Veterinary Underbody Warming Mattress + Return Electrode U501V

Instructions for Use

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DEVICE DESCRIPTION

The HotDog® Veterinary Underbody Warming Mattresses + Return Electrode is a component of the HotDog Temperature Management System and can only be used with the Veterinary HotDog Controller Model WC77V to provide underbody warming for veterinary patients at a specified and uniform temperature. The U501V incorporates an integrated multilayer foam construction designed to provide pressure reduction while also functioning as a return electrode for compatible isolated monopolar electrosurgical generators. The Mattress is water- and solvent-resistant. All seams are fully sealed to allow for easy cleaning and disinfection.

HotDog Veterinary Warming Mattresses + Return Electrode require a Return Electrode Cable, 13 ft (4.0 m) [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	Compatible Controller
HotDog Veterinary Underbody Warming Mattress + Return Electrode, 82 cm (32in)	U501V	WC77V
Blue Mattress Cable, 16.4 ft (5.0 m) (sold separately)	A112	WC77V
Return Electrode Cable, 13.1 ft (4.0 m) (sold separately)	A136	Connects to User Supplied ESU
Return Electrode, Dual Generator "Y" Cable, 11.5 ft (main) 4.9 ft (Y lengths) (3.5 m, 1.5 m) (sold separately)	A137	Connects to User Supplied ESU
REM Enabled Return Electrode Cable, 16.5 in (42 cm) (sold separately)	A138	Connects to User Supplied ESU

INDICATIONS FOR USE

The HotDog Temperature Management System is intended to prevent or treat hypothermia and to provide warmth to veterinary patients. The System should be used in circumstances in which veterinary patients may not maintain a state of normothermia.

The System is intended primarily for use in veterinary surgical environments, including, without limitation, operating rooms, dental suites, and other veterinary surgical areas.

The HotDog Return Electrode Mattress is intended to conduct monopolar electrosurgical energy from the target tissue of a veterinary patient back to one or two electrosurgical generators in monopolar surgery. The Return Electrode Mattress is restricted to use with isolated monopolar electrosurgical generators. The Return Electrode Mattress is intended for use with veterinary patients weighing at least 4.4 lb (2 kg).

WARMING MATTRESS CONTRAINDICATIONS

(FOR CONTRAINDICATIONS SPECIFIC TO USE OF RETURN ELECTRODE FUNCTION, SEE PAGE 6)

- 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 6)

- 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

WARMING MATTRESS PRECAUTIONS

(FOR PRECAUTIONS SPECIFIC TO USE OF RETURN ELECTRODE FUNCTION, SEE PAGE 7 & 8)

- 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.
- Do not allow other warming devices to come into direct contact with the Warming Mattress. This may result in nuisance alarms.
- 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.
- Always use a thin barrier between the patient and Warming Mattress. Best practice = barrier < 0.8mm.
- 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 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 partially cover the Warming Mattress with thick insulation unless the sensor is also covered, or product damage may occur.
- Position the patient appropriately for the planned procedure and duration of use. Assess the patient's condition throughout use according to institutional protocol.

INSTRUCTIONS FOR USE

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

Use only with HotDog Controller model WC77V

1. Inspect the Warming Mattress for signs of damage, such as cuts, tears, creases, or abrasions. Do not use the device if damaged.
2. Place the Warming Mattress on the intended procedure surface. The black (patient-facing) side should face up. *(Image 1)*
3. Place a thin barrier, such as a disposable veterinary drape or thin sheet, over the Warming Mattress before positioning the patient. Best practice = barrier < 0.8mm
4. Insert the blue Mattress Cable (PN A112) into the Mattress Connector, (Image 2). 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.

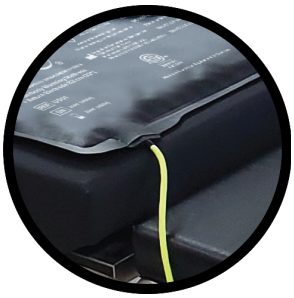


Image 1

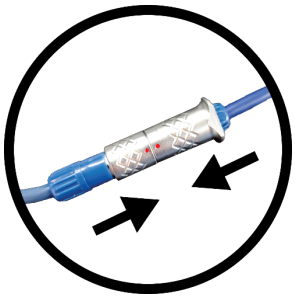


Image 2

Image 3

Image 4

5. Insert the other end of the blue Mattress Cable (PN A112) into the blue port on the Controller *(Image 3)* with the red dot at the top of the connector *(Image 4)*.
6. 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.
7. 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 on pgs. 11 & 12)
8. At the conclusion of warming, clean Warming Mattress as necessary. (Refer to "Care and Maintenance" section on pg. 9)
9. To disconnect the Mattress Cable, grip the connector bodies and pull them apart *(Image 5).* 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.

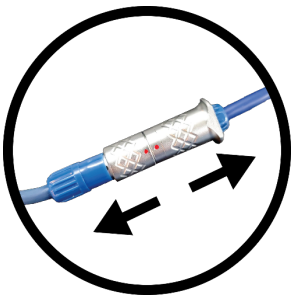
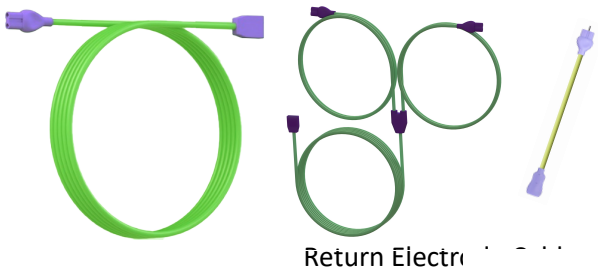


Image 5

INSTRUCTIONS RELATED TO THE USE OF THE RETURN ELECTRODE FUNCTION (FOR INSTRUCTIONS SPECIFIC TO WARMING FUNCTION, SEE PAGE 4)

Return Electrode Function Setup Instructions

Each Warming Mattress + Return Electrode requires a green



Return Electr

Image 8 (A138)

13 ft (4.0 m) [A136] *(Image 6)* to connect to one electrosurgical generator or an A137 Return Electrode D Generator "Y" Cable *(Image 7)* 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 setup in *Image 16 (next page)*.

To enable the use of the return-electrode function,

1. Connect a green A136 Return Electrode Cable, 13 ft (4.0 m) (Image 6) to the green side-entry cable extending from the Return Electrode Mattress (Image 9).

2. Connect the other end of the A136 cable (Image 10) to the electrosurgical generator (Images 14 and 15).

3. If using two electrosurgical generators, use the A137 Return Electrode Dual Generator "Y" Cable (Image 7). Connect each end of the "Y" cable to its respective generator after the split.
    a. **Note:** If only one generator is being used with the A137 "Y" Cable, ensure the unused leg of the cable is secured off the floor to avoid damage or interference.

4. Some electrosurgical generators offer a choice between dual plate and single plate return electrode modes (Images 12 and 13). When this option is presented, select the single plate mode (Image 13).

5. For generators that use Contact Quality Monitoring (CQM) — also referred to as Return Electrode Monitoring (REM) — the A138 Adapter (Image 8) may be required. If needed, connect the A136 cable to the A138 Adapter before attaching it to the generator (Images 11 and 15).
    a. **Note:** If using the A137 "Y" Cable and CQM/REM is required, two A138 adapters will be necessary — one for each generator connection

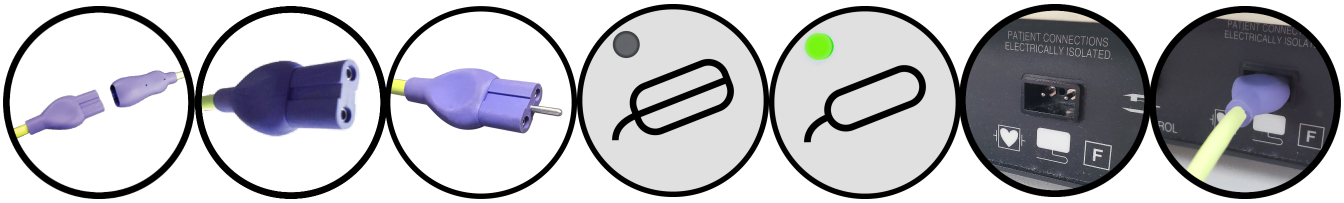


Image 9 **Image 10** **Image 11** **Image 12** **Image 13** **Image 14** **Image 15**

These cables are for use with the HotDog Temperature Management System only and should not be used with single-use adhesive return electrodes, or any other brand of return electrodes.

PATIENT-SIZE & PAD-CONTACT GUIDANCE FOR SAFE RETURN-ELECTRODE USE

Use the color-coded chart below to verify that the animal's body area on the mattress is large enough for safe capacitive coupling. A detailed explanation of the chart's weight limits, capacitance rationale, and positioning tips follows on the next page.

Quick Reference Chart:

Zone	Patient Mass*	Pad-Contact Expectation	Action
Green	**≥ 5 kg (≥ 11 lb)**	**Torso + limbs cover ≥ 65 % of pad**	**Proceed as normal.**
Yellow	**2 – < 5 kg (4.4 – < 11 lb)**	**Aim for ≥ 50 % pad coverage; spread limbs.**	**Use low-to-moderate ESU power. If cutting feels weak → improve contact, don't raise power first.**
Red	**< 2 kg (< 4.4 lb) OR contact area < ~120 cm²**	**Very small torso footprint (< ½ pad)**	**Do NOT use U501V Mattress. Switch to adhesive pad or bipolar technique.**

Why this guidance is needed:
The capacitive return-electrode mattress works like a giant, safe "antenna plate." It must sense enough of the animal's body area to build at least 4 nanofarads (nF) of capacitance—otherwise the electrosurgical unit (ESU) may raise its voltage and send current along unintended, higher-risk pathways.

- 4 nF ≈ 120 cm² (≈ 19 in²) of body contact on the U501V mattress.
- Most dogs and cats ≥ 2 kg easily exceed that area; smaller patients often do not.
- Avian, reptile, and other exotic species have feathers, scales, or narrow body profiles that reduce capacitance even further, so treat them as one size category smaller than their weight alone suggests.

Why the "≥ 2 kg" threshold?
Below ≈ 2 kg the typical patient covers < 120 cm², dropping capacitance below 4 nF and pushing return-path impedance above 120 Ω. Many ESUs then approach their voltage ceiling, increasing the chance that RF current will hunt for an easier exit through ECG leads, table rails, or other metal objects.

Options for patients < 2 kg or with < 120 cm² pad contact
- Apply an adhesive return pad to a hair-free site and connect it to the ESU.
- Switch to bipolar electrosurgery, laser, or cold techniques that do not require a return electrode.
    - ***Note:*** *The U501V is not compatible with bipolar electrosurgery.*

Positioning Checklist for Best Capacitance:
1. Whenever possible, position the animal so that all limbs, tail, and body surfaces rest fully on the return-electrode mattress or on non-conductive padding.
2. Insulate any body part that extends beyond the mattress (e.g., paw, tail tip) with a dry towel, foam block, or plastic trough so it does not touch stainless-steel table tops, side rails, restraint hooks, instrument trays, or other grounded metal fixtures.
3. If a procedure requires the patient to contact a grounded device, interpose a non-conductive barrier

4. Spread limbs to enlarge torso footprint.
5. Perform a test cut at normal power: if coag/cut is weak, improve contact before increasing ESU power.

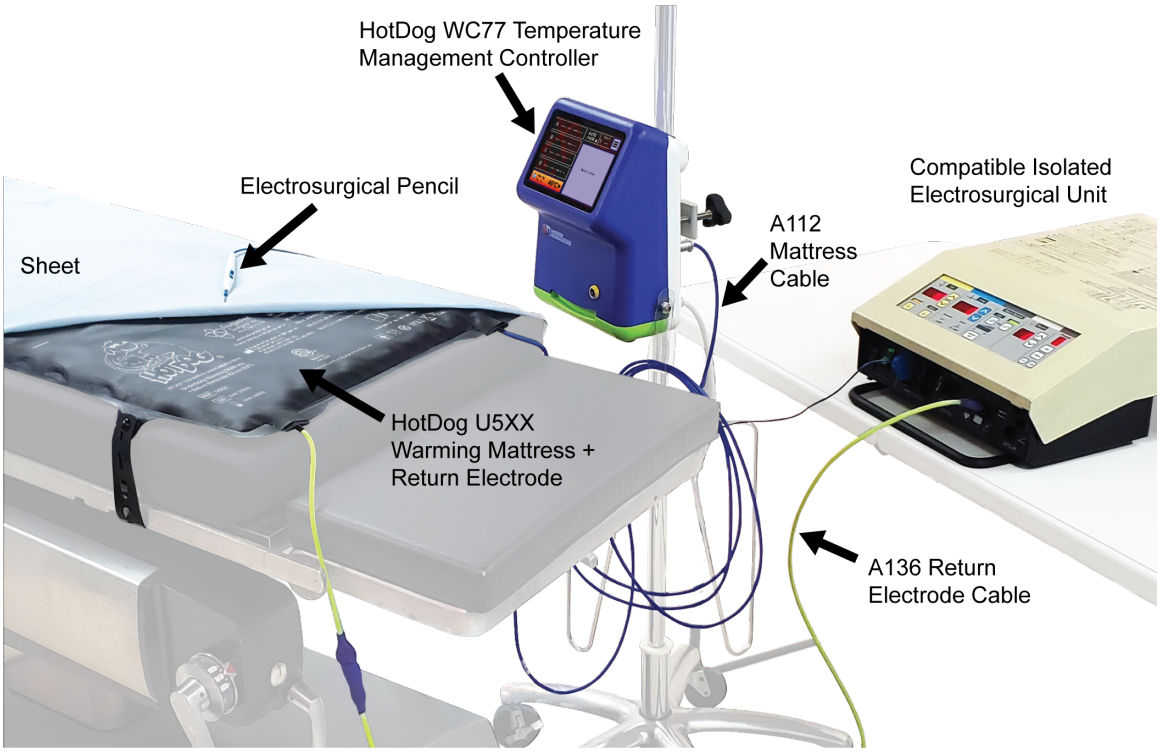


Image 16

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 veterinary patients weighing less than **4.4 lb (2 kg).**
- Use caution if the patient has a cardiac pacemaker or other conductive implant. Consult with a veterinary cardiologist if uncertain.

RETURN ELECTRODE MATTRESS WARNINGS

(FOR WARNINGS SPECIFIC TO USE OF WARMING MATTRESS FUNCTION, SEE PAGE 3)

- Use the lowest possible power settings that can achieve the desired surgical effect.
- Use only with isolated electrosurgical generators.
- Do not use the Return Electrode with specialty generator modes. For example, HIGH CUT or ENDO CUT modes on ERBE ICC 200, 300, 350, or VIO series may produce unintended effects.
- When the generator is operational, keep active accessories away from the animal and the device when not in use, or store in an electrically isolated container.
- Inspect components prior to each use for damage or excessive wear, such as cuts, holes, cold areas, or loose electrical connections. Do not use if the device has been pinched, crushed, or otherwise damaged until it is inspected by technical staff.
- Do not use needle-monitoring electrodes.
- Fire hazard: Cotton or gauze saturated with oxygen may ignite from sparks during electrosurgery.
- The Warming Mattress + Return Electrode is not sterile and is intended for non-sterile use only.
- If the patient has a cardiac pacemaker or other active implant, appropriate precautions must be taken. Electrosurgery can cause electromagnetic interference with such devices.

RETURN ELECTRODE CAUTIONS

- Federal law (USA) restricts this device to sale by or on the order of a licensed veterinary professional.
- Ensure patient positioning is appropriate for the planned procedure and duration of use.
- Do not place hard objects (e.g., return electrode cable, ECG cables, fluid lines) between the Return Electrode Mattress and the patient.
- Do not place fluid lines beneath the mattress.
- Do not place the mattress directly on metal surfaces.
- In animals with pacemakers or conductive implants, high-frequency currents may be redirected, causing device malfunction or tissue damage. Consult the implant manufacturer if needed.
- Not all electrosurgical units (ESUs) are compatible with the Warming Mattress + Return Electrode. Refer to Augustine Surgical's compatibility list before use.

RETURN ELECTRODE MATTRESS PRECAUTIONS

(FOR PRECAUTIONS SPECIFIC TO USE OF WARMING MATTRESS FUNCTION, SEE PAGE 3 & 4)

- Use under the direct supervision of a Veterinarian.
- 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/drape, 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 limbs 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 anatomical depressions or recessed areas such as natural body cavities or surgical pockets.
- Fluids pooled in body depressions and cavities should be removed before electrosurgery.

- To avoid the risk of airway fires, never use electrosurgery to enter the trachea during tracheostomy procedures.
- For surgical procedures involving small anatomical structures or narrow appendages, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- Only veterinary professionals 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 600 kHz.
- Return Electrode Mattress is restricted to use with isolated monopolar electrosurgical generators; it is not intended for radiofrequency ablation.
- Dispose of per local regulations.

The U5XX Warming Mattress + Return Electrode, and A136/A137 cables are compliant with IEC-60601-2-2 only in the following parameters:

Frequency [kHz]	Cut Power [watts]	COAG Power [watts]	Voltage, V_p [volts]
300-600	0-300	0-120	0-4800

CARE AND MAINTENANCE – GENERAL

- Do not continue to use a Warming Mattress + Return Electrode beyond the labeled expiration date, found on the cable. Product malfunction may occur.
- Do not launder or sterilize, as this may damage a Warming Mattress + Return Electrode.
- Do not immerse or submerge the Warming Mattress + Return Electrode in liquids.
- Do not place components in autoclaves, sterilizers, or high-temperature cleaning systems.
- Do not use high-level disinfectants (e.g., glutaraldehyde, peracetic acid) or hydrogen peroxide-based solutions to clean a Warming Mattress + Return Electrode.
- Do not spray cleaning solutions into the electrical connector, cable ports, or other openings.
- 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 the device to determine if it is safe for use.
- Do not disassemble a Warming Mattress + Return Electrode. The device contains no user-serviceable parts. If service is required, contact an authorized service representative.
- Do not fold or crease the Warming Mattress + Return Electrode sharply, or fold repeatedly in the same location.

STORAGE - GENERAL

- Store a Warming Mattress + Return Electrode in a dry location. Do not allow the device 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 or damage to the internal foam layers. 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 veterinary patients 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 veterinary devices include reusable monitoring cuffs, surgical table pads, positioning supports, and exam table covers.

DO NOT USE Hydrogen peroxide-based cleaning solutions, as the vapors degrade the conductive fabric heaters and may damage the outer surface.

Alcohol-based disinfectants are generally preferred because they are fast-acting and can be sprayed or wiped onto the surface. Other compatible disinfectants include:

- Alcohol-based disinfectants *(spray or wipe)*
- Diluted bleach solutions *(per disinfectant manufacturer's instructions)*
- Ammonia-based disinfectants
- Diluted chlorhexidine *(per disinfectant manufacturer's instructions)*
- Hospital-grade low- or intermediate-level disinfectants

Iodine-containing cleaners may cause surface discoloration and are **not recommended** for routine 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.

- **Do not allow cleaning fluids to enter the electrical connector.**
- If visible soiling is present, remove it before applying a disinfectant. Scrub the affected area with a mild detergent using a soft brush or sponge. Rinse using a cloth dampened with clean water. **Do not immerse** the device.
- 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 effective disinfection.
- **Thoroughly dry the surface** using a clean towel and allow the device to air dry fully before folding, rolling, or reuse.

ALARMS – GENERAL (CHART ON NEXT PAGE)

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 contact customer service at (952) 465-3500

Error Codes	Error Description	Problem Solving Steps
E1	Over-Temperature	If the temperature exceeds one degree above the set point, the alarm will sound, and power to the Blanket will be automatically discontinued. To reset the alarm, unplug the Blanket and wait for 5 minutes before reconnecting it. Before turning the Controller back on, inspect the setup to ensure the Warming Blanket is not in contact with any other warming modality or device. Turn the Controller back on and select the desired temperature**. If the alarm sounds again, discontinue use and contact customer service.**
E2	Failure To Reach Temp	If the Blanket does not reach the set temperature within 10 minutes, the alarm will sound, and power to the Blanket will be automatically discontinued. To resolve this, check that the Blanket is in proper contact with the patient and that the sensor area is touching the patient. Unplug the Blanket, then reconnect it to reset the alarm**. If the alarm sounds again, discontinue use and contact customer service.**
E3	Port Current Reached	If the electrical current in the Blanket exceeds the allowable limit, the alarm will sound, and power to the Blanket will be automatically discontinued. This may indicate an electrical issue with the Blanket. Unplug the Blanket from the Controller, then reconnect it to reset the alarm. **If the alarm occurs again, discontinue use and contact customer service.** **Note:** If using four Extra Large (V106) Blankets simultaneously, stagger the start of warming for each Blanket by 2 minutes to prevent excessive electrical load.
E4	Sensor or Cable Failure	If the Controller loses communication with the sensor in the Warming Blanket, the alarm will sound, and power to the Blanket will be automatically discontinued. This may indicate an electrical issue with either the Blanket or the Controller. To isolate the problem, swap the cables and Blanket with known good components. **If the issue persists, discontinue use of the affected Blanket or cable and contact customer service.**
E5	Blanket Fold Detection	Not applicable to veterinary devices. **Contact customer service if this error is not resolved after resetting the Controller.**
E7	Auto Mode Disengaged	Not applicable to veterinary devices. **Contact customer service if this error is not resolved after resetting the Controller.**
E8	Over-Temperature Sensor (Secondary)	The temperature sensor has exceeded 46° C. **Disconnect the Blanket and contact customer service.**

DEFINITION OF SYMBOLS

	Attention, consult accompanying documents.		Temperature Sensor		Keep Dry
SN	Serial Number	REF	Reference Number		Do not use after YYYY-MM-DD
	Manufacture Date	UDI	Unique Device Identifier		Do not submerge
	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)				
	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.**				

<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><th>Time (s)</th><th>Temperature (C)</th></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

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</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 ESU. 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	Rated Frequency	417 kHz
	Crest Factor, C	1.8
	Max HF voltage, peak to peak	9000 V_{P-P}

	Max HF voltage, peak	4800 V_P
	HF rated Power	300 watts
ERBE ICC 350	Rated Frequency	330 kHz
	Crest factor, C	1.4 for all settings
	Max HF voltage, peak	4000 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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