




HEAD WARMING WRAP INSTRUCTIONS FOR USE

INTRODUCTION

The HotDog Head Warming Wrap is an accessory for the HotDog Patient Warming System. These instructions apply to the following catalog numbers:

HotDog Accessory	Catalog Number		Quantity	
Head Warming Wrap	B107	B507	1	

HotDog Head Warming Wrap 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 Head Warming Wrap in the presence of flammable anesthetics or oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- DO NOT place the heated area of the Head Warming Wrap under the patient.
- Inspect the Head Warming Wrap 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 Head Warming Wrap 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.
- The Head Warming Wrap is not sterile.
- Use only with HotDog Controllers.

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.
- Dispose of the blankets per local regulations.
- The risk of skin irritation caused by pooling of surgical prep solutions under the patient may increase with warming; follow surgical prep solution instructions.
- Always use a barrier, such as a hair net, between the patient and the Head Warming Wrap.
- Head Warming Wrap placement should be considered during X-ray imaging as the white labeling and internal wiring located primarily along the edges of the device may appear in images.

INSTRUCTIONS FOR USE

1. Inspect the surface of the Head Warming Wrap for damage (e.g., cuts, holes, loose electrical connections). Do not use the Head Warming Wrap if it is damaged.
2. Place the Head Warming Wrap around the patient's head.

Warning: DO NOT place the heated area of the Head Warming Wrap under the patient.

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

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

4. Insert the other end of the cable into the electrical connector on the Head Warming Wrap.
5. 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 Head Warming Wrap does not reach the selected temperature within 10 minutes an alarm will sound (Refer to the HotDog Controller User Manual.)
6. If the HotDog Controller alarm sounds when the Head Warming Wrap is connected, do not use the Head Warming Wrap until the alarm condition is resolved. (Refer to the "Alarms" section.)
7. When use of the Head Warming Wrap is complete, clean the Head Warming Wrap as necessary. (See "Care and Maintenance" section below.)

CARE AND MAINTENANCE

- DO NOT continue to use the Head Warming Wrap beyond the labeled expiration date.
- DO NOT launder or sterilize as this may damage the Head Warming Wrap.
- DO NOT immerse the Head Warming Wrap in liquids.
- DO NOT use high-level disinfectants (e.g. glutaraldehyde and peracetic acid) or hydrogen peroxide-based solutions to clean the Head Warming Wrap.
- 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 Head Warming Wrap 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 Head Warming Wrap; the product contains no serviceable parts. If service is required, call an authorized service representative for assistance.

Storage

Store the Head Warming Wrap in a dry place and in a manner that prevents it from being cut or crushed.

Cleaning—General

Clean and disinfect the Head Warming Wrap between patient uses if it appears visibly soiled. If the Warming Wrap 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 wrap. Other cleaners that are compatible with the outer surfaces of the wrap 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 Head Warming Wrap 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 wrap using a dampened cloth. Do not immerse the wrap in liquids.
3. Apply a low or intermediate level disinfectant to the entire wrap 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

	Attention, consult accompanying documents.		Natural Latex Free		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
	Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.		Do Not Place Under Patient
	Do not use after YYYY-MM-DD		Manufacturer		Medical Device restricted to sale by or on the order of a physician
	See IFU for Warnings		Medical Device		See electronic IFU on website at URL provided
	EU Authorized Representative				
	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.				

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

EU Authorized Representative:

	
---	--

EMERGO EUROPE
 Prinsessegracht 20
 2514 AP The Hague
 The Netherlands
 Tel: (31) (0) 70 345-8570
 Fax: (31) (0) 70 346-7299

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