



Pediatric Patient Warming Mattress Model U220 Instructions for Use

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DEVICE DESCRIPTION

The HotDog Pediatric Patient Warming Mattress Model U220 is a component of the HotDog Patient Warming System and should only be used with HotDog Controller Model WC5X. These instructions apply only to Warming Mattress Model U220.

Warming Mattress Model U220 is specifically designed for patients at or under 20Kg. For patients over 20Kg, please use HotDog Underbody Warming Mattress Model U10X.

The Warming Mattress provides a surface area for under-body patient warming at a specified and uniform temperature. An internal temperature sensor provides output to the HotDog Controller to maintain the set temperature. The Warming Mattress is water- and solvent-resistant. All seams are fully sealed to allow for easy cleaning and disinfection.

INDICATIONS FOR USE

Warming Mattress U220 is intended to prevent or treat hypothermia and to provide warmth to patients. The HotDog Patient Warming Mattress 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.
- DO NOT use the Warming Mattress with other under-patient thermal management systems.

WARNINGS

- EXPLOSION HAZARD – DO NOT use the Warming Mattress in the presence of flammable anesthetics or highly oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- Inspect the Warming Mattress 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 Mattress until it is inspected by technical staff.
- DO NOT continue to use the Warming Mattress if the HotDog Controller over-temperature indicator and/or alarm continues to sound after reset.
- The Warming Mattress is not sterile.
- Use only with HotDog Controller Model 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.
- Ensure that the Warming Mattress is securely fastened to the table.
- The risk of skin irritation caused by pooling of surgical prep solutions under the patient may increase with warming; follow surgical prep solution instructions.
- The use of gel pads between the Warming Mattress and the patient is not recommended; gel pads may cause a loss of warming performance.
- Always use a patient barrier between the patient and the Warming Mattress.
- Position the patient on flat Warming Mattress.
- Care should be taken to alleviate or remove the risk of heating skin under pressurized bony prominences.
- Care should be taken to place the patient's body in contact with the labeled sensor on the Warming Mattress.
- DO NOT use operating table clamps or similar devices on the Warming Mattress as they may cause damage to the product and result in loss of the heating function and/or localized heat build-up in the damaged area.
- DO NOT place the Warming Mattress over a table joint that will move during surgery.
- DO NOT use the Warming Mattress as a stand-alone patient pressure relief system.
- DO NOT place any hard objects (e.g., mattress cables, EKG cables, hard cautery return pads, patient fluid lines, etc.) between the Warming Mattress and the patient's body.
- DO NOT fold the Warming Mattress during use as localized heat build-up may occur in the overlapped area.
- Adjust placement of the Warming Mattress during X-ray imaging as the white labeling and internal wiring located primarily along the edges of the Warming Mattress may appear in images.

INSTRUCTIONS FOR USE

Contents

The following components are included in the HotDog Pediatric Patient Warming Mattress Model U220 package:

- 1 – Pediatric Warming Mattress Model U220
- 1 – Mattress Cable (P/N A112)
- 1 – Under Mattress Strap Kit containing 2 straps (P/N A124)
- 1 – Mattress Side Rail Strap Kit containing 4 straps (P/N A123)

The following supplies are not provided, but are required for use with the Warming Mattress:

- 1 -- Patient barrier (e.g., thin cotton sheet, pillow case or disposable barrier (S220)). A thick barrier will restrict heat transfer and is, therefore, not recommended.

General Instructions

1. Inspect the surface of the Warming Mattress for damage (e.g., cuts, tears, creases). Do not use the Warming Mattress if it is damaged.
2. Place the Warming Mattress on the padded operating table. The patient’s head should be directed toward the end of the warming mattress with the cable. See Figure 1.

Note: Ensure “THIS SIDE UP” labeling faces up.

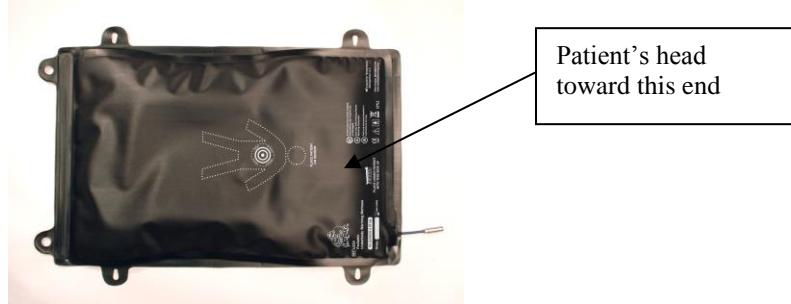


Figure 1

3. Attach the Warming Mattress straps to the operating table. See Figure 2.

Warning: Ensure that the straps on each side of the Warming Mattress are firmly secure. If the straps are not secure, the mattress can slide off the table, resulting in patient injury.

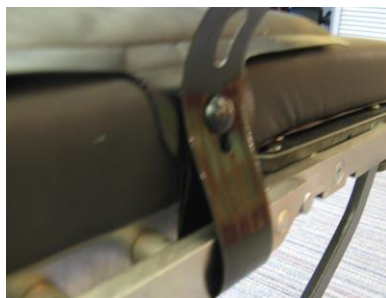


Figure 2

- 4. Place a thin patient barrier (thin sheet, pillow case or disposable cover (S220) over the entire warming panel (see fig. 3) of the Warming Mattress. Lower panel back down on the base panel.

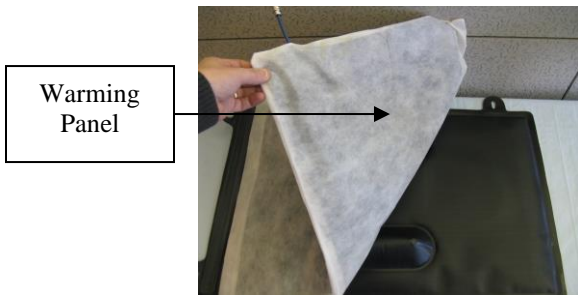


Figure 3

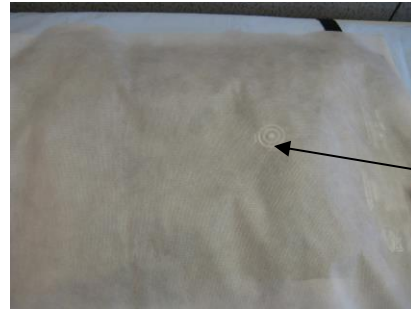


Figure 4

- 5. If you are using any patient positioning devices (foam forms, rolled towels, rolled pillow cases, etc.) place them under the warming panel. See figures 5, 6 and 7.

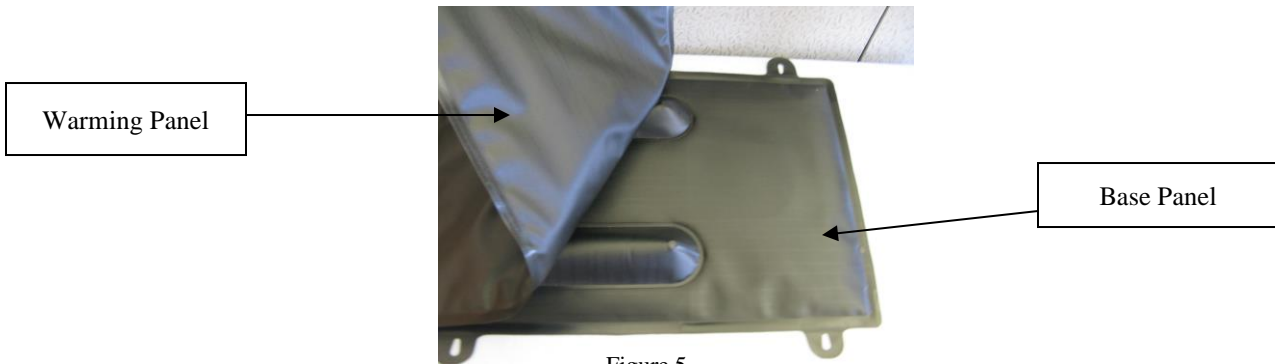


Figure 5



Figure 6



Figure 7

- 6. When placing the patient on the pad, it is critical that the patient is on top of the warming panel on the sensor. Use the two raised, completely compressible, contoured foam guides running parallel in the center of the mattress to ensure placement on the sensor. See figure 8. These guides, along with any patient positioning devices create a channel for maximum patient contact. See figure 9.

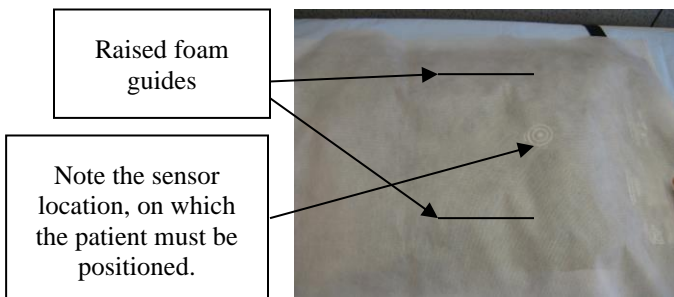


Figure 8

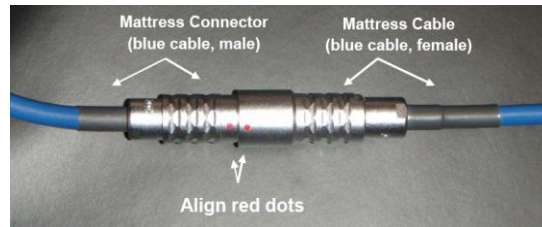


Figure 9

7. Insert the female end of the blue Mattress Cable into the Mattress Connector (Figure 10).

Note: Do not force the connector into the socket. Align the red dots on each connector and gently push the connectors together. You will feel a click when the connectors engage.

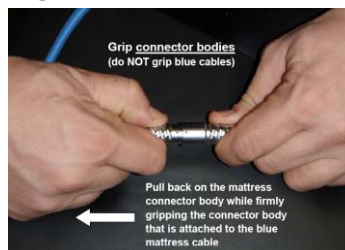
Figure 10: Cable Connection



8. Insert the male end of the blue Mattress Cable into the blue port on the HotDog Controller.
9. 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.) Max. set point is 39° C. Start warming as early as possible for best results.
10. If the HotDog Controller alarm sounds when the Warming Mattress is connected, do not use the Warming Blanket until the alarm condition is resolved. (Refer to the “Alarms” section.) .
11. When use of the Warming Mattress is complete, clean as necessary. (Refer to the “Care and Maintenance” section.)
12. To disconnect the Mattress Cable, grip the connector bodies and pull them apart (Figure 11).

Note: Do not pull on the cables or attempt to rotate or unscrew the connectors. Bending or twisting the cables or connectors may result in damage to the wires or the connector pins.

Figure 11: Cable Disconnect



CARE AND MAINTENANCE

- DO NOT continue to use HotDog Warming Mattress beyond the labeled expiration date.
- DO NOT launder or sterilize as this may damage the Warming Mattress.
- DO NOT immerse the Warming Mattress in liquids.
- DO NOT use high-level disinfectants (e.g., glutaraldehyde and peracetic acid) or hydrogen peroxide-based solutions to clean the Warming Mattress.
- DO NOT spray cleaning solutions into the electrical connector.
- DO NOT use cleaning or disinfection methods different from those recommended in the User Manual without first checking with an authorized service representative to ensure that the proposed methods will not damage the equipment.
- DO NOT use the Warming Mattress if it shows signs of damage or excessive wear such as cuts, holes or loose electrical connectors. Technical staff should inspect the Warming Mattress to determine if it is safe for use.
- DO NOT disassemble the Warming Mattress; the product contains no user serviceable parts. If service is required, call an authorized service representative for assistance.

Storage

- Store the Warming Mattress in a dry place and in a manner that prevents the product from being cut or crushed.
- DO NOT freeze the Warming Mattress; store at room temperature.

Note: If the Warming Mattress has been exposed to freezing temperatures, do not bend or roll the product as this may result in cracks to the pressure relief pad. Allow the product to reach room temperature prior to handling.

- DO NOT store any other objects on top of the Warming Mattress.
- DO NOT fold or sharply bend the Warming Mattress; the recommended storage configuration is flat.



Cleaning—General

Clean and disinfect the Warming Mattress between patient uses if it appears visibly soiled. If the Warming Mattress is not visibly soiled, disinfection at the end of the operating day is recommended. Wipe the mattress with a damp soapy cloth and disinfect following standard hospital protocol. In general, alcohol-based disinfectants are easiest to use since they are fast acting and can be either sprayed or wiped on the mattress. Other cleaners that are compatible with the outer surface of the mattress 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 Warming Mattress 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 mattress using a dampened cloth. Do not immerse the mattress in liquids.
3. Apply a low or intermediate level disinfectant to the entire mattress 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

	Attention, consult accompanying documents.		This Side Up		BF Patient Applied Part according to IEC60601-1.
	Serial Number		Reference Number		Do not use after YYYY-MM-DD
	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.
	Manufacturer		EU Authorized Representative		
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)				