



Pediatric Head Wraps Models B270 and B271 Instructions for Use

Manufactured by:

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INTRODUCTION

HotDog Pediatric Head Warming Wraps are Warming Blankets for the HotDog Patient Warming System. These instructions apply to the following catalog numbers:

Description	Patient Size	Catalog Number
Small Pediatric Head Warming Wrap	≤ 8 kg	B270
Large Pediatric Head Warming Wrap	> 8 kg	B271

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 Pediatric 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 Pediatric Head Warming Wrap under the patient.
- Inspect the Pediatric 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 Pediatric 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 Pediatric Head Warming Wrap is not sterile.
- Use only with HotDog Controller Models WC0X or WC5X.

CAUTION

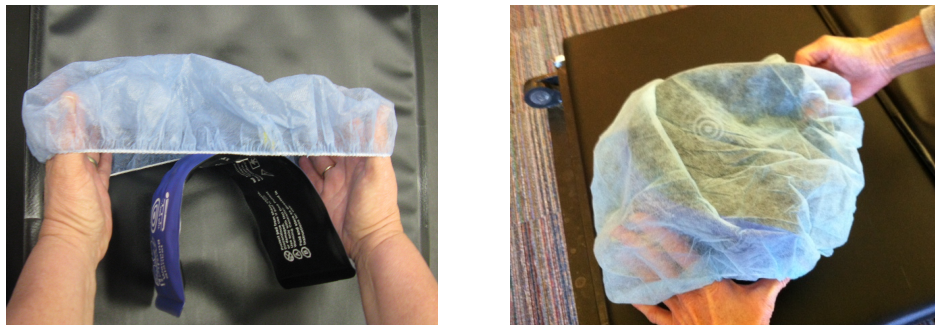
Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.

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 to avoid overheating when using multiple warming methods.
- Always use a patient barrier, such as a disposable polypropylene bouffant cap, between the patient and the Pediatric Head Warming Wrap.
- The Pediatric Head Warming Wrap should be positioned carefully 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. Select the correct size Pediatric Head Warming Wrap for the patient. Use the B270 for patients 8 kg or smaller. Use the B271 for pediatric patients weighing more than 8 kg.
2. Inspect the surface of the Pediatric Head Warming Wrap for damage (e.g., cuts, holes, loose electrical connections). Do not use the Pediatric Head Warming Wrap if it is damaged.
3. Open a polypropylene bouffant cap and apply to the front of the Pediatric Head Warming Wrap so that it covers the entire Warming Wrap as shown in Figures 1 and 2. It will serve as a thin barrier. Position the Head Warming Wrap so that the heated portion (**black side**) will face the patient.



Figures 1 and 2 – Applying the polypropylene bouffant cap

4. Push down the center of the bouffant cap so there is space for the patient's head. Ensure that the bouffant cap does not cover access to the controller cable connection. (see Figure 3)



Figure 3

5. Place the Head Warming Wrap around the patient's head to ensure maximum contact between the wrap and head. Be sure the sensor is in contact with the patient. Position as shown in Figure 4.



Figure 4

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

6. Adjust both formable edges of the wrap to hold it in the correct position and to ensure maximum patient contact. If there is extra wrap length, bend the formable edges to position the extra wrap on the patient's shoulders, as shown in Figure 5.



Figure 5

7. **Alternate Application:** Use Pediatric Head Warming Wraps (B270 and B271) as pediatric utility blankets. You can still use the same polypropylene bouffant cap as a thin barrier. Be sure that the black side of the Pediatric Head Warming Wrap is positioned toward the patient with the sensor in contact with the patient. See Figure 6 for example of placement option as a pediatric utility blanket.



Figure 6

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

Controller Model	Port
WC0X	A
WC5X	A or B

9. Insert the other end of the cable into the electrical connector on the Head Warming Wrap.
10. 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.)
11. If the HotDog Controller alarm sounds when the Pediatric Head Warming Wrap is connected, do not use the Warming Blanket until the alarm condition is resolved. (Refer to the “Alarms” section.)
12. When use of the Pediatric Head Warming Wrap is complete, discard the bouffant cap and clean the Pediatric Head Warming Wrap 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 Pediatric Head Warming Wrap.
- DO NOT immerse the Pediatric Head Warming Wrap in liquids.
- DO NOT use high-level disinfectants (e.g. gluteraldehyde and peracetic acid) or hydrogen peroxide-based solutions to clean the Pediatric 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 Pediatric 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 Pediatric Head Warming Wrap; 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 the Warming Wrap to be cut or crushed.

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 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. Cleaners containing accelerated hydrogen peroxide (e.g. Virox) may adversely affect the heater fabric 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 Pediatric 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 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 away from the patient		This side toward the patient
 	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 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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