Pediatric Patient Warming Mattress Models U220 and U522 Instructions for Use

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CE
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DEVICE DESCRIPTION

The HotDog Pediatric Underbody Warming Mattress U220 ("Warming Mattress") is a component of the HotDog Patient Warming System (System) and should only be used with HotDog Controller WCXX. Warming Mattresses provide a surface area for under-body patient warming at a specified and uniform temperature. An internal temperature sensor provides output to the Controller to maintain the set temperature. Warming Mattresses, 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.

The HotDog Pediatric Underbody Warming Mattress + Return Electrode (U522) (Return Electrode Mattress) is a component of the System and should only be used with HotDog Controller Model WC77. The Return Electrode Mattress is a component of the System and should only be used with Controller Model WC77. Each Return Electrode Mattress is sold with a *return electrode, dual generator "Y" cable (A137)* that enables connection to one or two electrosurgical generators. When connected to an electrosurgical generator, the Return Electrode Mattress functions as both a warming mattress and a neutral return electrode. This consolidation of underbody warming and electrosurgical grounding reduces cleaning and handling of multiple cumbersome pads. The Return Electrode Cable (A136) or the Return Electrode, Dual Generator "Y" Cable, (A137) allows for use of one or two electrosurgical generators with the Return Electrode Mattress, respectively. Do not use the return electrode function when patient's body weight is less than 0.35 kg (0.8lb). There is no upper weight limit.

Warming Mattress Models U220 and U522 were specifically designed for patients at or under 20Kg. For patients over 20Kg, please use HotDog Underbody Warming Mattress Model U10X, U3XX or U50X

These instructions apply to the following part numbers:

HotDog Product Description	Part Number	Qty/Pkg	Compatible Controllers	
Pediatric Underbody Warming Mattress + Return Electrode	U522	1	WC77	CE 2797
Pediatric Underbody Warming Mattress	U220	1	WC77, WC52	

Each Mattress includes (1) A112 cable.

One (1) return electrode, Dual Generator "Y" cable (A137) is included with U522.

INDICATIONS FOR USE

Warming Mattresses and Return Electrode Mattresses are intended to prevent or treat hypothermia and to provide warmth to patients. They should be used in circumstances in which patients could become cold. In addition, Warming Mattresses and Return Electrode Mattresses are designed to provide pressure relief (although they are not stand-alone pressure-relief devices). The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating, recovery, and emergency rooms and on medical/surgical floors.

The Return Electrode Mattresses is designed to be used whenever monopolar electrosurgery is indicated. The intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units (ESU) or generators in monopolar surgery.

This device is restricted to use with isolated monopolar electrosurgical generators, not intended for radio frequency ablation.

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 Mattresses or Return Electrode Mattresses with other under-patient thermal management systems.

WARMING MATTRESS WARNINGS

- Explosion Hazard – Do not use Warming Mattresses and Return Electrode 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 product 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 and Return Electrode Mattresses are not sterile.

CAUTION

Federal law (USA) restricts this device 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.
- Take caution when using multiple warming methods.
- Ensure that Warming Mattresses and Return Electrode Mattresses are securely fastened to the table.
- 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 Return Electrode Mattresses and the patient is not recommended; gel pads may cause a loss of warming performance.
- To avoid skin-to-skin contact, always use a thin barrier between the patient and Warming Mattresses.
- Position the patient on flat Warming Mattresses and Return Electrode Mattresses.
- Do not use Warming Mattresses and Return Electrode Mattresses when the risk of pressure injury cannot be mitigated.
- Maintain contact between the patient and the labeled sensor on Warming Mattresses or Return Electrode Mattresses.
- Do not use operating table clamps or similar devices on Warming Mattresses or Return Electrode 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 or Return Electrode Mattresses over a table joint that will move during surgery.
- Do not use Warming Mattresses or Return Electrode Mattresses 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 Warming Mattresses or Return Electrode Mattresses and the patient.
- Do not fold Warming Mattress or Return Electrode Mattress during use, as localized heat may build-up.

- Adjust placement of Warming Mattress or Return Electrode 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 Return Electrode Mattresses or between Warming Mattresses or Return Electrode Mattresses other warming devices.
- Do not position the patient's head directly on Warming Mattresses or the Warming Return Electrode Mattress.

INSTRUCTIONS FOR USE

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.

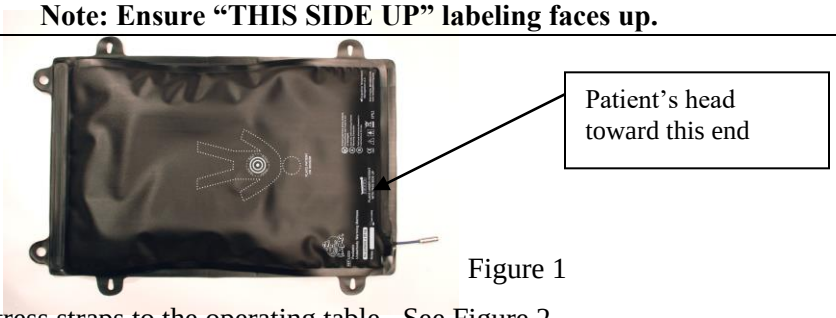


Figure 1

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 is firmly secure. If the straps are not secure, the mattress can slide off the table, resulting in patient injury.

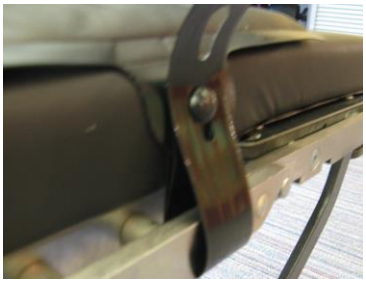


Figure 2

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

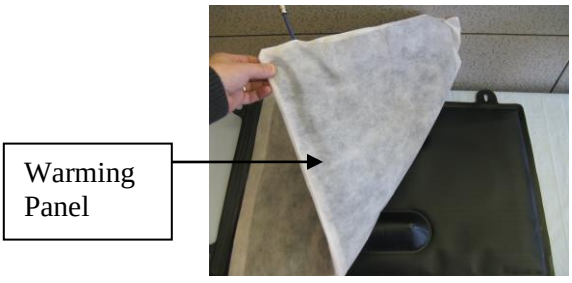


Figure 3

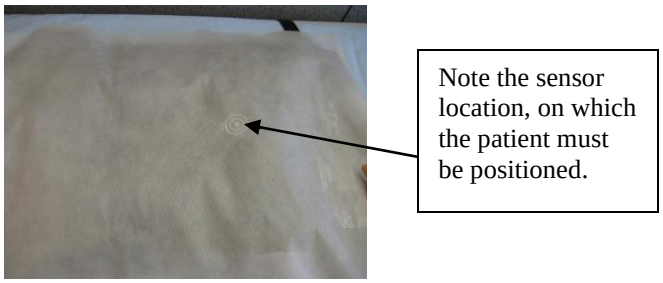


Figure 4

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.

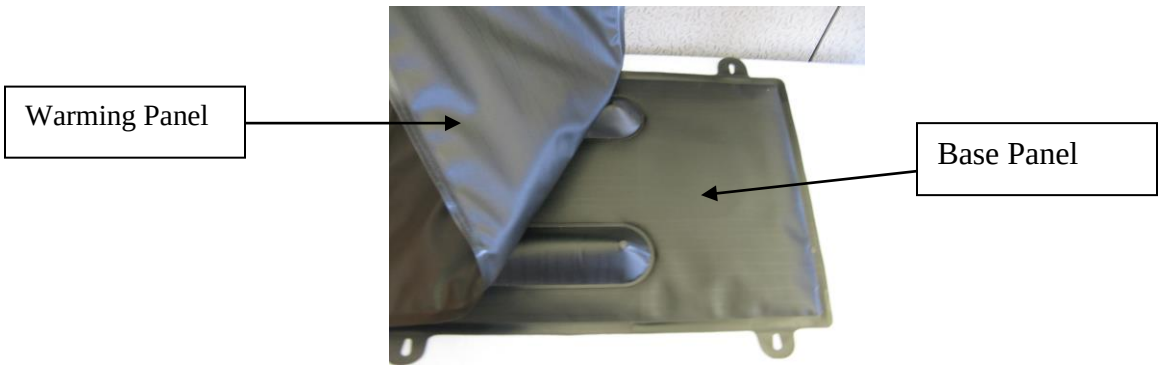


Figure 5

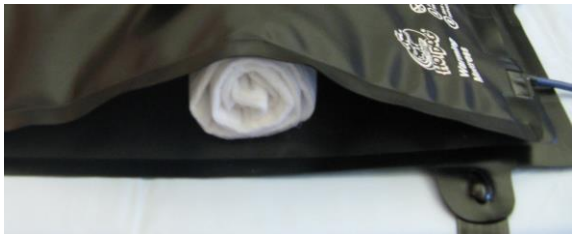


Figure 7

Figure 6

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.

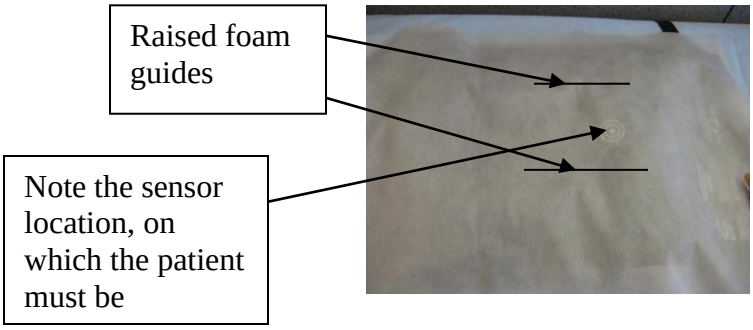


Figure 8

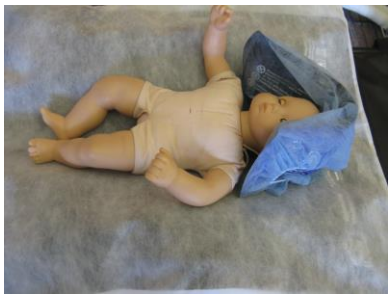
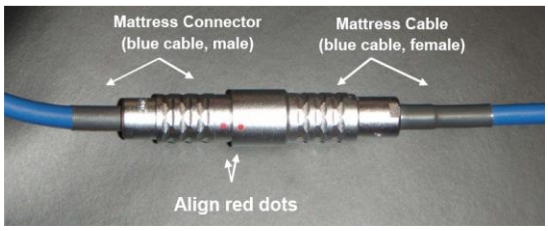


Figure 9

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.

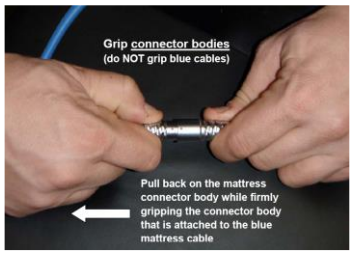
Figure 10: Cable Connection



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. Allow 5 minutes for the Warming Mattress to reach set point. (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, 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



RETURN ELECTRODE MATTRESS INSTRUCTIONS

Capacitive Return Electrode Principles

The Return Electrode Mattress completes the circuit required for electrosurgery through capacitance.

The separation of two conductive plates by an insulator creates a capacitor. The insulator prevents current from flowing directly between the two plates, *thereby avoiding the resistance which creates heat.* With capacitive grounding, current from the active electrode produces a charge on the first conductive plate. This causes an equal (but opposite) charge to form on the second conductive plate. Current produced by the charge on the second plate produces electrical returns to the generator and completes the circuit.

Enabling the Return Electrode Mattress

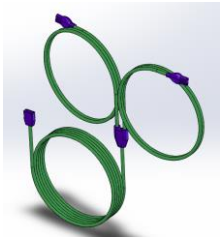
Each Return Electrode Mattress is sold with a green Return Electrode, Dual Generator "Y" Cable, A137 (Figure 3) that enables connection to one or two electrosurgical generators. When connected to an electrosurgical generator the Return Electrode Mattress functions both as a warming mattress and a neutral return electrode. This consolidation of underbody warming and electrosurgical grounding reduces cleaning and handling of multiple cumbersome pads. Also available is an A136 (Figure 5) return electrode cable for use with one electrosurgical generator.

Instructions for Use – Return Electrode Mattress

To enable the use of the return electrode function, connect a green return electrode cable (A136 or A137) to the green side entry cable extending from the Return Electrode Mattress. Then connect the other end (Figure 4) to an electrosurgical generator.

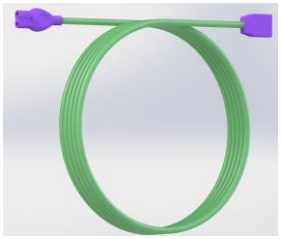
For simultaneous operations of two electrosurgical generators or ESUs, connect each end of the Dual Generator "Y" Cable A137 to separate generator. If only connecting to one generator with the "Y" cable, secure unused cord. Failure to secure extra cord during use many result in an electrical hazard.

Only use the A136 and the A137 cables with the Return Electrode Mattress. Do not use these cables with single-use adhesive grounding or any other brand of return electrodes.



(Figure 3.)

(Figure 4.)



(Figure 5.)

All previous warnings and precautions relating to Warming Mattresses apply to the Return Electrode Mattress.

RETURN ELECTRODE MATTRESS WARNINGS

- Use the lowest possible power settings that can achieve the desired effect.
- Do not use the return electrode function when patient's body weight is less than 0.35 kg (0.8lb).
- Use with isolated generators only.
- Do not use HIGH CUT or ENDO CUT modes when using the ERBE 200, 300 and 350. Doing so may result in a different electrosurgical effect than intended.
- When the generator is operational, keep active accessories away from the patient and the device when not in use, or store in an electrically isolated container.

RETURN ELECTRODE MATTRESS PRECAUTIONS

- Only use the A136 and the A137 cables with the Return Electrode Mattress. Do not use these cables with single-use adhesive grounding or any other brand of return electrodes.
- The Return Electrode Mattress should only be used with WC77 Controller.
- Do not place the Return Electrode Mattress directly onto a metal surface.
- The use of excessive materials between the patient and the Return Electrode Mattress may result in a diminished electrosurgical effect. The patient should be maximally in contact with the Return Electrode Mattress As thin a barrier as possible should be placed between the patient and the Return Electrode Mattress to increase effectiveness.
- Refer to the generator manufacturer's operating manual for proper usage of electrosurgical equipment.
- Protect the patient from contact with grounded metal objects or parts with appreciable capacitance to earth. (e.g., operating table supports, etc.)
- Avoid having the patient make contact with other conductors and personnel during use.
- Apparent low power output or failure of the electrosurgical equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power output before checking for obvious defects or misapplication. For monopolar surgery, effective contact between the patient and dispersive electrode must be verified whenever the patient is repositioned.
- Use of electrosurgical devices can cause severe electromagnetic interference in other devices, particularly cardiac pacemakers; precautions should be taken to ensure that the patient's well-being is maintained in the event of such interference.
- When using the A137 with only one electrosurgical generator, choose the most convenient cable and secure the other cable that is not in use.
- The Return Electrode Mattress is recommended for use with RF generators at frequency rating from 300 to 600 kHz.
- Position patient leads in such a way that contact with the patient or other leads is avoided.
- Avoid skin-to-skin contact, (for example between the arms and body of the patient).by placement of dry gauze.
- Place monitoring electrodes (e.g. ECG leads) as far as possible from surgical electrodes when electrosurgical and monitoring equipment are used simultaneously.
- Do not use needle-monitoring electrodes.
- Use monitoring systems incorporating high frequency current-limiting devices (note: The WC77 Controller is designed to be compatible with high frequency electrosurgery).
- Use non-flammable agents for cleaning and disinfection wherever possible.
- Flammable agents used for cleaning or disinfecting or as adhesive solvents should be allowed to evaporate before beginning electrosurgery.
- Avoid the pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities, such as the vagina.

- Fluids pooled in the body depressions and cavities should be removed before electrosurgery.
- Attention: danger of ignition of endogenous gases (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of electrosurgical equipment).
- Not for use with generators operating at greater than 1000kHz.

This device is compliant with IEC-60601-2-2 only in the following parameters:

Frequency	Cut Power	COAG Power
[kHz]	[watts]	[watts]
300-600	0-300	0-120

CARE AND MAINTENANCE

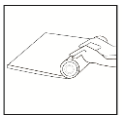
- Do not continue to use Warming Mattresses or the Return Electrode Mattress beyond the labeled expiration date.
- Do not launder or sterilize as this may damage Warming Mattresses or the Return Electrode Mattress.
- Do not immerse Warming Mattresses or the Return Electrode Mattress in liquids.
- Do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

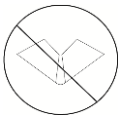
STORAGE

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

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

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





CLEANING - GENERAL

Clean and disinfect Warming Mattresses or the Return Electrode 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. Wipe the device 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 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. Hydrogen peroxide-based cleaning solutions are NOT recommended because the vapors degrade the conductive fabric heaters. Dry thoroughly before use.

Caution: Do not place Warming Mattresses or the Return Electrode 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 Warming Mattresses or the Return Electrode 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 or the Return Electrode Mattress 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. 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.

When in use as a return electrode, the Return Electrode Mattress is designed to be compatible with contact quality monitoring systems and will not cause such systems to alarm.

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		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				
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)				

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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