ArcticSun®

TEMPERATURE MANAGEMENT SYSTEM

Model 2000

Service Manual

Medivance®

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CHAPTER 1 INTRODUCTION

1.1 Use of the Model 2000 Service Manual

The Arctic Sun Temperature Management System provides a safe and effective way of modifying patient temperature and delivering precise temperature control in a novel way. This Service Manual provides a detailed description of the Model 2000, its construction, routine maintenance and calibration. The Model 2000 Operators Manual should be consulted for general operation detail. It is important that the Model 2000 be properly maintained and serviced in accordance with the instructions described in this manual. Only trained personnel should service this product.

1.2 Customer Information and Technical Support

Prior to using the Arctic Sun System, a Medivance representative will provide on-site in-services to ensure adequate training has occurred.

Additional requests for technical support, information or orders may be placed by mail, fax, or by calling Medivance Customer Service.

Medivance hours of operation are 8 am to 5 pm Mountain Standard Time. Emergency support is offered after hours in the U.S. by calling 303-926-1917 or 877-267-2314. Other customers should contact their local distributor.

Additional educational materials, such as training programs for in-house staff, operator manuals, quick reference guides, and a bibliography of relevant materials are available to all Medivance customers.

1.3 System Description

The Arctic Sun Temperature Management System is a thermoregulatory device that monitors and controls patient temperature within a range of 33°C to 37°C (91.4°F to 98.6°F). The Arctic Sun System consists of the Model 2000 and disposable Arctic Sun Energy Transfer Pads. The Model 2000 consists of the Control Module, Remote Display, Fluid Delivery Line, cables and accessories.

With the Energy Transfer Pads adhered to the patient's skin, the Model 2000 pulls temperature-controlled water ranging between 4°C and 42°C (39.2°F and 107.6°F) through the pads. This results in heat exchange between the water and the patient. Unlike conventional water based systems, this system operates under negative pressure relative to ambient. Any break or leak in the fluid path will result in air entering the circuit instead of water leaking out.

The system functions in either an Automatic Mode or Manual Mode. In Automatic Mode, a patient temperature probe, connected to the Control Module, provides feedback to an internal control algorithm. The temperature of the water increases or decreases automatically to achieve a pre-set patient target temperature determined by the clinician. In Manual Mode, the feedback control algorithm is not activated. The operator adjusts the temperature of the water delivered to the pads directly and is responsible for monitoring patient temperature.

Model No. .....Arctic Sun Temperature Management System Model 2000

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MDCI, Ltd., Arundel House, 1 Liverpool Gardens,
Worthing, West Sussex, BN11 1SL, United Kingdom

1.4 Symbols and Standards

The Model 2000 bears the following symbols affixed to the system:

Table 1.1
Model 2000 Symbols

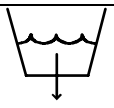
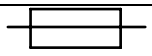
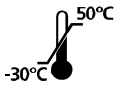
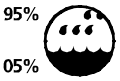
	For the safe and effective use of this device, the operator must consult the accompanying documents prior to use.
	This symbol adjacent to the patient connections means that the thermal probe connection is a "Defibrillator-Proof, Type BF Applied Part", per standard IEC 60601-1 and affords the degree of patient protection defined in that standard for this type of applied part.
	Models of the Arctic Sun that bear the Entela US/C Monogram have been Certified for Safety by Entela, Inc. against standards C22.2, No. 601.1 and UL 2601.
	Identifies the equipotential terminal on the equipment, which is intended to be connected with the equipotential terminal(s) on one or more other types of equipment in close proximity, in order to bring all pieces of equipment to the same potential for safety purposes.
	Indicates high temperature part or component.
	Indicates that only sterile or distilled water should be used when filling the Arctic Sun Control Module.
	Identifies Patient Temperature 1, the primary patient temperature probe input.
	Identifies Patient Temperature 2, the secondary patient temperature probe input.
	Identifies the drain port.
	Identifies the heater fuse.

Table 1.1
Model 2000 Symbols
(continued)

	Identifies the storage temperature range.
	Identifies the storage relative humidity range.
	Indicates electrical hazard.
	Indicates Earth Ground.
	Indicates sharp object or a moving part.

1.5 Environmental Conditions

The Model 2000 should be stored and used in specific operating conditions:

Ambient Temperature Range:

Operating Temperatures: ..... 10ºC to 27ºC (50ºF to 80ºF)

Note: At higher room operating temperatures, the units cooling capacity is compromised.

Storage Temperatures:..... -30ºC to 50ºC (-20ºF to 120ºF)

Note: If the device is stored in a location where the temperature may fall below the freezing point, the unit should be completely drained of water to prevent damage. See Section 4.6.

Ambient Humidity Range:

Operating: ..... 50% to 70% relative humidity, non-condensing
Storage: ..... 5% to 95% relative humidity, non-condensing

1.6 General Warnings

- Do not use the Arctic Sun in the presence of flammable agents because an explosion and/or fire may result.
- There is a risk of electrical shock and hazardous moving parts inside the machine. Care should be exercised by service personnel and attention should be particularly paid to areas highlighted with warning symbols.
- North America only: 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".

1.7 Cautions

See Operator's Manual for complete list of Cautions prior to using the Arctic Sun Temperature Management System to treat a patient. This is not an exhaustive list and is not intended to replace the Operator's Manual.

- Federal law (USA) restricts this device to sale, by or on the order of a physician.
- Medivance will not be responsible for patient safety or equipment performance if the procedures to operate, maintain, modify or service the Medivance Arctic Sun are other than those specified by Medivance.
- This product should be serviced only by trained, qualified personnel.
- Use only distilled or sterile water. The use of other fluids will damage the Arctic Sun System.
- Any device connected to the RS232 data port must comply with the applicable IEC standard for that device.
- When the system is powered off, all changes will revert to the default unless the new settings have been established as new defaults.
- 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.
- It is advisable not to cancel the alarm or alert until the situation is resolved. If an alarm is cancelled and the condition has not been cleared, the alarm will recur. If an alert is cancelled and the alert condition has not been cleared, the alert will not recur unless the Stop Mode is activated.
- Do not operate the unit in a diagnostic mode while delivering therapy to a patient.

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CHAPTER 2 THEORY OF OPERATION

2.1 Introduction

The Model 2000 was designed to control patient temperature with a high level of precision by rapidly altering water temperature in response to a patient core temperature sensor using a closed-loop algorithm. To achieve rapid response with tight control, the system is designed to circulate a minimum volume of water, have a high heating and cooling capacity, and include sensors for real-time feedback of energy transfer.

2.2 System Components

The Model 2000 system is composed of several components.

- Control Module – The main unit which includes the hydraulics and major elements of the electronics.
- Remote Display Module – The primary control and monitoring interface for the user.
- Fluid Delivery Line – The reusable dual lumen tubing connecting the Control Module to the pads.
- Interconnect Cables and Accessories – The cables that connect the Control Module to mains power, the Control Module to the Remote Display Module, and optional patient temperature cables. Accessories include fill tubes, drain bags, Fluid Delivery Line straps and others.

2.3 Hydraulic System

The hydraulic system within the Control Module consists of the following major elements:

- Pumps
  - Circulating pump
  - Chiller pump
  - Mixing pump
- Sensors
  - 4 Water temperature sensors
  - Flow meter
  - Pressure sensor
- Valves
  - Vent valve
  - Bypass valve
  - Fill valve
- Heater
- Tanks
  - Circulating Tank
  - Chiller Tank
  - Main Tank
- Inlet/Outlet Manifold
- Chiller

The hydraulic system is composed of two major fluid circuits; the circulating circuit and the chiller circuit (see Figure 2.1). The circulating circuit controls the flow of water to the pads. The chiller circuit provides a constant source of cold water that is pumped, as needed, into the circulating circuit.

Water in the circulating circuit is pulled from the Circulating Tank through the Inlet/Outlet Manifold and out to the Energy Transfer Pads. Water then returns from the pads through the Inlet/Outlet Manifold to the negative pressure side of the positive displacement Circulating Pump. Water leaves the Circulating Pump under positive pressure then passes through a turbine flow meter and heater before returning to the Circulating Tank. Water in the Main Tank replenishes the circulating circuit.

The chiller circuit operates independent of the circulating circuit. Water in the Chiller Tank drains into the centrifugal Chiller Pump where it then is pumped under positive pressure through the Chillers' evaporator. The evaporator is a heat exchanger with cold refrigerant on one side and water on the other. Water then returns to the Chiller Tank to complete the cycle. The system controls the temperature of the water in the Chiller Tank to 4°C by activating a valve on the refrigerant side when additional cooling is no longer needed.

When the system determines water must be warmed, the heater is activated in the circulating circuit. When the system determines water must be cooled, water is drawn out of the Circulating Tank by the positive-displacement Mixing Pump and metered into the Chiller Tank. This causes water to overflow the Chiller Tank and refill the Circulating Tank with cold water where it mixes, cooling the circulating water.

The flow of water to the pads is controlled by regulating the Circulating Pump speed using pressure sensor (P1). The pressure is regulated to -7 psi. This assures that the flow through each pad is maintained regardless of how many pads are connected. Since water in the pads and lines is at a negative pressure relative to ambient, any break causes air to enter the circuit instead of water leaking out where it may contaminate the patient. This valuable feature can make troubleshooting leaks more difficult.

The temperature of the water going out to the pads is controlled using a temperature sensor (T2) and monitored by a temperature sensor (T1). Both sensors are located in the Circulating Tank. Temperature sensor (T3) measures the temperature of water returning from the pads. The difference between outlet and inlet water temperature along with the flow rate provides the control algorithm real-time feedback on the current heat load for optimal temperature regulation. Temperature sensor (T4) is used to regulate the cold water within the chiller circuit.

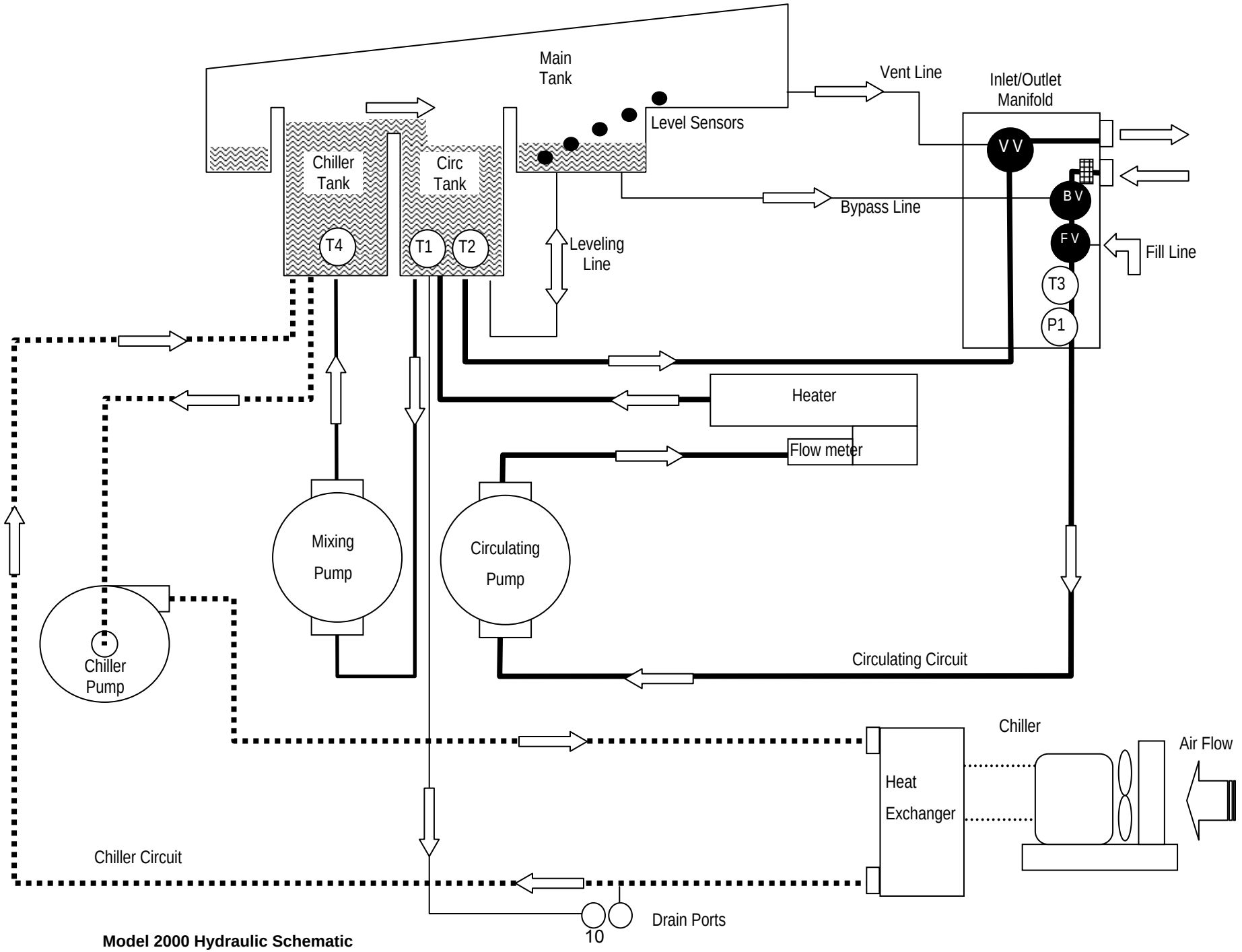
There are three valves installed in the Inlet/Outlet manifold to permit filling the system with water, pre-conditioning the water to a desired temperature, and emptying the pads of water at the end of a case. When the Fill mode is activated, water is drawn up through the Fill Tube, through the Fill Valve (FV) by the Circulating pump. The water then enters the Circulating Tank and by gravity passes to the Main Tank. Air, displaced by the water, exits the Main Tank through a small hole in the top of the tank. It is important to note that pads cannot be connected during this operation.

The user may wish to pre-condition the temperature of the water prior to pads being connected. The system will detect the absence of pads connected by feedback from the flow meter and pressure sensor and will open the Bypass Valve (BV). Water is drawn out of the Main Tank through the Bypass Line and is shunted past the Fluid Delivery Lines into the circulating circuit

where it returns back into the Circulating Tank. Water flows through the leveling line from the Circulating Tank back into the Main Tank. During this cycle, the temperature of the water is controlled by activating the Heater or Mixing Pump. Automatic activation of the Bypass Valve occurs briefly at the beginning of both Automatic Mode and Manual Mode in order to completely prime the Circulating Pump. If pads are connected, the Bypass Valve will close after one minute.

A user can initiate the Purge Mode in order to empty the pads of water prior to disconnecting them. Purge Mode causes the Vent Valve (VV) to open to atmosphere through the vent line communicating with the top of the Main Tank. This causes air to be drawn into the pads and the circulating circuit, emptying the pads.

The water level in the Main Tank is sensed by detecting conductivity with an array of stainless steel studs in the tank. There are five level sensors and a reference sensor.



Model 2000 Hydraulic Schematic

Figure 2.1

2.4 Electronic Control System

The electronic control system consists of two independent subsystems, the Control and the Monitor. The Control Subsystem performs all of the normal machine operations while the Monitor Subsystem continually monitors important machine operations with independent sensors. If the Control acts incorrectly with respect to the safety of the patient, the monitor will disable pump power, thus preventing inappropriate therapy from being delivered. Each subsystem has a microprocessor, watchdog, keyboard input circuitry, audio alarm, outlet water temperature sensing circuitry, and patient temperature sensing circuitry.

The Control Subsystem performs the following functions:

- Command (keyboard) interpretation and information display
- Outlet water temperature control
- Water flow control
- Patient temperature measurement (Patient Temperature 1) and control
- Temperature Out signal generation
- Cold water supply temperature control
- Valve control

The Monitor Subsystem performs the following functions:

- Redundant command (keyboard) interpretation
- Outlet water temperature monitoring
- Patient temperature measurement (Patient Temperature 2)
- Pump power control
- Power supply monitoring
- Data logging output to the RS-232 port

The majority of the hardware comprising the electronic control system is located within the card cage. The card cage consists of six major elements (See Figure 7.4).

- Power Module: The Power Module includes a 24VDC medical universal input switching power supply (IEC601.1 compliant), a Mains circuit breaker, cooling fan, heater circuit fuse, equipotential stud, and solid state relay. The Power Module is connected to the Power Card by two pigtail connectors.
- Backplane: The Backplane is passive, serving only to connect the four circuit cards listed below.
- Power Circuit Card: The Power Card provides low voltage power regulation to the balance of the electronics as well as Mains line synchronization (with 4000V isolation from Mains), pump power control, a Mains loss alarm, and a secondary audible alarm. The Mains loss circuit is powered by low leakage capacitors and needs no battery.
- Processor Circuit Card: The Processor Card houses the Control and Monitor microprocessors and their associated circuitry, including nonvolatile memory for each.
- Isolation Circuit Card: Five isolated "islands" of circuitry comprise the Isolation Card. One island is connected to the Backplane and provides an interface to the rest of the card cage. This island

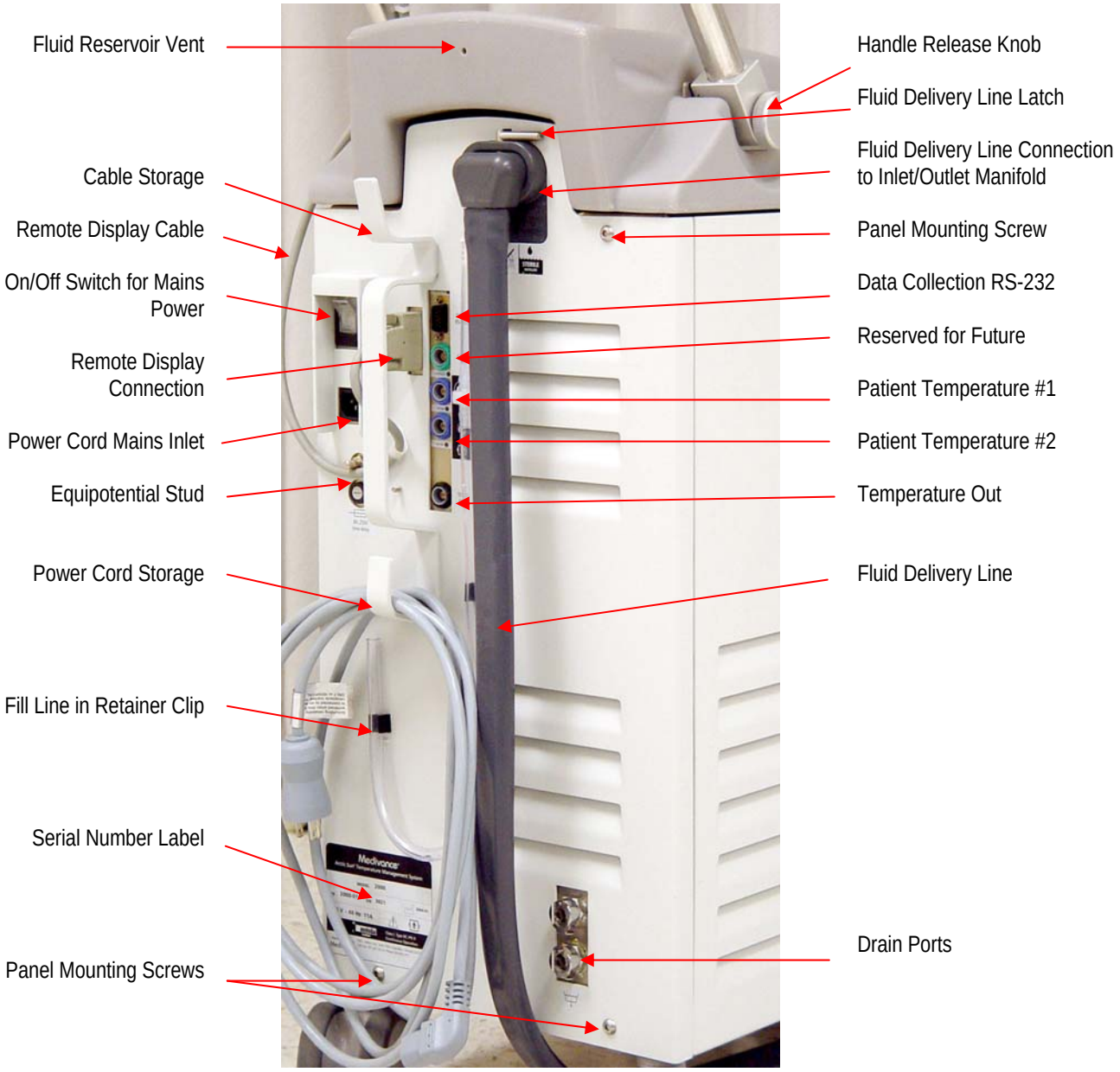
is referenced to chassis ground. The other islands are isolated from the Backplane island by opto-isolators or transformers. The RS-232 #1, RS-232 #2, and Temperature Out (Echo) islands are isolated from the Backplane and from each other to a breakdown voltage of at least 500V. The patient temperature island is isolated from all others to a level of 1500V. It should be noted that, in addition to this, the 24V power supply in the Power Module isolates all low voltage circuitry to a level of 4000V from Mains.

- Input/Output (I/O) Circuit Card: The I/O Card contains the majority of the actuator and sensor circuitry. T1, T2, T3, and T4, the flowmeter, pressure sensor, and level sensor are conditioned on the I/O Card. Both pump motors, the valves, and the refrigeration system are controlled by this circuit card.

The remaining circuitry is housed in the Remote Display Module. This module communicates with the card cage via a cable having 13 twisted pairs using a technology called Low Voltage Differential Signaling (LVDS) which minimizes both the risk of spurious signals interfering with communication and the emission of electromagnetic energy. The Remote Display Module houses LED display drivers, keyboard interpretation circuitry, an audible alarm (primary), and an LCD text module.

There is also a manually resettable thermal breaker mounted on the heater casing. This breaker is not used for normal temperature control, only to ensure that in the event of control failures the heater does not over heat.

CHAPTER 3 INSTALLATION



Control Module Rear

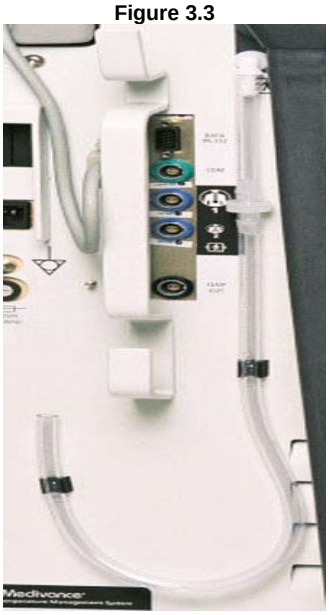
Figure 3.1

3.1 Installation of Cables and Accessories

1. Unpack the Model 2000 and accessories.
2. Adjust the Control Module handle to a vertical position and secure by tightening the knobs on both sides.
3. Connect the Remote Display Cable to the back of the Remote Display. Install the Remote Display clamp onto the handle. Route the cable through the three clips on the side of the handle. Connect the Remote Display Cable connector at the labeled location on rear panel of the Control Module.
4. Insert the Patient Temperature Cable into the labeled location on the rear panel of the Control Module.
5. Insert the optional Patient Temperature #2 Cable into the labeled location on the rear panel of the Control Module.
6. Insert the optional Patient Temperature Out Cable into the labeled location on the rear panel of the Control Module.
7. Using the clips and wing nuts from the Strain Relief Kit, anchor the cables to the back panel.
8. Move the latch of the fluid In/Out Manifold to the left. Connect the Fluid Delivery Line to the Inlet/Outlet Manifold. Move the latch on the manifold to the right to lock it in place.
9. Gently push the fitting of the fill line into the fill port. Secure the line to the rear panel as shown in the picture.

Remote Display Cable and Clamp Rear View
Figure 3.2

Strain Relief
Figure 3.3



Fill Line
Figure 3.4

3.2 Power Up System

1. Insert the power cord into the power inlet. Using the clips and wing nuts from the Strain Relief Kit, anchor the cord to the back panel. Plug the power cord into the wall outlet. Locate the switch on the rear panel and turn the power on.
2. After the software initializes an alarm will sound and the display will read: “Alarm 5: Water level below minimum. Fill reservoir or purge pads”.
3. Clear the alarm by pressing the alarm key.
4. The display reads:” Medivance Arctic Sun Temperature Management System”.

3.3 Filling the Control Module

1. Add one vial of Arctic Sun Cleaning Solution to 4 liters of sterile or distilled water. The solution is contained in the Arctic Sun Maintenance Kit.

   Caution: Use only sterile or distilled water. The use of other fluids will damage the system.
2. From Stop Mode, press the down arrow until the fill screen appears: “Water Level Empty. Enter to Fill”. Press Enter to proceed.

   Note: Pads cannot be attached to the Fluid Delivery Line during the fill process.
3. Follow directions on the display screen which read:” Place the Fill Tube in the container of water. Press Enter to fill”.
4. Press Enter again and the Model 2000 will automatically fill until the reservoir is full.

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CHAPTER 4 MAINTENANCE

4.1 Recommended Maintenance Schedule

Procedure	Interval
Clean External Surfaces	As required
Adjust Remote Display Clamp	As required
Inspect connectors and cables	3 months
Clean the Condenser	3 months
Replace Fluid	3 months
Calibration and Operational Check	Every 2000 hours or 250 uses, which ever is less, as indicated by system display

4.2 Clean External Surfaces

Cleaning should include the exterior of the Control Module and the power cord. Use a soft cloth and mild detergent or disinfectant according to hospital protocol. The display screen can be wiped with a clean, lint-free, moist cloth. Fluid Delivery Lines and Temperature Cables should be cleansed with a hospital approved disinfectant.

4.3 Adjust Remote Display Clamp

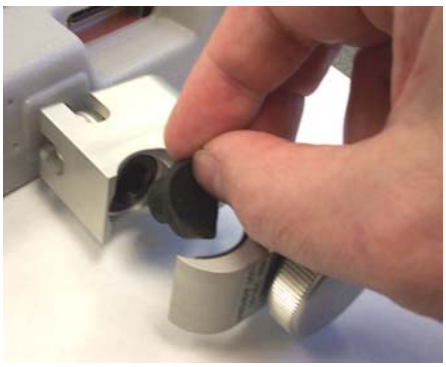
Tools and Supplies Required:

- 1/2” hex key.

The Remote Display clamp tension may need adjusting over time.

1. Remove the Remote Display from the handle. Disconnect the Remote Display Cable.
2. Loosen the clamp knob until the bottom jaw swings clear of the top head. Remove the black rubber plug in the top head by grabbing an edge and pulling straight out.
3. Using a ½” hex key, adjust the hex bolt until proper tension is achieved. Replace the plug and tighten the clamp knob.

Remote Display
Figure 4.1



Removing Rubber Plug
Figure 4.2

Adjusting Tension
Figure 4.3

4.4 Inspect Connectors and Cables

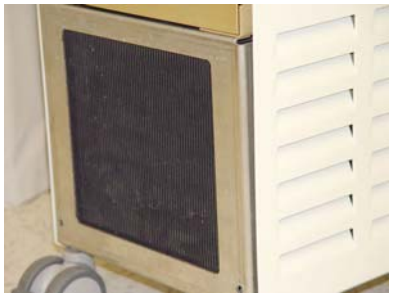
Inspect all cables for breakage, fraying, excessive twisting or other signs of damage. Replace damaged cables.

4.5 Clean the Condenser

The Arctic Sun condenser fins should be inspected for dirt and debris every three months or more often with heavy use or dusty environment. The condenser is located underneath the grill on the front of the control module.

1. Remove the front grill by pulling the bottom out, then using both hands at the top of the panel pull it straight out and away from the control module. For maximum performance, the condenser fins should be free of dust and debris.
2. Use a brush or vacuum to remove any dust or debris.

Removing Front Grill
Figure 4.4



Condenser
Figure 4.5

4.6 Drain and Replace Fluid

Tools and Supplies Required:

- Arctic Sun Drain Bag

It is recommended the Control Module be drained and refilled every 3 months to assure a satisfactory concentration of Cleaning Solution in the circulating water. In addition, draining is required for replacement of some components or prior to shipment or storage.

1. Power off the system.

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

2. Attach the two fittings on the bag to the two drain ports on the back of the control module. The device will passively drain all tubing, reservoirs and pumps within the system. This is an adequate drain for maintenance procedures.
3. Proceed with a complete drain for shipping or storage when freezing is a risk.
   - 3.1 Perform the partial drain procedure in step 2.
   - 3.2 Allow the control module to stand for 15 minutes to allow the chiller to return to room temperature.
   - 3.3 Power on the system. The "Level Empty" alarm should occur and the chiller should not run. Cancel the alarm. If the chiller runs, do not continue and power down immediately. Drain the system again as in step 2 and power up again.
   - 3.4 From the main screen, press the Down key three times to enter the Fill Mode. Press enter. Do not place the fill tube in water.
   - 3.5 With the Drain Bag still attached, press enter to start a fill cycle which will empty the Circulating Pump.
   - 3.6 Press and hold the Down key for a minimum of 20 seconds to empty the internal Mixing Pump.
   - 3.7 Press the Stop key then power off the system. Remove the Drain Bag and empty it.
4. Fill Control Module per Section 3.3 prior to returning to use.

Drain Bag Attached
Figure 4.6

4.7 Calibration and Safety Check

See Chapter 5 for the complete procedure for calibration and safety check.

CHAPTER 5 CALIBRATION AND SAFETY CHECK

5.1 The Calibration and Test Unit

The Model 2000 Calibration and Test Unit (CTU) is an instrument that is used to calibrate the Model 2000 Control Module. It is a hand sized unit that connects directly to the fluid delivery line port, taking the place of the Model 2000 fluid delivery lines and pads.

5.1.1 Basic CTU Operation

The CTU is used as an external stimulus and measuring device by software embedded in the Control Module. The CTU contains precision resistors, a sensor for measuring water temperature, and water heaters that are calibrated at the factory. The factory calibration data is listed on the CTU and is entered into the Control Module during the calibration process. The resistors simulate several patient temperatures. After a warm-up period, the simulated temperatures are first applied to the patient temperature inputs to temporarily calibrate each channel. This calibration is temporary in the sense that it is used to perform the balance of the testing. It is not saved by the Control Module until the operator accepts it. Once the patient temperature channel's accuracy has been established, the Temperature Out circuit and the CTU's temperature sensor are connected to the Control Module's Patient Temperature inputs, in turn. The Control Module then circulates water through the CTU at various temperatures. In this way the patient temperature channel can then be used to check and calibrate the accuracy of the Control Module's internal water temperature sensors and circuits.

The fluid path in the CTU is designed to allow a specific flow rate at the operating pressure. Since the Model 2000 controls the inlet pressure at a constant -7 psi, a crosscheck of flow and pressure measurement accuracy can be obtained. The inlet pressure offset is zeroed during the initial warm-up period.

The CTU water heaters are used to slowly raise the system water temperature above its high temperature limits in order to verify correct operation of the Control Module's safety systems. The test unit heaters are thermally and electrically protected, and are only powered while pressing the Heater Power Switch.

5.1.2 Warnings

- The CTU must not be used on equipment connected to a patient.
- Do not use the Calibration and Test Unit in the presence of flammable agents because an explosion or fire may result.
- Anyone performing the procedures must be appropriately qualified.
- Carefully observe the Calibration and Test unit for fluid leaks before and during use. Leakage may result in lower flow rates or an electrical shock hazard.

5.1.3 Electrical Ratings

- Voltage: 115V/60Hz or 230V/50Hz
- Current: 4.5A or 2.25A
- Fuse: 6.3A Slow Blow (2)
- Power: 500W

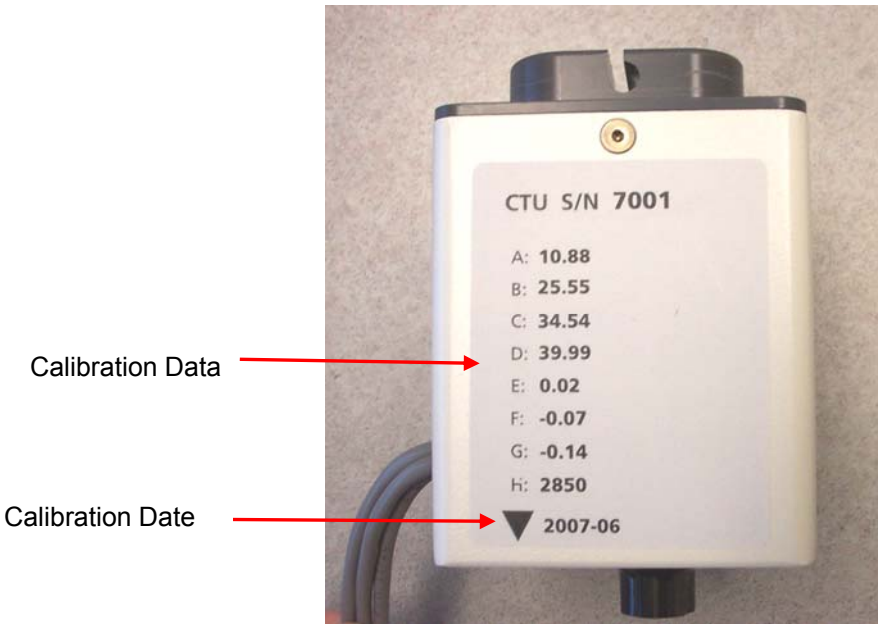
5.1.4 Maintenance

The CTU contains no serviceable parts. Other than periodic cleaning of the exterior surfaces, none is required. To clean the CTU, spray a mild detergent solution onto a towel and wipe down the unit. Do not submerge the unit in water.

If heater becomes inoperative, return the CTU to Medivance for service. An open fuse is indicative of a problem that requires immediate service.

5.1.5 Calibration

The CTU should be returned to the manufacturer for calibration every two years. The date of last calibration is indicated by the international symbol for calibration, an upside down solid black triangle, ▼ which can be found on the top of the CTU.



CTU Calibration Data
Figure 5.1

5.1.6 Environmental Requirements

The Calibration Test Unit should be stored and used in specific operating conditions:

Ambient Temperature Range:

Operating Temperatures: ..... 18ºC to 24ºC (65ºF to 75ºF)
Storage Temperatures:..... -30ºC to 50ºC (-20ºF to 120ºF)

Ambient Humidity Range:

Operating Relative Humidity.....5% to 95% non-condensing

Note: If the CTU is used at a room temperature outside of the specified operating range, the test system's accuracy will be degraded.

5.2 The Test and Calibration Procedure

The entire test and calibration process takes approximately 75 minutes. Operator assistance is required only in certain stages:

- Stage 1: Warm-up, Flow Check, and Patient Temperature Calibration: 10 minutes (after a 10 minute warm-up), operator assistance required.
- Stage 2: Water Temperature Calibration: 30 minutes, automatic.
- Stage 3: Interim Results Reporting: 1 minute, operator assistance required.
- Stage 4: Temperature Out Calibration: 30 minutes, automatic.
- Stage 5: Acceptance: 1 minute, operator assistance required.
- Stage 6: Water Temperature Alarm Test: 15 minutes, operator assistance required
- Stage 7: Chiller Capacity Test: 15 minutes, operator assistance required

5.2.1 Stage 1, 2, and 3: Warm-up, Flow Check, Patient Temperature Calibration, Water Temperature Calibration, and Interim Results Reporting

1. Replace the fluid delivery lines with CTU.
2. Connect the Blue circular connector labeled “PT1” to the Model 2000 connector Patient Temperature 1 (larger thermometer and patient symbol).
3. Connect the Blue circular connector labeled “PT2” to the Model 2000 connector Patient Temperature 2 (smaller thermometer and patient symbol).
4. Connect the Black circular connector labeled “TO” to the Model 2000 connector labeled “TEMP OUT”.
5. Set the CTU switches:
   - S1: B
   - S2: A
   - S3: A

Note: For best results, act promptly when instructed by the machine. Do not allow the machine to lie idle waiting for data input or test unit switching.

Note: If an alarm occurs during calibration, check the CTU connections and switch positions. If the alarm persists, power down and start over. If the alarm persists, call Medivance Service.

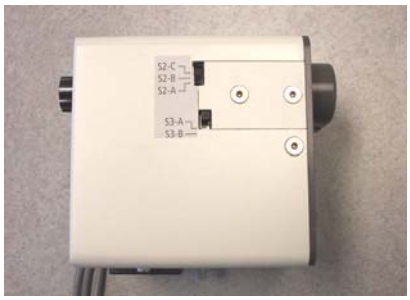
Note: The calibration process can be aborted and restarted at any time by pressing Enter.

6. Power up while holding the Automatic and Purge Keys.
7. At the User Diagnostic Home Screen, press the Up Key once (twice if Patient Temperature 2 is enabled.) to scroll to the UD4 Screen. Press the Enter Key to initiate the Test and Calibration Mode.
8. Follow the prompts on the Remote Display Module.

Note: The Control Module software will ask for the CTU calibration data, termed "A" through "G", at various points in the process. This data is printed on the CTU label.

CTU Connections
Figure 5.2

CTU Switch 1
Figure 5.3



CTU Switches 2 and 3
Figure 5.4

CTU Calibration Data
Figure 5.5

5.2.2 Stage 4: Temperature Out Calibration

1. Press the Enter Key if calibration is desired. The sequence may be aborted at this stage if only verification is desired.
2. The “Calibrate System” menu screen displays the number of “Cal Hours” that have elapsed since the system was last calibrated.

5.2.3 Stage 5: Acceptance

1. Save the calibration data, if desired, by pressing Enter on the “Save Calibration Values” screen. If only verification is desired, do not save. If the new data is not saved, the calibration will revert to the previous set of values.

   Note: If the Up arrow is pressed at this time a “No Calibration Values were Saved” prompt displays and pressing the Enter produces the Exit screen.

5.2.4 Stage 6: Water Temperature Alarm Test

1. Press the Manual Mode Key.
2. Press the Down Key once and change the “Water Target Temperature” to 42°C.
3. Press the Home Key.
4. Allow the water temperature to stabilize at 42°C for at least 5 minutes.

   Note: It is important to allow the temperature to fully stabilize at 42°C. If it does not, it may not be possible to attain the alarm conditions.
5. Press the S4 switch on the CTU. Monitor the **T3** temperature and release the switch once the temperature reaches 44.5°C.
6. Start the timer when the **T1** temperature reaches 43.01°C. Verify that Alarm 37 sounds in less than 18 seconds.

   Note: If the T1 water temperature drops below 43.01°C, restart the timer when the water again reaches 43.01°C.
7. Turn power off.
8. Turn power on and allow the Control Module to start normally.
9. Press the Manual Mode Key.
10. Press the Down Key once and change the “Water Target Temperature” to 42°C.

11. Press the Home Key.
12. Allow the water temperature to stabilize at 42°C for at least 5 minutes.

    Note: It is important to allow the temperature to fully stabilize at 42°C. If it does not, it may not be possible to attain the alarm conditions.

13. Press the S4 switch on the CTU. Monitor the User Interface Water temperature and start the timer once the temperature reaches 42.6 . Verify that alarm 34 sounds in less than 14 seconds. Release the switch immediately.

    Note: If the water temperature drops below 42.6°C, restart the timer when the water again reaches 42.6°C.

    Note: If the water temperature exceeds 44.1°C for more than 1 second Alarm 33 will occur, and the test must be repeated

    Note: If S4 is held too long or is pressed when no water is flowing, a safety circuit will turn off power to the heater. The CTU must be allowed to cool completely if this should occur.

5.2.5 Stage 7: Chiller Capacity Test

1. Press the Manual Mode Key.
2. Press the Down Key once and change the “Water Target Temperature” to 6°C.
3. Press the Home Key.
4. Allow the water temperature to stabilize at 6°C for at least 5 minutes.
5. Press and hold S4 for 10 minutes. Note the temperature of the water. Release the switch.
6. **Note:** If S4 is held too long or is pressed when no water is flowing, a safety circuit will turn off power to the heater. The CTU must be allowed to cool completely if this should occur.
7. Once verification and calibration is complete, press the “Purge” key to remove the water from the CTU.
8. Turn off the Arctic Sun Model 2000, and remove the CTU. Disconnect associated cabling from the Model 2000 and reconnect operator cabling.
9. Drain the water from the CTU before storing

Table 5.1
Model 2000 Verification Data

Test	Criteria
Flow Rate	Factor H - 300ml/min ≤ Flow ≤ Factor H + 300ml/min
Inlet water pressure	-7.2 psi ≤ P ≤ -6.8 psi
Patient Temperature 1 PT1 (4 checks)	-0.3 °C ≤ CK1 ≤ 0.3°C -0.3 °C ≤ CK2 ≤ 0.3°C -0.1°C ≤ CK3 ≤ 0.1°C -0.3°C ≤ CK4 ≤ 0.3°C
Patient Temperature 2 PT2 (4 checks)	-0.3°C ≤ CK1 ≤ 0.3°C -0.3°C ≤ CK2 ≤ 0.3°C -0.1°C ≤ CK3 ≤ 0.1°C -0.3°C ≤ CK4 ≤ 0.3°C
Patient Temperature Echo Out (4 checks)	-0.2°C ≤ CK1 ≤ 0.2°C -0.2°C ≤ CK2 ≤ 0.2°C -0.2°C ≤ CK3 ≤ 0.2°C -0.2°C ≤ CK4 ≤ 0.2°C
Water Temperature T1 (3 checks)	-0.4°C ≤ CK1 ≤ 0.4°C -0.4°C ≤ CK2 ≤ 0.4°C -0.2°C ≤ CK3 ≤ 0.2°C
Water Temperature T2 (3 checks)	-0.4°C ≤ CK1 ≤ 0.4°C -0.4°C ≤ CK2 ≤ 0.4°C -0.2°C ≤ CK3 ≤ 0.2°C
Water Temperature T3 (3 checks)	-0.4°C ≤ CK1 ≤ 0.4°C -0.4°C ≤ CK2 ≤ 0.4°C -0.4°C ≤ CK3 ≤ 0.4°C
Water Temperature T4 (3 checks)	-0.4°C ≤ CK1 ≤ 0.4°C -1.0°C ≤ CK2 ≤ 1.0°C -1.0°C ≤ CK3 ≤ 1.0°C
Miscellaneous Heat Cool Flow	 Heat ≤ 120 seconds Cool ≤ 150 seconds Factor H - 300ml/min ≤ Flow ≤ Factor H + 300ml/min
Secondary Alarm	Alarm 37 in ≤ 18 seconds

Test	**Criteria**
Primary Alarm	Alarm 34 in ≤ 14 seconds
Chiller Capacity Test	Model 2000-02: Water Temp. ≤ 12°C Model 2000-03 or -10: Water Temp. ≤ 13°C

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CHAPTER 6 TROUBLESHOOTING

6.1 Diagnostic Mode

The Model 2000 has a diagnostic mode which is designed to provide assistance with troubleshooting and provides access to the Calibration software. To enter this mode, power up the Control Module while holding the Automatic and Purge Mode keys located on the Remote Display. The keys must be held for at least 5 seconds. The LCD display will appear as shown below (See Figures 6.1 and 6.2) after the normal power up screen sequence. The control module will operate normally, except these displays will replace the home display.

Caution: Do not operate the device in Diagnostic Mode when the device is providing therapy to a patient unless closely monitored.

Access to screens is available through the Up and Down Arrow Keys. The order of screens in the Diagnostic Mode while in Stop mode are as follows:

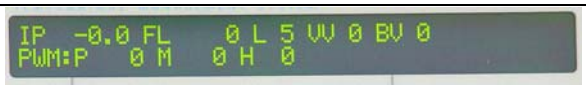
1. Diagnostic Home Screens
2. Standard Operation Screens
3. UD1 – System hours, pump hours, and system voltage setting
4. UD2 – Operational Log
5. UD3 – Error Log
6. UD4 – Calibration Procedure

6.1.1 Diagnostic Home Screens

Toggle between these two diagnostic displays by pressing the Home key.

Diagnostic Home Page #1

Figure 6.1



Diagnostic Home Page #2

Figure 6.2

The display fields are:

Table 6.1

Display Field Definitions

Field	Definition	Units or Range of Values
PT1	Patient Temperature #1	°C
PT2	Patient Temperature #2	°C
FL	Water Flow Rate	ml/min
T1	Monitor Water Temperature:	°C
T2	Control Water Temperature:	°C
T3	Return from Pad Water Temperature	°C
T4	Chiller Loop Water Temperature	°C
IP	Inlet Water Pressure	0 to -10 psi
L	Reservoir Level	1 = Empty, 5 = Full
VV	Vent Valve	1=Open, 0 = Closed
BV	Bypass Valve	1=Open, 0 = Closed
PWM P	Circulating Pump Speed	0= Stop to 235 = Full
PWM M	Mixing Pump Speed	0 = Stop to 150 = Full
PWM H	Heater Power	0 = Off to 32 = Full Power

6.1.2 Error Log and Operational Log

The Model 2000 maintains two history logs. The logs may be accessed while in Stop mode, once Diagnostic Mode is activated, by pressing the Down Arrow key. The Error Log screens are labeled UD2 and the Operational Log screens are labeled UD3. The Operational Log contains a history of the last 16 alerts and recoverable alarms. The Error Log contains a history of the last 8 non-recoverable alarms. Note that power failures do not generate a logged alarm. Each screen provides information on the state of the Control Module when the event occurred including the current system hours.

Error Log Display

Figure 6.3

The history logs are interpreted as follows:

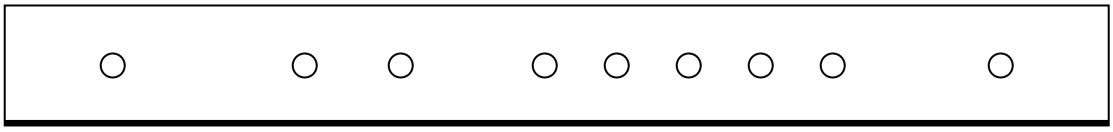
Table 6.2
Log Definitions

Field	Definition	Units or Range of Values
C	Error Code	See Table 6.4
M	Control Module Operating Mode	0 = Initialization, 1= Stop, 2 = Automatic, 3 = Manual, 4 = Purge, 5 = Fill
P	Patient Temperature 1	°C
OM	Outlet Temperature Monitor (T1)	°C
O	Outlet Temperature Control (T2)	°C
I	Inlet Temperature (T3)	°C
F	Flow Rate	ml/min
P	Inlet Pressure	0 to -10 psi
L	Water Level	1 = Empty, 5 = Full
P	Circulating Pump PWM	0= Stop to 235 = Full
C	Mixing Pump PWM	0 = Stop to 150 = Full
H	Heater PWM	0 = Off to 32 = Full Power
V	Vent Valve State	1=Open, 0 = Closed
B	Bypass Valve State	1=Open, 0 = Closed
Hr	System Hours	Hours

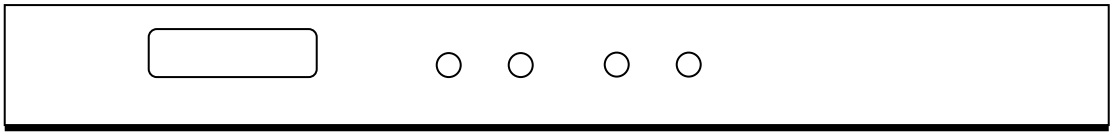
6.2 Card Cage Indicators and Test Points

LEDs on the edges of the cards indicate the status of major functions and may be helpful in troubleshooting. (Figures 6.4 to 6.7) Access to the power supply voltages is also available at the card edge.

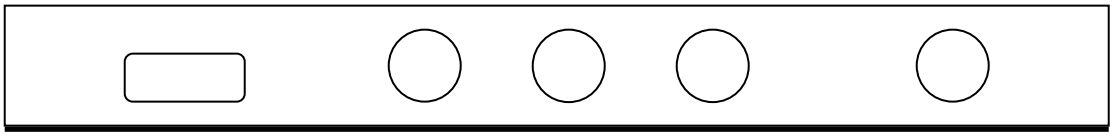
Note: Use care in accessing these test points! An insulated probe is needed to avoid shorting the test point to the frame. Doing so will cause circuit board fuses to blow, resulting in the need for component level repair.



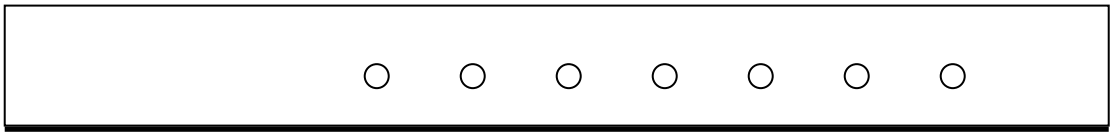
Power Card
Figure 6.4



Processor Card
Figure 6.5



Isolation Card
Figure 6.6



I/O Card
Figure 6.7

6.3 General Troubleshooting Guide

The following is a list of potential issues and methods of resolution. The suggestions for each issue are listed from most to least probable. Therefore, each step assumes the previous steps have been checked. For component replacement instructions, see Chapter 7.

Note that this guide assumes that no special equipment, such as the Medivance Calibration Test Unit is available. If available, the Calibration Test Unit is a powerful diagnostic tool and it should be used in association with the instruction in its manual.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
An alarm or alert not solved by recommendations in the Operator's			See Section 6.4, Troubleshooting Alarms and Alerts
Pads connected. Low water flow or air continuously streaming from pads. The pump can be heard.	The pads have been filled, then purged and then refilled.	Trapped air bubbles may restrict flow temporarily.	Allow the flow to stabilize for over 20 minutes before rechecking the flow rate. Air can be removed by lightly tapping on the pads.
	The pad connectors are not fully seated in the fluid delivery line manifolds.	Air leak in fluid delivery line manifold connection.	Reseat connectors.
	Pad lines are kinked or occluded at either the connector and pad ends.	Restriction in fluid lines	Remove kinks. Recommend use of fluid delivery line straps to keep lines from kinking.
	Look for pad leaks by inspecting for a continuous stream of bubbles in the tubes exiting the pads when no air is entering.	Leak in pad.	Replace pad.
	Enter Stop Mode, then hold manifold above Control Module and pads, pad connector side up. Air fills the connectors.	Leak at seal between pad connector and the fluid delivery line manifold. Air may be entering the return side of the fluid delivery line and is not visible in the pad lines.	Reseat the connector. If leak continues, replace fluid delivery line.
	Disconnect each pad in turn from the manifold to determine whether one pad is contributing to the low flow. Try to prevent air from entering the lines when removing the pads and run long enough to assure stability before checking the flow.	One pad is not functioning properly. There is an air leak in the manifold.	Replace pad. Replace fluid delivery line.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
Pads connected. Low water flow or air continuously streaming from pads. The pump can be heard.	Disconnect all pads from Fluid Delivery Line. Enter Manual Mode. The system does not remain in bypass mode for at least 3 minutes or “Alert 1" occurs.	There is an external or internal leak in the system of fluid line. This observation rules out leaks in the pad.	Replace Fluid Delivery Line.
	Run in Manual Mode for 5 minutes with pads connected. Place the pads on the floor and then place the system in Stop Mode. Dry all water from the pads, lines and manifold then place them on the floor. Wait 5 minutes, check carefully for water leaking from the pads, lines or valves.	Water leaking under positive pressure will indicate the exact leak site.	Replace the leaking component.
Pads connected. Low water flow. The pump can be heard.	Check the pads for folds or buckles created during placement.	Pads folded or creased foam-to-foam will reduce flow significantly.	Smooth out and reapply pad to remove buckles or creases.
CTU connected. Low water flow, low pressure, or high PWM. The pump can be heard.	Power up in User Diagnostic Mode. Enter Manual Mode with a water target of 28°C. After stabilizing for several minutes, note whether the display indicates: • 2550 <= FL (flow) <= 3150 • P = -6.7 to -7.2 (psi) If value is less than 6.7 then the system is unable to generate full negative pressure. • Circulating Pump PWM is greater than 200 indicating pump is running faster than normal to maintain flow and pressure.	If the pressure cannot be maintained, the flow is low, or the PWM is greater than 175, there may be an external or internal leak or debris is caught in a pump valve causing inefficient pumping.	Debris may be cleared by running the pump a full speed. To attempt to dislodge debris, replace the CTU with a fluid delivery line and connect two shunt tubes to the fluid delivery line manifold. Enter Manual Mode. The flow rate should exceed 4 lpm for 5 minutes. Remove the shunts and reconnect the CTU. Repeat the check of pump PWM.
	No leak is found. Operate the system as above. Circulating Pump PWM is high.	The pump head may be ineffective due to debris stuck in the pump.	Replace the Circulating Pump.
CTU connected. Low water flow, low pressure, or high PWM. The pump can be heard.	No leak is found. Operate the system as above. No flow is indicated in User Diagnostic Mode although some water appears to be flowing.	Flowmeter fault.	Replace the Heater / Flowmeter assembly.
CTU connected. Low water flow, low pressure, or high PWM.	Check the Circulating Pump connection at the I/O Card. Verify that the circuit card is not wet.	Pump connection fault.	Reseat the connector. Allow the card to dry, if necessary.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
The pump cannot be heard.	Swap the Circulating Pump and Mixing pump connections on the I/O Card. Attempt to operate the system. Mixing pump does not run.	Pump electronics failure.	Replace the Circulating Pump.
	Pressure is more negative than -8PSI for more than a minute.	Pressure sensor or cable fault	Replace the I/O Manifold Assembly
Pads connected. Poor temperature control of patient	Low water flow or air leaving pads.	Air leak in pads or lines.	See “Low Water Flow”
	Low water flow and flow through one pad is different from other.	Restriction in one pad allows flow to preferentially shunt through other pad. This causes significant efficiency loss.	Eliminate kinks in lines or replace low flow pad.
	Pads not adhered completely.	Movement of pads relative to patient. Pads drying out causing loss of adhesion.	Adhere or replace pads to assure full contact.
	Small pads used on large patient	Improper size selection reduces surface area available for transfer.	Use largest pads that can fit on patient. Assure pads are not overlapped in back.
	Poor water temperature control, but flow appears to be good.	Main Tank is overfilled.	Drain 0.5 liter water from the upper drain port. Power up in User Diagnostic Mode and check the level. Repeat this process until the level is less than 5.
	Poor water temperature control, Main Tank is not full.	Heater or chiller circuit fault.	See "Water does not heat" or "Water does not cool"
Pads connected. Water does not heat to target temperature in Manual Mode.	Flow rate less than 800 ml/min.	Heater does not provide full power at low flow rates.	See Low Water Flow.
CTU connected. Water does not heat to target temperature in Manual Mode.	Power up in User Diagnostic Mode. Enter Manual Mode with a water target of 42°C. After stabilizing for several minutes, note whether the display indicates any rise in the water temperature T2. Water does not warm at all.	Heater fuse is open, caused by fault in heater circuit.	Replace fuse and Heater / Flowmeter assembly.
CTU connected. Water does not heat to target temperature in Manual Mode.	Heater fuse is intact. Power up in User Diagnostic Mode. Enter Manual Mode with a water target of 42°C. After stabilizing for several minutes, note whether the display indicates any rise in the water temperature T2. Water does not warm at all.	Power Module fault.	Replace the Power Module.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
	Heater fuse is intact. Power Module replacement was unsuccessful. Power up in User Diagnostic Mode. Enter Manual Mode with a water target of 42°C. After stabilizing for several minutes, note whether the display indicates any rise in the water temperature T2. Water does not warm at all.	Heater thermal breaker tripped, caused by fault in heater control circuit.	Call Medivance Service.
Pads connected. Water cools but is reported to be unable to cool effectively when used with a patient.	Remove plastic grille and examine the condenser.	Chiller condenser clogged with lint.	Clean condenser.
CTU connected. Water does not cool to target temperature in Manual Mode.	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes. No sound emanates from the chiller. The CHILL LED on the I/O Card is on.	Chiller Power Relay or cable fault.	Check the cables between the relay and the I/O Card. Also check the cables between the relay and the Power Module and chiller. Replace cables and/or the relay, if necessary.
	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes. No sound emanates from the chiller. The CHILL LED on the I/O Card is off. The reservoir level in the diagnostic display (Lx) is less than 2.	Water reservoir level insufficient to run the chiller.	Fill reservoir. If unsuccessful, see "Will Not Fill".
	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes. No sound emanates from the chiller. The CHILL LED on the I/O Card is off. The reservoir level in the diagnostic display (Lx) is greater than 2.	Electronics or chiller fault.	Call Medivance Service.
CTU connected. Water does not cool to target temperature in Manual Mode.	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes. The chiller runs but T4 remains at or above room temperature.	Chiller fault.	Call Medivance Service.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes. The cooling command (PWM-Mxx) is nonzero and T4 stabilizes below 6C.	Pump cable or connection fault.	Check the Mixing Pump connection at the I/O Card. Verify that the circuit card is not wet. Reseat the connector. Allow the card to dry, if necessary.
	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes. The cooling command (PWM-Mxx) is nonzero and T4 stabilizes below 6C. The Mixing Pump connection at the I/O Card is dry and secure.	The pump head may be ineffective due to debris stuck in a valve or the pump electronics have failed.	Replace the Mixing Pump.
	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes. The cooling command is nonzero and T4 stabilizes below 6C. Mixing Pump replacement ineffective.	Electronics fault	Call Medivance Service.
	Power up in User Diagnostic Mode. Operate the system in Manual Mode with a water target of 4°C for 5 minutes, the cooling command is nonzero and T4 changes little.	Electronics or chiller fault.	Call Medivance Service.
Water drained from system appears green		Highly alkaline tap water used at some point to fill system. Causes chelating of copper ion from chiller evaporator.	Drain and only use distilled or sterile water to fill the system.
Pads connected. System fails to purge completely.	Pads do not empty well during purge cycle. A "click" is heard when the purge is initiated.	Vent line is kinked	Inspect vent line which is small diameter line exiting the bottom of the Inlet/Outlet Manifold and entering top of tank. Replace if kinked.
	Pads do not empty well during purge cycle. A "click" is heard when the purge is initiated.	Water has inadvertently entered purge line or valve.	Repeat purge multiple times to attempt to clear water. If necessary, detach one end and drain.
Pads connected. System fails to purge completely.	Pads do not empty well during purge cycle. A "click" is heard when the purge is initiated. Multiple purge cycles are unsuccessful.	Tank is overfilled.	Drain 0.5 liter water from the upper drain port. Power up in User Diagnostic Mode and check the level. Repeat this process until the level is less than 5.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
	Pads do not empty well during purge cycle. No "click" is heard when the purge is initiated. The VV LED on the I/O CCA illuminates during the purge.	Purge valve inoperative.	Replace the I/O Manifold assembly. Recalibrate upon completion.
	Pads unable to empty during purge cycle. No "click" is heard when the purge is initiated. The VV LED on the I/O CCA does not illuminate during the purge.	Electronics fault.	Call Medivance Service.
Water spills from the Main Tank Vent in Manual or Automatic Modes.	Control Module has been switched into service during a case.	Overfilled tank due to pads being purged into a full Control Module.	Drain some water from the upper drain port.
Water jets from the Main Tank Vent in Purge Mode.	Control Module has been switched into service during a case.	Overfilled tank due to pads being purged into a full Control Module.	Drain some water from the upper drain port.
Water jets from the Main Tank Vent in Fill Mode.	Cleaning Solution has not been added to the distilled water being used to fill the Control Module.	Low conductivity of the fluid.	Drain all water from the upper drain port. Refill after adding Cleaning Solution to fluid being used to fill the Control Module.
Reservoir overfills	Cleaning Solution has been added to the fluid being used to fill the Control Module.	Level sensor or cable fault.	Check the sensor connection at the I/O Card. Replace the level sensor harness.
	Cleaning Solution has been added to the fluid being used to fill the Control Module. Level sensor cable replacement unsuccessful.	Electronics fault.	Call Medivance Service.
Control Module will not fill	At power-up, the level is read and indicates “full”. The Control Module will not even attempt to fill. Attempting to drain the tank yields little or no water. (Note: the tank can hold about 2.8 liters. The resistance between the GND TEST point on the Power Card and the chassis is greater than 1 ohm.	Low voltage circuitry ground fault.	Replace the Power Module.
	Indicates "full" when tested as above, ground resistance low.	Electronics fault.	Call Medivance Service.
Control Module will not fill	At power-up, the level is read and indicates less than full. Upon initiation of fill, two "clicks" are heard. The Control Module tries to fill (the pump can be heard), but no water is ingested.	Pads are connected to the patient lines, preventing suction from being applied to the fill tube.	Disconnect all pads.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
	At power-up, the level is read and indicates less than full. Upon initiation of fill, two "clicks" are heard. The Control Module tries to fill (the pump can be heard), but no water is ingested. Pads not connected.	Vacuum leak in a patient line manifold valve.	See Low Water Flow.
	At power-up, the level is read and indicates less than full. Upon initiation of fill, one or no "clicks" are heard. The Control Module tries to fill (the pump can be heard), but no water is ingested. Both the BV and FILL LEDs on the I/O Card illuminate.	Bypass or Fill Valve fault	Check the I/O Manifold connector at the I/O Card. Replace the I/O Manifold assembly, if necessary. Recalibrate upon completion.
	At power-up, the level is read and indicates less than full. Upon initiation of fill, one or no "clicks" are heard. The Control Module tries to fill (the pump can be heard), but no water is ingested. Only one or neither of the BV and FILL LEDs on the I/O Card illuminate.	Electronics fault.	Call Medivance Service.
No patient temperature is displayed even though a probe is installed.	The probe and cable have not been tested on another Control Module.	An open circuit exists in either the probe or cable.	Replace the probe and cable in turn, or try each on another Control Module, to determine which is at fault. Flex the cable and probe, particularly near connections to determine whether there is an intermittent connection.
	The probe and cable have been shown to work on another Control Module.	Electronics fault.	Call Medivance Service.
A patient temperature is displayed, but no probe is installed.	At power-up, no alarm occurs.	The patient temperature channel is out of calibration.	Calibrate the Control Module.
	At power-up, no alarm occurs. Recalibration unsuccessful.	Electronics fault	Call Medivance Service.
The Control Module is noisy.	The noise is present at all times and emanates from the Power Module.	A cooling fan is failing.	Replace the Power Module.
Control Module is noisy	The noise is present at all times and emanates from the bottom of the card cage.	A cooling fan may be failing.	Replace the Card Cage. (Circuit cards need not be replaced.)
	The noise is present at all times and emanates from the lower frame chiller area.	The chiller fan may be failing.	Call Medivance Service.

Table 6. 3
General Troubleshooting Guide

Conditions / Symptom	Observation	Cause	Solution
	The noise occurs only when water is flowing.	The Circulating Pump may have air trapped in the pump head.	Debris may be cleared by running the pump a full speed. Connect two shunt tubes to the fluid delivery line manifold. Enter Manual Mode. The flow rate should exceed 4 lpm for 5 minutes. If the pump is still noisy, call Medivance Service.
	The noise occurs only when water is flowing. High flow flush is unsuccessful.	The Circulating Pump may be failing.	Replace Circulating Pump.
	The noise occurs only during a control mode when the temperature is being regulated at the target. The noise seems to burst on and off.	The Mixing Pump may be failing.	Replace the Mixing Pump.
Control Module will not power up.	When turned on, the Control Module beeps, possibly flashes the displays, and goes silent, beeps again, and continues.	Electronics fault	Call Medivance Service.
	When turned on, a fan can be heard, but no lights appear.	Power Card fault.	Replace the Power Card.
The Control Module has failed Biomed checkout.			Call Medivance Service.

6.4 Troubleshooting Alarms and Alerts

The Arctic Sun is designed with the patient's and operator's safety in mind. The Control Module has redundant, cross-checking systems and a multitude of self-tests. It detects inappropriate conditions and notifies the user. Many of these conditions can be addressed by clinical actions alone. These are described in the Operator's Manual. If the alarm or alert cannot be resolved clinically or is recurrent, the matter should be addressed by technical personnel. Table 6.4 below is intended as an aid in such an investigation.

Alerts and Alarms have specific definitions:

Alert: Alerts are intended to inform the user about patient and equipment status without interrupting the procedure.

Alarm: When an Alarm condition occurs, there is a chance that a potentially unsafe condition has occurred, or could occur with respect to the equipment, the patient, or an improperly functioning component.

Alarms are divided into two types – recoverable and non-recoverable. Recoverable alarms may be cleared when a condition is met. Non-recoverable alarms require correcting the condition and powering the system back up to clear the alarm. Non-recoverable alarms are identified as such on the display.

Refer to the Alarm & Alert Troubleshooting Table for a description of alarm and alert codes and messages and the condition limits that triggered the alarm or alert.

Note: This guide includes non-recoverable alarms. These alarms should be address only by someone trained and qualified to work on this system.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
01	Low fluid pressure in lines. Check connections. Alert	Fluid delivery line is open to air, leaking or has significant air in line	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	See General Troubleshooting - Low Flow.
02	Low water flow to pads Check lines, connections and pads. Alert	Flow to the pads is decreased by >50% of the maximum flow detected during the case or since the last low flow alert, or the flow is < 0.3 liters per minute (300 ml/minute).	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	See General Troubleshooting - Low Flow.
03	Water reservoir level low. Alert	Reservoir fluid level almost empty. There is only enough water left in the reservoir to run one procedure.	Alert occurs after Purge is complete, at start up, or after a fill cycle. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Fill Reservoir. If the error persists, see General Troubleshooting.
04	Water reservoir level below minimum. Fill reservoir. Alarm	Reservoir level is empty or below the minimum to run the system.	Remains in Stop Mode. Audio alarm half second tone every 10 seconds. Alarm indicator flashing.	Fill Reservoir. If the error persists, see General Troubleshooting - Will Not Fill.
05	Water reservoir level below minimum. Fill reservoir or purge pads Alarm	After pads are purged, reservoir is empty or below minimum required to run the system.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm indicator flashing.	If connected to pads, purge pads. Fill Reservoir. If the error persists, see General Troubleshooting - Will Not Fill.
07	Purge not complete. Pads may contain extra water. Alert	A significant amount of water was still being returned from the pads at the end of the purge cycle.	Remains in Stop Mode (at end of purge). Audio alarm half second tone every 2 minutes. Alarm indicator flashing.	See General Troubleshooting - Fails To Purge

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
08	System warming and Patient Temperature 1 high. Alarm	Patient Temperature 1 reading is above 38.◦C (100.4°F) and water temperature is above 38.◦C (100.4°F) and system is unable to cool in Automatic Mode	Changes to Stop Mode. Audio alarm half second tone every 2 minutes. Alarm indicator flashing	Operate the system in Manual Mode with a setpoint below 38°C until the water temperature is less than 38°C. Press Automatic and retest. If the error persists, see General Troubleshooting - Will Not Cool.
09	Patient Temperature 1 above user defined limit. Alert	Patient Temperature 1 reading is equal or greater than the user-defined value established in the custom settings menu.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Adjust Patient High Temperature Alert in the custom menu if desired.
10	System cooling and Patient Temperature 1 low. Alarm	Patient Temperature 1 reading is below 32.0◦C (89.6°F) and water temperature is below 32.0◦C (89.6°F) and the system is unable to heat in Automatic Mode	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing	Operate the system in Manual Mode with a setpoint above 32°C until the water temperature is greater than 32°C. Press Automatic and retest. If the error persists, see General Troubleshooting - Will Not Heat.
11	Patient Temperature 1 below user defined limit Alert	Patient Temperature 1 reading is equal or less than the user-defined value established in the custom settings menu.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Adjust Patient High Temperature Alert in the custom menu if desired.
12	Patient and water temperature high. Check water temperature. Alert	Patient Temperature 1 reading is above 38.0◦C (100.4°F) and water temperature is above 38.0◦C (100.4°F) and the system is unable to cool in Manual Mode	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Operate the system in Manual Mode with a setpoint below 38°C until the water temperature is less than 38°C. If the error persists, see General Troubleshooting - Will Not Cool.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
13	Patient and water temperature low. Check water temperature. Alert	Patient Temperature 1 reading is below 32.◦C (89.6°F) and outlet water temperature is below 32.0◦C (89.6°F) and the system is unable to heat in Manual Mode	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Operate the system in Manual Mode with a setpoint above 32°C until the water temperature is greater than 32°C. If the error persists, see General Troubleshooting - Will Not Heat.
14	Patient Temperature 1 probe disconnected or out of range. Alarm	Patient Temperature 1 reading is outside the lower limits of the display range in Automatic Mode.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Use the CTU to verify the accuracy of the Control Module. Check connection of patient temperature probe and cable. If wet, replace cable. Check temperature cable connection at the rear of the Control Module. Flex the cable to ensure that there is not an intermittent fault. Test the input with a cable and probe proven good on another Control Module. If the Control Module proves inaccurate, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
15	Unable to obtain stable patient temperature for automatic control. Alarm	Patient temperature discontinuity. Significant change in patient temperature reading for more than 10 minutes.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Use the CTU to verify the accuracy of the Control Module. Check connection of patient temperature probe and cable. If wet, replace cable. Check temperature cable connection at the rear of the Control Module. Flex the cable to ensure that there is not an intermittent fault. Test the input with a cable and probe proven good on another Control Module. If the Control Module proves inaccurate, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
16	Temperature probe 1 malfunction. Replace temperature probe or cable. Alarm	Patient Temperature 1 reading is outside the high limit of the display range in Automatic Mode. (shorted)	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Use the CTU to verify the accuracy of the Control Module. Check connection of patient temperature probe and cable. If wet, replace cable. Check temperature cable connection at the rear of the Control Module. Flex the cable to ensure that there is not an intermittent fault. Test the input with a cable and probe proven good on another Control Module. If the Control Module proves inaccurate, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
17	Patient Temperature calibration error. Restart system. Alarm	In Automatic Mode, internal temperature calibration from Patient Temperature 1 probe input is not functioning.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
18	Patient Temperature calibration error. Restart system. Alert	In Manual Mode, internal temperature calibration from the Patient Temperature 1 probe input is not functioning.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
19	Patient Temperature calibration error. Restart system. Alarm	In Automatic Mode, internal temperature calibration from the Patient Temperature 1 probe input is not functioning.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
20	Patient Temperature calibration error. Restart system. Alert	In Manual Mode, internal temperature calibration from the Patient Temperature 1 probe input is not functioning.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
21	Patient Temperature 2 high. Check patient temperature. Alarm	Patient Temperature 2 reading is above 38.◦C (100.4°F) and water temperature is above 38.◦C (100.4°F) and system is unable to cool in Automatic Mode	Changes to Stop Mode. Audio alarm half second tone every 2 minutes. Alarm indicator flashing	Operate the system in Manual Mode with a setpoint below 38°C until the water temperature is less than 38°C. Press Automatic and retest. If the error persists, see General Troubleshooting - Will Not Cool.
22	Patient Temperature 2 above user defined limit. Alert	Patient Temperature 2 reading is equal or greater than the user-defined value established in the custom settings menu.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Adjust Patient High Temperature Alert in the custom menu if desired.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
23	Patient Temperature 2 low. Check patient temperature. Alarm	Patient Temperature 2 reading is below 32.0◦C (89.6°F) and water temperature is below 32.0◦C (89.6°F) and the system is unable to heat in Automatic Mode	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing	Operate the system in Manual Mode with a setpoint above 32°C until the water temperature is greater than 32°C. Press Automatic and retest. . If the error persists, see General Troubleshooting - Will Not Heat.
24	Patient Temperature 2 below user defined limit. Alert	Patient Temperature 2 reading is equal or less than the user-defined value established in the custom settings menu.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Adjust Patient High Temperature Alert in the custom menu if desired.
25	System is warming and Patient Temperature 2 high. Alert	Patient Temperature 2 reading is above 38.0◦C (100.4°F) and water temperature is above 38.0◦C (100.4°F) and the system is unable to cool in Manual Mode	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Operate the system in Manual Mode with a setpoint below 38°C until the water temperature is less than 38°C. If the error persists, see General Troubleshooting - Will Not Cool.
26	System is cooling and Patient Temperature 2 low. Alert	Patient Temperature 2 reading is below 32.◦C (89.6°F) and water temperature is below 32.0◦C (89.6°F) and the system is unable to heat in Manual Mode.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Operate the system in Manual Mode with a setpoint above 32°C until the water temperature is greater than 32°C. If the error persists, see General Troubleshooting - Will Not Heat.
27	Patient Temperature 2 probe disconnected or out of range. Alarm	Patient Temperature 2 reading is outside the lower limits of the display range in Automatic Mode.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Use the CTU to verify the accuracy of the Control Module. Check connection of patient temperature probe and cable. If wet, replace cable. Check temperature cable connection at the rear of the Control Module. Flex the cable to ensure that there is not an intermittent fault. Test the input with a cable and probe proven good on another Control Module. If the Control Module proves inaccurate, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
28	Temperature probe 2 malfunction. Replace temperature probe or cable. Alarm	Patient Temperature 2 reading is outside the upper limits of the display range in Automatic Mode.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Use the CTU to verify the accuracy of the Control Module. Check connection of patient temperature probe and cable. If wet, replace cable. Check temperature cable connection at the rear of the Control Module. Flex the cable to ensure that there is not an intermittent fault. Test the input with a cable and probe proven good on another Control Module. If the Control Module proves inaccurate, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
29	Patient Temperature 2 calibration error. Restart system. Alert	In Automatic Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
30	Patient Temperature 2 calibration error Restart system. Alert	In Manual Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
31	Patient Temperature 2 calibration error. Restart system. Alert	In Automatic Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
32	Patient temperature 2 calibration error. Restart system. Alert	In Manual Mode, internal temperature calibration from the Patient Temperature 2 probe input is not functioning.	Current Mode continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Isolation Card and retest. If the error persists, call Medivance Service. Calibrate upon completion.
33	Water temperature high. Allow system to cool. Alarm	Water temperature is above 44.0°C (111.2°F).	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Call Medivance Service.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
34	Water temperature high. Allow system to cool. Alarm	Water temperature is above 42.5°C (108.5°F).	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Allow the system to cool, then press Automatic or Manual. (This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition.) If the alarm is recurrent, use the CTU to check the calibration of the Control Module. Calibrate if necessary. If the alarm persists, call Medivance Service.
35	Water temperature low. Allow system to warm. Alarm	Water temperature is below 3.5°C (38.3°F).	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Operate the unit in User Diagnostic Mode and Manual Mode with the CTU attached at a setpoint of 4°C. Observe T1, T2, T3, and T4 for at least 10 minutes after reaching stability. If T4 drops below 3°C for more than a few seconds, check the connector at J5 of the I/O Card. Verify that it is plugged in securely, the wires emanating from it are intact, and that the other end of the wires entering the solid state relay are intact. Repeat the test. Replace cables or the relay, if necessary, and retest. If the error persists, call Medivance Service.
36	Water temperature above safety level. Allow system to cool. Alarm	Water temperature is above 44°C (111.2°F).	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Call Medivance Service.
37	Water temperature above safety level. Allow system to cool. Alarm	Water temperature is above 43°C (109.4°F).	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Allow the system to cool, then press Automatic or Manual. (This alarm may be caused by transient conditions such as a momentary occlusion, air bolus, hot restart, or no-load condition.) If the alarm is recurrent, use the CTU to check the calibration of the Control Module. Calibrate if necessary. If the alarm persists, call Medivance Service.
38	Water temperature below safety level. Allow system to warm. Alarm	Water temperature is below above 3.0°C (37.4°F).	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Operate the unit in User Diagnostic Mode and Manual Mode with the CTU attached at a setpoint of 4°C. Observe T1, T2, T3, and T4 for at least 10 minutes after reaching stability. If T4 drops below 3°C for more than a few seconds, check the connector at J5 of the I/O Card. Verify that it is plugged in securely, the wires emanating from it are intact, and that the other end of the wires entering the solid state relay are intact. Repeat the test. Replace cables or the relay, if necessary, and retest. If the error persists, call Medivance Service.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
40	System unable to maintain stable water temperature. Alarm	In Manual Mode, system is unable to control water within 1.0°C/F of set point after 25 minutes in current mode or at the time of last change in Water Target Temperature.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Use the CTU to check the calibration the Control Module. Calibrate if necessary. If the error persists, call Medivance Service.
41	Low bypass flow. Heating not available. Alert	Insufficient internal flow during priming or bypass mode.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Use the CTU to check the calibration of the Control Module. Calibrate if necessary. If the error persists, call Medivance Service.
43	User settings not saved. System default settings restored. Alert	Saved customer user profile settings are invalid.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
44	Invalid system log entry. Service information may be corrupt. Alert	In Diagnostic Mode, one or more entries in the internal system event log are invalid. Used by a designated clinical engineering or Medivance service.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
46	Non-recoverable system error Refer to Operator Manual. Alarm	User interface not detected by control system.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Check Remote Display Cable connections on the remote display module and Control Module. Ensure that they are secure. Turn the Control Module off for 30 seconds and turn power back on. If the error persists, replace the Remote Display. If unsuccessful, call Medivance Service.
47	Non-recoverable system error Refer to Operator Manual. Alarm	User interface not detected by monitor system.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Check Remote Display Cable connections on the remote display module and Control Module. Ensure that they are secure. Turn the Control Module off for 30 seconds and turn power back on. If the error persists, replace the Remote Display. If unsuccessful, call Medivance Service.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
48	Patient temperature out invalid. Alert	Patient Temperature Output (Echo) calibration data in non-volatile memory invalid.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
50	Patient Temperature 1 erratic. Check temperature probe. Alert	Patient temperature discontinuity. Significant change in patient temperature reading for more than 8 minutes.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Use the CTU to verify the accuracy of the Control Module. Check connection of patient temperature probe and cable. If wet, replace cable. Check temperature cable connection at the rear of the Control Module. Flex the cable to ensure that there is not an intermittent fault. Test the input with a cable and probe proven good on another Control Module. If the Control Module proves inaccurate, replace the Isolation Card and retest. If the error persists, call Medivance Service. Recalibrate upon completion.
51	Patient Temperature 1 below control range. Check temperature probe. Alert	Patient temperature less than 33°C when Automatic mode entered.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing	Use the CTU to verify the accuracy of the Control Module. Check connection of patient temperature probe and cable. If wet, replace cable. Check temperature cable connection at the rear of the Control Module. Flex the cable to ensure that there is not an intermittent fault. Test the input with a cable and probe proven good on another Control Module. If the Control Module proves inaccurate, replace the Isolation Card and retest. If the error persists, call Medivance Service. Recalibrate upon completion.
52	Extended period of cold water delivery. Assess Patient Alert	Circulating water temperature has been below 10°C/50°F for 8 of the previous 10 hours.	Remains in current mode. Audio alarms.	Assess patient's skin. Check to determine if water circulating through the pads is at least 2.3 liters per minute. Determine whether the temperature probe is placed properly. Check to make sure the recommended number of pads is in use. Determine whether the patient requires additional sedation for shivering. Assess whether environmental factors, such as room temperature and hot lamps are interfering with the cooling process.
53	Prolonged cold exposure Alarm	The Arctic Sun has issued 11 alerts for extended periods of cold water delivery.	Changes to Stop Mode	Assess patient's skin. Assess whether the minimum water temperature should be increased or whether the temperature management therapy should be discontinued.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
60	Non-recoverable system error Refer to Operator Manual. Alarm	Control and Monitor start up synchronization fault	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
61	Non-recoverable system error Refer to Operator Manual. Alarm	Control Processor parameter memory fault	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
62	Non-recoverable system error Refer to Operator Manual. Alarm	Monitor Processor parameter memory fault	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
64	Non-recoverable system error Refer to Operator Manual. Alarm	Unable to enable pump power (Control)	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the Power Card and attempt to power-up. If the error persists, call Medivance Service.
65	Non-recoverable system error Refer to Operator Manual. Alarm	Unable to enable pump power (Monitor)	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the Power Card and attempt to power-up. If the error persists, call Medivance Service.
66	Non-recoverable system error Refer to Operator Manual. Alarm	Unable to disable pump power (Control)	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the Power Card and attempt to power-up. If the error persists, call Medivance Service.
67	Non-recoverable system error Refer to Operator Manual. Alarm	Unable to disable pump power (Monitor)	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the Power Card and attempt to power-up. If the error persists, call Medivance Service.
70	Non-recoverable system error Refer to Operator Manual. Alarm	Mains signal is missing or inconsistent	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the Power Card and attempt to power-up. If the error persists, call Medivance Service.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
71	Non-recoverable system error Refer to Operator Manual. Alarm	T2 Thermistor signal out of range - high resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Check the connector at J10 of the I/O Card. Verify that it is plugged in securely, the wires emanating from it are intact, and that the other end of the wires entering the sensor body is intact. Power up and allow the Control Module to run for 10 minutes. If the error persists, call Medivance Service.
72	Non-recoverable system error Refer to Operator Manual. Alarm	T2 Thermistor signal out of range - low resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Ensure that the I/O Card or J10 connector on it are not wet. Allow them to dry, if necessary, and retest. If the error persists, call Medivance Service.
73	Non-recoverable system error Refer to Operator Manual. Alarm	T1 Thermistor signal out of range - high resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Check the connector at J10 of the I/O Card. Verify that it is plugged in securely, the wires emanating from it are intact, and that the other end of the wires entering the sensor body is intact. Power up and allow the Control Module to run for 10 minutes. If the error persists, call Medivance Service.
74	Non-recoverable system error Refer to Operator Manual. Alarm	T1 Thermistor signal out of range - low resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Ensure that the I/O Card or J10 connector on it are not wet. Allow them to dry, if necessary, and retest. If the error persists, call Medivance Service.
75	Non-recoverable system error Refer to Operator Manual. Alarm	T3 Thermistor signal out of range - high resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Check the connector at J9, pin 1 and J9, pin 7 of the I/O Card. Verify that it is plugged in securely, the wires emanating from it are intact, and that the other end of the wires entering the sensor body is intact. Power up and allow the Control Module to run for 10 minutes. If the error persists, call Medivance Service.
76	Non-recoverable system error Refer to Operator Manual. Alarm	T3 Thermistor signal out of range - low resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Ensure that the I/O Card or J9, pin 1 and J9, pin 7 connector on it are not wet. Allow them to dry, if necessary, and retest. If the error persists, call Medivance Service.
77	Non-recoverable system error Refer to Operator Manual. Alarm	T4 Thermistor signal out of range - high resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Check the connector at J10 of the I/O Card. Verify that it is plugged in securely, the wires emanating from it are intact, and that the other end of the wires entering the sensor body is intact. Power up and allow the Control Module to run for 10 minutes. If the error persists, call Medivance Service.
78	Non-recoverable system error Refer to Operator Manual. Alarm	T4 Thermistor signal out of range - low resistance	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Ensure that the I/O Card or J10 connector on it are not wet. Allow them to dry, if necessary, and retest. If the error persists, call Medivance Service.

Table 6.4
Alarm and Alert Troubleshooting

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
79	Non-recoverable system error Refer to Operator Manual. Alarm	T1 and T2 differ by more than 1.0 degree C	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, call Medivance Service.
80	Non-recoverable system error Refer to Operator Manual. Alarm	The Control Processor has failed to detect a simulated water temperature fault.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the I/O Card and attempt to power-up. If the error persists, call Medivance Service. Calibrate upon completion.
81	Non-recoverable system error Refer to Operator Manual. Alarm	The Monitor Processor has failed to detect a simulated water temperature fault.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the I/O Card and attempt to power-up. If the error persists, call Medivance Service. Calibrate upon completion.
82	Non-recoverable system error Refer to Operator Manual. Alarm	A/D converter fault	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
83	Non-recoverable system error Refer to Operator Manual. Alarm	The Monitor Processor does not communicate.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
84	Non-recoverable system error Refer to Operator Manual. Alarm	The Control Processor does not communicate.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Processor Card. If unsuccessful, call Medivance Service. Calibrate upon completion.
85	Non-recoverable system error Refer to Operator Manual. Alarm	The model of the Control Module could not be verified.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Call Medivance Service.

Table 6.4
Alarm and Alert Troubleshooting

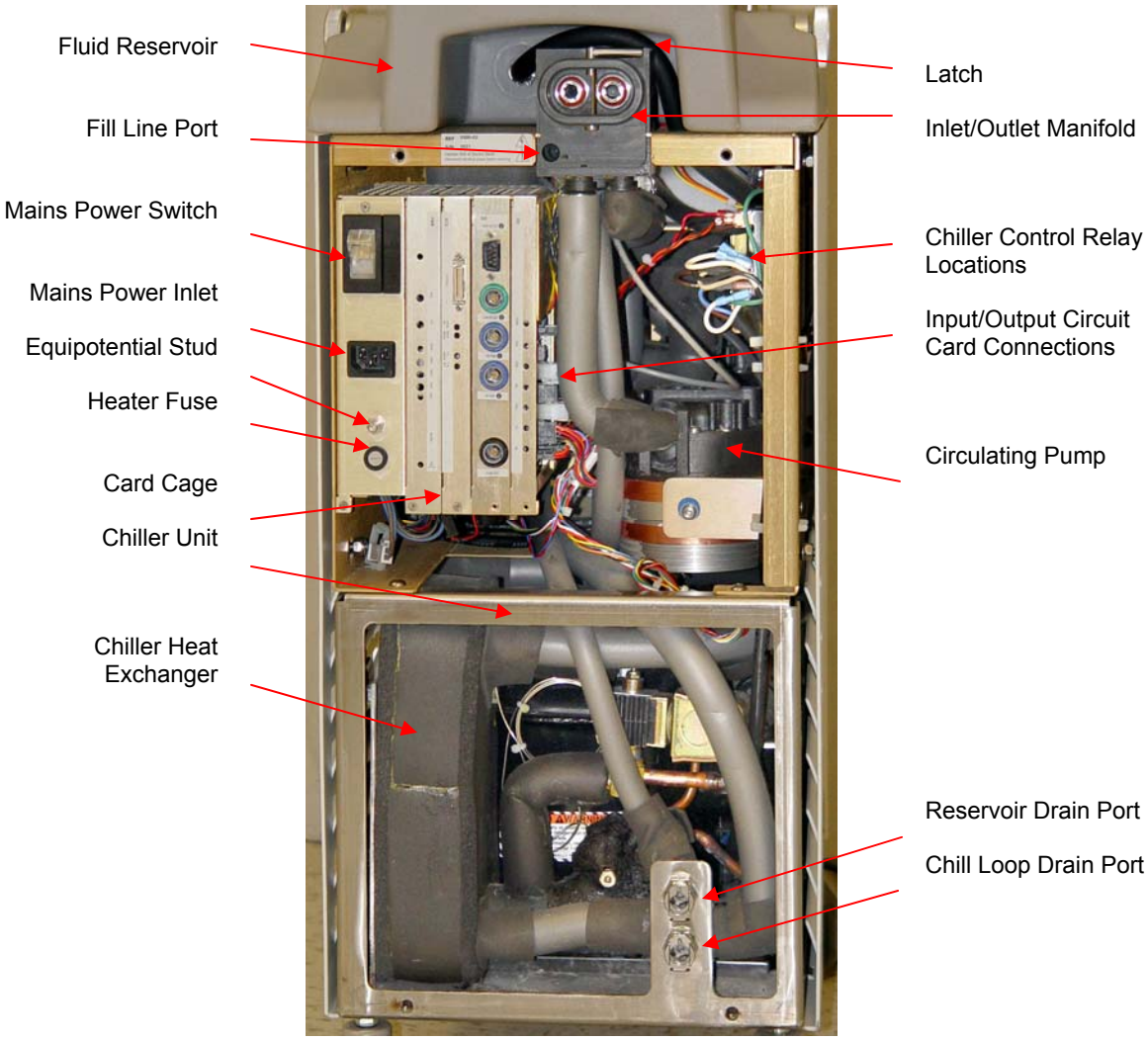
Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Troubleshooting
86	Non-recoverable system error Refer to Operator Manual. Alarm	Power supply voltage out of range.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Turn the Control Module off. Wait 30 seconds and turn power back on. If the error persists, replace the Power Card and attempt a power-up. If the error persists, call Medivance Service. Calibrate upon completion.
98.x	Non-recoverable system error Refer to Operator Manual. Alarm	Processor fault	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the Processor and retest. Calibrate upon completion.
99	Non-recoverable system error Refer to Operator Manual. Alarm	Processor Fault	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Replace the Processor Card. Calibrate upon completion.

CHAPTER 7 COMPONENT REPLACEMENT

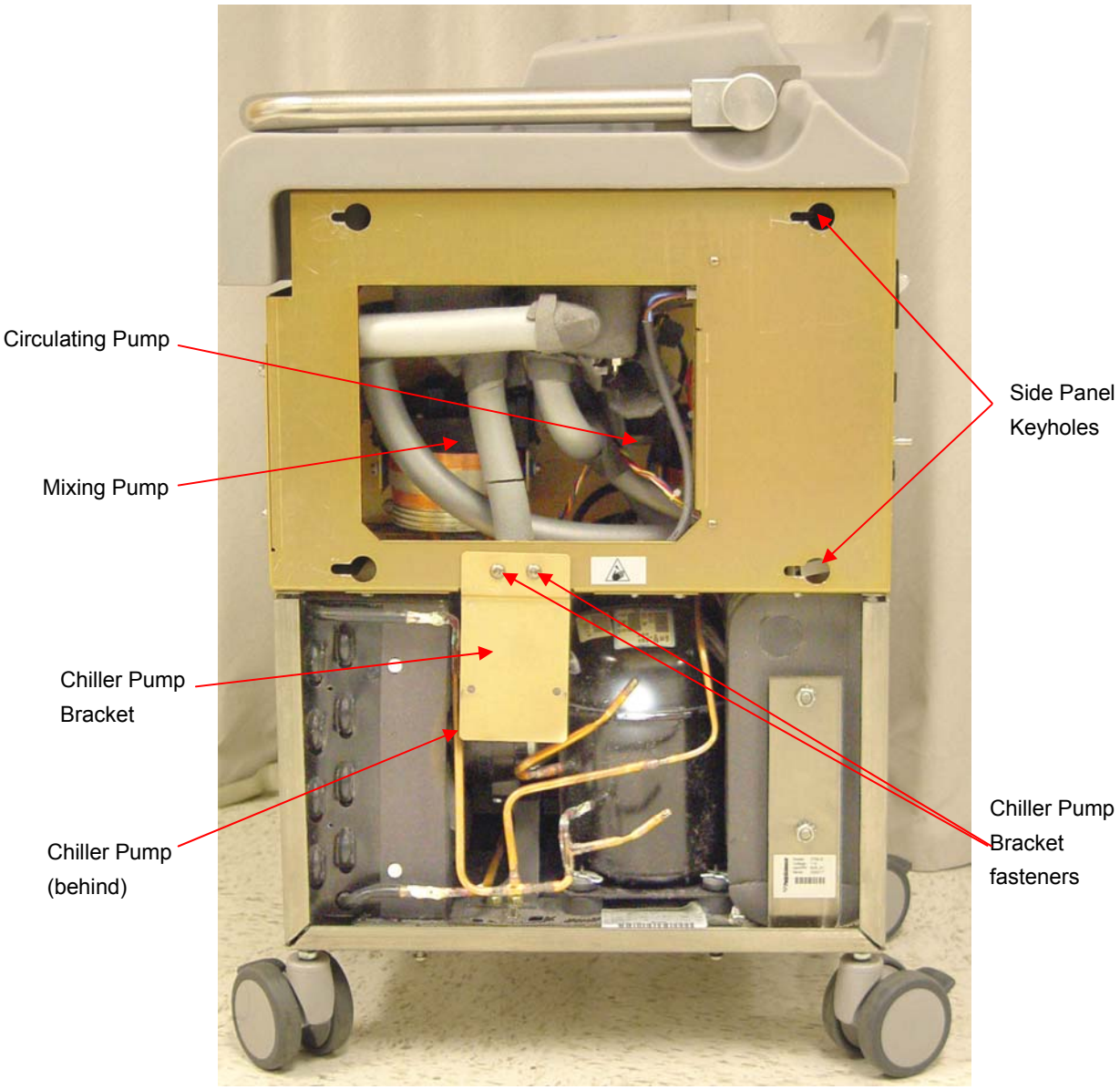
The Model 2000 is designed and built to have a high degree of reliability; however, occasional failures do occur. Use the trouble shooting methods in Chapter 6 or consult with Medivance Customer Service to determine the source component of the failure. Once the source of the failure has been determined, follow the appropriate procedure for replacement of the component. Not all components can be replaced in the field. A complete list of spare parts is available from Medivance Customer Service. If a component fails that is not available as a spare part, contact Medivance Customer Service.

In general, reverse the order of removal to install a component. Otherwise, note any special instructions.

Caution: Observe the electrostatic discharge control procedures (ESD) when working with any circuit card assembly.

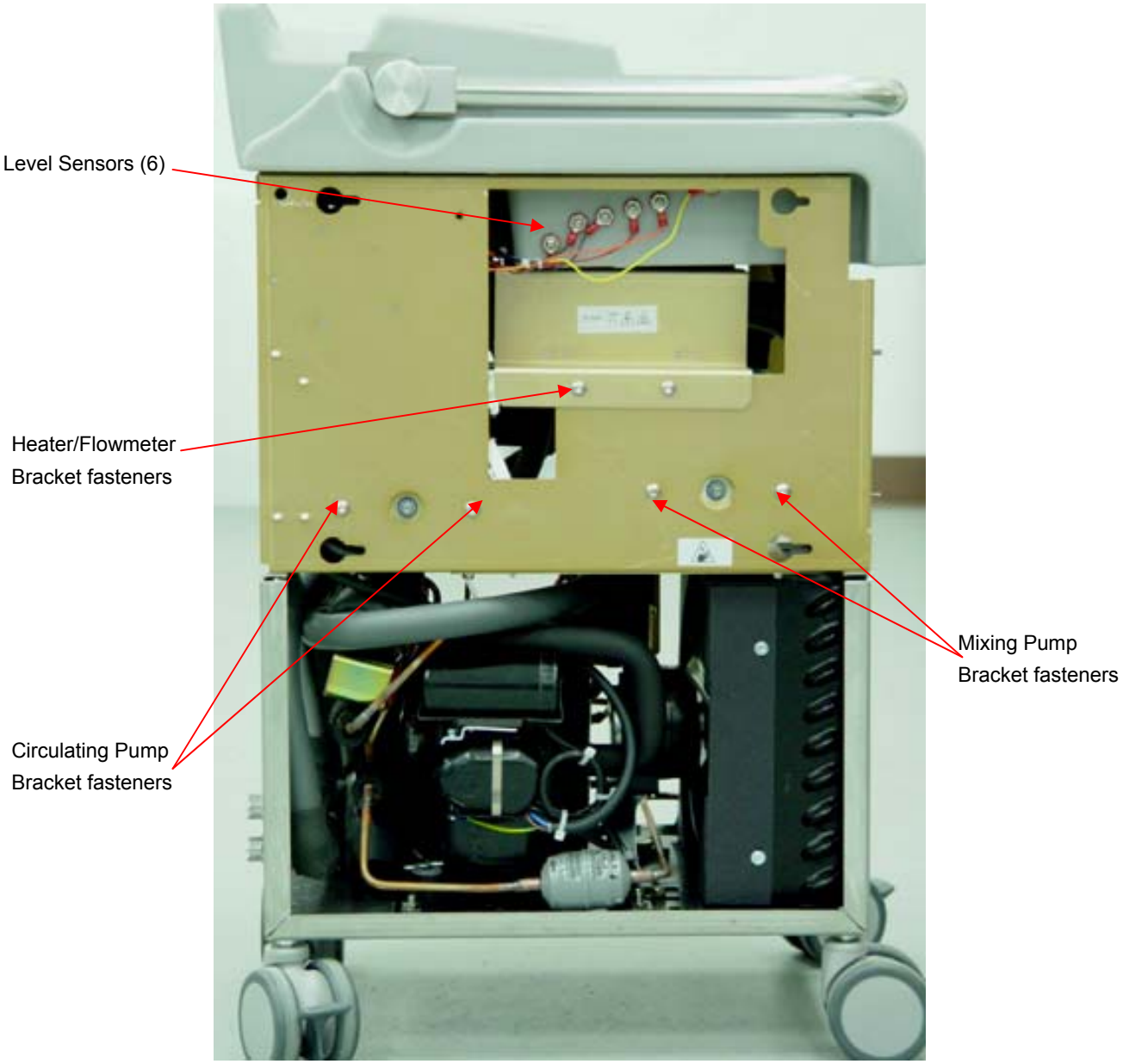


Control Module
Rear Inside View
Figure 7.1



Control Module
Right Side

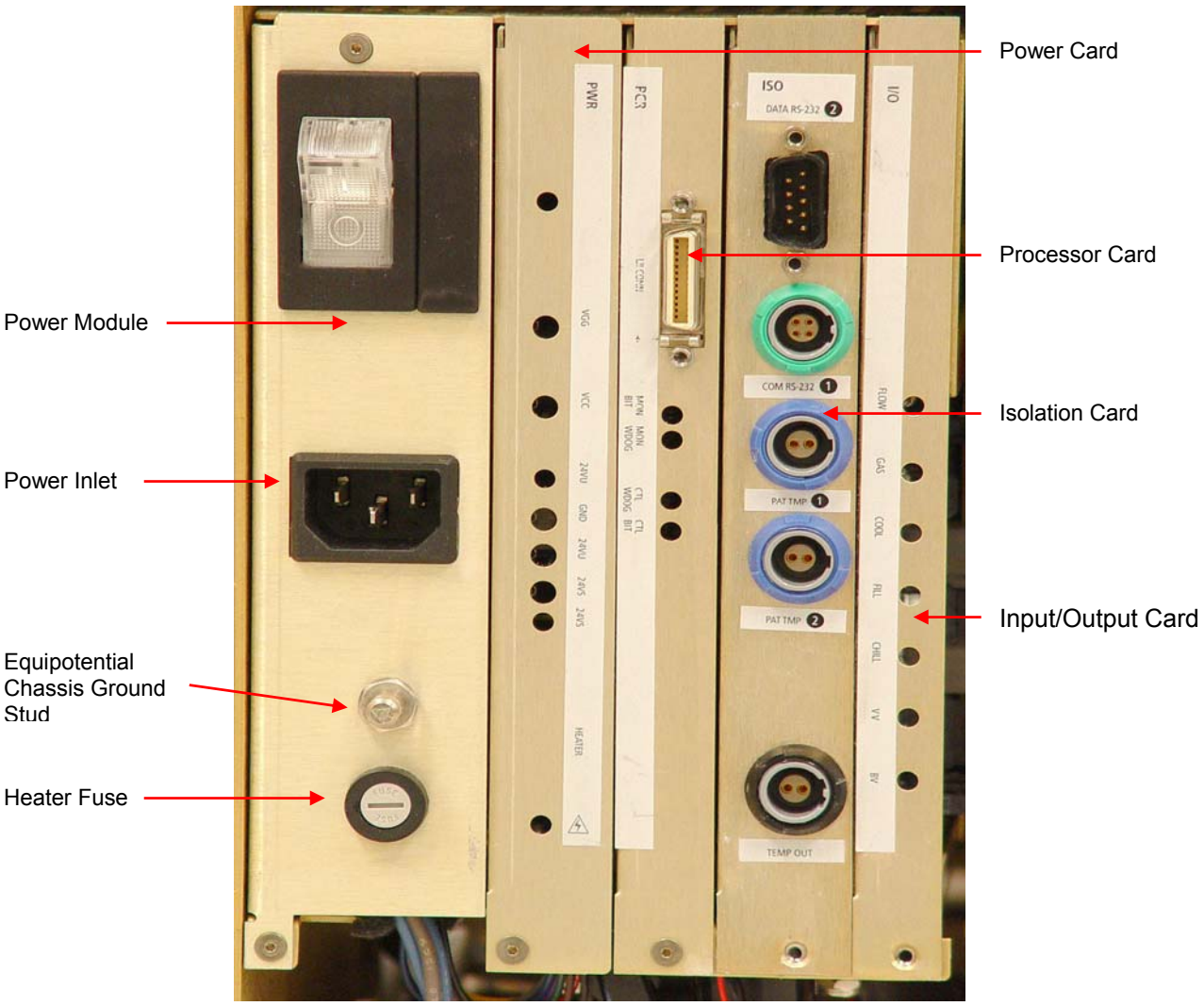
Figure 7.2



Control Module
Left Side
Figure 7.3

The electronics are housed in the Electronics Card Cage and control all machine processes. Five subassemblies comprise the electronics:

- The Power Module converts AC to DC power and controls the heater.
- The Power Card provides low voltage power for the electronics.
- The Processor Card houses the microprocessors and peripherals.
- The Isolation Card provides interfaces to the patient and external devices.
- The I/O (Input/Output) Card interfaces to the internal sensors and actuators.



Card Cage
Circuit Card Identification
Figure 7.4

7.1 Drain the Control Module

Tools and Supplies Required:

- Arctic Sun Drain Bag

1. Turn the Control Module off.

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

2. Attach the two fittings on the bag to the two drain ports on the back of the control module. The device will passively drain all tubing, reservoirs and pumps within the system. This is an adequate drain for maintenance procedures.

Drain Bag Attached
Figure 7.5

7.2 Front Grill

1. Remove the front grill by first pulling the bottom out by reaching under the center of the bottom edge.
2. Using both hands at the top sides of the panel, pull it straight out and away from the control module.
3. To replace, align the studs with the holes and push all four corners.

Front Grill Removal
Figure 7.6

7.3 Rear Panel

Tools and Supplies Required:

- 5/32” hex key

1. Turn off the power and unplug the power cord.
2. Detach all cables and lines from the rear panel: fluid delivery line, fill line, patient temperature cables, remote display cable and strain relief.
3. Remove the four mounting screws at the corners with the hex key from the rear panel.
4. Pull the panel off horizontally.

Rear Panel Removal
Figure 7.7

7.4 Side Panels

Tools and Supplies Required:

- 5/32” hex key

1. Remove the rear panel per Section 7.3.
2. Remove the front grill per Section 7.2.
3. Remove the two screws located on the underside of one side panel with a 5/32” hex key.
4. Hold the panel on both sides and move it towards the rear of the unit. Slide the panel out from front to back. There are four key slots which accept white plastic key nuts.
5. Repeat this process for the other side panel.
6. To replace the side panels, align the white key nuts horizontally, rotated to allow the threaded stud to engage the slots in the frame.

Side Panel Screw Removal
Figure 7.8

7.5 Card Cage

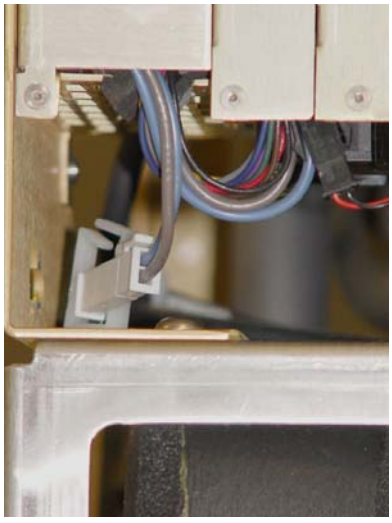
Tools and Supplies Required:

- 5/64” hex key
- 5/16” nut driver

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

1. Remove the rear panel per Section 7.3
2. Remove right side panel Section 7.4.
3. Through the right side of the frame, disconnect the wire which connects to the rear of the card cage.
4. Disconnect the (heater) cable from under the card cage.

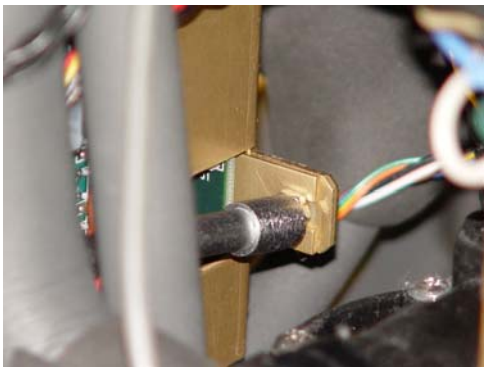
Chiller Power Wire Harness
Figure 7.9



Heater Wire Harness
Figure 7.10

5. Disconnect all cables on the Input/Output circuit card on the right side of the card cage per Section 7.10.
6. Remove the two screws on the right side of the chassis (left of the card cage) with a 5/64” hex key.
7. Remove the two nuts in the back of the Input/Output circuit card on the right side, on the top and bottom with a 5/16” nut driver.
8. Lift out the card cage.
9. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Chassis Test per Section 7.23.

Card Cage Mounting Screws
Figure 7.11



Card Cage Mounting Nuts
Figure 7.12

7.6 Power Circuit Card

Tools and Supplies Required:

- 1/16” hex key

Note: The machine does not have to be drained in order to complete this procedure.

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

1. Remove the rear panel per Section 7.3.
2. Remove the Power Circuit Card (second from left) by removing the bottom allen head screw with a 1/16" allen wrench and carefully prying the bracket at the top with a flat head screw driver.
3. Carefully slide the circuit card out of the card cage until the card protrudes approximately one inch to expose the Piezo Alarm and the DC Power cable connectors. Disconnect the Piezo Alarm and DC Power cables.
4. Carefully slide the Power circuit card approximately another inch and disconnect the AC Sync cable.
5. Now the Power circuit card may be fully removed.
6. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Chassis Test per Section 7.23.

Power Circuit Card
Figure 7.13

7.7 Power Module

Tools and Supplies Required:

- 1/16” hex key

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

1. Remove the rear panel per Section 7.3.
2. Remove the right side panel per Section 7.4.
3. Remove the Power circuit card per Section 7.6.
4. Disconnect the Chiller Power cable from the back of the card cage per Section 7.5.
5. Disconnect the heater power cable at the bottom of the card cage per Section 7.5.
6. Remove the Power Module by removing the 1/16" hex head screws at the top and bottom of the bracket and carefully pulling outward.
7. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Chassis Test per Section 7.23.

Power Module
Figure 7.14

7.8 Processor Circuit Card

Tools and Supplies Required:

- 1/16” hex key

Note: The machine does not have to be drained in order to complete this procedure.

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

1. Remove the rear panel per Section 7.3.
2. Remove the Processor circuit card by removing the bottom hex head screw with a 1/16” hex key and carefully prying outward at the top with a flat head screw driver. Carefully pull outward until the circuit card is removed.
3. If the Processor circuit card is replaced, calibrate per Chapter 5.

7.9 Isolation Circuit Card

Tools and Supplies Required:

- 1/16” hex key

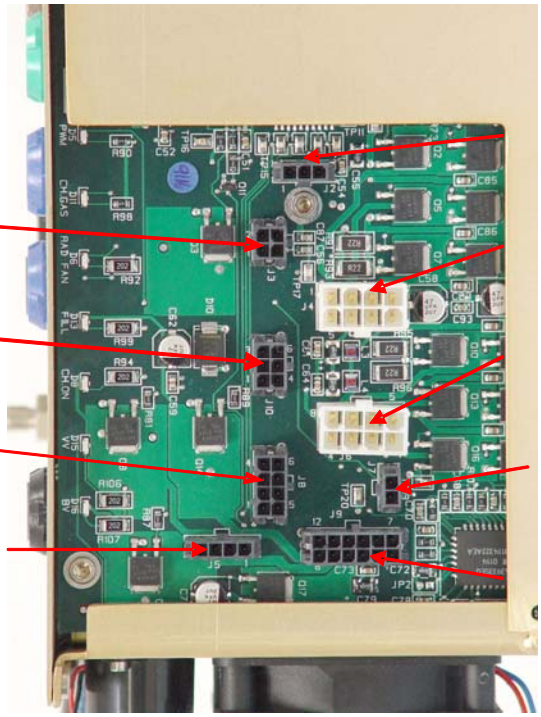
Note: Observe electrostatic discharge control procedures when handling circuit cards.

1. Remove the rear panel per Section 7.3.
2. Remove the Isolation circuit card by removing the bottom allenhead screw with a 1/16” allen wrench and carefully prying outward at the top slot with a flat head screw driver. Then, carefully pull outward until the circuit card is removed.
3. If the Isolation circuit card is replaced, calibrate per Chapter 5.
4. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Patient Applied Part Test per Section 7.24.

Isolation Circuit Card
Figure 7.15

7.10 Input / Output Circuit Card Connections

1. Many of the wiring harnesses connect to the Input / Output circuit card. In the course of troubleshooting or repair, it may be necessary to remove some or all of the connections. The following figure describes these connections



Input/Output Circuit Card Connections
Figure 7.16

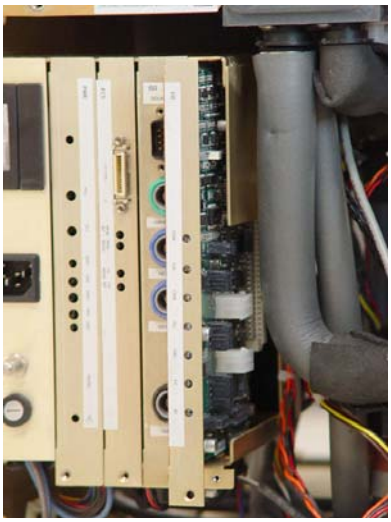
7.11 Input / Output Circuit Card

Tools and Supplies Required:

- 1/16" hex key

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

1. Remove the rear panel per Section 7.3.
2. Carefully disconnect all connectors from the Input/Output circuit card, releasing each locking tab before pulling.
3. Remove the Input/Output circuit card by removing the allen head screw with a 1/16" hex key and carefully prying outward at the top with a flat head screw driver. Carefully pull outward until the circuit card is removed.
4. If the Input/Output circuit card is replaced, calibrate per Chapter 5.



Input/Output Circuit Card
Figure 7.17

7.12 Software Chips

Tools required:

- PLCC extractor

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

1. Remove the rear panel per Section 7.3.
2. Remove the Processor circuit card per Section 7.8.

Note: The software upgrade is performed by replacing the firmware chips Handle the chips as little as possible to avoid static damage.

Control Software Chips

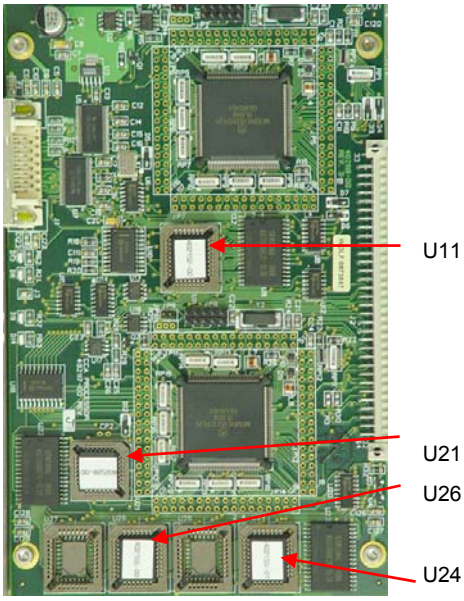
1. Using the extractor tool remove the chips from U 24 and U 26.
2. Place the new chip with the odd number extension (number after the dash) into U24.
3. Place the new chip with the even number extension into U 26.

Monitor Software Chips

1. Using the extractor tool remove the chip from U11.
2. Install the new chip.

Programmable Logic Device

1. Using the extractor tool remove the chip from U 21.
2. Install the new chip.



Software Chip Location
Figure 7.18

7.13 Handle

1. Unscrew the knobs on both sides of the handle.
2. Replace with a new handle

7.14 Circulating Pump

Tools and Supplies Required:

- 5/32” hex key

1. Remove the rear panel per Section 7.3
2. Remove the left side panel per Section 7.4.
3. Drain the control unit per Section 7.1.
4. Locate the cable that comes from the pump and unplug from the Input/Output circuit card.

Note: Observe the routing of the wire harness for the installation of the new pump assembly.

5. With a 5/32” hex key remove the 2 screws on the side panel that hold the bracket of the pump. The two screws are located toward the rear of the unit.
6. Disconnect the tube from the pump by pushing the lever on the pump up.
7. Remove the tube fitting.
8. Repeat the process for the tube fitting in the back of the pump.
9. At this point the pump assembly can be removed from the chassis.

Circulating Pump Location
Figure 7.19

Circulating Pump Mounting Screws
Figure 7.20

7.15 Mixing Pump

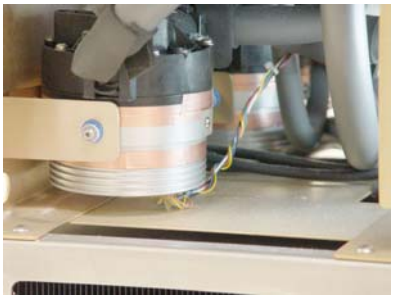
Tools and Supplies Required:

- 5/32” hex key

1. Remove front grill per Section 7.2.
2. Remove rear panel per Section 7.3.
3. Remove the side panels per Section 7.4.
4. Disconnect the cable that comes from the pump to the Input/Output Circuit Card (see Section 7.10).

Note: Observe the routing of the wire harness for installation of the new pump assembly.

5. Remove the two screws that hold the pump bracket using a 5/32” hex key, located to the front of the unit.
6. Push the lever up on the pump ports to disconnect the tube fitting.
7. Repeat the process for the tube fitting on the back of the pump.
8. At this point the mixing pump can get removed from the chassis.



Mixing Pump Mounting Screws
Figure 7.21

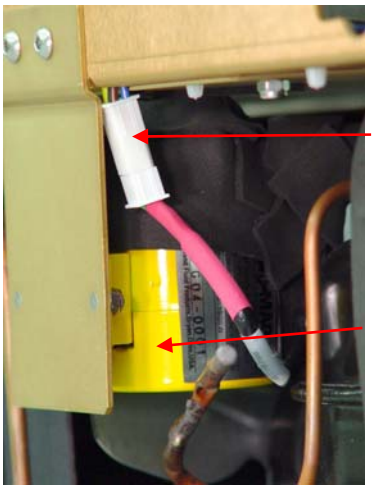
Mixing Pump Mounting Screws
Figure 7.22

7.16 Chiller Pump

Tools and Supplies Required:

- Blade screwdriver
- 5/32” hex key

1. Remove the rear panel per Section 7.3.
2. Remove the right side panel per Section 7.4.
3. Disconnect the chiller harness at the connector located directly above the chiller pump assembly.
4. Remove the insulation from around the tubing on the bottom of the chiller reservoir.
5. With a screwdriver, loosen the hose clamp ring around the tubing.
6. Pull the tubing off from under the tank.
7. Remove the two screws on the metal frame that hold the bracket of the chiller pump assembly with a 5/32” hex key.
8. Remove the insulation from around the tube attached to the chiller pump, which extends to the back of the pump (in the lower part of the unit).
9. Loosen the hose clamp ring with a small screwdriver.
10. Pull the pump assembly off the tubing.
11. To replace, insulate the pump head and the tubing with the adhesive coated foam insulation provided.
12. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Chassis Test per Section 7.23.



Chiller Pump Harness Location
Figure 7.23

7.17 Heater

Tools and Supplies Required:

- Blade screwdriver
- 5/32” hex key

1. Drain the control unit per Section 7.1.
2. Remove front grill per Section 7.2.
3. Remove rear panel per Section 7.3.
4. Remove the side panels per Section 7.4**.**
5. Disconnect the cable that comes from the heater and goes to the cable connection directly behind the circulating pump.
6. Disconnect the flowmeter cable that comes from the heater assembly and plugs into the Input / Output circuit card (see Section 7.10).

   Note: Observe the routing of the cable to the Input/Output circuit card.
7. Disconnect the tubing from the upper drain port: Push the insulation back where the tubing meets the elbow fitting. Open the snap ring with a small screwdriver and pull the tubing from the fitting.
8. Disconnect the tube from the bottom of the mixing reservoir. The tube is located closest to the bottom of the outside of the chassis: Pull back the insulation where the tube meets the reservoir. Open the snap ring with a small screwdriver and pull the tube off the reservoir.
9. Reach through the right side of the chassis and slide the lever up to unlock the fitting from the flow pump.
10. Remove the fitting.
11. Unscrew the bracket screws on the left side of the control unit chassis with a 5/32” hex key and remove the heater assembly and the bracket through the opening.
12. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Chassis Test per Section 7.23.

Snap Ring Removal
Figure 7.24

7.18 Chiller Power Relay

Tools and Supplies Required:

- 5/16” nut driver

1. Remove the rear panel per Section 7.3.
2. Note the position of each wire and remove all connections from the relay.
3. Remove the nut on the top and on the bottom of the relay with a 5/16” nut driver.
4. Remove the relay.
5. Reverse the process to replace the relay with a new one.
6. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Chassis Test per Section 7.23.

7.19 Chiller Control Relay

Tools and Supplies Required:

- 1/4” nut driver

1. Remove the rear panel per Section 7.3.
2. Note the position of each wire and remove all connections from the relay.
3. Remove the standoffs on the top and on the bottom of the relay with a ¼” nut driver.
4. Remove the relay.
5. After re-assembly of the unit, it is recommended to perform a Dielectric Withstand (Hipot) Chassis Test per Section 7.23.

7.20 Inlet / Outlet Manifold

Tools and Supplies Required:

- 5/32" hex key
- 3/32" hex key

13. Remove the rear panel per Section 7.3.
14. **Note:** Observe the routing of the cable to the Input/Output circuit card. Ensure that wires are not pinched when reassembling.
15. The Inlet / Outlet Manifold is attached to the chassis by two shoulder screws inserted into keyholes. Pull the Inlet /Outlet manifold forward then down to slide it off the chassis.
16. Remove the tubing and connectors from the bottom of the manifold by first removing the screws securing each connector using a 3/32” hex key.
17. Unplug the manifold harness from the Input/Output Circuit Card (see Section 7.10).

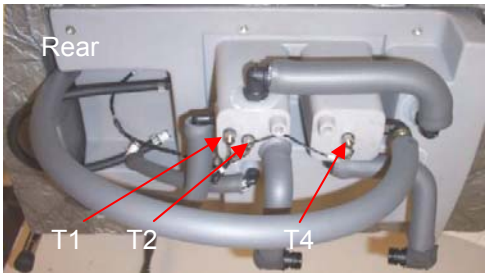
Inlet / Outlet Manifold

Figure 7.25

7.21 Temperature Sensor Harness

Tools and Supplies Required:

- 7/16” open-end wrench
- 5/32” hex key



Sensor Locations
(tank insulation not shown for clarity)

Figure 7.26

1. Drain the control unit per Section 7.1.
2. Remove the rear panel per Section 7.3
3. Remove the right side panel per Section 7.4.

Note: Observe the routing of the harness.

4. Remove the Inlet /Outlet manifold block for access. Pull the block toward you until it disengages from the chassis.
5. Remove the harness from the cable clip located behind the manifold block.
6. Through the opening of the right side of the chassis remove the insulation from all three temperature sensors located on the bottom of the mixing and chilled water reservoirs.
7. Remove the temperature sensors from the reservoirs using a 7/16" open-end wrench.
8. Ensure that the rubber washers are installed on the temperature sensors of the new harness. Observe the labeling on the cable to identify the temperature sensors.
9. Install T4 into the chilled water reservoir located toward the front of the control module.
10. Install T1 in the bottom corner of the mixing reservoir.
11. Install T2 in the bottom center of the mixing reservoir.
12. Cover the temperature sensors with the provided insulation.

Note: Don’t bend the wires too sharply while applying the insulation.

13. If the temperature sensor harness is replaced, calibrate per Chapter 5.

7.22 Level Sensor Harness

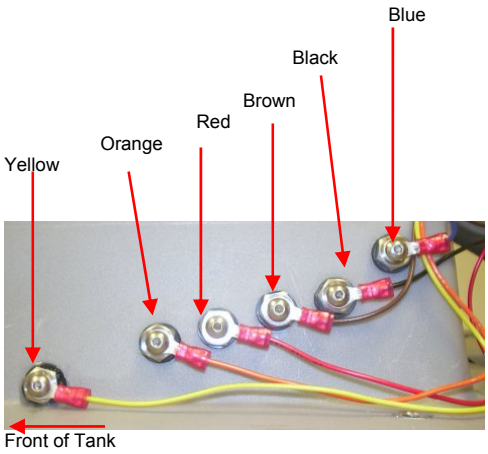
Tools required:

- 7/16” nut driver
- 7/16” open-end wrench
- 3/32” hex key
- Silicone RTV Adhesive

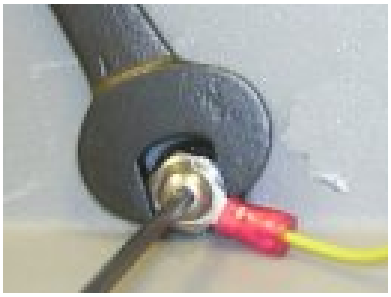
1. Drain the control module per Section 7.1.
2. Remove the front grill per Section 7.2.
3. Remove the rear panel per Section 7.3.
4. Remove the left side panel per Section 7.4.

   Note: Observe the routing of the Level Sensor Harness.
5. Remove the Input/Output Manifold for access per Section 7.20. Pull the block toward you until it disengages from the chassis but do not remove connectors or lines.
6. With a 7/16” wrench hold the tank insert in place so it does not rotate. This can be done through the opening of the left side of the control module.
7. Remove the screw and terminal with a 3/32” hex key from the tank insert.
8. Remove the remaining screws and terminals in the same fashion.
9. Note: It might be necessary to remove the silicone sealant for the upper tank insert.
10. Install the new harness in the same manner following the color coding as in Figure 7.27.

    Note: If a level sensor insert gets rotated, rotate it back into the position where there is only a very slight compression on the rubber washer. Seal the top level sensor insert with silicone RTV if it is removed or broken.
11. Route the harness back through the cable clip and plug it into the Input/Output Circuit Card (see Section 7.10).



Installation of Level Sensor Terminals
Figure 7.27

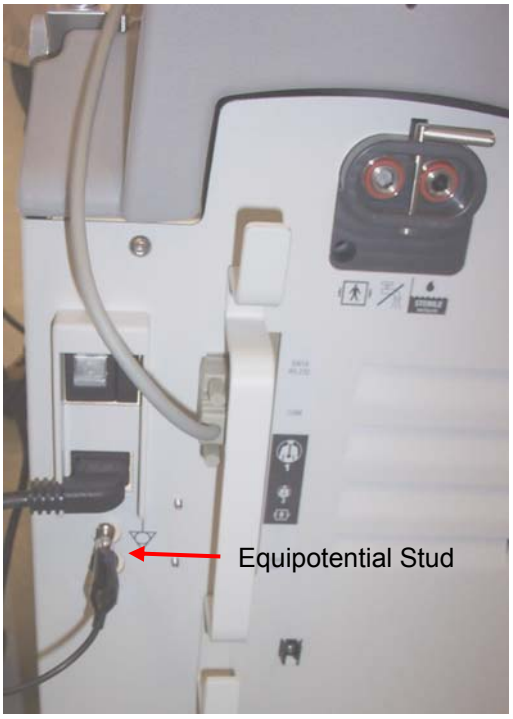


Hold Insert While Tightening Screw
Figure 7.28

7.23 Dielectric Withstand (Hipot) Chassis Test

This test is to be performed in accordance with UL2601-1 / EN60601-1, Section 20.4, which describes the application of voltage rising from no more than half the prescribed level to the peak over the course of ten seconds. The voltage is maintained at that level for one minute and is then decreased over the course of ten seconds to less than half the peak. A tester compliant with this standard should be used.

1. Turn off the tester and the Control Module.
2. Remove the Control Module power cord from Mains power and plug it into the tester outlet.
3. Connect the tester ground lead to the equipotential stud on the Control Module located just below the power inlet.
4. Turn on the Control Module power switch.
5. Turn on the tester.
6. Set the tester voltage to 1500VAC.
7. Stand clear of the Control Module and start the test. Do not touch the Control Module while the test is in progress.
8. Verify that no alarm occurs.



Tester Ground Lead to Equipotential Stud
Figure 7.29

7.24 Dielectric Withstand (Hipot) Patient Applied Part Test

Call Medivance Service for instructions.

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7.25 Inlet / Outlet Manifold Valve Harness

Tools and Supplies Required:

- 5/32" hex key
- 9/16” wrench
- 7/16” wrench

Inlet / Outlet Manifold

Figure 7.30

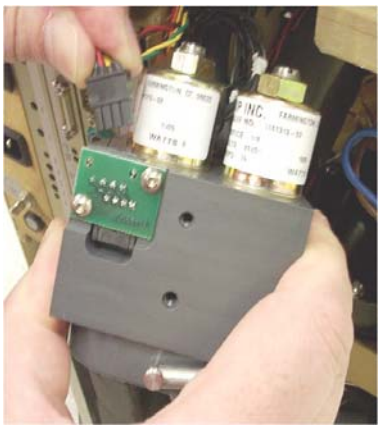
1. Remove the rear panel per Section 7.3.
2. **Note:** Observe the routing of the cable to the Input/Output circuit card. Ensure that wires are not pinched when reassembling.

3. Lift the lever on the Circulating Pump (located below the manifold) then remove the connector from the pump.

Removing Pump Port

Figure 7.31

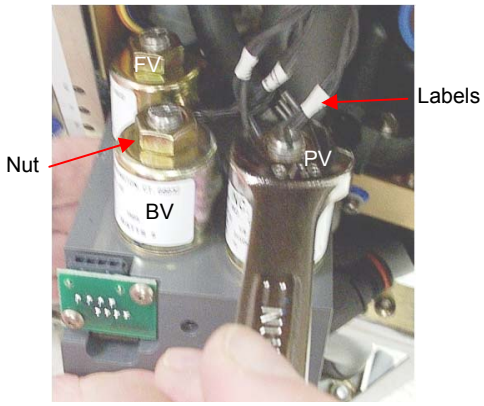
4. Pull the Inlet /Outlet manifold forward then down to slide it off the chassis.
5. Unplug the pressure transducer plug from the green circuit board by first compressing the tab on the underside of the connector. Do not stress the wires.



Removing Plug

Figure 7.32

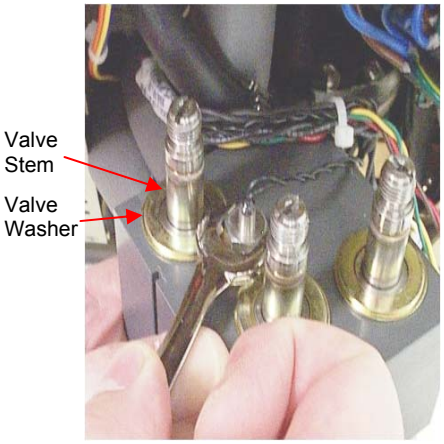
6. Remove the nut from the top of each solenoid coil being careful not to unscrew the valve stem (see Figure 7.34). If necessary, place a blade screwdriver into the slot at the top of the stem to hold it secure while loosening the nuts.
7. Remove the solenoid coils from the stems. Note the location of each and the associated label on the wire. The 3 wires are labeled FV, BV, and PV. The new solenoid coils will have to be returned to their proper location.



Removing Solenoid Nuts

Figure 7.33

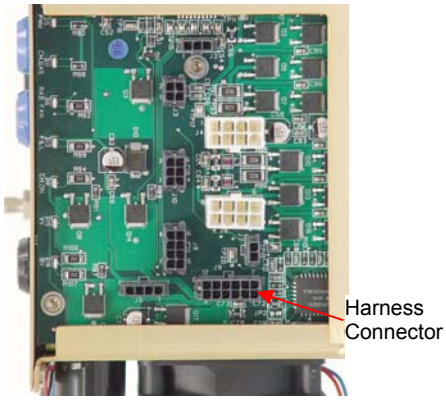
8. With a 7/16" wrench, loosen the temperature probe and remove it from the manifold block.
9. Unplug the manifold harness from the Input/Output Circuit Card by first compressing the tab on the top of the plug. Do not stress the wires. It may be necessary to unplug the three closest connectors to gain access. The tabs on these connectors must be compressed in the same manner to release them.
10. Replace the harness. Install the new temperature probe into the manifold replacing the orange rubber washer. Tighten the probe until finger tight then tighten ½ turn.
11. Check that the valve stems are tight but do not over tighten. Replace valve washers then each solenoid assuring the proper location of each (see Figure 7.33 above). Tighten the nuts onto the valve stems assuring the solenoid covers are properly aligned with the valve washers.



Removing Temperature Probe

Figure 7.34

12. Reconnect the harness to the I/O board with the connector tab oriented down. Assure the connector is fully engaged.
13. Replace the manifold in the frame, assuring the wires do not become pinched or the lines kinked.
14. Reconnect the line onto the circulating pump. Push the lever on the pump down to latch. Reinstall the back panel.
15. Check the calibration according to Section 5.1.5 using a Calibration Test Unit. Recalibrate if required.



I/O Manifold Connector Location

Figure 7.35

APPENDIX A SPECIFICATIONS

Parameter	Specification
Control Modes	Automatic, Manual, Purge, Stop
Heater Capability	750 W
Circulating Fluid	Distilled or Sterile Water
Reservoir Capacity	5 liters
Water flow rate (total)	0.5 - 8.0 liter/min
Patient Probe Type	YSI 400 Series compatible
Number of Patient Probes	2 (1 monitor, controls, alarms + 1 monitor, alarms)
Patient Temperature Display Range Resolution	10°C to 42°C, 50°F to 107.6°F in 0.1°C/°F
Patient Temperature Measurement Accuracy	±0.4ºC (10ºC to 32ºC) ±0.2ºC (32ºC to 38ºC) ±0.4ºC (38ºC to 42ºC) (includes ±0.1ºC external probe)
Patient Temperature Control Range - Automatic Mode	33°C to 37°C, 91.4°F to 98.6°F in 0.1°C/F increments
Water Temperature Display Range	3°C to 45°C, 37.4°F to 113.0°F in 1°C/F increments
Water Temperature Control Range - Manual Mode	4°C to 42°C,39.2°F to 107.6°F in 0.1°C/F increments
Maximum Water Temperature (Automatic Mode)	32°C to 42°C, 89.6°F to 107.6°F in 1°C/F increments
Minimum Water Temperature (Automatic Mode)	4°C to 32°C, 39.2°F to 89.6°F in 1°C/F increments
Mains Input*	115VAC, 60 Hz, 11 A (nominal) 230VAC, 50 Hz, 5.5 A (nominal)
Current Leakage	< 300uA
Circuit Breaker	12 Amp

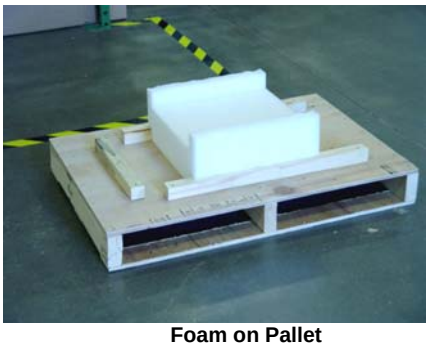
*Mains supply voltage fluctuations are not to exceed ±10% of nominal supply voltage.

Parameter	Specification
Relative humidity range (operating)	5-70%
Relative humidity range (storage)	5-95%
Temperature range (operating)	10°C to 27°C, 50°F to 80°F
Temperature range (storage)	-30°C to 50°C, -20°F to 120°F
Height of unit (handle down)	66.0cm, 26"
Length of unit	48.3cm, 19"
Width of unit	31.8cm, 12.5"
Weight of unit filled	52.7kg, 116 lbs

APPENDIX B SHIPPING

Due to the size and weight of the Model 2000 Control Module, 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. Drain the control module per Section 4.7. Note the additional steps to completely drain the unit in order to prevent damage from freezing.
2. Place the Control Module on the foam support which is mounted to the pallet (Figure B.1).
3. Cover the unit with the plastic bag (Figure B.2).
4. Place the cardboard tube over the top of the unit so the edges are outside the wood strips attached to the pallet.
5. Place the molded foam insert on top on the unit .
6. Place the cardboard cap on top of the tube.
7. Band the cardboard tube and cap securely with at least two bands evenly spaced (Figure B.3 and B.4).



Foam on Pallet
Figure B.1

Bagged Unit on Pallet
Figure B.2

Packaged and Banded to Pallet
Figure B.3

Packaged and Banded to Pallet
Figure B.4