



Pediatric Lower Body Warming Blanket Model B203 Instructions for Use

Manufactured by:

Augustine Temperature Management, LLC

6581 City West Parkway

Eden Prairie, MN 55344 USA

TEL 952.465.3500

FAX 952.465.3501

www.hotdogwarming.com

DEVICE DESCRIPTION

The HotDog Pediatric Lower Body Warming Blanket Model B203 is a component of the HotDog Patient Warming System and should only be used with HotDog Controller Model WC5X or WC0X. These instructions apply only to 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 Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The HotDog Patient Warming System should be used in circumstances in which patients may not maintain a state of normothermia.

The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating, recovery and emergency rooms and on 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 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 Patient Warming 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 secure the patient to the OR table.
- HotDog Warming Blankets and Disposable Sheets are not sterile.
- Use only with HotDog Controller Models WC0X or WC5X.

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.
- Care should be taken when using multiple warming methods.
- Avoid placing patient fluid lines between warming devices.
- Care should be taken to ensure the patient is in contact with the labeled sensor on the Warming Blanket.
- Always use a patient barrier, such as a HotDog Disposable Sheet or thin bed sheet, between the patient and the Warming Blanket.
- Diagnostic Images acquired while using HotDog Warming Blanket should be inspected by clinical professionals to determine the quality and diagnostic capability of image (CT, MRI, Xray)
- 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.

INSTRUCTIONS FOR USE

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 HotDog thin bed sheet, 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

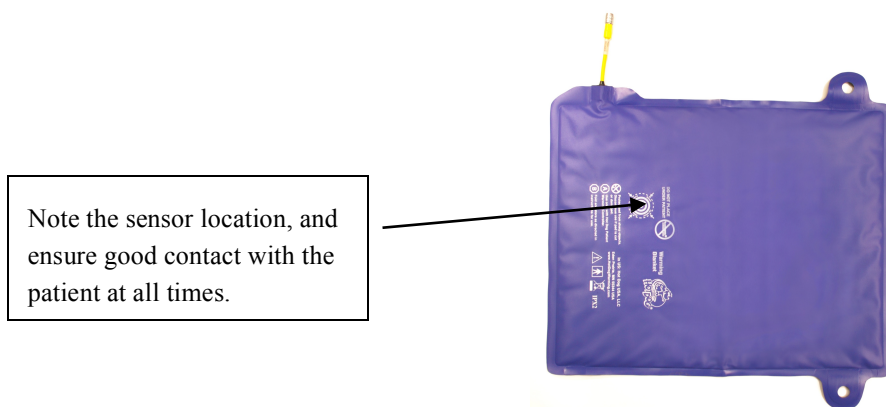


Figure 1.

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 foot print. Remember, never fold black on black, only purple on purple or black on purple. DO NOT tuck or place heater surface underneath patient.

See Figure 2.

When it is not possible to position the Warming Blanket on the core, then warm the lower body. See Figure 3. DO NOT tuck or place heater surface underneath patient.

6. Insert one end of the electrical cable into the appropriate port on the HotDog Controller.

Controller Model	Port
WC0X	A
WC5X	A or B



Figure 2



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. Follow the BEST practices guidelines (MT302) to achieve best warming results.
11. When use of the Warming Blanket is complete, 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.
- 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. glutaraldehyde 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.

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.

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.

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

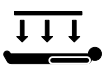
The cleaning steps below are general recommendations and are not meant to replace hospital-specific cleaning protocols.

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. 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.		Heating Area		BF Patient Applied Part according to IEC60601-1.
	Serial Number		Reference Number		Lot Number
	Manufacturer		Use only with HotDog Patient Warming Controller.		Store as directed in instructions for use.
	Temperature Sensor		Keep Dry		Conforms to European Medical Device Directive 93/42/EEC.
	Transport and Storage Humidity Range		Transport and Storage Temperature Range		Return to Authorized Representative
	Natural Latex Free		Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.
	Use by Date YYY-MM-DD		Manufacture Date		
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)				

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