HotDog Patient Warming Mattresses Models U1XX, U2XX and U3XX Instructions for Use

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CE 2460

DEVICE DESCRIPTION

HotDog Warming Mattresses, including OR table pad and table pad overlays (U1XX, U2XX and U3XX) ("Warming Mattresses") are components of the HotDog Temperature Management System ("System") and can be used with HotDog Controller Models WC5X or WC77, Warming Mattresses provide under-body patient warming at a specified and uniform temperature. An internal temperature sensor provides output to the Controller to maintain the specified temperature. Warming Mattress overlays, although not stand-alone pressure-relief devices, include a built-in pressure relief pad and are water- and solvent-resistant. All seams are fully sealed to allow for easy cleaning and disinfection.

These instructions apply to the following part numbers:

HotDog Product Description	Part Number	Qty/Pkg	Compatible Controllers	
Underbody Warming Mattress, 82 cm (32in)	U101	1	WC77, WC52	
Underbody Warming Mattress, 127 cm (50in)	U102	1	WC77, WC52	
Pediatric Underbody Warming Mattress 74 cm (29in)	U220	1	WC77, WC52	CE 2460
Trendelenburg Warming Mattress, 89 cm (35in)	U300	1	WC77, WC52	

A112 cables are available separately.

INDICATIONS FOR USE

The HotDog Temperature Management System is intended to prevent or treat hypothermia and to provide warmth to patients. The System should be used in circumstances in which patients may not maintain a state of normothermia. The System can be used with adult and pediatric patients. Warming Mattress are designed to provide pressure relief, although overlays are not stand-alone pressure-relief devices. The System can be used with adult and pediatric patients. The Pediatric Underbody Warming Mattress is intended for use with pediatric patients.

The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating rooms, recovery rooms, emergency rooms, burn units and on other medical/surgical floors.

TARGET PATIENT GROUP

The System can be used with adult or pediatric patients in circumstances in which patients may not be able to maintain a state of normothermia.

INTENDED USE

The System is designed to compensate for body heat loss before, during, and after surgery, and in other situations in which patients may not be able to maintain a state of normothermia.

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 Warming Mattresses with other under-patient thermal management systems.

WARMING MATTRESS WARNINGS

- Do not use Warming Mattresses when the risk of pressure injury cannot be mitigated.
- Explosion Hazard – Do not use Warming Mattresses in the presence of flammable anesthetics or highly oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- Inspect System components prior to each use for signs of damage or excessive wear such as cuts, holes, or loose electrical connections or cold areas. If signs of wear are evident or if the warming device has been

subjected to extreme physical force (e.g. pinched by clamps or run over by carts), do not use the device until it has been inspected by technical staff.

- Do not continue to use the System if the over-temperature indicator and/or any other alarms continue to sound after reset. Refer to the "Alarms and Alerts" section of this manual for more information.
- Warming Mattresses are not sterile.

CAUTION

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

WARMING MATTRESS 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.
- Exercise caution when using multiple warming methods.
- Ensure that Warming Mattresses are securely fastened to the table with "THIS SIDE UP" labeling facing up.
- 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.
- Gel pad placement between Warming Mattresses and the patient is not recommended; gel pads may cause a loss of warming performance.
- Always use a thin barrier between the patient and Warming Mattresses.
- Position the patient on flat Warming Mattress.
- Take extra precautions to alleviate pressure under bony prominences when warming under the patient. Ineffective pressure mitigation can result in under-perfused tissue and cause a pressure injury. Pressure injuries can be exacerbated by warming under-perfused tissue.
- Maintain contact between the patient and the labeled sensor on Warming Mattress. Alarms or ineffective warming may occur if contact is not maintained.
- Do not place cold objects, saline bags, or metal near or on the sensor. It can prevent the Warming Mattress from reaching the set temperature, resulting in an E2 alarm, negatively affecting product safety.
- Do not use operating table clamps or similar devices on Warming Mattresses as they may cause damage to the device and result in loss of the heating function and/or localized heat build-up in the damaged area.
- Do not place Warming Mattresses over a table joint that will move during surgery.
- Do not use Warming Mattress Overlays as a stand-alone patient pressure relief system. The Warming Mattress Overlays are pressure-neutral and are not designed to provide pressure relief. Stand-alone use could result in insufficient pressure relief and cause a pressure injury.
- The Warming Mattress is designed to not inhibit the pressure-relief qualities of the surface below. When adequate pressure relief is not provided by the surface below, warming may increase the severity of a pressure injury, typically at the location of bony prominences
- Do not place any hard objects (e.g., mattress cables, EKG cables, hard cautery return pads, patient fluid lines, etc.) between Warming Mattress and the patient. Hard objects under the patient can result in pressure injuries. Use additional pressure offloading under the Warming Mattress as needed, especially if using a pegboard or beanbag.
- Repeatedly overriding alarms can negatively affect patient safety.
- Do not fold Warming Mattresses during use, as localized heat may build-up.
- Adjust placement of Warming Mattress during X-rays as the internal wiring, located primarily along the edges of the device, and the sensor with associated wire may appear in images.
- Do not place fluid lines under Warming Mattresses or between Warming Mattresses and other warming devices.
- Do not position the patient's head directly on Warming Mattress.
- Do not partially cover the Warming Mattress with thick insulation unless the sensor is also covered, or product damage may occur.

- Do not continue to use Warming Mattresses beyond the labeled expiration date found on the cable. Alarms, ineffective warming, and product failure could occur.
- Follow local and national pressure injury mitigation guidelines. These may include applying prophylactic dressing to bony prominences, such as heels and sacrum, in high-risk patients (e.g. semi-permeable film dressings, hydrocolloid dressings, and foam dressings).
- This device should not be disposed of with general waste at the end of life. Follow local regulations for disposal. The device does not pose any potential hazard.
- Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the country in which it occurred.

INSTRUCTIONS FOR USE

Follow BEST practices to achieve optimal results, as described in part MT302 BEST Results Poster (downloadable at hotdogwarming.com under Brochures). Use only with HotDog Controllers, models WC5X or WC77.

1. Inspect the surface of Warming Mattress for damage (e.g., cuts, tears, creases). Do not use the device if it is damaged.
2. Place Warming Mattress on the padded operating table. Note: For U300, align the device's perineal cutout with OR table mattress perineal cutout in Trendelenburg positioning.

Note: Ensure "THIS SIDE UP" labeling faces up.

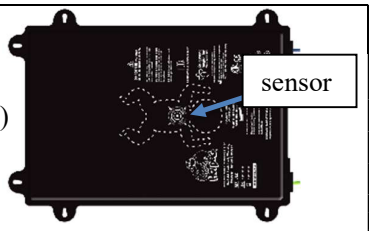
3. Attach Warming Mattress straps to the operating table.

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

4. Place a thin barrier over the entire surface of Warming Mattress. Note: For U300 in Trendelenburg positioning, the A30X WaffleGrip accessory functions as the thin barrier.

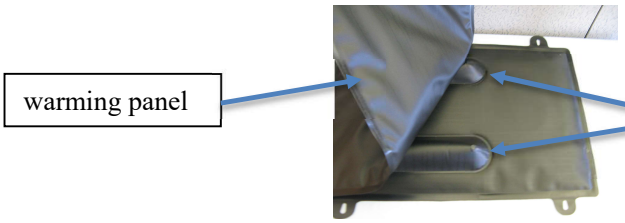
Note: For U220 (Pediatric Warming Mattress) users.

- U220 are intended for use with patients ≤ 20 kg.
- Ensure the patient is on top of the warming panel, over the sensor. (Figure 1.) Use a thin barrier between the patient and the mattress (Figure 3.).

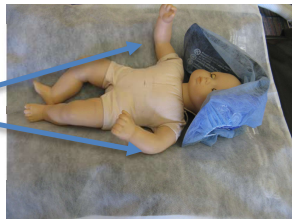


(Figure 1.)

- Use the two foam guides below the warming panel to locate the sensor (Figure 2.) and ensure placement of the patient on top of the warming panel over the sensor and on top of the thin barrier. (Figure 3.)



(Figure 2.)



(Figure 3.)

- Place any patient-positioning devices under the patient below the warming panel. (Figure 4.)

Do not place patient under the warming panel.

(Figure 4.)

5. Turn on the Controller.

6. Insert the blue Mattress Cable (PN A112) into the Mattress Connector.

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.

7. Insert the other end of the blue Mattress Cable (PN A112) into the blue port on the Controller.
8. Set the M port to the desired temperature setting to begin warming. It will automatically start on the highest setting. Allow up to 10 minutes for Warming Mattress to reach set point. The time to reach the set-point temperature from 23 C +/-2 C is less than 10 minutes. If the device does not reach the selected temperature within 10 minutes, an alarm will sound (Refer to the HotDog Controller User and Technical Manual.)
9. If the Controller alarm sounds when Warming Mattress are connected, do not use the device until the alarm condition is resolved. (Refer to the "Alarms" section.)
10. At the conclusion of warming, clean Warming Mattress as necessary. (Refer to "Care and Maintenance" section.)
11. To disconnect the Mattress Cable, grip the connector bodies and pull them apart.

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

CARE AND MAINTENANCE

- Do not continue to use Warming Mattresses beyond the labeled expiration date found on the cable.
- Do not launder or sterilize as this may damage Warming Mattresses.
- Do not immerse Warming Mattresses in liquids.
- Do not use high-level disinfectants (e.g., gluteraldehyde and peracetic acid) or hydrogen peroxide-based solutions to clean Warming Mattresses.
- 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 Warming Mattresses if they show signs of damage or excessive wear such as cuts, holes or loose electrical connectors. Technical staff should inspect devices to determine if they are safe for use.
- Do not disassemble Warming Mattresses; the devices have no user- serviceable parts. If service is required, call an authorized service representative for assistance.
- Do not fold and crease the Warming Mattress sharply or fold repeatedly in the same location.

STORAGE

- Store Warming Mattresses in a dry place, and do not allow the devices to be cut or crushed.
- Do not freeze Warming Mattresses; store at room temperature.

Note: If Warming Mattresses have been exposed to freezing temperatures, do not bend or roll the devices as this may result in cracks to the pressure-relief foam. Allow the devices to reach room temperature prior to handling.

- Do not store any other objects on top of Warming Mattresses.
- Do not fold or sharply bend Warming Mattresses; the recommended storage configuration is flat (preferred) or rolled.

CLEANING - GENERAL

Clean and disinfect the Warming Mattress between patient uses if the device appears visibly soiled. If the device 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.

Hydrogen peroxide-based cleaning solutions should NOT be used because the vapors degrade the conductive fabric heaters.

In general, alcohol-based disinfectants are easiest to use since they are fast-acting and can be either sprayed or wiped on the device. Other cleaners that are compatible with the outer surface of the device 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 Mattress in an autoclave, sterilizer, automatic washer-disinfector or any other high-temperature system as this may damage the device.

CLEANING AND DISINFECTION STEPS

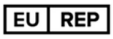
The cleaning steps below are general recommendations and are not meant to replace hospital-specific cleaning protocols.

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 Warming Mattress using a dampened cloth. Do not immerse the device in liquids.
3. Apply a low- or intermediate-level disinfectant to the entire surface of Warming Mattresses by spraying or wiping. Follow the disinfectant manufacturer's application instructions to ensure disinfection.
4. Dry thoroughly before use.

ALARMS

All alarm conditions in the Controller are classified as Medium Priority Technical Alarms. If an alarm occurs, unplug the device to reset the Controller. Check the Warming Mattress and attempt to resolve the alarm. If Alarm Lights illuminate after a reset is performed, discontinue use and refer the system to Biomedical Engineering. Refer to the Controller **User and Technical Manual** for specific information on the Error Codes displayed.

DEFINITION OF SYMBOLS

	Attention, consult accompanying documents.		Place under patient with this side up		BF Patient Applied Part according to IEC60601-1.
	Serial Number		Reference Number		Do not use after YYYY-MM-DD
	Manufacture Date		Unique Device Identifier		Do not submerge
	Temperature Sensor		Keep Dry		Conforms to European Medical Device Regulation 2017/745
	Transport and Storage Humidity Range		Transport and Storage Temperature Range		Separate treatment from general waste at end of life. See Precautions for details.
	Natural Latex Free		Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.
	Manufacturer		Consult the electronic instructions for use on the website at the URL provided.		EU Authorized Representative

MD	Medical Device	⚠	See IFU for Warnings and Precautions	Rx only	Medical Device restricted to sale by or on the order of a physician
	MDR Importer				
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)				
	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 European Medical Device Regulation 2017/745 as a Class IIb device.				

HotDog is a trademark of Augustine Temperature Management, registered in the U.S. Patent & Trademark Office. Devices are protected by some or all of the following patents: (US Patents 7,543,344; 7,714,255; 7,851,729; 7,786,408; 8,062,343; 8,283,602; 8,604,391; 8,624,164; 8,772,676; 8,986,359; 9,962,122; 9,668,303; 10,154,543; 10,201,935; 10,206,248; 10,506,668; PCT Patent EP 2,062,460) . Other patents are pending.

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