ARCTIC SUN®
TEMPERATURE MANAGEMENT SYSTEM

MODEL 5000 SERVICE MANUAL

Simply Advanced®

Medivance®

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Chapter 1 – Getting Started

Introduction

The Arctic Sun® Temperature Management System is a device that monitors and controls patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F). The system consists of the Arctic Sun® Temperature Management System and disposable ArcticGel™ Pads. The Arctic Sun® Temperature Management System delivers temperature-controlled water ranging between 4°C and 42°C (39.2°F and 107.6°F) through the pads adhered to the patient's skin. This results in highly efficient conductive heat transfer between the water and the patient.

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 and water gels, in use while warming or cooling 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 warming can increase drug delivery, resulting in possible harm to the patient.
- ⚠ **WARNING**: Parts sold for use with the Arctic Sun® Temperature Management System device can expose you to chemicals including di(2-ethylhexyl) phthalate (DEHP), antimony trioxide, lead, and di-isodecyl phthalate (DIDP), which are known to the State of California to cause negative impacts to health, such as cancer and birth defects or other reproductive harm. For more information, go to: https://www.P65Warnings.ca.gov.
- The Arctic Sun® Temperature Management System is not intended for use in the operating room environment.

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 is responsible to determine the appropriateness of custom parameters. When the system is powered off, all changes to parameters will revert to the default unless the new settings have been saved as new defaults in the Advanced Setup screen. For small patients (≤30 kg) it is recommended to use the following settings: Water Temperature High Limit ≤40°C (104°F); Water Temperature Low Limit ≥10°C (50°F); Control Strategy = 2.
- The operator must continuously monitor patient temperature when using Manual Control and adjust the temperature of the water flowing through the pads accordingly. Patient temperature will not be controlled by the Arctic Sun® Temperature Management System in Manual Control.
- Due to the system's high efficiency, Manual Control is not recommended for long duration use. The operator is advised to use the automatic therapy modes (e.g. Control Patient, Cool Patient, Rewarm Patient) for automatic patient temperature monitoring and control.
- The Arctic Sun® Temperature Management System will monitor and control patient core temperature based on the temperature probe attached to the system. The clinician is responsible for correctly placing the temperature probe and verifying the accuracy and placement of the patient probe at the start of the procedure.
- Medivance 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 hyper-thermia.
- Medivance recommends measuring patient temperature from a second site to verify patient temperature. Medivance recommends the use of a second patient temperature probe connected to the Arctic Sun® Temperature Management System Temperature 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 Systems.
- 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 the 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.
- 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, water flow is greater than or equal to 2.3 liters per minute 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.
- 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.
- 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 skin burns.
- 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.
- Medivance will not be responsible for patient safety or equipment performance if the procedures to operate, maintain, modify or service the Medivance Arctic Sun® Temperature Management System are other than those specified by Medivance. Anyone performing the procedures must be appropriately trained and qualified.

System Setup

Unpack

1) Unpack the Arctic Sun® Temperature Management System Control Module and accessories.
2) Allow the control module to remain upright for at least 2 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 Medivance approved cables and accessories with the Arctic Sun® Temperature Management System Control Module. Connect the Fluid Delivery Line, Patient Temp 1 cable, Patient Temp 2 cable (optional) and Fill Tube to the back of the control module.
2) Plug the Power Cord into the wall outlet. Position Arctic Sun® Temperature Management System so that access to the power cord is not restricted.

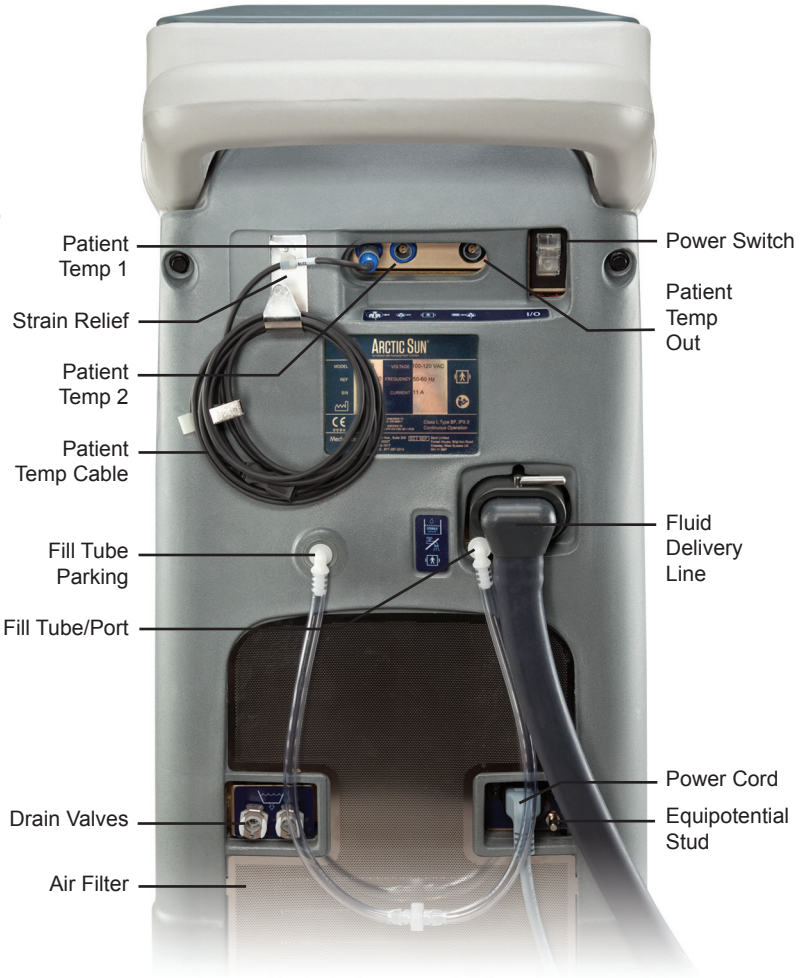


Fig. 1-1 Arctic Sun® Temperature Management System Control Module

System Navigation

Fig. 1-2 Start-up screen with training module

A training module including a section for Clinical Engineering (Setup and Maintenance) is available from the start-up screen.

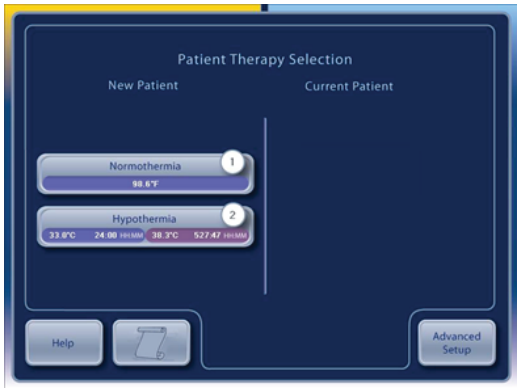


Fig. 1-3 Therapy Selection screen

When the self-test is complete, the **Patient Therapy Selection** screen will appear on the control panel.

Therapy Screens

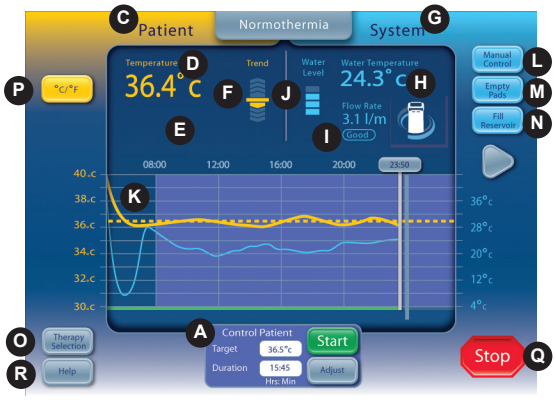


Fig. 1-4 Normothermia Therapy screen

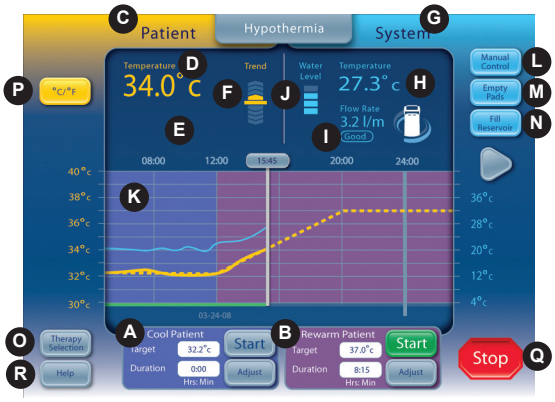


Fig. 1-5 Hypothermia Therapy screen

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

A Cool Patient window (Hypothermia screen)
Control Patient window (Normothermia screen)
B Rewarm Patient window (Hypothermia screen)
C Patient Monitoring area
D Patient Temperature
E Patient Temperature 2 (if enabled)
F Patient Temperature Trend Indicator
G System Monitoring area
H Water Temperature
I Water Flow Rate
J Reservoir Water Level
K Therapy Graph
L Manual Control button (if enabled)
M Empty Pads button
N Fill Reservoir button
O Therapy Selection / Screen Lock button
P Temperature Units button (if enabled)
Q Stop button
R Help button

Fill Reservoir

1) Fill the reservoir with sterile water only.
2) Four liters of water will be required to fill the reservoir at initial installation.
3) Add one vial of Arctic Sun® Temperature Management System Cleaning Solution to the sterile water.
4) From the **Patient Therapy Selection** screen, press either the **Normothermia** or **Hypothermia** button, under the New Patient heading.
5) From the **Hypothermia** or **Normothermia** therapy screen, press the **Fill Reservoir** button.
6) The **Fill Reservoir** screen will appear. Follow the directions on the screen.

Fig. 1-6 Fill Reservoir screen

Manual Control

Manual Control allows the user to directly set the water temperature in the Circulating Tank. It does not require a patient temperature probe to be connected and therefore can be used for troubleshooting and diagnostic purposes.

If Manual Control has been disabled it will need to be enabled. To enable Manual Control, from the Normothermia Therapy screen press the Adjust button located at the bottom center of the screen. From the Control Patient-Adjust screen, press the More button. This will display the Normothermia Settings screen (Fig. 1-9). Press the adjust button for manual control. Select the desired water temperature and time. Press Save. Enabling Manual Control will not automatically change the default settings.

When enabled, the Manual Control button is visible in the upper right hand corner of the Therapy screen. Pressing the Manual Control button allows the user to change the water target and duration, and to start Manual Control.

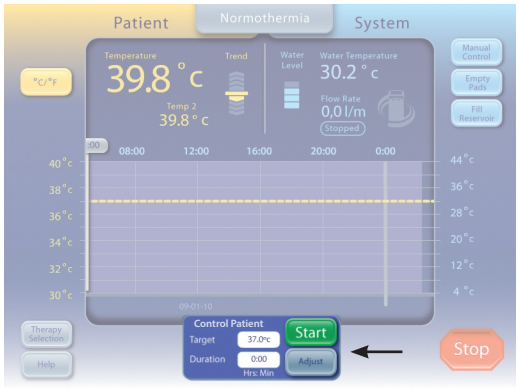


Fig 1-7 Control Patient panel from Normothermia screen

Fig 1-8 Control Patient - Adjust panel
(appears after user presses Adjust on Control Patient panel)

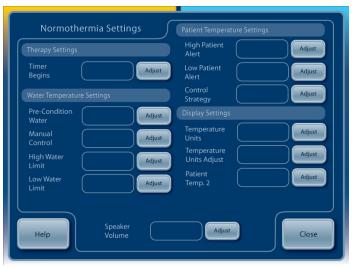


Fig 1-9 Normothermia Settings screen

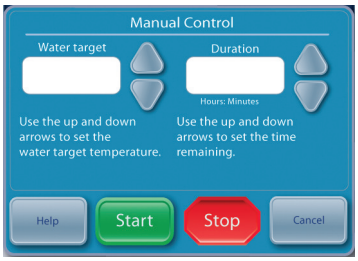


Fig. 1-10 Manual Control panel (appears after user presses Manual Control on main Normothermia or Hypothermia Screen)

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:

1) Power **On** the control module
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) 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 30°C.
9) Press the **Stop** button.
10) Set the Manual Control water target temperature to 4°C and the duration to 30 minutes.
11) Press the **Start** button to initiate **Manual Control**.
12) Monitor the flow rate and water temperature in the **System** status area of the **Hypothermia** therapy screen. Verify that the water temperature drops to 6°C.
13) Press the **Stop** button to stop **Manual Control**
14) Press the **Cancel** button to close the **Manual Control** window
15) Power **Off** the control module.

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

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 E.

The Mains Voltage Circuit Card – 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 Module – located next to the Mains Voltage Circuit Card. 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. Also provides a simulated YSI 400 compatible patient temperature signal (Temperature Out) to an external monitor.

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.

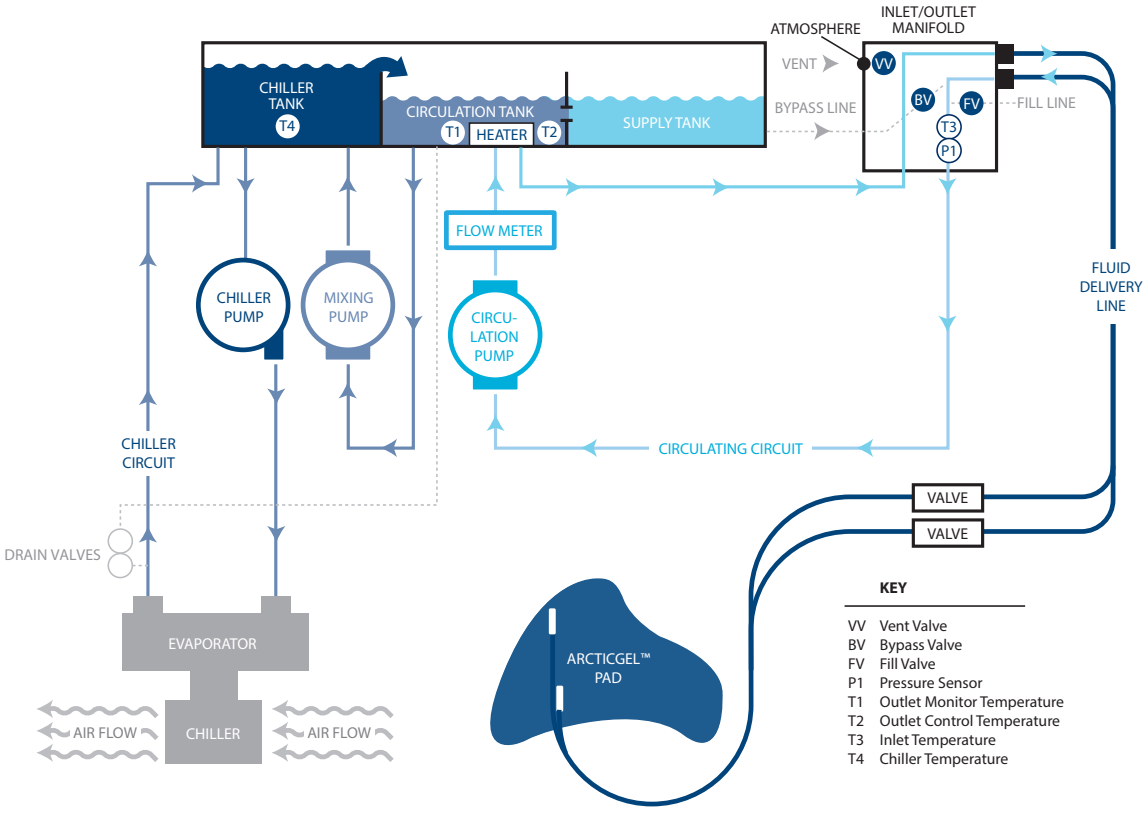


Fig. 2-1 The Hydraulic Schematic

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

Procedure	Interval
Clean external surfaces	As required
Inspect connectors and cables	6 months
Clean the condenser	6 months
Replenish Cleaning Solution	6 months
Inspect Screen Protector	6 months
Calibration	Every 2000 hours or 250 uses, whichever occurs first, as indicated by system display
Inspect Fluid Delivery Line	6 months
Inspect manifold O-rings for wear	6 months
Inspect foam adherence to hoses	During all internal service procedures

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

Clean the External Surfaces

Cleaning should include the exterior of the Control Module, Fluid Delivery Lines, Temperature Cables and the power cord. Clean visible contamination from the surfaces with a dampened cloth using a mild detergent. Rinse and dry thoroughly. Use a soft cloth dampened with disinfectant according to hospital protocol. Medivance has qualified and approves the use of the following types of disinfectants for exterior surfaces: sodium hypochlorite, isopropyl alcohol, and quaternary ammonium.

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.

Clean the 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.

Replenish Cleaning Solution

Replenish Internal Cleaning Solution

Contact Medivance Customer Service to order internal cleaning solution.

To replenish the internal cleaning solution:

1) Drain the reservoir.
   - Turn control module power Off.
   - Attach the drain line to the two drain valves 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.
   - 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 first bottle 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.

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 against the screen.

Inspect Fluid Delivery Line

1. Power On the system
2. From the Patient Therapy Selection screen press the **Hypothermia** button to display the **Hypothermia** therapy screen.
3. From the **Hypothermia** therapy screen, press the **Manual Control** button to open the **Manual Control** window.
4. Set the **Manual Control** water target temperature to 28°C and the duration to 30 minutes.
5. Connect a shunt to a set of fluid delivery line ports.
6. Press the **Help** button and then press the **Help Index** button. Select the topic **Maintenance and Service** and sub topic **System Diagnostics** then press the **Display** button. Verify that inlet pressure is -7 ± 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.

Preventative Maintenance

Preventative Maintenance is required to maintain continued and uninterrupted use of the Arctic Sun® Temperature Management System. Should the Arctic Sun® Temperature Management System become unavailable for use, alternative methods to control patient temperature should be utilized.

To purchase a *Preventative Maintenance Program* through Bard or to purchase components, please call 1-800-526-4455 or contact your local Bard representative.

Preventative maintenance includes the assessment of four key components of the Arctic Sun® Temperature Management System that have over 2,000 hours of use. Parts serviced will be covered with a new one year limited warranty.

Components assessed during preventative maintenance include the Mixing Pump, Circulation Pump, Heater, and Drain Valves.

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 **Adjust** button to the right of the parameter.

Location / Time Settings

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

The following functions can be initiated from the Advanced Setup screen.

- Download Patient Data: The Patient Data for the last 10 (ten) cases are stored on the Arctic Sun® Temperature Management System hard drive. This data is maintained when the Arctic Sun® Temperature Management System is powered down, or in the event of a total loss of power.
- Calibration
- Total Drain
- Save All Settings As Default
- Upload custom file

Additionally, the following information can be viewed in the Advanced Setup screen.

- Software Versions
- Last Calibration Date
- Next Calibration Due

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.

To access the Additional Protocol Selection screen:

Refer to the Arctic Sun®Temperature Management System Help screens for information regarding additional protocol setup.

Fig. 5 -1 Advanced Setup

Chapter 6 – Alarms and Alerts

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

There are two types of conditions: **Alarms** and **Alerts**.

An Alarm notifies the user that a condition that may potentially pose an unsafe situation with respect to the patient or the device. An Alarm is a High Priority condition that requires immediate operator response.

An Alert informs the user about patient and device status without interrupting the procedure. An Alert is a Medium Priority condition that requires prompt operator response.

Alarms

An Alarm is denoted by an audio signal that repeats every 10 seconds until the Alarm is cleared. The 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.

Fig. 6-1 Alarm screen

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 Customer Support.

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:

1) When an alarm is issued the device is placed into **Stop** mode.
2) Read the displayed instructions.
3) Note the **Alarm** number.
4) Press the **Close** button to clear the alarm.
5) Follow the instructions to correct the alarm condition. Perform the actions in the order listed until the alarm condition is resolved.
6) 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”. Additionally, the active therapy window and the Arctic Sun® Temperature Management System icon will blink.
7) If the condition does not resolve, contact Customer Support.

Alerts

Alerts are denoted by an audio signal that repeats every 25 seconds. The Alert screen will appear that displays the alert number, alert title, a description of the problem that triggered the alert, and solutions and instructions for troubleshooting and resolving the alert condition.

Fig. 6-2 Alert screen

If an Alert occurs:

1) Read the displayed instructions.
2) Note the Alert number.
3) Press the **Close** button to clear the alert.
4) Follow the instructions to correct the alert condition. Perform the actions in the order listed until the alarm condition is resolved. If the condition does not resolve, contact Customer Support.
5) Refer to the Arctic Sun® Temperature Management System Help screens for additional information regarding alarms and alerts.

Alarms and Alert Listing

The following table consists of a listing of the alarms and alerts that a user might observe during use of the Arctic Sun® Temperature Management System. Text highlighted in yellow denotes an alert, while red denotes an alarm.

Alarm Alert

Alarm/ Alert	Message Displayed	Problem
01	Patient Line Open	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.
02	Low Flow	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.
03	Water Reservoir Low	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.
04	Water Reservoir Below Minimum	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.
05	Water Reservoir Empty	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.
07	Empty Pads Not Complete	A significant amount of water was still being returned from pads at the end of the Empty Pads cycle.
08	Patient Temperature 1 high	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, Cool Patient or Rewarm Patient).
09	Patient Temperature 1 Above High Patient Alert	In Normothermia Therapy: The Patient Temperature 1 reading is above the High Patient Alert setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 1 reading is above the High Patient Alert setting in Hypothermia Settings.
10	Patient Temperature 1 Low	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, Cool Patient or Rewarm Patient).
11	Patient Temperature 1 Below Low Patient Alert	In Normothermia Therapy: The Patient Temperature 1 reading is below the Low Patient Alert setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 1 reading is below the Low Patient Alert setting in Hypothermia Settings.
12	Patient Temperature 1 High	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) while in Manual Control mode. Patient temperature is not automatically controlled while in Manual Control Mode.
13	Patient Temperature 1 Low	The Patient Temperature 1 reading is below 31°C (87.8°F), and the water temperature is below 31°C (87.8°F) when the system is in Manual Control mode. Patient temperature is not automatically controlled while in Manual Control mode.

14	Patient Temperature 1 Probe Out of Range	Patient Temperature 1 probe is not detected, or the temperature reading is below of the lower limits of the display range (10°C /50°F) while in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient).
15	Unable to Obtain a Stable Patient Temperature	Patient temperature discontinuity. A significant change in the patient temperature reading for more than 10 minutes while in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient).
16	Patient Temperature 1 Probe Out of Range	Patient Temperature 1 probe is not detected, or the temperature reading is above the upper limit of the display range (44°C/111.2°F) while in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient).
17	Patient Temperature 1 Calibration Error	The system is unable to internally check the calibration of the Patient Temperature 1 channel within ± 1.0°C while in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient).
18	Patient Temperature 1 Calibration Error	The system is unable to internally check the calibration of the Patient Temperature 1 channel within ± 1.0°C when the system is in Manual Control mode.
19	Patient Temperature 1 Calibration Error	The system is unable to internally check the calibration of the Patient Temperature 1 channel within ± 1.0°C while in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient).
20	Patient Temperature 1 Calibration Error	The system is unable to internally check the calibration of the Patient Temperature 1 channel within ± 1.0°C when the system is in Manual Control mode.
21	Patient Temperature 2 High	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 while in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient).
22	Patient Temperature 2 Above High Patient Alert	In Normothermia Therapy: The Patient Temperature 2 reading is above the High Patient Alert setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 2 reading is above the High Patient Alert setting in Hypothermia Settings.
23	Patient Temperature 2 Low	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, Cool Patient or Rewarm Patient).
24	Patient Temperature 2 Below Low Patient Alert	In Normothermia Therapy: The Patient Temperature 2 reading is below the Low Patient Alert setting in Normothermia Settings. In Hypothermia Therapy: The Patient Temperature 2 reading is below the Low Patient Alert setting in Hypothermia Settings.
25	Patient Temperature 2 High	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) while in Manual Control mode. Patient temperature is not automatically controlled while in Manual Control mode.
26	Patient Temperature 2 Low	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 while in Manual Control Mode.
27	Patient Temperature 2 Probe Out of Range	Patient Temperature 2 probe is not detected, or the temperature reading is below the lower display range (10°C /50°F).

28	Patient Temperature 2 Probe Out of Range	Patient Temperature 2 probe is not detected, or the temperature reading is above the upper limit of the display range (44°C/111.2°F) while in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient).
29	Patient Temperature 2 Calibration Error	The system is unable to internally check the calibration of the Patient Temperature 2 channel within ± 1.0°C when the system is in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient). Patient Temperature 2 channel is made inactive.
30	Patient Temperature 2 Calibration Error	The system is unable to calibrate the Patient Temperature 2 channel within ± 1.0°C when the system is in Manual Control mode. Patient Temperature 2 channel is made inactive.
31	Patient Temperature 2 Calibration Error	The system is unable to calibrate the Patient Temperature 2 channel within ± 1.0°C when the system is in a patient control mode (e.g. Control Patient, Cool Patient or Rewarm Patient). Patient Temperature 2 channel is made inactive.
32	Patient Temperature 2 Calibration Error	The system is unable to calibrate the Patient Temperature 2 channel within ± 1.0°C when in Manual Control mode. Patient Temperature 2 channel is made inactive.
33	Water Temperature High	The primary outlet water temperature is above 44°C (111.2°F).
34	Water Temperature High	The primary outlet water temperature is above 42.5°C (108.5°F)
35	Water Temperature Low	The primary outlet water temperature is below 3.5°C (38.3°F).
36	Water Temperature High	The secondary outlet water temperature is above 44°C (111.2°F).
37	Water Temperature High	The secondary outlet water temperature is above 43°C (109.4°F).
38	Water Temperature Low	The secondary outlet water temperature is below 3.0°C (37.4°F)
40	Unable to Maintain Stable Water Temperature	In Manual Control mode, the system is unable to control the water temperature within 1.0°C/°F of the water target after 25 min. in the current mode or since last change to water target temperature.
41	Low Internal Flow	Insufficient internal flow during system priming or pre-conditioning.
43	User Settings Not Saved	The user settings are invalid and are unable to be saved. The saved system default settings are restored.
44	Invalid System Log Entry	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.
45	AC Power Lost	The AC power was lost while the power switch was in the On position.
46	Control Panel Communication	The control panel is not communicating with the system.
47	Control Panel Communication	The control panel is not communicating with the system.
48	Patient Temperature Out Invalid	The Patient Temperature Out calibration data in non-volatile memory is invalid.
50	Patient Temperature 1 Erratic	Patient Temperature 1 discontinuity. There has been a significant change in patient temperature over the past 8 minutes.
51	Patient Temperature 1 Below Control Range	Patient Temperature 1 is less than 31°C (87.8°F) while in a patient control mode (e.g. Control Patient, Cool Patient, or Rewarm Patient).

52	Extended Period of Cold Water	The circulating water temperature has been below 10°C (50°F) for 8 of the previous 10 hours. The alert will recur after 1 hour if the condition continues. After the device has issued 11 extended cold water exposure alerts, 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.
53	Prolonged Cold Water Exposure	The circulating water temperature has been below 10°C (50°F) for a prolonged period of time. The extend period of cold water alert has been issued 11 times. The alert was first issued after the system sensed that the water temperature was below 10°C (50°F) for 8 of 10 hours. The alert was then issued an additional 10 times every 1 hour because the situation was not resolved. Prolonged cold water exposure may increase the risk for skin injury. Assess patient's skin underneath the ArcticGel™ Pads.
60	Non-Recoverable System Error	Control processor and Monitor processor start up synchronization fault.
61	Non-Recoverable System Error	Control processor parameter memory fault.
62	Non-Recoverable System Error	Monitor processor parameter memory fault.
64	Non-Recoverable System Error	Unable to enable pump power (Control processor).
65	Non-Recoverable System Error	Unable to enable pump power (Monitor processor).
66	Non-Recoverable System Error	Unable to disable pump power (Control processor).
67	Non-Recoverable System Error	Unable to disable pump power (Monitor processor).
71	Non-Recoverable System Error	Primary outlet water temperature sensor out of range – high resistance.
72	Non-Recoverable System Error	Primary outlet water temperature sensor out of range – low resistance.
73	Non-Recoverable System Error	Secondary outlet water temperature sensor out of range – high resistance.
74	Non-Recoverable System Error	Secondary outlet water temperature sensor out of range – low resistance.
75	Non-Recoverable System Error	Inlet water temperature sensor out of range – high resistance.
76	Non-Recoverable System Error	Inlet water temperature sensor out of range – low resistance.
77	Non-Recoverable System Error	Chiller water temperature sensor out of range – high resistance.
78	Non-Recoverable System Error	Chiller water temperature sensor out of range – low resistance.
79	Non-Recoverable System Error	Primary and secondary outlet water temperature sensors differ by greater than 1°C.
80	Non-Recoverable System Error	The control processor failed to detect a simulated water temperature fault.
81	Non-Recoverable System Error	The monitor processor failed to detect a simulated water temperature fault.
83	Non-Recoverable System Error	Monitor processor communications fault.
84	Non-Recoverable System Error	Control processor communications fault.
86	Non-Recoverable System Error	Power supply voltage fault.
99	Non-Recoverable System Error	Program unexpectedly aborted.
100	Unable to Save Default Settings	The system is unable to save the default settings in Advanced Setup.
101	No USB Drive Found During Save	When attempting to Download Patient Data, no flash drive was found in the USB port.

103	Unable to Communicate Settings	There was an error communicating Hypothermia Settings, Normothermia Settings or Advanced Setup settings to the system.
104	Manual Control End	The Manual Control has reached the end of its set duration.
105	Cool Patient End	Cool Patient timer has reached the end of its set duration and Rewarming Begins in Hypothermia Settings is set to Manually. See Help Index topic Hypothermia Settings – Rewarming Begins for more information.
106	Non-Recoverable System Error	Graphic user interface communications lost with control module control processor.
107	Non-Recoverable System Error	Graphic user interface communications lost with control module monitor processor
108	Operating Mode Incorrect	The system has not successfully entered the commanded therapy mode.
109	Esophageal Probe Recommended	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 32ºC to 32.9ºC (89.6ºF to 91.2ºF) 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 33ºC.
110	Data File Not Readable	The data file which contains the system default settings has been corrupted. The system has automatically reset the system to the factory defaults.
112	Confirm Return to Cooling Phase	Treatment is currently programmed to be in the Rewarming phase, but the Start button in the Cool Patient window was pressed.
113	Reduced Water Temperature Control	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.
114	Treatment Stopped	Treatment has been stopped for the last ten (10) minutes.
115	Prolonged Warm Water Exposure	The circulating water temperature has been between 38°C (100.4°F) and 42°C (107.6°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.
116	Patient Temperature 1 Change Not Detected	Patient Temperature 1 has not changed for an extended period of time.
117	Patient Temperature 1 Change Not Detected	Patient Temperature 1 has not changed for an extended period of time.
118	Hospital Form Not Found	When attempting to Upload Hospital Form, file was not found or it was not readable.

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 from the Maintenance and Service Topic in the Help Index.

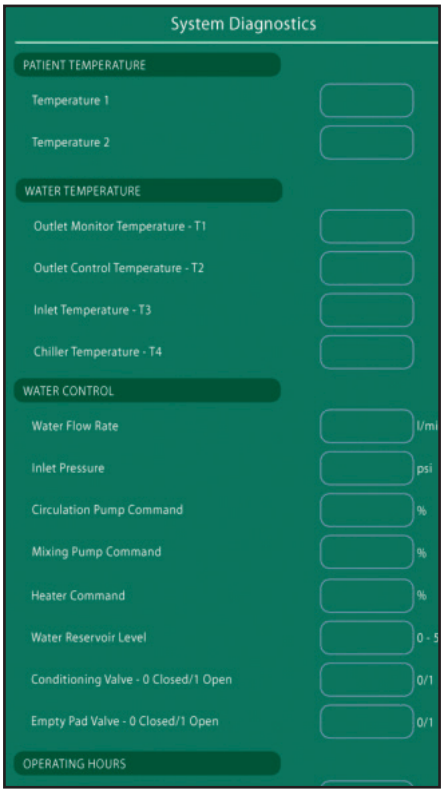


Fig. 7-1 System Diagnostics

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 from the Maintenance and Service Topic in the Help Index.

Fig. 7-2 Help Index

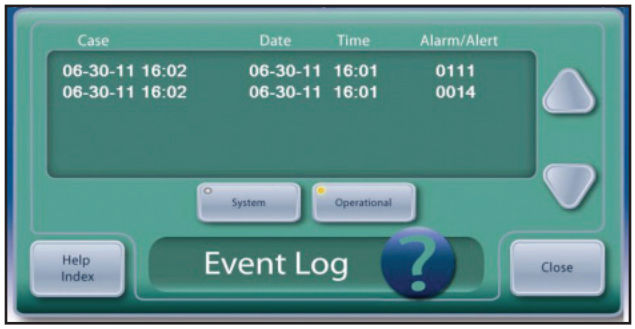


Fig. 7-3 Event Log

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 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 Settings 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, alert 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 Patient Does Not Cool

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 Tube, 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 Patient Does Not Warm

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 42°C (108°F).
- Verify water temperature increases from room temperature to at least 35°C (95°F) within 10 minutes.
- If unsuccessful, remove back panel and shell and check Heater power connection on Mains Voltage Circuit Card.
- Test heating elements as follows:
  Remove heater power connection from mains voltage circuit card then check resistance of heating elements.

Fig. 7-4 Location of connector

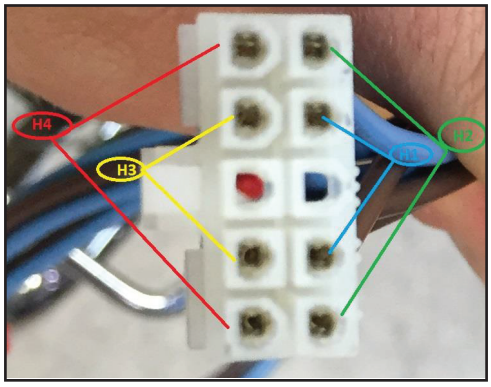


Fig. 7-5 Pins to test for each heating element

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.
- Replace 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.

7.4 Troubleshooting Assistance

For further assistance with troubleshooting, contact your distributor or Medivance 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 Medivance 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. An abbreviated list of spare parts and accessories is located in Appendix D. For parts not listed, contact Medivance Technical Support. In general, reverse the order of removal to install a replacement component. Please note any special instructions to the contrary.

Caution: Observe precautionary electrostatic discharge control procedures (ESD) when working with circuit card assemblies.

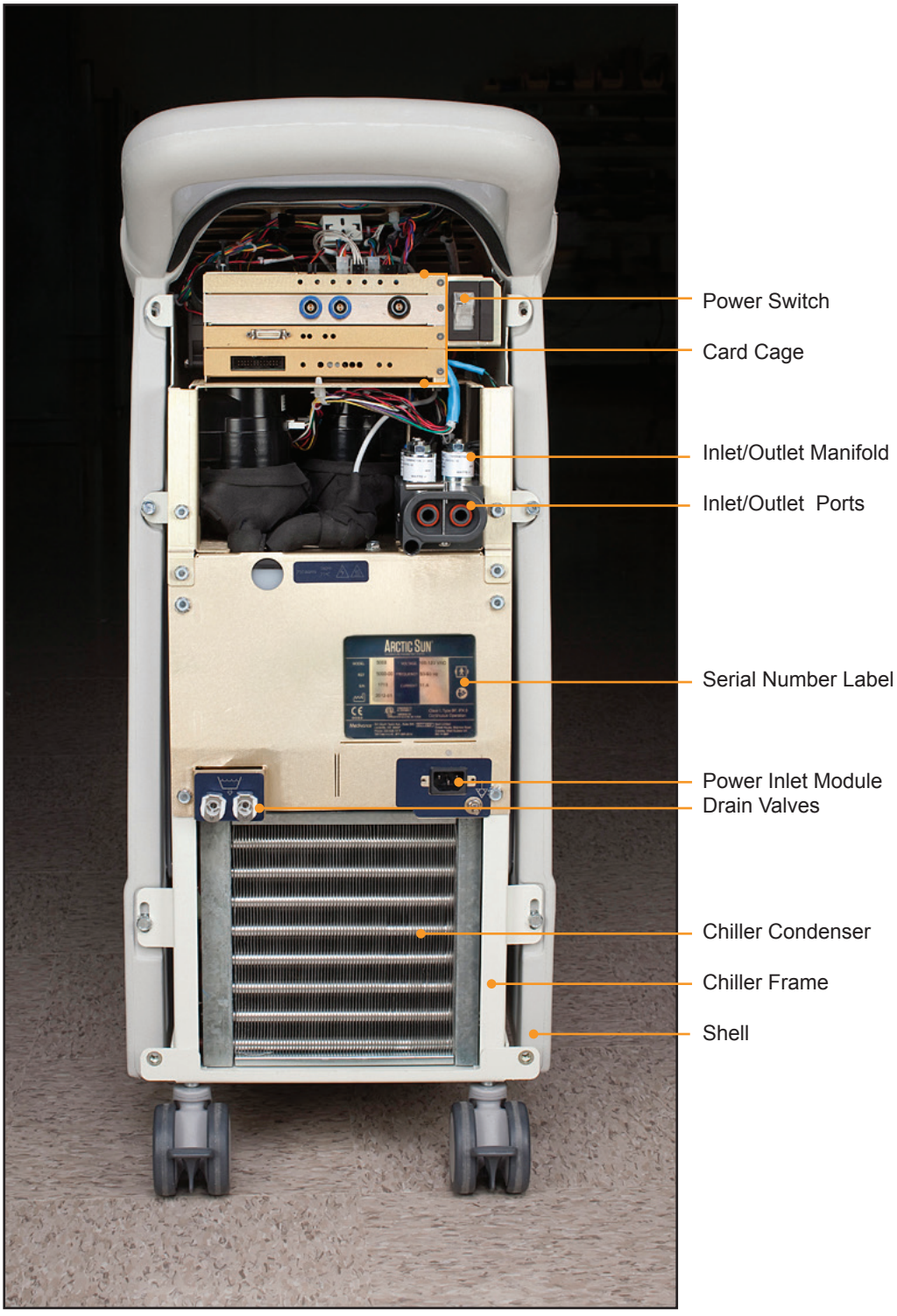


Fig. 8-1 Control Module, rear view after removal of Back Panel

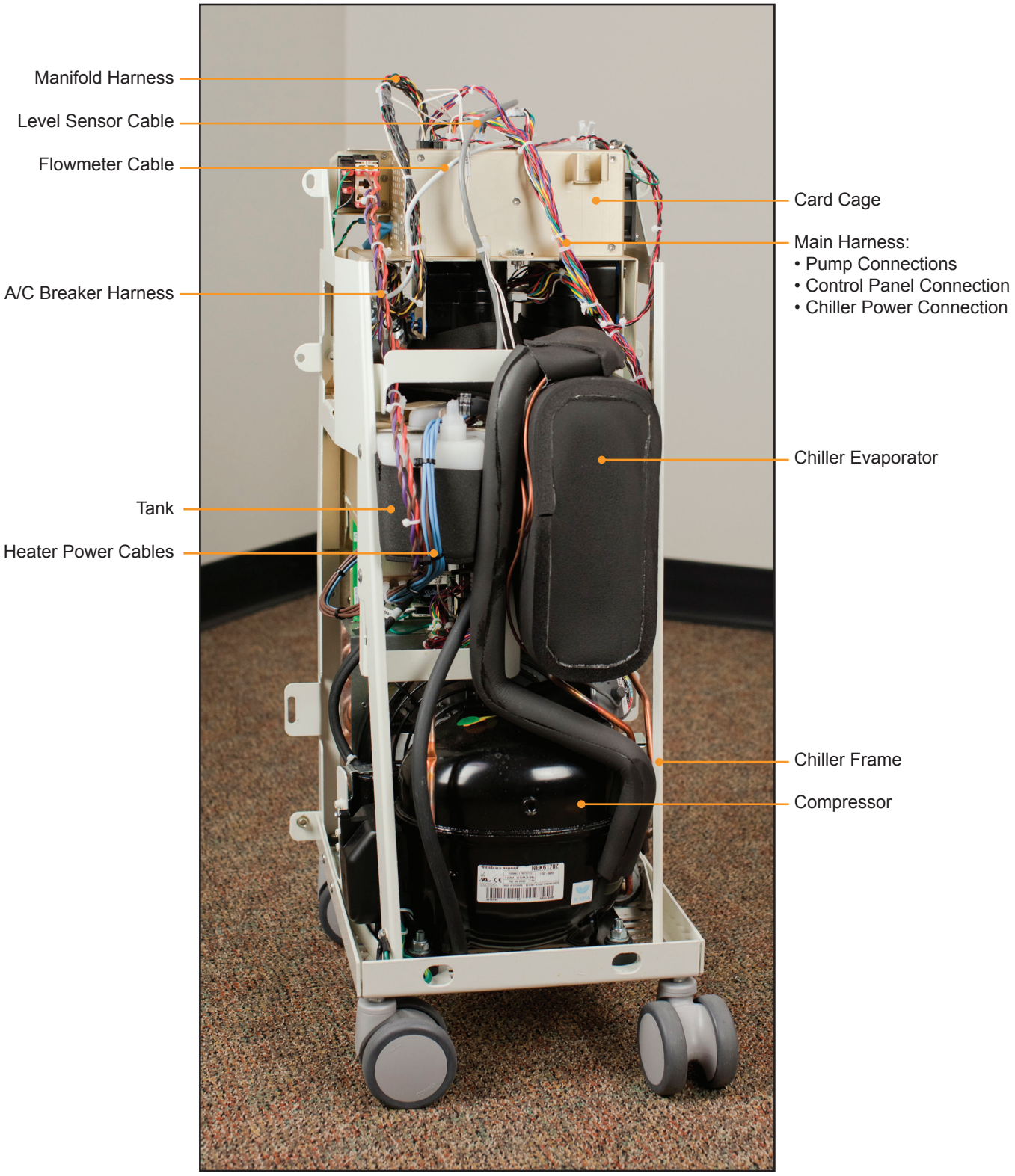


Fig. 8-2 Control Module, front inside view

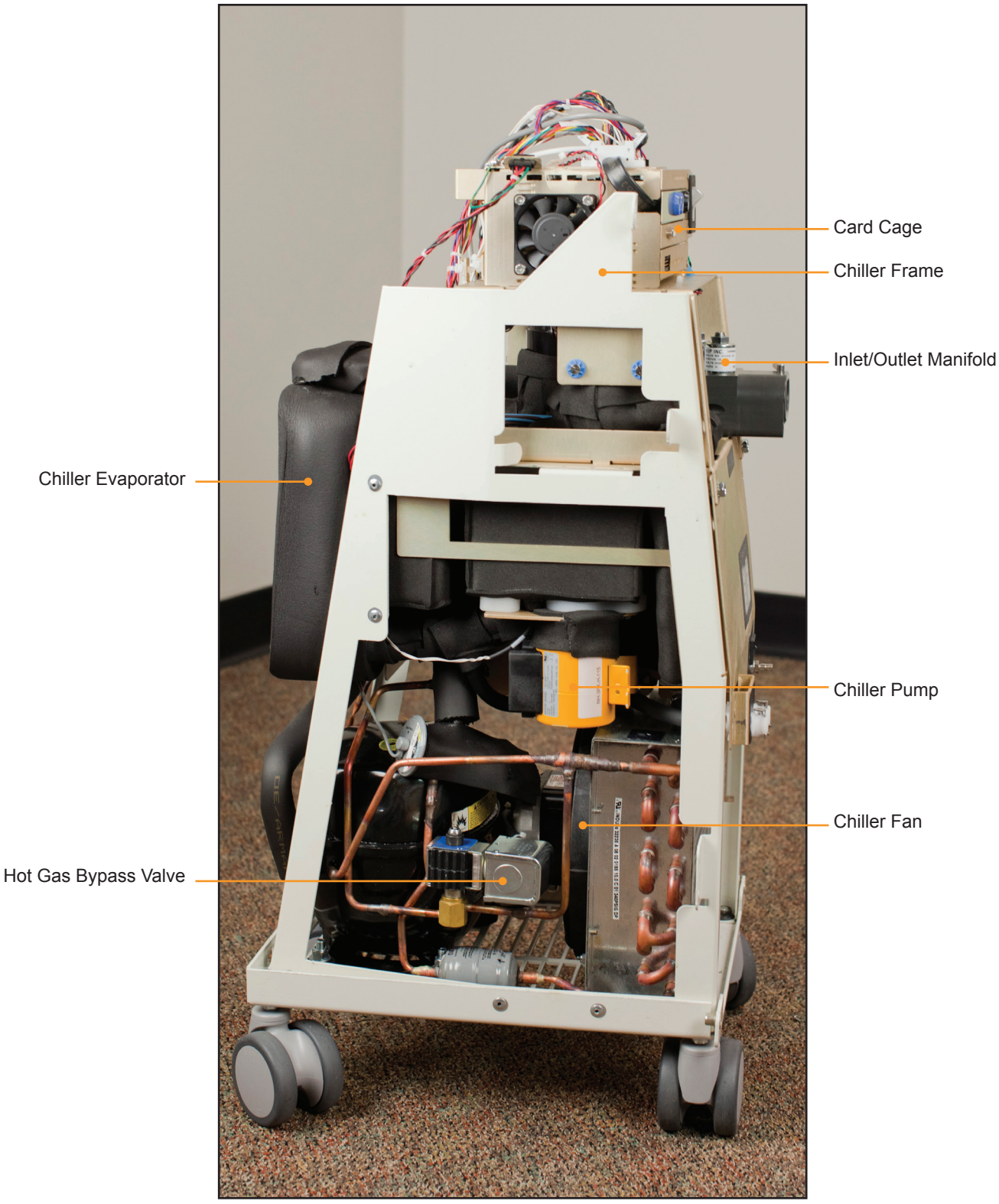


Fig. 8-3 Control Module, right inside view

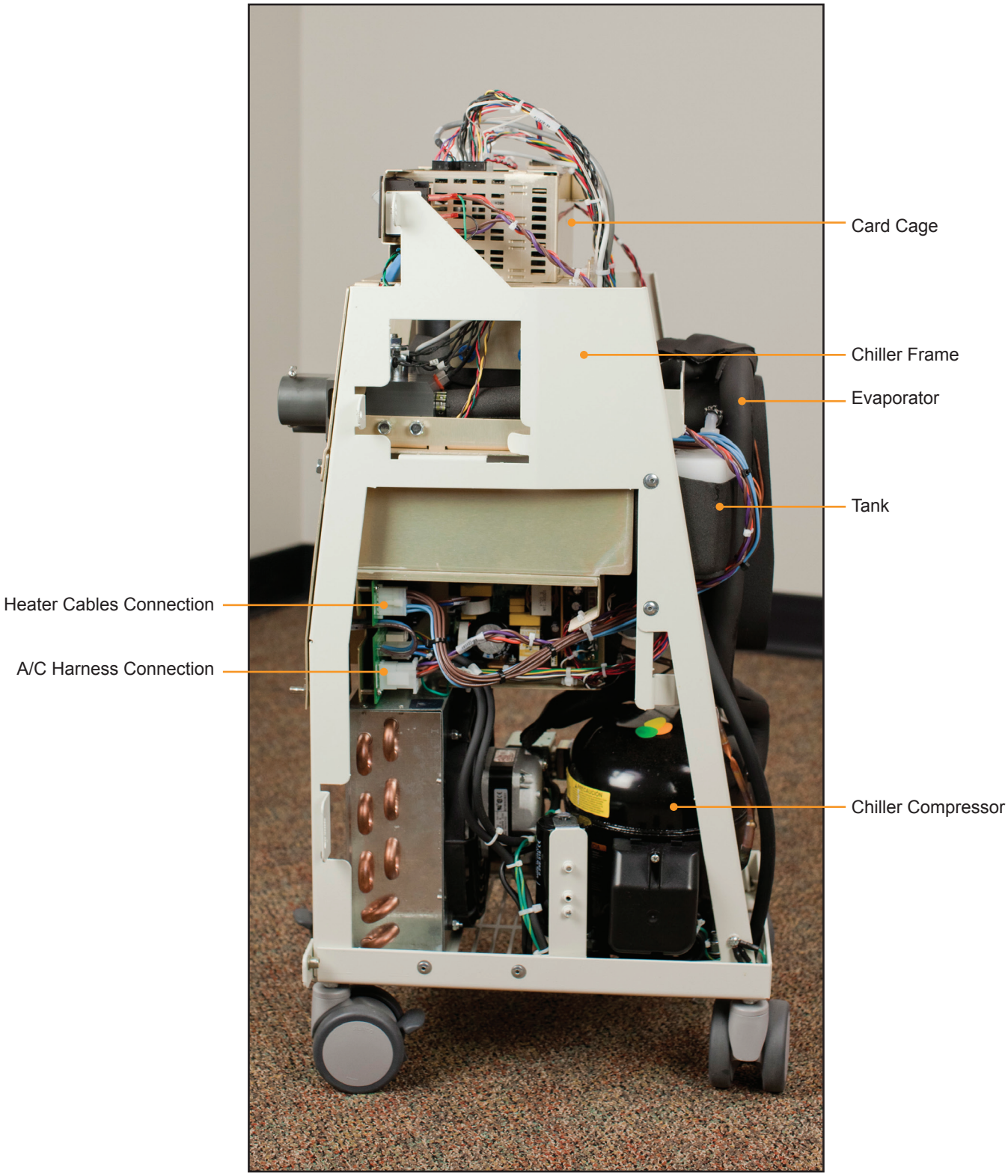


Fig. 8-4 Control Module, left inside view

The electronics controlling all machine processes are found in two areas: (1) the card cage, located at the top of the internal components, and (2) mounted to the lower part of the frame.

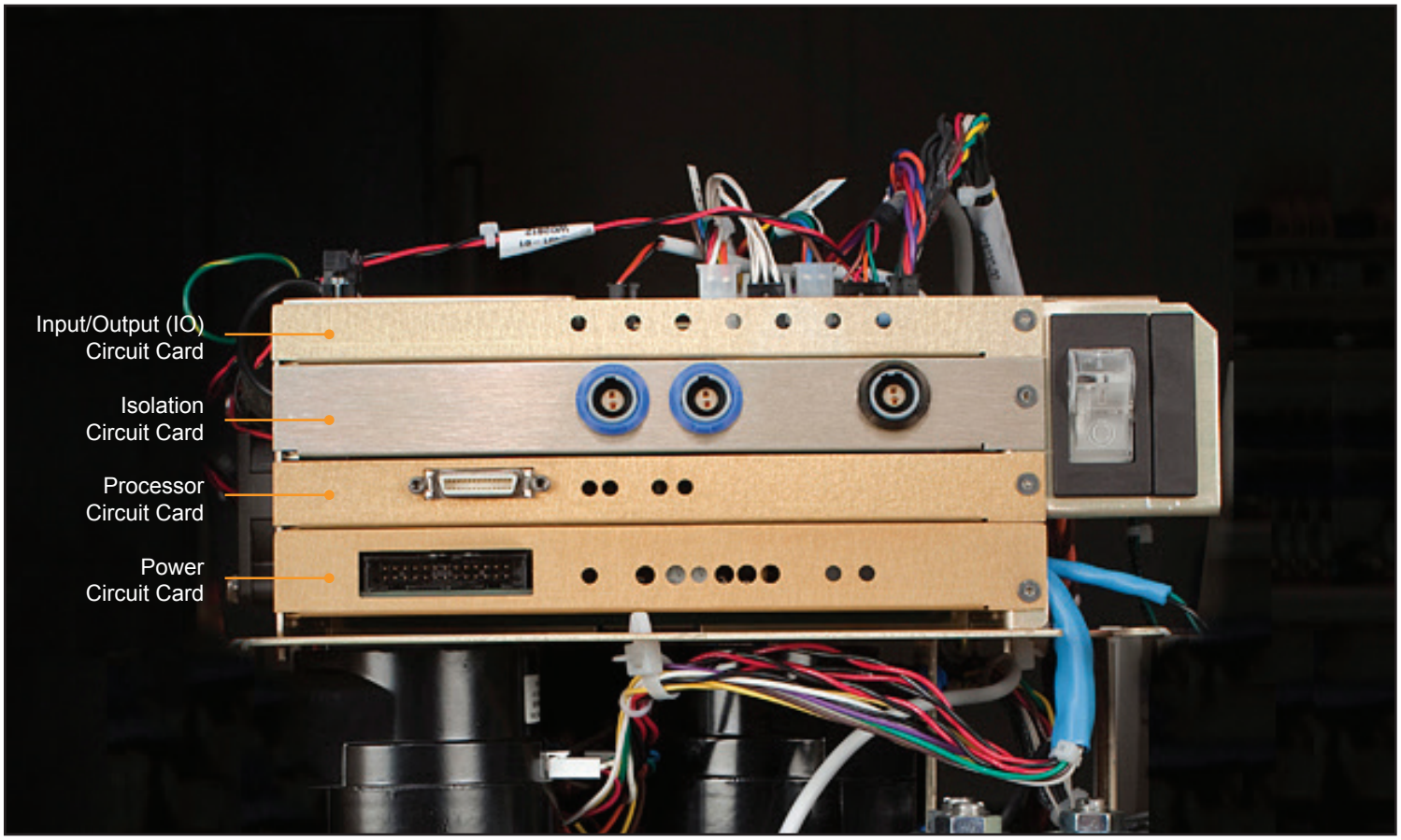


Fig. 8-5 Card cage, circuit card identification

The following two circuit cards are mounted on the lower part of the frame:

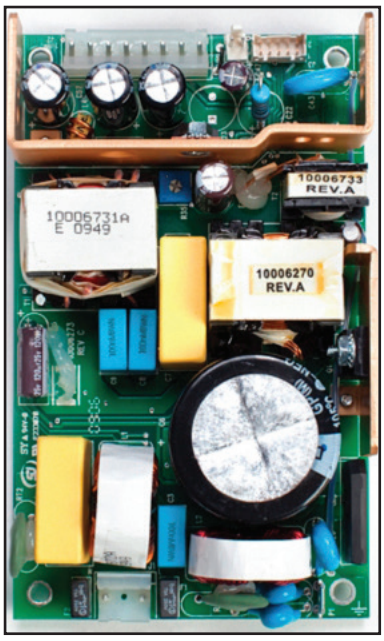


Fig. 8-6 Power Module

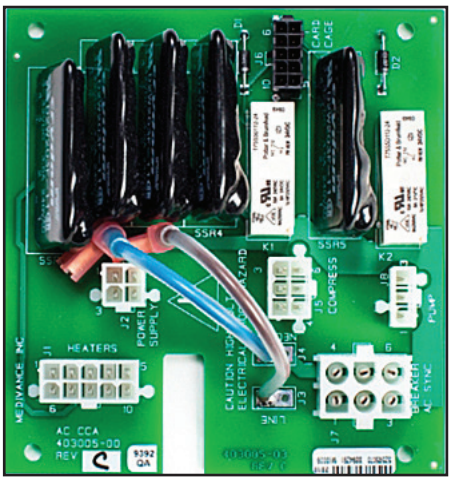


Fig. 8-7 Mains Voltage Circuit Card

8.1 Tools Required

Tools required for component replacement are as follows:	
• 3/8” nut driver	• wire cutter, small
• 5/16” nut driver	• pliers
• 7/16” nut driver	• 7/16” wrench
• Phillips head screwdriver	• 9/16” wrench
• small flat blade screwdriver	• 1/16” hex key

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® Temperature Management System drain tube

1. Turn the Control Module off. Caution: draining the system with power on may damage the chiller.
2. Connect the Drain Tube to the two drain valves on the back of the device. Place the other end of the Drain Tube into a container with a capacity of at least four liters. The device will passively drain all tubing, reservoirs and pumps within the system. 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 (above), 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.

Fig. 8-9 “Total Drain” option on Advanced Setup screen

8.3 Remove Back Panel

Tools and supplies required:
• 3/8” nut driver
• Phillips head screwdriver

1. Remove Fluid Delivery Line and Patient Temperature Cable.
2. Using the 3/8” nut driver, remove the four black bolts on the back panel.
3. Using the Phillips head screwdriver, remove the two screws holding the power cord bracket and unplug the power cord. Take extra care not to drop these screws into the unit.
4. Lift off the back panel and set it aside.

Fig. 8-10 Back panel with indication of bolts to be removed (Step 2, left)

8.4 Remove Outer Shell

Tools and supplies required:
• 7/16” nut driver

1. Remove the four bolts that hold the metal frame to the shell.
2. With one hand holding the back handle and the other hand in the horizontal slot on the front (located a few inches below the Control Panel), gently rock the shell forward. The Outer Shell will slide off. Set it down a few inches away from the frame.
3. There are two cable harnesses connecting the control panel on the shell to the top of the card cage. Disconnect these at the card cage.

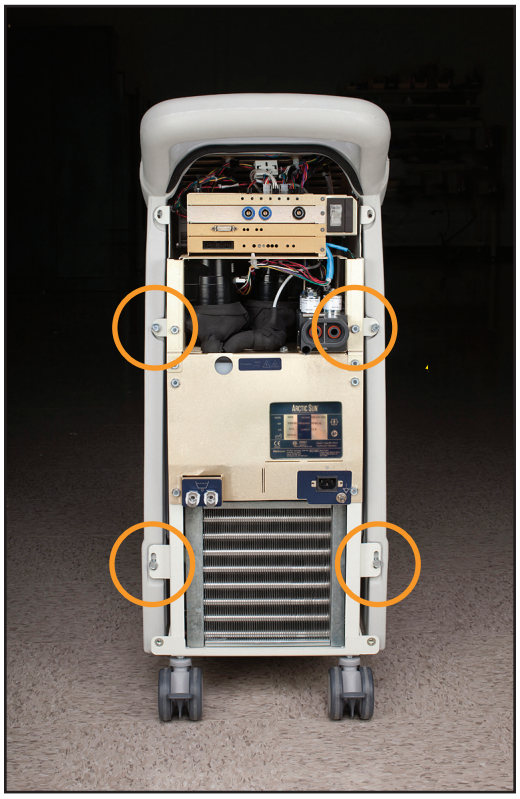


Fig. 8-11 Remove 4 bolts (Step 1)

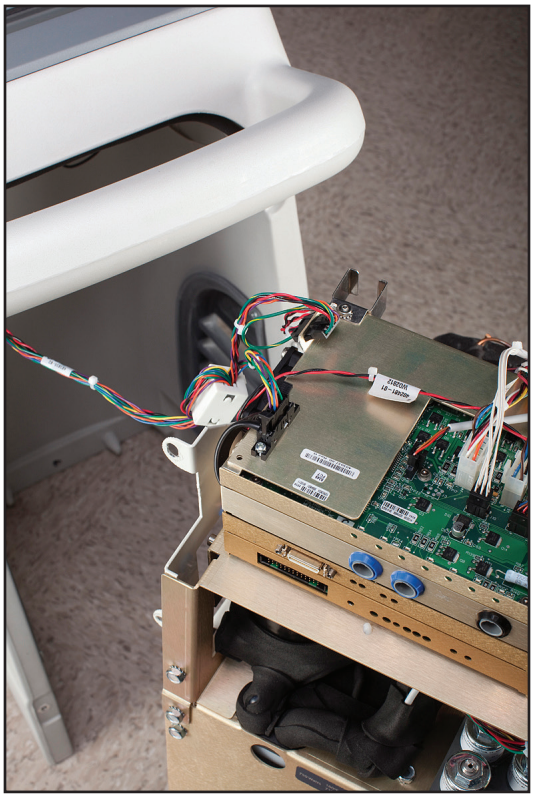


Fig. 8-12 Cable harnesses to be removed (Step 3)

Fig. 8-13 Shell separated from internal components

8.5 Removing / Replacing Circuit Cards from Card Cage

To access the cards in the card cage, remove the back panel and the outer shell as shown in Steps 8.3 and 8.4.

Caution: Observe electrostatic discharge control procedures when handling circuit cards.

A) Input / Output Circuit Card

Tools and supplies required:
• wire cutters
• 1/16” Allen wrench / hex key
• flat blade screwdriver

1. Carefully disconnect each of the eight cables connected to the card, releasing each locking tab before pulling. These connections are illustrated in Fig. 8-15.
2. Clip cable ties with wire cutters as needed.
3. When re-connecting the connections after repair, check labels on J6 and J4 connectors to ensure correct connections.
4. Remove the Allen head screw on the right of the I/O Circuit Card face plate.
5. Slide a screwdriver beneath the I/O Circuit Card to gently pry it away from its base.
6. Carefully pull the circuit card outward to release it from the slots it sits in.
7. When replacing the circuit card, ensure that the card fits into the retaining grooves on either side of the card cage.
8. After replacing the I/O Circuit Card, perform a calibration (see Chapter 9).

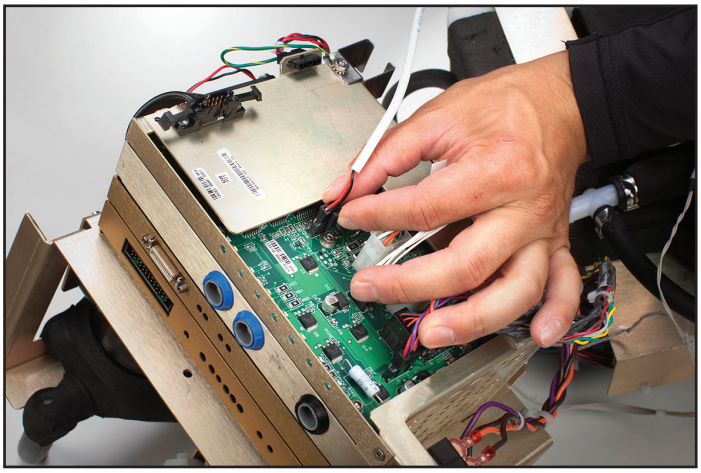


Fig. 8-14 Unplug connections from I/O Card (Step 1)

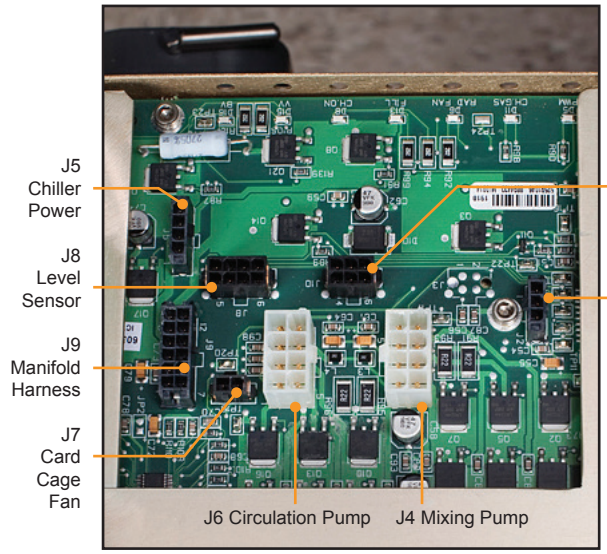


Fig. 8-15 I/O Circuit Card connections

B) Isolation Circuit Card

Tools and supplies required:
• Phillips head screwdriver
• 1/16” hex key
• flat blade screwdriver

1. Remove the Allen head screw on the right of the Isolation Circuit Card face plate.
2. Slide a screwdriver beneath the Isolation Circuit Card to gently pry it away from its base.
3. Carefully slide the circuit card out of the card cage until the card protrudes approximately one inch to expose the cable connecting this card to the top of the card cage.
4. Remove the screws holding the cable that connects this card to the top of the card cage.
5. Carefully pull the circuit card outward to release it from the grooves it sits in.
6. When replacing the circuit card, ensure that the card fits into the retaining slots on either side of the card cage.
7. After replacing the Isolation Circuit Card, perform a calibration (see Chapter 9).

C) Processor Circuit Card

Tools and supplies required:
• 1/16” hex key
• flat blade screwdriver

1. Remove the Allen head screw on the right of the Processor Circuit Card face plate.
2. Slide a screwdriver beneath the Processor Circuit Card to gently pry it away from its base.
3. Carefully pull the circuit card outward to release it from the grooves.
4. When replacing the circuit card, ensure that the card fits into the retaining slots on either side of the card cage.
5. After replacing the Processor Circuit Card, perform a calibration (see Chapter 9).

D) Power Circuit Card

Tools and supplies required:
• 1/16” hex key • flat blade screwdriver

1. Remove the Allen head screw on the right of the Power Circuit Card face plate.
2. Slide a screwdriver beneath the Power Circuit Card to gently pry it away from its base.
3. Carefully slide the circuit card out of the card cage until the card protrudes approximately one inch (3 cm) to expose the three connections.
4. Carefully disconnect each of the three connections, releasing each locking tab before pulling. (When replacing these connections, tuck the wires into place against the foam.)
5. When replacing the circuit card, ensure that the card fits into the retaining slots on either side of the card cage.

8.6 Replacing Upper Components

Tools and supplies required:
• Flat blade screwdriver • small flat blade screwdriver • wire cutters

1. Remove the four bolts on the back of the device.
2. Remove the two bolts on the front of the device.
3. Carefully pull up on the top half of the unit leaving the front in contact with the lower half to prevent the wire harness from getting damaged.

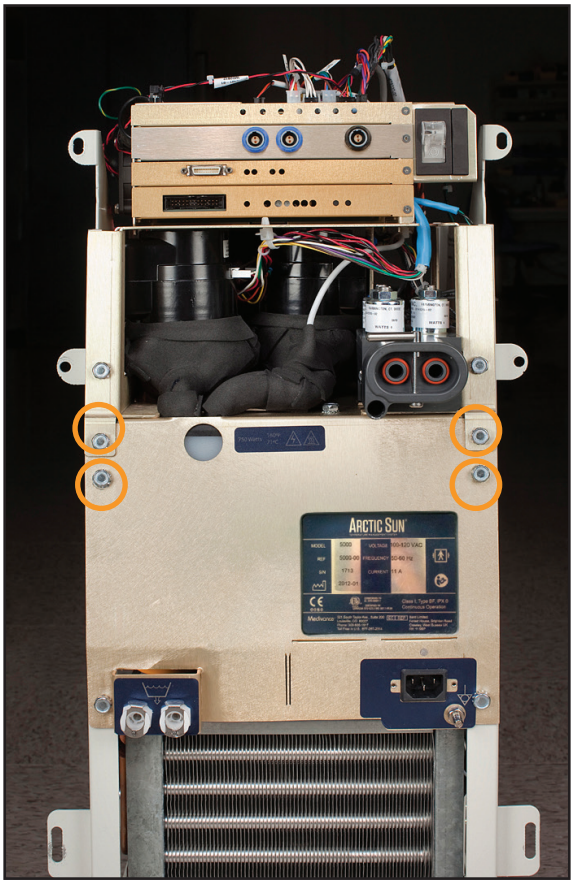


Fig. 8-16 Remove four bolts (Step 1)

Fig. 8-17 Remove two bolts (Step 2)

Fig. 8-18 Pull up top half (Step 3)

8.7 Removing Internal Components from Chiller Frame

Tools and supplies required:
• 7/16” nut driver • small-blade flat head screwdriver

1. Remove six bolts holding internal components onto frame.
2. From the right side of the Control Module, carefully disconnect the Chiller power connection gray cable.
3. If device is equipped with an AC pump from the left side of the Control Module, disconnect the black compressor-evaporator tubing from the white plastic fitting it connects to. Use the small flat blade screwdriver to pop the snap fitting open. (Use pliers to re-close the snap fitting upon reassembly.) If device is equipped with a DC pump, from the left side of the control module, remove black molded tubing connecting chiller pump to chiller evaporator. Use a small flat-head screwdriver to loosen and disconnect two clamps. Discard them.
4. From the front of the Control Module, place one hand underneath the internal components and tilt them forward, and then lift out the internal components.

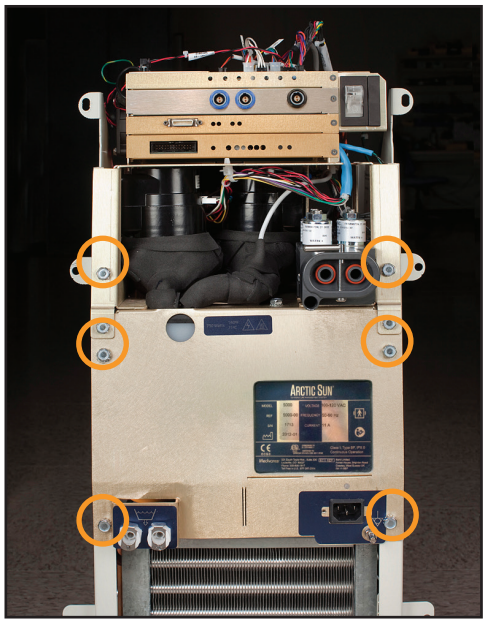


Fig. 8-19 Remove six bolts (Step 1)

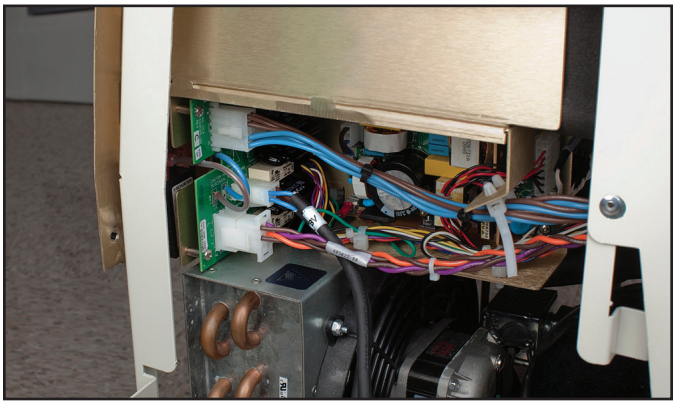


Fig. 8-20 Disconnect Chiller power connection gray cable; location indicated (Step 2)

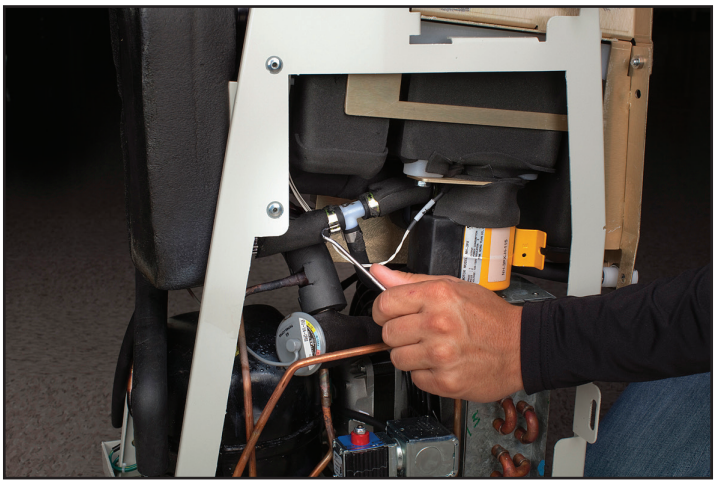


Fig. 8-21 Open the snap fitting (Step 3 - AC pump)

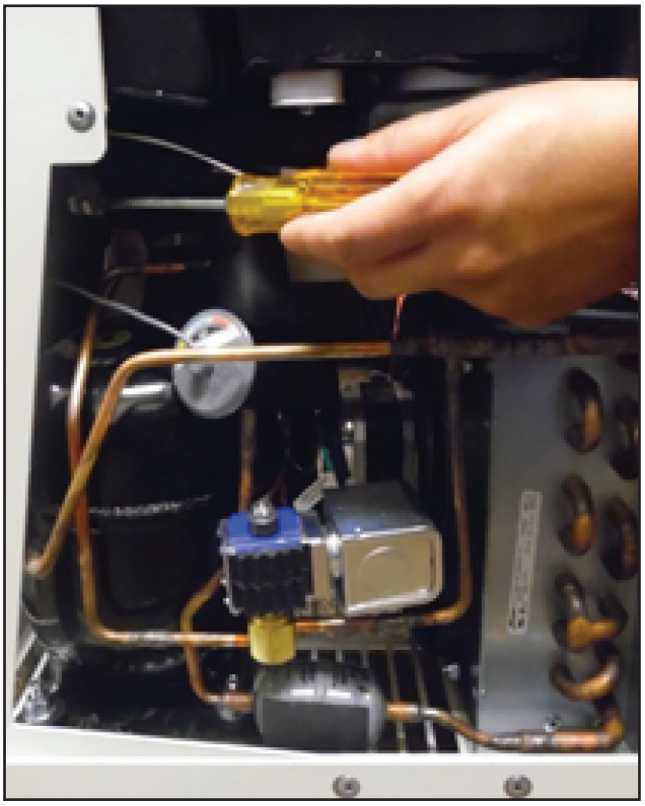


Fig. 8-22 Disconnect two clamps (Step 3- DC pump)

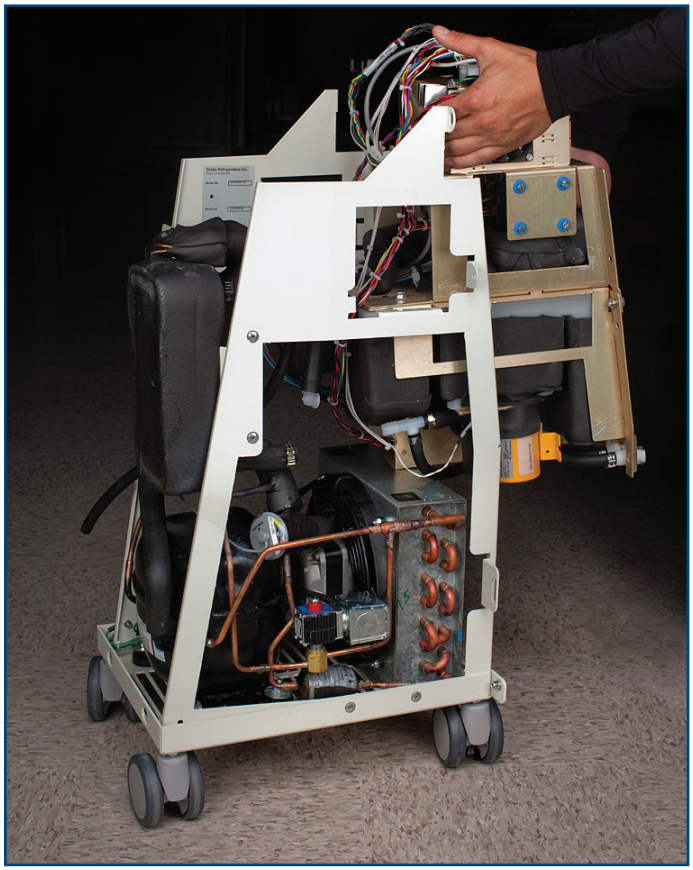


Fig. 8-23 Lift out the internal components (Step 4)

8.8 Separating the Internal Components into Two Sections

The internal components separate into two sections, one of which contains the Circulation Pump and Mixing Pump, and the other the Heater and tank.

Tools and supplies required:
• 7/16” nut driver • wire cutter

1. Remove the four bolts as shown (see Fig. 8-24 and Fig. 8-25).
2. Slide the two sections apart.
3. Disconnect the AC Breaker Harness, cutting cable ties as necessary.

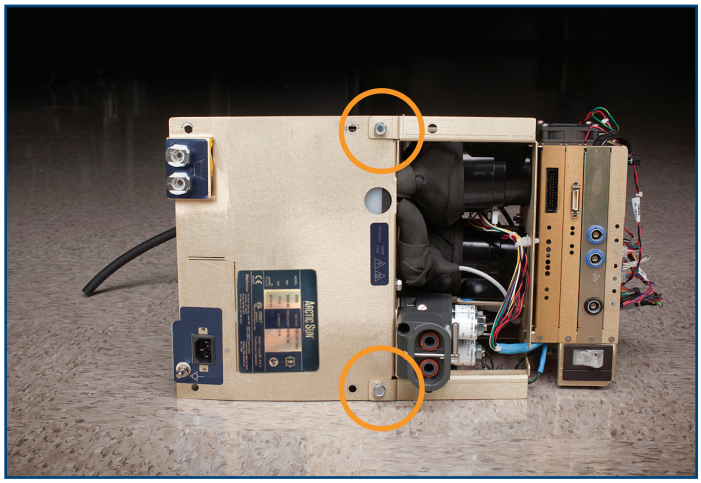


Fig. 8-24 Internal components prior to being separated into two sections (front view)

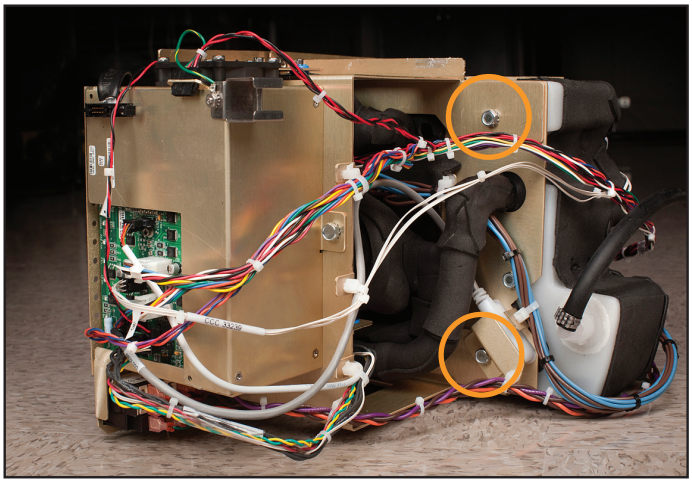
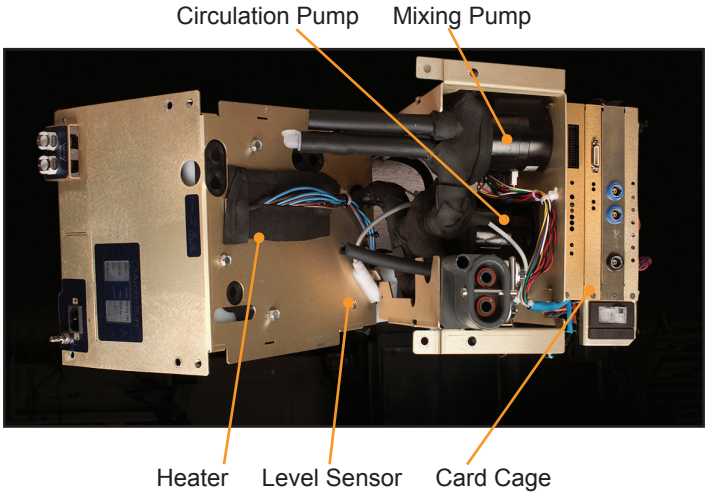


Fig. 8-25 Internal components (rear view); circles indicate bolts to remove (Step 1)



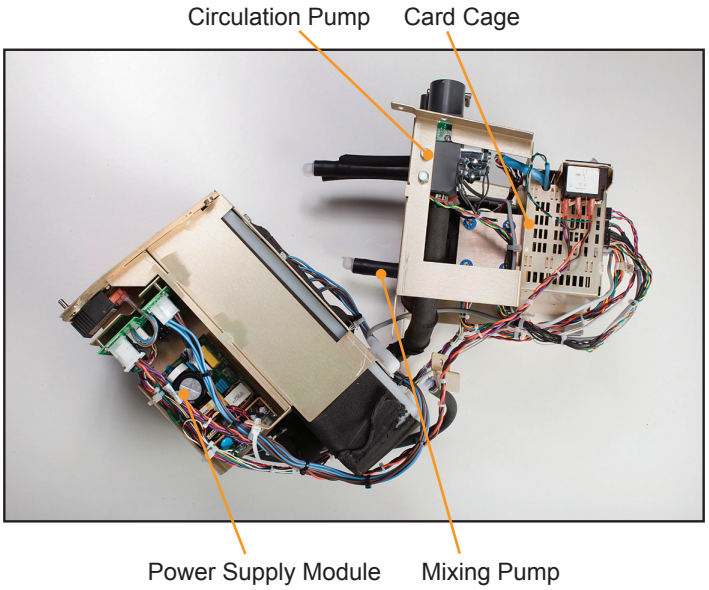


Fig. 8-26 Internal components separated into two sections (2 views)

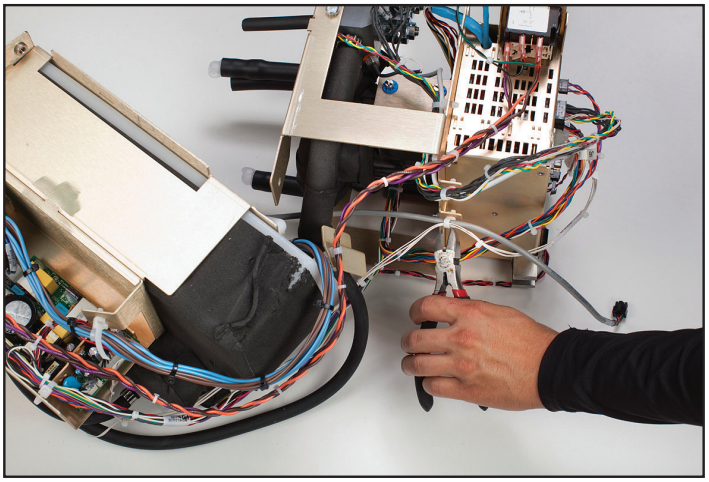


Fig. 8-27 Cut cable ties (Step 3)

Fig. 8-28 Chiller frame

8.9 Replacing Mixing Pump

Tools and supplies required:
• flat blade screwdriver

1. Remove internal components from the Chiller frame and separate them into two sections (Steps 8.6, 8.7 or 8.8).
2. Disconnect the cable that connects the Mixing Pump to the I/O Board. When re-connecting, ensure that the connector is correctly seated; with no exposed pins on either side (see Figure 8-32).
3. Using the screwdriver, remove the four mounting screws.
4. Leave cable ties intact.
5. Carefully remove the Mixing Pump.
6. When re-connecting, ensure that the connector is correctly seated, with no exposed pins on either side (see Figure 8-32).

Fig. 8-29 Mixing Pump

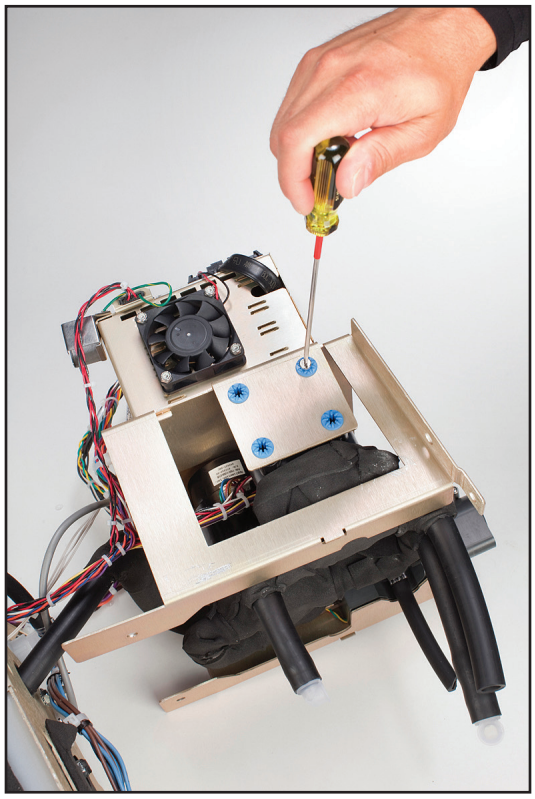


Fig. 8-30 Remove four mounting screws (Step 3)

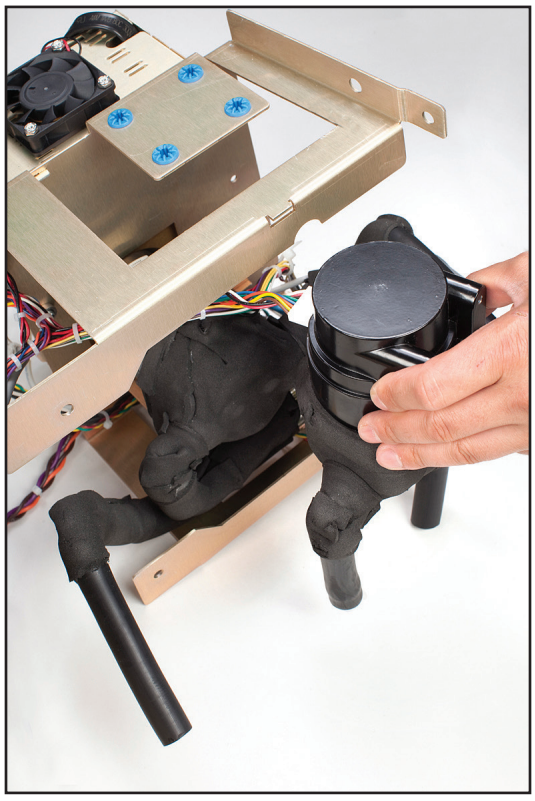


Fig. 8-31 Carefully remove the Mixing Pump (Step 5).

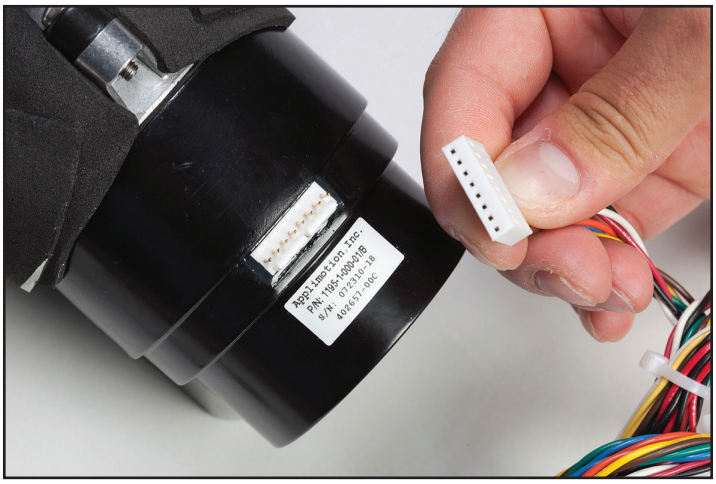


Fig. 8-32 Illustration of pump connector prior to being connected (above), connected but seated incorrectly with one pin exposed (below left), and seated correctly (below right)

8.10 Replacing Circulation Pump

Tools and supplies required:
• flat blade screwdriver • small flat blade screwdriver • wire cutters

1. Remove internal components from the Chiller frame and separate them into two sections (Steps 8.6, 8.7 or 8.8).
2. Disconnect the cable that connects the Circulation Pump to the I/O Board.
3. Using the screwdriver, loosen the four blue-circled screws on the brass plate that is part of the frame until the pump is loose.
4. Use the small flat blade screwdriver to pop the snap fitting open.
5. Carefully remove the Circulation Pump.
6. When re-connecting, ensure that the connector is correctly seated, with no exposed pins on either side (see Figure 8-32).
7. Reconnect the cable connecting the Circulation Pump to the I/O Board.

Fig. 8-33 Circulation Pump

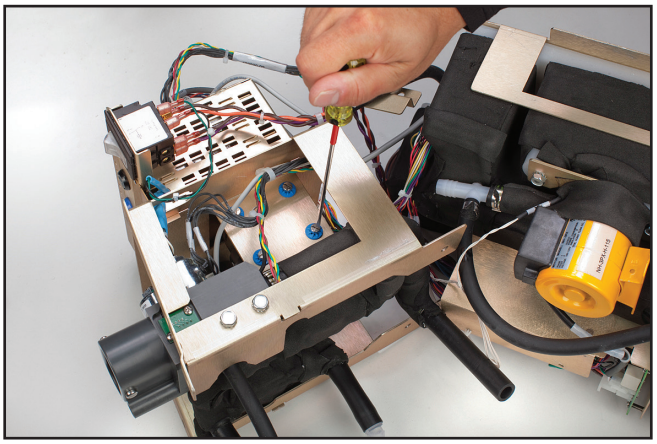


Fig. 8-34 Loosen the four blue-circled screws (Step 3)

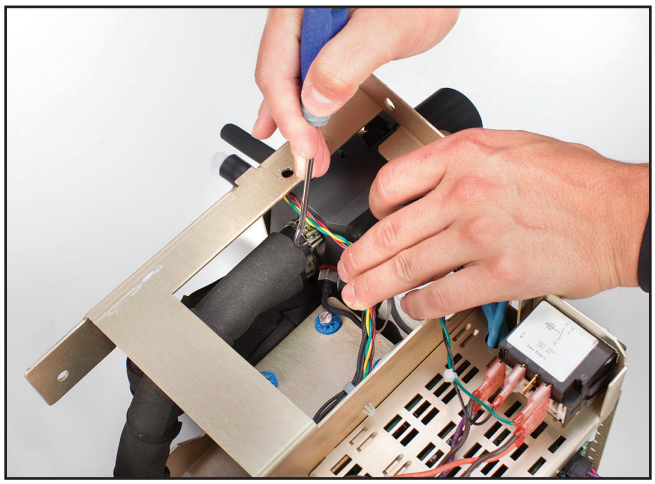


Fig. 8-35 Pop snap fitting open (Step 4)

8.11 Replacing Drain Valves

Tools and supplies required:
• flat blade screwdriver • pliers

1. Remove the back panel as shown in Section 8.3.
2. Remove outer shell as shown in Section 8.4.
3. Remove the 6 bolts as shown in figure 8-36.

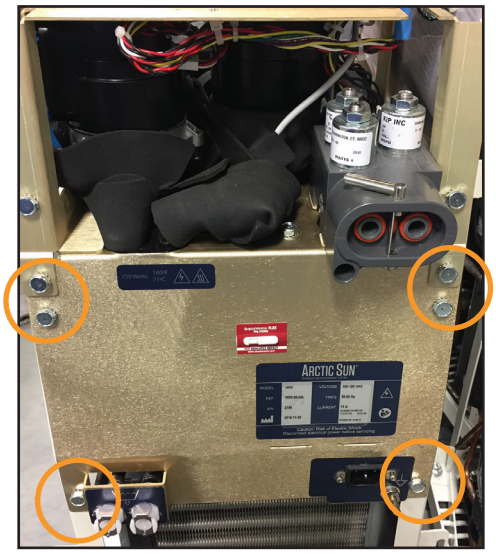


Fig. 8-36 Remove six bolts (Step 3)

4. Extend the Internal Components approximately an inch as shown in Figure 8-37.

Fig. 8-37 Internal Components Extended (Step 4)

5. Using the tip of a flat blade screwdriver, open clamps that secure tube to back of valve (see Figure 8-38).

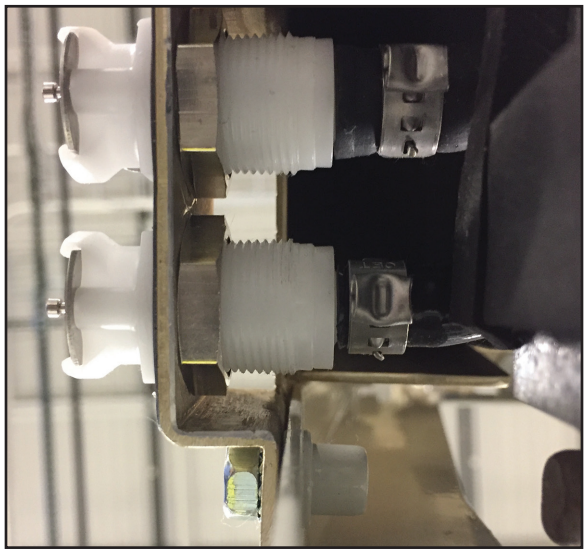


Fig. 8-38 Rear of Drain Valves (Step 5)

6. Loosen nuts on backside of valve until they are clear of the valve threads.
7. Grasp the tube while removing the valve from the chassis to prevent damage to the tube when removing the valve.
8. Remove and discard old nuts from tubing.
9. Place the nuts and the new clamps over the molded tubing.
10. Insert valve from front of chassis. Press tubing onto valve. Slide nuts up and thread onto valves until valves are secure.
11. Position clamps against the body of the valve and then tighten the clamps.
12. Observe the tubing during filling to ensure no leaking is present.

8.12 Replacing AC Chiller Pump

Tools and supplies required:
• 7/16” wrench • 5/16” nut driver • small flat blade screwdriver

1. Remove internal components from the Chiller frame and separate them into 2 sections (Steps 8.6, 8.7 or 8.8).
2. Remove the pump power connector from the Mains Voltage Circuit Card.
3. Using the 5/16” nut driver, remove the ground connection by unscrewing and removing the nut shown in Figure 8-40.
4. Remove the two bolts on either side of the Chiller Pump.
5. Remove the Chiller Pump.
6. Use the small flat blade screwdriver to pop open the clamp connecting the Chiller Pump tubing to the drain valve. (Use pliers when reconnecting.)
7. When reinstalling, insert the seal into the tank first and then reinstall the pump.

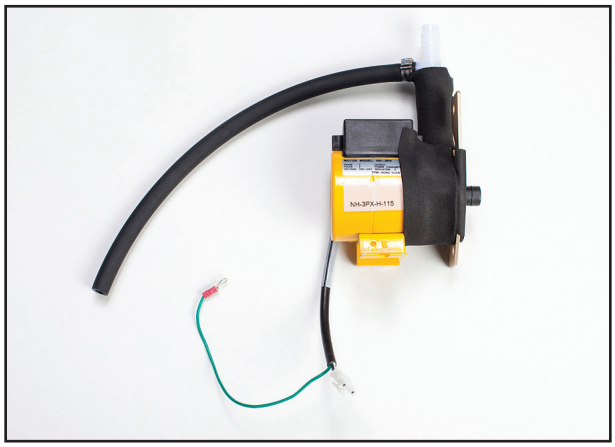


Fig. 8-39 Chiller Pump

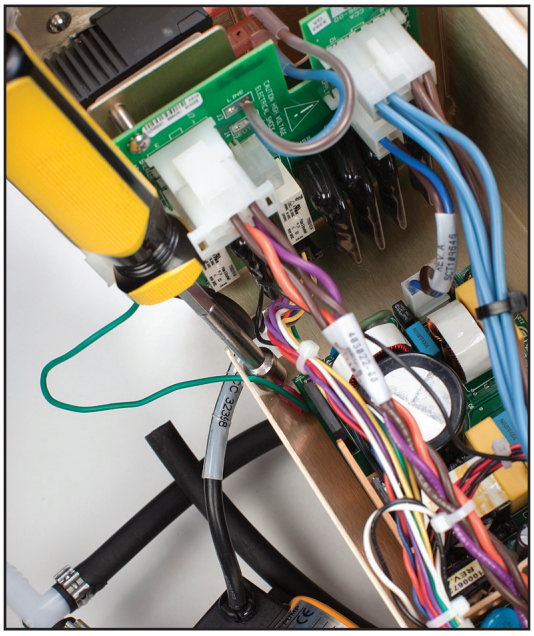


Fig. 8-40 Ground connection to be removed; location of nut is indicated (Step 3)

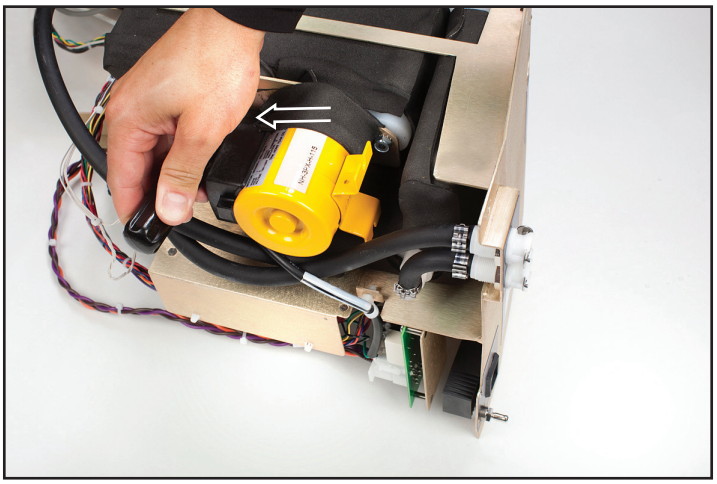


Fig. 8-41 Remove bolts on either side of Chiller Pump (Step 4)

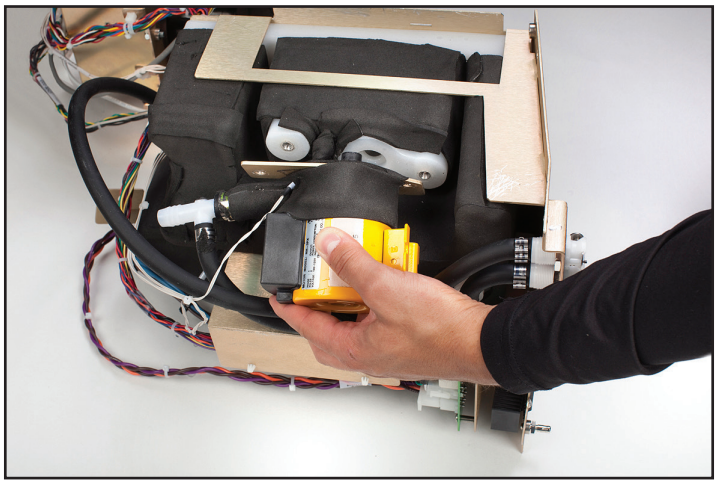


Fig. 8-42 Remove Chiller Pump

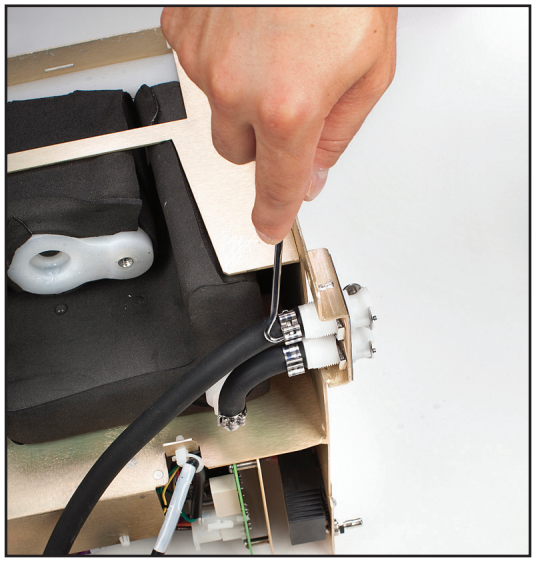


Fig. 8-43 Open clamp connecting Chiller Pump tubing to the drain valve

8.13 Replacing DC Chiller Pump

Tools and supplies required:
• 7/16” nut driver • small flat blade screwdriver • wire cutters

1. Remove the internal components (Steps 8.6, 8.7, or 8.8).
2. Using the wire cutters cut the cable tie to free up chiller pump power supply connectors and disconnect cables from AC circuit board.
3. Loosen chiller pump clamp and remove tube from drain valve.
4. Remove two 5/16” bolts securing chiller pump to frame.
5. Pull chiller pump assembly from device.
6. When reinstalling DC chiller pump, place two O-rings on inlet side and insert chiller into tank. Ensure even insertion of O-rings.
7. Reassemble device.

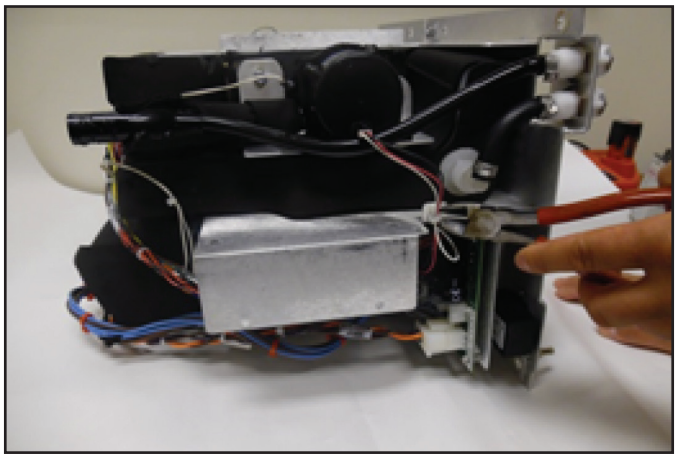


Fig. 8-44 Cut cable tie (Step 2)

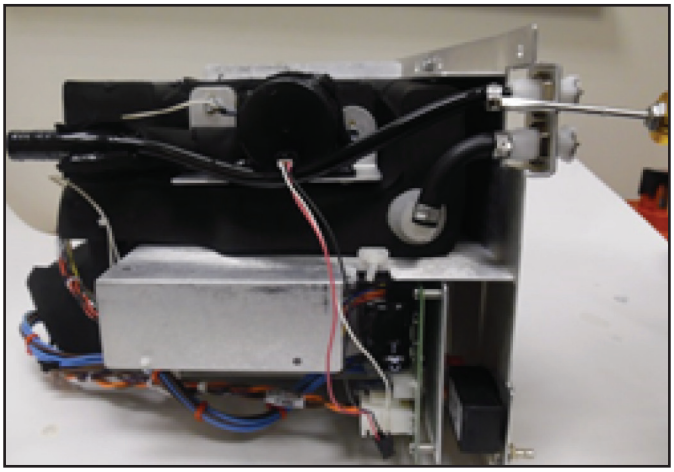


Fig. 8-45 Loosen clamp (Step 3)

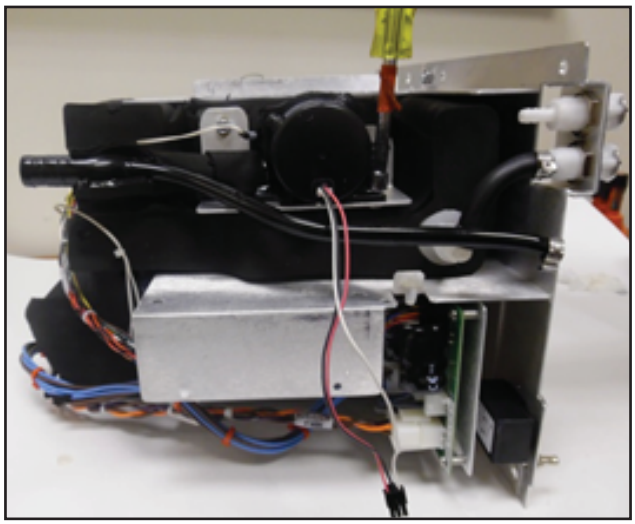


Fig. 8-46 Remove bolts (Step 4)

Fig. 8-47 Reinstall pump (Step 6) (two views)

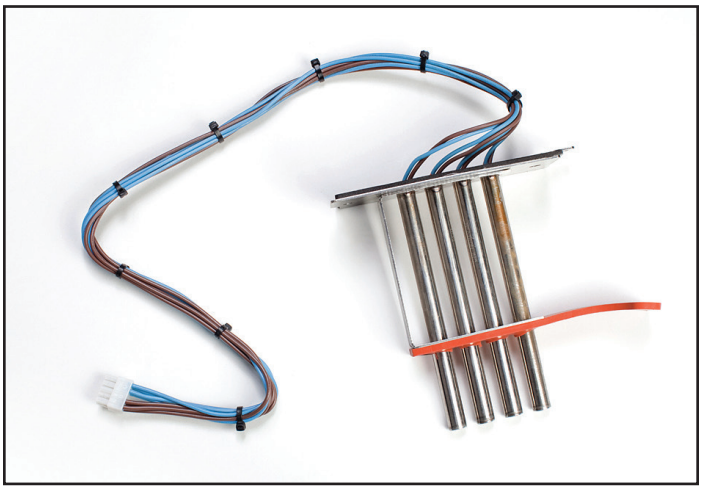


Fig. 8-48 Heater

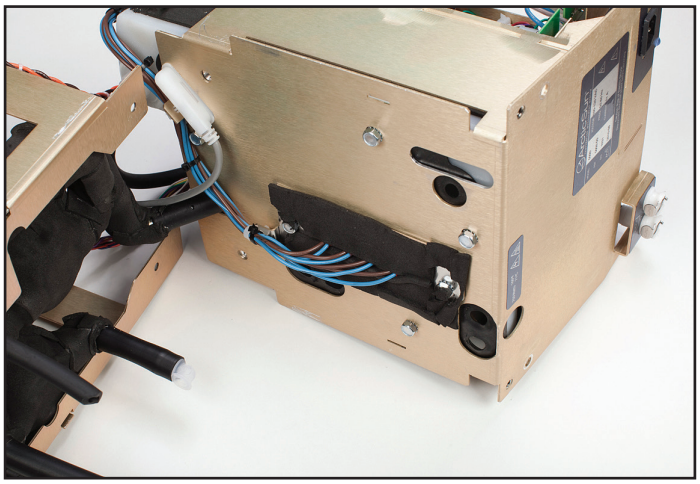


Fig. 8-49 Tank and Heater with indication of cable ties to be removed (Step 2)

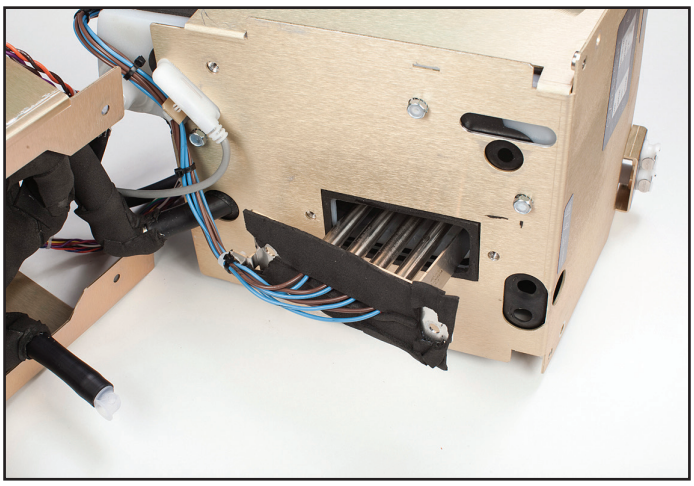


Fig. 8-50 Remove the Heater (Step 4)

8.14 Replacing Heater

Tools and supplies required:
• wire cutters • 7/16” nut driver

1. Remove internal components from the Chiller Frame and separate them into two sections (Steps 8.6, 8.7 or 8.8).
2. Using the wire cutters, cut the cable ties holding the cable to the frame.
3. Remove the two bolts on either side of the black foam covering the Heater.
4. Carefully remove the Heater unit.
5. When replacing the Heater, ensure that the orange rubber tab faces the back of the unit. It is important that the tab is horizontal and not bent.

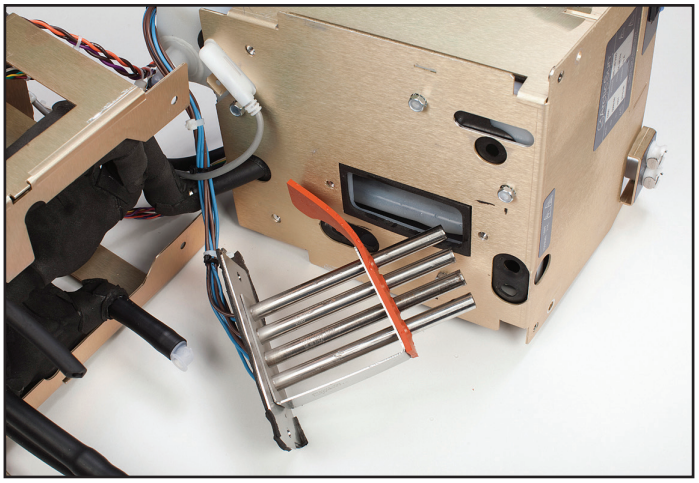


Fig. 8-51 Proper direction for orange tab to face when replacing Heater (Step 5)

8.15 Replacing Flowmeter

Tools and supplies required:
• flat blade screwdriver
• small flat blade screwdriver
• wire cutters

1. Remove internal components from the Chiller frame and separate them into two sections (Steps 8.6, 8.7, or 8.8).
2. Remove Circulation Pump as described in step 8.10.
3. Remove insulation covering the Flowmeter.
4. Unscrew the Flowmeter tube from the pump.
5. When installing a new Flowmeter, note that there is a white arrow on the Flowmeter that indicates direction of flow. It needs to be pointed away from the pump.
6. Re-insulate the Flowmeter.

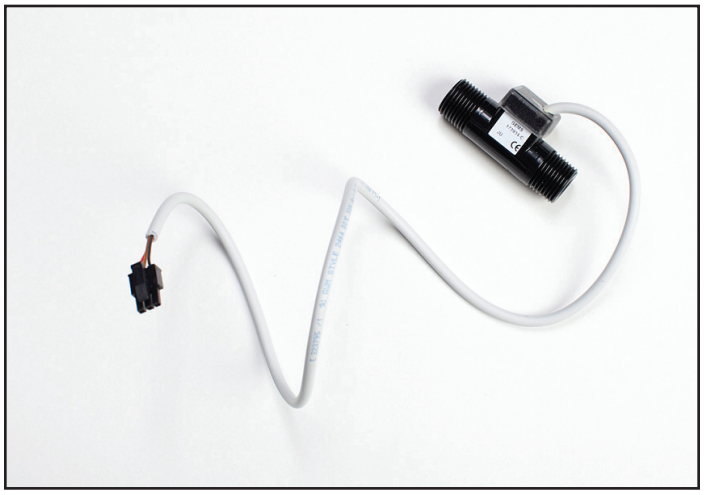


Fig. 8-52 Flowmeter and cable

Fig. 8-53 Flowmeter with arrow indicating direction of flow; same direction as Circulation Pump output

8.16 Replacing Control Panel

Tools and supplies required:
• 7/16” nut driver

1. Remove Back Panel (Step 8.3).
2. Remove Outer Shell (Step 8.4).
3. From the inside of the Outer Shell, using the 7/16” nut driver, remove the four bolts holding the Control Panel to the shell.
4. Press the Control Panel outward.
5. When replacing, gently set the new Control Panel into place and tighten bolts.

Fig. 8-54 Control Panel (front view)

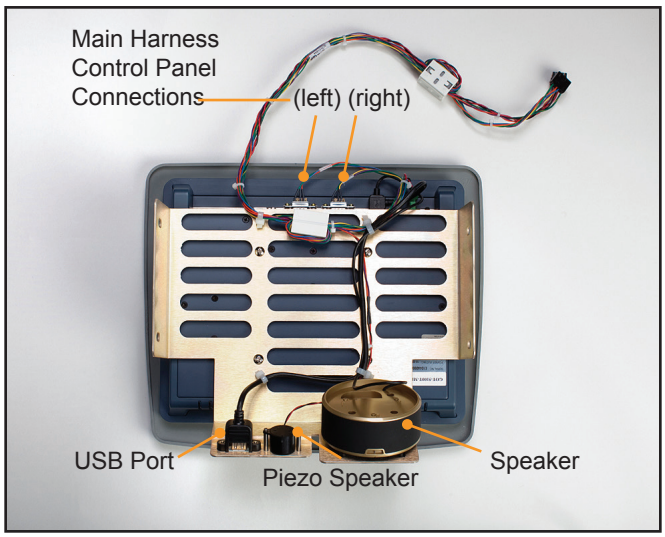


Fig. 8-55 Control Panel (rear view)

8.17 Replacing Chiller

Tools and supplies required:
• pliers

1. Remove internal components from Chiller Frame that is being replaced (Step 8.7).
2. Connect the black compressor-evaporator tubing to the white plastic fitting it connects to. Use pliers to close the snap fitting (reverse of Step 8.7, no. 3).
3. Connect the Chiller Pump.
4. Reconnect Chiller power connection (reverse of Step 8.7, no. 2).

Fig. 8-56 Chiller Frame

8.18 Replacing Tank Temperature Sensor Harness

The Tank Temperature Sensor Harness connects the Chiller Pump with the tank.

Tools and supplies required:
• wire cutters

1. Remove internal components from the Chiller frame and separate them into two sections (Steps 8.6, 8.7, or 8.8).
2. Remove insulation from the point at which the thermister enters the tank.
3. Remove the associated cable ties.
4. Remove the piece of insulation tape that holds the sensor to the top of the tank.
5. Remove the Chiller Pump (Step 8.12 or 8.13).
6. Remove the old Tank Temperature Sensor Harness, making note of where each of the two temperature sensors, labeled T1/T2 and T4, plug in.
7. Modify insulation as shown such that T4 fits properly into tank (see Figure 8-58)
8. Plug in the new Harness. The T1/T2 and T4 connections will rotate into place. To avoid damaging the wire, twist each of these wires in the opposite direction to provide some slack before slipping the washer on and rotating the connection into place.
9. Reinstall the Chiller Pump.
10. Use the provided insulation material to seal the connection between the sensor and the tank.
11. Perform a calibration (see Chapter 9).

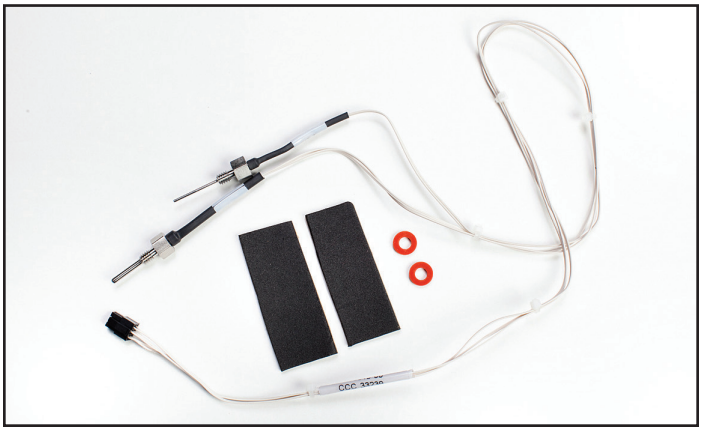


Fig. 8-57 Tank Temperature Sensor Harness

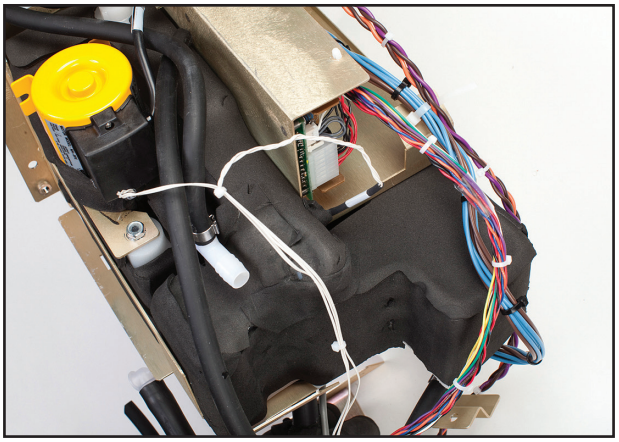


Fig. 8-58 Tank Temperature Sensor Harness in place.

8.19 Replacing Manifold Harness

Tools and supplies required:
• 9/16” wrench • small flat blade screwdriver • 7/16” wrench or nut driver

1. Remove internal components from the Chiller frame and separate them into two sections (Steps 8.6, 8.7, or 8.8).
2. Using the 9/16” wrench or nut driver, loosen and remove the two bolts that connect the Manifold to the brass frame
3. Using small flat blade screwdriver, pop open the two clamps connecting the tubing to the Manifold, opening the clamp closest to the metal frame first.
4. The Manifold Harness connects to three Solenoids (FV - Fill Valve, BV - Bypass Valve, and VV - Vent Valve); 1 Thermistor and 1 Pressure Transducer. Medivance ships replacement Manifold Harnesses complete with the three valve stems and the T3 thermistor.
5. Using the 9/16” wrench, disconnect the Manifold Harness from the solenoids by removing the nut on each solenoid.
   Use a screwdriver to prevent the stem of the valve from rotating during removal.
6. Using the 7/16” wrench, unscrew and remove the thermistor.
7. Disconnect the pressure transducer.
8. When reinstalling the Manifold Harness, note that there are labels on the harness identifying the solenoids (FV, BV, VV). If the solenoids are not in the proper position as shown, the device will not work properly (Fig. 8-62).
9. Perform a calibration (see Chapter 9).

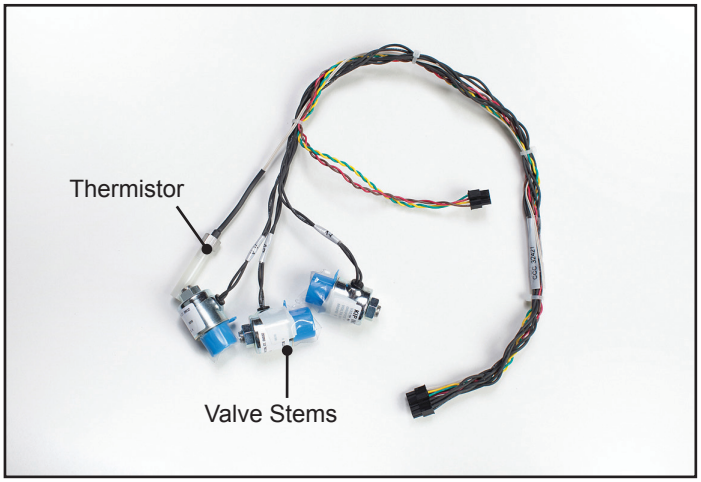


Fig. 8-59 Manifold Harness (shown with protective caps)

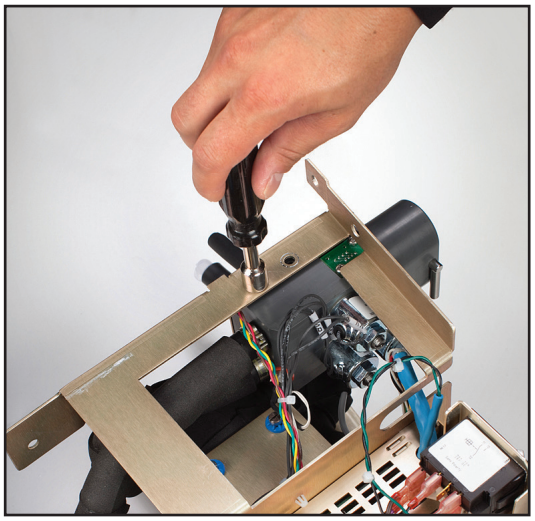


Fig. 8-60 Remove bolts (Step 2)

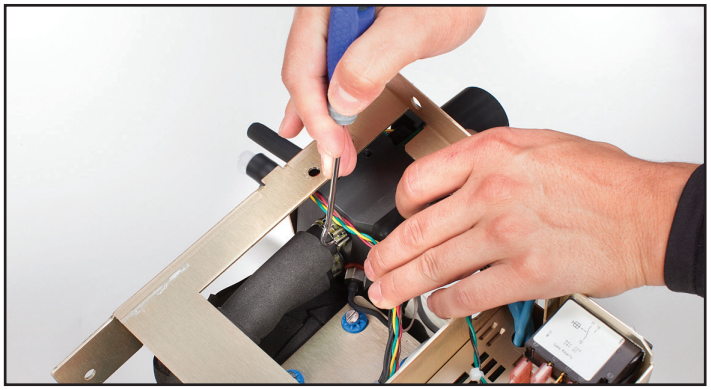


Fig. 8-61 Pop open clamps (Step 3)

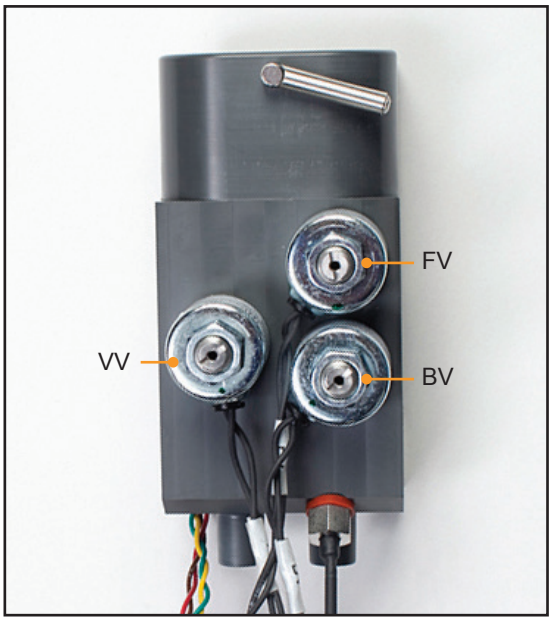


Fig. 8-62 Manifold, showing position of the 3 solenoids (Step 8)

8.20 Replacing Inlet/Outlet Manifold

Tools and supplies required:
• 9/16” nut driver • Phillips head screwdriver • flat blade screwdriver

1. Remove bolts as in Step 8.19.2.
2. Remove the clamps as in Step 8.19.3.
3. Using Phillips head screwdriver, disconnect pressure transducer from the Manifold.
4. Disconnect the entire Manifold Harness.
5. Remove the solenoids and valve stems using flat blade screwdriver.
6. Remove the thermistor.
7. When reinstalling, connect the valve stems first, then the solenoids, then the pressure transducer, then the thermistor.
8. When reinstalling the Manifold Harness, note that there are labels on the harness identifying the solenoids (FV, BV, VV). If the solenoids are not in the proper position as shown, the device will not work properly (Fig. 8-62).

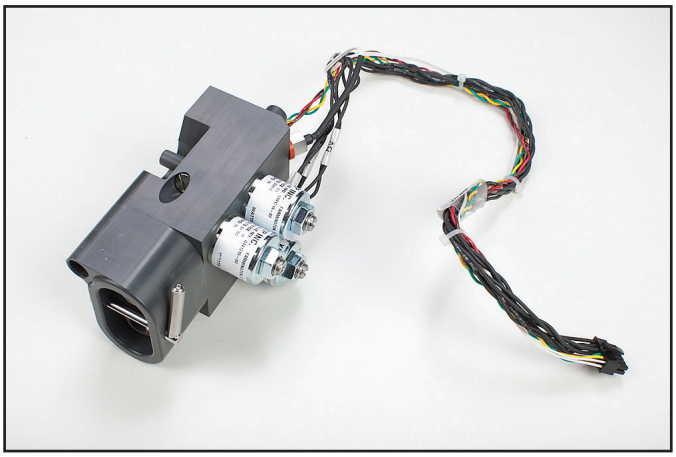


Fig. 8-63 Manifold Assembly

8.21 Replacing Level Sensor

Tools and supplies required:
• wire cutters

1. Disconnect gray cable from the I/O board (See Fig. 8-15, I/O Circuit Card connections).
2. Using wire cutters, remove the cable tie
3. Remove the bracket holding the level sensor into the tank.

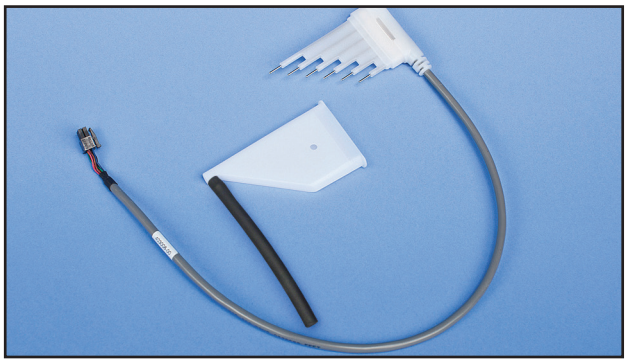


Fig. 8-64 Level Sensor

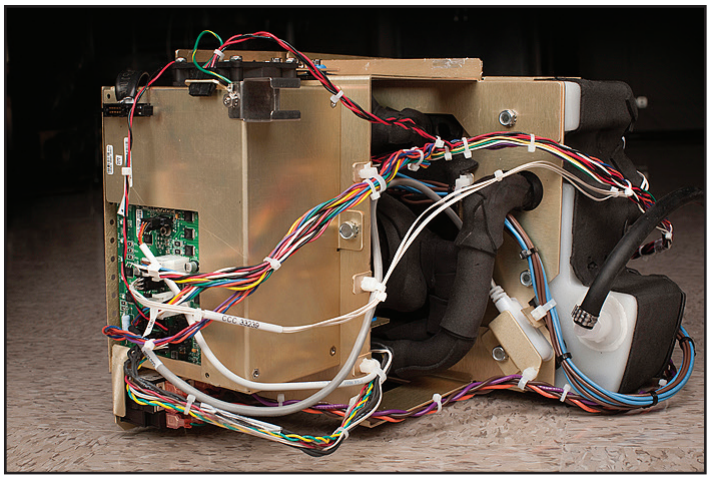


Fig. 8-65 Position of Level Sensor is indicated

8.22 Replacing Power Module

Tools and supplies required:
• Phillips head screwdriver • flat blade screwdriver

1. Using Phillips head screwdriver, remove the four screws that connect the board to the frame.
2. Wedge the flat blade screwdriver underneath the board and carefully pry the board loose.
3. Disconnect the smaller connector.
4. Disconnect the jumper from the Mains Voltage Card.

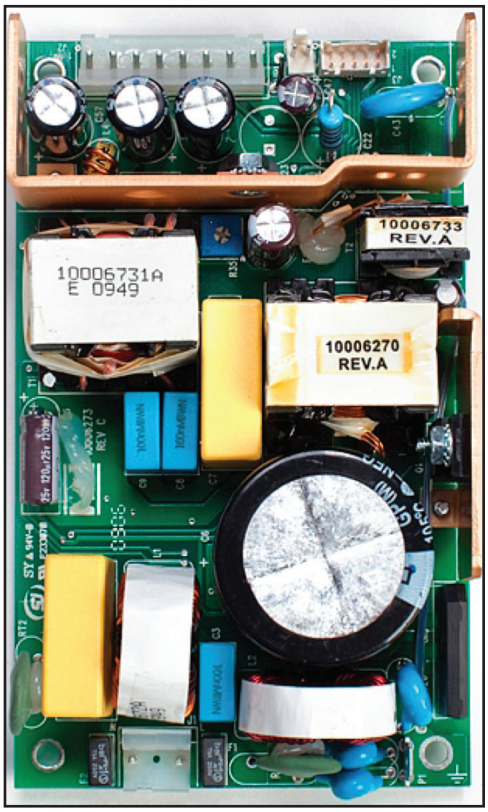


Fig. 8-66 Power Module

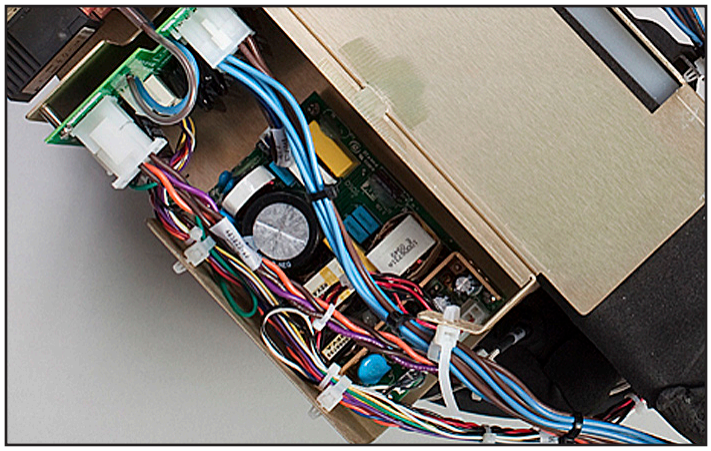


Fig. 8-67 Power Module in position with connections in place

8.23 Replacing Mains Voltage Circuit Card

Tools and supplies required:
• pliers • Phillips head screwdriver

1. Disconnect the AC Breaker Harness.
2. Disconnect jumper to Power Circuit Card.
3. Disconnect Chiller Pump power.
4. Disconnect two connectors that go to power inlet module (plug).
5. Disconnect the Heater power cable.
6. Using Phillips head screwdriver, unscrew the board from the metal frame.

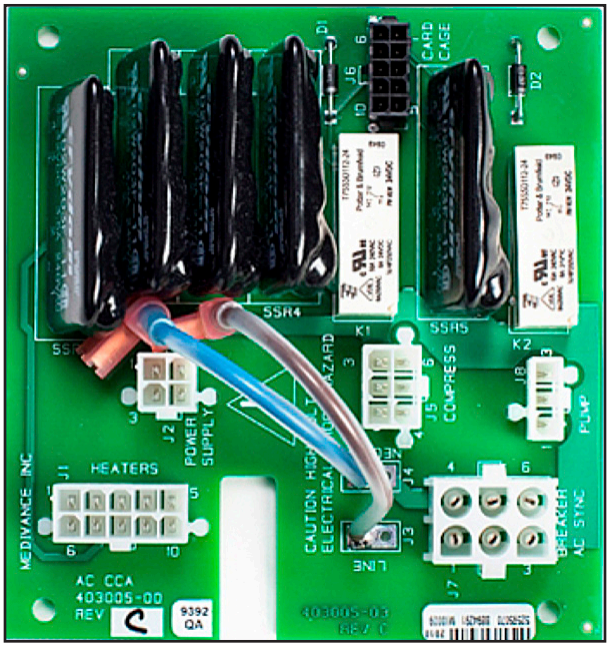


Fig. 8-68 Mains Voltage Circuit Card

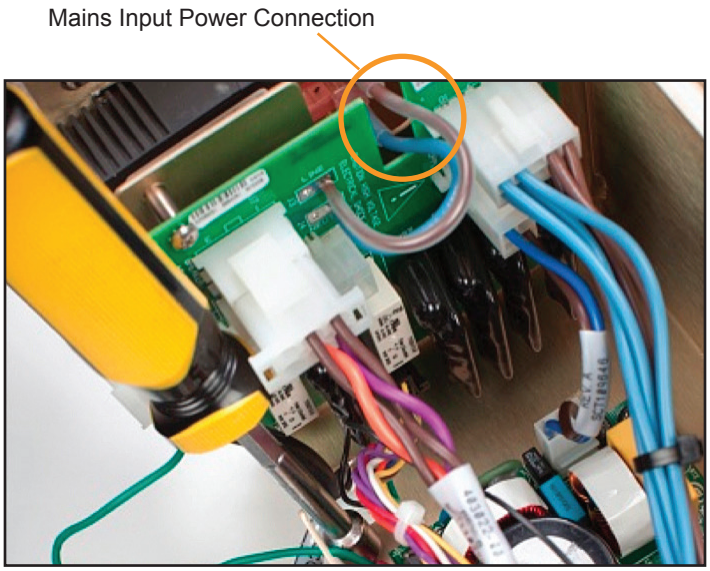


Fig. 8-69 Mains Voltage Circuit Card in position, with connections in place

8.24 Replacing the AC Breaker Harness

If the harness must be replaced, connections on the switch should be made as indicated below. Ensure all connections are secured tightly. If a connector must be removed, do not move connector side to side, pull straight back. If any of these connections appear loose, remove the harness and completely replace. A loose connection between the harness and the breaker could cause excessive heat to be generated at the connections.

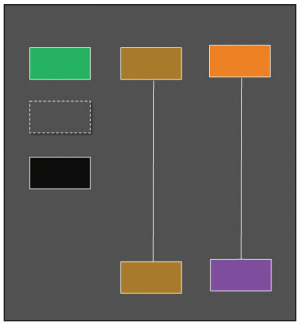


Fig 8-70 wiring diagram for AC breaker

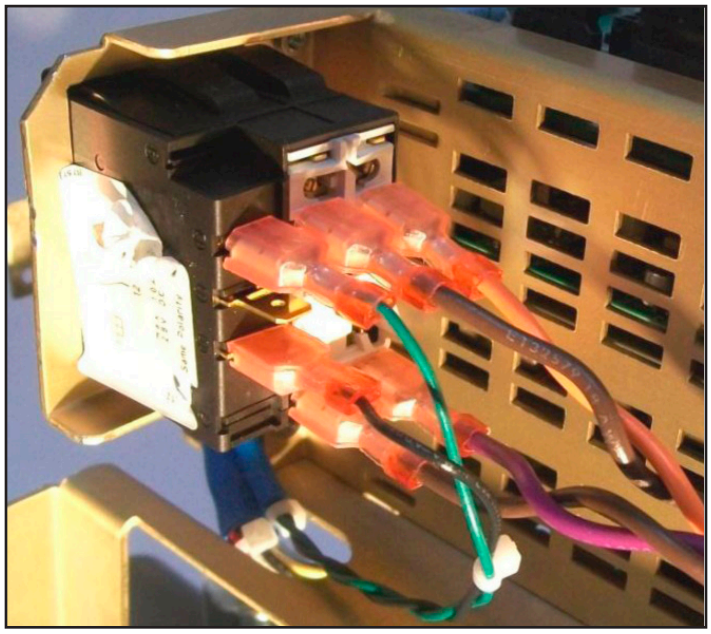


Figure 8-71 AC Breaker Harness connections to AC breaker

8.25 Installing Transmission Interface Module

Tools and supplies required:
• 3/8” Socket wrench

1. Remove the bolt from the upper left of the back of the device.
2. Place the bracket on the back of the device and use bolt provided to secure.
3. Insert transmission interface module (TIM) into bracket.
4. Connect USB cable to left side of module and front of device.
5. Connect RS232 cord to right side of module and hospital IT system.
6. Power on system and start therapy to begin data output.

NOTE: Software version 2.0 or higher required.

Fig. 8-72 Remove bolt (Step 1)

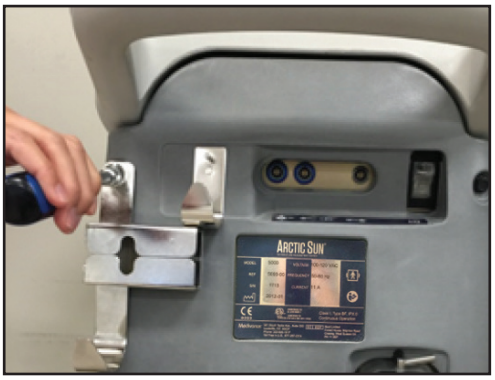


Fig. 8-73 Secure bracket (Step 2)

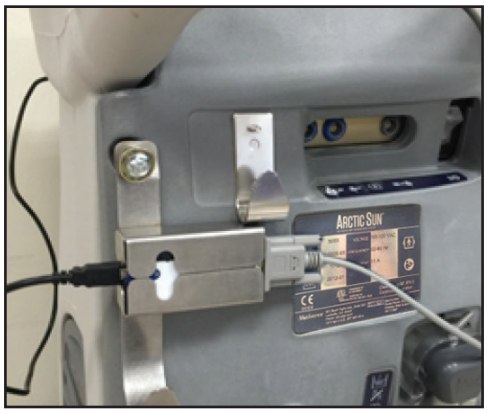


Fig. 8-74 Insert TIM and connect cables (Steps 3-5)

Chapter 9 – Calibration / Calibration Check

9.1 Calibration Test Unit

A separate device, the Calibration Test Unit (CTU) is required to perform periodic calibration on the Arctic Sun® Temperature Management System.

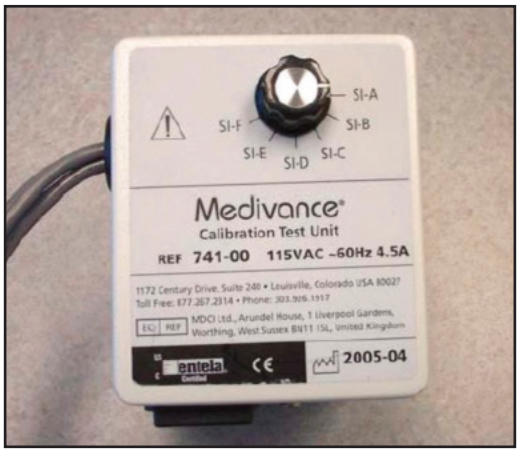


Fig. 9-1 Calibration Test Unit

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. 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® Temperature Management System. Lock in place by flipping latch from left to right.
2. Attach three cables coming from CTU to PT1, PT2, and T0.

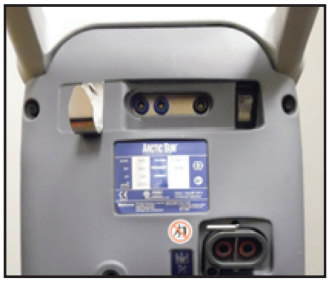


Fig. 9-2 Attach CTU (Step 1)

Fig. 9-3 Attach cables (Step 2)

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 Calibration and follow the on-screen instructions.

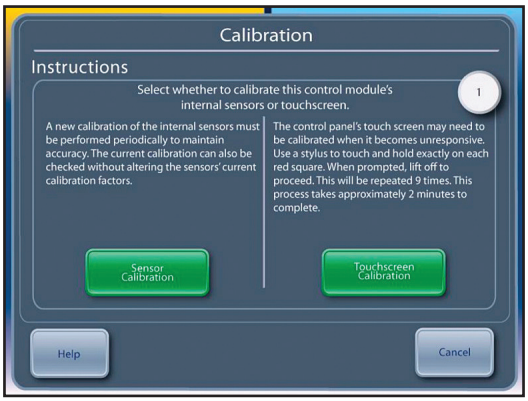


Fig. 9-4 Calibration screen

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). The Arctic Sun® Temperature Management System consists of the Control Module and disposable ArcticGel™ Pads.

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 42°C (39.2°F and 107.6°F) through the ArcticGel™ Pads at approximately 0.7 liter per minute per pad. 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 the Arctic Sun® Temperature Management System Service Manual for the full declaration regarding electromagnetic compatibility.

Environmental Conditions

Temperature Range
Operating:.....10°C to 27°C (50°F to 80°F)
Storage:..... -30°C to 50°C (-20°F to 120°F)

At operating temperatures higher than 27°C (80°F), the refrigeration system's cooling capacity and therefore its ability to cool a patient is compromised.

Humidity Range (relative humidity, non-condensing)
Operating:.....5% to 70%
Storage:.....5% to 95%
Atmospheric Pressure Range: 60 kPa to 110 kPa

Disposal

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

Arctic Sun® Temperature Management System Specifications

Parameter	Specification
Therapy Modes	Normothermia: Control Patient, Rewarm Patient Hypothermia: Cool Patient, Rewarm Patient
Heater Capacity	2500 BTU/hr / 750 Watts
Circulating Fluid	Sterile Water
Reservoir Capacity	3.5 liters
Water Flow Rate	5 liters per minute
Patient Probe Type	YSI 400 Series compatible
Patient Temperature Inputs	Patient Temp 1: control, monitor, alarm Patient Temp 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) ±0.2°C (32°C to 38°C) ±0.4°C (38°C to 44°C) Includes ± 0.1°C external probe
Responses of the PCLCS (Physiologic Closed-Loop Control System)	Settling Time: ~4.5 hrs Relative Overshoot: <0.5°C Command Overshoot: <0.5°C Response Time: Warming (max) 33°C to 37°C: ~6 hrs Cooling 37°C to 33°C: ~2 hrs 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 42°C / 39.2°F to 107.6°F 1°C/°F increments
High Water Temperature Limit	36°C to 42°C / 96.8°F to 107.6°F 1°C/°F increments
Low Water Temperature Limit	4°C to 25°C / 39.2°F to 77°F 1°C/°F increments
Time to heat water from 20°C to 37°C	8 minutes (approximate)
Sound Pressure	Alarm Tone: 70dB to 80dB at 1 meter, repeats every 10 seconds Alert Tone: 63dB to 71dB at 1 meter, repeats every 25 seconds Reminder Tone: 65dB at 3 meters, 0.5 seconds on/20 seconds off
Mains Input	100-120VAC, 50-60Hz, 11A 220-240VAC, 50-60Hz, 5.5A
Leakage Current	<300 µA
Operating Relative Humidity Range	5% to 70% non-condensing
Storage Relative Humidity Range	5% to 95% non-condensing
Operating Temperature Range	10°C to 27°C / 50°F to 80°F
Storage Temperature Range	-30°C to 50°C / -20°F to 120°F
Atmospheric Pressure Range	60 kPa to 110 kPa
Dimensions	Height: 35 inches (89 cm) Width: 14 inches (36 cm) Depth: 18.5 inches (47 cm)
Weight	Empty: 43 kg / 95 lbs ; Filled: 47 kg / 103 lbs

Appendix B - Symbols

The Arctic Sun® Temperature Management System Control module bears the following symbols:

	For the safe and effective use of this device, the operator must consult the accompanying documents prior to use.
	Indicates the Authorized representative in the European Community.
	This symbol adjacent to the patient connections means that the thermal probe connection is a “Defibrillator-Proof, Type BF Applied Part”, per standard IEC 60601-1 and affords the degree of patient protection defined in that standard for this type of applied part.
	Per ETL Intertek, models of the Arctic Sun® Temperature Management System that bear the ETL Monogram conform to AAMI ES 60601-1, IEC 60601-1-8, IEC 60601-10, IEC 80601-2-35 and are certified to CSA C22.2 No. 60601-1.
	Indicates high temperature part or component. The maximum temperature of this internal component allowed by the protective system is also listed.
	Indicates that only sterile water should be used when filling the Arctic Sun® Temperature Management System Control Module.
	Identifies Patient Temperature 1, the patient temperature probe input for monitoring and control.
	Identifies Patient Temperature 2, the patient temperature probe input for monitoring.
	Identifies Patient Temperature Out, the patient temperature output to an external hospital monitor.
	Identifies the drain valve.
	Indicates electrical hazard.
	Identifies the storage temperature range.
	Identifies the storage relative humidity range.
	Manufacturer.
	Date of Manufacture.
	Do not re-use.
	Risk of overbalance due to pushing, leaning, resting, etc.
	Arctic Sun® Temperature Management System must be disposed of properly. DO NOT dispose of into the garbage.
	Identifies mechanical hazard.
	General warning sign.

Appendix C - Electromagnetic Compatibility

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

- The use of accessories or cables other than those specified or sold by Medivance (shown below) is not recommended. Use of unapproved accessories or cables may result in increased emissions or in decreased immunity of the Arctic Sun® Temperature Management System.
- If the Arctic Sun® Temperature Management System is used directly adjacent to or stacked with other equipment, the user should periodically observe the Arctic Sun® Temperature Management System device to verify it operates normally in that environment.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Accessories and cables approved by Medivance for use with the Arctic Sun® Temperature Management System	Part #
Temperature In-Cable - Nellcor	735-02
Temperature In-Cable - Bard	735-03
Temperature In-Cable - Rusch	735-04
Temperature In-Cable - GE	735-05
Temperature In-Cable - Philips	735-06
Temperature Out-Cable - Nellcor	735-52
Temperature Out-Cable - Bard	735-53
Temperature Out-Cable - Rusch	735-54
Temperature Out-Cable - GE	735-55
Temperature Out-Cable - Philips	735-56
Power Cord, US, Canada, Mexico	733-00
Power Cord, Continental Europe	733-01
Power Cord, UK, Ireland	733-02
Power Cord, Australia, New Zealand	733-03
Power Cord, Mainland China	733-04
Power Cord, Brazil	733-05
Power Cord, Switzerland	733-07
Power Cord, South Africa	733-08
Transmission Interface Module (TIM) Kit	760-00
Transmission Interface Module (TIM)	761-00
RS232 Cord	762-00

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

1.2 EN/IEC 60601-1-2 Table 2			
Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Arctic Sun® Temperature Management System unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the Arctic Sun® Temperature Management System unit should assure it is used only in such an environment.			
Immunity Test	IEC60601 test level	Compliance Level	Intended Electromagnetic Environment
Electromagnetic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	± 2kV for power supply lines ± 1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode (line-line) ± 2kV common mode (line-earth)	± 1kV differential mode (line-line) ± 2kV common mode (line-earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 seconds	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Arctic Sun® Temperature Management System unit requires continued operation during power mains interruptions, it is recommended that the Arctic Sun® Temperature Management System unit be powered from an uninterruptible power supply with sufficient capacity to run the unit for the maximum required time of interruption.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Appendix C - Electromagnetic Compatibility (continued)

1.3 EN/IEC 60601-1-2:2007 Sub-clause 5.2.2.2 Table 3:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The ARCTIC SUN® Temperature Management System unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the ARCTIC SUN® Temperature Management System unit should assure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance Level	Intended Electromagnetic Environment
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of the ARCTIC SUN® Temperature Management System unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from objects, structures and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ARCTIC SUN® Temperature Management System unit is used exceeds the applicable RF compliance level above, the ARCTIC SUN® Temperature Management System unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ARCTIC SUN® Temperature Management System unit.
[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

1.4 EN/IEC 60601-1-2:2007 Sub-clause 5.2.2.2 Table 4:

Recommended separation distances between portable and mobile RF communications equipment and the ARCTIC SUN® Temperature Management System unit.

RF communications equipment can effect medical electrical equipment. The ARCTIC SUN® Temperature Management System unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARCTIC SUN® Temperature Management System unit can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the ARCTIC SUN® Temperature Management System unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D - Spare Parts and Accessories

Cables and Accessories

Cleaning Solution (4 bottles)	739-05
Calibration Test Unit (CTU) 100 -120V	741-00
Calibration Test Unit (CTU) 100V Japan	741-10
Calibration Test Unit (CTU) 230V EU	741-01
Calibration Test Unit (CTU) 230V UK	741-02
Calibration Test Unit (CTU) 230V Australia	741-03
Calibration Test Unit (CTU) 230V Brazil	741-05
Calibration Test Unit (CTU) 230V Switzerland	741-07
Calibration Test Unit (CTU) 230V South Africa	741-08
Shunt Line	709-04
Fluid Delivery Line	734-07
Drain Tube	719-00
Fill Tube	718-00
Temperature In Cable - Nellcor	735-02
Temperature In Cable - GE	735-05
Temperature In Cable - Bard	735-03
Temperature In Cable - Rusch	735-04
Temperature In Cable - Phillips	735-06
Temperature Out Cable - Nellcor	735-52
Temperature Out Cable - GE	735-55
Temperature Out Cable - Bard	735-53
Temperature Out Cable - Rusch	735-54
Temperature Out Cable - Phillips	735-56
Service Kit	771-00
Temperature Simulator, 37°C	748-37
Screen Protector Kit	753-00
Cover	752-00
Power Cord, US, Canada, Mexico	733-00
Power Cord, Continental Europe	733-01
Power Cord, UK, Ireland	733-02
Power Cord, Australia, New Zealand	733-03
Power Cord, Mainland China	733-04
Power Cord, Brazil	733-05
Power Cord, Switzerland	733-07
Power Cord, South Africa	733-08
Memory Stick	775-00
Transmission Interface Module (T.I.M.) Kit	760-00
Transmission Interface Module (T.I.M.)	761-00
RS232 Cord	762-00
Transmission Interface Module (T.I.M.) Bracket Assembly	763-00

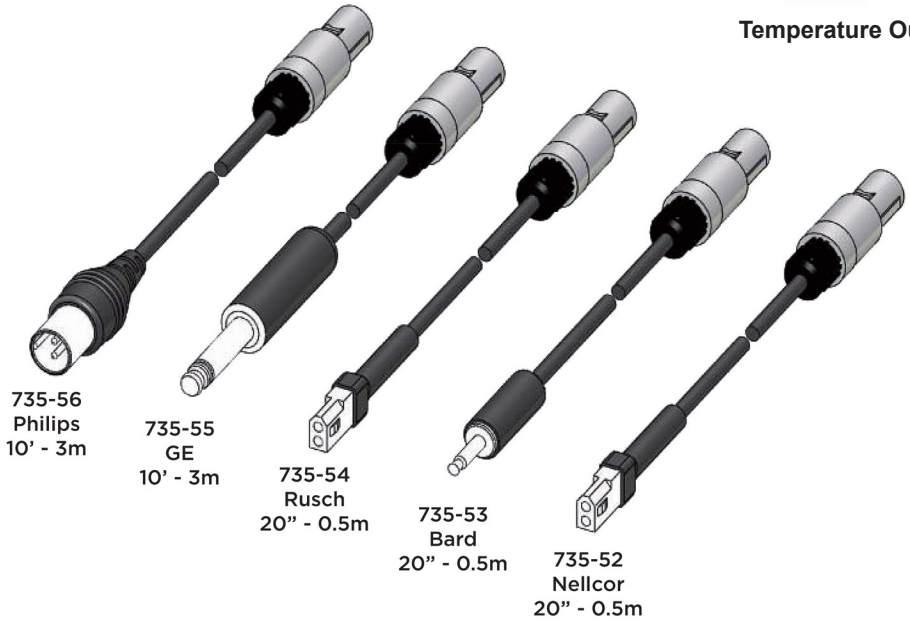
Spare Parts

Caster with Brake	402341-00
Caster without Brake	402341-01
Air Filter	403003-00
DC Chiller Pump	403114-00
Heater,100-120V	403074-00
Heater, 200-230V	403074-01
Flowmeter	403075-00
Mixing Pump Assy.	403076-00
Circulation Pump Assy.	403077-00
Manifold Assy.	403078-00
Manifold Harness	403079-00
Tank Harness	403080-00
Chiller Pump, 100-120V	403081-00
Chiller Pump, 200-230V	403081-01
Control Panel Assembly	403082-00
Input/Output Circuit Card	403083-00
Processor Circuit Card	403084-00
Power Circuit Card	403085-00
Isolation Circuit Card	403086-00
Mains Voltage Circuit Card	403087-00
Main Harness	403089-00
Power Module	403091-00
Level Sensor	403102-00
Drain Valve	403105-00
O-Ring Kit	403107-00
Replacement Temperature Connection Ring Kit	403108-00

Appendix E - Temperature Cables

Temperature In Cables

Temperature Out Cables



Appendix F - Software Upgrade

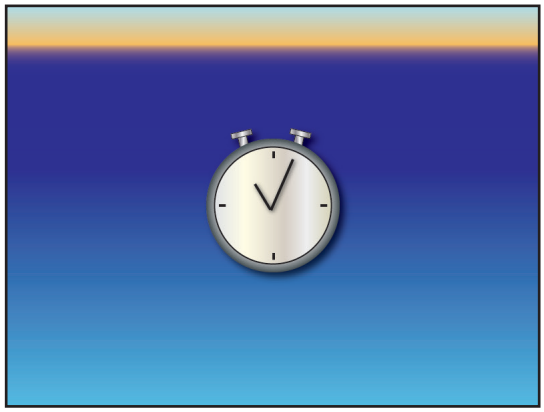
Installing Software on Control Panel

Tools and supplies required:
• 765-01 Graphics Software Flash Drive

1. Power unit ON (using ON/OFF switch at the rear), and wait for the Arctic Sun® Temperature Management screen to appear.

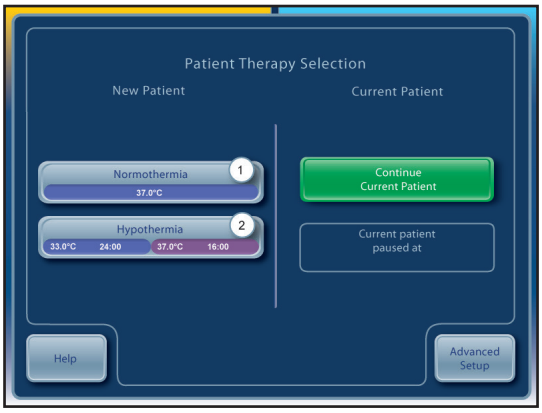
2. Immediately insert flash drive into USB port and then wait a minimum of three (3) minutes (error messages may appear - disregard error messages).

3 Power unit OFF.
4. Power unit back ON with the flash drive still installed.
5. Wait while stopwatch is displayed (approximately 30-45 minutes).



6. Power unit OFF only after the black screen appears for a minimum of 30 seconds.

7. Remove flash drive from USB port.
8. Verify the graphics software has been updated per the following:
9. Power unit ON.
10. Press the Advanced Setup button when the Patient Therapy Selection window appears.



11. Verify the graphics software version has been updated. If the graphics software version did not update, repeat steps 1-8. If after two (2) attempts the software has not updated, contact Bard Customer Service (800.526.4455).

Appendix G - Shipping

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

1) Perform a total drain of the system.

   a) After the device has been drained, power On, from the Therapy Selection screen, press the Advanced Setup button to display the Advanced Setup screen.

   b) Press the Start button next to Total Drain and follow the instructions

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 the square cardboard piece with the foam down on top of the unit and place any accessories on top of the foam piece.

4) Slide the cardboard tube over the unit ensuring it meets flush with the top surface of the pallet.

5) 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 H - Warranty

BARD®

LIMITED WARRANTY

ON NEW ARCTIC SUN® Temperature Management System

Limited Warranty

Bard Medical Division, C. R. Bard, Inc. (“Bard”) warrants to the original purchaser that each ARCTIC SUN® Temperature Management System (“Equipment”) and ARCTICGEL™ Pad (“Disposables”) 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 Disposables may be repaired, replaced, refunded or credited, at Bard’s option. An extended warranty for Equipment is available for purchase. The warranty covers all parts and labor associated with defects in material and workmanship of the Equipment. Bard will, at its discretion, determine if the Equipment is to be repaired on site, or at the Bard service center. If Equipment is to be returned for service, Bard will supply packaging materials and pay for ground shipping. However, it is the hospital’s responsibility to prepare and package the Equipment for shipment at its own cost. Any expedited shipment request will be at the customer’s expense. Any unauthorized equipment 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 sterile water, routine maintenance, recalibration, or its repair by any person or entity not authorized by a Bard representative.

THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. 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 DISPOSABLES.

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 8am to 5pm 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 hospital must provide personnel to assist Technical Support with troubleshooting.

Loaned Equipment

If Equipment under warranty is returned for service, loaned Equipment will 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 $40 per day.

Shipping

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.

Bard will attempt to maintain parts inventory for Equipment a minimum of six years beyond the end of production.

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
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	0-255 where 255 = 100%
21	Flow Pump Power	0-255 where 255 = 100%
22	Control Parameter Mode	0-5
23	Software Version	Software Version

Medivance®

www.medivance.com

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0050

Manufacturer:

Medivance, Inc.
321 South Taylor Avenue, Suite 200
Louisville, Colorado 80027 USA
Phone: 303.926.1917
Toll Free: 800.526.4455
Fax: 720.880.5400
arcticsun@crbard.com

EC REP

Bard Limited
Forest House
Brighton Road
Crawley, West Sussex UK
RH11 9BP
+44 1293 527888

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

PK2800264 10/2018