Guidelines

Using the Arctic Sun®
Temperature Management System
for Cooling Applications.

Medivance®

PREFACE

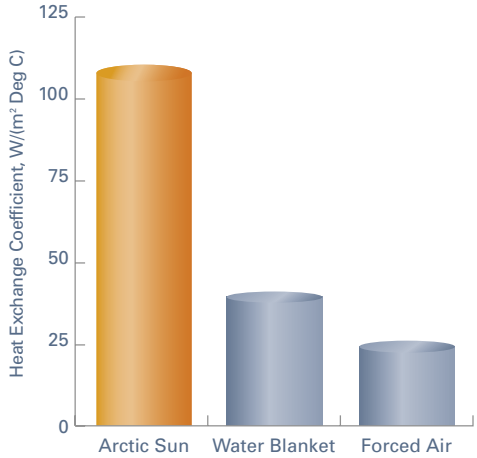
The Medivance Arctic Sun 2000 is a new generation temperature management system that features an efficient, noninvasive approach to precisely and automatically control patient temperature. Unlike conventional cooling technologies, the Arctic Sun can effectively transfer energy through the skin to alter core body temperature rapidly and consistently. Because of its high efficiency in energy transfer, the Arctic Sun **should not** be operated in the same manner as other cooling devices, such as forced air, water blankets, ice or fans. The automated control algorithm works precisely to drive the patient to a target temperature with minimal overshooting. Care needs to be taken to observe and record patient and water temperature frequently and verify temperature from additional sites. A full list of cautions has been provided on page 14 and 15.

This booklet has been designed to provide guidelines for the safe use of the Arctic Sun during procedures that require cooling and/or rewarming. It is important to recognize that these are merely guidelines. Each patient's medical history, current condition, the goal of therapeutic temperature management, and current medications should be reviewed carefully prior to initiating a treatment.

Refer to the Operator's Manual for complete instructions for using the Arctic Sun 2000.

OVERVIEW OF THE CONCEPT

Water immersion has been reported to be the most effective way of modifying core body temperature non-invasively.[1] Water and/or ice baths are impractical solutions for therapeutic temperature management because of imprecise control and the risk of overshooting patient target temperature. The Arctic Sun transfers heat by direct conduction and approximates the performance of water immersion by providing high energy transfer and precise control.[2]



Bench test and human volunteer studies of heat exchange co-efficient comparing the Arctic Sun, traditional water blanket, and forced air systems.

[1] Plattner O, Kurz A, Sessler DI, Ikeda T, Christensen R, Marder D, Clough, D. Efficacy of Intraoperative cooling methods. Anesthesiology 1997; 87: 1089-95.

[2] English, MJ. Department of Anesthesia, Montreal General Hospital, Quebec. Heat exchange coefficient of the Arctic Sun Energy Transfer Pads.

OVERVIEW OF THE ARCTIC SUN SYSTEM

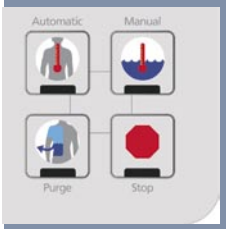
The Arctic Sun Control Module – Model 2000

The Medivance Arctic Sun Temperature Management System includes the Arctic Sun Control Module and the Arctic Sun Energy Transfer Pads. Patient temperature can be controlled within a range of 33° to 37°C (91.4° to 98.6°F). The temperature of the water is automatically adjusted in response to actual patient temperature to achieve the desired patient target temperature. The temperature of circulating water is controlled between 4° and 42°C (39.2° to 107.6°F).

The Arctic Sun circulates water through the Energy Transfer Pads under negative pressure. This allows the pads to be thin and conformable and minimizes the chance of leakage in case of inadvertent puncture or disconnection. To ensure flow and prevent leakage, the surface of the patient's bed should be placed between 30 and 60 inches (75 to 150 cm) above the floor.

The Arctic Sun is a closed system in which the water circulates through the pads and through the system. At no time does the water come in contact with the patient.

There are four main operating modes:



Automatic Mode
controls patient temperature and should always be used when cooling a patient

Manual Mode
controls temperature of circulating water – not patient temperature

Purge Mode
always use to empty pads at the end of a procedure, or when disconnecting the system for a period of time

Stop Mode
halts all current modes of operation and provides access to menu options

The Arctic Sun contains several features and custom parameters to ensure safe and individual patient management. Specific parameters can be set for individual patients or protocols:

Automatic Mode
Patient target temperature – 33° to 37°C (91.4° to 98.6°F)

Manual Mode
Water target temperature – 4° to 42°C (39.2° to 107.6°F)

Automatic Mode
Maximum water temperature – 32° to 42°C (89.6° to 107.6°F)

Automatic Mode
Minimum water temperature – 4° to 32°C (39.2° to 89.6°F)

The latter two parameters allow the operator to determine the highest or lowest temperature that the water will reach during cooling or warming. This may be required for patients who have fragile skin, adequate but below normal tissue perfusion, or for general patient comfort.

While there are multiple safety alarms in the Arctic Sun, the following are a few key alarms that will stop an active mode until the operator intervenes:♦

- **Water temperature > 42.5°C (108.5°F)**
- **Water temperature < 3.5°C (38.3°F)**
- **Patient temperature > 38°C (100.4°F) with water temperature > 38°C (100.4°F)**
- **Patient temperature < 32°C (89.6°F) with water temperature < 32°C (89.6°F)**
- **In Automatic Mode, temperature probe not placed and/or not connected to the Arctic Sun**
- **Insufficient water to operate the system**
- **Not able to sustain stable patient temperature**
- **Patient temperature below control range of 33°C (91.4°F)**

There are custom alerts that can be programmed in the machine, which will cause the system to alarm, but will not stop the mode in progress:

- **User defined patient high alert**
- **User defined patient low alert**

These alerts are available to either notify the clinician when a patient reaches a specific temperature or to establish a low or high temperature limit notification.

♦ Refer to Operator's Manual for complete list of alarms.

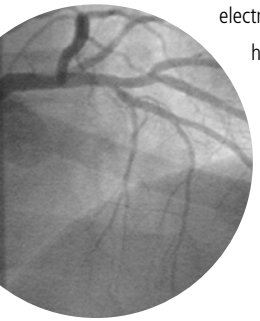
OVERVIEW OF THE ARCTIC SUN ENERGY TRANSFER PADS

The Arctic Sun Energy Transfer Pads™

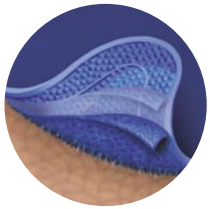
The Arctic Sun Energy Transfer Pads are applied directly to intact skin. Based on the patient's body temperature and a predetermined target temperature, temperature-controlled water will circulate through the pads in automatic mode. Patient skin integrity should be assessed often during treatment with the Arctic Sun. Suggested times for examining skin include once a shift or every eight hours. Skin should be checked more frequently if a patient has been cooled for prolonged periods of time or if a patient's condition warrants it. It is the operator's responsibility to assess the appropriate water temperatures for the patient's condition, the duration of the cooling, and the use of pressure related devices.

Other events during a procedure may impact skin integrity, such as hypoperfused states (hypotension) and high dose or multiple vasopressors. With extreme peripheral vasoconstriction and poor tissue perfusion, blood flow to the skin will be reduced and skin temperatures may be too cold.

The Arctic Sun Energy Transfer Pads are single use, biocompatible, latex-free and radiolucent. They can be used on the same patient for 72 hours consecutively. Pads can remain in place during radiographic imaging, even with the water flowing. The pads can be placed over ECG electrodes and defibrillator pads, but they should never be placed over grounding electrodes, such as electrocautery or RF ablation grounding pads. The pads do not contain metallic material and are MRI compatible.
NOTE: Verify whether the patient temperature probe is MRI compatible.



The Arctic Sun Energy Pads consists of a three layer construction:



1. An outer foam layer provides insulation for heat loss into the environment. Dimples molded on the foam layer help distribute flow through the pads and prevent the film from collapsing on itself.
2. An ultra-thin film seals the fluid channels.
3. A biocompatible hydrogel material adheres to the skin. It is comprised of 50% water and acts as an excellent media for heat conduction to and from the skin.

Unlike conventional pressure sensitive adhesives, such as medical grade tape, the adhesive properties do not increase over time, which allows for repeated removal and replacement. There are no known allergies or sensitivities to the hydrogel material used in the Arctic Sun Energy Transfer Pads. Hydrogel materials have common medical applications including ECG electrodes, electrocautery grounding pads, and for use in wound healing. While hydrogel material has been used in wound healing, the non-sterile Arctic Sun Energy Transfer Pads were not intended to be used on open wounds or on patients with compromised skin integrity.

Arctic Sun Energy Transfer Pad Placement

The Energy Transfer Pads cover approximately 40% of the patient's total body surface area, which is the required amount to properly and efficiently cool a patient. Temperature controlled water circulates from the control module through all pads under negative pressure at a flow rate of approximately 2.5 liters per minute resulting in heat exchange from the water to the patient. The pads are placed on the back, abdomen, and legs as shown below:

NOTE: Flow rates are displayed in the lower right hand corner of the display screen. With all pads placed on the patient, it is important to maintain flow rates above 2.3 liters per minute to ensure adequate thermal transfer. If flow is lower, refer to the troubleshooting guide in the Operator's Manual.


STEP 1


STEP 2


STEP 3


STEP 4


STEP 5


STEP 6

1. Align top of pad with axilla of outstretched arm. Place the long side of the pad along the side of the spine.
2. Wrap the pad from back to front, ensuring that the lines are lying anteriorly.
3. Align the pad lines with the knee and point downward. Wrap the long end of the pad laterally and overlap medially if needed.
4. Turn the patient and repeat on the other side, leaving a space along the spine.
5. Wrap the second pad around the other leg, ensuring that the shorter edge is placed medially and the longer side is wrapped laterally.
6. (If needed) For additional surface coverage, use the Universal Pad on the abdomen.

It is essential that 40% of the patient's body surface area is covered when cooling with the Arctic Sun. If coverage is inadequate, patient care may be significantly altered in the following ways:

- Time to target might be significantly prolonged
- Patient may never reach target temperature
- Circulating water may remain at the lowest temperature for prolonged periods of time

CLINICAL APPLICATIONS

The Arctic Sun Model 2000 may be used in patients whose condition requires control of patient temperature in a range of 33° to 37°C (91.4º to 98.6ºF). In most instances, the Arctic Sun is used in intensive care units and/or emergency departments.

SPECIAL CONSIDERATIONS WHEN COOLING

When initiating a cooling treatment, it is essential to identify the main objectives for the patient and the key factors in successful cooling therapies. The physicians and nursing staff should determine an acceptable patient target temperature. At the time of initiation of cooling, the staff should also discuss the cooling strategy for the patient and the duration of cooling. This includes the maximum number of hours in which the patient is expected to reach target, the length of the rewarming time, and when the therapy should be terminated. The following are key considerations when cooling with the Arctic Sun:

1. Shivering

Unless a patient has severely compromised brain stem function or is anesthetized, it is inevitable that shivering will occur in patients during cooling. Shivering and vasoconstriction are the body's natural response to cold and occur when core temperature falls below the body's internal set point. This set point may vary from patient to patient, which is the reason why shivering may occur at different temperatures in different people. Even a patient with a fever may shiver during cooling because the internal temperature set point has been reset to a higher than normal level.

[3] Kurz A, Ikeda T, Sessler DI, Larson MD , Bjorksten AR, Dechert M, Christensen R: Meperidine decreases the shivering threshold twice as much as the vasoconstriction threshold. Anesthesiology 1997; 86: 1046-54

[4] Mokhtarani M, Mahgoub AN, Morioka N, Doufas AG, Dae M, Shaughnessy TE , Bjorksten AR, Sessler DI: Buspirone and meperidine synergistically reduce the shivering threshold. Anesth. Analg. 2001; 93: 1233-9

a. Shivering should be managed pharmacologically per the physician's orders. Most narcotics and sedatives do not adequately prevent or control shivering. Some drugs known to reduce the shivering threshold include meperidine (Demerol®)[3], buspirone (BuSpar®)[4], dexmedetomidine (Precedex®)[5] and skeletal muscle relaxants or paralytics, such as pancuronium[6].

   Significant doses of the drugs may be required to manage patient comfort and shivering. As a consequence, prior to cooling, the physician should determine whether the patient is an appropriate candidate for the anti-shivering drug regimen.

b. Shivering may also be reduced non-pharmacologically with the use of warming devices such as hand and foot warmers, facial warmers, or warmed air or oxygen[7].

c. Shivering increases metabolic rate and oxygen demand, which may result in fatigue, hypertension, tachycardia, and other adverse events.

d. Shivering interferes with the cooling process. If a patient is shivering, it is unlikely that the patient will achieve or maintain a target temperature.

2. Cooling and Warming Rates

Temperature change is not instantaneous after cooling or warming is initiated. Factors including patient weight, morphology, percentage of body fat, sex, age, and level of sedation may impact the rate of temperature change in the patient. Thermal transfer occurs from the peripheral compartment to the core. Temperature generally begins changing within 15 minutes to 45 minutes after cooling or warming begins. The rate of temperature change is also dependent on the site of the temperature probe. Temperatures recorded from different sites may vary slightly but will generally come into equilibrium after the patient temperature stabilizes.

3. Temperature Control in Automatic Mode

When cooling, the Arctic Sun should always be used in Automatic Mode.

a. A temperature probe must be placed in the patient and connected to the Arctic Sun to control temperature in Automatic Mode.

[5] Doufas AG, Lin CM, Suleman MI, Liem EB, Lenhardt R, Morioka N, Akca O, Shah YM, Bjorksten AR, Sessler DI: Dexmedetomidine and meperidine additively reduce the shivering threshold in humans. Stroke 2003; 34: 1218-23

[6] Polderman KH: Application of therapeutic hypothermia in the intensive care unit. Intensive Care Med 2004; 30: 757-769

[7] Iaizzo PA, Jeon YM, Sigg DC: Facial warming increases the threshold for shivering. J Neurosurg. Anesthesiol 1999; 11: 231-9

Good patient temperature management requires an accurate temperature site. The Arctic Sun accepts YSI-400 compatible temperature probes, such as nasopharyngeal, esophageal, bladder and rectal probes. However, when cooling a patient, consider the reliability and stability of the probe placement, e.g. an incontinent patient may repeatedly expel the rectal probe and render a false temperature, potentially resulting in inadequate temperature control. When using a bladder probe, there must be a continuous flow of urine present in the bladder to obtain a reliable temperature.

b. Automatic mode employs an algorithm that receives temperature feedback from the patient, which causes the temperature of the circulating water in the pads to increase or decrease to achieve a preset target.

c. During the initiation of cooling, circulating water temperature will decrease to approximately 4° to 6°C (39.2° to 42.8°F) and will remain at or about this temperature until the patient's temperature nears the target.

d. When cooling, water temperature will begin to increase before the patient reaches the target temperature. This is normal and occurs to minimize the chance of overshooting the target temperature.

e. When the patient reaches the preset target temperature, continue to operate the Arctic Sun in Automatic Mode. The control algorithm in the machine will continue to manage the patient's temperature to maintain the target. The Arctic Sun should remain ON and in Automatic Mode even after target temperature is achieved for optimal control of patient temperature. The Stop key should NOT be pressed when the patient achieves the target temperature. Each time the system is stopped or turned off, the control algorithm requires additional time to recalculate the patient's temperature and rate of change. The only time the system should be stopped is if the patient must be transferred, if the system appears to be non-functioning, i.e. cannot properly warm or cool, or with physician's order.

f. When the patient reaches the target temperature, the circulating water temperature will rise to a level that will maintain the patient at target temperature. This temperature is generally in the range of 18° to 25°C (64.4° to 77°F).

g. If the patient's temperature begins to increase before actual rewarming begins, the water temperature will automatically decrease to ensure that the target temperature is maintained.

4. Inability to Reach Target Temperature

The Arctic Sun was designed to efficiently warm and cool patients noninvasively. There may be times when a patient does not achieve target temperature in a reasonable amount of time. During the cooling process, always verify the following information to ensure successful cooling:

a. Obtain consensus on the target temperature and range if applicable.

b. Verify that all custom parameters have been properly set including:

   i. Patient target temperature

   ii. Automatic mode – maximum water temperature is set to the correct limit.

   iii. Automatic mode – minimum water temperature is set to the correct limit.

   iv. Time to target is set to the correct rate (see setting time to target on page 13).

c. If the patient does not reach target temperature within an agreed upon period of time for the individual patient, the physician and nursing staff must determine whether:

   i. The patient is shivering and needs additional medication to prevent shivering.

   ii. The full recommended number of pads was used.

   iii. The therapy should be discontinued.

   iv. The lowest temperature achieved becomes the new target temperature.

5. Defibrillating the Patient While the Arctic Sun is Operational

Patients can be defibrillated while the Arctic Sun is operational and while water is flowing. Defibrillation pads can be placed under the Energy Transfer Pads. The Energy Transfer Pads can be peeled back to access defibrillation sites. NOTE: Do not defibrillate over the Arctic Sun Energy Transfer Pads.

6. Effect of Vasoactive Drugs on Cooling Rates

It is not uncommon to see some peripheral vasoconstriction when cooling or vasodilatation when warming. Either response may have an impact on the cooling and/or warming rate during the initiation of the therapy.

a. Both cooling and warming rates can be affected by vasoactive drugs. Drugs such as neuromuscular blockades, anesthesia, nitroglycerin, nitroprusside, and narcotics can cause instant and profound vasodilatation and cause a rapid decrease in temperature when cooling, or rapid rise in temperature when warming.

   Vasoconstrictive drugs, such as epinephrine, neosynephrine, and Levophed®, may cause rapid vasoconstriction and cause a decrease in the cooling and/or warming rates.

   As a consequence, any patients receiving vasoactive drugs during the initiation of cooling or warming should have their temperatures closely monitored.

b. If a patient is given a drug with vasodilating properties when the patient's temperature approaches the target, it is possible to overshoot the target temperature. The Arctic Sun temperature control algorithm will respond to the rapid decrease in temperature and will attempt to compensate and warm or cool the patient quickly. NOTE: Since the peripheral compartment must be warmed prior to the core, there will be a lag in rewarming.

   i. If drugs with vasodilating properties are to be given during a cooling procedure, administering them early in the cooling process will help the temperature to decrease rapidly and limit the potential for overshooting the target.

   ii. Consistent administration of the neuromuscular blockades, narcotics, or vasodilators will limit peaks and valleys in temperature control.

   iii. If it is unavoidable to administer drugs with vasodilating properties after the cooling therapy has been in process for an hour or more, be aware that the patient may overshoot the target temperature by as much as a degree. NOTE: Do not stop the machine if the patient overshoots the target. The machine will automatically rewarm the water flowing through the pads to rewarm the patient. The machine should only be stopped if the water temperature does not rise to warm the patient, or on the recommendation of a physician.

   iv. If drugs with vasoconstrictive properties are administered, note the time and dose, and observe if delays in cooling or warming occur.

REWARMING: TIME TO TARGET FEATURE

After the cooling cycle has been completed, the Arctic Sun has a special feature that will allow patients to be rewarmed at a specific rate. This feature is known as the "Time to Target" feature and can be enabled in the Setup Screen from the Main Menu. If required, ask your Medivance representative to enable this feature or refer to the Operator's Manual or Quick Reference Guide for further instructions. Once enabled, a new screen will be displayed in the custom menu that will read "Warm Max - Automatic Mode - Enter to Change". The rate of rewarming is 0.05°C to 0.5°C/hour (0.1° to 0.9°F/hour).

For fast control during cooling, the rewarming rate should be set on Max (maximum) and should not be changed until warming begins.

DOCUMENTATION

When using the Arctic Sun, documentation should be based on hospital protocols and standards. Frequent documentation of the following parameters is important in monitoring the patient and success of the cooling treatment:

- Initial patient temperature prior to cooling
- Initial time of cooling
- Time target temperature achieved
- Patient temperature displayed on the Arctic Sun
- Water temperature displayed on the Arctic Sun
- Verification of patient temperature using secondary temperature site
- Condition of the skin under the pads
- Time of rewarming
- Time of termination of treatment

CAUTIONS

The following is the full list of cautions for using the Arctic Sun 2000:

1. This product is to be used by or under the supervision of trained, qualified medical personnel.
2. Federal law (USA) restricts this device to sale, by or on the order of a physician.
3. Use only distilled or sterile water. The use of other fluids will damage the Arctic Sun Model 2000.
4. 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.
5. The operator is responsible to determine the appropriateness of custom parameters.
6. 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.
7. The operator must continuously monitor patient temperature in Manual Mode. Patient temperature will not be controlled by the Arctic Sun in Manual Mode.
8. 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.
9. 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.
10. Due to the system's high efficiency, Manual Mode is not recommended for non-surgical treatments that require cooling.
11. 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.
12. 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.
13. 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.
14. The Arctic Sun Model 2000 is for use only with the Arctic Sun Energy Transfer Pads.
15. The Arctic Sun Energy Transfer Pads are only for use with an Arctic Sun Model 2000.
16. The Energy Transfer 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. Energy Transfer Pads should not be placed on a sterile field.
17. Use pads immediately after opening. Do not store pads once the kit has been opened.
18. Do not allow circulating water to contaminate the sterile field when patient lines are disconnected.

19. The Energy Transfer Pads must be changed after 72 hours of use. After 72 hours use, the pads should be removed. If temperature management is to continue, a new set of pads should replace the old pads.

20. Do not puncture the Energy Transfer Pads with sharp objects. Punctures will result in air entering the fluid pathway and may reduce performance.

21. If accessible, examine the patient's skin under the Energy Transfer Pads often, especially those at higher risk of skin injury.

22. 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 Energy Transfer Pads. Do not place positioning devices under the pad manifolds or patient lines.

23. 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.

24. 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.

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

26. Do not place Energy Transfer Pads over an electrosurgical grounding pad. The combination of heat sources may result in skin burns.

27. Carefully remove Energy Transfer Pads from the patient's skin at the completion of use.

28. Any device connected to the RS232 data port must comply with the applicable IEC standard for that device.

29. 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.

30. 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.

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