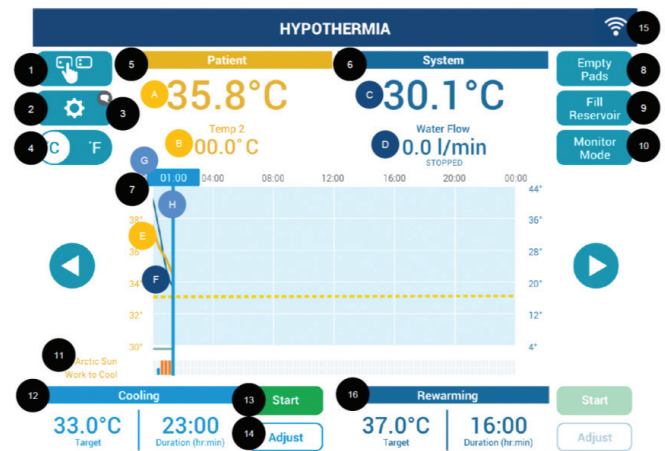


Fig 1-4 Hypothermia therapy screen (using Adult ArcticGel™ pads)

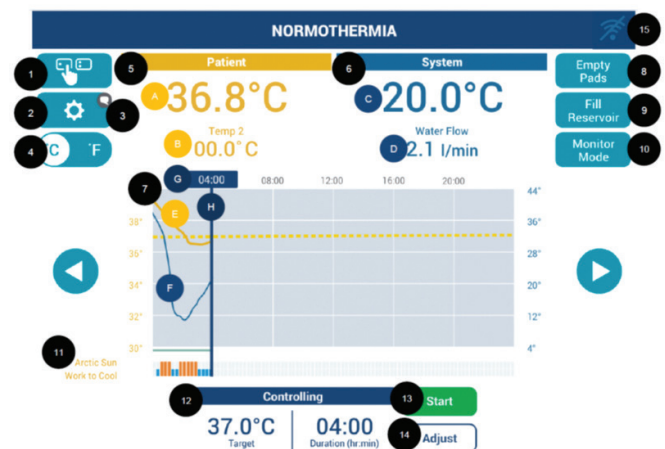


Fig 1-5 Normothermia therapy screen (using adult ArcticGel™ pads)

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 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 require filling after fewer patient therapies have been performed.

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



Fig 1-6 Fill Reservoir 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 by pressing the up arrow once and save your settings. Press close to close the settings window.

Note: Manual Control is disabled by default. Enabling Manual Control will not automatically change the default settings.

4. From the therapy screen, press the **Manual Control** button. 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. Set the Manual Control water target temperature to 4°C and the duration to 30 minutes.
10. 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.
11. Press the **Stop** button to stop **Manual Control**.
12. Press the **Cancel** button to close the **Manual Control** window.
13. Power Off the Control Module.

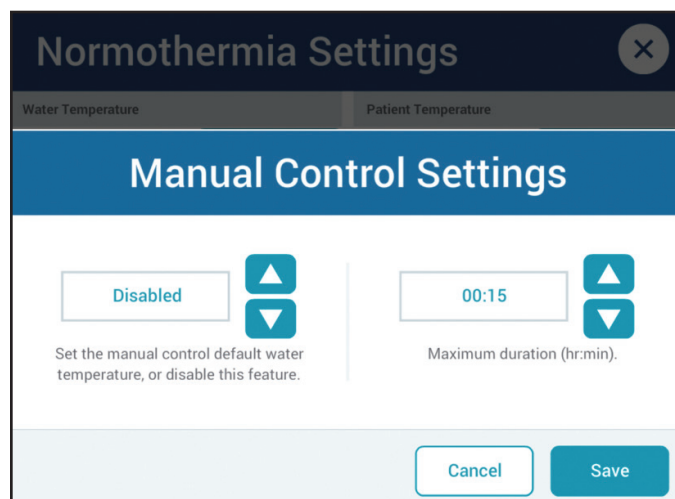


Fig 1-7 Manual Control Settings Screen

Chapter 2- Components

Hydraulic Components

Fluid Delivery Line – reusable dual lumen tubing that connects the Control Module to the ArcticGel™ Pads.

Pumps

Circulation Pump – pumps water from the Circulation Tank through the ArcticGel™ Pads.

Mixing Pump – Transfers cold water from the Chiller Tank to the Circulation Tank.

Chiller Pump – continuously circulates the water from the Chiller Tank through the chiller's evaporator.

Tanks

Circulation Tank – contains temperature-controlled water that supplies the ArcticGel™ Pads.

Chiller Tank – contains water that is maintained at approximately 4°C.

Supply Tank – contains water that is used to replenish the Circulation Tank when the ArcticGel™ Pads are filled.

Sensors

Outlet Monitor Temperature - T1 – located within the Circulation Tank. Used to monitor the temperature of water that supplies the ArcticGel™ Pads.

Outlet Control Temperature - T2 – located within the Circulation Tank. Used to control the temperature of water that supplies the ArcticGel™ Pads.

Inlet Temperature – T3 – located within the Inlet/Outlet Manifold. Monitors the temperature of water returning from the ArcticGel™ Pads.

Chiller Temperature – T4 – located within the Chiller Tank. Used to control temperature of water in the Chiller Tank.

Pressure Sensor – located within the Inlet/Outlet Manifold. Used to maintain a constant negative pressure within the ArcticGel™ Pads by controlling the speed of the Circulation Pump.

Flow Sensor – located at the outlet of the Circulation Pump. Monitors the flow rate in the Circulation Circuit.

Valves

Conditioning Valve – located within the Inlet/Outlet Manifold. When open, allows water to circulate internally when priming or preconditioning.

Fill Valve – located within the Inlet/Outlet Manifold. When open, allows the Circulation Pump to draw water into the system.

Vent Valve – located within the Inlet/Outlet Manifold. When open, allows air to supply ArcticGel™ Pads and the displaced water to be returned to the Supply Tank.

Heater – located in the Circulation Tank. The heater consists of 4 heating rods. The heating element within each rod is in series with a non-resettable thermal fuse, which protects each rod against an over-temperature condition.

Inlet/Outlet Manifold – connects to Fluid Delivery Line and Fill Tube. Contains the valves, the inlet temperature sensor, and the pressure sensor.

Chiller – a refrigeration unit that continuously cools the evaporator.

Electronic Components

Transmission Interface Module (T.I.M.) – an integrated transmission interface module located on top of the Card Cage converts real time data for transmission to a hospital EMR system.

Cables – power cord and temperature cables. Additional adapter cables are available to purchase for use with different manufacturers' temperature probes. In addition, temperature out cables can be purchased to allow output of patient temperature to an external monitor. Please refer to the Temperature Cables in Appendix D.

Panel ESD Board – located on the connector panel bracket. Provides electrical isolation for YSI 400 compatible patient temperature input/output signal.

AC PCB – located below the Supply Tank. Includes electromechanical relays to control mains power to the chiller and heater. Also includes solid state relays to control power to each of the four heating elements.

Power Supply – located next to the AC PCB. Converts AC mains voltage to 24 VDC.

Power Circuit Card – located within the Card Cage. Converts 24 VDC to lower DC voltages used by the system.

The Processor Circuit Card – located within the Card Cage. Includes both the control and monitor microprocessors and associated circuitry, including nonvolatile memory.

The Isolation Circuit Card – located within the Card Cage. Provides electrical isolation for the Patient Temperature circuits to a level of 1500V.

The Input/Output Circuit Card – located within the Card Cage. Contains circuits that monitor water temperature, pressure and flow. Provides control for Circulation and Mixing Pumps, valves, and Chiller.

The Backplane Circuit Card – located at the back of the Card Cage. Interconnects the circuit cards within the card cage.

Control Panel – located at the top of the Control Module. Consists of touch screen, microprocessor, hard drive, USB interface, and USB-powered speaker.

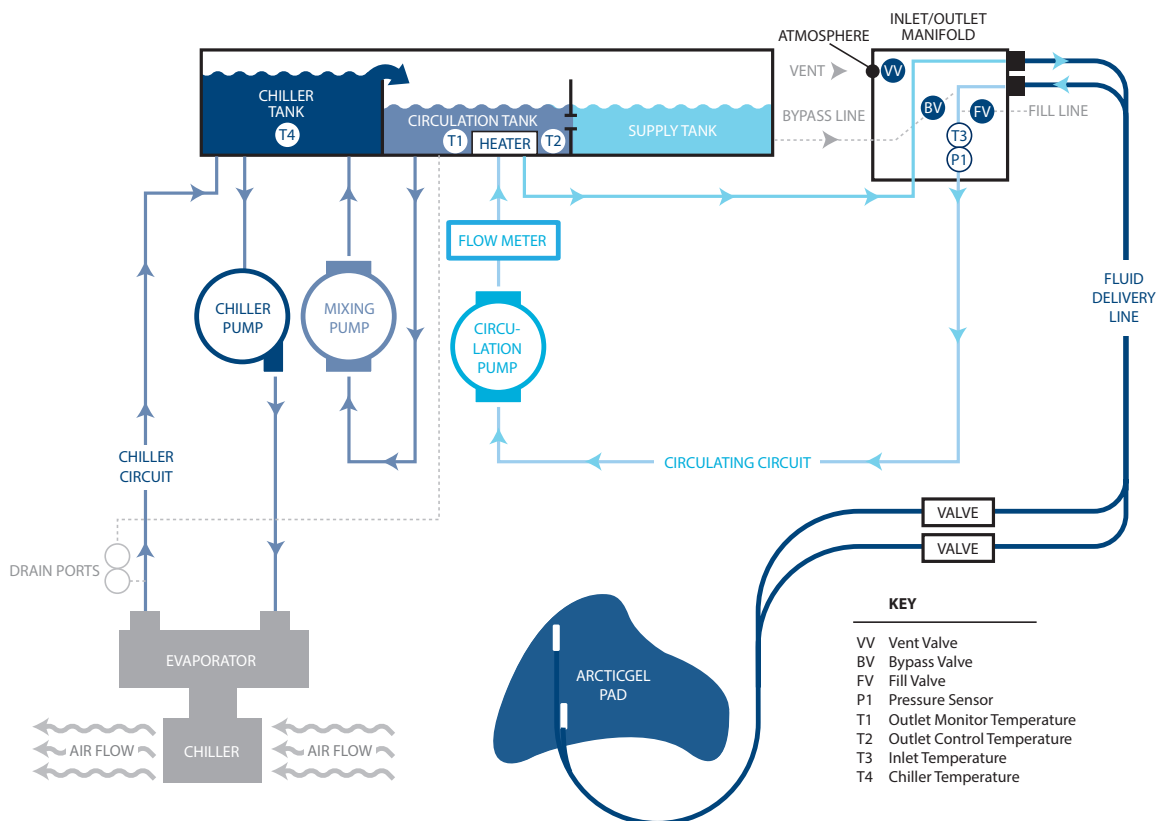


Fig 2-1 Hydraulic Schematic

Chapter 3 – Theory of Operation

Main Hydraulic Circuits

Circulation Circuit – circulates temperature-controlled water from the Circulation Tank through the ArcticGel™ Pads and returns to the inlet port of the Circulation Pump. The speed of the Circulation Pump varies to maintain -7.0 PSI (0.5 bar) at the Pressure Sensor. Since water in the ArcticGel™ Pads flows under negative pressure, a break in the circuit, such as a pad being punctured or disconnected, will result in air leaking into the system instead of water leaking out. Air in the system is removed in the Circulation Tank and exits through the tank vent. When warmer water is required, the heaters located in the Circulation Tank are energized. The heater power is dependent upon the flow rate through the circulation tank and the difference between the water temperature and the commanded water temperature. The heater has four elements that are cycled on sequentially to minimize power fluctuations in the mains supply.

Chiller Circuit – maintains the water in the Chiller Tank at approximately 4°C. Water is gravity-fed into the centrifugal Chiller Pump and is then pumped through the chiller's evaporator and returned to the Chiller Tank. The refrigerant system's cooling capacity is controlled by a refrigerant valve. When the Chiller Circuit approaches 4°C, the cycling of the valve can be heard.

Mixing Circuit – when cold water is required to cool the Circulation Circuit, the Mixing Pump pulls water from the Circulation Tank and meters it into the Chiller Tank. Cold water overflows from the Chiller Tank into the Circulation Tank. The speed of the mixing pump is dependent upon the flow rate through the circulation tank and the difference between the water temperature and the commanded water temperature.

Ancillary Hydraulic Circuits

Filling – When filling, the Fill Valve is opened, and water is drawn up through the valve by the Circulation Pump. Water returns through the Circulation Tank to the Supply Tank. Negative Pressure must be generated at the inlet of the Inlet/Outlet Manifold for filling to occur, therefore the Fluid Delivery Line must be attached. ArcticGel™ Pads should not be attached to the Fluid Delivery Line during filling.

Preconditioning – The system can be programmed to precondition water prior to initiating therapy. In this mode, the Bypass Valve opens and allows temperature-controlled water to circulate internally to bring the Circulation Tank and Supply Tank water to a pre-programmed temperature.

Empty Pads – To empty water from the ArcticGel™ Pads, the Vent Valve is opened, which enables air to enter the pads. Water is pulled from the pads by the Circulation Pump and returned through the Circulation Tank to the Supply Tank.

Electronic Control System

The electronic system consists of two independent subsystems: control and monitor. The control subsystem is responsible for delivering therapy to the patient. The monitor subsystem confirms the safe operation of the control subsystem. Each subsystem has an independent microprocessor, audio alarm, and both water and patient temperature sensing circuits.

The control subsystem performs the following functions:

- Command interpretation from the Control Panel
- System information update to the Control Panel
- Circulation Tank water temperature control (T1 & T2)
- Circulation Pump speed control from pressure sensor (P1)
- Patient temperature measurement (PT1)
- Temperature Out signal generation
- Chiller Tank water temperature control (T4)
- Valve control (VV, BV and FV)
- Chiller control

The monitor subsystem performs the following functions:

- Redundant command interpretation from Control Panel
- Circulation Tank temperature monitoring (T1)
- Patient temperature measurement (PT2)
- Circulation Pump power interrupt control
- Power Circuit Card voltage monitoring

Chapter 4- Maintenance

Maintenance Schedule

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.

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-Rings	6 months
Calibration	Every 2000 hours or 250 uses, whichever occurs first, as indicated by system display

Required accessories and supplies can be ordered separately. Refer to Appendix D for the Spare Parts and Service Items.

Clean the External Surfaces

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 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 surface 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.

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.

Note: Do not use cleaning solution that has passed the use by date listed on the bottle.

Note: The Cleaning Solution must be stored inside the UV resistance pouch.

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.

Note: Manual control is disabled by default. To enable, from the Normothermia Therapy screen, press the adjust button at the bottom center of the screen. Then press the More button. Then press the manual control adjust button. Select the desired temperature and time, and press save. Enabling Manual Control will not automatically change the default settings.

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 psi ± 0.2.
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.

Inspect Manifold O-Rings

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.

Calibration

To perform a calibration on the Arctic Sun™ Temperature Management System, press the **Advanced Setup** button on the **Therapy Selection Screen**. Press the **Start** button and follow the on-screen directions. Refer to Chapter 9 for additional instructions.

Chapter 5 - 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.

Advanced Setup

Data	Calibration
Download	Begin Process
Connectivity Settings	Last Calibrated
Location / Time	Next Calibration (uses)
Language	(or hours)
Number Format	System
Current Time	Maintenance
Date Format	Total Drain
Current Date	Default Settings
Software Version	Save as Default
Version	Last Saved

Fig 5-1 Advanced Setup Screen

Functions

- Download Patient Data
- Connectivity Settings
- Calibration
- Total Drain
- Save All Settings As Default

Location / Time Settings

- Number Format
- Current Time
- Date Format
- Current Date

Information

- Software Versions
- Last Calibration Date
- Next Calibration Due

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 front 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.

Note: 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 Wi-Fi data only

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 **Configure** 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 **Confirm** button to confirm
- Select **Edit/View** 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 **Configure**.
- Select **Configure** 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

Calibration

Calibration is recommended after 2,000 hours of operation or 250 uses, whichever occurs first as indicated on the display screen. Calibration instructions are stored in the device and can be accessed from the calibration screens on the Advanced Setup Screen. Calibration should be done only by trained service personnel.

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.

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.*

Number Format

- To set the number format to the local requirements:
- From the **Advanced Setup** screen, press the button to 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.

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.

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.

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.

Software Versions

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

Last Calibration Date

The last calibration date of the device is displayed.

Next Calibration Due

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

Chapter 6 - 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 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 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:

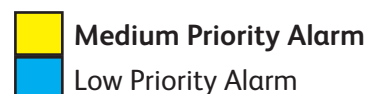
- Read the displayed instructions.
- Note the Alarm number.
- Press the Close button to clear the alarm.
- Follow the instructions to correct the alarm condition. Perform the actions in the order listed until the alarm condition is resolved. If the condition does not resolve, contact BD Customer Support.

Notes: 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.

Alarms Listing

The following table consists of a listing of the medium and low priority alarms that a user might observe during use of the Arctic Sun™ Temperature Management System.



Alarm	Problem	Solution
00 Communications Failure <i>Medium Priority Alarm</i>	Communications to control panel have failed upon power up	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	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.	<ol style="list-style-type: none"> 1. Check that patient line connectors are fully seated in the fluid delivery line manifold. If indicated, reseal 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 <i>Low Priority Alarm</i>	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.	<ol style="list-style-type: none"> 1. Check that patient line connectors are fully seated in the fluid delivery line manifold. If indicated, reseal 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 <i>Low Priority Alarm</i>	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.	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	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.	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	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.	<p>Fill the water reservoir. See VI. Operation Guide-Therapy Screens-Fill Reservoir for instructions.</p>
07 Empty Pads Not Complete <i>Low Priority Alarm</i>	A significant amount of water was still being returned from the pads at the end of the Empty Pads cycle.	<ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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	<p>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).</p>	<ol style="list-style-type: none"> Verify Patient Temperature Accuracy <ul style="list-style-type: none"> Confirm patient temperature using a secondary site. Confirm that the primary temperature probe is properly placed and registering an accurate temperature. Verify Patient / Water Temperature Control <ul style="list-style-type: none"> 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? <p>If the water and/or patient temperatures are beginning to decrease, the system is working correctly. Continue to monitor patient temperature.</p> Verify Water Temperature Limits <ul style="list-style-type: none"> 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. Verify Water Cooling – External Factors <ul style="list-style-type: none"> Check environmental conditions that may affect cooling. <ul style="list-style-type: none"> 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. Verify Water Control – System Performance <ul style="list-style-type: none"> 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. Verify Patient Control – System Performance <ul style="list-style-type: none"> 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	<p>In Normothermia Therapy: The Patient Temperature 1 reading is above the High Patient Alarm setting in Normothermia Settings.</p> <p>In Hypothermia Therapy: The Patient Temperature 1 reading is above the High Patient Alarm setting in Hypothermia Settings.</p>	<p>If desired, adjust the High Patient Alarm setting in Normothermia Settings or Hypothermia Settings.</p>

Alarm	Problem	Solution
10 Patient Temperature 1 Low Medium Priority Alarm	<p>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).</p>	<ol style="list-style-type: none"> Verify Patient Temperature Accuracy <ul style="list-style-type: none"> Confirm patient temperature using a secondary site. Confirm that the primary temperature probe is properly placed and registering an accurate temperature. Verify Patient / Water Temperature Control <ul style="list-style-type: none"> 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. Verify Water Temperature Limits <ul style="list-style-type: none"> 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. Verify Water Control – System Performance <ul style="list-style-type: none"> 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> 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. Verify Patient Control – System Performance <ul style="list-style-type: none"> 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	<p>In Normothermia Therapy: The Patient Temperature 1 reading is below the Low Patient Alarm setting in Normothermia Settings.</p> <p>In Hypothermia Therapy: The Patient Temperature 1 reading is below the Low Patient Alarm setting in Hypothermia Settings.</p>	<p>If desired, adjust the Low Patient Alarm setting in Normothermia Settings or Hypothermia Settings.</p>
12 Patient Temperature 1 High Low Priority Alarm	<p>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.</p> <p>Patient temperature is not automatically controlled while in Manual Control mode</p>	<p>Decrease Manual Mode water target temperature to a setting that is ≤ 38.5°C (101.3°F).</p> <p>See VI. Operation Guide–Therapy Settings–Manual Control for further instructions.</p>
13 Patient Temperature 1 Low Low Priority Alarm	<p>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.</p> <p>Patient temperature is not automatically controlled while in Manual Control mode</p>	<p>Increase Manual Mode water target temperature to a setting that is ≥ 32°C (89.6°F).</p> <p>See VI. Operation Guide–Therapy Settings–Manual Control for further instructions.</p>

Alarm	Problem	Solution
14 Patient Temperature 1 Probe Out of Range <i>Medium Priority Alarm</i>	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).	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	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).	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	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).	<ol style="list-style-type: none"> 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 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 <i>Medium Priority Alarm</i>	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).	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	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.	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	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).	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	The system is unable to calibrate the Temp In 1 channel within ± 1.0°C when the system is in Manual Control mode.	<ol style="list-style-type: none"> 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	<p>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).</p>	<ol style="list-style-type: none"> Verify Patient Temperature Accuracy <ul style="list-style-type: none"> 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. Verify Patient / Water Temperature Control <ul style="list-style-type: none"> 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. Verify Water Temperature Limits <ul style="list-style-type: none"> 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. Verify Water Cooling – External Factors <ul style="list-style-type: none"> Check environmental conditions that may affect cooling. <ul style="list-style-type: none"> 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. Verify Water Control – System Performance <ul style="list-style-type: none"> 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. Verify Patient Control – System Performance <ul style="list-style-type: none"> 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	<p>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.</p>	<p>If desired, adjust the High Patient Alarm setting in Normothermia Settings or Hypothermia Settings.</p>

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).	<ol style="list-style-type: none"> Verify Patient Temperature Accuracy <ul style="list-style-type: none"> 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. Verify Patient / Water Temperature Control <ul style="list-style-type: none"> 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. Verify Water Temperature Limits <ul style="list-style-type: none"> 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. Verify Water Control – System Performance <ul style="list-style-type: none"> 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> increasing to the commanded temperature, the water heating system is not working. Call BD Customer Support. Verify Patient Control – System Performance <ul style="list-style-type: none"> 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).	<ol style="list-style-type: none"> 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).	<ol style="list-style-type: none"> 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 $\pm 1.0^{\circ}\text{C}$ when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming). Patient Temperature 2 channel is made inactive.	<ol style="list-style-type: none"> 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 $\pm 1.0^{\circ}\text{C}$ when the system is in Manual Control mode. Patient Temperature 2 channel is made inactive.	<ol style="list-style-type: none"> 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 $\pm 1.0^{\circ}\text{C}$ when the system is in a patient control mode (e.g. Control Patient, Cooling or Rewarming). Patient Temperature 2 channel is made inactive	<ol style="list-style-type: none"> 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 $\pm 1.0^{\circ}\text{C}$ when in Manual Control mode. Patient Temperature 2 channel is made inactive.	<ol style="list-style-type: none"> 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).	<ol style="list-style-type: none"> 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).	<ol style="list-style-type: none"> 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).	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	The secondary outlet water temperature is above 44°C (111.2°F).	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	The secondary outlet water temperature is above 43°C (109.4°F).	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	The secondary outlet water temperature is below 3.0°C (37.4°F).	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	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.	<ol style="list-style-type: none"> 1. Contact your hospital clinical engineering department to perform calibration check on the device. 2. Contact BD Customer Support.
41 Low Internal Flow <i>Low Priority Alarm</i>	Insufficient internal flow during system priming or pre-conditioning.	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	The user settings are invalid and are unable to be saved. The saved system default settings are restored.	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	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.	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	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 <i>Medium Priority Alarm</i>	The control panel is not communicating with the system.	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	The control panel is not communicating with the system.	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	The Patient Temperature Out calibration data in non-volatile memory is invalid.	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	Patient Temperature 1 discontinuity. There has been a significant change in patient temperature over the past 8 minutes.	<ol style="list-style-type: none"> 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).	<ol style="list-style-type: none"> 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	<p>The circulating water temperature has been below 10°C (50°F) for 8 of the previous 10 hours.</p> <p>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.</p>	<ol style="list-style-type: none"> 1. Verify the custom parameters. <ul style="list-style-type: none"> ▪ 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 <ul style="list-style-type: none"> ▪ 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 <ul style="list-style-type: none"> ▪ 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 <ul style="list-style-type: none"> ▪ 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 <ul style="list-style-type: none"> ▪ 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 <i>Medium Priority Alarm</i>	<p>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.</p> <p>Prolonged cold water exposure may increase the risk for skin injury. Assess patient's skin underneath the ArcticGel™ pads.</p>	<ol style="list-style-type: none"> Verify the custom parameters. <ul style="list-style-type: none"> 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. Verify Pad Sizing and Coverage <ul style="list-style-type: none"> 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. Verify System Performance <ul style="list-style-type: none"> 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. Verify Shivering Control <ul style="list-style-type: none"> 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. Make Clinical Decision <ul style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	Control processor and Monitor processor start up synchronization fault.	<ol style="list-style-type: none"> Turn Control Module Off. Wait 30 seconds and turn Control Module On. If alarm persists, contact BD Customer Support.
61 Non-Recoverable System Error <i>Medium Priority Alarm</i>	Control processor parameter memory fault.	<ol style="list-style-type: none"> Turn Control Module Off. Wait 30 seconds and turn Control Module On. If alarm persists, contact BD Customer Support.
62 Non-Recoverable System Error <i>Medium Priority Alarm</i>	Monitor processor parameter memory fault.	<ol style="list-style-type: none"> Turn Control Module Off. Wait 30 seconds and turn Control Module On. If alarm persists, contact BD Customer Support.
64 Non-Recoverable System Error <i>Medium Priority Alarm</i>	Unable to enable pump power (Control processor).	<ol style="list-style-type: none"> Turn Control Module Off. Wait 30 seconds and turn Control Module On. If alarm persists, contact BD Customer Support.
65 Non-Recoverable System Error <i>Medium Priority Alarm</i>	Unable to enable pump power (Monitor processor).	<ol style="list-style-type: none"> Turn Control Module Off. Wait 30 seconds and turn Control Module On. If alarm persists, contact BD Customer Support.
66 Non-Recoverable System Error <i>Medium Priority Alarm</i>	Unable to disable pump power (Control processor).	<ol style="list-style-type: none"> Turn Control Module Off. Wait 30 seconds and turn Control Module On. If alarm persists, contact BD Customer Support.

Alarm	Problem	Solution
67 Non-Recoverable System Error Medium Priority Alarm	Unable to disable pump power (Monitor processor).	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 1. Turn Control Module Off. Wait 30 seconds and turn Control Module On. 2. If alarm persists, contact BD Customer Support.
99 Non-Recoverable System Error Medium Priority Alarm	Program unexpectedly aborted.	<ol style="list-style-type: none"> 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 front 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.

Alarm	Problem	Solution
105 Cooling End <i>Low Priority Alarm</i>	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 <i>Medium Priority Alarm</i>	Graphic user interface communications lost with Control Module control processor.	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	Graphic user interface communications lost with Control Module monitor processor.	<ol style="list-style-type: none"> 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 <i>Medium Priority Alarm</i>	The Control Module has not entered the commanded therapy mode.	<ol style="list-style-type: none"> 1. Press the Start button to initiate therapy. 2. If alarm persists, contact BD Customer Support
109 Esophageal Probe Recommended <i>Low Priority Alarm</i>	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 <i>Low Priority Alarm</i>	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.
112 Confirm Return to Cooling Phase <i>Low Priority Alarm</i>	Treatment is currently programmed to be in the Rewarming phase, but the Start button in the Cooling window was pressed.	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	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.	<ol style="list-style-type: none"> 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 <i>Low Priority Alarm</i>	Treatment has been stopped for the last ten (10) minutes.	Press the green Start button to continue treatment

Alarm	Problem	Solution
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.	<ol style="list-style-type: none"> Verify the custom parameters. <ul style="list-style-type: none"> 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. Verify Pad Sizing and Coverage <ul style="list-style-type: none"> 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. Verify System Performance <ul style="list-style-type: none"> 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. Make Clinical Decision <ul style="list-style-type: none"> 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.	<ol style="list-style-type: none"> Verify that the Temp In 1 probe is correctly positioned and correctly connected to the system. Verify patient temperature by an independent measurement. 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.	<ol style="list-style-type: none"> Verify that the Temp In 1 probe is correctly positioned and correctly connected to the system. Verify patient temperature by an independent measurement. Verify that the rate of temperature change is intentionally set to a low value.
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.

Chapter 7- Troubleshooting

7.1 Diagnostic Screen

The Diagnostic screen allows the user to view the flow, pressure, patient temperatures and individual water temperature sensor readings. This information is valuable during the troubleshooting process. The Diagnostic screen can be accessed by selecting the **System Access** button on the Normothermia therapy or Hypothermia therapy screen then selecting **Diagnostics**.

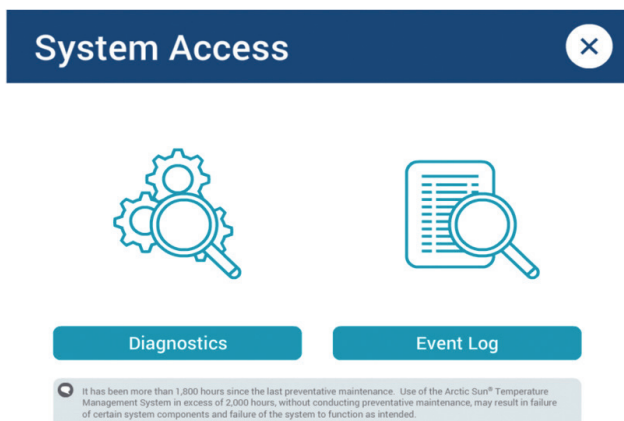


Fig 7-1 System Access Screen

7.2 Event Log

The Event Log will record non-recoverable system alarms and recoverable operational alarms and alerts from the last 10 cases. The Event Log can be accessed by selecting the **System Access** button on the Normothermia therapy or Hypothermia therapy screen then selecting **Event Log**.

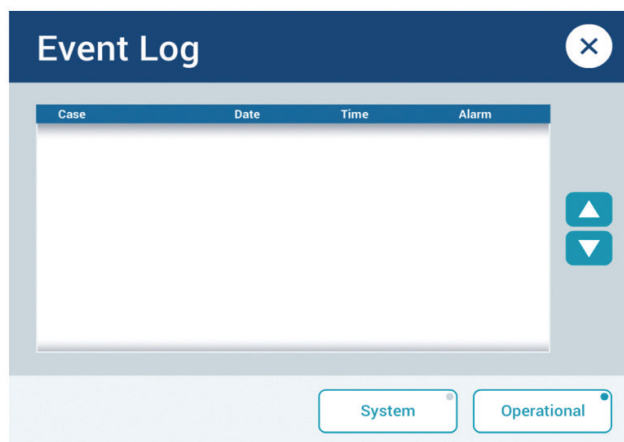


Fig 7-2 Event Log

7.3 General Troubleshooting Guide

A calibration check is an effective method for verifying proper operation of the device. Many technical issues with the Arctic Sun™ Temperature Management System can be diagnosed during a calibration check. See Chapter 9 for the Calibration Check procedure.

Case data recorded at one (1) minute intervals such as water flow rate, pressure, water and patient temperatures, pump and heater commands for the previous 10 cases are available for download from the USB port. This can be valuable information when attempting to troubleshoot reported problems from previous cases. The download feature is available from the **Advanced Setup** screen.

The following are the most common issues and methods of resolution:

7.3.1 Device Not Controlling Patient Temperature

The Arctic Sun™ Temperature Management System has a sophisticated control algorithm which calculates the appropriate water temperature based on a comparison of the patient's actual temperature versus the programmed target temperature. The system also monitors the actual water temperature versus the commanded water temperature. If the system fails to deliver the commanded temperature within a short period of time, alarm 113 will occur. This is the best indication as to whether the system was controlling appropriately during patient therapy. If this alarm has occurred, it can be viewed in the Event Log viewable on the device, as described in Section 7.2.

7.3.2 Water Not Cooling

To verify the cooling function of the device, perform the following steps:

- Check that the water temperature limits have not been adjusted too high on the Normothermia or Hypothermia Therapy Setting screen.
- With the device at room temperature power the device on, wait 5 minutes, and check the Chiller temperature (T4 on the Diagnostic screen). This temperature should be below 10°C (50°F).
- Connect the Fluid Delivery Line and a Shunt Line, initiate Manual Control, and set water target to 4° C (39°F).
- Verify that the water temperature lowers to less than 10°C (50°F) within 10 minutes.
- If no problems seem evident, perform a calibration check.

7.3.3 Water Not Heating

To verify the heating function of the device, perform the following steps:

- Verify with clinical staff that flow rate during therapy was at least 1 lpm as water flow rates below this will limit heater power.
- Check that the water temperature limits have not been adjusted too low on the Normothermia or Hypothermia Therapy Setting screen.
- Connect the Fluid Delivery Line and the Shunt Tube, initiate Manual Control, and set water target to 40° C (104.0°F).
- Verify water temperature increases from room temperature to at least 30° C (86°F) within 10 minutes.
- If unsuccessful, remove back panel and shell and check Heater power connection on AC PCB.
- Test heating elements as follows: Remove heater power connection from AC PCB then check resistance of heating elements.

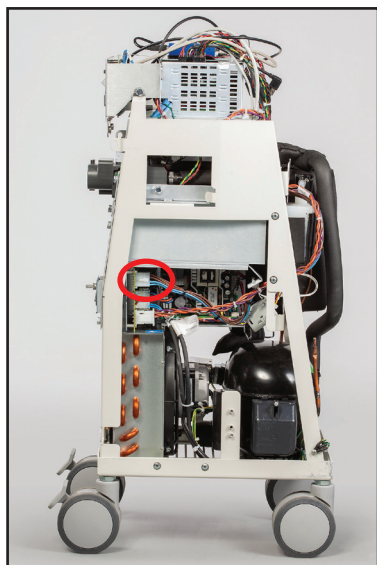


Fig. 7-3 Location of connector

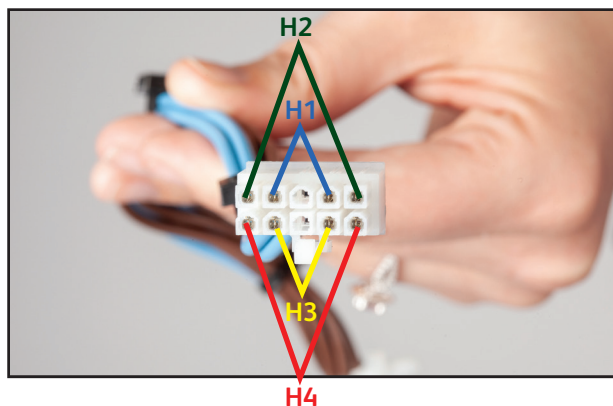


Fig. 7-4 Pins to test for each heating element

- For 115V devices, resistance should be 70-81 ohm each element.
- For 230V devices, resistance should be 280-327 ohm each element.
- If no problems seem evident, consider performing a calibration check.

7.3.4 Device Will Not Fill

If the device will not fill, perform the following steps:

- Ensure the Fluid Delivery Line is connected with no Shunt Tube or pads connected. The Fluid Delivery Line must be connected in order for the device to fill.
- Install the fill tube. Attempt filling to check for resolution.
- To confirm Fluid Delivery Line does not leak air, remove the Fluid Delivery Line, place thumb over the left port of the Inlet/ Outlet Manifold, and repeat fill process.

7.3.5 Control Panel Will Not Power On

To verify proper operation of the Control Panel, perform the following steps:

- Check that mains power is available by ensuring the amber light is lit on the power switch.
- Remove the back panel and shell. Check connection at top of card cage to Control Panel and verify the connection is seated properly.

7.3.6 Low Flow Alarm

If the device shows a Low Flow alarm, perform the following steps:

- Power device on; ensure Fluid Delivery Line is connected.
- With no pads or Shunt Tube attached, start the device in Manual Control and allow 3 minutes for bypass flow to stabilize.
- Using the Diagnostic screen, verify a flow rate of > 1.5 lpm and a Circulation Pump Command of less than 70%. If this cannot be achieved it indicates an air leak either internal to the device or in the Fluid Delivery Line.
- To confirm there is no internal air leak, remove Fluid Delivery Line and place thumb over the left port. Repeat the test in step 3.
- To confirm there are no leaks in the Fluid Delivery Line valves, attach a shunt tube to any set of valves and, initiate Manual Control. Watch for water to flow through tube, then without stopping, move shunt tube quickly to the opposite branch of the Fluid Delivery Line. Watch for water flow through the tube. Place the Fluid Delivery line on the floor. Press Stop. Remove the shunt tube. Monitor the Fluid Delivery Line valves for any water leaks over the next 5 minutes.
- To confirm the pad connector seals are not damaged, inspect the orange seal at the end of each valve and look for damage. Actuate each valve and ensure it moves freely.

7.3.7 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 screen lock 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

7.3.8 Wireless Connection

Wireless Connection Lost

- Confirm the connectivity icon is dark blue with a slash through it as shown in **Figure 1-5**.
- See **Chapter 5 –Advanced Setup** 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.

7.4 Troubleshooting Assistance

For further assistance with troubleshooting, contact your distributor or BD Technical Support.

Chapter 8- Component Replacement

The Arctic Sun™ Temperature Management System is designed and built to have a high degree of reliability; however, failures can occur. Use the troubleshooting methods in Chapter 7 or consult with BD Technical Support to determine the root cause component for the failure. Once this root cause component for the failure has been determined, follow the appropriate procedure for removal and replacement of the component. A list of spare parts and accessories is located in Appendix D. In general, reverse the order of removal to install a replacement component. Please note any special instructions to the contrary. All images are for reference only. Some images may appear slightly different than the device/screen.

Attention: Observe local procedures for electrostatic discharge control (ESD) when working with circuit card assemblies.

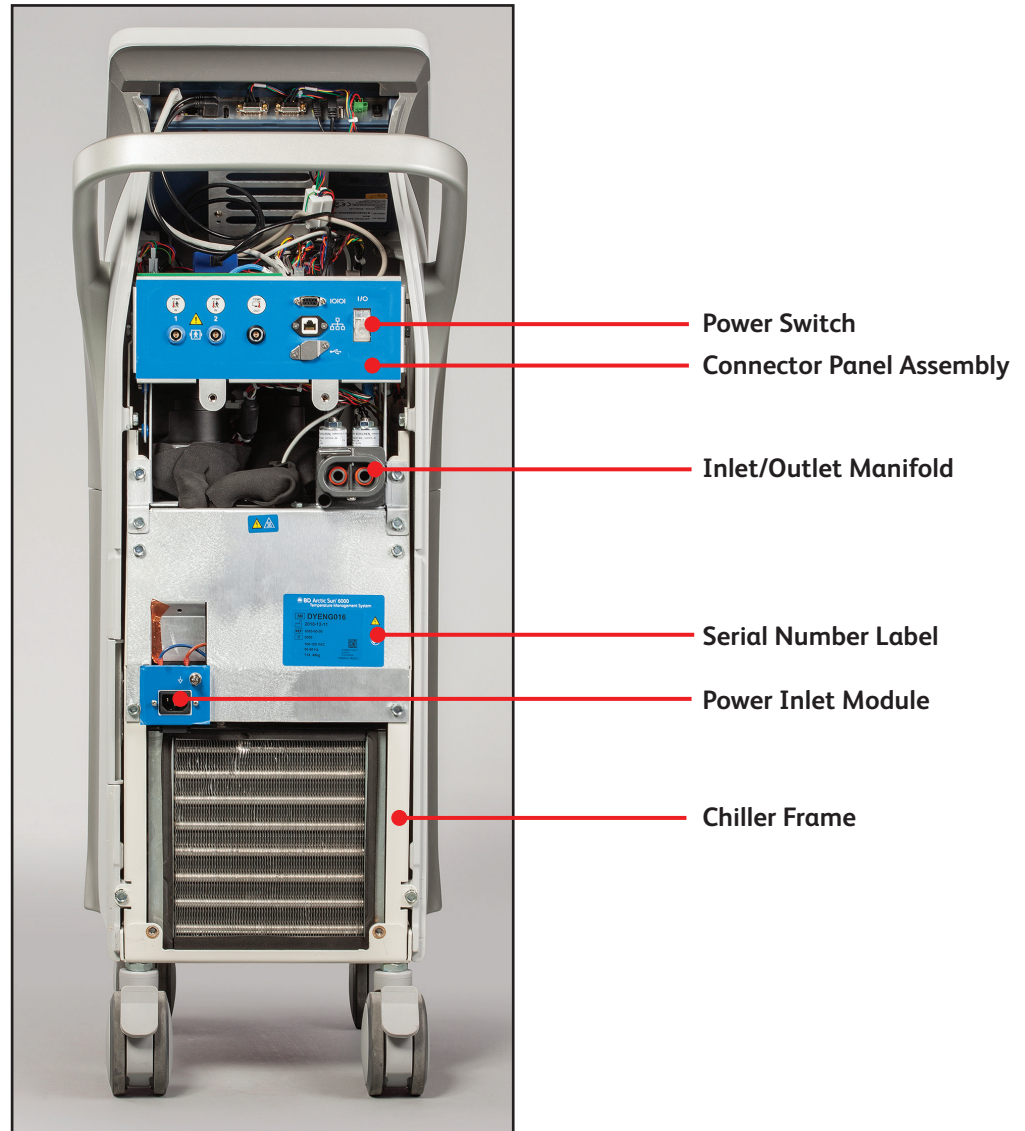


Fig 8-1 Control Module, Rear View after removal of RIM Back Panel

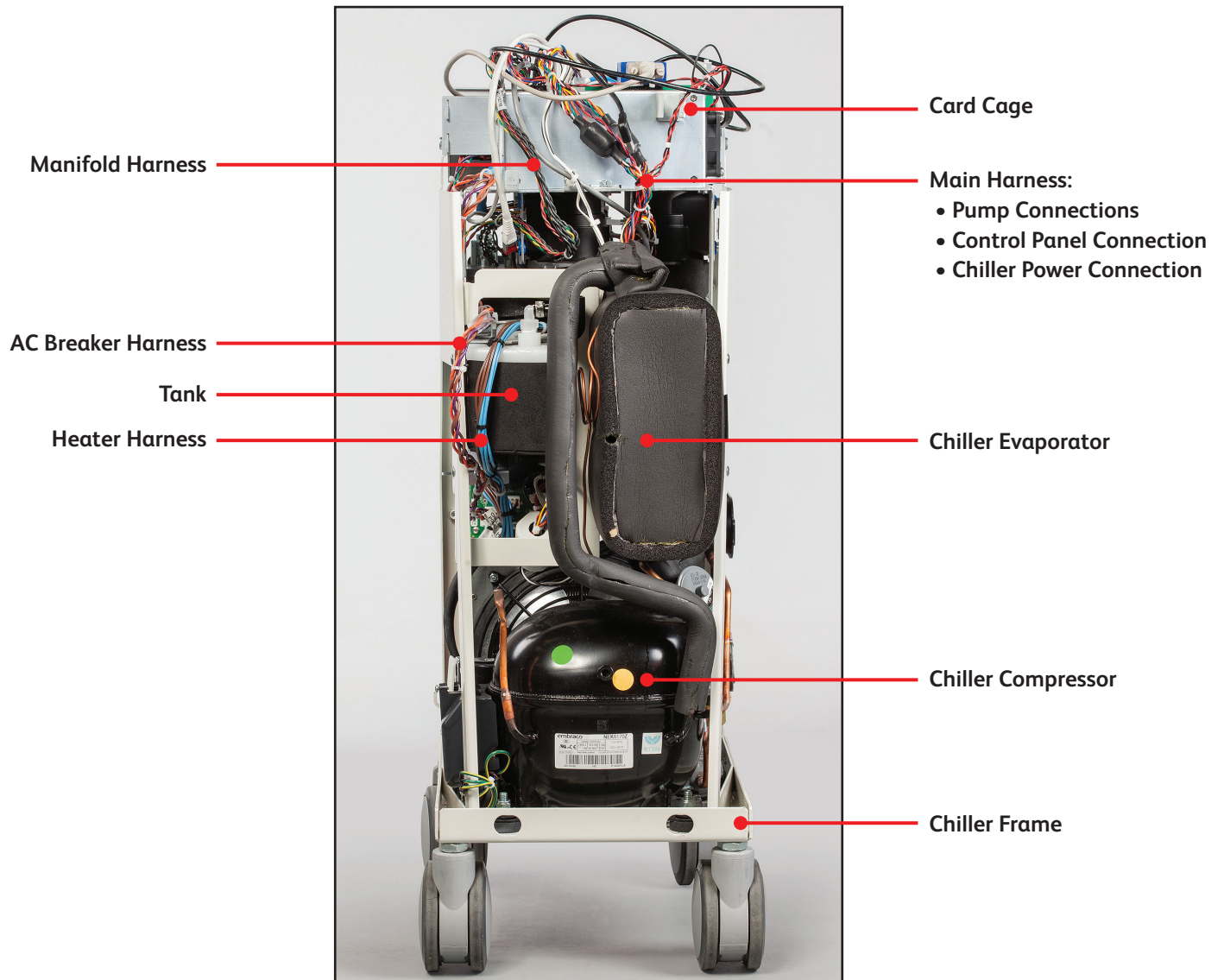


Fig 8-2 Control Module, Front inside view

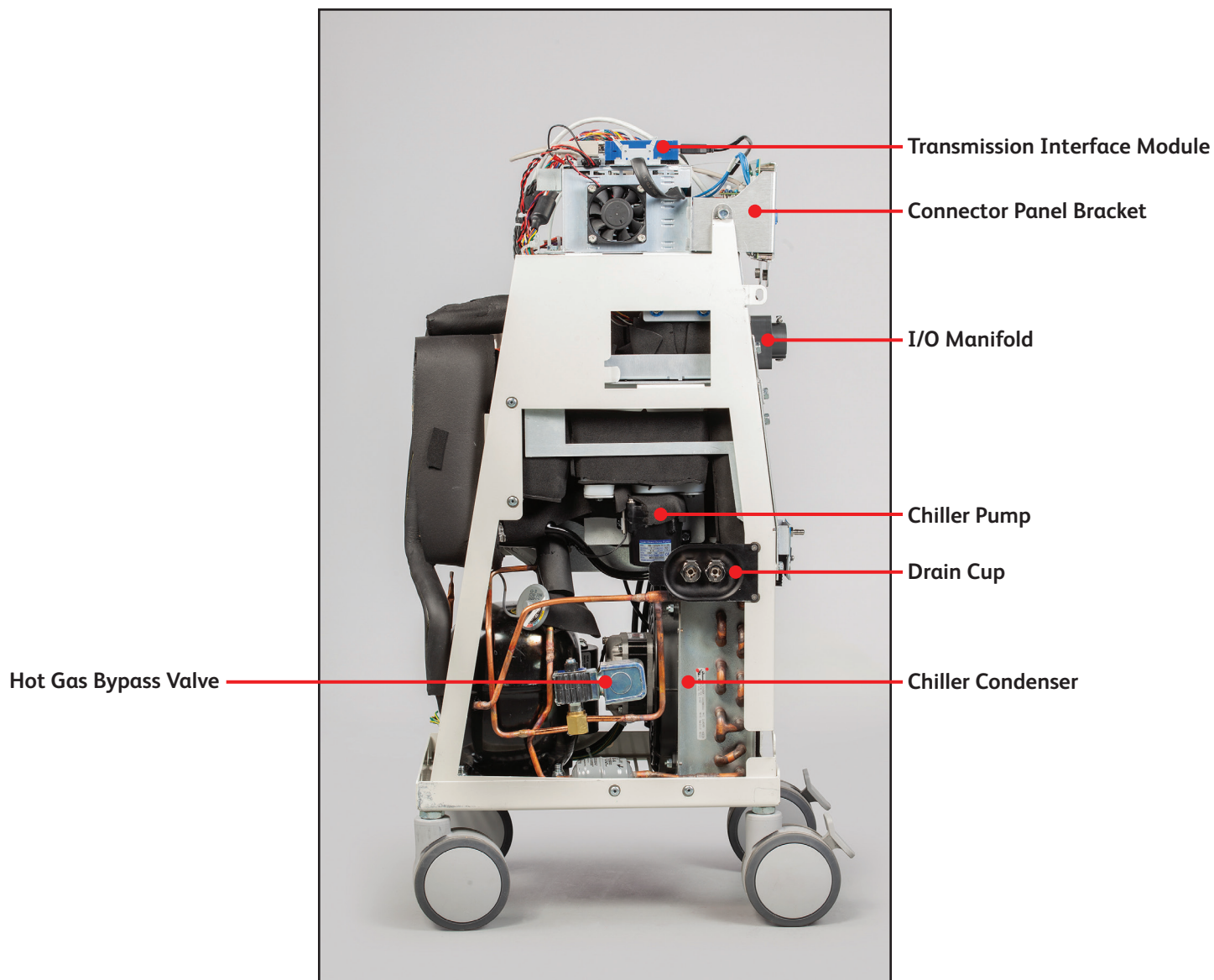


Fig 8-3 Control Module, Right inside view

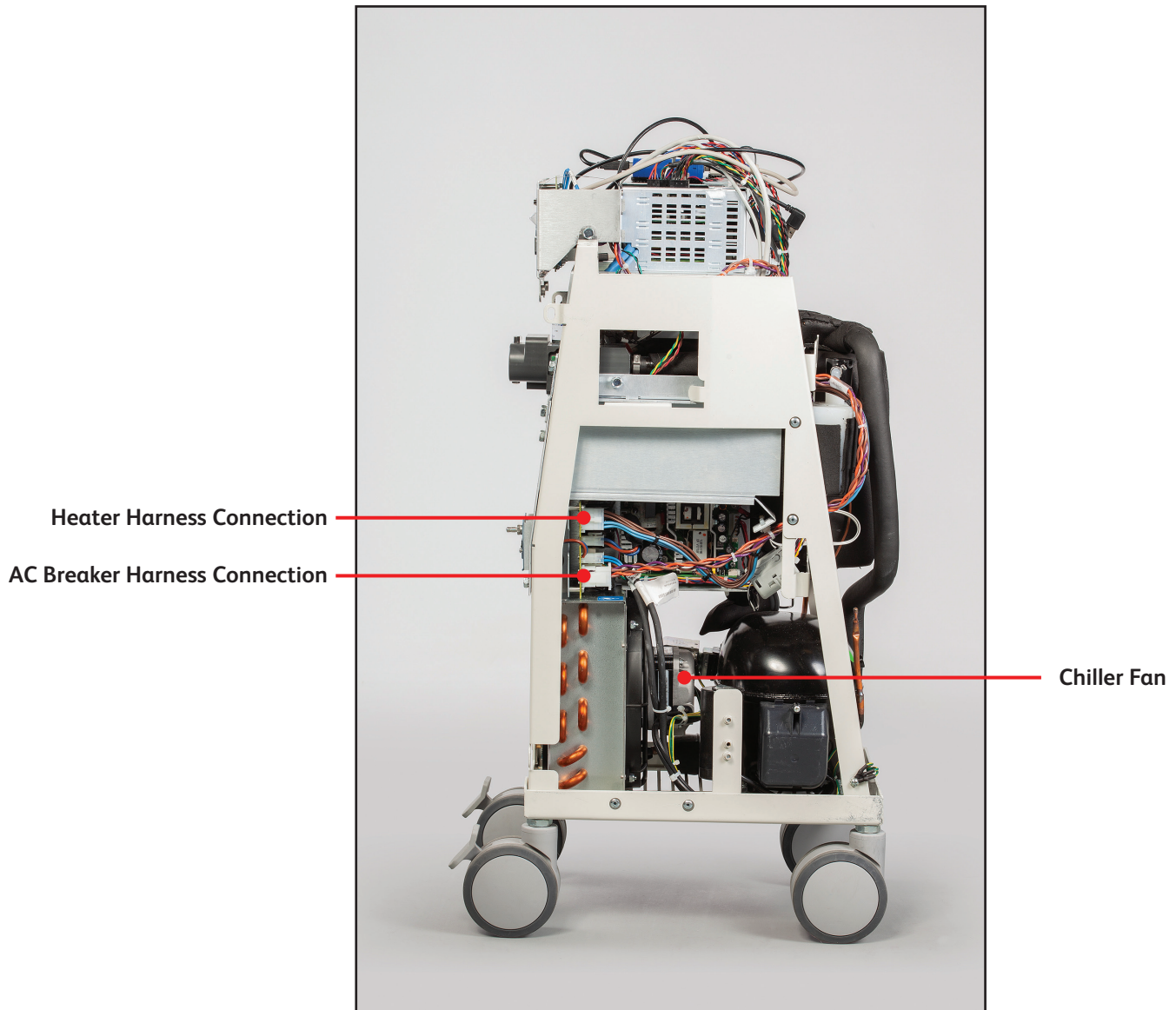


Fig 8-4 Control Module, Left inside view

Input/Output (I/O)
Circuit Card

Isolation
Circuit Card

Processor
Circuit Card

Power
Circuit Card



Fig 8-5 Card Cage, Circuit Card Identification

The following two (2) Circuit Cards are mounted on the lower bracket next to the Chiller Condenser.

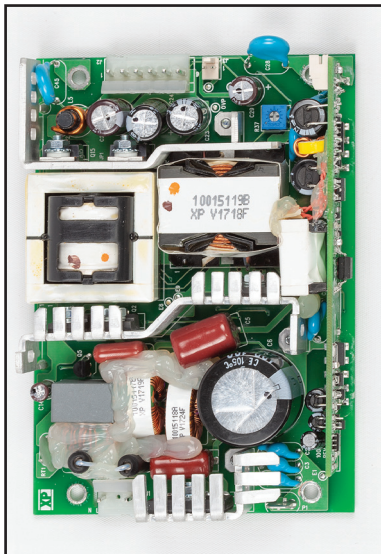


Fig 8-6 Power Supply

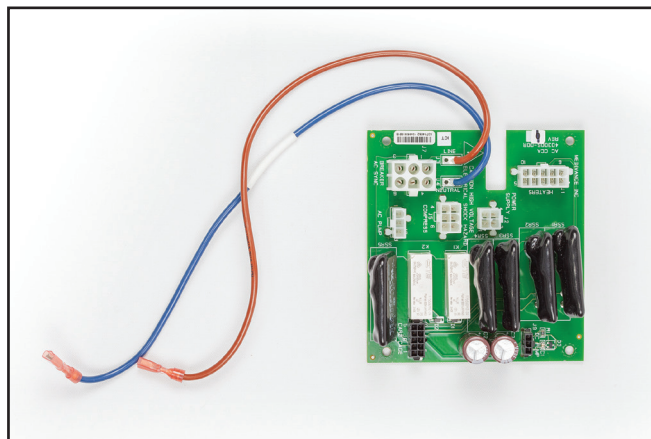


Fig 8-7 AC PCB

8.1 Tools/Pre-service Requirements

Tools required for component replacement:

- 7/16" (11mm) nut driver
- 5/16" (8mm) nut driver
- 5/32" (4mm) hex wrench
- Phillips head screwdriver
- Flat blade screwdriver
- 13/16" (21mm) wrench
- 9/16" (14mm) wrench
- 7/16" (11mm) wrench
- 1/16" (1.5mm) hex key
- Wire cutter, small
- Needle nose pliers

Attention: After completion of the total drain, prior to beginning repair of the device, ensure that the device is unplugged from the power supply.

When working on or servicing any equipment that is suspected of being exposed to bodily fluids or pathological samples, ensure that the unit is decontaminated prior to beginning service.

8.2 Drain the Control Module

Drain the device before disassembling it. A passive drain is adequate for most maintenance procedures.

Passive Drain

Tools and Supplies required:

- Arctic Sun™ Drain Tube

1. Turn the Control Module off.

Attention: Draining the system with power on may damage the chiller.

2. Connect the Drain Tube to the two drain ports on the side of the device behind the drain door. Place the other end of the Drain Tube into a container with a capacity of at least four (4) liters.

Note: There will still be some moisture present as you disassemble the unit.



Fig. 8-8 Passive drain

Total Drain

A total drain activates the pumps to remove residual water. It is essential to perform this process if the device is to be shipped or if the hydraulic components are to be removed.

1. After completing a Passive Drain, power on the Control Module.
2. Go to the Advanced Setup screen from the Patient Therapy Selection screen on the Control Panel, press the Total Drain Start button and follow the instructions.

Advanced Setup	
Data	Calibration
Download	Begin Process
Connectivity Settings	Last Calibrated
Location / Time	Next Calibration (uses)
Language	(or hours)
Number Format	System
Current Time	Maintenance
Date Format	Total Drain
Current Date	Default Settings
Software Version	Save as Default
Version	Last Saved

Fig. 8-9 "Total Drain" on Advanced Setup screen

8.3 Remove RIM Back Panel

Tools and Supplies required:

- 7/16" (11mm) nut driver
or 5/32" (4mm) hex wrench
- Phillips head screwdriver

Note: Removal of the RIM back panel and front case assembly is required for all maintenance steps in this section.

1. Remove the fluid delivery line and patient temperature cables if present.
2. Using a phillips head screwdriver, remove the two (2) screws securing the power cord bracket to the back of the device then unplug the power cord.
3. Loosen the two (2) thumbscrews holding the screen filter to the back panel, then slide the filter to the right to remove.
4. Using a 7/16" (11mm) nut driver or 5/32" hex wrench (whichever is applicable for the screw installed), remove the four (4) screws holding the back panel to the front case assembly and remove the back panel.



Fig 8-10 Back Panel with removal of screen filter and screws

8.4 Remove Front Case Assembly

Tools and Supplies required:

- 7/16" (11mm) nut driver
- Flat blade screwdriver

1. Lock all casters prior to attempting to remove the front case assembly.
2. Disconnect the ethernet cable, USB cable and T.I.M. cable from the control panel.
3. Using a 7/16" (11mm) nut driver, remove the four (4) screws that hold the front case assembly to the frame.
4. If necessary, use a flathead screwdriver to gently pry the front case assembly from the frame. Take care not to damage shell if using a tool to pry shell from frame.
5. Slide the front case assembly forward and rest on the ground. Remove the ferrite from the bracket on the back of the card cage.
6. Remove the zip tie around the communications connector and disconnect both communications and power connections from the top of the card cage.

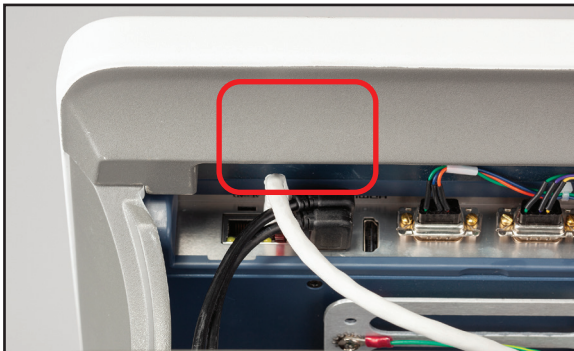


Fig 8-11 Disconnect cables from control panel (step 2)

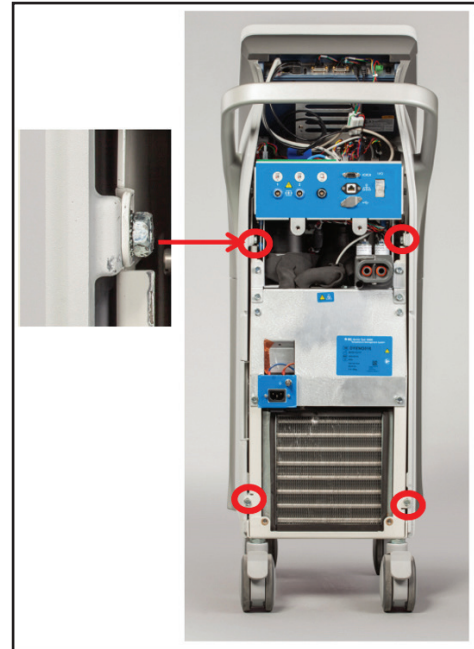


Fig 8-12 Remove screws from Front Case Assembly (step 3)

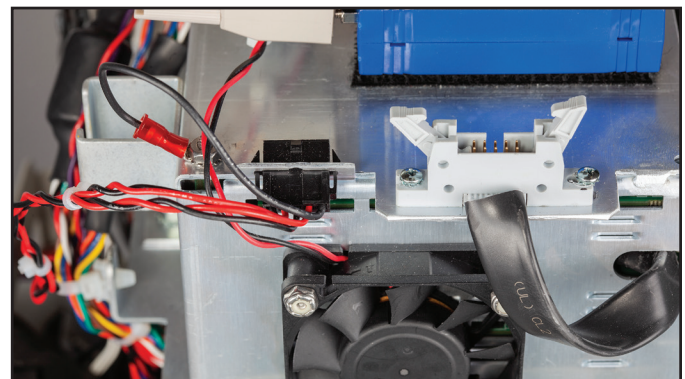


Fig 8-13 Disconnect communications/power connectors (step 6)

8.5 Replace Front Case Assembly Components

Tools and Supplies required:

- 7/16" (11mm) nut driver

1. Place the front case assembly on its side to allow for easier access to the control panel assembly.
2. Disconnect the upper main harness and speaker harness from the control panel.
3. Using a phillips screwdriver, remove the four (4) screws securing the control panel bracket to the control panel then remove the bracket assembly with harnesses attached from the control panel.
4. Using a 7/16" (11mm) nut driver, remove the two (2) screws securing the control panel strap then remove the control panel and strap from the front panel.
5. Using a 7/16" (11mm) nut driver, remove the two (2) screws on each side securing the handle support plates to the left and right side panels then remove the support plates.

6. Using a 7/16" (11mm) nut driver, remove the six (6) screws holding the front panel to the side panels then disengage each of the side panels from the slots in the top of the front panel and remove the side panels and handle.

Note: Some minor mechanical agitation may be required

7. Replace desired component and reassemble.



Fig 8-14 Disassemble Front Case Assembly

8.6 Replace the Control Panel Assembly

Tools and Supplies required:

- 7/16" (11mm) nut driver
- Phillips head screwdriver

1. Place the front case assembly on its side to allow for easier access to the control panel assembly.
2. Disconnect the upper main harness and speaker harness from the control panel.
3. Using a phillips screwdriver, remove the four (4) screws securing the control panel bracket to the control panel then remove the bracket assembly with harnesses attached from the control panel.
4. Using a 7/16" (11mm) nut driver, remove the two (2) screws securing the control panel strap then remove the control panel and strap from the front case assembly.
5. Disconnect the upper main harness and speaker harness from the new control panel assembly.
6. Using a phillips screwdriver, remove the four (4) screws securing the control panel bracket to the new control panel assembly then remove the bracket assembly with harnesses attached from the control panel.
7. Grasp new Control Panel and slide into the front panel by first aligning the panel just below the screws in the handle support plates.

Note: The speaker should be facing to the right inside the shell and the control panel wiring connections should be facing upwards.

8. Install the control panel strap to secure the panel in place.
9. Install the control panel bracket assembly back onto the control panel securing with the four (4) screws previously removed. Ensure the ground wire is routed under the lower right screw. Reference Fig 8-16.

10. Connect the speaker harness and the three (3) connectors connecting the upper main harness to the top of the control panel.

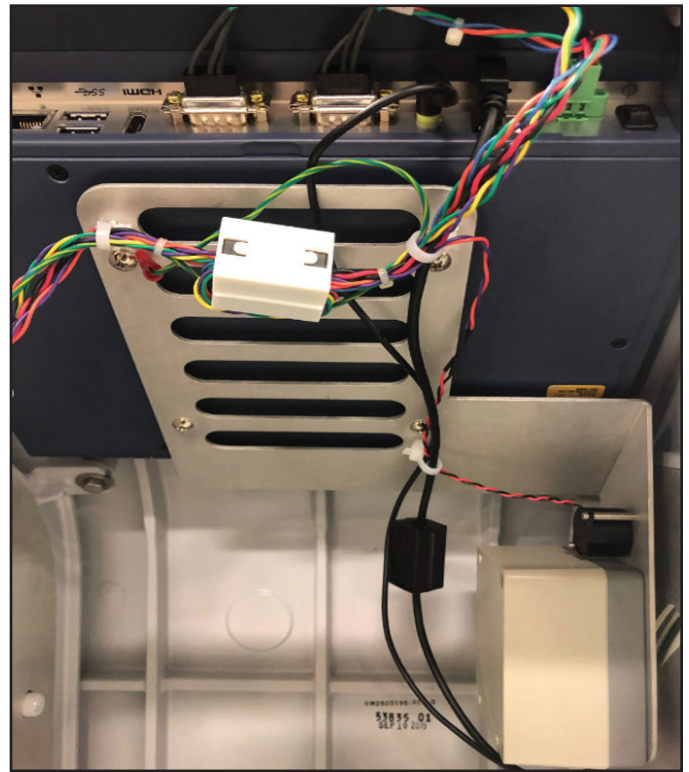


Fig 8-15 Control Panel Assembly installed in front case assembly

8.7 Removing / Replacing Circuit Cards from Card Cage

Tools and Supplies required:

- Wire cutters (small)
- 1/16" (1.5mm) hex key
- Flat blade screwdriver
- Phillips head screwdriver

Attention: Observe local electrostatic discharge control procedures when handling circuit cards.

1. Using a 7/16" (11mm) nut driver, disassemble the connector panel assembly from the frame by removing the two (2) screws on either side of the panel. Gently suspend the panel by the wiring harness.
2. Disconnect the blue temp connector PCB cable from the isolation board.
3. Using a 1/16" (1.5mm) hex key, remove the four (4) screws securing the circuit cards and grounding spring then carefully remove the grounding spring for use in reassembly.

A) Input / Output (I/O) Circuit Card

1. Carefully disconnect each of the eight (8) cables connected to the I/O card, releasing each locking tab before pulling. These connections are illustrated in Fig. 8-19. Clip cable ties with wire cutters as needed.
2. Gently pry the I/O board away from card cage backplane, then slide and remove the I/O board from the card cage.
3. Obtain a new I-O circuit card and gently slide the board into the card cage.

Note: When replacing the circuit card, ensure the card fits into retaining grooves on either side of the card cage.

4. When re-connecting the connections after repair, check labels on J6 and J4 connectors to ensure correct connections.
5. After replacing the I/O Circuit Card, perform a calibration (see Chapter 9).

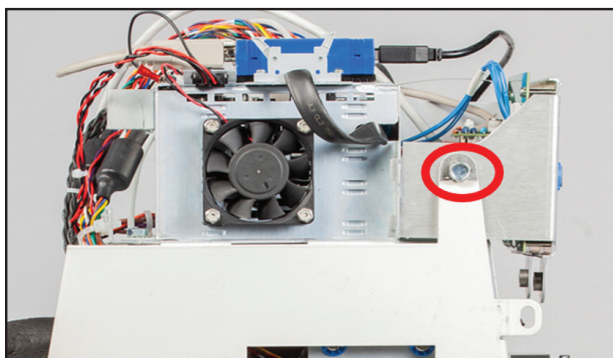


Fig 8-17 Disassemble Connector Panel from Chiller Frame



Fig 8-18 Suspend Connector Panel by wiring harness

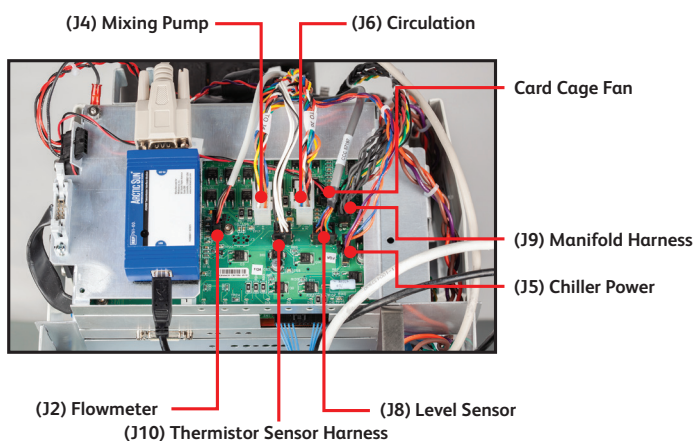


Fig 8-19 I/O Circuit Card Connections

B) Isolation Circuit Card

1. Remove and retain the two (2) screws attaching the ribbon cable to the top of the card cage.
2. Gently pry the isolation board away from card cage backplane, then slide and remove the isolation board from the card cage.

Note: When replacing the circuit card, ensure the card fits into retaining grooves on either side of the card cage.

3. Obtain a new Isolation Board Assembly and gently slide the board into the card cage.
4. Connect the ribbon cable to the top of the card cage using the two (2) screws previously removed.
5. After replacing the Isolation Circuit Card, perform a calibration (see Chapter 9).

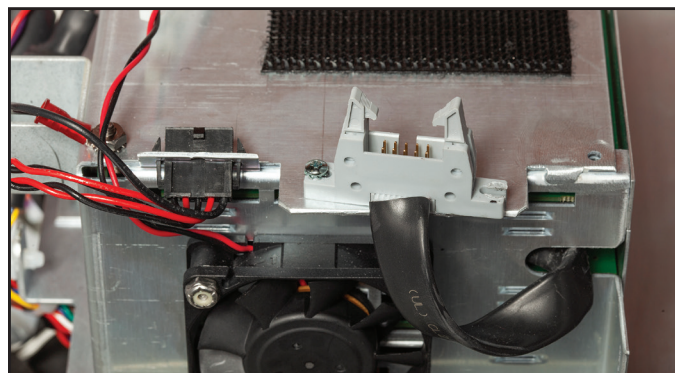


Fig 8-20 Remove Ribbon Cable Connection from Card Cage

C) Processor Circuit Card

1. Gently pry the processor board away from card cage backplane, then slide and remove the processor board from the card cage.
2. Obtain a new Processor circuit card and gently slide the board into the card cage.

Note: When replacing the circuit card, ensure the card fits into retaining grooves on either side of the card cage.

3. After replacing the Processor Circuit Card, perform a calibration (see Chapter 9).

D) Power Circuit Card

1. Gently pry the power board forward from the card cage backplane approximately 3-5 inches (1.2-2.0 cm).
2. Carefully disconnect each of the three (3) connections on the circuit board, releasing each locking tab before pulling. Then slide the power board completely out of the card cage and remove.
3. Obtain a new Power Circuit Card and gently slide the board partially into the card cage.

Note: When replacing the circuit card, ensure the card fits into retaining grooves on either side of the card cage.

4. Reconnect the three (3) wiring harnesses to the power board (J2, J4 and J6) then slide the circuit card in ensuring that all wiring fits into the groove in the sheet metal and no wires are pinched.

- After replacing the Power Circuit Card, perform a calibration (see Chapter 9).

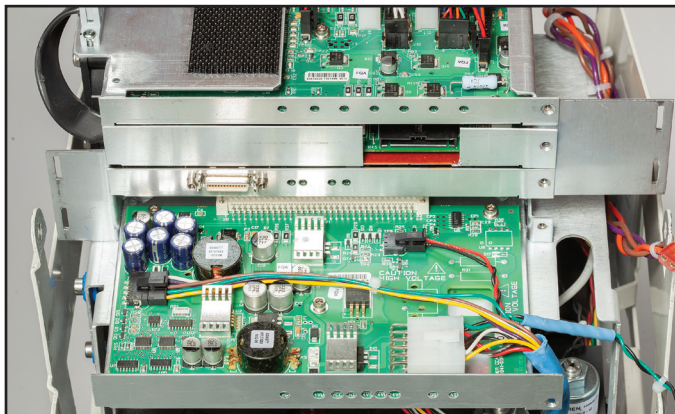


Fig 8-21 Power Circuit Card Connections

8.8 Replace the Panel ESD Board

Tools and Supplies required:

- 7/16" (11mm) nut driver
- Phillips screwdriver

- Using a 7/16" (11mm) nut driver, disassemble the connector panel assembly from the frame by removing the two (2) screws on either side of the panel. Gently suspend the panel by the wiring harness (see figures 8-17 & 8-18).
- Disconnect the blue temp connector PCB cable from the isolation board.
- Unthread and remove the three (3) plastic Lemo nuts for PT1, PT2, and Temp Out from the front of the connector bracket.
- Disconnect the blue temp connector PCB cable from the back of the panel ESD board.
- Remove the four (4) screws that secure the panel ESD board to the connector bracket and remove the board.
- Install the new panel ESD board and secure with the four (4) phillips head screws then reattach the blue temp connector PCB cable to the back of the board.
- Reinstall the Lemo nuts for PT1, PT2 and Temp out on the front of the connector bracket.
- Assemble the connector panel bracket assembly to the device and connect the blue temp connector PCB cable to the isolation board.
- Perform a Calibration (see chapter 9)

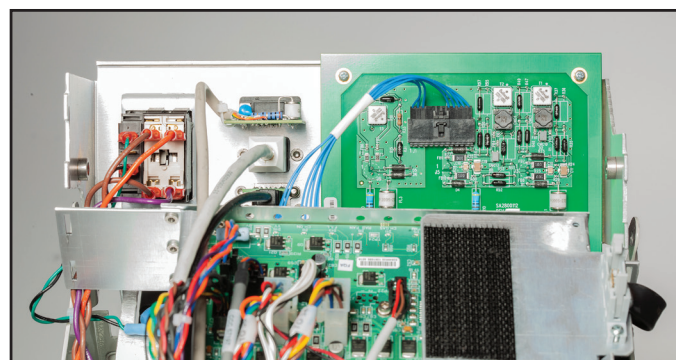


Fig 8-22 Back of Panel ESD Board

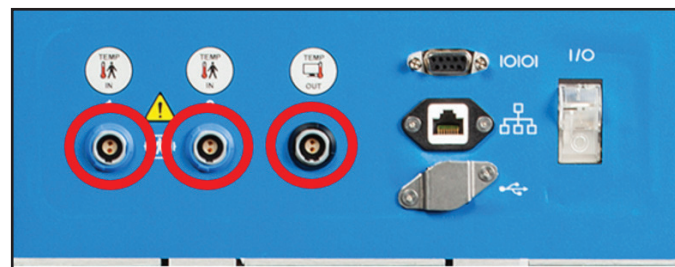


Fig 8-23 Lemo Nuts on front of Connector Bracket Assembly

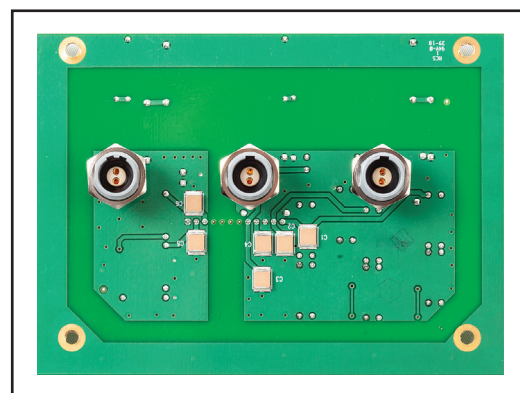


Fig 8-24 Panel ESD Board

8.9 Replace the Connector Panel Bracket Assembly

Tools and Supplies required:

- 7/16" (11mm) nut driver
- Needle nose pliers
- Phillips screwdriver

- Using a 7/16" (11mm) nut driver, disassemble the connector panel assembly from the frame by removing the two (2) screws on either side of the panel. Gently suspend the panel by the wiring harness (see figures 8-17 & 8-18).
- Disconnect the blue temp connector PCB cable from the isolation board.
- Carefully disconnect the AC breaker harness from the back of the power inlet switch using needle nose pliers as necessary.

Attention: Do not rock spade connectors back and forth when removing as this can distort connectors.

4. Disconnect the RS232 cable from the back of the USB to RS232 converter (T.I.M.) and the USB cable from connector panel bracket then remove the connector panel bracket assembly from the device.
5. Remove the panel ESD board with blue temp connector PCB cable from the connector panel per step 8.8 and install on the new Connection Bracket Assembly.
6. Reconnect and route all wiring, reference (figure 8-25) for placement of AC Breaker harness on the back of the power switch.

Note: Orientation of AC Breaker Harness Connections:

- Brown wrapped with orange stays with orange
- Brown wrapped with purple stays with purple

7. Assemble the connector panel bracket assembly to the device and connect the blue temp connector PCB cable to the isolation board.



Fig 8-25 Placement of AC Breaker Harness Connections

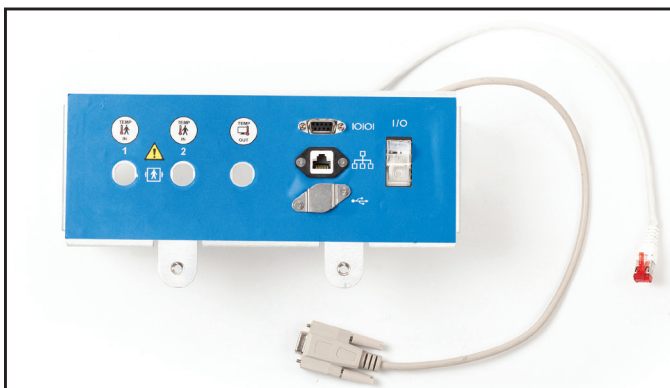


Fig 8-26 Connector Panel Bracket Assembly

8.10 Replace the USB to RS232 Converter (T.I.M.)

1. Disconnect the RS232 cable from the back of the USB to RS232 converter (T.I.M.).
2. Detach the USB to RS232 converter (T.I.M.) from the top of the card cage.

3. Assemble the new USB to RS232 converter (T.I.M.) to the top of the card cage with the USB connection towards the connector panel (see figure 8-27).
4. Reconnect the RS232 cable to the back of the USB to RS232 converter (T.I.M.).

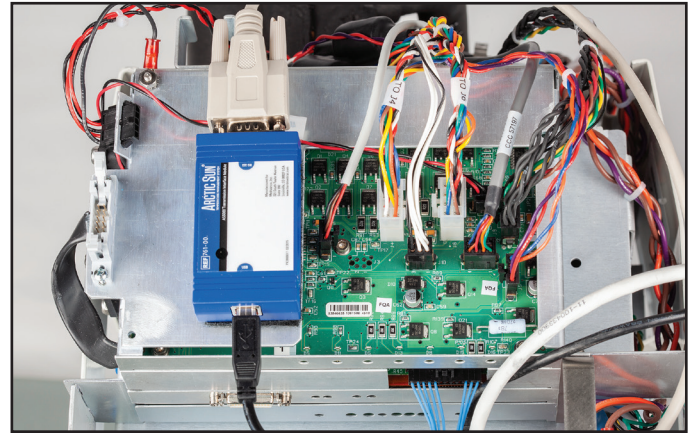


Fig 8-27 Orientation of T.I.M. on top of the card cage



Fig 8-28 USB to RS232 Converter (T.I.M.)

8.11 Replace the Level Sensor

Tools and Supplies required:

- 7/16" (11mm) nut driver
- Wire cutters

1. Disconnect the gray Level Sensor harness from the I/O Circuit Card. Remove the cable tie securing the harness to the bracket.
2. Using a 7/16" (11mm) nut driver, remove the screw securing the level sensor bracket.
3. Remove the level sensor along with the plastic sheath from the tank.
4. Insert the new level sensor into the tank, ensure the curve of the tube is facing the bottom of the tank.
5. Reinstall the bracket, reroute and connect the gray Level Sensor harness to the I/O Circuit Card.

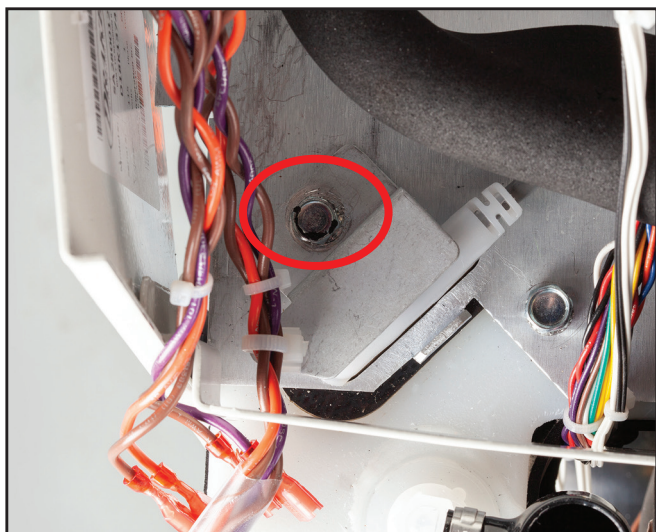


Fig 8-29 Remove Level Sensor bracket



Fig 8-30 Remove Level Sensor and sheath from tank

8.12 Replace the Drain Valves

Tools and Supplies required:

- 1/16" (1.5mm) hex key
- 13/16" (21mm) wrench

Note: Ensure unit is drained prior to performing this repair.

1. Using a 1/16" (1.5mm) hex key, remove the two (2) screws that hold the drain cup to the chiller frame.
2. Gently pull the tubes off the valves from the back side of the drain cup. Support the tubing while removing to ensure tubing is not damaged.
3. Remove the nuts, holding the valves to the drain cup, from the backside of the cup using a 13/16" (21mm) wrench.
4. Insert new valves through drain cup, orient the tabs at the 12 O'clock position and replace the nuts to the backsides of valve.
5. Connect tubes to backside of drain valve and refasten drain cup to chiller frame with the hex screws.

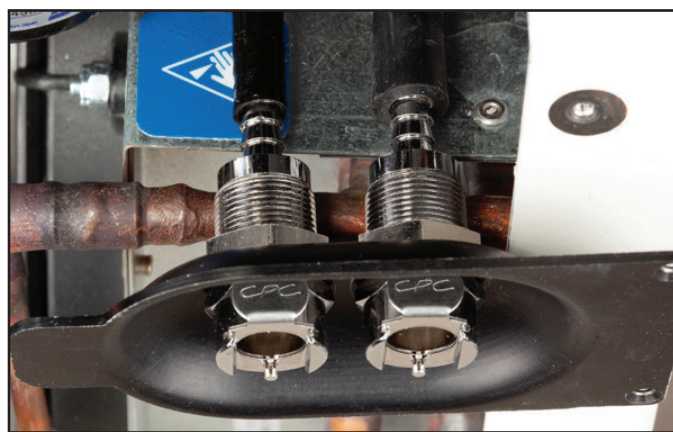


Fig 8-31 Remove tubing from back of drain valves



Fig 8-32 Drain Valves at 12 O'clock position in drain cup

8.13 Replace the Inlet/Outlet Manifold

Tools and Supplies required:

- 7/16" (11mm) nut driver
- Small flat blade screwdriver
- Wire cutters

1. Disconnect the manifold harness from the I/O circuit card. Remove cable ties routing the harness to the upper bracket.
2. Using a 7/16" (11mm) nut driver, loosen and remove the two (2) screws securing the manifold to the upper bracket.
3. Use a small flat blade screwdriver to loosen the clamps that secure the tubing to the back of the manifold.
4. Install new manifold and route wiring for manifold harness to I/O circuit card.
5. Perform calibration (see chapter 9).

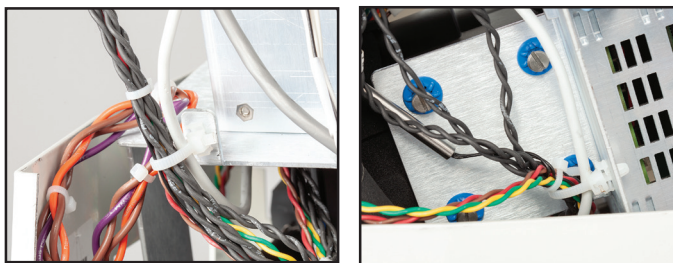


Fig 8-33 Cut cable ties routing manifold harness to upper bracket

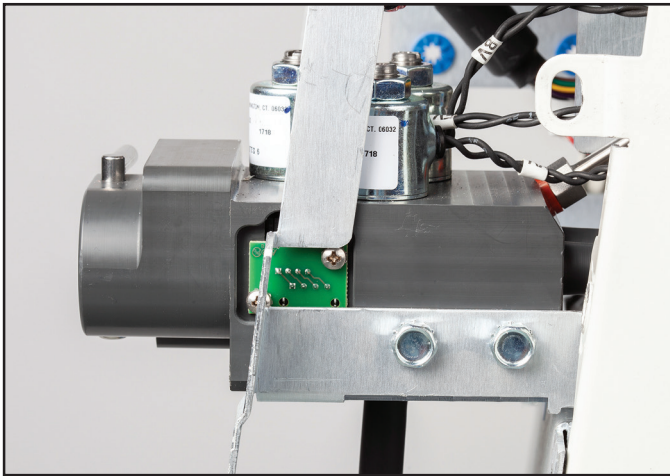


Fig 8-34 Remove screws securing manifold to upper bracket

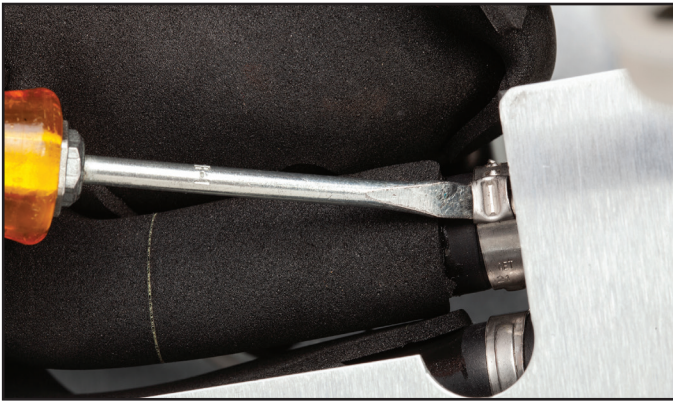


Fig 8-35 Remove hose clamps from back of manifold

8.14 Replace the Inlet/Outlet Manifold Harness

Tools and Supplies required:

- 7/16" (11mm) wrench
- 9/16" (14mm) wrench
- Small flat blade screwdriver

1. Remove the Manifold per (step 8.13).
2. Using a 9/16" (14 mm) wrench, loosen and remove the nuts that secure the solenoids to the manifold. Use a screwdriver to remove the old valves.
3. Using a 7/16" (11mm) wrench, unthread and remove the T3 thermistor from the back of the manifold.
4. Disconnect the manifold harness from the pressure transducer.
5. When installing the new manifold harness, prior to threading in the T3 thermistor, twist the wiring in the counterclockwise direction 3 full rotations to preload the wiring so that when threading the thermistor into the manifold the wires will not be strained.
6. Ensure the solenoids are installed in the correct locations (see fig 8-37)

Note: When reinstalling the solenoids, if they are not installed properly it will prevent the device from functioning properly.

7. Remount the manifold back into the upper bracket.
8. Perform a calibration (see chapter 9).



Fig 8-36 Manifold Harness

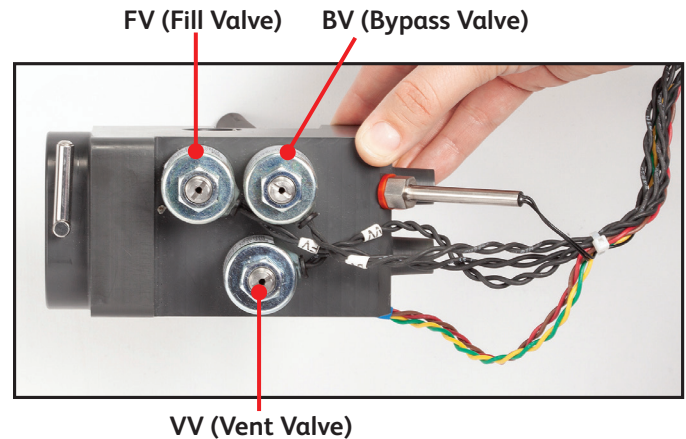


Fig 8-37 Manifold, showing position of the 3 solenoids (step 6)

8.15 Replace the Power Supply

Tools and Supplies required:

- Phillips screwdriver

1. Disconnect the jumper from the AC PCB and the two (2) lower main harness connections on the power supply board.
2. Using a phillips screwdriver, remove the four (4) screws holding the power supply to the lower bracket and carefully remove the power supply.
3. When installing the replacement power supply, ensure the two (2) ground wire ring terminals are installed with the upper right screw on the circuit card.
4. Reinstall the jumper to the AC PCB and connect the two (2) lower main harness connections on the power supply board.

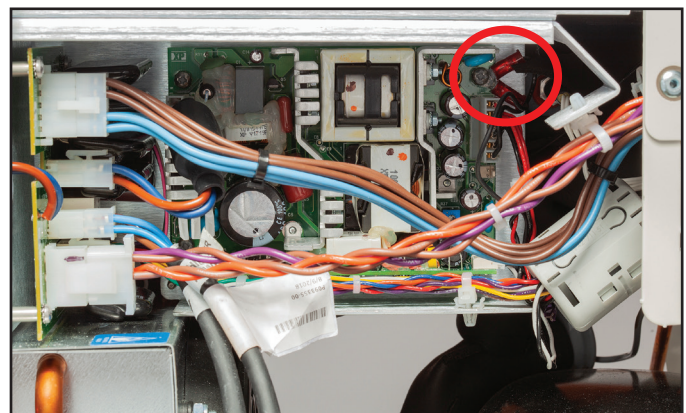


Fig 8-38 Ground wires installed under the upper right screw

8.16 Replace the AC PCB

1. Remove the power supply per step 8.15.
2. Disconnect the AC breaker harness, power supply jumper, lower main harness, chiller pump harness, chiller harness, and the heater harness from the AC PCB.
3. Using needle nose pliers, carefully disconnect the two (2) spade terminals connected to the top of power inlet module. Carefully feed the wires through the opening in the sheet metal prior to removing circuit card.
4. Using a phillips head screwdriver, remove the four (4) screws connecting the AC PCB to the lower bracket.
5. Mount the new AC PCB back to the frame using the four screws.

Note: When installing, reconnect the lower main harness and chiller pump connections first.

6. Route the two (2) power inlet wires through the opening and reconnect them to the power inlet module. Note the orientation of the wires (see figure 8-39).
7. Reconnect the AC breaker harness, chiller harness lower main harness, chiller pump harness, and heater harness, if not already connected.
8. Reinstall the power supply, ensure the two (2) ground wire ring terminals are installed with the upper right screw on the circuit card.
9. Reinstall the jumper to the AC PCB and connect the two (2) lower main harness connections on the power supply board.

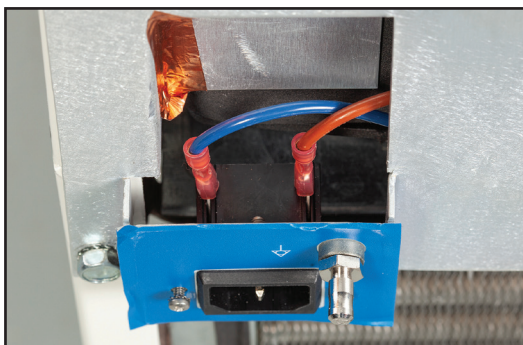


Fig 8-39 Placement of power inlet wires (blue on left, red on right)

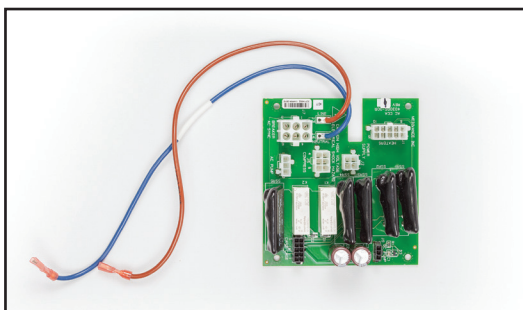


Fig 8-40 AC PCB

8.17 Repairs Requiring removal of the Upper Components

Tools and Supplies required:

- 7/16" (11mm) nut driver

The following repairs will require the removal of the Upper Components via the following steps.

1. Using a 7/16" (11mm) nut driver, disassemble the connector panel assembly from the frame by removing the (2) screws on either side of the panel. Gently suspend the panel by the wiring harness.
2. Using a 7/16" (11mm) nut driver, remove the two (2) screws on the front of the device holding the upper bracket to the lower bracket.
3. Using a 7/16" (11mm) nut driver, remove the four (4) screws on the back of the device holding the upper bracket to the frame.
4. Remove L tube, connected to the top of the chiller evaporator, from the tank and push off to the side.
5. Carefully pull up on the upper bracket, leaving the front in contact with the lower half to prevent the wire harnesses from getting damaged. It may be necessary to flex the chiller frame out slightly in order to clear the flanged sheet metal.

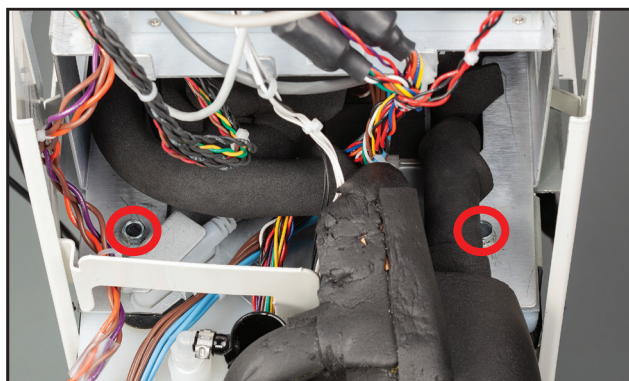


Fig 8-41 Remove screws on front of device (step 2)

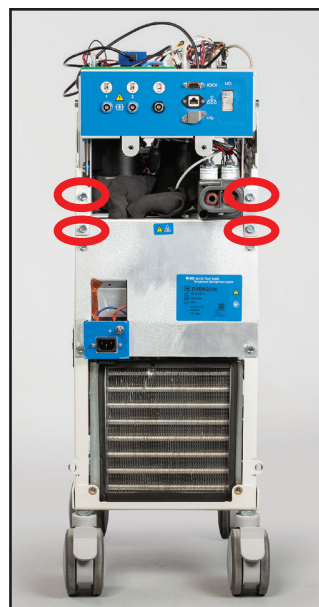


Fig 8-42 Remove screws on back of device (step 3)

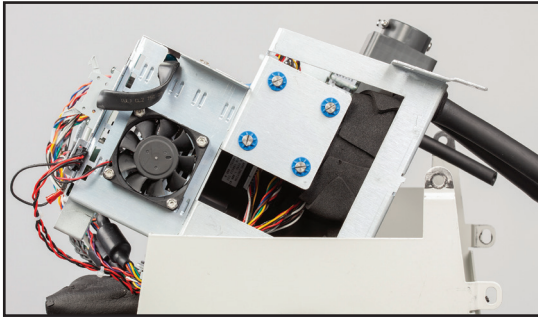


Fig 8-43 Lift up upper bracket (step 5)

8.18 Replace Mixing Pump

Tools and Supplies required:

- Flat blade screwdriver

1. Lift upper bracket to allow access to the pump per step 8.17.
2. Disconnect the cable that connects the Mixing Pump to the I/O Board.
3. Using a flat blade screwdriver, remove the four (4) mounting screws that secure the pump leaving cable ties intact.
4. Carefully remove the Mixing Pump and replace.

Note: When re-connecting cable to pump motor, ensure that the connector is correctly seated, with no exposed pins on either side (see Figure 8-46).

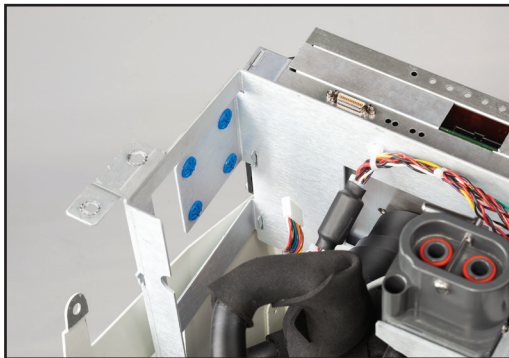


Fig 8-44 Remove mounting screws then remove mixing pump



Fig 8-45 Mixing Pump

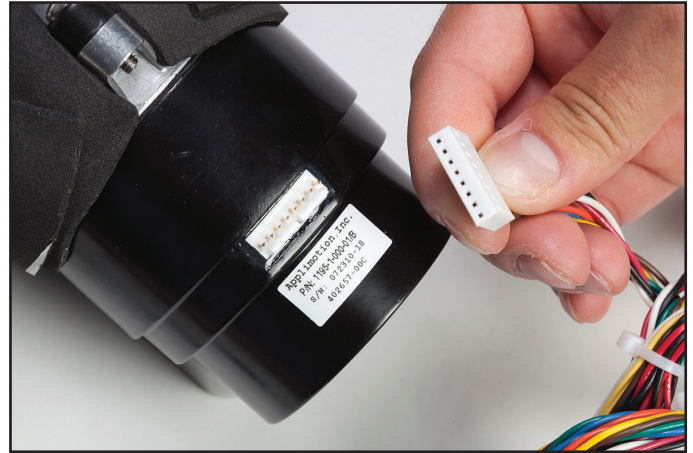


Fig 8-46 Illustration of pump connector prior to being connected (above), connected but seated incorrectly with one pin exposed (below left), and seated correctly (below right)



8.19 Replace Circulation Pump

Tools and Supplies required:

- Flat blade screwdriver
- Small flat blade screwdriver
- Wire cutters

1. Lift upper bracket to allow access to the pump per step 8.17.
2. Disconnect the cable that connects the Circulation Pump to the I/O Board.
3. Using a small flat blade screwdriver, loosen the hose clamp that secures the tubing to the back of the manifold. Slide hose clamp backwards onto tube and then remove tube from manifold.
4. Locate the flowmeter cable and disconnect it from J2 on the I/O Circuit card. Cut the two wire ties that secure the flowmeter cable to the upper bracket.
5. Using a flat blade screwdriver, remove the four (4) mounting screws that secure the pump to the upper bracket.
6. Carefully remove the Circulation Pump and replace.

Note: When re-connecting cable to pump motor, ensure that the connector is correctly seated, with no exposed pins on either side (see Figure 8-46).



Fig 8-47 loosen the hose clamp that secures tubing to manifold

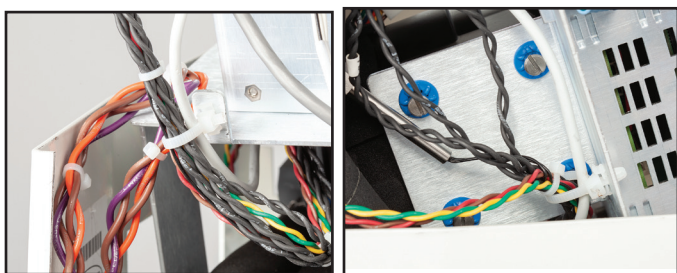


Fig 8-48 Cut cable ties routing flowmeter cable to upper bracket



Fig 8-49 Circulation Pump

8.20 Replace the Heater

Tools and Supplies required:

- 7/16" (11mm) nut driver
- Wire cutters

1. Lift upper bracket to allow access to the heater per step 8.17.
2. Using wire cutters, cut cable ties securing the heater harness to the upper and lower bracket then disconnect the harness from J1 on the AC PCB.

3. Remove the black foam covering the two (2) hex head screw securing the heater to the lower bracket. Then using a 7/16" (11mm) nut driver, remove the two (2) screws.

Attention: Be careful not to knock either of the external tooth washers, located under the heater flange, into the reservoir tank. Remove from tank if this does occur.

4. Carefully remove the heater from the device.
5. Install the new heater assembly into the tank by first directing the orange flow deflector towards the level sensor (see figure 8-52).

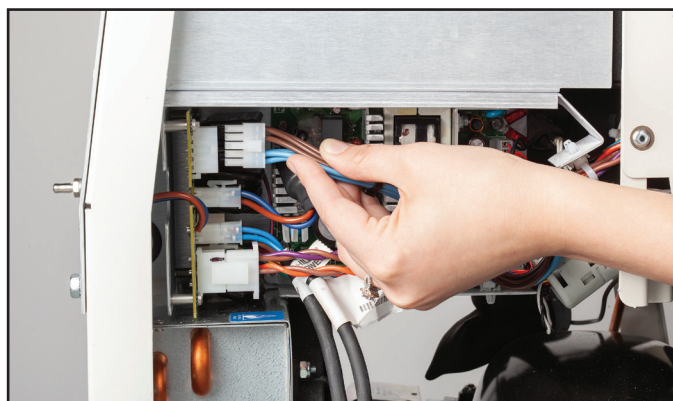


Fig 8-50 Disconnect heater harness from AC PCB

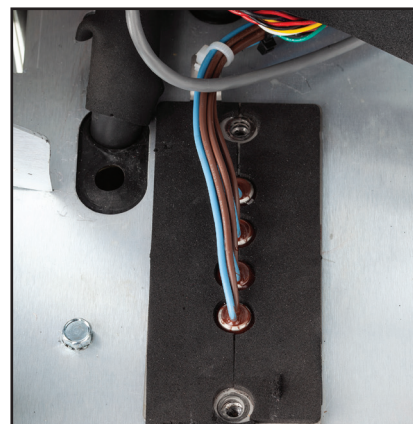


Fig 8-51 Remove screws securing heater (step 3)

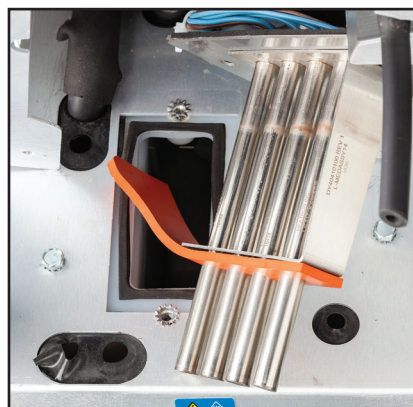


Fig 8-52 Install heater with flow deflector towards level sensor (step 5)

8.21 Replace the Flowmeter

Tools and Supplies required:

- Flat blade screwdriver
- Small flat blade screwdriver
- Wire cutters

1. Remove the Circulation Pump per step 8.19.
2. Remove the insulation from around the flowmeter.
3. Unscrew the flowmeter with tubing attached from the outlet of the pump head. Remove tubing from opposite end of flowmeter for reuse during reassembly.
4. Install the new flowmeter on the pump outlet and install tubing previously removed. Insulate the flowmeter after installation is complete.

Note: When installing the new flowmeter observe arrow that indicates direction of flow. **This arrow should be oriented away from the pump.**

5. Reinstall the Circulation pump.

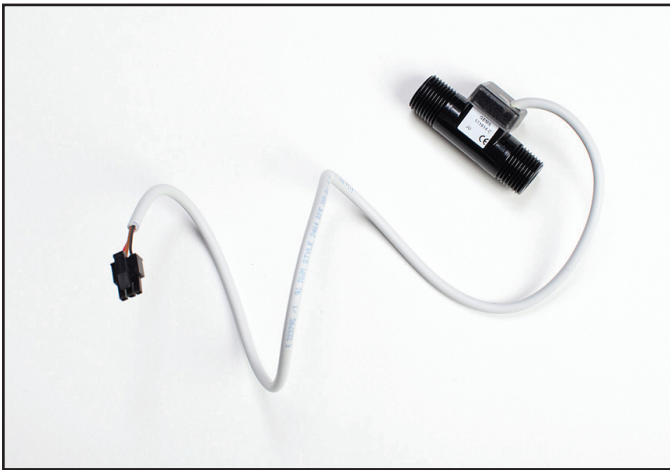


Fig 8-53 Flowmeter



Fig 8-54 Flowmeter with arrow indicating direction of flow; same direction as Circulation Pump outlet

8.22 Repairs requiring removal of Internal Components

Tools and Supplies required:

- 7/16" (11mm) wrench
- 1/16" (1.5mm) hex key
- Small flat blade screwdriver

The following repairs will require the removal of the Internal Components via the following steps.

Attention: Ensure the unit is drained prior to completing any repairs in this section.

1. Loosen the two (2) hose clamps that hold the molded tube (Y tube) to the chiller evaporator.
2. Using a 7/16" (11mm) nut driver, remove the two (2) screws that hold the connection panel to the chiller frame.
3. Using a 7/16" (11mm) nut driver, remove the six (6) screws that mount the internal components to the chiller frame.
4. Using a 1/16" (1.5mm) hex key, remove the two (2) screws that hold the drain cup to the chiller frame.
5. Disconnect the chiller wire harness (J5) from the AC PCB.
6. Remove L tube, connected to the top of the chiller evaporator, from the tank and push off to the side.
7. Gently pull the drain cup/drain valves from tubing and set to the side for reassembly.
8. If desired, gather and secure cabling to prevent the cables from being caught and damaged on frame prior to removing internal components. Photo
9. Lock the caster wheels and pull the internal components from the chiller frame.
10. After removing the internal components, lay the components in a secure place on its side.

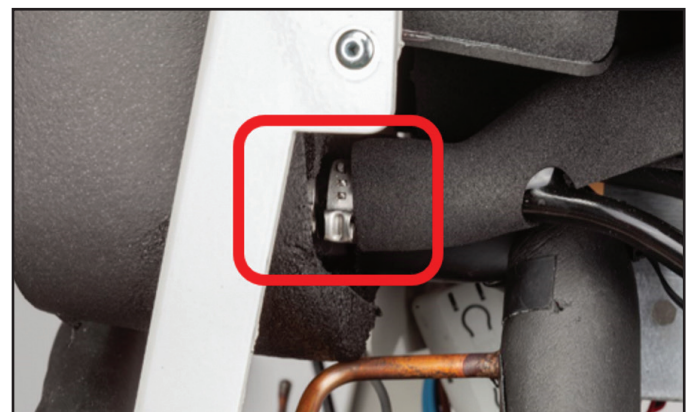


Fig 8-55 Loosen hose clamps connecting Y-tube to evaporator

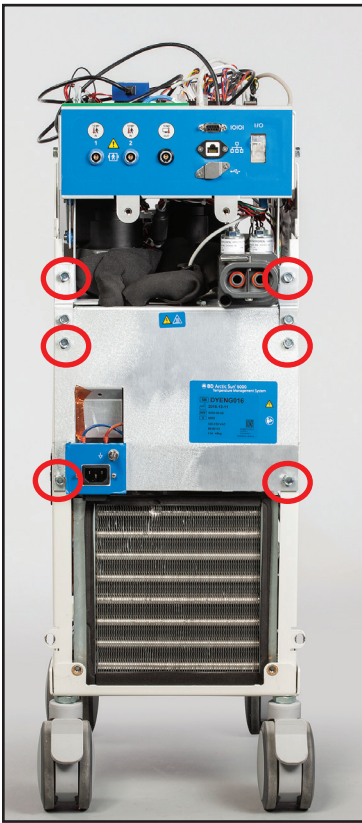


Fig 8-56 Remove six screws securing internal components

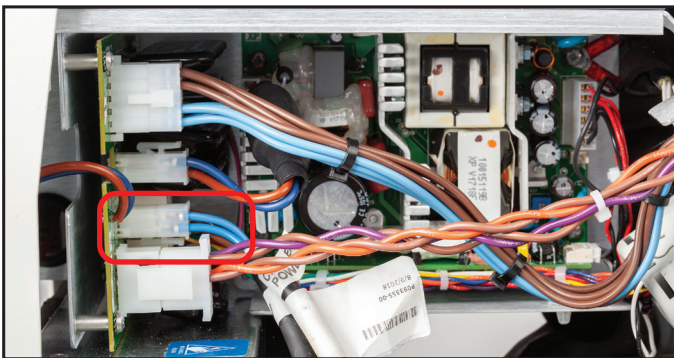


Fig 8-57 Disconnect chiller harness (J5) from AC PCB

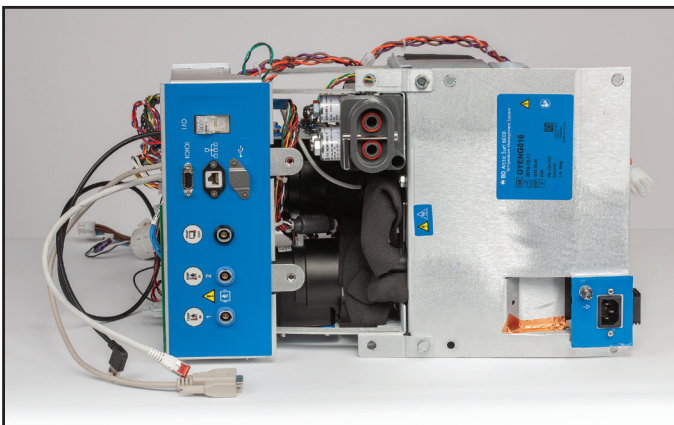


Fig 8-58 Remove internal components

8.23 Replace the Chiller Pump

Tools and Supplies required:

- 5/16" (8mm) nut driver

1. Remove Internal Components per step 8.22.
2. Disconnect the chiller pump harness from the bottom of the pump.

Note: The chiller pump harness will be reused during reassembly as long as no damage or defects are present on the harness. If harness is damaged/defective disconnect the harness from J9 on the AC PCB and remove the cable tie holding the cable to the lower bracket.

3. Using a 5/16" (8mm) nut driver, remove the two (2) screws holding the Chiller Pump to the bracket.
4. Carefully pull down on the chiller pump to remove it from the tank.
5. Place two (2) new O-rings in the slots on the chiller pump outlet as shown. Ensure that the O-rings sit completely inside the slots and the ring is not twisted.
6. Wet the surface of the chiller pump outlet/ previously installed O-rings and slots inside the tank to assist with assembly of the pump in the tank.
7. Carefully install the pump into the tank by lining up the outlet of the pump with the hole in the tank and pushing upwards.

Attention: Ensure that the O-rings do not move out of slots during assembly. Inspect the seal between the tank and pump for any protruding O-ring. If any part of the O-ring is protruding, remove the pump and inspect the O-ring for damage before reinstalling.

8. Reinstall the two (2) screws securing the chiller pump to the bracket.
9. Reconnect the chiller pump harness to the bottom of the pump.
10. Reassemble the device.

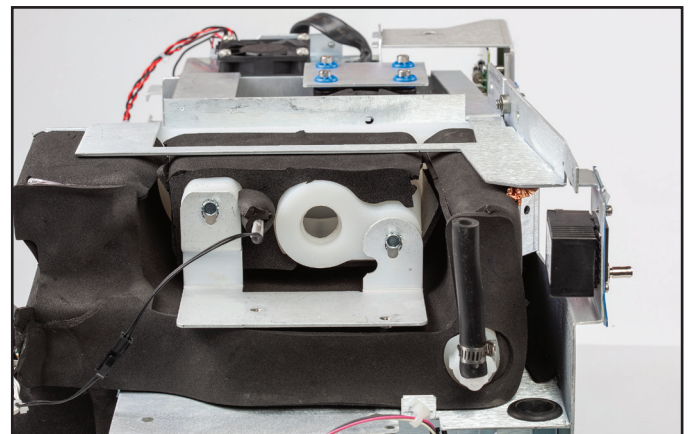


Fig 8-59 Remove Chiller Pump from bracket



Fig 8-60 Install Chiller Pump with O-Rings on Pump Outlet



Fig 8-61 Chiller Pump

8.24 Replace the Thermistor Sensor Harness

Tools and Supplies required:

- 7/16" (11mm) wrench

1. Remove Internal Components per step 8.22.
2. Remove the foam insulation from around the T4 thermistor (next to the chiller pump) and T1/T2 thermistor (next to the power supply).
3. Remove the associated cable ties for the harness wiring.
4. Remove the chiller pump per step 8.23.
5. Using a 7/16" wrench, loosen the T1/T2 & T4 thermistors from the tank and remove.
6. Obtain new thermistor sensor harness and disconnect the sensors by unclipping the connection on the harness.
7. Install rubber washers over the T1/T2 & T4 thermistors and carefully install the thermistors into the tank. Tighten the thermistors finger tight plus ¼ turn, ensuring washer is compressed between the tank and sensor housing.

Note: Verify the proper locations of T1/T2 (next to the power supply) and T4 (next to the chiller pump). If replaced in incorrect position, it would prevent device operation.

Attention: To avoid damaging the harness, carefully twist each of these wires in the opposite direction to provide some slack before slipping the washer on and rotating the thermistor into place.

8. Reconnect the T4 and T1/T2 sensors harnesses.
9. Reroute the harness and secure to the upper bracket using a cable tie.
10. Reinstall the chiller pump per step 8.23 and replace insulation between the sensors and tank.
11. Reassemble the device.
12. Perform a calibration see chapter 9.

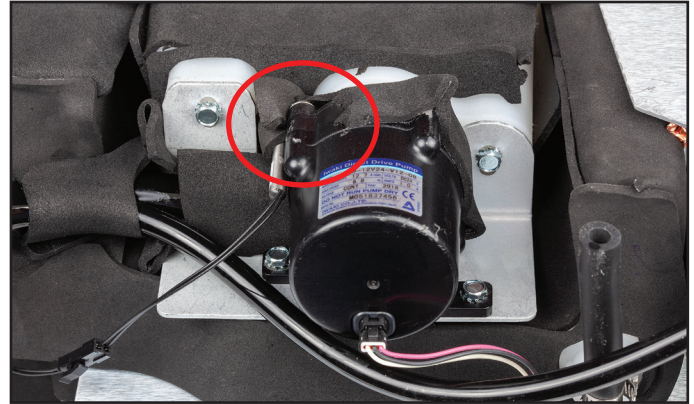


Fig 8-62 T4 Thermistor Location

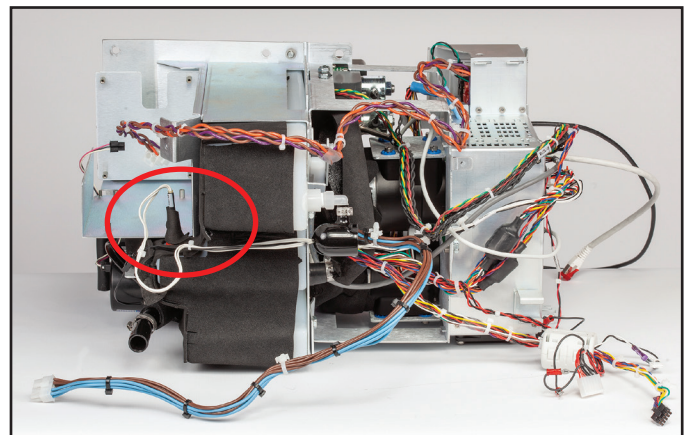


Fig 8-63 T1/T2 Thermistor Location

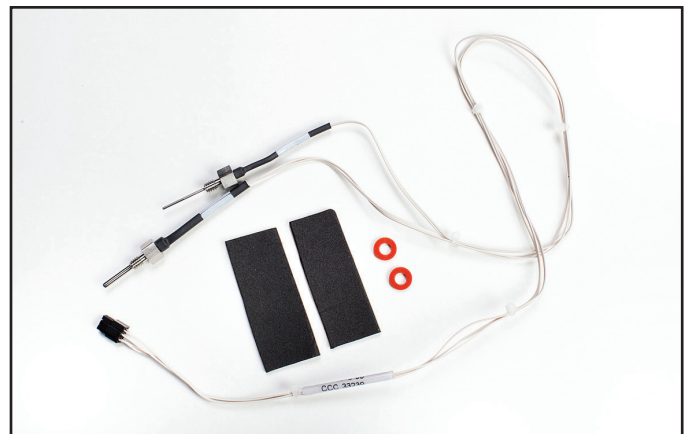


Fig 8-64 Thermistor Sensor Harness

Chapter 9 – Calibration / Calibration Check

9.1 Calibration Test Unit

The Arctic Sun™ Temperature Management System Calibration Test Unit (CTU) is an instrument that is purchased separately and is used to calibrate and verify operation of the Arctic Sun™ Temperature Management System Control Module. It connects directly to the Inlet/Outlet Manifold and temporarily replaces the Fluid Delivery Line. Cables from the CTU connect to the Temp In 1, 2 and Temp Out connectors. The CTU is used to semi-automatically calibrate the two patient temperature circuits, the Patient Temperature Out circuit, and the four water temperature circuits. It is also used to verify the flow rate and inlet pressure circuits. Correct operation of the water over-temperature alarm can also be verified manually using this device. Optionally, just a check of the current calibration can be performed.



Fig. 9-1 Calibration Test Unit

For the theory of the operation of the calibration process, please refer to the CTU Operator's Manual that is included with the CTU.

9.2 When to Perform a Calibration or Calibration Check

1. Calibration is recommended after 2000 hours of operation or 250 uses, whichever occurs first. The status of Calibration is available in the **Advanced Settings** screen.
2. In addition, Calibration may be required after replacing certain components (see Chapter 8).
3. Calibration should be done only by trained service personnel.
4. A Calibration Check confirms the device flow, ability to heat and cool, and the temperature sensing systems are all within specification. During the calibration check errors may be displayed with diagnostic information assisting with performance or calibration issues. After successful completion of a calibration check, a report is displayed showing a pass or fail status of all parameters checked.

9.3 Calibration Setup

1. Remove fluid delivery line by flipping latch from right to left and attach CTU to Arctic Sun™ device. Lock in place by flipping latch from left to right.
2. Attach the three cables coming from the CTU to PT1, PT2, and TO.

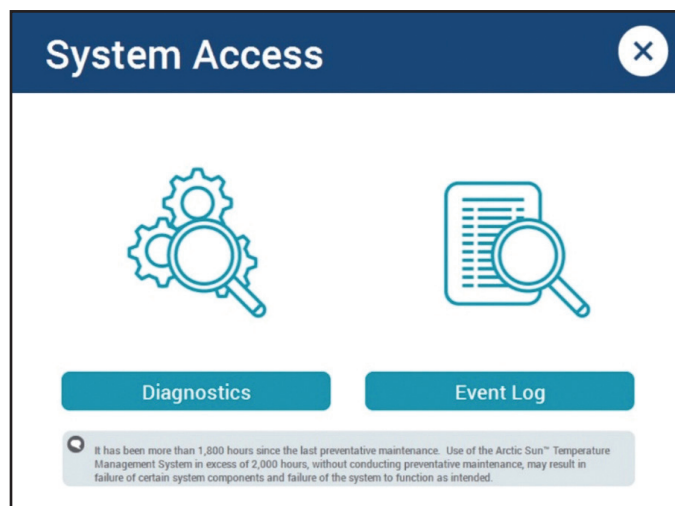
9.4 Performing a Calibration

To perform a calibration on the Arctic Sun™ Temperature Management System, press the **Advanced Setup** button on the **Therapy Selection** screen. Press the **Start** button next to Begin Process in the Calibration section and follow the on-screen instructions.

Chapter 10 - 2,000 Hour Service

Use of the Arctic Sun™ Temperature Management System in excess of 2,000 hours without conducting maintenance, may result in failure of certain system components and failure of the system to function as intended. A maintenance message will appear on the System Access screen indicating preventative maintenance is due. To maintain system performance, the Arctic Sun™ Temperature Management System requires periodic service and/or replacement of the following key components.

- o Circulation Pump - 403077-00
- o Mixing Pump - 403076-00
- o Heater - 403074-00
- Refer to Chapter 8 for component replacement instructions.
- Perform general maintenance steps per Chapter 4.
- Select the "Maintenance Reset" button on the Advanced Setup screen to set the maintenance hours on the system back to zero (0). This step shall be done post software install if one is required.
- A functional verification (Chapter 1) and calibration is required after the completion of 2,000-hour Service. Refer to Chapter 9 for calibration instructions.
- A qualified person familiar with electrical safety testing setups shall upon completion of Servicing, perform an electrical safety test per IEC62353 or IEC 60601-1 Class I type BF requirements, or as per local hospital procedures direct.
- Complete applicable service record documenting service performed



Appendix A: Product Specifications

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 C for the full declaration regarding electromagnetic compatibility.

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 **Chapter 8- Drain the Control Module, Total Drain**, for further instructions.









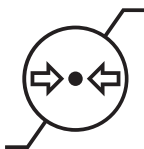


Disposal




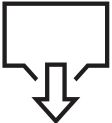
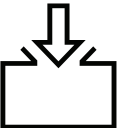



Upon end of life, dispose of in accordance with local WEEE regulations or contact your local BD Supplier or Distributor to arrange for disposal.









Parameter	Specification
Therapy Modes	Normothermia: Control Patient, Rewarming Hypothermia: Cooling, Rewarming
Heater Maximum Power	814 Watts
Circulating Fluid	Sterile Water with Cleaning Solution
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/91.4°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




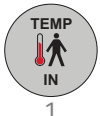

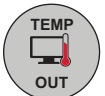




Appendix B: Symbols

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.
	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.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	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.
I/O	IEC TR 60878 Reference no. 5007 & 5008	Graphical Symbols for Electrical Equipment in Medical Practice	Power On/Off	Indicates power on/off switch

	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™ Stat 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.

	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™ Stat 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

Appendix C: Electromagnetic Compatibility

See operator manual for information on electromagnetic compatibility, emissions, and immunity.

Appendix D- Spare Parts and Accessories

Cables and Accessories

Shunt Line	709-04
Drain Bag	709-05
Drain Tube	719-00
Fill Tube	728-00
Power Cord, US, Canada, Mexico	733-00
Fluid Delivery Line	734-07
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
Arctic Sun Cleaning Solution	739-01
Calibration Test Unit (CTU) 120V	741-00
Temperature Simulator, 37°C	777-00
Screen Protector Kit	753-00
RS232 Cord	764-00
Service Kit	772-00

Accessories are based on availability

Spare Parts

Control Panel Assembly	404082-00
Isolation Board Assembly	404086-00
Panel ESD Board	404121-00
Connector Panel Assembly	404122-00
Control Panel Strap	404123-00
Fluid Drain Door Assembly	404124-00
Bracket, Power Cord, RoHS	404130-00
RIM Back Panel	404131-00
PCB Connector Cable	404125-00
Drain Port	404105-00
Left Panel	404132-00
Right Panel Assembly	404133-00
Front Panel	404134-00
Handle Plate	404135-00
Handle	404136-00
Marked Cable Lever	404126-00
Unmarked Cable Lever	404127-00
Screen Filter	404003-00
Power Supply	404128-00
Manifold	404078-00
AC Board	404087-00
Main Harness	404036-00
USB Cover	404129-00
Caster	404341-00
USB A to A	404141-00
Spring Finger	404142-00
Power Inlet Module	404143-00
O-rings	403107-00
Replacement Temperature Connector Rings	403108-00
Input / Output Circuit Card	403083-00
Power Circuit Card	403085-00
Processor Circuit Card	403084-00
Circulation Pump Assy.	403077-00
Arctic Sun Stat, Chiller Pump	404114-00
Flowmeter	403075-00
Heater, 100-120V	403074-00
Level Sensor	403102-00
Manifold Harness	403079-00
Mixing Pump Assy.	403076-00
Tank Harness	403080-00
Molded Tube	403106-00
Fluid Delivery Line Valve	402638-00
Arctic Sun Stat, Packaging Kit	404104-00

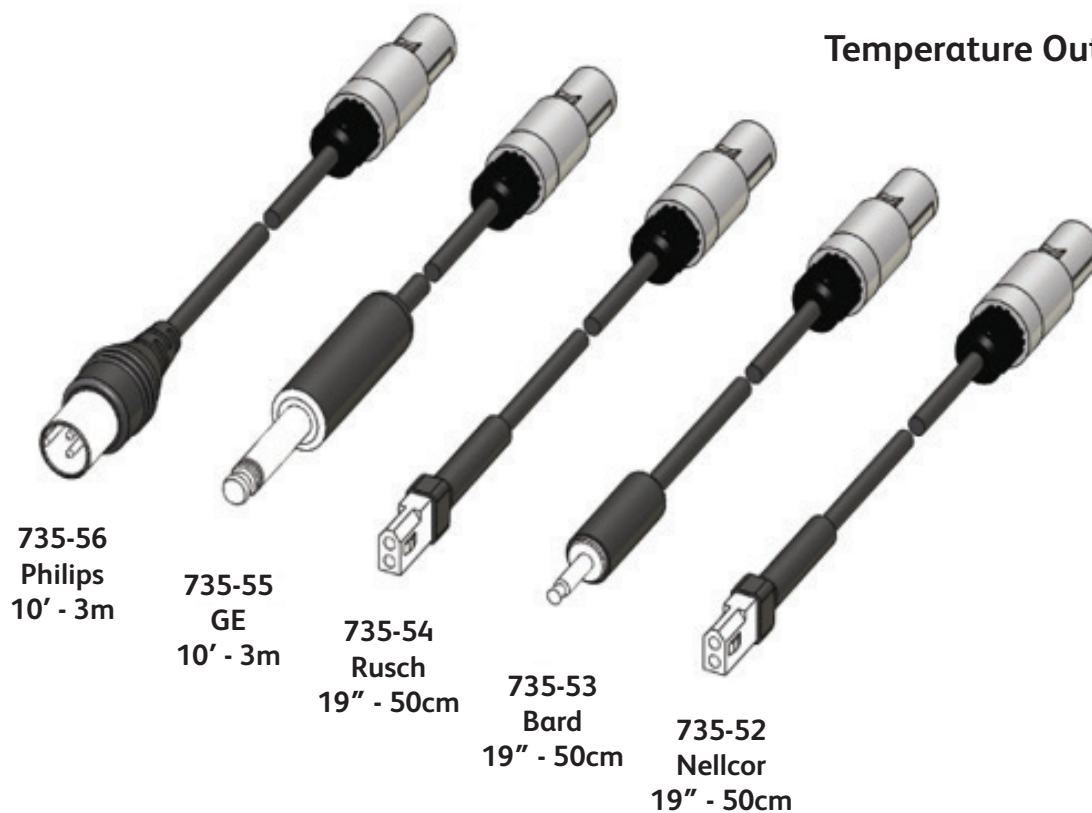
Spare Parts are based on availability

Appendix E- Temperature Cables

Temperature In Cables



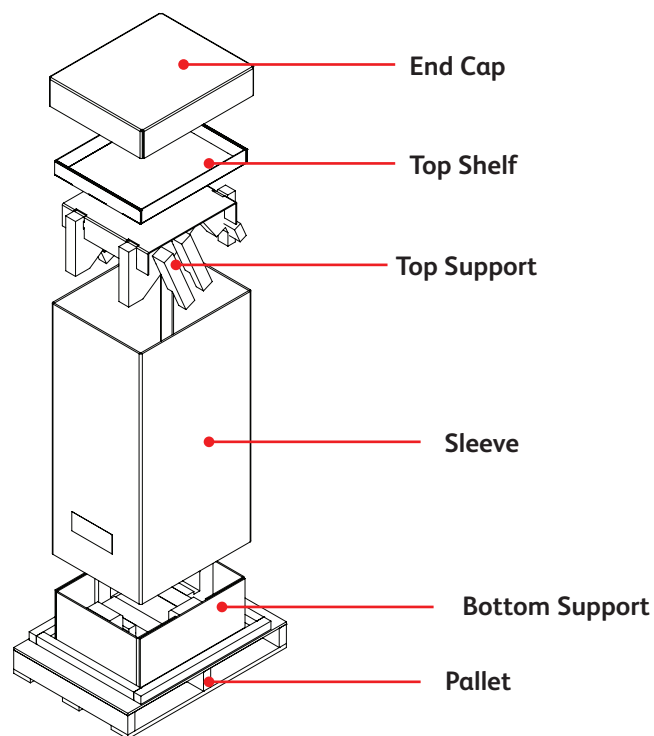
Temperature Out Cables



Appendix F- Shipping

Due to the size and weight of the Arctic Sun™ Temperature Management System, it should be shipped on a pallet using BD provided packaging materials. If the original packaging is not available, a shipping kit may be ordered.

1. Perform a total drain of the system per instructions in Chapter 8.
2. Place the Arctic Sun™ Temperature Management System onto the white foam attached to the pallet and center the unit so that it straddles the foam.
3. Place top support on top of the device with the foam side down.
4. Add top shelf to the top of the support and place any accessories being shipped with the unit into the shelf.
5. Install sleeve over packaged Arctic Sun™ Temperature Management System ensuring the sleeve is flush with the top surface of the pallet.
6. Place end cap on top of the sleeve.
7. Using the strap provided, tightly secure the unit to the pallet. Please firmly tighten the strap so the unit and its contents are secured to the pallet for shipment.



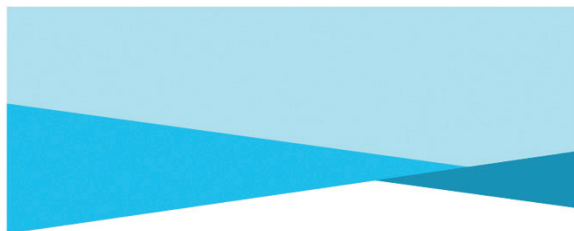
Appendix G- Software Upgrade

Installing Software on Control Panel

Upon availability of new software release

1. Insert flash drive into USB port then power unit ON (using ON/OFF switch at the rear) and wait for the Arctic Sun splash screen to appear.

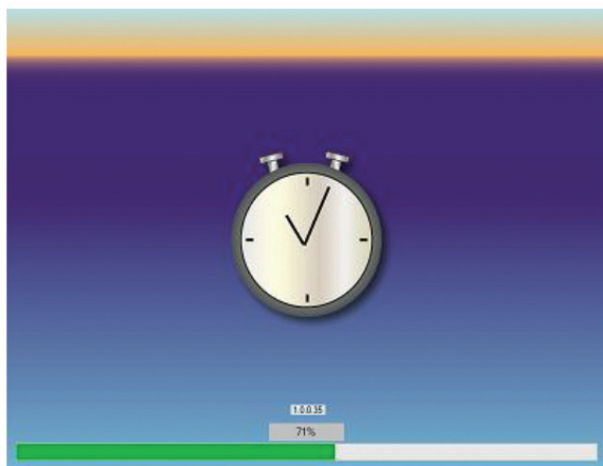
Note: A USB cover may be present over USB port. Remove cover using a 1/16" (1.5mm) hex key.



BD Arctic Sun™ Stat
Temperature Management System
Arctic Sun Stat Splash Screen

2. A progress bar and stopwatch will appear on the screen.

Note: Image is for reference only, software version may vary.



Stopwatch and progress bar on screen

3. The control panel may restart a few times during the programming. The unit shall NOT be turned off and back on during this time.
4. Once the install reaches 100%, a screen will appear indicating the success or failure of the software install. If software install fails at any point, a red "X" will appear, and process will not reach 100%.
5. Screen will go blank after completion, wait for a minimum of 1 minute then power OFF the device.
6. Remove flash drive from USB port.
7. Verify the software has been updated per the following:
 - a. Power unit ON and verify the single loud beep and multiple start-up speaker tones can be heard.
 - b. Press the Advanced Setup button when the Patient Therapy Selection window appears.

Therapy Selection

Current Patient	New Patient
No current patient.	Normothermia <input type="radio"/> 37.0°C
	Hypothermia <input type="radio"/> 33.0°C 24:00
	<input type="radio"/> 37.0°C 16:00

Advanced Setup

Patient Therapy Selection screen

- c. Verify the software version has been updated. If the software version did not update, repeat steps above. If after two (2) attempts the software has not updated, contact BD Customer Service (844.823.5433).

Advanced Setup

Data		Calibration	
Download	Start	Begin Process	Start
Connectivity Settings	Start	Last Calibrated	10/12/2020
Location / Time		Next Calibration (uses)	98
Language	English	(or hours)	112
Number Format	1,234.5	System	
Current Time	12:49	Maintenance	Reset
Date Format	MM/DD/YY	Total Drain	Start
Current Date	10/12/2020	Default Settings	
Software Version		Save as Default	Start
Version	0.0.0.0	Last Saved	12:49 10/12/202

Advanced Setup Screen

8. Reinstall USB cover using a 1/16" (1.5mm) hex key.

Appendix H- 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; (iii) customer's failure to maintain the physical environment for the Equipment (including normal maintenance) specified in the relevant documentation provided by Bard; (iv) malicious software not introduced by Bard; or (v) 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.

Appendix I - Transmission Interface Module Data Output Format

The data output stream is a repeating sequence of ASCII characters every five seconds. A “\$” is sent as the first item of a new data sequence. Each data item within the sequence is separated by a comma (ASCII 44). The data sequence is terminated with a carriage return character (ASCII 13) followed by a new line character (ASCII 10). The time since the power up of each data sequence can be calculated from the serial sequence number and communications output interval.

Example: \$,13,36.5,36.4,34.5,2,0,14.3,14.4,16.5,4.6,14.2,0,60,0,2.3,5,-7.1,0,45,165,1,4.00

Output Data Parameters are listed in the table below.

Transmission Interface Module - Data Output Parameters

Sequence No.	Description	Values
1	Sequence Start Indicator	\$ (ASCII 36)
2	Serial Sequence Number	1,2,3,4,5..., Initialized at power up
3	Patient Temperature 1	°C, 0 if probe not connected
4	Patient Temperature 2	°C, 0 if probe not connected
5	Patient Target Temperature in Auto Mode	°C, regardless of current mode
6	Operating Mode	0=Initialization, 1=Stop, 2=Automatic, 3=Manual, 4=Purge, 5=Fill, 6=Monitor Mode
7	Diagnostic Mode	0=Normal Mode, 1=Diagnostic Mode
8	Outlet Water Temperature Monitor	°C
9	Outlet Water Temperature	°C
10	Inlet Water Temperature	°C
11	Chiller Water Temperature	°C
12	Water Outlet Target Temperature	°C
13	Temperature Display Mode	0=°C, 1=°F
14	Communications Output Interval	Seconds
15	Current Alarm Number	See Alarm/Alert list for corresponding numbers
16	Flow Rate	Liters/minute
17	Reservoir Level Last Measured	5 or 4=Full, 3=3/4, 2=1/2, 1=Low, 0=Empty
18	Inlet Pressure	Pounds per square inch
19	Heater Power	0-32 where 32 =100%
20	Mixing Pump Power	0-200 where 200 = 100%
21	Circulation Pump Power	0-235 where 235 = 100%
22	Control Strategy Mode	1,2,3
23	Software Version	Software Version



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Federal Law (USA) restricts this device to sale by or on the order of a physician.

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