HotDog Pediatric Lower Body Warming Blanket

Model B203

Instructions for Use

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CE
2460

INTRODUCTION

The HotDog Pediatric Lower Body Warming Blanket is a component of the HotDog Temperature Management System. These instructions apply only to the following catalog number:

HotDog Product Description	Patient Size	Catalog Number	Quantity	
Pediatric Lower Body Warming Blanket	8 to 40 kg	B203	1	CE 2460

A101 Cables are available separately.

HotDog Pediatric Lower Body Blanket Model B203. Designed for patients weighing from 8 to 40 kg. It can be used on any patient over 8 kg, including adults.

The Warming Blanket provides a surface area for over-body patient warming at a specified and uniform temperature. An internal temperature sensor provides output to the HotDog Controller to maintain the set temperature. The Warming Blanket is water and solvent resistant. All seams are fully sealed to allow for easy cleaning and disinfection.

INDICATIONS FOR USE

The HotDog 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 Pediatric Lower Body Warming Blanket is intended for use with 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.

TARGET PATIENT GROUP

The Pediatric Lower Body Warming Blanket is intended for use with pediatric patients in circumstances in which patients may not be able to maintain a state of normothermia.

INTENDED USE

The System is designed to compensate for body heat loss before, during, and after surgery, and in other situations in which patients may not be able to maintain a state of normothermia.

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 severe, prolonged vasoconstriction.
- Do not warm patients receiving transdermal medication; increased drug delivery may occur.

WARNINGS

- Explosion Hazard– Do not use the HotDog Controller or Warming Blankets 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, or loose electrical connections. 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 HotDog Temperature Management System if the over-temperature indicator and/or alarm continue to sound after reset.

- Do not place Warming Blankets under straps that are used to tightly secure the patient to the OR table.
- HotDog Warming Blankets are not sterile.

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.
- Always use a patient 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 sensor is also covered, or product damage may occur.
- This device 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

Follow BEST practices to achieve optimal results, as described in MT302 BEST Results Poster (downloadable at hotdogwarming.com).

1. Inspect the surface of 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 patient barrier, such as a thin bed sheet or the patient gown, over the patient. A thick blanket or multiple layers of sheet may prevent warmth from the Warming Blanket from reaching the patient and actively warming the patient.
3. Place the Warming Blanket on top of the patient barrier, ensuring the heated portion of the Warming Blanket (**black side**) faces the patient. On blankets with unheated areas, the heated portion of the blanket is 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.

4. Ensure that the Warming Blanket temperature sensor (indicated by a white target) is in good contact with the patient. See Figure 1

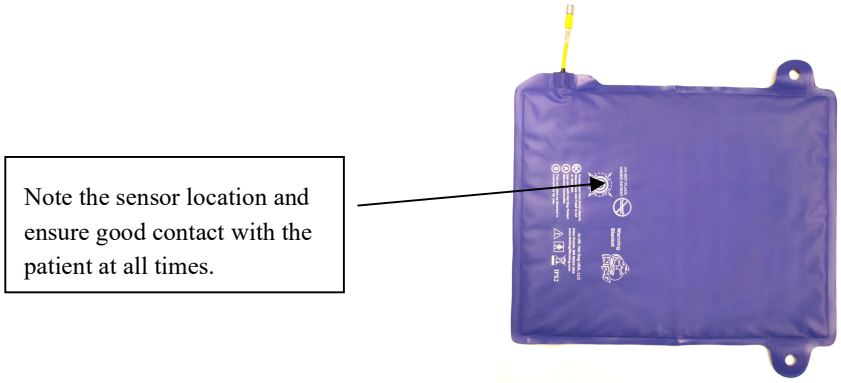


Figure 1.

5. Position the Warming Blanket on as much of the patient as possible. Give priority to warming the patient's core (trunk) when possible.

   If the Warming Blanket would interfere with the surgical site, fold back the blanket to reduce its footprint. The purple sides of the blanket may be folded back one another to facilitate effective positioning. Do not fold black-side to black-side. Do not tuck or place heater surface underneath patient.

   See Figure 2.

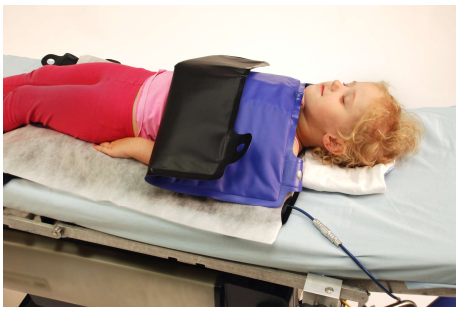


Figure 2

When it is not possible to position the Warming Blanket on the patient's core, then warm the lower body. See Figure 3.

6. Insert one end of the electrical cable into the appropriate port on the HotDog Controller. Use only with HotDog Controllers.

Controller Model	Port
WC0X	A
WC5X	A or B
WC71	A
WC77	A, B, C or D

Figure 3

7. Insert the other end of the cable into the electrical connector on the Warming Blanket.
8. Turn the HotDog Controller 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 HotDog Controller User Manual.)
9. If the HotDog Controller alarm sounds when the Warming Blanket is connected, do not use the Warming Blanket until the alarm condition is resolved. (Refer to the "Alarms" section.)
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 HotDog 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 product contains no serviceable parts. If service is required, call an authorized service representative for assistance.
- Do not fold and crease the Pediatric Lower Body Warming Blanket sharply or fold repeatedly in the same location.

Storage

Store the Warming Blanket in a dry place and in a manner that prevents it from being cut or crushed. Blankets may be stored folded or on hanging hooks using the designated holes along the edges of the blankets. If folding is the preferred method of storage, please fold loosely and ideally not always in the same manner. Repetitive folding, especially if done so in a tight manner, may damage internal components and effect the product's 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 should NOT be used 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 product.

Cleaning & Disinfection Steps

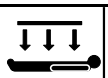
The cleaning steps below are general recommendations and are not meant to replace hospital-specific cleaning protocols.

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 was performed, discontinue use and refer the system to Biomedical Engineering. Refer to Controller 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.	EC REP	EU Authorized Representative		BF Patient Applied Part according to IEC60601-1.
SN	Serial Number	REF	Reference Number	LOT	Lot Number
	Manufacturer	UDI	Unique Device Identifier		Do not submerge
	Temperature Sensor		Keep Dry	CE 2460	Conforms to European Medical Device Regulation 2017/745
	Transport and Storage Humidity Range		Transport and Storage Temperature Range		Separate treatment from general waste at end of life. See Precautions for details.
	Natural Latex Free		Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.
	Do not use after YYY-MM-DD		Manufacture Date	Rx only	Medical Device restricted to sale by or on the order of a physician
	See IFU for Warnings and Precautions	MD	Medical Device		Consult the electronic instructions for use on the website at the URL provided.
	MDR Importer				
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 European Medical Device Regulation 2017/745 as a Class IIb device.				

HotDog is a trademark of Augustine Temperature Management, registered in the U.S. Patent & Trademark Office. 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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