HotDog Patient Warming Mattresses Models U1XX, U2XX, U3XX and HotDog Patient Warming Mattress + Return Electrode Model U5XX Instructions for Use

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CE 2797

DEVICE DESCRIPTION

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

The HotDog Patient Warming Mattress + Return Electrode (U5XX) ("Return Electrode Mattress") includes both a warming and a return-electrode function. The Return Electrode Mattress is a component of the System and should only be used with Controller Model WC77. Each Return Electrode Mattress is sold with a Return Electrode Cable, 4m (A136) that enables connection to one electrosurgical generator. When connected to an electrosurgical generator, the Return Electrode Mattress functions as both a warming mattress and a neutral return electrode. This consolidation of underbody warming, and electrosurgical grounding reduces cleaning and handling of multiple cumbersome pads. The Return Electrode Cable, 4m (A136) or the Return Electrode, Dual Generator "Y" Cable, (A137) allows for use of one or two electrosurgical generators with the Return Electrode Mattress, respectively. Do not use the return-electrode function when the patient's body weight is less than 0.35 kg (0.8lb). There is no upper weight limit.

These instructions apply to the following part numbers:

HotDog Product Description	Part Number	Qty/Pkg	Compatible Controllers	
Underbody Warming Mattress + Return Electrode, 82 cm (32in)	U501	1	WC77	
Underbody Warming Mattress + Return Electrode, 127 cm (50in)	U502	1	WC77	
Pediatric Underbody Warming Mattress + Return Electrode 74 cm (29in)	U522	1	WC77	
Trendelenburg Warming Mattress + Return Electrode 89 cm (35in)	U530	1	WC77	
Underbody Warming Mattress, 82 cm (32in)	U101	1	WC77, WC52	
Underbody Warming Mattress, 127 cm (50in)	U102	1	WC77, WC52	
Pediatric Underbody Warming Mattress 74 cm (29in)	U220	1	WC77, WC52	CE 2797
Trendelenburg Warming Mattress, 89 cm (35in)	U300	1	WC77, WC52	

Each Mattress includes (1) A112 cable.
One (1) Return Electrode Cable, 4m (A136) is included with U501, U502, U522 and U530.

INDICATIONS FOR USE – WARMING MATTRESS

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

INDICATIONS FOR USE – RETURN ELECTRODE MATTRESS

The HotDog Return Electrode Mattress is intended to conduct monopolar electrosurgical energy from the target tissue of a patent back to one or two electrosurgical units (ESU) or generators in monopolar surgery. The Return Electrode Mattress can be used with adult and pediatric patients.

This device is intended to be used whenever monopolar electrosurgery is indicated. Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators.

CONTRAINDICATIONS

- Do not warm ischemic or non-perfused tissue; thermal injury may result. Examples include tissue distal to aortic cross clamping, or when vasoconstrictive drugs would lead to severe, prolonged vasoconstriction.
- Do not warm patients receiving transdermal medication; increased drug delivery may occur.
- Do not use Warming Mattresses or Return Electrode Mattresses with other under-patient thermal management systems.

WARMING MATTRESS WARNINGS

- Explosion Hazard – Do not use Warming Mattresses or Return Electrode Mattresses in the presence of flammable anesthetics or highly oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- Inspect System components prior to each use for signs of damage or excessive wear such as cuts, holes, or loose electrical connections or cold areas. If signs of wear are evident or if the warming device has been subjected to extreme physical force (e.g. pinched by clamps or run over by carts), do not use the 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 and Return Electrode Mattresses are not sterile.

CAUTION

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

WARMING MATTRESS PRECAUTIONS

- Use under the direct supervision of a clinician.
- Monitor the patient's vital signs regularly during warming according to institutional protocol. If vital sign instability occurs, notify the clinician.
- Take caution when using multiple warming methods.
- Ensure that Warming Mattresses and Return Electrode Mattresses are securely fastened to the table.
- The risk of skin irritation caused by pooling of surgical prep solutions under the patient may increase with warming; ensure that surgical prep solution instructions for use are followed.
- Gel pad placement between Warming Mattresses and Return Electrode Mattresses and the patient is not recommended; gel pads may cause a loss of warming performance.
- Always use a thin barrier between the patient and Warming Mattresses or Return Electrode Mattresses.
- Dispose of per local regulations.
- Do not use Warming Mattresses or Return Electrode Mattresses when the risk of pressure injury cannot be mitigated.
- Maintain contact between the patient and the labeled sensor on Warming Mattress or Return Electrode Mattress.
- Do not use operating table clamps or similar devices on Warming Mattresses or Return Electrode Mattresses as they may cause damage to the device and result in loss of the heating function and/or localized heat build-up in the damaged area.
- Do not place Warming Mattresses or Return Electrode Mattresses over a table joint that will move during surgery.
- Do not use Warming Mattresses or Return Electrode Mattresses as a stand-alone patient pressure relief system.
- Do not place any hard objects (e.g., mattress cables, EKG cables, hard cautery return pads, patient fluid lines, etc.) between Warming Mattress or Return Electrode Mattress and the patient.
- Do not fold Warming Mattresses or Return Electrode Mattresses during use, as localized heat may build-up.

- Adjust placement of Warming Mattress or Return Electrode Mattress during X-rays as the internal wiring, located primarily along the edges of the device, and the sensor with associated wire may appear in images.
- Do not place fluid lines under Warming Mattresses or Return Electrode Mattresses or between Warming Mattresses or Return Electrode Mattresses and other warming devices.
- Do not position the patient's head directly on Warming Mattress or Return Electrode Mattress.

INSTRUCTIONS FOR USE

Follow BEST practices to achieve optimal results, as described in part MT302 BEST Results Poster (downloadable at hotdogwarming.com under Brochures).

1. Inspect the surface of Warming Mattress or Return Electrode Mattress for damage (e.g., cuts, tears, creases). Do not use the device if it is damaged.
2. Place Warming Mattress or Return Electrode Mattress on the padded operating table. Note: For U300 and U530, align the device's perineal cutout with OR table mattress perineal cutout in Trendelenburg positioning.

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

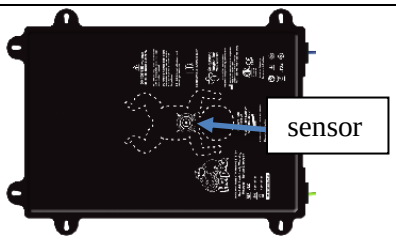
3. Attach Warming Mattress or Return Electrode Mattress straps to the operating table.

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

4. Place a thin barrier over the entire surface of the Warming Mattress or Return Electrode Mattress. Note: For U300 and U530 in Trendelenburg positioning, the A300 WaffleGrip accessory functions as the thin barrier.

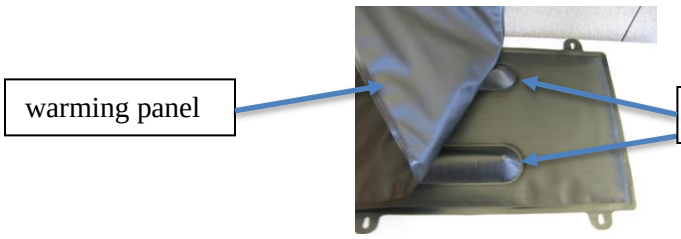
Note: For U220 and U522 (Pediatric Warming Mattress) users.

- U220 and U522 Mattresses are intended for use with patients ≤ 20 kg.
- Ensure the patient is on top of the warming panel, over the sensor. (Figure 1.) Use a thin barrier between the patient and the Mattress (Figure 3.).

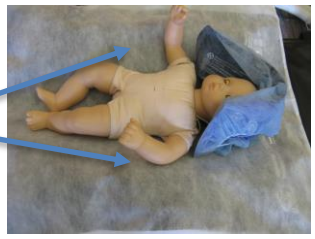


(Figure 1.)

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



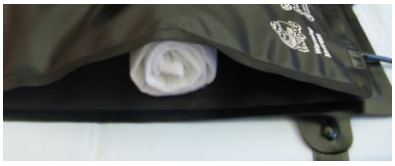
(Figure 2.)



(Figure 3.)

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

Do not place patient under the warming panel.



(Figure 4.)

5. Insert the female end of the blue Mattress Cable into the Mattress Connector.

Note: Do not force the connector into the socket. Align the red dots on each connector and gently push the connectors together. You will feel a click when the connectors engage.

6. Insert the male end of the blue Mattress Cable into the blue port on the Controller.
7. Turn the Controller on and select the desired temperature setting to begin warming. Allow up to 10 minutes for the Warming Mattress or Return Electrode Mattress to reach the 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 the Warming Mattress or Return Electrode 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 the Warming Mattress or Return Electrode Mattress as necessary. (Refer to "Care and Maintenance" section.)
10. To disconnect the Mattress Cable, grip the connector bodies and pull them apart (Figure 2).

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

RETURN ELECTRODE MATTRESS INSTRUCTIONS

Capacitive Return Electrode Principles

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

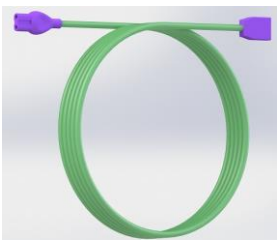
The separation of two conductive plates by an insulator creates a capacitor. The insulator prevents current from flowing directly between the two plates, thereby avoiding the resistance that creates heat. With capacitive grounding, current from the active electrode produces a charge on the first conductive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

Setting Up the Return Electrode Mattress

Each Return Electrode Mattress is sold with a green Return Electrode Cable, 4m A136 (Figure 5.) that enables connection to one electrosurgical generator. When connected to an electrosurgical generator, the Return Electrode Mattress functions as a neutral return electrode.

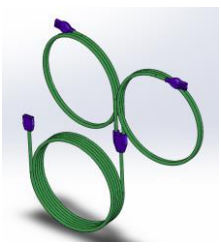
To enable the use of the return-electrode function, connect a green Return Electrode Cable (A136 or A137) to the green side entry cable extending from the Return Electrode Mattress. Then connect the other end (Figure 6.) to an electrosurgical generator. For simultaneous operation of two electrosurgical generators, connect each end of the Dual Generator "Y" Cable (A137) to separate generators. If only connecting to one generator with the dual generator "Y" cable, secure the unused cable. Failure to secure extra cable during use may result in an electrical hazard.

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



(Figure 5.)

(Figure 6.)



(Figure 7.)

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

RETURN ELECTRODE MATTRESS WARNINGS

- Use the lowest possible power settings that can achieve the desired effect.
- Do not use the return electrode function when patient's body weight is less than 0.35 kg (0.8lb). There is no upper weight limit.
- Use with isolated generators only.
- Do not use HIGH CUT or ENDO CUT modes when using the ERBE 200, 300 and 350. Doing so may result in a different electrosurgical effect than intended.
- When the generator is operational, keep active accessories away from the patient and the device when not in use, or store in an electrically isolated container.

RETURN ELECTRODE MATTRESS PRECAUTIONS

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

- Avoid the pooling of flammable solutions under the patient or in body depressions such as the umbilicus and in body cavities, such as the vagina.
- Fluids pooled in the body depressions and cavities should be removed before electrosurgery.
- Attention: danger of ignition of endogenous gases (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of electrosurgical equipment).
- Not for use with generators operating at greater than 1000kHz.
- Return Electrode Mattress is restricted to use with isolated monopolar electrosurgical generators; it is not intended for radio frequency ablation.

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

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

CARE AND MAINTENANCE

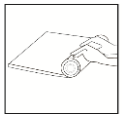
- Do not continue to use Warming Mattresses or Return Electrode Mattresses beyond the labeled expiration dates.
- Do not launder or sterilize as this may damage Warming Mattresses or Return Electrode Mattresses.
- Do not immerse Warming Mattresses or Return Electrode Mattresses in liquids.
- Do not use high-level disinfectants (e.g., gluteraldehyde and peracetic acid) or hydrogen peroxide based solutions to clean Warming Mattresses or Return Electrode Mattresses.
- Do not spray cleaning solutions into the electrical connector.
- Do not use cleaning or disinfection methods different from those recommended in the User Manual without first checking with an authorized service representative to ensure that the proposed methods will not damage the equipment.
- Do not use Warming Mattresses or Return Electrode Mattresses if they show signs of damage or excessive wear such as cuts, holes or loose electrical connectors. Technical staff should inspect devices to determine if they are safe for use.
- Do not disassemble Warming Mattresses or Return Electrode Mattresses; the devices have no user- serviceable parts. If service is required, call an authorized service representative for assistance.

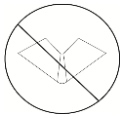
STORAGE

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

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

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





CLEANING - GENERAL

Clean and disinfect the Warming Mattress or the Return Electrode Mattress between patient uses if the device appears visibly soiled. If the device is not visibly soiled, disinfection at the end of the operating day is recommended. Wipe the device with a damp soapy cloth and disinfect following standard hospital protocol. In general, alcohol-based disinfectants are easiest to use since they are fast-acting and can be either sprayed or wiped on the device. Other cleaners that are compatible with the outer surface of the device include sodium hypochlorite (diluted bleach), phenolic germicidal detergent, and quaternary ammonium detergent. Iodine-containing cleaners may cause discoloration of the surface material and are, therefore, NOT recommended for routine cleaning. Hydrogen peroxide-based cleaning solutions are NOT recommended because the vapors degrade the conductive fabric heaters. Dry thoroughly before use.

Caution: Do not place the Warming Mattress or the Return Electrode Mattress in an autoclave, sterilizer, automatic washer-disinfector or any other high-temperature system as this may damage the device.

CLEANING AND DISINFECTION STEPS

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

1. Do not allow cleaning fluids to get into the electrical connector.
2. If visible soiling is present, remove before applying a disinfectant. Scrub the affected area with detergent, using a soft brush or sponge to remove organic matter. Rinse the surface of the Warming Mattress or the Return Electrode Mattress using a dampened cloth. Do not immerse the device in liquids.
3. Apply a low- or intermediate-level disinfectant to the entire surface of Warming Mattresses or the Return Electrode Mattress by spraying or wiping. Follow the disinfectant manufacturer's application instructions to ensure disinfection.
4. Dry thoroughly before use.

ALARMS

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

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

DEFINITION OF SYMBOLS

	Attention, consult accompanying documents.		Place under patient with this side up		BF Patient Applied Part according to IEC60601-1.
	Serial Number		Reference Number		Do not use after YYYY-MM-DD
	Manufacture Date		Use only with HotDog Patient Warming Controller.		Store as directed in instructions for use.
	Temperature Sensor		Keep Dry		Conforms to European Medical Device Directive 93/42/EEC.
	Transport and Storage Humidity Range		Transport and Storage Temperature Range		Separate treatment from general waste at end of life.
	Natural Latex Free		Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.
	Manufacturer		Consult the electronic instructions for use on the website at the URL provided.		EU Authorized Representative
	Medical Device		See IFU for Warnings and Precautions		Medical Device restricted to sale by or on the order of a physician
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 Medical Device Directive (93/42/EEC) as a Class IIb device.				

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