



HEAD WARMING WRAP & DISPOSABLE SHEETS

INSTRUCTIONS FOR USE

INTRODUCTION

Hot Dog Head Warming Wraps 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	Quantity	
Head Warming Wrap	B107	1	CE 0086
Head Warming Disposable Sheet	S107	1	CE

Hot Dog Head Warming Wrap 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 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 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.
- The Head Warming Wrap 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.
- Always use a patient barrier, such as the Hot Dog Head Warming Disposable Sheet, 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 blankets 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. Unfold the Hot Dog Head Warming Disposable Sheet.
3. Insert the Head Warming Wrap into the Disposable Sheet, positioning the black side of the Head Warming Wrap against the white fabric layer of the Disposable Sheet.
4. 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.

5. Tear away the tie straps from the ends of the Disposable Sheet and tie under the patient’s chin. Avoid compromising any tubes or apparatus.
6. Insert one end of the electrical cable into the appropriate port on the Hot Dog Controller.

Controller Model	Port
WCOX	A
WC5X	A or B

7. Insert the other end of the cable into the electrical connector on the Head Warming Wrap.

Note: To make this connection, use the end of the connector to puncture a hole through the Disposable Sheet.

8. Turn the Hot Dog Controller on and select the desired temperature setting to begin warming. Allow up to 10 minutes for the Head Warming Wrap to reach set point. (Refer to the Hot Dog Controller User Manual.)
9. If the Hot Dog Controller alarm sounds when the Head Warming Wrap is connected, do not use the Head Warming Wrap. (Refer to the “Alarms” section.)
10. When use of the Head Warming Wrap is complete, discard the Disposable Sheet and clean the Head Warming Wrap as necessary. (See “Care and Maintenance” section below.)

CARE AND MAINTENANCE

- 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, peracetic acid) 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 the Head Warming Wrap 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 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. 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 to ensure disinfection.
4. Dry thoroughly before use.

ALARMS

If the Head Warming Wrap 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 Head Warming Wrap. 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 Head Warming Wrap 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 Head Warming Wrap.

DEFINITION OF SYMBOLS

	Attention, consult accompanying documents.		Latex Free		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
	Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.		Do Not Place Under Patient

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