ARCTIC SUN® 5000

TEMPERATURE MANAGEMENT SYSTEM

OPERATOR'S MANUAL

Medivance®

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

Languages

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Chapter 1 – Getting Started

Indications for Use

The Arctic Sun® Temperature Management System is intended for monitoring and controlling patient temperature.

Warnings and Cautions

Warnings

- Do not use the Arctic Sun® Temperature Management System in the presence of flammable agents because an explosion and/or fire may result.
- Do not use high frequency surgical instruments or endocardial catheters while the Arctic Sun® Temperature Management System is in use.
- There is a risk of electrical shock and hazardous moving parts. There are no user serviceable parts inside. Do not remove covers. Refer servicing to qualified personnel.
- Power cord has a hospital grade plug. Grounding reliability can only be achieved when connected to an equivalent receptacle marked "hospital use" or "hospital grade".
- When using the Arctic Sun® Temperature Management System, note that all other thermal conductive systems, such as water blankets and water gels, in use while warming or cooling with the Arctic Sun® Temperature Management System may actually alter or interfere with patient temperature control.
- Do not place ArcticGel™ Pads over transdermal medication patches as warming can increase drug delivery, resulting in possible harm to the patient.

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® Temperature Management System system.
- When moving the Arctic Sun® Temperature Management System always use the handle to lift the controller over an obstacle to avoid over balancing.
- The patient's bed surface should be located between 30 and 60 inches (75 cm and 150 cm) above the floor to ensure proper flow and minimize risk of leaks.
- The clinician is responsible to determine the appropriateness of custom parameters. When the system is powered off, all changes to parameters will revert to the default unless the new settings have been saved as new defaults in the Advanced Setup screen. For small patients (≤30 kg) it is recommended to use the following settings: Water Temperature High Limit ≤40°C (104°F); Water Temperature Low Limit ≥10°C (64.4 °F); Control Strategy =2.
- The operator must continuously monitor patient temperature when using Manual Control and adjust the temperature of the water flowing through the pads accordingly. Patient temperature will not be controlled by the Arctic Sun® Temperature Management System in Manual Control.
- Due to the system's high efficiency, Manual Control is not recommended for long duration use. The operator is advised to use the automatic therapy modes (e.g. Control Patient, Cool Patient, Rewarm Patient) for automatic patient temperature monitoring and control.
- The Arctic Sun® Temperature Management System will monitor and control patient core temperature based on the temperature probe attached to the system. The clinician is responsible for correctly placing the temperature probe and verifying the accuracy and placement of the patient probe at the start of the procedure.
- Medivance recommends measuring patient temperature from a second site to verify patient temperature. Medivance recommends the use of a second patient temperature probe connected to the Arctic Sun® Temperature Management System Temperature 2 input as it provides continuous monitoring and safety alarm features. Alternatively, patient temperature may be verified periodically with independent instrumentation.
- The displayed temperature graph is for general information purposes only and is not intended to replace standard medical record documentation for use in therapy decisions.
- Patient temperature will not be controlled and alarms are not enabled in Stop Mode. Patient temperature may increase or decrease with the Arctic Sun® Temperature Management System in Stop Mode.
- Carefully observe the system for air leaks before and during use. If the pads fail to prime or a significant continuous air leak is observed in the pad return line, check connections. If needed, replace the leaking pad. Leakage may result in lower flow rates and potentially decrease the performance of the system.
- The Arctic Sun® Temperature Management System is for use only with the ArcticGel™ Pads.
- The ArcticGel™ Pads are only for use with the Arctic Sun® Temperature Management Systems.
- The ArcticGel™ Pads are non-sterile for single patient use. Do not reprocess or sterilize. If used in a sterile environment, pads should be placed according to the physician's request, either prior to the sterile preparation or sterile draping. ArcticGel™ Pads should not be placed on a sterile field.
- Use pads immediately after opening. Do not store pads once the kit has been opened.
- Do not place ArcticGel™ Pads on skin that has signs of ulceration, burns, hives, or rash.
- While there are no known allergies to hydrogel materials, caution should be exercised with any patient who has a history of skin allergies or sensitivities.
- Do not allow circulating water to contaminate the sterile field when patient lines are disconnected.
- The water content of the hydrogel affects the pad's adhesion to the skin and conductivity, and therefore, the efficiency of controlling patient temperature. Periodically check that pads remain moist and adherent. Replace pads when the hydrogel no longer uniformly adheres to the skin. Replacing pads at least every 5 days is recommended.
- Do not puncture the ArcticGel™ Pads with sharp objects. Punctures will result in air entering the fluid pathway and may reduce performance.
- If accessible, examine the patient's skin under the ArcticGel™ Pads often, especially those at higher risk of skin injury. Skin injury may occur as a cumulative result of pressure, time and temperature. Do not place bean bag or other firm positioning devices under the ArcticGel™ Pads. Do not place positioning devices under the pad manifolds or patient lines.
- The rate of temperature change and potentially the final achievable patient temperature is affected by many factors. Treatment application, monitoring and results are the responsibility of the attending physician. If the patient does not reach target temperature in a reasonable time or the patient is not able to be maintained at the target temperature, the skin may be exposed to low or high water temperatures for an extended period of time which may increase the risk for skin injury. Ensure that pad sizing / coverage and custom parameter settings are correct for the patient and treatment goals, water flow is greater than or equal to 2.3 liters per minute and the patient temperature probe is in the correct place. For patient cooling, ensure environmental factors such as excessively hot rooms, heat lamps, and heated nebulizers are eliminated and patient shivering is controlled. Otherwise, consider increasing minimum water temperature, modifying target temperature to an attainable setting or discontinuing treatment. For patient warming, consider decreasing maximum water temperature, modifying target temperature to an attainable setting or discontinuing treatment.
- Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status, steroid use or high dose vasopressor therapy. If warranted, use pressure relieving or pressure reducing devices under the patient to protect from skin injury.
- Do not allow urine, antibacterial solutions or other agents to pool underneath the ArcticGel™ Pads. Urine and antibacterial agents can absorb into the pad hydrogel and cause chemical injury and loss of pad adhesion. Replace pads immediately if these fluids come into contact with the hydrogel.
- Do not place ArcticGel™ Pads over an electrosurgical grounding pad. The combination of heat sources may result in skin burns.
- If needed, place defibrillation pads between the ArcticGel™ pads and the patient's skin.
- Carefully remove ArcticGel™ Pads from the patient's skin at the completion of use. Discard used ArcticGel™ Pads in accordance with hospital procedures for medical waste.

- The USB data port is to be used only with a standalone USB flash drive. Do not connect to another mains powered device during patient treatment.
- Users should not use cleaning or decontamination methods different from those recommended by the manufacturer without first checking with the manufacturer that the proposed methods will not damage the equipment. Do not use bleach (sodium hypochlorite) as it may damage the system.
- Medivance will not be responsible for patient safety or equipment performance if the procedures to operate, maintain, modify or service the Medivance Arctic Sun® Temperature Management System are other than those specified by Medivance. Anyone performing the procedures must be appropriately trained and qualified.

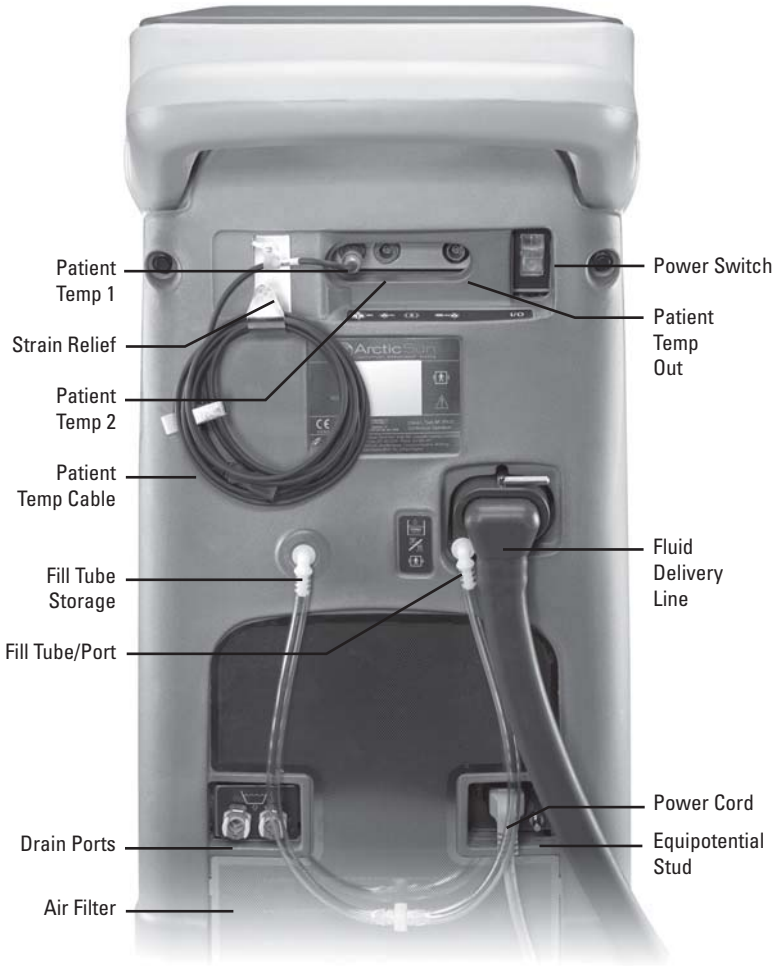
System Setup

Unpack

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

Connections

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



Power On

1) Turn the power ON by activating the Power Switch.
2) The control module will automatically go through a brief self-test of the independent safety alarm.
3) A New User Training module option is available from the start up screen.

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

Fill Reservoir

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

Functional Verification
Perform the following functional verification procedure after initial setup and installation of the control module.

1) Power **On** the control module
2) From the **Patient Therapy Selection** screen, press the **Hypothermia** button to display the **Hypothermia** therapy screen.
3) From the **Hypothermia** therapy screen, press the **Manual Control** button to open the **Manual Control** window.
4) Use the Up and Down arrows to set the **Manual Control** water target temperature to 40°C and the duration to 30 minutes.

5) Press the **Start** button to initiate **Manual Control**. Allow at least 3 minutes for the system to stabilize.
6) Monitor the flow rate and water temperature in the **System** status area on the **Hypothermia** therapy screen.
7) Verify that the flow rate reaches at least 1.5 liters/minute.
8) Verify that the water temperature increases to 30°C.
9) Press the **Stop** button.
10) Set the Manual Control water target temperature to 4°C and the duration to 30 minutes.
11) Press the **Start** button to initiate **Manual Control**.
12) Monitor the flow rate and water temperature in the **System** status area of the **Hypothermia** therapy screen. Verify that the water temperature drops to 6°C.
13) Press the **Stop** button to stop **Manual Control**
14) Press the **Cancel** button to close the **Manual Control** window
15) Power **Off** the control module.

Chapter 2 – Patient Therapy

Place ArcticGel™ Pads
Read the Instructions for Use that accompany the ArcticGel™ Pads. Examine each pad for damage prior to placement.

Connect ArcticGel™ Pads
Orient the blue and white colors on the pad line connector and Fluid Delivery Line. While holding the pad line tubing, insert the clear pad line connector into the Fluid Delivery Line manifold. Do not press or squeeze the wings when connecting. The connector will click into place.

Temperature Probe Placement
Patient temperature control with the Arctic Sun® Temperature Management System requires patient temperature feedback provided by an indwelling patient temperature probe connected to the Patient Temperature 1 connector on the back of the Control Module. Any commercially-available Yellow Springs Instrument 400 Series (YSI 400) compatible patient temperature probe can be connected to the Arctic Sun® Temperature Management System. Refer to the manufacturer's Instructions for Use for the specific indications and temperature probe placement.

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

New Patient - Normothermia
Select **Normothermia** if the therapy goal is to maintain a patient temperature at a pre-defined target temperature for an indefinite period of time. Press the **Normothermia** button to display the **Normothermia** therapy screen.

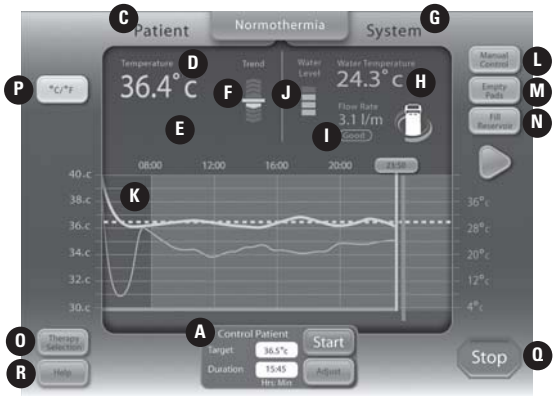
New Patient - Hypothermia
Select **Hypothermia** to reduce and maintain a patient temperature at a set target temperature for a defined period of time, then slowly re-warm the patient at a controlled re-warming rate. Press the **Hypothermia** button to display the **Hypothermia** therapy screen.

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

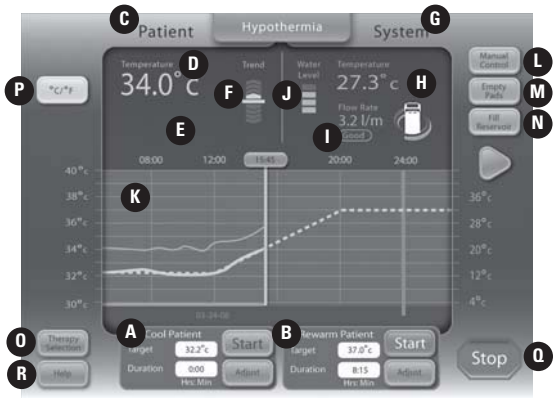
Press the **Continue Current Patient** button to resume a paused patient therapy.

Therapy Screens

Normothermia Therapy Screen



Hypothermia Therapy Screen



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

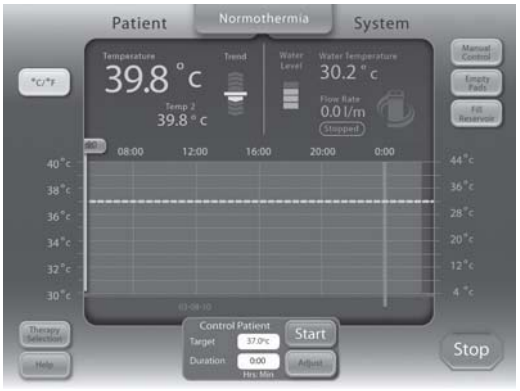
A Cool Patient window (Hypothermia screen)
Control Patient window (Normothermia screen)
B Rewarm Patient window (Hypothermia screen)
C Patient Monitoring area
D Patient Temperature
E Patient Temperature 2 (if enabled)
F Patient Temperature Trend Indicator
G System Monitoring area
H Water Temperature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

Initiate Normothermia (Control Patient)

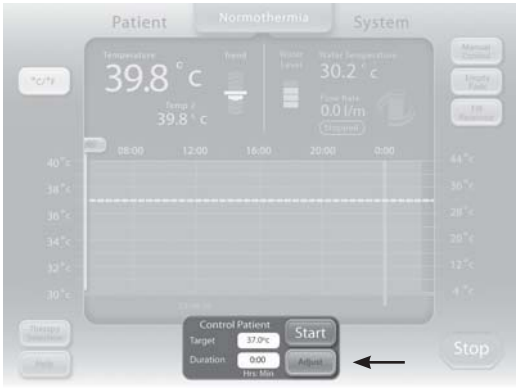
Normothermia therapy is initiated and managed, and patient temperature is automatically controlled to a set target temperature from the **Control Patient** window in the **Normothermia** therapy screen. The **Control Patient** window displays the patient target temperature and the duration since the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

To initiate Normothermia therapy:

1) From the **Patient Therapy Selection** screen, press the **Normothermia** button to display the **Normothermia** therapy screen.

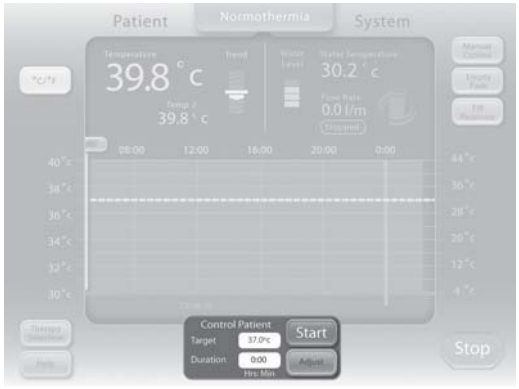


2) The default patient target temperature will display in the **Control Patient** window.



3) To modify the patient target temperature, press the **Adjust** button to display the **Control Patient-Adjust** window.

4) **Control Patient** To: Use the Up and Down arrows to set the desired patient target temperature to control the patient.
5) Press the **Save** button to save the new settings and close the **Control Patient-Adjust** window
6) Press **Start**, in the **Control Patient** window to initiate therapy. You will hear a tone and then a voice stating "Therapy Started". Additionally, the **Control Patient** window and the ARCTIC SUN® Temperature Management System icon will blink, indicating that therapy is in progress.



Initiate Hypothermia (Cool Patient and Rewarm Patient)

Hypothermia therapy is initiated and managed, and patient temperature is automatically controlled to a set target temperature from the **Cool Patient** and **Rewarm Patient** windows in the **Hypothermia** therapy screen.

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

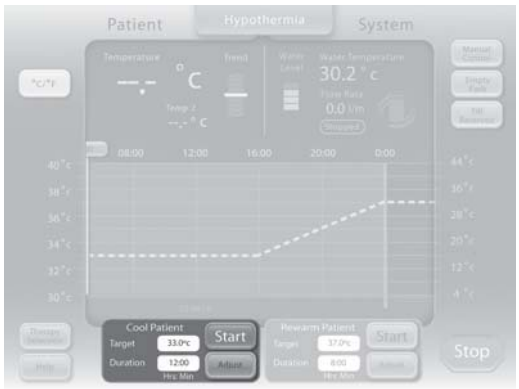
The **Rewarm Patient** window displays the rewarming phase patient target temperature and the length of time remaining in the rewarming phase of the **Hypothermia** therapy.

To initiate hypothermia therapy:

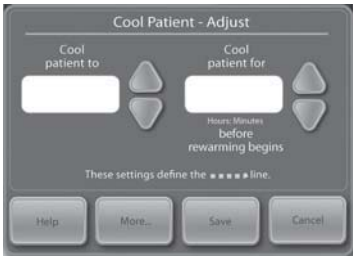
From the **Patient Therapy Selection** screen, press the **Hypothermia** button to display the **Hypothermia** therapy screen.

1. Cool Patient Settings

- The default patient target temperature and duration will display in the **Cool Patient** window.



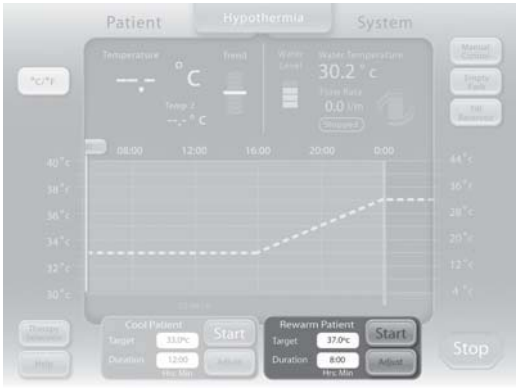
- To modify the patient target temperature and duration, press the **Adjust** button to display the **Cool Patient-Adjust** window.



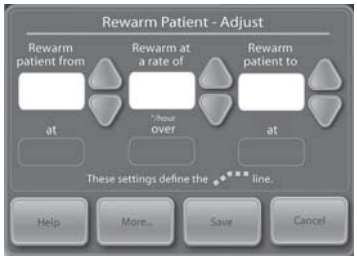
- **Cool Patient To:** Use the Up and Down arrows on the left side to set the desired patient target temperature to cool the patient
- **Cool Patient For:** Use the Up and Down arrows on the right side to set the cooling duration to cool the patient before rewarming begins.
- Press the **Save** button to save the new settings and close the **Cool Patient-Adjust** window

2. Rewarm Patient Settings

- The default patient target temperature and duration will display in the **Rewarm Patient** window.



- To change the rewarming phase patient target temperature and rewarming rate, press the **Adjust** button in the **Rewarm Patient** window to display the **Rewarm Patient-Adjust** screen. Use the Up and Down arrows on the left side to set the desired final patient target temperature.

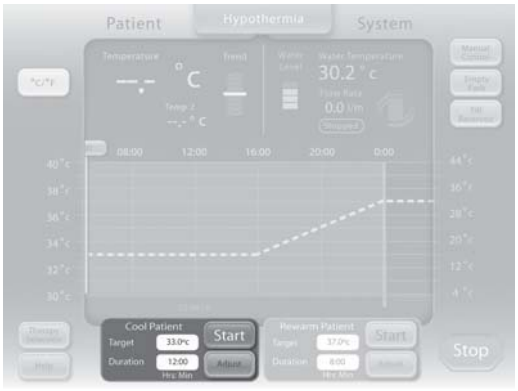


- **Rewarm Patient To:** Use the Up and Down arrows on the right side to set the desired final patient target temperature.
- **Rewarm at a Rate of:** Use the Up and Down arrows in the center of the screen to set the rewarming rate.
- **Rewarm Patient From:** When cooling a patient, adjustment of the **Rewarm Patient From** setting on the left side of the screen is disabled and defaults to the **Cool Patient** target temperature.
- When rewarming a patient, the **Rewarm Patient From** adjustment is enabled and the value can be modified. The **Rewarm Patient From** setting is the temperature to which the system is currently controlling the patient. The **Rewarm Patient From** temperature will automatically increase as the rewarming process continues. This feature allows the rewarming procedure to be optimized by allowing complete control of the rewarming ramp.

- Using the **Rewarm Patient From** temperature, the **Rewarm Patient To** temperature and the rewarming rate settings, the system will calculate and display the rewarming duration and the date/time at which the the patient will reach the final rewarming target temperature.
- Press the **Save** button to save the new settings and close the **Rewarm Patient-Adjust** window.

3. Initiate Patient Cooling

- Press **Start**, in the **Cool Patient** window to initiate therapy. You will hear a tone and then a voice stating "Therapy Started". Additionally, the **Cool Patient** window and the ARCTIC SUN® Temperature Management System icon will blink, indicating that therapy is in progress.



4. Initiate Patient Rewarming

- Upon completion of the cooling phase, there are two options for initiation of patient rewarming, either Automatically or Manually, depending on the **Rewarming Begins** setting in **Hypothermia Settings**.
- If **Rewarming Begins** is set to **Automatically**, the rewarming process starts automatically when the **Cool Patient** therapy is complete and the duration reaches zero.
- If **Rewarming Begins** is set to **Manually**, the rewarming process starts when the **Start** button is pressed in the **Rewarm Patient** window. The cooling process will continue until the **Rewarm Patient Start** button is pressed. An **Alert** will occur when the **Cool Patient** duration reaches zero.

End Therapy

- From the **Normothermia** therapy or **Hypothermia** therapy screen, press the **Stop** button to terminate water circulation to the pads.
- Press the **Empty Pads** button, and follow the instructions to purge the pads of water.
- Disconnect the pads from the Fluid Delivery Line.
- Slowly and carefully remove pads from the patient skin.
- Discard the used pads in accordance with hospital procedures for medical waste.
- Press the power switch **Off**.

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

Chapter 3 – Normothermia Settings

Normothermia Settings

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

Normothermia Settings screen parameters:

Therapy Settings
- Timer Begins

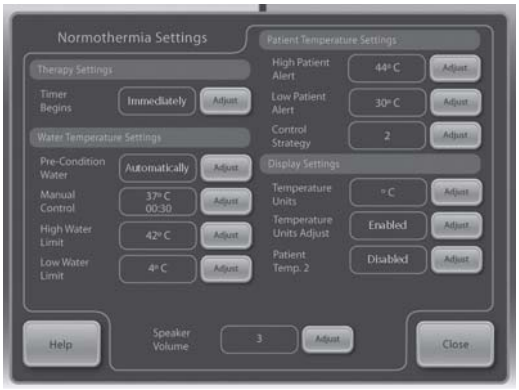
Water Temperature Settings
- Pre-Condition Water
- Manual Control
- High Water Limit
- Low Water Limit

Patient Temperature Settings
- High Patient Alert
- Low Patient Alert
- Control Strategy

Display Settings
- Temperature Units
- Temperature Units Adjust
- Patient Temp 2
- Speaker Volume

To access the Normothermia Settings screen:

1) Press **Adjust** on the **Control Patient** window.
2) Press the **More** button on the **Control Patient Adjust** window.
3) The **Normothermia Settings** screen will be displayed.



4) To save the new settings as the current patient therapy settings, press the **Close** button. For instructions on saving the settings as the system defaults, see **Advanced Setup**.

Chapter 4 – Hypothermia Settings

Hypothermia Settings

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

Hypothermia Settings screen parameters:

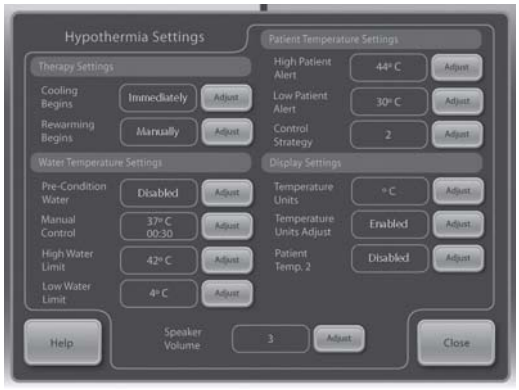
Therapy Settings
- Cooling Begins
- Rewarming Begins

Water Temperature Settings
- Pre-Condition Water
- Manual Control
- High Water Limit
- Low Water Limit

Patient Temperature Settings
- High Patient Alert
- Low Patient Alert
- Control Strategy

Display Settings
- Temperature Units
- Temperature Units Adjust
- Patient Temp 2
- Speaker Volume

To access the Hypothermia Settings screen:
1) Press **Adjust** on the **Cool Patient** window or the **Rewarm Patient** window.
2) Press the **More** button on the **Cool Patient Adjust** window or **Rewarm Patient Adjust** window.
3) The **Hypothermia Settings** screen will be displayed.



4) To save the new settings as the current patient therapy settings, press the **Close** button. For instructions on saving the settings as the system defaults, see **Advanced Setup**.

Chapter 5 – Advanced Setup

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

Location / Time Settings
- Language
- Number Format
- Current Time
- Date Format
- Current Date

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

Additionally, the following information can be viewed in the Advanced Setup screen.
- Software Versions
- Last Calibration date
- Next calibration due

To access the Advanced Setup screen:
1) Press **Advanced Setup** button on the **Patient Therapy Selection** screen.
2) The **Advanced Setup** screen will be displayed.

Chapter 6 – Alarms and Alerts

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

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

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

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

Alarms

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

Main Safety Alarms

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

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

Each time the Arctic Sun® Temperature Management System is powered On, a system self test for the independent safety alarm is automatically run. This test stimulates a "water high temperature" fault situation on both the primary and secondary water temperature sensors. Both the primary and secondary safety systems must respond to the fault and be verified by the opposing safety system. If either safety systems do not respond appropriately either an alarm 80 or 81 will be issued. Contact Medivance Customer Support.

Non-Recoverable Alarms

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

Recoverable Alarms

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

If a Recoverable Alarm occurs:

1) When an alarm is issued the device is placed into **Stop** mode.
2) Read the displayed instructions.
3) Note the **Alarm** number.
4) Press the **Close** button to clear the alarm.
5) Follow the instructions to correct the alarm condition. Perform the actions in the order listed until the alarm condition is resolved.
6) Once you have cleared the alarm, press the Start button in the therapy window to restart therapy. You will hear a tone and a voice stating "Therapy Started". Additionally, the active therapy window and the Arctic Sun® Temperature Management System icon will blink.
7) If the condition does not resolve, contact Medivance Customer Support.

Alerts

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

If an Alert occurs:

1) Read the displayed instructions.
2) Note the Alert number.
3) Press the **Close** button to clear the alert.
4) Follow the instructions to correct the alert condition. Perform the actions in the order listed until the alarm condition is resolved. If the condition does not resolve, contact Medivance Customer Support.

Chapter 7 – Maintenance and Service

Cleaning and Maintenance

Cleaning and Maintenance Routine cleaning and preventive maintenance should be performed on the Arctic Sun® Temperature Management System control module every 6 months at a minimum. This consists of cleaning the external surfaces, accessories and chiller condenser, inspecting the device, and replenishing the internal cleaning solution that suppresses microorganism growth in the water reservoir and hydraulic circuit.

External Surfaces

- Clean the exterior body of the control module, fluid delivery lines, power cords and temperature cables using a soft cloth and mild detergent or disinfectant according to hospital protocol.

Condenser

- A dirty chiller condenser will significantly reduce the cooling capacity of the control module.
- To clean the condenser, wipe the dust from the exterior grill using a soft cloth. Depending on the quality of your institution's air, periodically

remove the back cover and vacuum or brush the condenser fins. At a minimum the condenser fins should be cleaned annually. Maintenance activities should be performed by qualified personnel.

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

Replenish Internal Cleaning Solution
Contact Medivance Customer Service to order internal cleaning solution.

To replenish the internal cleaning solution:
1) Drain the reservoir.
   - Turn control module power Off.
   - Attach the drain line to the two drain ports on the back of the control module. Place the end of the drain line into a container. The water will passively drain into the container.
2) Refill the reservoir.
   - From the Hypothermia therapy screen or the Normothermia therapy screen, press the Fill Reservoir button.
   - The Fill Reservoir screen will appear. Follow the directions on the screen.
   - Add one vial of Arctic Sun® Temperature Management System cleaning solution to the first bottle of distilled or sterile water.
   - The filling process will automatically stop when the reservoir is full. Continue to replace the bottles of sterile or distilled water until the filling process stops.
   - When the Fill Reservoir process is complete, the screen will close.

Software Update
Software updates will be provided from Medivance on a flash drive. Installation of software updates will be performed via the USB port on the front of the control module.

The software update feature will automatically initiate if the control module detects the proper files on a flash drive inserted in the USB port at power On.

To install software update:
1) Insert flash drive provided by Medivance into the USB port.
2) An image of a timer will display while the software update in being installed, and will disappear when the software installation process is completed.
3) After installation, the new software version will display in the **Software Version** field in **Advanced Setup**.

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

Calibration
See Arctic Sun® 5000 Temperature Management System Service Manual for calibration requirements and instructions.

Appendix A: Product Specifications

Technical Description

The Arctic Sun® Temperature Management System is a thermoregulatory device that monitors and controls patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F). The Arctic Sun® Temperature Management System System consists of the Control Module and disposable ArcticGel™ Pads.

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

The Arctic Sun® Temperature Management System pulls temperature-controlled water ranging between 4°C and 42°C (39.2°F and 107.6°F) through the ArcticGel™ Pads at approximately 0.7 liter per minute per pad. This results in heat exchange between the water and the patient.

The Arctic Sun® Temperature Management System System Control Module is a CLASS I mobile device (Type BF, IPX0 and Mode of Operation – Continuous) per classification scheme of IEC 601-1.

The Arctic Sun® Temperature Management System System Control Module meets both the electromagnetic interference and susceptibility requirements of IEC 60601-1, and is compatible with other equipment that also conforms to that standard. There is no known failure mode in the Arctic Sun® Temperature Management System System Control Module associated with electromagnetic interference from other devices. See the Arctic Sun® 5000 Temperature Management System Service Manual for the full declaration regarding electromagnetic compatibility.

Environmental Conditions
Temperature Range
Operating: .....10ºC to 27ºC (50ºF to 80ºF)
Storage: .....-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.

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

ARCTIC SUN® 5000 Temperature Management System Specifications

Parameter	Specification
Therapy Modes	Normothermia: Control Patient Hypothermia: Cool Patient, Rewarm Patient
Heater Capacity	2500 BTU/hr / 750 Watts
Circulating Fluid	Distilled or Sterile Water
Reservoir Capacity	3.5 liters
Water Flow Rate	5 liters per minute
Patient Probe Type	YSI 400 Series compatible
Patient Temperature Inputs	Patient Temp 1: control, monitor, alarm Patient Temp 2: monitor, alarm
Patient Temperature Display Range	10°C to 44°C 50°F to 111.2°F 0.1°C / °F increments
Patient Temperature Measurement Accuracy	±0.4°C (10°C to 32°C) ±0.2°C (32°C to 38°C) ±0.4°C (38°C to 44°C) Includes ±°0.1C external probe
Responses of the PCLCS (Physiologic Closed-Loop Control System)	Settling Time: ~4.5 hrs Relative Overshoot: <0.5°C Command Overshoot: <0.5°C Response Time: Warming (max) 33°C to 37°C: ~6 hrs Cooling 37°C to 33°C: ~2 hrs Steady State Deviation: 0 Tracking Error: 0 Note: All values derived from testing in simulated use.
Patient Temperature Control Range	32°C to 38.5°C 89.6°F to 101.3°F 0.1 °C/°F increments
Water Temperature Display Range	3°C to 45°C / 37.4°F to 113.0°F 0.1 °C/°F increments
Water Temperature Control Range (Manual)	4°C to 42°C / 39.2°F to 107.6°F 1 °C/°F increments
High Water Temperature Limit	36°C to 42°C / 96.8°F to 107.6°F 1 °C/°F increments
Low Water Temperature Limit	4°C to 25°C / 39.2°F to 77°F 1 °C/°F increments
Time to heat water from 20°C to 37°C	8 minutes (approximate)
Sound Pressure	Alarm Tone: 70dB to 80dB at 1 meter, repeats every 10 seconds Alert Tone: 63dB to 71dB at 1 meter, repeats every 25 seconds Reminder Tone: 65dB at 3 meters, 0.5 seconds on/20 seconds off
Mains Input	115 VAC, 60 Hz, 11.0 Amp (nominal) 230 VAC, 50 Hz, 5.5 Amp
Leakage Current	<300 µA
Operating Relative Humidity Range	5% to 70% non-condensing
Storage Relative Humidity Range	5% to 95% non-condensing
Operating Temperature Range	10°C to 27°C / 50°F to 80°F
Storage Temperature Range	-30°C to 50°C / -20°F to 120°F
Atmospheric Pressure Range	60 kPa to 110 kPa
Dimensions	Height: 35 inches (89 cm) Width: 14 inches (36 cm) Depth: 18.5 inches (47 cm)
Weight	Empty: 43 kg / 95 lbs ; Filled: 47 kg / 103 lbs

Appendix B: Symbols

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

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

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® Temperature Management System that bear the ETL Monogram have been Certified for Safety by ETL Intertek in accordance with CAN/CSA C22.2 STD 601.1-M90 and UL STD 6060.1.

Indicates high temperature part or component

Indicates that only sterile or distilled water should be used when filling the Arctic Sun® Temperature Management System Control Module

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

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

Identifies the drain port

Identifies the storage temperature range

Identifies the storage relative humidity range

Indicates electrical hazard

Do not re-use.

Risk of overbalance due to pushing, leaning, resting, etc.

Manufacturer

Appendix C: Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility. Ensure that the ARCTIC SUN® 5000 Temperature Management System is installed and used according to the electromagnetic compatibility information provided. The following are guidance and manufacturer's declarations regarding electromagnetic compatibility for the ARCTIC SUN® 5000 Temperature Management System.

- The use of accessories or cables other than those specified or sold by Medivance is not recommended. Use of unapproved accessories or cables may result in increased emissions or in decreased immunity of theARCTIC SUN® Temperature Management System.
- If the ARCTIC SUN® 5000 Temperature Management System is used directly adjacent to or stacked with other equipment, the user should periodically observe the ARCTIC SUN® 5000 Temperature Management System device to verify it operates normally in that environment.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

1.1 EN/IEC 60601-1-2 Table 1		
Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ARCTIC SUN® 5000 Temperature Management System is intende d for use in the electromagnetic environment specified below. The customer or the end user of the Arctic Sun 5000 Temperature Management System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ARCTIC SUN® 5000 Temperature Management System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ARCTIC SUN® 5000 Temperature Management System unit is suitable for use in all establishments other than domestic, establishments and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

1.2 EN/IEC 60601-1-2 Table 2			
Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ARCTIC SUN® 5000 Temperature Management System unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the ARCTIC SUN® 5000 Temperature Management System unit should assure it is used only in such an environment.			
Immunity Test	IEC60601 test level	Compliance Level	Intended Electromagnetic Environment
Electromagnetic discharge (ESD) IEC 61000-4-2	+- 6kV contact +- 8kV air	+- 6kV contact +- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+-2kV for power supply lines +-1kV for input/ output lines	+-2kV for power supply lines +-1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+-1kV differential mode (line-line) +-2kV common mode (line-earth)	+-1kV differential mode (line-line) +-2kV common mode (line-earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ARCTIC SUN® 5000 Temperature Management System unit requires continued operation during power mains interruptions, it is recommended that the ARCTIC SUN® 5000 Temperature Management System unit be powered from an uninterruptible power supply with sufficient capacity to run the unit for the maximum required time of interruption.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Arctic Sun® 5000 Temperature Management System unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the Arctic Sun® 5000 Temperature Management System unit should assure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance Level	Intended Electromagnetic Environment
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Arctic Sun® 5000 Temperature Management System unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Arctic Sun® 5000 Temperature Management System unit is used exceeds the applicable RF compliance level above, the Arctic Sun® 5000 Temperature Management System unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Arctic Sun® 5000 Temperature Management System unit.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

1.4 EN/IEC 60601-1-2:2007 Sub-clause 5.2.2.2 Table 6:

Recommended separation distances between portable and mobile RF communications equipment and the Arctic Sun® 5000 Temperature Management System unit

RF communications equipment can effect medical electrical equipment. The Arctic Sun® 5000 Temperature Management System unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Arctic Sun® 5000 Temperature Management System unit can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the Arctic Sun® 5000 Temperature Management System unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	.38	.38	.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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