



KIMBERLY-CLARK* Patient Warming System

Clinical Guidelines



*Superior warming and improved
outcomes mean one less worry.*

 **Kimberly-Clark**

*Trusted Clinical Solutions**

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Introduction

Kimberly-Clark is pleased to offer these Clinical Guidelines for use with the KIMBERLY-CLARK* Patient Warming System M1000 and M100. The recommendations are compiled from Kimberly-Clark's experience in thousands of surgical procedures.

This guideline has been designed to promote safe use of the KIMBERLY-CLARK* Patient Warming System during surgical procedures that require rewarming or temperature management. It is important to recognize that although these guidelines exist, each patient's medical history, condition, and current medications should be considered prior to initiating thermal treatment.

Unintentional hypothermia may occur for a variety of reasons, including exposure to cold environments, brain injury, or complex surgical procedures. During surgery, a patient typically experiences mild hypothermia due to the effect of general anesthesia on the body's thermoregulatory system and prolonged exposure of internal organs. Mild hypothermia in the medical or surgical patient has been proven to prolong the time to extubation, contribute to coagulopathies, increase the chance of infection, and increase cardiac demand. The use of the Patient Warming System is designed to be an effective means of counteracting this drop in patient temperature by applying heat to the patient through a set of patented hydrogel heat-conductive pads.

If you have any questions regarding these Clinical Guidelines, please contact your sales representative or clinical specialist.

Do's

1. Do check and document skin integrity when placing the pads over well perfused intact skin.
2. Do assess patient for underlying medical or physiological conditions that may make the patient 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.¹
3. Do use pads immediately after opening the foil package.
4. Do ensure the fluid lines fit securely in manifold receptacle.
5. Do pre-warm pads for patient comfort.
6. Do document control unit serial number and thermal pad lot number.
7. Do monitor the patient's core temperature during temperature management therapy.
8. Do remove pads while they are warm and discard. (Removing cold pads may result in skin irritation or patient discomfort.)
9. Do shut off machine at the end of the day.
10. Do wipe down fluid delivery lines and control unit between uses with a standard disinfectant solution.
11. Do use sterile or distilled water in the control unit.
12. Do clean the internal reservoir every 3 months.
13. Do note alarm code number before silencing alarm.

Precautions

1. Don't place thermal pads over or under electrocautery (Bovie) pads.
2. Don't use positioning devices (such as towels, shoulder rolls/pads, bean bags, kidney rests, Jackson frames, etc.) under the thermal pads.
3. Don't place thermal pads on limbs with low perfusion. (Pads may be placed on the thighs at the clinician's discretion; however, caution is advised if low or no perfusion (such as femoral cannulation or balloon pump insertion) is anticipated or performed. Place thermal pads on the leg that is not cannulated or disconnect the pad during loss of perfusion to the limb.)
4. Don't use saline or tap water in the control unit.
5. Don't allow prep solutions or other fluids to pool between the patient and the thermal pads.
6. Don't allow patient to lie on manifold or clear fluid delivery lines on top of the pads.
7. Don't place thermal pads on skin that has signs of open wounds, burns, rashes, or ulcerations.
8. Don't leave thermal pads on patients for more than 24 hours.
9. Don't use adhesive tapes if patient is sensitive to tapes/adhesives.
10. Don't place pads in the sterile field.
11. If the pads are positioned underneath the patient, maximum water target temperature should not exceed 41°C.

Start-up Procedure

- 1) Press the ON/OFF Switch to the ON position. Push the Manual Mode Button (unit will begin to warm). Set water target temperature to 38°- 41°C. Connect the fluid lines to the pads and allow the pads to warm.
- 2) Inspect and document skin integrity in the area of thermal pad application and determine if thermal pads should be applied (avoid open wounds, burns, rashes, and ulcerations).
- 3) Remove liner and apply pre-warmed pads to the patient.
- 4) Confirm that the thermal pads are lying smoothly against the skin and that the fluid lines are hanging freely (not occluded).
- 5) Temperature Modes (See specific Temperature Mode Guidelines below).

MANUAL MODE

- For some surgical procedures where the clinician may prefer direct control of the amount of heat provided to the patient, the KIMBERLY-CLARK* Patient Warming System M1000 Control Unit may be run in Manual Mode.
- When operating the Patient Warming System M1000 Control Unit in Manual Mode, it is important to remember that patient temperature is not being controlled by the control unit. It is the responsibility of the clinician or operator to monitor patient temperature and adjust the water target temperature appropriately during Manual Mode operation.

AUTOMATIC MODE

- After the temperature probe is placed and the temperature is stable, switch to Automatic Mode at a patient target temperature setting of 33° to 37°C (Most patients require a patient target temperature of 37°C.)
 - Automatic Mode will utilize the MAX pre-set water temperature to attempt to bring the patient target temperature setting to 33° - 37°C.
- 6) Document the serial # of the control unit, temperature settings and lot # of the thermal pads.
 - 7) At the end of treatment, purge the thermal pads, remove carefully and discard. Inspect and document the patient treatment area. If needed, thermal pads may be left on the patient for up to 24 hours of continuous use and transferred with the patient to the recovery area for continued warming.

On-Pump Cardio-Pulmonary Bypass Guidelines

- 1) Press the ON/OFF switch to the ON position. Push the Manual Mode button (unit will begin to warm). Set water target temperature to 38°-41°C. Connect the fluid lines to the pads.
- 2) Inspect and document skin integrity in the area of thermal pad application and determine if thermal pads should be applied. (Avoid open wounds, burns, rashes, and ulcerations.)
- 3) Remove liners and apply pre-warmed pads to the patient.
- 4) Confirm that the thermal pads are lying smoothly against the skin and that the fluid lines are hanging freely (not occluded).
- 5) During pump run, do not turn off the KIMBERLY-CLARK* Patient Warming System.
- 6) The water target temperature may be reduced during the pump run, depending on patient target temperature.
- 7) At the initiation of rewarming, increase the water target temperature to 41°C in Manual Mode.

Special Case: Off-Pump Coronary Artery Bypass to On-Pump Coronary Artery Bypass

- 1) At the time of conversion to an on-pump procedure, do not turn off the Patient Warming System.
- 2) The water target temperature may be reduced during the pump run, depending on patient target temperature.
- 3) At the initiation of rewarming, increase the water target temperature to 41°C in Manual Mode.

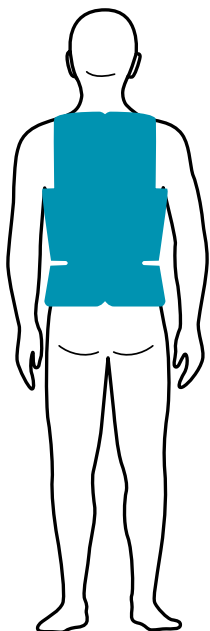
Special Cases: Deep Hypothermia and Circulatory Arrest

- 1) Start at 38°C in Manual Mode; once the patient is asleep, press the STOP button. **WARNING: DO NOT OPERATE UNIT DURING DEEP HYPOTHERMIA OR CIRCULATORY ARREST.**
- 2) At initiation of re-warming — when the patient has reached 28°C — start the control unit at 38°C, keeping the water temperature target within 10° C of patient's core temperature — increase to a maximum water temperature target of 41° C.

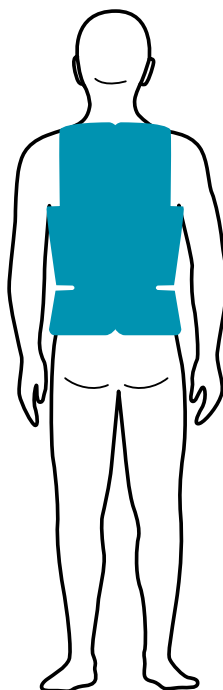
End of Treatment

- 1) At the end of treatment, document the serial number of the control unit, temperature settings, and lot number of the thermal pads.
- 2) Purge the thermal pads, remove carefully, and discard. Inspect and document the patient treatment area. If needed, thermal pads may be left on the patient for up to 24 hours on continuous warming and transferred with the patient to the recovery area for continued warming.

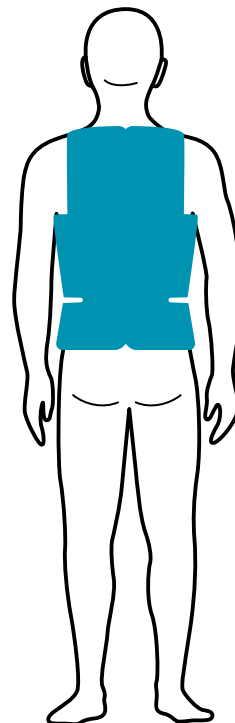
Split Torso Pad Size Selection



Small
<5'3"
<160cm



Medium
5'3" – 5'8"
160cm – 173cm



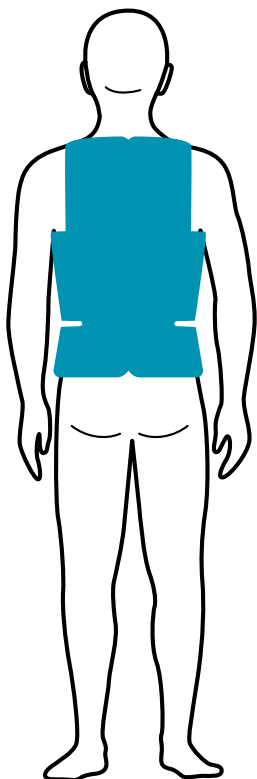
Large
>5'8"
>173cm

Pad Placement

KIMBERLY-CLARK* Warming Pads can be placed anywhere there is well-perfused, intact skin. The combination of bean bags, shoulder rolls, or other rigid positioning devices and warming pads could contribute to an increased risk of pressure-related skin injury and are not recommended. Suggestions for possible pad placement are as follows:

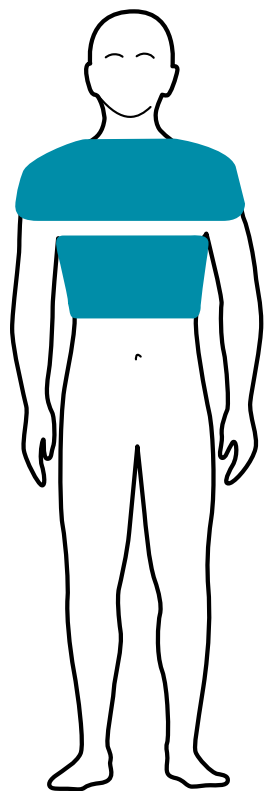
Supine Position, Posterior

Thermal Pad Recommendation: **Torso, S, M, or L**

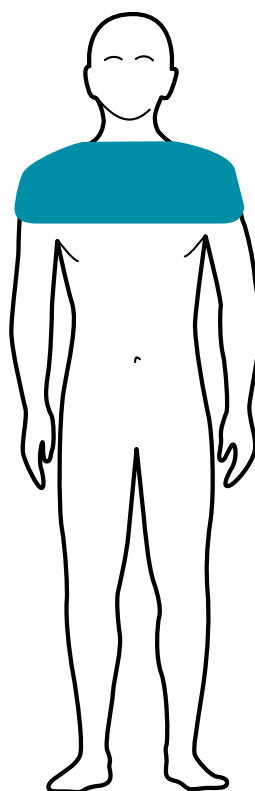


Supine Position, Upper Torso

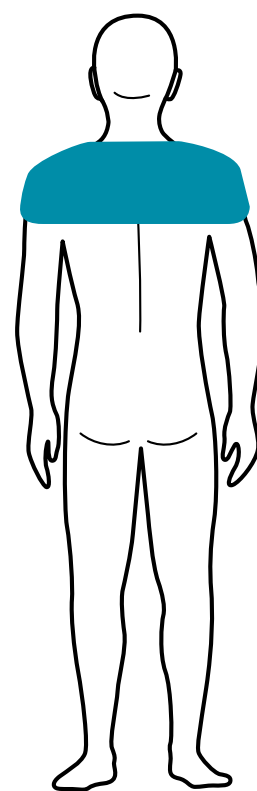
Thermal Pad Recommendation: **Universal, Large**



Primary

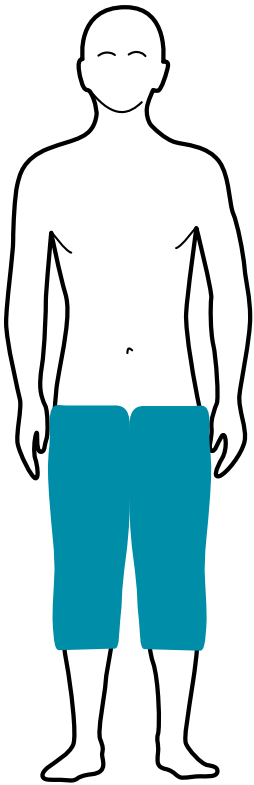


Alternative

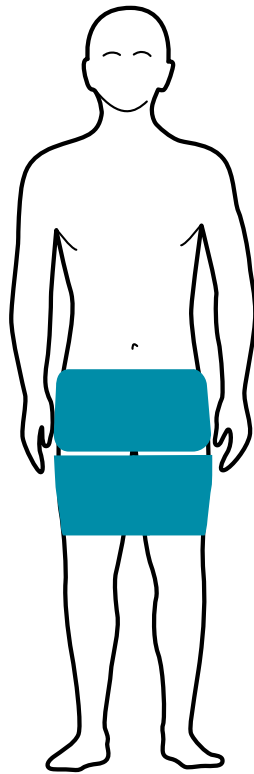


Supine Position, Lower Torso

Thermal Pad Recommendation: **Universal, Large**



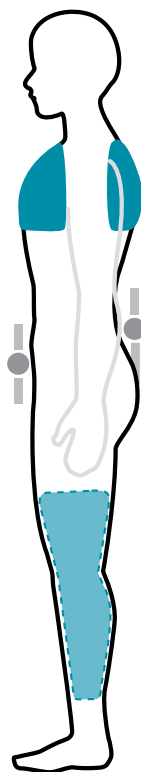
Primary



Alternative

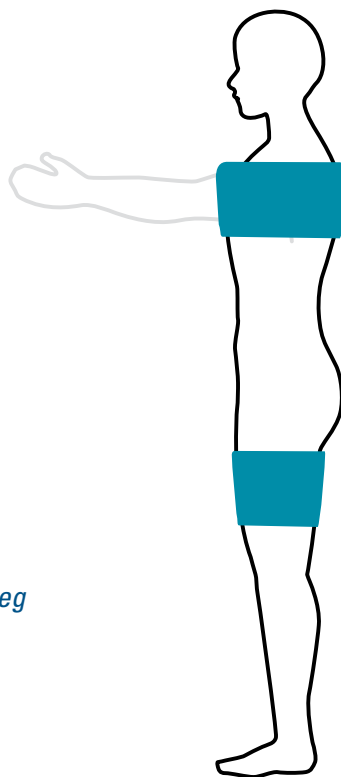
Lateral Position

Thermal Pad Recommendation: **Universal**, Large and Small



Primary

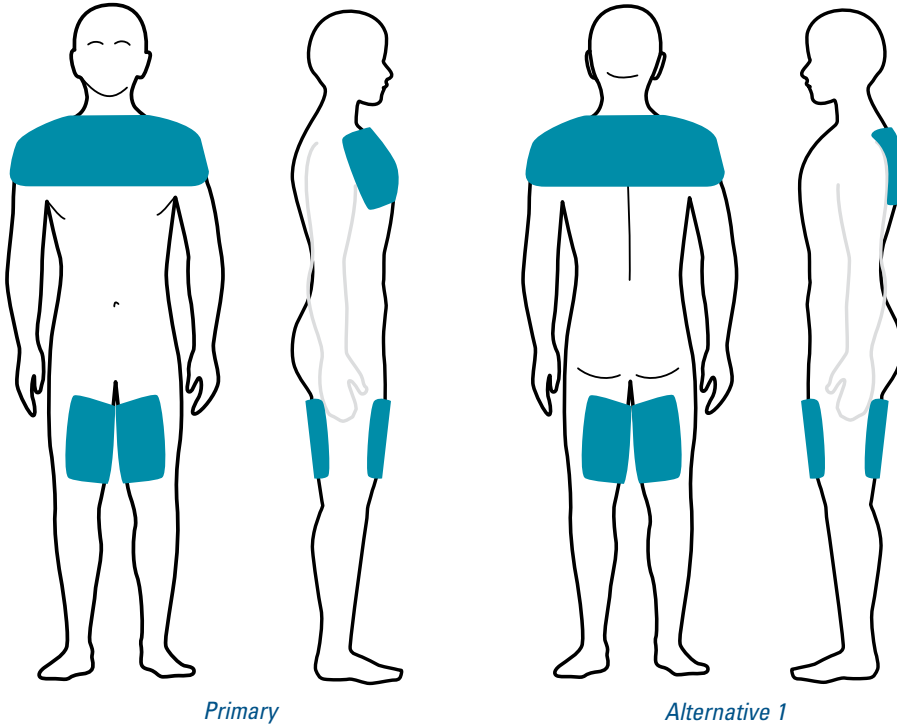
NOTE:
Pad is on Medial LOWER leg



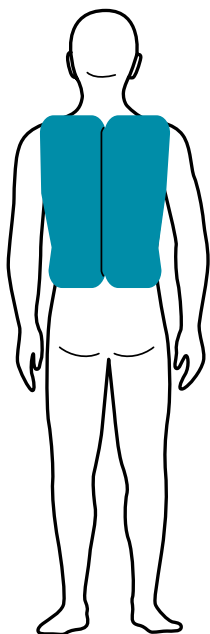
Alternative

Lithotomy Position

Thermal Pad Recommendation: **Universal**, Large



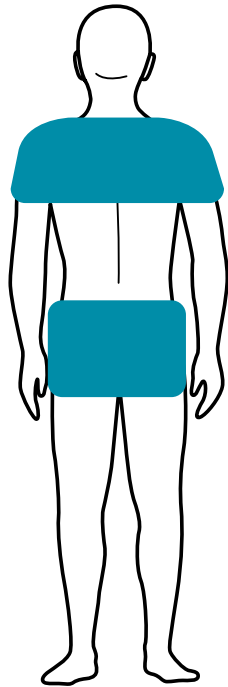
Thermal Pad Recommendation: **Torso S, M or L**



Posterior — Alternative 2

Prone Position

Thermal Pad Recommendation: **Universal, Large**



Post O.R. Guidelines

In most cases, thermal pads will be removed at the end of the surgery and prior to transferring the patient to the recovery unit. However, should the specific situation warrant additional postoperative warming, the following guidelines are recommended:

Use in the Patient Care Unit after Transfer from the Operating Room

- 1) If the patient is arriving directly from the O.R., the O.R. should inform the appropriate unit that the patient will be arriving with thermal pads in place.
- 2) Place the control unit in Manual Mode (water control) with a water target temperature of 40°C. Pre-warm the unit for 15 minutes prior to patient arrival.
- 3) Upon patient arrival to the unit, hang fluid line manifolds on each side of the bed or place beside the patient, on top of the mattress. Connect thermal pad fluid lines to the manifold.
- 4) If a patient temperature probe is in place, connect to the control unit and place the system in Automatic Mode (patient temperature control) with a patient temperature target of 37°C. Automatic Mode will utilize the MAX water temperature to attempt to bring the patient to the target of 37°C. The Manual Mode setpoint does not impact Automatic Mode operation.
- 5) Monitor the patient's temperature according to unit protocols and policy.
- 6) **Remove the adhesive tapes from contact with the patient's skin. The tapes on the edges of the thermal pads are intended to prevent prep solutions from pooling under the thermal pads and, therefore, are not needed for warming outside the OR. The thermal pads will continue to adhere to the patient.**
- 7) Discontinue thermal treatment when the patient's temperature reaches the established standard according to the unit protocol and policy. Thermal pads may be left on the patient for up to 24 hours of **continuous use. If thermal treatment is to continue after 24 hours, a new set of pads should replace the old pads.** Ensure pads are warm prior to removal.
- 8) At the end of treatment, purge the thermal pads, remove them carefully, and discard them. Inspect and document the patient treatment area.

Trauma Arrival Guidelines

Patient Arriving to Trauma/ICU without Thermal Pads

- 1) Follow normal start-up procedure for the Control Unit.
- 2) Place the control unit in Manual Mode with a water temperature target of 41°C if pads are placed posterior and 42°C if pads are placed anterior.
- 3) Once the patient arrives to the unit, inspect and document skin integrity in the area of thermal pad application and determine if thermal pads should be applied (avoid open wounds, burns, rashes, and ulcerations).
- 4) Select appropriate thermal pads based on available surface area and patient size using the rule of 9's as a guide.
- 5) Pre-warm thermal pads by connecting the fluid lines to the pads.
- 6) Once pads are warm, remove liner and apply them to the patient.
- 7) Confirm that the thermal pads are lying smoothly against the skin and that the fluid lines are hanging freely (not occluded).
- 8) Once the patient temperature probe is in place, connect to the control unit and place the system in **Automatic Mode with a patient temperature target of 33°-37°C.**
- 9) Monitor and manage the patient's temperature per unit protocols and policy.
- 10) Document the serial # of the control unit, temperature settings and lot # of the thermal pads.
- 11) Discontinue thermal treatment when the patient's temperature reaches the established standard for the unit protocol and policy. **Pads should be removed after 24 hours of continuous use. If thermal treatment is to continue, the pads should be replaced. Ensure pads are warm prior to removal.**
- 12) At the end of treatment, purge the thermal pads, remove them carefully, and discard them. Inspect and document the patient treatment area.

Potential for Pressure-Related Skin Injuries

While the use of temperature management systems addresses a clinical need, there is also an increased risk for skin injury. This risk is exacerbated by the use of positioning devices that would cause localized areas of increased pressure. Therefore, Kimberly-Clark does not recommend the use of any positioning devices that come in direct contact with the Patient Warming System thermal pads.

Positioning devices to be avoided include, but are not limited to:

- Shoulder rolls (performed, rolled towels, wedges, gel, etc).
- Bean bags or other lateral positioning devices that place pressure in the location of thermal pads.
- Kidney rests or other firm devices (total hip positioners, Jackson frames, etc.)

Kimberly-Clark understands that the use of positioning devices is unavoidable in certain situations, and often those situations involve procedures in which additional warming of the patient is desirable. As a result of this, we have developed these Clinical Guidelines, which are based on the AORN Standards, Recommended Practices, and Guidelines to mitigate the potential for injury.

- Per the AORN Recommended Practices, if a positioning device is required, it should be made of durable material and design and should be able to disperse skin interface pressure.²
- Thermal pads should be placed away from the positioning devices, on any area of intact, perfused skin out of the surgical field.
- If the pads cannot be placed away from the positioning devices, the MAX water temperature in both **Manual** and **Automatic** Mode should be set to 41°C or lower to reduce the risk of injury.

Frequently Asked Questions

1. What is the risk to the patient of inducing an electrosurgical thermal injury, since the thermal pads have water circulating through them?

A: If electrosurgical grounding pads are properly placed on the patient as indicated by the manufacturer and a thermal pad is not placed over the grounding pad, there is no increase in risk to the patient. The thermal pad is not an alternative current path for the electrosurgical generator. However, the electrical current flowing through the grounding pad has the potential to increase the local temperature of the skin, depending on the power settings and duration of use of the electrosurgical generator. Placement of a thermal pad over the grounding pad may cause the heat generated from both devices to exceed the safe thermal threshold of the skin.

2. What is the recommendation for thermal pad placement related to EKG leads and defibrillation pads?

A: EKG leads and defibrillation pads may be placed between the patient's skin and the thermal pads. EKG leads and defibrillation pads should NOT be placed between the thermal pads and the OR table.

3. Do the thermal pads contain natural rubber latex?

A: The disposable thermal pads do NOT contain natural rubber latex.

4. Are my patients at risk of thermal injury due to heat?

A: The threshold for thermal injury due to heat is reported as either 44°C or 45°C in much of the early literature. The data reported by Moritz and Henrique (1947) is the most comprehensive study performed on humans and has been cited by numerous authors in later works. The extrapolation of their data using the equation developed by Xu and Qian (1995) predicts the time threshold for a 1st degree burn to be 16 hours at a skin temperature of 42°C and 6.5 hours at a skin temperature of 43°C. When used in automatic mode, the KIMBERLY-CLARK* Patient Warming System has redundant operating control limits to prevent the skin temperature from exceeding 41°C. In manual mode, physicians must determine the appropriate water temperature to be used, with consideration to all of the patient and surgical conditions.

5. What do you recommend for use with ablation equipment?

A: Don't use thermal pads during an ablation procedure (e.g. MAZE) that requires the grounding pad to be placed between the patient and the thermal pads. If the grounding pad can not be placed away from the thermal pads, turn the control unit to STOP mode during the ablation procedure. If the ablation unit does not require a grounding pad, there is no need to alter protocol.

6. Are the thermal pads radiolucent (can they be used with imaging equipment)?

A: Yes, the thermal pads are radiolucent and should have no impact on imaging quality or clarity.

7. How do I manage an epidural line under the thermal pads?

A: There is a risk of pulling out the epidural line placed under the thermal pads during thermal pad removal. Any soft, non-adherent covering, 4X4 can be placed over the epidural line (under the thermal pad) to keep the epidural line from sticking to the Hydrogel. As always, the thermal pads should be removed slowly and carefully, especially when there is an epidural line underneath.

8. How long can I leave the pads on a patient?

A: The thermal pads should not be left on a patient for more than 24 hours of continuous use. **If thermal treatment is to continue after 24 hours, a new set of pads should replace the old pads.**

9. How many thermal pads should I use?

A: We recommend that you use at least 2 pads for optimal performance. Utilize the Rule of 9's to achieve 18-20% body surface coverage. Additional pads will improve performance in both the time it takes to reach target temperature and temperature stability. Additionally, depending on the MAX water temperature set point, additional pads will compensate for lower temperatures.

10. Can I use the Thermal pads with the Megadyne Electrocautery Pad?

A: Yes, these products are compatible.

References

1. KIMBERLY-CLARK* Patient Warming System Model 1000 Operator's Manual.
2. 2008 AORN Standards, Recommended Practices and Guidelines, Section 3, Recommended Practices for Positioning the Patient in the Perioperative Practice Setting, Recommendation I- XIV.

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