



WARMING BLANKETS & DISPOSABLE SHEETS

INSTRUCTIONS FOR USE

INTRODUCTION

HotDog Warming Blankets and optional Disposable Sheets are part of the HotDog Patient Warming System. These instructions apply to the following catalog numbers:

HotDog Product Description	Catalog Number		Qty/Pkg	
Warming Blanket, Lower Body	B103	B503	1	CE 0086
Warming Blanket, Full Body	B104	B504	1	
Warming Blanket, Multi-Position	B105	B505	1	
Warming Blanket, Torso	B110	B510	1	CE
Disposable Sheet	S104		1	

HotDog Warming Blanket cables are provided separately.

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 HotDog Patient Warming 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. Take appropriate precautions to protect the sterile field.
- 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.
- Take caution when using multiple warming methods.
- The risk of skin irritation caused by pooling of surgical prep solutions under the patient may increase with warming; ensure that surgical prep solution instructions for use are followed.
- Maintain contact between the patient and the labeled sensor on the Warming Blanket.
- DO NOT fold or wrinkle the Warming Blanket during use as localized heat build-up may occur in the overlapped area.
- Always use a barrier (e.g., HotDog Disposable Sheet, thin bed sheet, patient gown) between the patient and the Warming Blanket.
- Adjust placement of Warming Blanket during X-ray imaging as the white labeling and internal wiring located primarily along the edges of the blankets may appear in images.

INSTRUCTIONS FOR USE

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

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., HotDog Disposable Sheet, thin bed sheet, patient gown) over the patient. Follow the instructions on the HotDog Disposable Sheet labeling to ensure proper positioning.
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 portion 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	<ul style="list-style-type: none"> Secure the Warming Blanket by tucking the unheated portions of the blanket and the sheet around the patient, where possible.
Full Body	
Multi-Position	<ul style="list-style-type: none"> Secure the Warming Blanket to the patient using the included multi-position reusable straps, Velcro straps or tape. Connect blanket segments together using the button and loop connector, located on the inside of the blanket segments. Fit the button and loop together to secure the two sections.
Torso	<ul style="list-style-type: none"> Position the Warming Blanket on the patient, maintaining as much contact as possible between the blanket and the patient's chest, arms and shoulders. Tuck the unheated insulated flaps around the patient's neck and shoulders.

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

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, discard the Disposable Sheet 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.
- 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, 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, folded or on hanging hooks using the designated holes along the edges of the blanket. Do not allow it to be cut or crushed.

Cleaning—General

Clean the Warming Blanket between patient uses and anytime it appears soiled. 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 to ensure disinfection.
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
	Manufacture Date		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.
	Do not use after YYYY-MM-DD		Manufacturer		
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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