Lower Body Blanket and Universal Warming Blanket Instructions for Use

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INTRODUCTION

The Lower Body Blanket and the Universal Warming Blanket (Warming Blankets), used in conjunction with the Temperature Management Controller MP and an Integrated Warming Pad, constitute a Temperature Management System (System). These instructions apply to the following catalog numbers:

Product Description	Catalog Number	Qty/Pkg
Lower Body Blanket	2083518	1
Universal Warming Blanket	2083519	1

2083508 Warming Blanket Cables are available separately.

INDICATIONS FOR USE

The Temperature Management System is intended to prevent or treat hypothermia and to provide warmth to patients. The System should be used in circumstances in which patients may not maintain a state of normothermia. The System can be used with adult and pediatric patients.

The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating rooms, recovery rooms, emergency rooms, burn units and on other medical/surgical floors.

CONTRAINDICATIONS

- Do not warm ischemic or non-perfused tissue; thermal injury may result. Examples include tissue distal to aortic cross clamping, or when vasoconstrictive drugs would lead to prolonged vasoconstriction.
- Do not warm patients receiving transdermal medication; increased drug delivery may occur.

WARNINGS

- Explosion Hazard – Do not use the System in the presence of flammable anesthetics or oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- Do not place Warming Blankets under the patient.
- Inspect Warming Blankets prior to use for signs of damage or excessive wear such as cuts, holes, loose electrical connection, or cold areas. If signs of wear are evident, do not use the Warming Blanket until it is inspected by technical staff.
- Do not continue to use the System if the over-temperature indicator and/or any other alarms continue to sound after reset. Refer to the “Alarms and Alerts” section of this manual for more information.
- Do not place Warming Blankets under straps that tightly secure the patient to the OR table.
- Warming Blankets are not sterile.
- California Proposition 65 Warning: The medical devices and products mentioned in this IFU may contain chemicals including Urethane, which is known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information go to, www.p65warnings.ca.gov

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.

PRECAUTIONS

- Use under the direct supervision of a clinician.
- Monitor the patient's vital signs regularly during warming according to institutional protocol. If vital sign instability occurs, notify the clinician.
- Exercise caution when using multiple warming methods.
- Maintain contact between the patient and the labeled sensor on the Warming Blanket.
- Do not fold the Warming Blanket black-side to black-side during use as localized heat build-up may occur in the overlapped area.
- Always use a barrier (e.g. thin bed sheet, patient gown) between the patient and the Warming Blanket.
- Adjust placement of the Warming Blanket during X-ray imaging as the white labeling and internal wiring located primarily along the edges of the Warming Blankets may appear in images.
- Do not partially cover the Warming Blanket with thick insulation unless the sensor is also covered, or product damage may occur.
- Warming Blankets should not be disposed of with general waste at end of life. Follow local regulations for disposal. The device does not pose any potential hazard.
- Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the country in which it occurred.

INSTRUCTIONS FOR USE

Use only with the Temperature Management Controller MP.

1. Inspect the Warming Blanket for damage (e.g., cuts, holes, loose electrical connections). Do not use the Warming Blanket if it is damaged.
2. Place a suitable barrier (e.g. thin bed sheet, patient gown) between the patient and the Warming Blanket.
3. Place the Warming Blanket on top of the barrier, ensuring the heated portion of the Warming Blanket (**black side**) faces the patient. On Blankets with unheated areas, the heated portions of the Blankets are marked with the "heating area" symbol. (See "Definition of Symbols" section.)

   Warning: Do not place the Warming Blanket under the patient and do not roll or fold heated (black) sides of Blankets together during use.
4. Ensure patient is in contact with the Warming Blanket temperature sensor (indicated by a white target).
5. Position and secure the Warming Blanket following the instructions below for the applicable Blanket model. The purple sides of the Blanket may be folded back on one another to facilitate effective positioning.

Blanket Model	Blanket Positioning/Securement Instructions
Lower Body	• The Warming Blanket should maintain its position without securement. If necessary, tape, Velcro straps, or reusable straps may be used to secure the Blanket as long as it doesn't create excessive pressure on the patient.
Universal	• Secure the Warming Blanket to the patient using the formable edge. • Connect two Universal Warming Blankets together using the button and loop connector located on the sides of the Blankets.

6. Insert one end of the yellow Warming Blanket cable (2083508) into the appropriate port on the Temperature Management Controller.

Controller Model	Port
2082516	A, B, C or D

7. Insert the other end of the yellow warming blanket cable (2083508) into the electrical connector on the Warming Blanket.
8. Turn the Temperature Management Controller MP on and select the desired temperature setting to begin warming. The time to reach the set-point temperature from 23 C +/-2 C is less than 10 minutes. If the Blanket does not reach the selected temperature within 10 minutes, an alarm will sound (Refer to the Temperature Management Controller MP IFU.)
9. If the Temperature Management Controller MP alarm sounds when the Warming Blanket is connected refer to the "Alarms" section of this IFU.
10. At the conclusion of warming, remove the barrier and clean the Warming Blanket as necessary. (See "Care and Maintenance" section below.)

CARE AND MAINTENANCE

- Do not continue to use the Warming Blankets beyond the labeled expiration date found on the cable.
- Do not launder or sterilize as this may damage the Warming Blanket.
- Do not immerse the Warming Blanket in liquids.
- Do not use high-level disinfectants (e.g. gluteraldehyde, and peracetic acid) or hydrogen peroxide-based solutions to clean the Warming Blanket.
- Do not spray cleaning solutions into the electrical connector.
- Do not use cleaning or disinfection methods different from those recommended in the Instructions for Use without first checking with an authorized service representative to ensure that the proposed methods will not damage the equipment.
- Do not use the Warming Blanket if it shows signs of damage or excessive wear such as cuts, holes, or loose electrical connectors. Technical staff should perform inspection, such as electrical leakage and resistance testing, to determine if it is safe for use.
- Do not disassemble the Warming Blanket; the device contains no serviceable parts. If service is required, call an authorized service representative for assistance.
- Do not sharply fold and crease the Warming Blanket sharply or fold repeatedly at the same point.

Storage

Store the Warming Blanket in a dry place, folded or on hanging hooks using the designated holes along the edges of the Blanket. Do not allow the Blanket to be cut or crushed. If folding is the preferred method of storage, please fold loosely and not always at the same point. Repetitive folding, especially if done so sharply, may damage internal components and effect longevity.

Cleaning—General

Clean and disinfect the Warming Blanket between patient uses if it appears visibly soiled. If the Warming Blanket is not visibly soiled, disinfection at the end of the operating day is recommended. Follow protocols for non-critical, non-sterile medical devices that may contact intact skin. Examples of similar devices include blood pressure cuffs, exam table covers, operating room table pads and surgical supports.

Hydrogen peroxide-based cleaning solutions are NOT recommended because the vapors degrade the conductive fabric heaters.

In general, alcohol-based disinfectants are easiest to use since they are fast-acting and can be sprayed or wiped on the blanket. Other cleaners that are compatible with the outer surfaces of the blanket include sodium hypochlorite (diluted bleach), phenolic germicidal detergent, and quaternary ammonium detergent. Iodine-containing cleaners may cause discoloration of the surface material and are, therefore, NOT recommended for routine cleaning. Dry thoroughly before use.

Caution: Do not place the Warming Blanket in an autoclave, sterilizer, automatic washer-disinfector or any other high temperature system as this may damage the device.

Cleaning & Disinfection Steps

The cleaning steps below are general recommendations and are not meant to replace hospital-specific cleaning protocols.

1. Do not allow cleaning fluids to get into the electrical connector.
2. If visible soiling is present, remove before applying a disinfectant. Scrub the affected area with detergent, using a soft brush or sponge to remove organic matter. Rinse the surface of the Blanket using a dampened cloth. Do not immerse the Blanket in liquids.
3. Apply a low- or intermediate-level disinfectant to the entire Blanket by spraying or wiping. Follow the disinfectant manufacturer’s application instructions.
4. Dry thoroughly before use.

ALARMS

All alarm conditions are classified as Medium Priority Technical Alarms. If an alarm occurs, unplug the device to reset the controller. Check the Warming Blanket and attempt to resolve the alarm. If Alarm Lights illuminate after a reset is performed, discontinue use and refer the system to Biomedical Engineering. Refer to Temperature Management Controller MP IFU for specific information on the Error Codes displayed.

DEFINITION OF SYMBOLS

	Do not Place Under Patient		This Side Down		This Side Up
	Attention, consult accompanying documents.		Heating Area		BF Patient Applied Part according to IEC60601-1.
SN	Serial Number	REF	Reference Number	LOT	Lot Number
	Manufacture Date	UDI	Unique Device Identifier		Do not submerge.
	Temperature Sensor		Keep Dry	Rx only	Medical Device restricted to sale by or on the order of a physician
	Transport and Storage Humidity Range		Transport and Storage Temperature Range		Separate treatment from general waste at end of life. See Precautions for details.
LATEX	Natural Latex Free	NON STERILE	Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.
	Do not use after YYYY-MM-DD		Manufacturer		Consult the electronic instructions for use on the website at the URL provided.
	See IFU for Warnings and Precautions		Indicates the entity distributing the medical device into the locale.		
IPX2	Protected against dripping water when tilted up to 15°; Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position. (The Controller)				
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL **60601-1.** Classified under the Medical Device Directive (93/42/EEC) as a Class IIb device.				

Devices are protected by some or all of the following patents: (US Patents 7,543,344; 7,714,255; 7,851,729; 7,786,408; 8,062,343; 8,283,602; 8,604,391; 8,624,164; 8,772,676; 8,986,359; 9,962,122; 9,668,303; 10,154,543; 10,201,935; 10,206,248; 10,506,668; PCT Patent EP 2,062,460) . Other patents are pending.

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