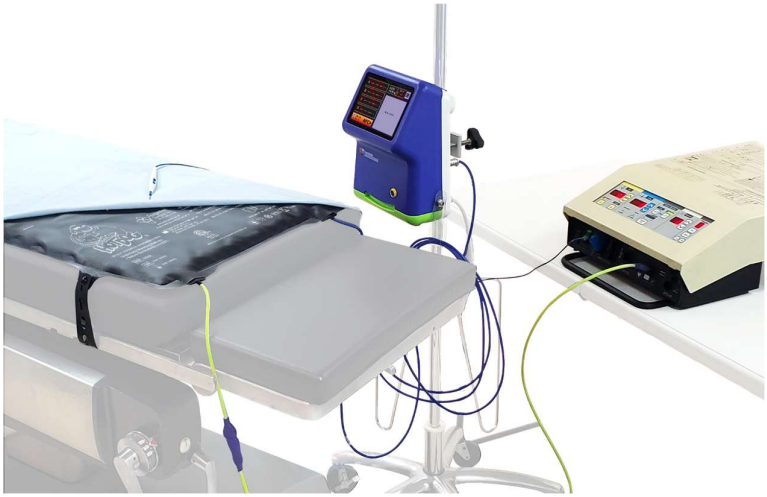
HotDog Underbody Warming Mattress + Return Electrode Models U501, U502, and U530 Instructions for Use



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CE 2460

DEVICE DESCRIPTION

HotDog Underbody 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 require a Return Electrode Cable, 4m (A136) that enables connection to one electrosurgical generator or an A137 Return Electrode Dual Generator "Y" Cable to connect to two electrosurgical generators

These instructions apply to the following part numbers:

HotDog Product Description	Part Number	Qty/Pkg	Compatible Controller	
HotDog Underbody Warming Mattress + Return Electrode, 82 cm (32in)	U501	1	WC77	CE 2460
HotDog Underbody Warming Mattress + Return Electrode, 127 cm (50in)	U502	1	WC77	
HotDog Underbody Warming Mattress + Return Electrode, 89 cm (35in)	U530	1	WC77	

All cables are available separately.

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

TARGET PATIENT GROUP

The System is intended for use with adult patients in circumstances in which patients may not be able to maintain a state of normothermia. The HotDog Underbody Warming Mattress + Return Electrode can also be used when adult patients are undergoing surgical procedures that require monopolar electrosurgical grounding. It is not intended for pediatric patient use.

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. The HotDog Underbody Warming Mattress + Return Electrode is intended to conduct monopolar electrosurgical energy from the target tissue of a patient back to one or two electrosurgical units (ESU) or generators in monopolar surgery.

WARMING MATTRESS 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)

- 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.

WARMING MATTRESS 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.
- 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.
- 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 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 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.

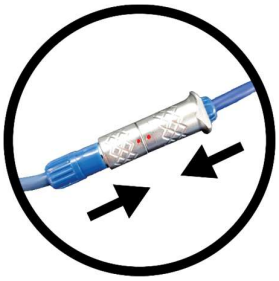

Image 6

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 is 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.

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

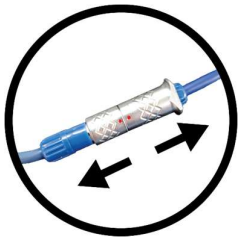

Image 9

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 requires a green Return Electrode Cable, 4m A136 (Image 10) to connect to one electrosurgical generator or an A137 Return Electrode Dual Generator "Y" Cable (Image 11) to connect to two electrosurgical generators. When connected to an electrosurgical generator, the Warming Mattress + Return Electrode functions as a neutral return electrode. See final set up in Image 20.

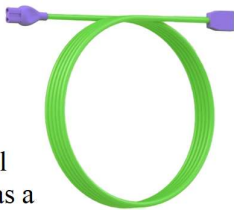

Image 10

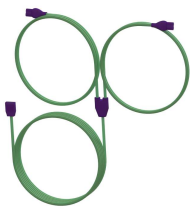

Image 11

Image 12

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 (Image 13). Then connect the other end (Image 14) to the electrosurgical generator (Images 18 and 19). If using two electrosurgical

generators, use the A137 Return Electrode Dual Generator "Y" Cable (Image 11) and connect each end of the dual cable after the "Y" to its own generator. If using the A137 Return Electrode Dual Generator "Y" Cable with only one generator, ensure that the unused length of the second cable is loosely secured away from the floor. Some generators offer the choice between dual plate or single plate return electrode (Images 16 and 17). If given this choice you should select the single plate option. (Image 17). Generators that use Contact Quality Monitoring (CQM), sometimes also called Return Electrode Monitoring (REM), with no single-plate option will require the use of the A138 adapter (Image 12) or the A139 adapter. Contact your sales representative to determine the adapter model you require. Use an adaptor only in dual-plate setting. If required, connect the A136 cable to the adapter before connecting it (Images 15 and 19) to the generator. Two adapters would be needed for the A137 Dual Generator "Y" Cable if adapters are required.

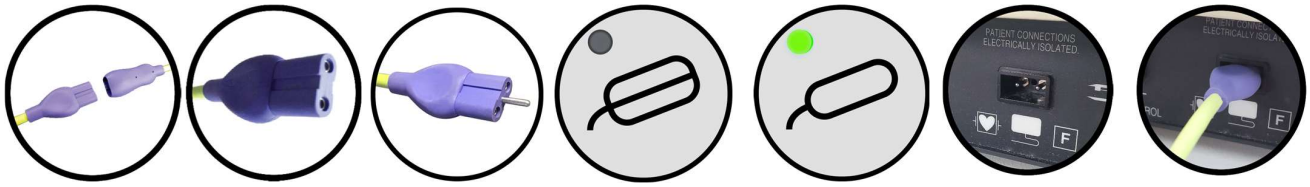

Image 13 Image 14 Image 15 Image 16 Image 17 Image 18 Image 19

Do not use this cable with single-use adhesive grounding or any other brand of return electrodes.

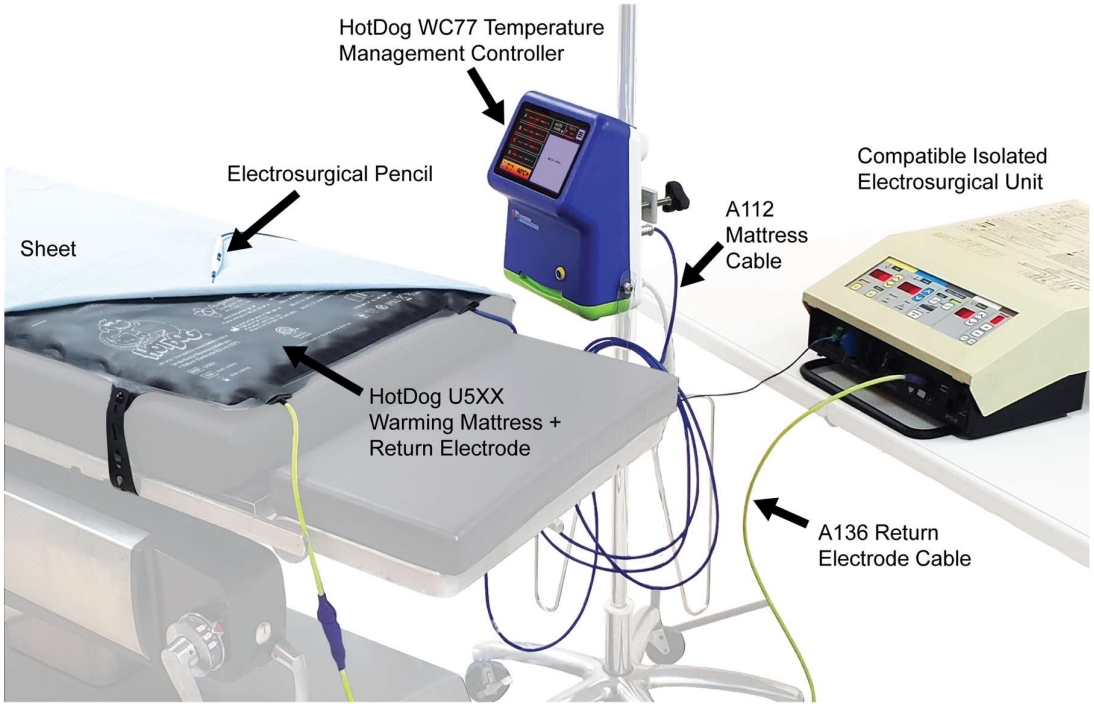

Image 20

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 overlay 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 automatic implantable cardioverter 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 the Return Electrode with specialty modes on generators. For example, HIGH CUT or ENDO CUT modes when using the ERBE ICC 200, 300, 350, or VIO series of electrosurgical generator(s). 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.
- Inspect components prior to each use for signs of damage or excessive wear such as cuts, holes, 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.
- If patient has a cardiac implantable electronic device (CIED), take appropriate action to ensure that the patient's well-being is maintained during electrosurgery, regardless of surgical location. Use of electrosurgical devices can cause severe electromagnetic interference in other devices, such as cardiac pacemakers and implantable cardioverter defibrillators.

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.
- Use of electrosurgical devices can cause severe electromagnetic interference in other devices, for patients with cardiac pacemakers, electrically conductive or other active implants, a possible hazard exists due to the concentration or re-direction of HF currents. The pacemaker or other active implant may be damaged due to the interreference of HF currents. In case of doubt, approved qualified advice should be obtained from the device manufacturer.
- Not all Electrosurgical Units (ESUs, Generators) are compatible with this Warming Mattress + Return Electrode. Augustine Surgical maintains a list of compatible generators. Confirm compatibility before use.

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 Warming Mattress + Return Electrode. As thin a barrier as possible, such as no more than 0.8 mm of bedsheet, should be placed between the patient and the Warming Mattress + Return Electrode 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.
- 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.
- 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.
- To avoid the risk of tracheal fires, never use electrosurgery to enter the trachea during tracheostomy procedures.
- For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area (e.g. Circumcisions), the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- Only physicians familiar with electrosurgical effects on surgical patients should operate this device.
- To reduce the chance of alternate site burns due to alternate current pathways, the patient, when practical, should not be allowed to come into contact with metal parts that are grounded. It is recognized that this recommendation may not be practical during certain procedures; however, to maximize patient safety during the use of electrosurgical devices, such practices should be minimized.
- Electrosurgical cables should be positioned to minimize contact with the patient and avoid contact with other leads to avoid adversely influencing the operation of other electronic equipment.
- 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 it shows 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 it 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 + Return Electrode 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
	Conforms to European Medical Device Regulation 2017/745		EU Authorized Representative		Medical Device
	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.				

<table>
<tr><td colspan="2">Essential Performance</td></tr>
<tr><td>Warming</td><td>
1. If the applied part cannot reach set point within 10 minutes, the warming device shall turn off and a low priority technical alert shall be generated

2. Minimum watt density of the heater shall be sufficient to achieve clinically effective warming (0.10 watts per square inch (155 watts per square meter))

3. Maximum watt density of the heater shall be less than 0.45 watts per square inch (620 watts per square meter)

4. Patient contact surfaces of the HotDog System shall operate at a set point +/- 5°C at steady state when device is under even thermal load

5. The thermal storage capacity of the applied part shall be less than 100% of the power output of the heater

6. In normal or single fault conditions, the warming device shall not raise skin temperature above 43°C. If skin temperatures exceed 43°C, they will stay within the following time/temperature limits:
<table>
<tr><td>Time (s)</td><td>Temperature (C)</td></tr>
<tr><td>10000</td><td>43.5</td></tr>
<tr><td>6000</td><td>44</td></tr>
<tr><td>3300</td><td>44.5</td></tr>
<tr><td>1990</td><td>45</td></tr>
<tr><td>1000</td><td>45.5</td></tr>
<tr><td>600</td><td>46</td></tr>
<tr><td>350</td><td>46.5</td></tr>
<tr><td>225</td><td>47</td></tr>
<tr><td>110</td><td>47.5</td></tr>
<tr><td>80</td><td>48</td></tr>
<tr><td>60</td><td>48.5</td></tr>
<tr><td>38</td><td>49</td></tr>
<tr><td>28</td><td>49.5</td></tr>
<tr><td>22</td><td>50</td></tr>
<tr><td>17</td><td>50.5</td></tr>
</table>
</td></tr>
<tr><td>Return Electrode</td><td>1. As a capacitive neutral electrode (NE), contact capacitance shall be no less than 4 nF over the frequency range of 300-600 kHz, tested per IEC 60601-2-2 ed6.0, clause 201.15.101.6</td></tr>
</table>

Electrosurgical Unit (ESU, Generator) Compatibility

As indicated, the HotDog Return Electrode Mattress is restricted to use with isolated monopolar electrosurgical generators. The HotDog Return Electrode Mattress has been tested to be compatible with the generators in the table below, in both single ESU use and 2 ESU use. Contact Augustine technical support for a list of additional compatible ESUs. Use of ESU models that have not been tested with system could function improperly and could lead to harm of the patient.

ESU Model	**ESU Specification**	**Value**
Conmed Sabre 2400	Operating Frequency	417 kHz
	Crest Factor	1.8
	Max. Open Circuit Volt P-P	2000
	Max Power	300 watts
ERBE ICC 350	Rated Frequency	330 kHz
	Crest factor C, at R_L = 500 ohms	C = 1.4 for all settings
	Max HF volatage at load resistance $R_L = \infty$	650 V_P

	HF rated Power	300 watts at R_L = 500 ohms

Electromagnetic Compatibility (EMC) of the HotDog System
The System requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided in this User Manual.

Warning

- Warning per IEC 60601-1-2 (ed. 4.0) Standard:
    - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
    - Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
    - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the WC7X, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The HotDog™ System is intended for use in the electromagnetic environment specified below. The customer or user of the HotDog System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions, CISPR 11	Group 1	The HotDog Patient Warming System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class A	NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions, IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The HotDog™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or the user of the HotDog Patient Warming System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2, 4, 8 kV contact ±2, 4, 8, 15 kV air	±2, 4, 8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% *U*T for 0,5 cycle (0-315° with 45° increments) 0% *U*T (100 % dip in *U*T) for 1 cycles 70 % *U*T (30 % dip in *U*T) for 25/30 cycles 0 % *U*T (100 % dip in *U*T) for 5 sec	0% *U*T for 0,5 cycle (0-315° with 45° increments) 0% *U*T (100 % dip in *U*T) for 1 cycles 70 % *U*T (30 % dip in *U*T) for 25/30 cycles 0% *U*T (100 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HotDog Patient Warming System requires continued operation during power mains interruptions, it is recommended that the HotDog Patient Warming System be powered from an uninterruptible power supply or a battery.
Power frequency 50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (cont'd)

The HotDog™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or the user of the HotDog Patient Warming System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms with 6 Vrms in ISM bands 150 kHz to 80 MHz 10 V/m 80 MHz to 2,7 GHz	3 V, and 6 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HotDog Patient Warming System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}7\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HotDog Patient Warming System is used exceeds the applicable RF compliance level above, the HotDog Patient Warming System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HotDog Patient Warming System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the HotDog Patient Warming System

The HotDog Patient Warming System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 0{,}7\sqrt{P}$
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,2	0,35	0,70
10	3,7	1,1	2,2
100	12	3,5	7,0

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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