ArcticSun®
TEMPERATURE MANAGEMENT SYSTEM

ARCTIC SUN® 2000

Operator's Manual

Medivance®
Committed to Restoring Life™

contents

preface

This Operator's Manual provides a detailed discussion of the Arctic Sun Temperature Management System from Medivance, Inc., its components, and relevant accessories. The Arctic Sun System provides a safe and effective way of modifying patient temperature, providing precise temperature control in a novel approach. The Arctic Sun Model 2000 is equipped with numerous safety and control features, such as temperature and system alarms and alerts, and programmability. It is important for the operator to become familiar with the operation of the system prior to use. Reading and understanding this Operator's Manual will guide the user in the safe and effective use of the system.

This manual is associated with software version 4.xx. The version of software installed in each Model 2000 is displayed on the Remote Display's custom menu display at power up. Features may differ with other versions.

Medivance hours of operation are 8 am to 5 pm Mountain Standard Time. Emergency support is offered after hours by calling 303-926-1917 or 877-267-2314. 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. Prior to using the Arctic Sun, 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:

Model No.	Arctic Sun Model 2000
Phone:	Toll free 877-267-2314 or 303-926-1917
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section 1

1.1 Introduction

The effect of temperature variations on the human body has been well documented. Elevated temperatures may be harmful to the brain under normal conditions, and even more importantly, during periods of physical stress, such as illness or surgery. Conversely, lower body temperatures, or mild hypothermia, may offer some degree of neuroprotection.[1] Moderate to profound hypothermia (below 32ºC) tends to be more harmful to the body and may lead to death.[2]

Temperature management or thermoregulation can be viewed in two different ways. The first aspect of temperature management includes treating abnormal body temperatures, i.e. cooling the body from elevated temperatures (hyperthermia), or warming the body to manage hypothermia. The second aspect of thermoregulation is an evolving treatment that employs techniques that physically control a patient's temperature to provide a physiological benefit, such as cooling for a degree of neuroprotection[3,4].

Hypothermia may occur for a variety of reasons, including exposure to cold environments, trauma, or long complex surgical procedures. Hyperthermia may occur as a result of systemic inflammatory response, sepsis, stroke, or other brain injury. While the mechanism of the effect of the hyperthermia on the brain is not clearly understood, there is evidence to indicate that even mild increases in temperature may contribute to neurological deficits.[5]

The Medivance Arctic Sun Temperature Management System has been designed to regulate body temperature for those patients who require procedures requiring therapeutic temperature management and/or to assist in controlling temperature for specific medical or surgical conditions.

CAUTION: This product is to be used by or under the supervision of trained, qualified medical personnel.

[1] Schwab S, Schwartz S, Spranger M, et al. Moderate Hypothermia in the Treatment of Patients with Severe Middle Cerebral Artery Infarction. Stroke 1998; 29 (12): 2461-6

[2] Guyton A, Hall J. Textbook of Medical Physiology, Ninth Ed (Philadelphia, PA: W.B. Saunders, 1996): 119

[3] Ginsberg M, Sternau L, et al. Therapeutic Modulation of Brain Temperature: Relevance to Ischemic Brain Injury. Cerebrovascular Brain Metabolism Review 1992; 4 (3): 189- 225

[4] Corbett D,; Thornhill J. Temperature Modulation (Hypothermic and Hyperthermic Conditions) and its Influence on Histological and Behavioral Outcomes Following Cerebral Ischemia. Brain Pathology 2000; 10(1): 145-52.

[5] Sessler DI. Perioperative Heat Balance. Anesthesiology 2000; 92: 578-96

1.2 Symbols and Standards

The Arctic Sun Model 2000 bears the following symbols:

For the safe and effective use of this device, the operator must consult the accompanying documents prior to use.

Identifies European Representative.

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.

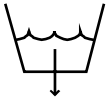
Identifies the equipotential terminal on the equipment, which is intended to be connected with the equipotential terminal(s) on one or more other types of equipment in close proximity, in order to bring all pieces of equipment to the same potential for safety purposes.

Indicates high temperature part or component.

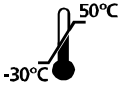
Indicates that only sterile or distilled water should be used when filling the Arctic Sun Control Module.

Identifies Patient Temperature 1, the patient temperature probe input for monitoring and control.

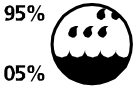
Identifies Patient Temperature 2, the patient temperature probe input for monitoring.



Identifies the drain port.



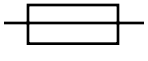
Identifies the storage temperature range.



Identifies the storage relative humidity range.

Indicates electrical hazard

Indicates Earth Ground



Identifies the heater fuse.

The Arctic Sun Control Module meets both the electromagnetic interference and susceptibility requirements of IEC 601-1, and is compatible with other equipment that also conforms to that standard. There is no known failure mode in the Arctic Sun Control Module associated with electromagnetic interference from other devices.

1.3 Environmental Conditions

The Arctic Sun Model 2000 should be stored and used in specific operating conditions: Operating Temperature Range: 10ºC to 27ºC (50ºF to 80ºF)
Storage Temperature Range: -30ºC to 50ºC (-20ºF to 120ºF)

At operating temperatures higher than 27ºC (80ºF), the refrigeration system's cooling capacity and therefore its ability to cool a patient is compromised. If the Control Module is to be exposed to subfreezing temperatures, refer to the Service Manual for special draining procedures.

Ambient Humidity Range:
Operating: 5% to 70% relative humidity, non-condensing
Storage: 5% to 95% relative humidity, non-condensing

1.4 Indications for Use

The Arctic Sun Temperature Management System is intended for monitoring and controlling patient temperature within a range of 32°C to 38.5°C (89.6ºF to 101.3ºF).

The indications for use include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required. This would include, but not limited to, medical, surgical, febrile, accidental hypothermia, or heat stroke patients.

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

1.5 Contraindications for Use

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

Do not place ArcticGel Pads™ on skin that has signs of ulceration, burns, hives, or rash.

While there are no known allergies to hydrogel materials, caution should be exercised with any patient who has a history of skin allergies or sensitivities.

1.6 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. There are no user serviceable parts inside. Do not remove covers. Refer servicing to qualified personnel.
- Power cord has a hospital grade plug. Grounding reliability can only be achieved when connected to an equivalent receptacle marked “hospital use” or “hospital grade”.
- When using the Arctic Sun, note that all other thermal conductive systems, such as water blankets and water gels, in use while warming or cooling with the Arctic Sun may actually alter or interfere with patient temperature control.

1.7 Cautions

- This product is to be used by or under the supervision of trained, qualified medical personnel.
- Federal law (USA) restricts this device to sale, by or on the order of a physician.
- Use only distilled or sterile water. The use of other fluids will damage the Arctic Sun Model 2000.
- The patient's bed surface should be located between 30 and 60 inches (75 cm and 150 cm) above the floor to ensure proper flow and minimize risk of leaks.
- The operator is responsible to determine the appropriateness of custom parameters.
- When the system is powered off, all changes to parameters will revert to the default unless the new settings have been saved as new defaults.
- The operator must continuously monitor patient temperature in Manual Mode. Patient temperature will not be controlled by the Arctic Sun in Manual Mode.
- The Arctic Sun will monitor and control patient core temperature based on the temperature probe attached to the system. Medivance recommends measuring patient temperature from a second site to verify patient temperature.
- It is the sole responsibility of the clinician or operator to monitor patient temperature during Manual Mode and to adjust the temperature of the water flowing through the pads accordingly.
- Due to the system's high efficiency, Manual Mode is not recommended for non-surgical treatments that require cooling.

- Patient temperature will not be controlled and alarms are not enabled in Stop Mode. Patient temperature may increase or decrease with the Arctic Sun in Stop Mode.
- 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 corrected, the alarm will recur. If an alert is cancelled and the alert condition has not been corrected, the alert will not recur unless the Stop Mode is activated.
- Carefully observe the system for air leaks in the system before and during use. If the pads fail to prime or a significant continuous air leak is observed in the pad return line, check connections. If needed, replace the leaking pad. Leakage may result in lower flow rates and potentially decrease the performance of the system.
- The Arctic Sun Model 2000 is for use only with the ArcticGel Pads.
- The ArcticGel Pads are only for use with an Arctic Sun Model 2000.
- The ArcticGel Pads are non-sterile for single patient use. Do not reprocess or sterilize. If used in a sterile environment, pads should be placed according to the physician's request, either prior to the sterile preparation or sterile draping. ArcticGel Pads should not be placed on a sterile field.

- Use pads immediately after opening. Do not store pads once the kit has been opened.
- Do not allow circulating water to contaminate the sterile field when patient lines are disconnected.
- The water content of the hydrogel affects the pad's adhesion to the skin and conductivity, and therefore, the efficiency of controlling patient temperature. Periodically check that pads remain moist and adherent. Replace pads when the hydrogel no longer uniformly adheres to the skin. Replacing pads at least every 5 days is recommended.
- Do not puncture the ArcticGel Pads with sharp objects. Punctures will result in air entering the fluid pathway and may reduce performance.
- If accessible, examine the patient's skin under the ArcticGel Pads often, especially those at higher risk of skin injury.
- Skin injury may occur as a cumulative result of pressure, time and temperature. Do not place bean bag or other firm positioning devices under the ArcticGel Pads. Do not place positioning devices under the pad manifolds or patient lines.
- The rate of temperature change and potentially the final achievable patient temperature is affected

by many factors. Treatment application, monitoring and results are the responsibility of the attending physician. If the patient does not reach target temperature in a reasonable time or the patient is not able to be maintained at the target temperature, the skin may be exposed to low water temperatures for an extended period of time which may increase the risk for skin injury. Ensure that pad sizing / coverage and custom parameter settings are correct for the patient and treatment goals, environmental factors such as excessively hot rooms, heat lamps, and heated nebulizers are eliminated, water flow is greater than or equal to 2.3 liters per minute, a patient temperature probe is in the correct place, and patient shivering is controlled. Otherwise, consider increasing minimum water temperature, modifying target temperature to an attainable setting, or discontinuing treatment.

- Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy. If warranted, use pressure relieving or pressure reducing devices under the patient to protect from of skin injury.
- Do not allow antibacterial agents to pool underneath the ArcticGel Pads. Excess antibacterial agents can absorb into the pad adhesive and cause chemical burns and loss of pad adhesion.

- Do not place ArcticGel Pads over an electrosurgical grounding pad. The combination of heat sources may result in skin burns.
- Carefully remove ArcticGel Pads from the patient's skin at the completion of use.
- Any device connected to the RS232 data port must comply with the applicable IEC standard for that device.
- 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.
- 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. Anyone performing the procedures must be appropriately trained and qualified.

section

2

Figure 1
The Remote Display can be stored in its parking spot on the Control Module when not in use.

Figure 2 (right)
When in use, the display is attached to the upright handle for easy visibility.

2.1 System Description

The Arctic Sun Temperature Management System is a thermoregulatory device that monitors and controls patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F). The Arctic Sun System consists of the Model 2000 and disposable ArcticGel Pads. The Model 2000 consists of the Control Module, Remote Display, Fluid Delivery Line, cables and accessories.

The Model 2000 pulls temperature-controlled water ranging between 4°C and 42°C (39.2°F and 107.6°F) through the ArcticGel Pads at approximately 0.7 liter per minute per pad. This results in heat exchange between the water and the patient. Unlike conventional water based systems, this system operates under negative pressure relative to ambient. Any break or leak in the system 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.

The Arctic Sun Control Module must be used only with the ArcticGel Pads. The pads are thin, and anatomically shaped to cover areas of the patient's skin. They come in non-sterile kits in sizes to cover a broad range of patients, fit both males and females, and are for single patient use only. Each pad has an inlet and an outlet connection that attaches to a Fluid Delivery Line. Up to six pads can be connected at one time. The pads are designed so that water flows within internal pathways across its surface to provide even, efficient heat transfer between the skin and water. The pads adhere to the patient's skin by the use of a biocompatible compatible hydrogel adhesive. The hydrogel maintains its adhesion level over extended periods. The pads can be repositioned on the patient's skin if needed. The back of each pad is insulated to minimize heat transfer to the environment and condensation when cooling.

The Arctic Sun Model 2000 is a CLASS I (Type BF, IPX0 and Mode of Operation - Continuous) portable device per classification scheme of IEC 601-1.

CAUTION: The Arctic Sun Model 2000 is for use only with the ArcticGel Pads.

The Arctic Sun Control Module can be placed in various locations in the intensive care unit or operating room while being controlled from the Remote Display. The Control Module has a four wheel independent locks. Its handle can be raised and locked for transport or placed in the down position for storage. (See figure 1 and 2) Do not lift the Control Module by the handle.

2.2 Model 2000 Components

The Fluid Delivery Lines, Patient Temperature Cables, Temperature Out Cable, Remote Display Cable, and the Power Cord are connected to the rear of the Arctic Sun Control Module (See Figure 3), find lengths of tubes and cables in Table 1.

Table 1

Accessory	Length	
Remote Display Cable	42 inches	1.1 meters
Power Cord	15 feet	4.6 meters
Fluid Delivery Line	10 feet	3.0 meters
Patient Temperature Cable	10 feet	3.0 meters
Temperature Out Cable	5 inches	13 centimeters
Fill/Drain Tube	24"	0.6 meters

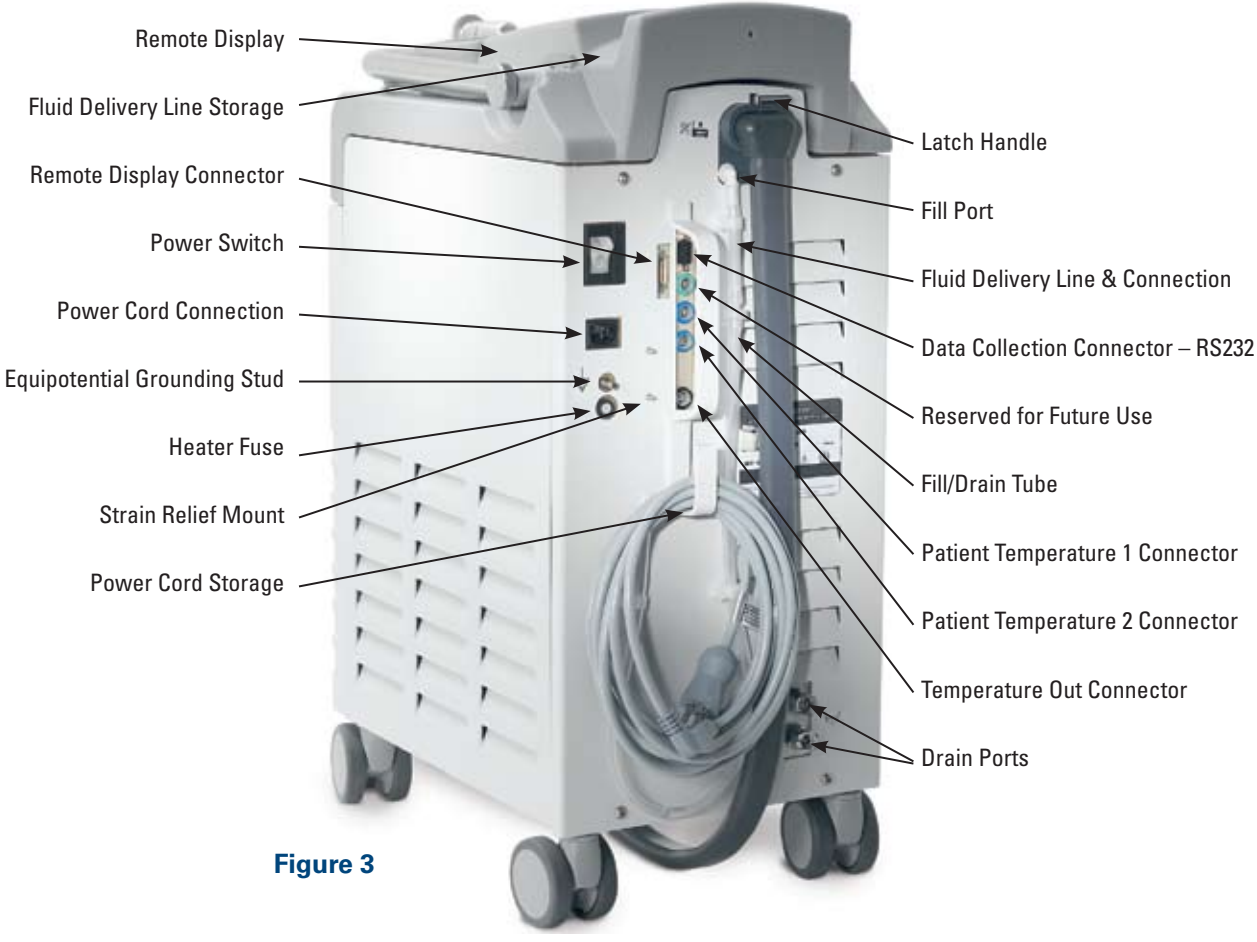

Remote Display
Fluid Delivery Line Storage
Remote Display Connector
Power Switch
Power Cord Connection
Equipotential Grounding Stud
Heater Fuse
Strain Relief Mount
Power Cord Storage
Latch Handle
Fill Port
Fluid Delivery Line & Connection
Data Collection Connector – RS232
Reserved for Future Use
Fill/Drain Tube
Patient Temperature 1 Connector
Patient Temperature 2 Connector
Temperature Out Connector
Drain Ports

Figure 3

2.3 Remote Display and Controls

The Arctic Sun Model 2000 is operated from the Remote Display (Figure 4). The display is clamped to the Control Module handle. The Remote Display is connected to the Control Module by a 42 inch (1.1 meter) Remote Display Cable.

Modes of Operation

There are four principle modes of operation. These can be accessed by pressing any of the four keys on the lower right side of the display: Automatic, Manual, Purge, and Stop. Each key represents a unique function:

Automatic Mode The Automatic Mode only operates when an appropriate patient temperature probe is placed and connected to the Control Module. The Arctic Sun will adjust the temperature of the water flowing through the ArcticGel Pads to achieve a pre-set patient target temperature. The maximum and minimum water temperatures allowed during this mode can also be set by the user. Patient target temperature and water temperature limit settings can only be changed by returning to Stop Mode and accessing the custom menu with the down or up arrows. Note: If a patient temperature probe is not attached to the Patient Temperature 1 Connector, the display will alarm and return to Stop Mode.

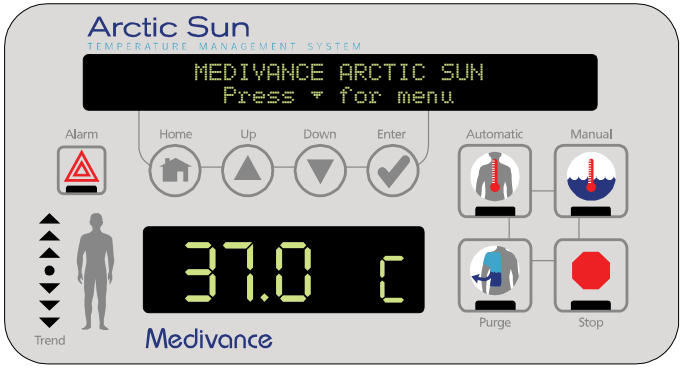


Figure 4

Manual

Manual Mode The Manual Mode operates with or without a patient temperature probe placed and connected to the Control Module. Water temperature is set and managed directly by the operator. Patient temperature is not controlled in Manual Mode. The operator must monitor patient temperature when Manual Mode is active. Water temperature can be modified during the Manual Mode Operation.

Note: Manual Mode may be enabled/disabled in Advanced Settings. An alarm will be generated if the Manual Key is pressed when Manual Mode is disabled. When Manual Mode is disabled, the water target display is not accessible. To disable Manual Mode and make as the default setting, see instructions in Chapter 4.

CAUTION: Manual mode is not recommended for non-surgical treatments that require cooling.

CAUTION: The operator must monitor patient temperature in Manual Mode. Patient temperature will not be automatically controlled in Manual Mode.

Purge

Purge Mode The Purge Mode removes water from the ArcticGel Pads prior to disconnection. Water flows from the pads back to the reservoir, which minimizes leaks and reduces the amount of water remaining in the pads. Purge will automatically stop after 30 seconds.

Note: Pads should be purged prior to a Fill Cycle. Failure to purge pads before filling may be result in overfilling the Control Module.

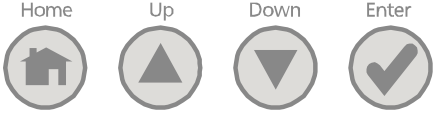
Stop Mode The Stop Mode halts all other modes of operation. During power up and alarm states, the system defaults to Stop Mode. The Stop Mode offers a secondary function, serving as the access point for the custom menu settings.

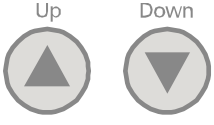
CAUTION: Patient temperature will not be controlled in the Stop Mode. Patient temperature may increase or decrease with the Arctic Sun in Stop Mode. Alarms are not enabled in the Stop Mode.

Custom Menu Display and Keys The Remote Display offers a variety of custom menu options that are displayed on the custom menu display. Alarms, alerts and system status are also displayed.

The custom menu display can be modified by using the menu control keys.

Figure 5





Down and Up Arrow Keys In Stop Mode, allows the operator to review custom menu options screens. The arrows are also used for adjusting custom option parameters. During Manual Mode, these arrows provide access to modify the Water Target Temperature.

Enter

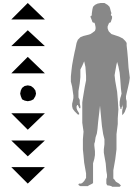
Enter Key Press the Enter key when accepting modifications or changes to a custom parameter.

Home

Home Key Press the Home key to return to the current operating mode's main screen when in any custom display screen. Pressing this key does not accept modifications or changes to custom parameter. The display will automatically return to the current operating mode's main screen if there are no keys pressed within 60 seconds.

Alarm

Alarm Key The Alarm Key is illuminated when situations arise that may pose a safety issue for the patient or if the system detects it may not be performing properly. Press the Alarm key to acknowledge and silence an alarm or alert



Trend

Patient Temperature Trend Indicator The Patient Temperature Trend Indicator reflects the rate of change in the patient's temperature over the previous five minutes. Yellow arrows will flash at different times with differing rates of change. Up arrows indicate patient temperature is increasing. Down arrows indicate patient temperature is decreasing.

Center circle no change or less than 0.25°C (0.45°F) change per hour

One arrow (up or down) - 0.25°C to 0.5°C (0.45°F to 0.96°F) change per hour

Two arrows (up or down) - 0.5°C to 0.75°C (0.96°F to 1.35°F) change per hour

Three arrows (up or down) - 0.75°C to 2.0°C (1.35°F to 3.6°F) change per hour

Three arrows flashing simultaneously - > 2.0°C (> 3.6°F) change per hour

Patient Temperature Display The Patient Temperature Display indicates patient temperature from a probe installed in the Patient Temperature 1 Connector. The temperature can be displayed in either degrees Centigrade (C) or degrees Fahrenheit (F). The display type can be modified in the custom parameter menu found under the Stop Key under Advanced Settings. The temperature range that can be displayed is between 10° C and 44°C (50°F to 111.2°F).

2.4 Fluid Delivery Line

Water flows between the ArcticGel Pads and Control Module via a Fluid Delivery Line. The line is attached to the back of the Control Module. The Fluid Delivery Lines are reusable but may be replaced if necessary. Swing the latch handle to the left, insert the Fluid Delivery Line connector then lock it into place by swinging the handle to the right (Figure 6).

Figure 6

2.5 Patient Temperature Cables and Probes

To operate the Arctic Sun Model 2000 in Automatic Mode, an indwelling temperature probe must be inserted into the patient and connected to a Patient Temperature Cable. The cable is connected to the back of the Control Module at the Patient Temperature 1 Connector (see Figure 3).

Similarly, a second patient temperature probe may be connected to a second Patient Temperature Cable and the cable connected to the back of the Control Module Patient in the Patient

Temperature 2 (see Figure 3). Patient Temperature 2 is used to provide redundant monitoring from a second patient site for increased patient safety when patient temperature is not continuously monitored by a second device.

Note: Patient temperature is not controlled from the Patient Temperature 2 Connector. It is for patient temperature monitoring only.

Yellow Springs Instrument 400 Series (YSI 400) compatible patient temperature probes can be connected to the Arctic Sun Model 2000. These include nasopharyngeal, esophageal, tympanic, rectal, or bladder probes. Refer to the manufacturer's Instructions for Use for the specific indications and placement of these temperature probes. If there is any question regarding the use of a specific temperature probe, contact Medivance customer service for additional information.

2.6 Temperature Out

The Arctic Sun Control Module will output the current Patient Temperature 1 reading to a YSI 400 compatible hospital monitor. A Temperature Out Cable is used to connect between the Temperature Out connector (see Figure 3) and the monitor cable. The temperatures displayed on the Arctic Sun Remote Display and monitor represents the same probe reading but may not be identical due to calibration differences between the Control Module and the monitor. If the difference is greater than 0.3°C (0.6°F) have qualified personnel check the calibration of both devices.

2.7 ArcticGel Pads

The ArcticGel Pads are intended for single patient use. They are non-sterile, thin, conformable foam pads lined with a hydrogel layer that adheres to the patient's skin. The biocompatible hydrogel material consists of approximately 50% water and therefore is a good thermal conductor. Water from the Arctic Sun Control Module is pulled through the pads under negative pressure to minimize the chance of water leakage in case of accidental pad puncture. The ArcticGel Pads are available in a variety of shapes and sizes to accommodate patients in intensive care or surgical settings. ArcticGel Pads contain no latex.

Place the pads on healthy clean skin only. Remove any creams or lotions from patient's skin before pad application. Remove the release liner from each pad and apply to the appropriate area. The pads may be overlapped or folded adhesive to adhesive. The pads may be removed and reapplied as necessary. The pad surface must be contacting the skin for optimal energy transfer efficiency. Read the instructions-for-use accompanying the pads.

CAUTION: ArcticGel Pads are non-sterile. If used in a sterile environment, pads should be placed according to the physician's request, either prior to the sterile preparation or sterile draping. ArcticGel Pads should not be placed on a sterile field.

CAUTION: The ArcticGel Pads are only for use with an Arctic Sun Control Module.

section

3

3.1 Initial Setup

A Medivance representative or a hospital designated Clinical Engineer will install and check the Arctic Sun upon installation in the hospital. See Installation Procedure in Appendix A. Press the power switch to the ON Position. The system will go through a brief self-check. When finished, the display will read "Medivance Arctic Sun Press ▼ for menu".

Confirmation of Independent Safety Alarm

When the power is switched on, a power up test for the independent safety alarm is automatically run. The audio alarm will sound and the alarm indicator will illuminate during setup. The operator must verify that both are operational before operating the system. For additional information on alarms see Appendices B and C.

WARNING: Do not use the Arctic Sun in the presence of flammable agents because an explosion and/or fire may result.

WARNING: 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".

3.2 Filling the Control Module

The water level in the Control Module is displayed at a variety of times: when it is powered on; after completion of a fill; after the pads are emptied or purged and when accessing the Fill screen from the custom menu. The levels displayed indicate the following:

Table 2

Water Level Displayed	Water Required to Fill
Full	Do not add water
3/4 Full	Add approximately 1/2 liter
1/2 Full	Add approximately 3/4 liter
Water Level Low	Add approximately 1 liter
Water Level Empty	Add approximately 1.5 liters
Initial Installation & Refill After Draining	Add approximately 4 liters

The Arctic Sun can be operated at any level except when reading Water Level Empty.

CAUTION: Use only distilled or sterile water. The use of other fluids will damage the system.

When filling the Arctic Sun Control Module during the initial installation or when completely empty, obtain 4 liters of sterile or distilled water. Add one vial of Arctic Sun Cleaning Solution to the water. The solution is contained in the Arctic Sun Maintenance Kit. Fill with the mixture according to the following steps. Otherwise, fill with sterile or distilled water.

Fill Procedure:

1. From Stop Mode, press the down arrow until the fill screen appears: "Water Level Empty. Enter to Fill". Press Enter to proceed.
2. Follow the directions on the display screen which read: "Place the Fill Tube in the container of water. Press Enter to fill".
3. Press Enter again and the Arctic Sun will automatically fill until the reservoir is full.
4. Raise the Fill Tube out of the water. Press Enter to clear the tube.

5. Remove the Fill Tube from the container. Keep the fill tube connected to the device.

6. Press Home to return to Main Menu.

The filling cycle can be terminated at any point during the filling process by pressing the Enter Key. If the filling cycle is stopped prior to completion, the reservoir will have a volume less than full and may require filling after fewer procedures are performed. The number of procedures that can be conducted prior to filling depends on the number of pads used and the amount of water remaining in the pads after a Purge cycle is completed.

To avoid overfilling, do not fill the Arctic Sun Control Module unless pads have been emptied by pressing the Purge key. Overfilling will result in inefficient Purge cycle and may result in poor cooling and warming performance.

In the event of a power failure or shutdown of the system, the reservoir may read EMPTY if the pads are filled with water. Press Purge to refill the reservoir and then resume treatment.

3.3 Location of the Patient

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

CAUTION: The patient's bed surface should be located between 30 and 60 inches (75 cm and 150 cm) above the floor to ensure proper flow and minimize risk of leaks.

3.4 Draining the Control Module

For the purpose of routine maintenance or shipping the Control Module, use the Arctic Sun Drain Bag or Fill/Drain Line.

Turn off the power to the Control Module and unplug the power cord. Draining with the unit on may result in damage.

Attach the specialized fittings on the bag or line to the two connectors on the Control Module (see Figure 3). The device will passively drain all tubing, reservoirs & pumps within the system.

If the Control Module is to be shipped or exposed to freezing temperatures, refer to the Service Manual for instructions on special draining procedures.

Collect and dispose of all waste in accordance with all local, state and federal laws.

3.5 Cleaning and Maintenance

Routine maintenance should be performed on the Arctic Sun Model 2000 every three months. The maintenance consists of cleaning, replacing the Cleaning Solution and cleaning the condenser. The Arctic Sun Maintenance Kit includes necessary items to perform general maintenance. The Cleaning Solution is used for suppression of microorganism growth.

Cleaning of External Surfaces

Cleaning should include the exterior of the control module and the power cords. 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.

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

Cleaning the Fluid Delivery Lines and Temperature Cables

Fluid Delivery Lines and Temperature Cables should be cleansed with a hospital approved disinfectant.

Replenishing the Cleaning Solution

CAUTION: The cleaning solution must be handled with care. Read instructions, supplied with the Maintenance Kit, before use.

1. Turn off the main power switch on the control module. Draining with the power on can cause damage.
2. Drain the water from the control module using the Arctic Sun Drain Bag or Fill/Drain Line. Connect the fittings to the two connectors on the back of the module and drain all fluid.
3. Turn the main power switch back on.
4. Add one vial of cleaning solution to 4 liters of distilled or sterile water.
5. Refill the Control Module.

Each ArcticGel Pad contain a small amount of cleaning solution in order to maintain the concentration between replenishments. An MSDS sheet for the cleaning solution is available by contacting Medivance Customer Service.

CAUTION: Users should not use cleaning methods different from those recommended by the manufacturer.

Cleaning the Condenser

A dirty condenser will significantly reduce the cooling capacity of the control module.

1. The refrigeration system's condenser is located under the front grill. The grill is held in place by four spring loaded catches. Remove the grill by pulling gently on the bottom of the grill until the bottom just pulls free. Pulling straight out on each side, release the top of the grill.
2. Clean any dust or debris from the condenser fins using a vacuum cleaner with brush attachment or brush.
3. Replace the grill and snap into place by applying force at each corner.

3.6 Service and Calibration

The Arctic Sun Model 2000 should be inspected periodically for any problems such as bent or broken switches, frayed or extremely twisted power cords, and loose or missing hardware. Discontinue using any equipment displaying one or more of the above conditions until the problem is corrected and it has been verified that the device is operating correctly.

If the heater fuse must be replaced, refer to the Service Manual for instructions.

Medivance will provide on request a Service Manual that contains all necessary circuit diagrams, component parts lists, and service information to enable appropriately qualified technical personnel to repair those parts of this equipment which Medivance considers to be repairable.

Should additional technical support be required, contact Medivance toll free at 877-267-2314 or 303-926-1917.

When the Arctic Sun Control Module is powered on, the last start up screen will display the message "SYSTEM CALIBRATION DUE IN XXX HOURS or YYY USES". When this message changes to "SYSTEM CALIBRATION DUE", the Arctic Sun Control Module must be calibrated. See the Service Manual for a description of the calibration procedure.

CAUTION: 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. Anyone performing the procedures must be appropriately trained and qualified.

WARNING: There is a risk of electrical shock and hazardous moving parts. There are no user serviceable parts inside. Do not remove covers. Refer servicing to qualified personnel.

3.7 Warranty

Medivance offers a one year warranty on parts and labor provided the system has been used according to its intended use. Medivance accepts responsibility for the safety, reliability, and performance of this equipment only if: 1) operational procedures and repairs are performed by appropriately qualified persons; 2) if all equipment modifications are authorized in writing by Medivance and performed by appropriately qualified persons; 3) if the electrical installation of the relevant room complies with all applicable local electrical codes; and 4) if the equipment is used in accordance with the published instructions for use.

section

4

4.1 Beginning a Procedure

The Arctic Sun System offers an easy efficient way of managing patient temperature. The sophisticated control algorithm works to modify patient temperature precisely and accurately. It is essential that the clinician review the patient's medical history, inspect the skin integrity, and determine the adequacy of tissue perfusion prior to treating with the Arctic Sun System. The clinician can then adjust the specific parameters prior to cooling or warming the patient.

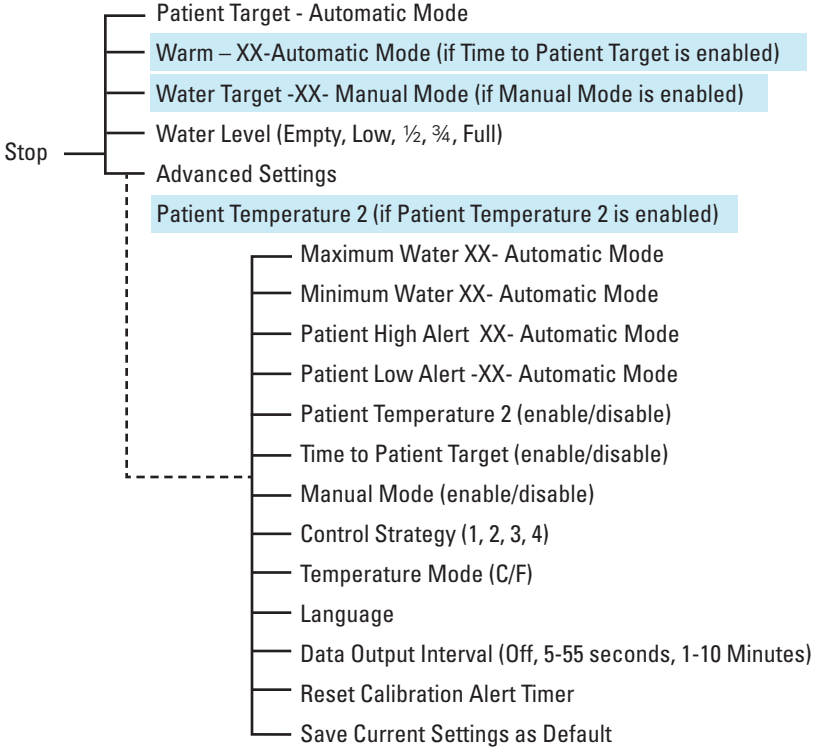
Locate the power switch on the rear of the Control Module. Press the switch to the ON position. A brief self-check will take approximately 15 seconds. The display screen will read "Medivance Arctic Sun Press ▼ for menu". This screen represents the Main Menu. Prior to using the Arctic Sun System, it is important to verify that all parameters are appropriately set for the particular patient or procedure.

4.2 Setting Custom Parameters

In Stop Mode, press the Down or Up arrow keys to access the custom menu display to verify or modify default parameters. To modify a setting, scroll to the appropriate parameter shown on the custom menu display. Press the Enter key. The parameter will flash indicating that the setting can be changed. Using the Down or Up arrows, change the parameter. Press Enter to accept the new setting.

Figure 7 illustrates the custom menu screen layout in Stop Mode.

Figure 7



The Arctic Sun is shipped with default settings (see Table 3 and 4), which may be modified as needed. Settings can be changed for individual patients or procedures, or permanently changed to create new default settings.

CAUTION: When the system is powered off, all changes to parameters will revert to the default unless the new settings have been saved as new defaults.

Table 3 lists the parameters, the default settings, the available ranges of settings, and resolution of the settings in Stop Mode. When pressing the Down arrow, the parameters that are displayed are shown in order of their appearance.

Table 3

Parameter - Default	Explanation	Range	Resolution
Patient Target XX°C (°F) -Automatic Mode (Default - 37°C /98.6°F)	Automatic Mode. Set desired target patient temperature. For patient target temperature 32.0°C - 32.9°C (89.6°F - 91.2°F), control strategy 3 must be chosen in Advanced Settings	32°C - 38.5°C (89.6°F - 101.3°F)	0.1°C (0.1°F) increments
Warm (Default - Max)	Automatic Mode. Set the rate of patient warming. Time to Target must be enabled (see Table 4) to modify this parameter. Otherwise, the maximum warming rate will be used.	0.05°C/hr - 0.5°C/hr (0.1° to 0.9°F/hour), Max	0.05°C/hr (0.1°F/hr)
Water Target XX°C (°F) -Manual Mode (Default - 37°C /98.6°F)	Manual Mode. Set desired water temperature.	4°C - 42°C (39.2°F- 107.6°F)	1.0°C (1.0°F) increments
Water Level	Shows the level of the water in the reservoir at any given time. This reading is updated during purge, fill cycle & power on.	Empty to Full	Empty, Low, 1/2, 3/4, Full
Advanced Settings	Provides a second tier of user defined options that pertain to equipment settings that may require less frequent changes.	See Table 4	

Certain parameters may not require frequent modification. As a result, these parameters are offset into a second tier of user-defined options known as Advanced Settings. This allows the operator to rapidly scroll through settings that may be used more frequently.

Some of the special features located in the Advanced Settings Screen include user-defined patient temperature alerts which are described in Table 4.

CAUTION: The operator is responsible to determine the appropriateness of custom parameters for each patient.

Table 4

Parameter - Default	Explanation	Range	Incremental Changes
Maximum Water XX°C (°F) -Automatic Mode (Default - 42°C /107.6°F)	Automatic Mode. Set the maximum water temperature the system will use to control patient temperature	36°C - 42°C (96.8°F to 107.6°F)	1.0°C (1.0°F) increments
Minimum Water XX°C (°F) Automatic Mode (Default - 4°C /39.2°F)	Automatic Mode. Set the minimum water temperature the system will use to control patient temperature	4°C - 25°C (39.2°F - 77.0°F)	1.0°C (1.0°F) increments
Patient High Alert XX°C (°F) -Automatic Mode (Default 42°C/107.6°F)	Define the temperature limit at which the system should issue an alert if the patient temperature exceeds that limit.	10.1°C - 44.0°C (50.1°F to 111.2°F)	0.1°C (0.1°F)
Patient Low Alert XX°C (°F) -Automatic Mode (Default 10°C/50°F)	Define the temperature limit at which the system should issue an alert if the patient temperature falls below that limit.	10.0°C - 41.9°C (50°F to 107.5°F)	0.1°C (0.1°F)
Patient Temperature 2 (Default - Disabled)	Allows user to enable the system for a second patient temperature probe if a probe is connected to the control module from a secondary site on the patient. The second site is for monitoring not controlling patient temperature.	Enabled/Disabled	
Time to Patient Target (Default - Disabled)	Enabling the Time to Patient Target feature allows the user to set the patient Warm rate. When the Time to Patient Target is disabled, the patient Warm rate defaults to Max.	Enabled/Disabled	
Manual Mode (Default - Enabled)	Allows the user to disable Manual Mode.	Enabled/Disabled	

Table 4 (continued)

Parameter - Default	Explanation	Range	Incremental Changes
Control Strategy (Default: 1)	Algorithms for use with specific patient populations and/or treatment goals: Strategy 1 - Awake patients Strategy 2 - Patients receiving anesthesia or neuromuscular blockades Strategy 3 - Patients receiving anesthesia or neuromuscular blockades, and patient target temperature 32.0°C to 32.9 °C (89.6 °F to 91.2 °F) Strategy 4 - Reserved for future use	1, 2, 3, 4	
Temperature Mode (Default - °C)	Select temperature units of measure. Note: All custom settings should be verified if changing between °C and °F.	°C (Centigrade) °F (Fahrenheit)	
Language (Default - English)	Select optional languages for all text appearing on the custom menu display.	Various	
Data Output Interval (Default - 1 minute)	Sends real time system information through the RS232 port for data collection. Data outlet intervals can be selected.	Off Between 5 and 60 seconds: 5 second increments Between 1 and 10 minutes: 1 minute increments	
Reset Calibration Alert Timer	Alert will notify user at defined intervals to contact Medivance or authorized biomedical engineer to verify system calibration and operation. System timer can be reset here. Reset calibration alert timer.	Do not reset until calibration is completed.	
Save Current Settings as Defaults	Press Enter to save all current settings as defaults except Time to Target.	Press Return to Main Menu key to return to the main screen.	

4.3 Collecting Data

The Arctic Sun Model 2000 has an RS232 Data output connector (see Figure 3). Data can be downloaded real time to a computer or PDA as the events occur. Data cannot be retrieved after an event has occurred. Refer to Appendix G for details on the data communication protocol.

CAUTION: Any device connected to the RS232 data port must comply with the applicable IEC electrical safety standards for that device.

4.4 Pre-warming or Pre-cooling the Model 2000

Manual

Prior to initiating a treatment, the Model 2000 can be setup and ready for use before connecting the ArcticGel Pads. After all parameters have been set, press the Manual Key to pre-cool or pre-warm the water in the reservoir. If the pre-warming or pre-cooling temperature is different from the Water Target - Manual Mode set parameters, press the down arrow to reach the Water Target screen. Follow the directions on the screen to set the water temperature to the desired setting. Press the Home key to return to the Manual Mode screen.

Water will begin flowing to prime the internal circuit. The screen will display current water temperature, water target temperature, and flow rate. During pre-warming or pre-cooling, also known as Bypass Mode, flow rate will be displayed as "Flow Bypass". Once pads are attached, flow rate will be established and shown in the lower right hand corner of the display screen. The flow rate will be displayed in L/min (liters per minute).

The time to raise the temperature of water at room temperature 20°C (68°F) in the Control Module reservoir to 37°C (98.6°F) is less than 7 minutes. The time to lower the temperature of the water at room temperature 20°C (68°F) in the reservoir to 4°C (39.2°F) is less than 15 minutes.

WARNING: When using the Arctic Sun System, note that all other thermal conductive systems, such as water blankets and water gels, in use may alter or interfere with patient temperature control.

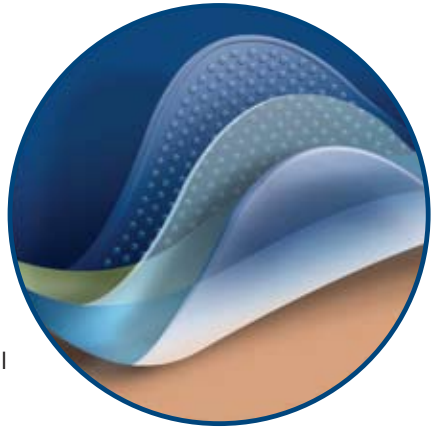


Figure 8

4.5 Placing the ArcticGel Pads

The Arctic Sun System can be used in the operating room, intensive care unit, or emergency room. The patient procedure, application, or available body surface area will dictate the style, size and number of pads that will be applied to the patient. The ArcticGel Pads consist of several layers (see Figure 8):

- An inner biocompatible hydrogel layer that adheres to the patient
- A thin film which serves as a fluid barrier
- An outer foam layer with water channels which prevents heat transfer to the environment

The ArcticGel Pads have inlet and an outlet lines known as pad lines. These lines are connected to the pads by means of a pad manifold.

Review the sizing chart on each kit or on the charts as shown in Figure 9. Select the proper size for the specific patient. The system operates properly with four pads, which come packaged in one kit. There are two L-shaped pads that wrap around the back and abdomen, and two that wrap around the thighs. One or two Universal Pads can be placed on exposed areas in larger patients weighing more than 100 kg (220 lb) as shown in step 6 of Figure 10.

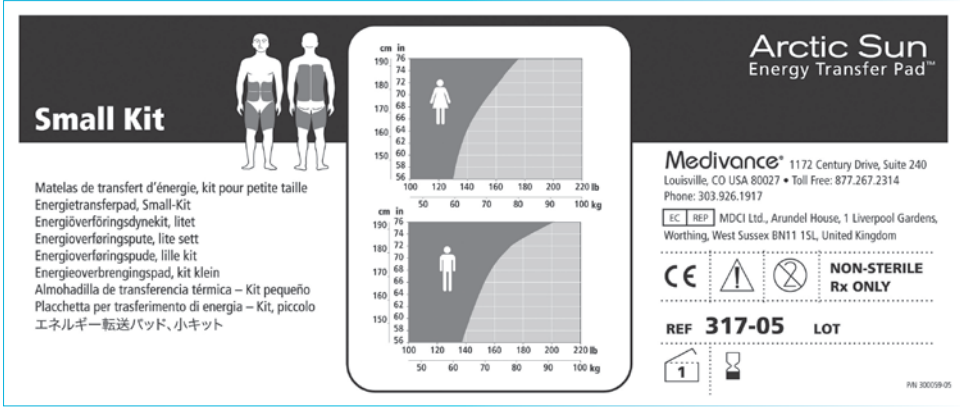


Figure 9

Examine each pad for damage prior to placement. Pads are typically stored at room temperature and may feel cool when applied to the patient. Depending on the objective of the treatment and the patient's level of arousal, the pads can be pre-warmed or pre-cooled prior to placement. The Arctic Sun will provide the best performance when the maximum number and correct size are used.

If pre-warming or pre-cooling is required, connect the pads to the fluid delivery line prior to placing the pads on the patient. Press Manual Mode to initiate the flow of water through the pads. Press the down arrow to adjust the water temperature. Follow the directions on the screen to either increase or decrease the temperature of the water. The ArcticGel Pads can be applied while water is flowing through the pads.

Place the pads as shown in Steps 1- 6 in Figure 10 below:

Figure 10

Place pads on one side and then turn patient and repeat on the other side

STEP 1:

Align top of pad with axilla of outstretched arm. Place the long side of the pad along the side of the spine.

STEP 2:

Wrap the pad from back to front, ensuring that the lines are lying anteriorly.

STEP 3:

Align the pad lines with the knee and point downward. Wrap the long end of the pad laterally and overlap medially if needed.

STEP 4:
Turn the patient and repeat on the other side, leaving a space along the spine.

STEP 5:
Wrap the second pad around the other leg, ensuring that the shorter edge is placed medially and the longer side is wrapped laterally.

STEP 6 (if needed):
For additional surface coverage, use the Universal Pad on the abdomen.

CAUTION: Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy.

CAUTION: If accessible, examine the patient's skin under the ArcticGel Pads often, especially those at higher risk of skin injury.

CAUTION: If warranted, use pressure relieving or pressure reducing devices under the patient to protect from of skin injury.

CAUTION: Skin injury may occur as a cumulative result of pressure, time and temperature. Do not place bean bag or other firm positioning devices under the ArcticGel Pads. Do not place positioning devices under the pad manifolds or patient lines.

CAUTION: Do not allow antibacterial agents to pool underneath the ArcticGel Pads. Excess antibacterial agents can absorb into the pad adhesive and cause chemical burns and loss of adhesion.

CAUTION: Do not place the ArcticGel Pads over an electrosurgical grounding pad. The combination of heat sources may result in skin burns.

CAUTION: Do not puncture the ArcticGel Pads with sharp objects. Punctures will result in air entering the fluid pathway and may reduce performance.

Figure 11

Figure 12

4.6 Connecting the Pads to the Fluid Delivery Line

The Y-shaped Fluid Delivery Line contains the one way valves that connect to the pad line connectors. Each side of the Fluid Delivery Line can be placed by the feet or along the lower legs (Figure 11).

There are three connectors on each side of the Y-line for a total of six connectors. These will accommodate a full set of four pads plus a maximum of two optional Universal Pads for use in larger patients.

The pad line connector and Fluid Delivery Line manifold (see Figure 12) are each color coded.

- To connect, orient the blue and white colors. Then while holding the pad line tubing, insert the clear pad line connector into the into the Fluid Delivery Line manifold. Do not press or squeeze the wings when connecting. The connector will click into place.
- To disconnect, squeeze the two wings on the connector together. Initially, PUSH the connector in toward the manifold to release the catches on both sides and then PULL APART.

If the connectors are not aligned properly, the connectors will not fit or click into place. If there is any difficulty making the connection, verify that the connectors are aligned matching blue to blue and white to white.

CAUTION: Carefully observe the system for air leaks in the system before and during use. If the pads fail to prime or if large air bubbles are observed in the pad line connector, indicating the presence of a significant continuous air leak, check connections, flow may be affected. If needed, replace the damaged pad. Leakage may result in lower flow rates and potentially decrease the performance of the system.

4.7 Pad Weights

The volume of water circulating in the pads at any given time may be greater than 1.0 liter. This could represent a significant weight gain for the patient and should be corrected accordingly. The following weight chart provides approximate dry and wet weights. Due to pad variability, it is important to recognize that the estimates are accurate to only ± .7 kg (1.5 lb). The weights listed do not include the Fluid Delivery Lines.

Table 5

	317-05 (Small)	317-07 (Medium)	317-09 (Large)	317-00 (Universal)
Empty	3.1 lbs 1.41 kg	3.2 lbs 1.46 kg	3.6 lbs 1.6 kg	0.5 lbs 0.24 kg
With water	4.6 lbs 2.07 kg	4.7 lbs 2.15 kg	5.3 lbs 2.39 kg	0.8 lbs 0.35 kg

It is not recommended to purge the pads prior to weighing the patient. Pressing the Stop key interrupts the temperature control process and may add delays to cooling and/or warming.

4.8 Treating a Patient Using Automatic Mode

Prior to beginning cooling or warming in Automatic Mode, adjust the following parameters as required:

- Patient Target XX°C (°F) - Automatic Mode: Determines the temperature set point for the patient. Temperature range is 32°C to 38.5°C (89.6°F to 101.3°F).

Note: For patient target temperatures between 32°C to 32.9°C (89.6°F to 91.2°F), Control Strategy 3 must be activated in Advanced Settings, and an esophageal temperature probe must be used. During the hypothermia induction phase, the esophageal temperature tracks real-time core temperature changes more closely than bladder or rectal temperatures. Due to this lag time when using bladder or rectal temperature sites, actual patient core temperatures may be lower than measured. Therefore, the use of esophageal temperature is recommended for patient temperature control below 33°C.

- Maximum Water XX°C (°F) -Automatic Mode: Limits the highest temperature of the water that will flow through the pads. Maximum water temperature is 42°C (107.6°F). This can be decreased for patients with fragile skin or other medical conditions.
- Minimum Water XX°C (°F) -Automatic Mode: Limits the lowest temperature of the water that will flow through the pads. The minimum water temperature is 4°C (39.2°F). This can be increased for patients with fragile skin or other medical conditions.

CAUTION: Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy.

CAUTION: The rate of temperature change and potentially the final achievable patient temperature is affected by many factors. Treatment application, monitoring and results are the responsibility of the attending physician. If the patient does not reach target temperature in a reasonable time or the patient is not able to be maintained at the target temperature, the skin may be exposed to low water temperatures for an extended period of time which may increase the risk for skin injury. Ensure that pad sizing / coverage and custom parameter settings are correct for the patient and treatment goals, environmental factors such as excessively hot rooms, heat lamps, and heated nebulizers are eliminated, water flow is greater than or equal to 2.3 liters per minute, a patient temperature probe is in the correct place, and patient shivering is controlled. Otherwise, consider increasing minimum water temperature, modifying target temperature to an attainable setting, or discontinuing treatment.

- Warm - Sets the rate of patient warming if enabled. This parameter is operable in Automatic Mode only. The default setting is Maximum (will work to warm the patient as fast as possible within the defined maximum water temperature setting). The setting range is from 0.05ºC/hr to 0.5ºC/hr (0.1° to .9°F/hr).

Note: The Time to Patient Target must be enabled in the Advanced Settings screen in order to adjust the patient warming rate. If the Time to Patient Target is disabled, the default setting for the Warm rates is set to Maximum.

- Patient Temperature High or Low Alerts - permits the operator to set the patient temperature limits at which alerts will occur.

Automatic

To begin a treatment in Automatic Mode, the following steps should be completed:

1. The ArcticGel Pads designed for the particular procedure should be placed on the patient.
2. All patient temperature setting and equipment parameters should be adjusted for the patient and procedure.
3. A YSI 400 compatible temperature probe must be inserted into the patient and connected to the Patient Temperature connector on the back of the Control Module, via the Patient Temperature Cable.

Note: For patient target temperatures between 32ºC to 32.9ºC (89.6ºF to 91.2ºF) an esophageal temperature probe must be used. During the hypothermia induction phase, the esophageal temperature tracks real-time core temperature changes more closely than bladder or rectal temperature Due to this lag time when using bladder or rectal temperature sites, actual patient core temperatures may be lower than measured. Therefore, the use of esophageal temperature is recommended for patient temperature control below 33ºC.

4. Press the Automatic Key to start the process.

If a patient temperature probe is not properly placed in the patient and connected to the Patient Temperature 1 probe input port, the system will issue an alarm and return to Stop Mode.

The Arctic Sun Control Module incorporates a control algorithm that responds to patient temperature and patient temperature trends. The temperature of the water flowing through the pads is automatically adjusted to transfer enough energy to reach a pre-determined patient target temperature. When cooling, water temperature will decrease to the minimum water temperature set for the patient or procedure. Water temperature may actually rise before reaching the target to avoid overshooting patient target temperature. Conversely, when warming, water temperature will increase to the maximum water temperature set for the patient or procedure. Water temperature may decrease before reaching its target to avoid overshooting patient target temperature.

While the operator should monitor water temperatures, an alarm is incorporated into the Model 2000 to alert the operator if water temperatures have remained lower than 10°C (50°F) for eight hours. The system will continue to alert the operator every four hours until the water temperature rises. If the condition is not corrected, eventually an alarm will occur and the system will switch to stop mode. If this occurs, the status of the patient's cooling therapy should be reviewed to determine whether the patient requires additional sedation, additional pad coverage, or correction of the environmental factors. The clinical staff should determine whether the minimum water temperature should be increased to a higher level to avoid prolonged cold exposure to the skin or whether the therapy should be terminated.

Heat transfer efficiency depends on the number of pads used or surface coverage, the rate of heat lost or generated, the time available to reach the target, and the temperature of the water used during the procedure. Effective patient temperature control with the Arctic Sun System requires approximately 40% of the patient's body surface area be covered with pads. It is important to apply pads sufficient to provide this coverage.

CAUTION: The Arctic Sun System will control and monitor core temperature based on the temperature probe attached to the Control Module's Patient Temperature 1 connector. Medivance recommends measuring patient temperature from a second site to verify core temperature while controlling and monitoring patient temperature.

A second patient temperature probe may be connected to the Patient Temperature 2 Connector on the rear of the Control Module and utilized to monitor patient temperature from an alternate site. Patient Temperature 2 will first have to be enabled in the custom menu display. The system does not control patient temperature from Patient Temperature 2 Connector. The operator can display the secondary patient temperature probe reading by pushing the Up arrow from the main screen when in Automatic, Manual or Stop modes.

Manual

4.9 Treating a Patient Using Manual Mode

When operating the Model 2000 in Manual Mode, it is important to remember that patient temperature is not automatically controlled. It is the responsibility of the clinician or operator to monitor patient temperature during Manual Mode operation.

To begin a treatment in Manual Mode, the following steps should be completed:

1. The ArcticGel Pads designed for the particular procedure should be placed on the patient.
2. All patient temperature settings and equipment parameters should be adjusted for the patient and procedure.
3. Insertion of a patient temperature probe is optional.
4. Press the Manual key to start the process.

Note: Manual Mode may be enabled/disabled in Advanced Settings. An alarm will be generated if the Manual key is pressed and Manual Mode is disabled.

CAUTION: It is the sole responsibility of the clinician or operator to continuously monitor patient temperature during Manual Mode and to adjust the temperature of the water flowing through the pads accordingly.

Table 6

Number of Pads	Recommended Flow Rate Liters per Minute
2	<1.3
3	<1.8
4	<2.3
5 (optional)	<2.8

CAUTION: Due to the system's high efficiency, Manual Mode is not recommended for non-surgical treatments that require cooling.

Water temperature can be modified during the Manual Mode Operation.

1. Press the Down Arrow to reach the Water Target screen. Message displays: Water Target XXºC (ºF) - Manual Mode. Enter to Change.
2. Press Enter key.
3. Numbers will flash on screen indicating that change can be made.
4. Press Down or Up arrow until desired temperature is displayed.
5. Press Enter Key again to accept.
6. Return to Main Menu by pressing the Home key.

4.10 Water Flow Rate

Many factors contribute to reaching a target temperature, including the patient's temperature, the size of the patient, the surface area covered, and the water flow rate through the pads.

Initially, when the Fluid Delivery Lines are connected to the Patient Lines, water will be pulled through the pads and will displace the air. This is reflected in the lower right hand corner of the menu display screen as "Flow Priming". After one minute, the system will automatically calculate flow and display the flow rate in L/min (liters per minute). To ensure that water is flowing adequately through the pads, verify that all patient lines are connected properly and are not kinked. After two minutes of flow, verify that a flow rate is present on the screen.

Once all the pads are primed, assure the flow rate displayed on the control panel is appropriate for the number of pads connected. See Table 6 for flow rate estimates. As water temperature decreases, expect a slight decrease in flow rate.

The Model 2000 will track the highest flow rate. If flow drops by 50%, the system will alert the operator to check the lines to ensure there are no obstructions or leaks.

4.11 Interrupting Treatment for Patient Transport

1. Press the Purge Key
2. The Purge Mode will stop automatically when completed and display the water level remaining in the reservoir.
3. Disconnect the pad lines from the Fluid Delivery Line and disconnect the patient probe from the Patient Temperature Cable(s).
4. Transfer patient on bed or stretcher with pads remaining in place.
5. When patient has returned for additional temperature management, reconnect the pad lines and temperature probe, then select mode to initiate cooling or warming.

CAUTION: If the Model 2000 is powered off, the settings will return to the default settings when powered on unless the new settings were saved as default settings

4.12 Ending a Procedure

After achieving the overall treatment goal or when terminating a procedure, the pads should be purged prior to removing:

1. Press the Purge Key
2 The Purge Cycle will stop automatically when completed and display the water level remaining in the reservoir.
3. Disconnect the Patient Pad Lines from the Fluid Delivery Lines.

4. Slowly and carefully remove the ArcticGel Pads from the patient skin, avoiding aggressive removal of the pad adhesive.
5. Press the power switch to Off. If power is lost while the power switch is in the on position, the Arctic Sun System will issue an audible warning until the switch is turned off. This alerts the user that treatment may have been accidentally stopped.

The pads may need to be replaced for patients undergoing prolonged use, several consecutive days of cooling, warming or maintenance of normothermia. At a minimum, the pads should be replaced every 5 days. Additionally, the pads should be periodically observed for loss of integrity, loss of adhesion and moisture, and replaced as necessary in order to maintain the effectiveness of energy transfer.

Discard used pads in accordance with hospital procedures for handling contaminated medical waste.

CAUTION: Carefully remove ArcticGel Pads from the patient's skin at the completion of use. Aggressive removal of the pad from the patient's skin may result in skin tears.

CAUTION: The ArcticGel Pads are non sterile. They are for single patient use. Do not reprocess or sterilize.

CAUTION: Do not allow circulating water to contaminate the sterile field when patient lines are disconnected

section

5

5.1 Alarms

The Arctic Sun has safety features to warn the user of certain conditions that may interfere with patient safety, system performance, or patient outcome. There are two types of warning conditions in the Arctic Sun - Alarms and Alerts.

When an Alarm condition occurs, there is a chance that a potentially unsafe condition has occurred or can occur with respect to the equipment, the patient, or an improperly functioning system. An Alarm is denoted by an audio signal that lasts for 0.5 seconds on and 10 seconds off, illumination of the Alarm Key on the Remote Display Screen, and a message on the Display Screen. An Alarm will repeat itself every 10 seconds until cleared. If the alarm condition is not addressed and the problem persists, the Alarm will recur.

While there are multiple alarms and safety features in the Arctic Sun, there are four main safety alarms that are non-changeable:

- High Patient Temperature Alarm - In Automatic Mode, an alarm condition will occur when the patient temperature reaches 39.5°C (103.1°F) and water temperature is greater than patient temperature and the system is unable to cool.
- Low Patient Temperature Alarm - In Automatic Mode, an alarm condition will occur when the patient temperature reaches 31°C (87.8°F) and water temperature is lower than patient temperature and system is unable to heat.
- High Water Temperature Alarm - an alarm will occur if the water temperature rises to 42.5°C (108.5°F).

- Low Water Temperature Alarm - an alarm will occur if the water temperature decreases to 3.5°C (38.3°F).

In each of these conditions, the system will switch to Stop Mode until the condition is rectified.

If an alarm condition occurs that prevents proper use of the machine or proper treatment of the patient, the system will not allow the operator to continue a treatment. This type of alarm is known as NON-RECOVERABLE. If this situation occurs, turn the machine off and contact Medivance. Alarms that are classified as RECOVERABLE may temporarily stop the machine until the operator takes action to correct the cause of the alarm.

Confirmation of Independent Safety Alarm

When the Arctic Sun is powered ON, a power up test for the independent safety alarm is automatically run. This test simulates a "water over temperature fault" on both the primary and secondary sensors. Both the primary and secondary control systems must respond to the fault as verified by the opposing system. If both control systems don't respond, either Alarm 80 (Outlet Water over temperature test-fail Control) or Alarm 81 (Outlet Water over-temperature test fail - Monitor) will be activated. Should either an Alarm 80 or 81 appear on the display screen, notify Medivance this has occurred. These alarms are unrecoverable errors and need to be checked by Medivance personnel. For additional information on alarms see Appendices B and C.

5.2 Alerts

Alerts are intended to inform the user about patient and equipment status without interrupting the procedure. Alerts are denoted by an audio signal that lasts 0.5 second and every 2 minutes off, illumination of the Alarm Key, and a message on the display screen. When an Alert condition occurs, the system continues to function in its current mode. An Alert will repeat itself every two minutes until cleared. Once cleared, the Alert will not be repeated unless the alert condition clears or the operational mode is stopped

Note: 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, and unit is restarted.

5.3 Troubleshooting the Arctic Sun System

The following is a list of suggestions for some commonly occurring conditions. If there are any questions, please contact Medivance Customer Service.

Issue: Water flow rate suddenly decreases.

- Check to ensure Fluid Delivery Lines and pad lines are patent and not compressed or kinked.
- Check that connections between pad lines and Fluid Delivery Line are secure.
- If a significant amount of air is present in the line and connections are secure, the Energy Transfer Pad or patient pad line may have been damaged. Disconnect the damaged pad and replace if possible. If not, disconnect the pad and allow the patient to be controlled with the remaining pads.

Issue: When cooling, patient temperature is not decreasing and trend indicator is either increasing or remaining stable despite prolonged cooling.

- Check the water temperature on the display screen. If the temperature of the water circulating through the pads is not at or near the minimum water temperature, check the following parameters:
- Is the system set to Automatic or Manual Mode? Manual Mode is not recommended during cooling procedures unless a clinician is monitoring the system very carefully. If operating in Manual Mode and the patient's skin integrity and tissue perfusion are acceptable, adjust the water target temperature to a lower set point.
- If operating in Automatic Mode, press Stop, using the up and down arrows, scroll to the Minimum Water Target Screen and ensure that the temperature is set to the lowest possible setting for the patient and procedure.
- Check the flow rate to ensure adequate flow has continued since the beginning of the treatment.
- If the patient is non-surgical, determine if the patient is shivering. Shivering may interfere with cooling and require clinical action.
- Ensure that no other cooling devices or water blankets are in use with the Arctic Sun System concurrently.

Issue: When warming, patient temperature is not increasing and trend indicator is either decreasing or remaining stable despite prolonged warming.

- Check the water temperature on the display screen. If the temperature of the water circulating through the pads is not at or near the maximum water temperature, check the following parameters:
  - Check the flow rate to ensure adequate flow has continued since the beginning of the treatment.
  - Ensure that no other warming devices or water blankets are in use with the Arctic Sun concurrently.
  - If operating in Manual Mode and the patient's skin integrity and tissue perfusion are acceptable, adjust the water target temperature to a higher set point.
  - If operating in Automatic Mode, press Stop, using the up and down arrows, scroll to the Maximum Water Target Screen and ensure that the temperature is set to the highest possible setting for the patient and procedure.

Issue: When cooling in Automatic Mode, water temperature begins to increase prior to reaching the target.

- As the patient's temperature decreases, the control algorithm will increase the water temperature to bring the patient to target with minimal overshoot. This is a normal function. Water temperature will increase or decrease to maintain the target

Issue: When warming in Automatic Mode, water temperature begins to decrease prior to reaching the target

- As the patient's temperature increases, the control algorithm will decrease the water temperature to bring the patient to target with minimal overshoot. This is a normal function. Water temperature will increase or decrease to maintain the target.

Issue: Patient Temperature on the display screen changes significantly within seconds.

- Check the connection between the patient temperature probe and the temperature cable attached to the Arctic Sun.
- Ensure that the connection between the temperature probe and cable is kept thoroughly dry. If wet, replace the cable.
- Foley probes may read low when urine flows retrograde past the sensor.
- Check location and security of the temperature probe. In some cases, rectal probes may be displaced in incontinent patients. Nasopharyngeal probes may slip into the mouth and read room temperature.
- If the temperature changes cannot be corrected, replace the temperature probe.

Issue: Patient Temperature is not displayed on the screen

- Ensure that the connection between the temperature probe and the cable is secure.
- Ensure the probe and associated cable is connected to Patient Temperature 1 and not Patient Temperature 2 Connector.
- Ensure that the cable connection to the back of the Arctic Sun Control Module is secure.
- If the temperature cable is wet, replace with a new cable.
- Note: If temperature is out of range three dashes (---) will appear on the screen.

Issue: Low Temperature Alert/Alarm

- If the patient temperature is 31°C (87.8°F) and water temperature is lower than patient temperature and decreasing, an alarm condition will occur and revert to Stop Mode. If this occurs, follow the suggestions in Appendix B and C.
- From the Stop Menu, press the up or down arrows to the Advanced Settings screen. Press Enter. Using the up and down arrows, scroll to the Low Patient Temperature Alert. If necessary, adjust the temperature setting for the particular patient or procedure.

Issue: High Temperature Alert/Alarm

- If the patient temperature is 39.5°C (103.1°F) and water temperature is higher than patient temperature and increasing, an alarm condition will occur and revert to Stop Mode. If this occurs, follow the suggestions in Appendix B and C on Alarms/Alerts.
- From the Stop Menu, press the up or down arrows to the Advanced Settings Key. Press Enter. Using the up and down arrows, scroll to the High Patient Temperature Alert. If necessary, adjust the temperature setting for the particular patient or procedure.

Appendix A - Installation Procedure

1. Unpack the Control Module, Remote Display, Fluid Delivery Line, cables and accessories.
2. Attach the Fluid Delivery Line by placing the connector into the fluid delivery line connection at the back of the Control Module.
3. Insert the Fill/Drain Tube connector into fill tube port located near the fluid delivery line connector.
4. Attach one end of the Remote Display Cable to the remote display connector on the Control Module, and the other end to the Remote Display.
5. Clamp the Remote Display to the Control Module handle and route the cable through the clips on the handle. The tension on the Remote Display clamp can be adjusted by using a 1/2 inch hex wrench.
6. Attach the power cord to the Arctic Sun plug into a wall outlet.
7. Cables can be strain relieved by using the Strain Relief Kit.
8. Turn the power on. Ensure the system goes through its self test described in Section 3.1
9. Fill the unit using the Cleaning Solution as described in Section 3.2

CAUTION: Use only distilled or sterile water. The use of other fluids will damage the Control Module.

10. Allow the Model 2000 to run for a minimum of 10 minutes.
11. Attach a Shunt Line to the end of the Fluid Delivery Line.
12. Initiate Manual Mode with a Water Target set to 4ºC.
13. Verify that the water flow rate reaches at least 3.0 LPM after priming.
14. Verify that the water temperature drops to 4ºC. If the initial water temperature is approximately 25ºC the water temperature should drop to 6ºC in less than 15 minutes.
15. Change the Manual Mode Water Target set to 40ºC.
16. Verify that the water temperature increases to 25ºC. If the initial water temperature is approximately 6ºC the water temperature should increase to 25ºC in less than 10 minutes.
17. Purge the system. Verify that water has been removed from the fluid line.
18. Turn off the Arctic Sun. Remove the shunt tube.

More comprehensive calibration, safety and functional checks are described in the Service Manual.

Contact Customer Service for technical support in performing or troubleshooting this installation procedure.

Appendix B - Alarms & Alerts Descriptions & Specifications

Alarm Condition: 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 system.

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

The following chart represents all potential alarms or alerts that might occur, a description of the condition, the status of the system during the alarm or alert, and potential corrective action items. If the operator cannot troubleshoot the condition, note the alarm or alert number and phone Medivance Customer Service.

CAUTION: 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 or the Arctic Sun has been turned to the OFF position.

Table 7

Alarms and Alerts Parameter	Specification
Water Temperature High Alarm	42.5ºC / 44ºC 108.5°F / 111.2°F
Water Temperature Low Alarm	3.5ºC 38.3°F
System Patient Temperature High Alarm	39.5ºC 103.1°F
System Patient Temperature Low Alarm	31.0ºC 87.8°F
Adjustable Patient Temperature High Alert	10.1°C to 44°C 50.1°F to 111.2°F
Adjustable Patient Temperature Low Alert	10.0°C to 41.9°C 50°F to 107.5°F
Patient Probe Fault Alarm	Short or Open
Water flow Alert	50% of case maximum
System Water Temperature High Alarm	43.0ºC/ 44ºC 109.4°F/ 111.2°F
System Water Temperature Low Alarm	3.0ºC 37.4°F
Reservoir level Alert then Alarm	Low then Empty
System Self Test Alarm	At power up

Appendix C - Alarms & Alert List and Actions to Correct

Table 8

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
01	Low fluid pressure in lines. Check connections. **Alert**	Patient 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.	Check all connections. Check for air leak in pads or patient lines. Check connections between patient lines and fluid delivery line. Check connection of fluid delivery line to the system. Make certain all fittings are secure. Listen to hear if pump is running. If not, contact Medivance service. If situation is corrected, cancel alert.
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.	Check all connections. Check for air leak in pads or patient lines. Check connections between patient lines and fluid delivery line. Check connection of fluid delivery lines to the system. Make certain all fittings are secure. Check to make sure that lines are not kinked or blocked. Listen to hear if pump is running. If not, contact Medivance service. If situation is corrected, cancel alert.
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.
04	Water reservoir level below minimum. Fill reservoir. **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.	Fill Reservoir.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
05	Water reservoir level below minimum. Fill reservoir or purge pads. **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.	If connected to pads, purge pads. Fill Reservoir.
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.	Pads may contain a significant amount of water. Caution when removing pads from machine to avoid spilling water. Machine may have been overfilled. Check level. May indicate a machine malfunction, contact biomedical engineering or Medivance service if problem persists and the reservoir is not overfilled.
08	System warming and Patient Temperature 1 high. **Alarm**	Patient Temperature 1 reading is above 39.5°C (103.1°F) and water temperature is above 39.5°C (103.1°F) and system is unable to cool in Automatic Mode.	Remains in Stop Mode. Audio alarm half second tone every 10 seconds. Alarm indicator flashing.	Verify patient temperature from another source. Press Automatic Mode and observe water temperature to see if it has started to cool. Check that the vents on the sides of the machine are not blocked. If water temperature does not decrease, turn system off and allow to system to cool. Restart Automatic Mode. If water temperature does not fall in response to patient temperature, shut system off and call Medivance service.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
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.	Check patient temperature. Cancel alert If system stopped, alert will re-appear. 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 31.0°C (87.8°F) and water temperature is below 31.0°C (87.8°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.	Press Automatic Mode and observe water temperature to see if it has started to warm. Verify patient temperature from another source Turn system off. Restart Automatic Mode. If water temperature does not rise in response to patient temperature, shut system off and call Medivance service.
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.	Check patient temperature. Cancel alert If system stopped, alert will re-appear. Adjust Patient Low Temperature Alert in the custom menu if desired.
12	Patient and water temperature high. Check water temperature. **Alert**	Patient Temperature 1 reading is above 39.5°C (103.1°F) and water temperature is above 39.5°C (103.1°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.	Check that the vents on the sides of the machine are not blocked. Reduce Water Target Temperature.
13	Patient and water temperature low. Check water temperature. **Alert**	Patient Temperature 1 reading is below 31.0°C (87.8°F) and outlet water temperature is below 31.0°C (87.8°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.	Increase Water Target Temperature.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
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.	Check patient temperature probe is properly placed and has not dislodged. Check connection of patient temperature probe and cable connection. If wet, replace cable. Check temperature cable at back of machine.
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.	Check patient temperature probe is properly placed and has not dislodged. Check connection of patient temperature probe and cable connection. If wet, replace cable. Check the integrity of the temperature cable. Check temperature cable at back of machine. Replace probe if necessary
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.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Check patient temperature probe is properly placed and has not dislodged. Check connection of patient temperature probe and cable connection. If wet, replace cable. Check the integrity of the temperature cable. Check temperature cable at back of machine.
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.	Contact Clinical Engineering or Medivance service to verify calibration. System may be run in Manual Mode, but patient temperature will be displayed as three dashes.
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.	Check patient temperature probe is properly placed and has not dislodged. Contact biomedical engineering or Medivance service to verify calibration. System will continue in Manual Mode, but patient temperature will be displayed as three dashes.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
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.	Contact biomedical engineering or Medivance service to verify calibration. System may be run in Manual Mode, but patient temperature will be displayed as three dashes.
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.	Check patient temperature probe is properly placed and has not dislodged. Contact biomedical engineering or Medivance service to verify calibration. System will continue in Manual Mode, but patient temperature will be displayed as three dashes.
21	Patient Temperature 2 high. Check patient temperature. **Alarm**	Patient Temperature 2 reading is above 39.5°C (103.1°F) and water temperature is above 39.5°C (103.1°F) and system is unable to cool in Automatic Mode.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Verify patient temperature from another source. Press Automatic Mode and observe water temperature to see if it has started to cool. Check that the vents on the sides of the machine are not blocked. If water temperature does not decrease, turn system off and allow to system to cool. Restart Automatic Mode. If water temperature does not fall in response to patient temperature, shut system off and call Medivance service.
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.	Check patient temperature. Cancel alert If system stopped, alert will re-appear. Adjust Patient High Temperature Alert in the custom menu if desired.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	
23	Patient Temperature 2 low. Check patient temperature. **Alarm**	Patient Temperature 2 reading is below 31.0°C (87.8°F) and water temperature is below 31.0°C (87.8°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.	Press Automatic Mode and observe water temperature to see if it has started to warm. Verify patient temperature from another source Turn system off. Restart Automatic Mode. If water temperature does not rise in response to patient temperature, shut system off and call Medivance service.
24	Patient Temperature 2 below 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.	Check patient temperature. Cancel alert If system stopped, alert will re-appear. Adjust Patient Low Temperature Alert in the custom menu if desired.
25	System is warming and Patient Temperature 2 high. **Alert**	Patient Temperature 2 reading is above 39.5°C (103.1°F) and water temperature is above 39.5°C (103.1°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.	Check that the vents on the sides of the machine are not blocked. Reduce Water Target Temperature.
26	System is cooling and Patient Temperature 2 low. **Alert**	Patient Temperature 2 reading is below 31.0°C (87.8°F) and water temperature is below 31.0°C (87.8°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.	Increase Water Target Temperature.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
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.	Check patient temperature probe is properly placed and has not dislodged. Check connection of patient temperature probe and cable connection. If wet, replace cable. Check temperature cable at back of machine.
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.	Check patient temperature probe is properly placed and has not dislodged. Check connection of patient temperature probe and cable connection. If wet, replace cable. Check the integrity of the temperature cable. Check temperature cable at back of machine.
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.	Contact Clinical Engineering or Medivance service to verify calibration. System will continue in Automatic Mode, but patient temperature 2 will be displayed as three dashes.
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.	Contact Clinical Engineering or Medivance service to verify calibration. System will continue in Automatic Mode, but patient temperature 2 will be displayed as three dashes.
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.	Contact Clinical Engineering or Medivance service to verify calibration. System will continue in Automatic Mode, but patient temperature 2 will be displayed as three dashes.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
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.	Contact Clinical Engineering or Medivance service to verify calibration. System will continue in Automatic Mode, but patient temperature 2 will be displayed as three dashes.
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.	Check flow rate. Low flow rate may cause overheating of the water. Wait until water cools. Restart Automatic Mode or Manual Mode. If problem persists, contact Medivance service.
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.	Check flow rate. Low flow rate or fluctuating flow rates may cause overheating of the water. Wait until water cools. Restart Automatic Mode or Manual Mode. If problem persists, contact 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.	Wait until water warms. Restart Automatic Mode or Manual Mode. If problem persists, contact 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.	Check flow rate. Low flow rate may cause overheating of the water. Wait until water cools. Restart Automatic Mode or Manual Mode. If problem persists, contact Medivance service. System can be run in Manual Mode, but Water Target Temperature should be reduced.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
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.	Check flow rate. Low flow rate may cause overheating of the water. Wait until water cools. Restart Automatic Mode or Manual Mode. If problem persists, contact Medivance service. System can be run in Manual Mode, but Water Target Temperature should be reduced.
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.	Wait until water warms. Restart Automatic Mode or Manual Mode. If problem persists, contact Medivance service. System can be run in Manual Mode, but Water Target Temperature should be increased.
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.	Contact 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	Contact Medivance service to determine cause of low bypass flow.
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	Check all custom user settings and temperature alerts before restarting procedure. Save all values. Contact Medivance service if problem persists.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
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.	Performance of the system is not affected. Contact Medivance Service is alert persists.
45	AC Power Lost. **Alert**	Notify user if AC power was previously lost while power switch was in ON position.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Check user settings before initiating treatment.
46	User Interface Disconnect. **Alarm**	User interface not detected by control system.	Changes to Stop Mode. Audio alarm every 20 seconds.	Check user interface cable connections on the user interface module and Arctic Sun control module.
47	User Interface Disconnect. **Alarm**	User interface not detected by monitor system.	Changes to Stop Mode. Audio alarm every 20 seconds.	Check user interface cable connections on the user interface module and Arctic Sun control module.
48	Patient Temperature Out invalid. **Alert**	Patient Temperature Out calibration data in non-volatile memory invalid.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Contact Medivance service.
49	Patient Temperature Out system error. **Alert**	Calculated Patient Temperature Out is (0.1(C from measured Patient Temperature 1 (primary patient temperature).	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Contact Medivance service.
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.	Check patient temperature probe is properly placed and has not dislodged.

Appendix C – Table 8 (continued)

Alarm/ Alert	Message Displayed	Alarm/Alert Description	System Status	Action
51	Patient Temperature 1 below control range. Check temperature probe. **Alert**	Patient temperature less than 31ºC when Automatic mode entered.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	Verify accuracy of reading. Make sure the probe is properly placed & hasn't been dislodged.
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. Reoccurs after 4 hours if condition continues.	Current Mode Continues. Audio alarm half second tone every 2 minutes. Alarm/Alert indicator flashing.	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. Evaluate procedure. **Alarm**	The Arctic Sun has issued 11 alerts for extended periods of cold water delivery.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Assess patient's skin. Assess whether the minimum water temperature should be increased or whether the temperature management therapy should be discontinued.
54	Manual Mode Disabled. **Alarm**	Manual key has been pressed while Manual Mode is disabled.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	**Enable Manual Mode in Advanced Settings if Manual Mode is desired.**
60 to 99	Non-recoverable system error. Refer to Operator Manual. **Alarm**	System error that cannot be managed without speaking to Medivance.	Changes to Stop Mode. Audio alarm half second tone every 10 seconds. Alarm/Alert indicator flashing.	Power off. Contact designated clinical engineer or Medivance service.

Appendix D - Model 2000 Specifications

Table 9

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
Patient Temperature Inputs	2 (1 monitors, controls, alarms + 1 monitor, alarms)
Patient Temperature Display Range	10°C to 44°C, 50°F to 111.2°F in 0.1°C/°F
Patient Temperature Measurement Accuracy	±0.4°C 10 to 32°C ±0.2°C 32 to 38°C ±0.4°C 38 to 44°C includes ± 0.1°C external probe
Patient Temperature Control Range - Automatic Mode	32°C to 38.5°C 89.6°F to 101.3°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
Water Temperature Control Range - Manual Mode	4°C to 42°C 39.2°F to 107.6°F in 0.1°C/F increments

Appendix D - Table 9 (continued)

Parameter	Specification
Maximum Water Temperature (Automatic Mode)	36°C to 42°C 96.8°F to 107.6°F in 1°C/F increments
Minimum Water Temperature (Automatic Mode)	4°C to 25°C 39.2°F to 77°F in 1°C/F increments
Mains Input*	115VAC, 60 Hz, 11.0 Amp (nominal) 230VAC, 50 Hz, 5.5 Amp
Current Leakage	< 300uA
Circuit Breaker	12.0 Amp
Operating relative humidity range	5 - 70%
Storage relative humidity range	5 - 95% non-condensing
Operating temperature range	10(C (50(F) - 27(C (80(F)
Storage temperature range	-30(C (-20(F) to 50(C (120(F)
Height (handle down)	30" (76cm)
Length	22" (56cm)
Width	12.5" (32cm)
Weight when filled	116 lbs (53kg.)

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

Appendix E - Data Collection

To collect data from the Arctic Sun System, use the RS232 data connector on the rear of the device (see Figure 3). A PDA (personal digital assistant) or computer can be connected to the Control Module to download data. To accept the data stream have Microsoft HyperTerminal or a similar communications program loaded on the receiving device to record the data. Data can be collected as often as every 5 seconds or as slow as every 10 minutes. To establish the desired interval, press the Stop Key. Scroll through the custom menu pressing the up arrows until the Advanced Settings screen is displayed. Press Enter and continue to scroll through the options until Data Output Interval screen is displayed. Press Enter and adjust the desired setting using the up or down arrows. Press Enter to accept the new value.

Configuration

Protocol: RS-232 Port Configuration

9600 Baud, 8 Data Bits, No Parity, 1 Stop Bit, No Handshake

Wiring

(DB-9 connector wiring is listed in Table 10)

Table 10

Pin No.	Function
Pin 2	Receive In
Pin 3	Transmit Out
Pin 5	Ground

The RS-232 connector wiring is configured for connection to a Palm PDA. Connection directly to a PC may require a "Null Modem" adapter.

Data Format

The data output stream is a repeating sequence of ASCII characters at intervals set from the custom menu display. A "$" is sent as the first item of a new data sequence. Each data item within the sequence is separated by a comma (ASCII 44). The data sequence is terminated with a carriage return character (ASCII 13) followed by a new line character (ASCII 10). The time since power up of each data sequence can be calculated from the serial sequence number and communications output interval.

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

Output Data Parameter Sequence is listed in Table 11.

Table 11

Sequence No.	Description	Values
1	Sequence Start Indicator	$ (ASCII 36)
2	Serial Sequence Number	1, 2, 3, 4, 5 ... , Initialized at power up
3	Patient Temperature 1	(C, 0 if probe not connected
4	Patient Temperature 2	(C, 0 if probe not connected
5	Patient Target Temperature in Auto Mode	(C, Regardless of current mode
6	Operating Mode	0 = Initialization, 1 = Stop, 2 = Automatic, 3 = Manual, 4 = Purge, 5 = Fill
7	Diagnostic Mode	0 = Normal Mode, 1 = Diagnostic Mode
8	Outlet Water Temperature Monitor	°C
9	Outlet Water Temperature	°C
10	Inlet Water Temperature	°C
11	Chiller Temperature	°C
12	Water Outlet Target Temperature	°C
13	Temperature Display Mode	0 = °C, 1 = °F
14	Communications Output Interval	Seconds
15	Current Alarm Number	See Alarm/Alert list for corresponding numbers
16	Flow Rate	Liters/minute
17	Reservoir Level Last Measured	5 or 4 = Full, 3 = 3/4, 2 = 1/2, 1= Low, 0 = Empty
18	Inlet Pressure	Pounds per square inch
19	Heater Power	0-32 where 32 = 100%
20	Mixing Pump Power	0-255 where 255 = 100%
21	Flow Pump Power	0-255 where 255 = 100%
22	Control Parameter Mode	0 = Surgical, 1 = ICU
23	Software Version	

If needed, contact Medivance Customer Service for assistance in establishing communications.

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