



WARMING BLANKETS & DISPOSABLE SHEETS INSTRUCTIONS FOR USE

INTRODUCTION

Hot Dog Warming Blankets and Disposable Sheets are accessories for the Hot Dog Patient Warming System. These instructions apply to the following catalog numbers:

Hot Dog Accessory	Catalog Number	Qty/Pkg	
Warming Blanket, Lower Body	B103	1	CE 0086
Warming Blanket, Full Body	B104	1	
Warming Blanket, Multi-Position	B105	1	
Warming Blanket, Torso	B110	1	
Disposable Sheet, Full/Lower Body	S104	1	CE

Hot Dog Warming Blanket cables are provided separately.

INDICATIONS FOR USE

The Hot Dog Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming System should be used in circumstances in which patients may not maintain a state of normothermia. The Hot Dog 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 patients during aortic cross-clamping; thermal injury may result.
- DO NOT warm patients with ischemic or non-perfused limbs; thermal injury may result.
- DO NOT warm patients receiving transdermal medication; increased drug delivery may occur.

WARNINGS

- EXPLOSION HAZARD – DO NOT use the Hot Dog 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 Hot Dog Patient Warming System if the over temperature indicator and/or alarm continue to sound after reset.
- Caution should be taken when using electric warming devices with HF surgical instruments or endocardial catheters in respect to potential equalization.
- DO NOT place Warming Blankets under straps that are used to secure the patient to the OR table.
- Hot Dog Warming Blankets and Disposable Sheets are not sterile. Take appropriate precautions, as necessary, to protect the sterile field.
- Use only with Hot Dog 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.
- 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.
- Care should be taken to place the patient’s body in contact with 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 patient barrier, such as a Hot Dog Disposable Sheet or thin bed sheet, between the patient and the Warming Blanket.
- Warming Blanket placement should be considered 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

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 Hot Dog Disposable Sheet or thin bed sheet, over the patient. Follow the instructions on the Hot Dog Disposable Sheet labeling to ensure proper positioning.
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 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 blankets during use.

4. Ensure that the Warming Blanket temperature sensor (indicated by a white target) is in good contact with the patient.
5. Position and secure the Warming Blanket following the instructions below for the applicable blanket model.

Blanket Model	Blanket Positioning/Securement Instructions
Lower Body Full 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.
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 to each other using the button and loop connector, which is 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 so that there is good contact 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 Hot Dog 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 Hot Dog Controller on and select the desired temperature setting to begin warming. Allow up to 10 minutes for the Warming Blanket to reach set point. (Refer to the Hot Dog Controller User Manual.)
9. If the Hot Dog Controller alarm sounds when the Warming Blanket is connected, do not use the Warming Blanket. (Refer to the “Alarms” section.)
10. When use of the Warming Blanket is complete, discard the Disposable Sheet and clean the Warming Blanket as necessary. (See “Care and Maintenance” section below.)

CARE AND MAINTENANCE

- 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, peracetic acid) 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 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. 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

If the Warming Blanket temperature exceeds one degree above set point or other fault conditions exist, an audible alarm sounds and the Controller Alarm Light illuminates red for the port that is alarming. The Controller will automatically discontinue power to the Warming Blanket. When the operating temperature is regained, the alarm will shut off and normal function will be restored. If the Alarm Light illuminates steadily and the alarm continues to sound, turn the Controller Mains Power Switch to the OFF position and disconnect the Warming Blanket from the Controller. If the Controller senses an over current, the audible alarm will sound and all alarm lights will illuminate. Power will be lifted from all ports and the Controller will need to be turned off to reset. If all Alarm Lights illuminate after resetting the Controller, discontinue use of the Warming Blanket.

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 Hot Dog 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
	Latex Free		Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.

Manufactured by:

Augustine Temperature Management
6581 City West Parkway
Eden Prairie, MN 55344 USA
TEL 952.465.3500
FAX 952.465.3501
www.hotdogwarming.com

EU Authorized Representative:

Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands
Tel: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

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