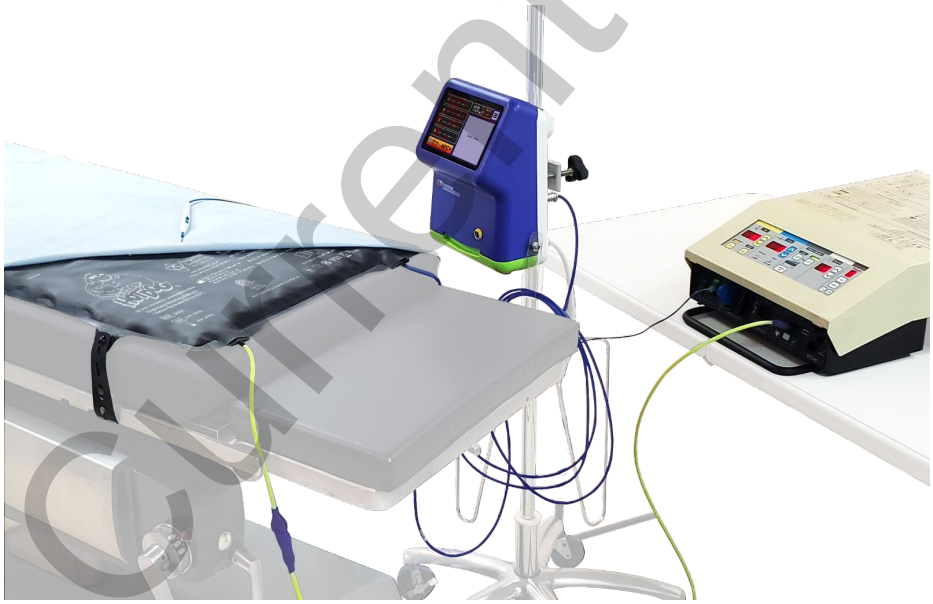
HotDog
Warming Mattress + Return Electrode
Models U501 and U502
Instructions for Use



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DEVICE DESCRIPTION

HotDog Warming Mattresses + Return Electrode are components of the HotDog Temperature Management System ("System") and can only be used with HotDog Controller Model WC77 to provide under-body patient warming at a specified and uniform 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. HotDog Warming Mattresses + Return Electrode are sold with a Return Electrode Cable, 4m (A136) that enables connection to one electrosurgical generator.

These instructions apply to the following part numbers:

HotDog Product Description	Part Number	Qty/Pkg	Compatible Controller
Underbody Warming Mattress + Return Electrode, 82 cm (32in)	U501	1	WC77
Underbody Warming Mattress + Return Electrode, 127 cm (50in)	U502	1	WC77

A112 cables are available separately. A136 cable included.

INDICATIONS FOR USE

The HotDog Temperature Management System (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 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.

The HotDog Return Electrode Mattress is intended to conduct monopolar electrosurgical energy from the target tissue of a patient back to one electrosurgical unit (ESU) or generator in monopolar surgery. The HotDog Return Electrode Mattress is restricted to use with isolated monopolar electrosurgical generators. The HotDog Return Electrode Mattress is intended for use with adult patients only.

CONTRAINDICATIONS (FOR CONTRAINDICATIONS SPECIFIC TO USE OF RETURN ELECTRODE FUNCTION SEE PAGE 5)

- 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 (FOR WARNINGS SPECIFIC TO USE OF RETURN ELECTRODE FUNCTION SEE PAGE 5)

- 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.

- California Proposition 65 Warning: The medical devices and products mentioned in this IFU may contain chemicals including Urethane, which is known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information go to, www.p65warnings.ca.gov

CAUTION (FOR CAUTIONS SPECIFIC TO USE OF RETURN ELECTRODE FUNCTION SEE PAGE 5)

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

WARMING MATTRESS PRECAUTIONS (FOR PRECAUTIONS SPECIFIC TO USE OF RETURN ELECTRODE FUNCTION SEE PAGE 6)

- 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.
- Do not use Warming Mattresses when the risk of pressure injury cannot be mitigated. Take extra precaution to alleviate pressure under bony prominences when warming under the patient.
- Maintain contact between the patient and the labeled sensor on Warming Mattress.
- 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.
- 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.
- 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 sensor is also covered, or product damage may occur.
- This device should not be disposed of with general waste at 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 (FOR INSTRUCTION SPECIFIC TO USE OF RETURN ELECTRODE FUNCTION SEE PAGE 4)

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 Controller model WC77.

1. Inspect the surface of the Warming Mattress for damage (e.g., cuts, tears, creases). Do not use the device if it is damaged.
2. Place the Warming Mattress on top of the padded operating table. (Image 1.) Ensure that “THIS SIDE UP” label faces up.

Image 1.

3. Attach each of the four included straps (image 2.) to loops on the Warming Mattress by connecting to a mushroom button (Image 3.), then sliding the strap through the operating table side rail (Image 4.) and connecting the other end of the strap to the mushroom button (Image 5.). Fold back any extra strap and attach to the mushroom button.

Image 2.

Image 3.

Image 4.

Image 5.

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, such as a sheet, over the entire surface of the Warming Mattress.
5. Insert the blue Mattress Cable (PN A112) into the Mattress Connector, (Image 6). Align the red dots on each connector and gently push the connectors together. Do not force the connector into the socket. You will feel a click when the connectors engage.

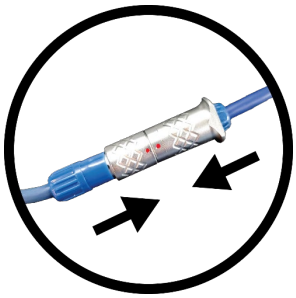


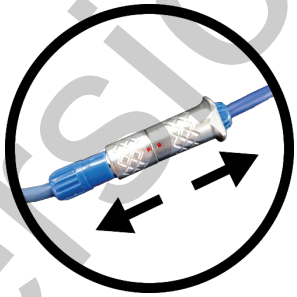
Image 6.

6. Insert the other end of the blue Mattress Cable (PN A112) into the blue port on the Controller (Image 7.) with the red dot at the top of the connector (Image 8.).

Image 7.

Image 8.

7. Turn the Controller on and select the desired temperature setting to begin warming. 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.)
8. 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.)
9. At the conclusion of warming, clean Warming Mattress as necessary. (Refer to "Care and Maintenance" section.)
10. To disconnect the Mattress Cable, grip the connector bodies and pull them apart (Image 9). Do not pull on the 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.



(Image 9.)

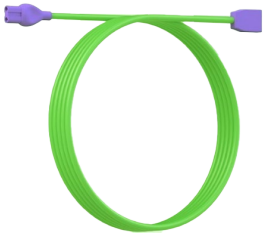
See page 8 for general information regarding care and maintenance, storage, cleaning and alarms.

INSTRUCTIONS RELATED TO THE USE OF THE RETURN ELECTRODE FUNCTION

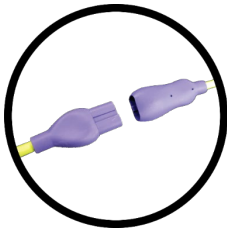
RETURN ELECTRODE FUNCTION SET UP INSTRUCTIONS

Setting Up the Return Electrode Function

Each Warming Mattress + Return Electrode is sold with a green Return Electrode Cable, 4m A136 (Image 10.) that enables connection to one electrosurgical generator. When connected to an electrosurgical generator, the Warming Mattress + Return Electrode functions as a neutral return electrode. See final set up (completed circuit) shown in Image 15.



(Image 10.)



(Image 11.)

To enable the use of the return-electrode function, connect a green Return Electrode Cable, 4m A136 (Image 10.) to the green side entry cable extending from the Return Electrode Mattress (Images 11.). Then connect the other end (Image 12.) to the electrosurgical generator (Images 13 and 14).

Image 12.

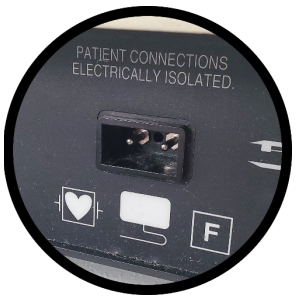


Image 13.

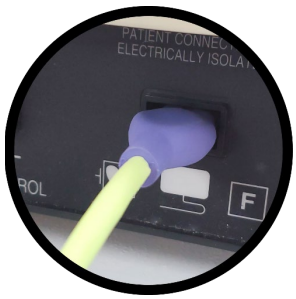
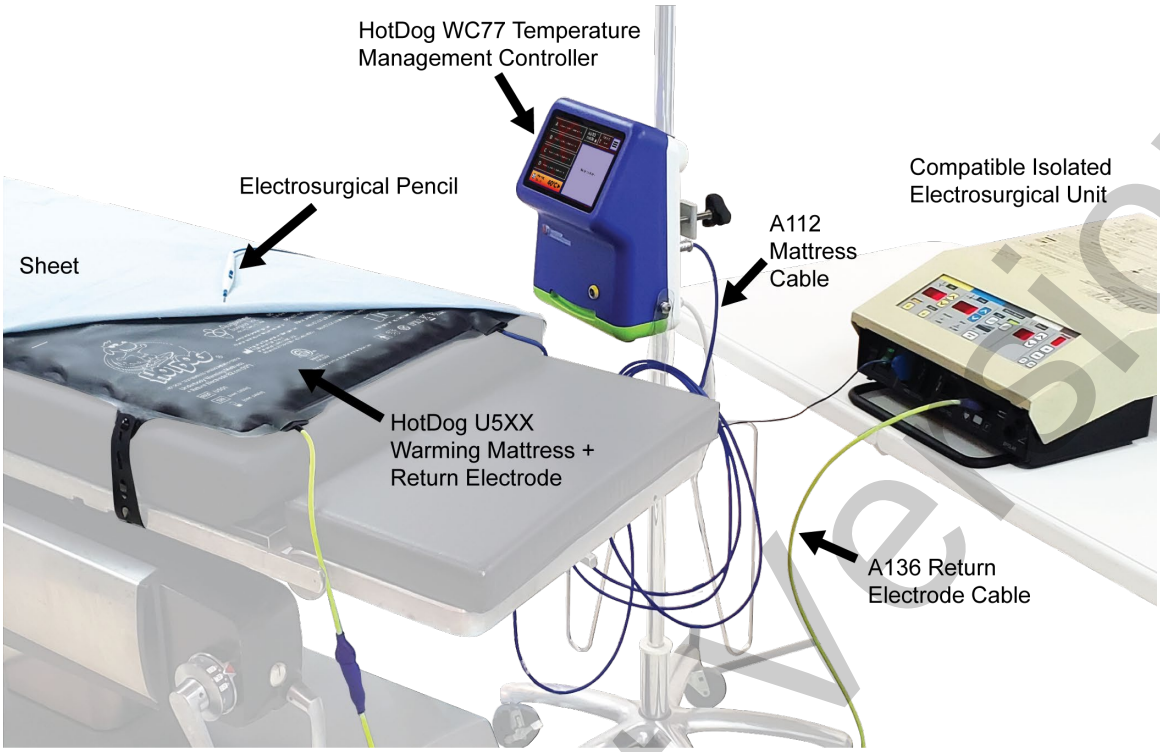


Image 14.

Only use the A136 cable with the Return Electrode Mattress. Do not use this cable with single-use adhesive grounding or any other brand of return electrodes.



(Figure 15.)

RETURN ELECTRODE MATTRESS CONTRAINDICATIONS (FOR CONTRAINDICATIONS SPECIFIC TO USE OF WARMING MATTRESS FUNCTION SEE PAGE 2)

- Do not use the Warming Mattress + Return Electrode with pediatric patients. It is for adult patient use only.
- Do not use the Warming Mattress + Return Electrode as a stand-alone patient pressure relief system.
- The Warming Mattress + Return Electrode Mattress should not be placed directly under the heart when a patient has a cardiovascular implant such as an activated implantable cardiac defibrillator.

RETURN ELECTRODE MATTRESS WARNINGS (FOR WARNINGS SPECIFIC TO USE OF WARMING MATTRESS FUNCTION SEE PAGE 2)

- Use the lowest possible power settings that can achieve the desired effect.
- Use with isolated generators only.
- Do not use HIGH CUT or ENDO CUT modes when using the ERBE 200, 300 and 350, as per warnings on other capacitive return electrodes.
- 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.
- Inspect 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 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 use needle-monitoring electrodes.
- 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).
- Warming Mattresses + Return Electrode are not sterile. For non-sterile use only.
- 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.

RETURN ELECTRODE CAUTIONS (FOR CAUTIONS SPECIFIC TO USE OF WARMING MATTRESS FUNCTION SEE PAGE 3)

- Federal law (USA) restricts these devices to sale by or on the order of a licensed healthcare physician.
- Do not use a Warming Mattress + Return Electrode when the risk of pressure injury cannot be mitigated.
- Do not place any hard objects (e.g., return electrode cable, EKG cables, patient fluid lines, etc.) between a Warming Mattress + Return Electrode and the patient.
- Do not place fluid lines under a Warming Mattress + Return Electrode.
- Do not place a Warming Mattress + Return Electrode directly onto a metal surface.

RETURN ELECTRODE MATTRESS PRECAUTIONS (FOR PRECAUTIONS SPECIFIC TO USE OF WARMING MATTRESS FUNCTION SEE PAGE 3)

- Use under the direct supervision of a clinician.
- Only use the A136 cable with the Warming Mattress + Return Electrode. Do not use these cables with single-use adhesive grounding or any other brand of return electrodes.
- The use of excessive materials between the patient and the Return Electrode Mattress may result in a diminished electrosurgical effect. Take care to maximize patient contact and minimize materials between the pad and patient. The patient should be maximally in contact with the Return Electrode Mattress. As thin a barrier as possible, such as no more than 0.762 mm of bedsheet, 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.
- Warming Mattresses + Return Electrode are recommended for use with isolated RF generators at frequency ratings 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.
- Use monitoring systems incorporating high frequency current-limiting devices.
- 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.
- Not for use with generators operating at greater than 600kHz.
- Return Electrode Mattress is restricted to use with isolated monopolar electrosurgical generators; it is not intended for radio frequency ablation.
- Dispose of per local regulations.

The Warming Mattress + Return Electrode and A136 cable are 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 - GENERAL

- Do not continue to use a Warming Mattress + Return Electrode beyond the labeled expiration date, found on the cable.
- Do not launder or sterilize as this may damage a Warming Mattress + Return Electrode.
- Do not immerse a Warming Mattress + Return Electrode in liquids.
- Do not use high-level disinfectants (e.g., glutaraldehyde and peracetic acid) or hydrogen peroxide-based solutions to clean a Warming Mattress + Return Electrode.
- 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 a Warming Mattress + Return Electrode 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 a Warming Mattress + Return Electrode; the devices have no user- serviceable parts. If service is required, call an authorized service representative for assistance.
- Do not fold and crease a Warming Mattress + Return Electrode sharply or fold repeatedly in the same location.

STORAGE - GENERAL

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

Note: If a Warming Mattress + Return Electrode has been exposed to freezing temperatures, do not bend or roll the device 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 a Warming Mattress + Return Electrode.
- Do not fold or sharply bend a Warming Mattress + Return Electrode; the recommended storage configuration is flat (preferred) or rolled.

CLEANING - GENERAL

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

ALARMS - GENERAL

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		Medical Device restricted to sale by or on the order of a physician
	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.		See IFU for Warnings and Precautions
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)				

Intertek	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.**

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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