Patient Warming System Controller Model WC5X Service Manual

Forward to the Biomedical Engineering Department

For information on operating the Hot Dog Patient Warming System, refer to the "User Manual"

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INTRODUCTION

The Hot Dog Patient Warming System consists of the Hot Dog Controller, reusable warming devices (e.g., Warming Blankets, Warming Mattresses) and accessories. This manual includes maintenance instructions and specifications for the Hot Dog Controller Model WC5X. For information about Hot Dog warming devices and accessories, refer to the "User Manual" provided with each device/accessory.

The Hot Dog Controller is designed to help maintain normothermia in patients before, during, and after surgical procedures and to help prevent unintended hypothermia. The system is powered and controlled by an electronic control unit. Warming devices (e.g., blankets, mattress) are powered at low voltage, ensuring safety for patients and operators. Warming temperatures are controlled automatically to user-selected levels, and over-temperature safety shut-offs are integrated into the controller as well as into each warming device.

The Hot Dog Controller can be placed on a flat surface, mounted on an IV pole, or suspended from the OR table/gurney rail using optional hooks. The Hot Dog Patient Warming System can be operated continuously to maintain uniform heat under or over the patient, depending on which warming device/accessory is selected. It is the responsibility of the user to determine whether warming is appropriate for each individual patient. The Hot Dog Patient Warming System should not be used when clinical considerations indicate that warming of the patient is not advisable.

Indications for Use

The Hot Dog Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming 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, recovery, and emergency rooms and on medical/surgical floors.

Contraindications

- DO NOT warm patients during aortic cross-clamping; thermal injury may result.
- DO NOT warm patients with ischemic or non-perfused limbs; thermal injury may result.
- DO NOT warm patients receiving transdermal medication; increased drug delivery may occur.

Warnings

- **EXPLOSION HAZARD – DO NOT** use the Hot Dog Patient Warming System in the presence of flammable anesthetics or highly oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- Caution should be taken when using electric warming devices with HF surgical instruments or endocardial catheters in respect to potential equalization.

- **Inspect Hot Dog components prior to use** for signs of damage or excessive wear such as cuts, holes, or loose electrical connections. If signs of wear are evident, do not use the product until it is inspected by technical staff.
- **DO NOT** continue to use the Hot Dog Patient Warming System if the over temperature indicator and/or alarm continue to sound after reset. See alarm section of this manual.

Warming Blanket

- DO NOT place Hot Dog Warming Blankets under the patient. The Warming Mattress and disposable sheets are the only accessories designed for use under the patient.

Warming Mattress

- The Hot Dog Warming Mattress is not sterile. Where necessary, take appropriate precautions to protect the sterile field.

Accessories and Other Equipment

- Accessories and cables other than those specified in the Instructions for Use may result in increased emissions or decreased immunity of the Hot Dog Patient Warming system.
- The Hot Dog Patient Warming System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, carefully observe the Hot Dog Patient Warming System to verify that it operates normally in this non-recommended configuration.

Caution

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

Precautions

General

- 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.
- Care should be taken when using multiple warming methods.
- 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.

Warming Mattress

- Ensure that the Warming Mattress is securely fastened to the table.
- The use of gel pads between the Warming Mattress and the patient is not recommended; gel pads may cause a loss of warming performance.

- Always use a patient barrier between the patient and the Warming Mattress.
- Care should be taken to alleviate or remove the risk of heating skin under pressurized bony prominences.
- Care should be taken to place the patient's body in contact with the labeled sensor on the Warming Mattress.
- DO NOT use operating table clamps or similar devices on the Warming Mattress as they may cause damage to the product and result in loss of the heating function and/or localized heat build-up in the damaged area.
- DO NOT place the Warming Mattress over a table joint that will move during surgery.
- DO NOT use on OR tables wider than 20 inches (50.8 cm).
- DO NOT use the Warming Mattress 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 the Warming Mattress and patient's body.
- DO NOT fold or wrinkle the Warming Mattress during use as localized heat build-up may occur in the overlapped area.
- DO NOT use the Warming Mattress when pressure injury is a concern.
- DO NOT X-ray or MRI through the white labeling or edges of the Warming Mattress.
- DO NOT allow patient fluid lines to be placed between the Warming Mattress and Warming Blanket or other warming equipment.
- DO NOT position the patient's head directly on the Warming Mattress.
- DO NOT allow the heated side of a Hot Dog Warming Blanket to come in continuous contact with the Warming Mattress when both devices are on.

Proper Use and Maintenance

Do not open the Hot Dog Controller. There are no user serviceable parts. If service is required, contact Technical Support (see **page 18**). The manufacturer assumes no responsibility for the reliability, performance, or safety of the Hot Dog Patient Warming System if the following events occur:

- The Controller is disassembled or serviced by an unauthorized person.
- The patient warming system components are used in a manner other than described in the User Manuals.
- The Controller is installed in an environment that does not meet the appropriate electrical and grounding requirements.
- The Controller is grounded and should not be attached to un-grounded tables intended for use with a hyfrecator or equivalent devices.

Read Before Servicing Equipment

Repair, preventive maintenance, safety testing and servicing of the Patient Warming System requires the skill of qualified medical equipment service technicians who are familiar with good practice for medical device repair. Do not open the Hot Dog Controller. There are no user serviceable parts. If service is required, contact Technical Support (see **page 18**). Perform all maintenance activities in accordance with the instructions in this service manual.

INITIAL SETUP & ASSEMBLY

Contents

The following components are included in the Hot Dog Controller box:

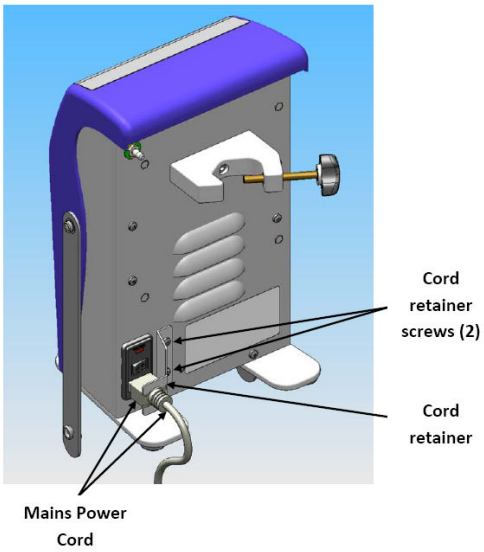
- 1—Hot Dog Controller Model WC5X
- 1—IV pole adapter and mounting hardware
- 1—Mains power cord
- 1—CD containing User Manual and Service Manual
- 1—Hot Dog Warming Blanket Cable (P/N A101)

Reusable Hot Dog accessories (e.g., Warming Blankets, Warming Mattress, connecting cables, OR table/gurney rail hooks with mounting hardware) and Hot Dog Disposable Sheets are sold separately.

Assembly Procedure

1. Remove all items from the box and discard packaging per institutional protocol.
2. Loosen and remove the two cord retainer screws and the cord retainer (see **Figure 1**; the cord retainer is located on the back of the Controller).
3. Firmly insert the mains power cord into the receptacle on the back of the Controller.
4. Place the cord retainer over the strain relief of the mains power cord; replace both screws and tighten to secure the cord retainer (see **Figure 1**).

Figure 1: Cord Retainer Assembly



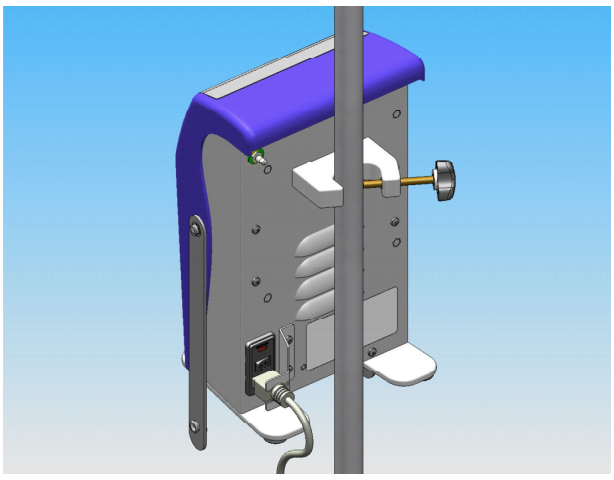
Mounting the Hot Dog Controller to an IV Pole

To mount the Hot Dog Controller to an IV pole, place the Controller IV pole adapter around the IV pole and turn the clamp handle clockwise until securely tightened (**Figure 2**). To remove the Controller from the IV pole, turn the clamp handle counterclockwise until the unit releases.

Caution

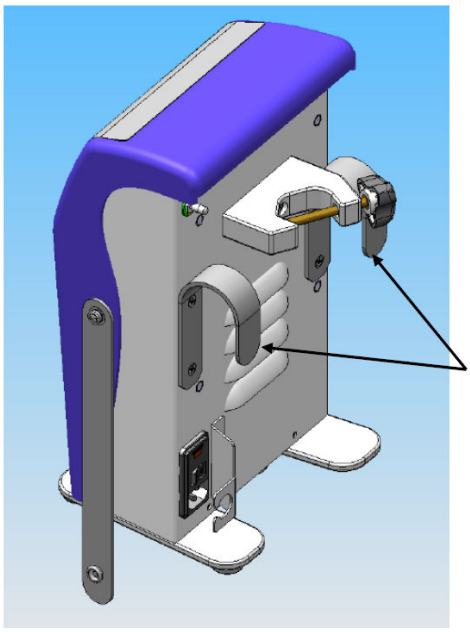
To prevent the IV pole from tipping, the Controller must be attached at a height that provides stability. It is recommended to use an IV pole with a minimum wheelbase radius of 35.6 cm (14 in) and to mount the Controller no higher than 112 cm (44 in) from the floor. Failure to properly mount the Controller may result in IV pole tipping, catheter site trauma, and patient injury.

Figure 2: Hot Dog Controller Mounted on an IV Pole



The Controller may also be suspended from the OR table/gurney rail using optional hooks (**Figure 3**).

Figure 3: Optional OR Table/Gurney Rail Hooks



OVERVIEW OF CONTROL PANEL & OPERATING MODES

Figure 4: Hot Dog Model WC5X Controls

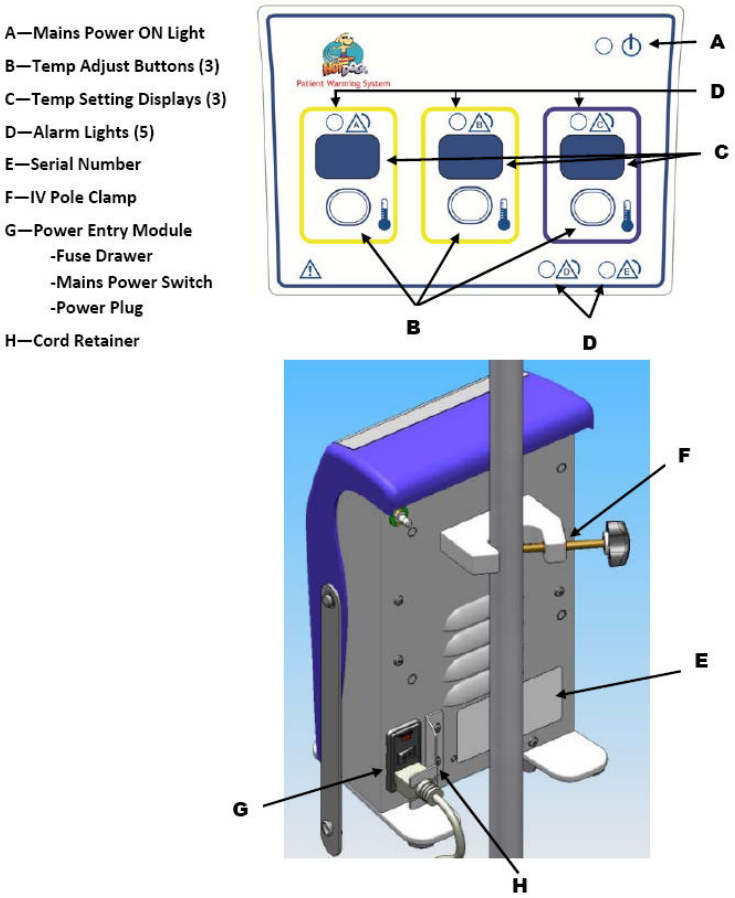
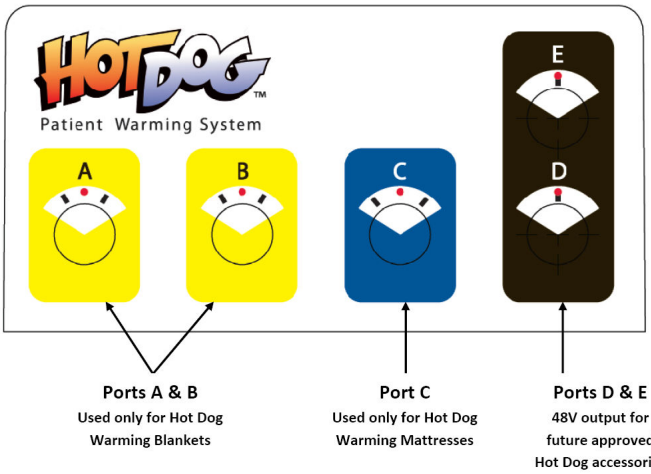


Figure 5: Hot Dog Model WC5X Ports



Mains Power Switch / ON Power Indicator

When the Hot Dog Controller is plugged into an electrical outlet and the Mains Power Switch on the back of the Controller is turned ON, all displays will illuminate briefly and the Controller will beep. Afterwards, the software version is displayed for approximately 2 seconds. The Mains Power ON Light will illuminate and the Controller will remain idle until a warming device is plugged in. When the unit is ON and idle (i.e., no Temperature Setting Lights are illuminated), no power is applied to the warming device and no alarm conditions are indicated.

Temperature Adjust Button / Temperature Setting Display

When a warming device is plugged into a port, an audible beep will sound and the display will show two dashes. Press the Temperature Adjust Button for the desired port until the desired temperature is displayed. The temperature can be selected in one degree increments from 37-43°C for Ports A and B (Warming Blankets) and 35-39°C for Port C (Warming Mattresses). The designated warming temperature will flash until the selected temperature is achieved, at which time the selected temperature will steadily display.

Port A, B and C

Ports A and B are used only for Hot Dog Warming Blankets, and Port C is used only for Hot Dog Warming Mattresses. When a warming device is plugged into the Controller, an audible beep indicates that the control and over temperature sensors are present and functioning properly.

Port D and E

Ports D and E supply a 48V output for future approved Hot Dog accessories.

Alarms

Alarm: Port A, B and C

If the warming device temperature exceeds one degree above set point or other fault conditions exist, an audible alarm sounds and the Alarm Light illuminates red for the port that is alarming. The Controller will automatically discontinue power to that warming device. When the operating temperature falls to within 1ºC of the selected set point, the alarm will shut off and normal function will be restored. If the Alarm Light illuminates steadily and the alarm continues to sound, disconnect the warming device from the Controller. If the Controller senses an over current, the audible alarm will sound and all Alarm Lights will illuminate. Power will be lifted from all ports. Turn the Controller off to reset. If all ports alarm again after a reset was performed, discontinue use of the Controller and refer the unit to biomedical engineering.

Alarm: Port D and E

If the accessory attached to Port D or E exceeds the pre-set current limit, an audible alarm sounds and the Alarm Light illuminates red. Power is removed from the port. Disconnect the accessory from Port D and E to reset the alarm.

- If the alarm occurs when connecting an accessory to the Controller, disconnect the accessory and replace it with another accessory.
- If the alarm occurs during use and the Alarm Light illuminates steadily, disconnect the accessory and replace with another accessory.

MAINTENANCE & TESTING

Testing of Indicator Light Function

Frequency

This test should be completed upon initial equipment check-in and once every 12 months (or more frequently if required by hospital guidelines).

Method

1. Insert the Hot Dog Controller power plug into a properly grounded hospital grade electrical outlet and confirm that NO cables or devices are connected to any of the ports.
2. Turn the Mains Power Switch to ON and observe for the following proper start-up sequence:
    a. Individual LED's power up sequentially
    b. Segmented displays power up as individual units (sequentially left to right)
3. After the lights illuminate in sequence, the unit will emit an audible tone and display the software revision on the Temp Setting Display for approximately 2 seconds.
4. After the sequence completes, only the Mains Power ON Light remains illuminated.
5. If this sequence varies or is incomplete, contact Technical Support (see **page 18**).

Electrical Safety Checks and Functional Testing

Frequency

These tests should be completed once every 12 months (or more frequently if required by hospital guidelines).

Tools/Equipment

- Test fixture (Ref. A115)
- Warming Device Cable (Ref. HDPC1, A101 or A102, A112)
- Ground continuity tester
- Leakage current tester
- Calibrated, fast-reacting thermocouple and meter
- Hot Dog Warming Blanket or Warming Mattress (optional)

Method

1. Perform "Testing of Indicator Light Function" as described on the previous page.
2. Perform the following tests on the Controller per standard institutional protocol:
    A. Ground continuity
    B. Connect a Warming Blanket to the Controller and test leakage current to ensure the maximum leakage current does not exceed the requirements in **Table 1**.

Note: The equipotential stud on the back of the Hot Dog Controller may be used as a grounding point for these tests.

Table 1: Maximum Allowable Leakage Current

Polarity	Condition	Current (mA)
Normal / Reversed	Normal	0.1
	Open Ground	0.5
	Open Neutral	0.5
	Open Ground & Open Neutral	0.5

3. Perform "Functional Testing" described on the following pages.

Functional Testing Method for Controller

Use a Temperature Test Fixture (Ref. A115) to perform the steps outlined below. The Test Fixture simulates a Warming Blanket that is operating at 43°C. If a failure is observed during any of these steps, call customer service.

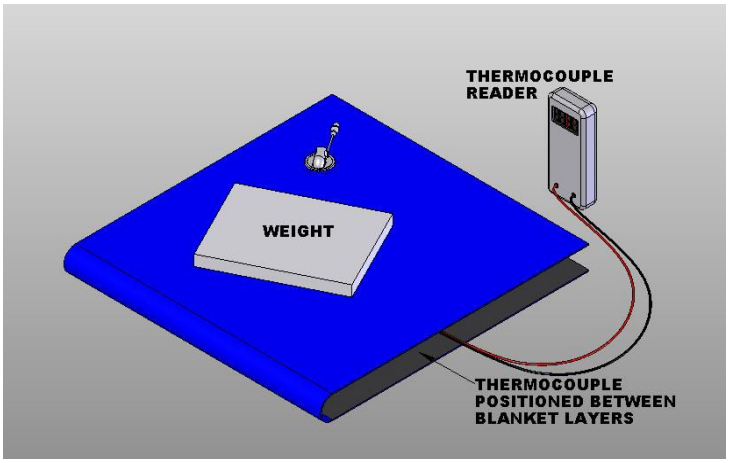
Step	Test Method	Test Result
1.	Using a standard blanket cable (Ref. HDPC1, A101 or A102), connect the test fixture to the Controller.	The Controller will emit an audible tone and the Mains Power ON Indicator will illuminate. The LED readout associated with the port under test will show two dashes, indicating a device is attached.
2.	Press the Temperature Adjust Button on the Controller once for the port under test to select the highest temperature setting.	The set point will display on the LED readout. The display will be constant to indicate that temperature is in-range. The heater indicator LED on the test fixture may flash intermittently or not at all, which is normal.
3.	Press the "Temperature Low" button on the test fixture to simulate a cold warming blanket.	The set point displayed on the Controller LED readout should flash and the LED at the top of the test fixture should illuminate to indicate that power is being applied to the test fixture (the alternating on/off shows the duty cycle applied by the Controller). ***Release the button and the Controller should return to "in range" as described in step 2.***
4.	Press the "Temperature High" button on the test fixture to trigger the primary over-temperature alarm.	The Controller alarm indicator for the port under test should illuminate, an audible alarm should sound, and the LED readout should indicate error code "E1." ***Release the button and the Controller should return to "in range" as described in step 2.***
5.	Press the "Primary Short" button on the test fixture to simulate a shorted primary sensor.	The Controller alarm indicator for the port under test should illuminate, an audible alarm should sound, and the LED readout should indicate error code "E4." ***Release the button and the Controller should return to "in range" as described in step 2.***
6.	Press the "Primary Open" button on the test fixture to simulate an open primary sensor.	The Controller alarm indicator for the port under test should illuminate, an audible alarm should sound, and the LED readout should indicate error code "E4." ***Release the button and the alarm state should be latched. Unplug the test fixture cord to clear the alarm. Plug the test fixture cord back in to prepare for the next step.***
7.	Press the "Secondary Open" button on the test fixture to simulate an open secondary sensor.	The Controller alarm indicator for the port under test should illuminate, an audible alarm should sound, and the LED readout should indicate error code "E4." ***Release the button and the alarm state should be latched. Unplug test fixture cord to clear the alarm. Plug the test fixture cord back in to prepare for the next step.***
8.	Press the "Secondary Short" button on the test fixture to simulate a shorted primary sensor or secondary over temperature.	The Controller alarm indicator for the port under test should illuminate, an audible alarm should sound, and the LED readout should indicate error code "E4." ***Release the button and the alarm state should be latched. Unplug test fixture cord to clear the alarm.***

Functional Testing for Blanket and Controller

Use a Hot Dog Warming Blanket to perform the steps outlined below. If a failure is observed during any of these steps, repeat testing using a different Warming Blanket. If failure is observed with the second Warming Blanket, contact Technical Support (see **page 18**).

1. Tape a calibrated, fast-reacting thermocouple to the patient-facing surface of the Warming Blanket directly over the sensor marking.
2. Fold the Warming Blanket back on itself (black face to black face) so that the thermocouple is between the two layers of the heated Blanket. Ensure that the Blanket layers are pressed together in the location of the thermocouple. Place a 750 to 1000gm weight (such as a small book or notebook) over the sensor location to ensure that the pad remains folded and that there is good contact between the sensor and the folded blanket (**Figure 6**)

Figure 6: Warming Blanket Test Configuration



3. Turn the Mains Power Switch to the ON position. Supply power to the Warming Blanket by connecting the Warming Blanket power cable to the Controller. *The Controller will emit an audible tone and the Mains Power ON* Indicator *will illuminate.*
4. Select the temperature to be verified. If checking all set-points, start with the low temperature setting.
5. After the warming device reaches set point (indicated when the set point readout is no longer flashing), allow the temperature to stabilize for an additional 3 minutes. *NOTE: A temperature overshoot will be noted when testing this way, which is normal.*
6. Check the reading of the thermocouple. The temperature should be within 1°C of the set-point temperature (including the additional tolerance of the thermocouple meter, which is usually $\pm$ 1°C).
7. Repeat steps 4-6 for the next temperature setting, if required.

CLEANING

Cleaning—General

Warnings

- DO NOT use a dripping wet cloth and DO NOT immerse Hot Dog components in liquid. Moisture will damage the components, and thermal injury may result.

Precautions

- DO NOT use pure harsh solvents (e.g., MEK, acetone, etc.) to clean Hot Dog components. Solvents may damage plastic parts, labeling and product finish.
- DO NOT use high-level disinfectants (e.g., gluteraldehyde, peracetic acid). The U.S. Centers for Disease Control (CDC) recommends against the use of high level disinfectants for cleaning environmental surfaces that may contact the patient since the chemicals are highly toxic.
- DO NOT spray cleaning solutions into electrical connectors.

Recommended cleaners

Alcohol-based disinfectants are easiest to use since they are fast-acting and can be either sprayed or wiped on. The following list of alcohol-based cleaners is provided for reference only and is not an endorsement of the manufacturers or their cleaning products: Ecolab (Incidin Liquid, Incides N, Incidin Foam, Incidin Sun, Mikro-Bak III), Merz (Pursept-A Xpress, Pursept Foam, Mucocit-A Economy) and Lysoform (Aerodesin 2000, Lysoform Spray).

Other cleaners that have been tested and are compatible with the outer surfaces of Hot Dog components include sodium hypochlorite (diluted bleach), phenolic germicidal detergent quaternary ammonium detergent and accelerated hydrogen peroxide (e.g., Virox).

Cleaners that contain iodine may cause surface discoloration and are therefore NOT recommended for routine cleaning.

Cleaning—Controller

Frequency

As needed

Tools/Equipment

- Sponge or soft cloth
- Mild detergent or anti-microbial spray
- Dry soft cloth

Method

1. Disconnect the Controller from the power source before cleaning.
2. Wipe unit with moistened sponge or soft cloth; avoid pushing fluids into any openings.
3. Dry with a separate soft cloth.

Cleaning—Warming Devices

Frequency

Clean between patient use and when the warming device appears soiled.

Method

Clean the warming devices following protocols for non-critical medical devices that may contact intact skin. Examples of similar devices are blood pressure cuffs, exam table covers, operating room table pads and surgical supports. **Cleaning steps are described in the User Manual provided with the warming device.** Note that the cleaning instructions are general recommendations and are not meant to replace hospital-specific cleaning protocols.

TROUBLESHOOTING/ERROR CODES

Error Code	Alarm Mode	Description
EE on all ports	System failure	Contact technical support.
E1 on affected port	Primary over-temp	When the temperature exceeds one degree above set point, audible and visual alarms are initiated and power is removed from the output. The alarm will reset when: • Temperature is within acceptable limits (± 1°C), or • Cable connecting warming device to Controller is disconnected, or power is removed at mains.
	Secondary over-temp	When the temperature exceeds 46°C, audible and visual alarms are initiated. The alarm will reset when the device is unplugged or power is removed at mains.
E2 on affected port	Failure to reach temp (Time to Temperature)	When the system does not achieve 43°C within 10 minutes, audible and visual alarms are initiated. The alarm will reset when the device is unplugged or power is removed at mains.
E3 on affected port	Port Over-current	When port current draw exceeds a predetermined level, audible and visual alarms are initiated. The alarm will reset when the device is unplugged or power is removed at mains.
E3 on all ports	System Over-current	When system current draw exceeds a predetermined level, audible and visual alarms are initiated. The alarm will reset when power is removed at mains.
E4 on affected port	Sensor failure	When either sensor is opened or shorted, audible and visual alarms are initiated and power is removed from output. If both sensors are opened or shorted, no alarms are initiated, power is removed from output, and the temperature selector switch becomes inactive. • Replace the warming device
E5 on affected port	Over-Temperature Array Alarm	In warming devices equipped with an over-temperature array, local overheating caused by folding of the warming blanket will initiate visual and audible alarms. The alarm will reset when the device is unplugged or power is removed at mains.
N/A	6-hour time-out timer	If a warming device is left operating for 6 hours with no changes to set point, power will be removed, three short audible chirps will sound, and the alarm Indicators will flash continuously. Pressing the temperature select button will clear the alarm and re-start normal operation.

TECHNICAL SUPPORT & CUSTOMER SERVICE

Please have the serial number of your Hot Dog Controller when you call for technical support. The serial number is located on the back of the Controller. If it is necessary to return the Controller for service or repair, contact your local supplier or sales representative.

Technical Support & Customer Service
Augustine Temperature Management
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www.hotdogwarming.com

DEFINITION OF SYMBOLS

	Do Not Place Under Patient		This Side Up		Mains Power On Indicator
	This Side Down		Heating Area		Alarm
	Attention, consult accompanying documents	REF	Reference Number	LOT	Lot Number
	BF Patient Applied Part according to IEC60601-1.	SN	Serial Number		Manufacture Date
	Temperature in Range		Transport and storage temperature range		Temperature Adjustment
	Keep Dry		Transport and storage humidity range		Fuse
	Equipotential	EC REP	EU Authorized Representative		Return to Authorized Representative
	Temperature Sensor	CE 0086	Conforms to European Medical Device Directive 93/42/EEC		
	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.				

ACCESSORY PART NUMBERS

The following cable part numbers are used with the Hot Dog Patient Warming System:

Part Number	Description
A101	Hot Dog Warming Blankets Cable, 4m (13ft)

Part Number	Description
A112	Hot Dog Mattress Cable, 4m (13ft)

SPECIFICATIONS

Physical Characteristics		
Dimensions		33 cm high x 14.0 cm deep x 19.7 cm wide13" high x 5.5" deep x 7.75" wide
Weight		5 kg (11 lbs)
Mounting		Can be placed on a horizontal flat surface (i.e. table top), clamped to an IV pole or hung on a OR/gurney rail using optional hanging hooks
Temperature Characteristics		
Temperature Control		Micro-processor
Operating Temperatures		Blanket Ports A and B adjustable in 1°C increments 37° to 43° ± 1.0°C 98.6° to 109.4° ± 1.8°F
		Mattress Port C adjustable in 1°C increments 35° to 39° ± 1.0°C 95° to 102.2° ± 1.8°F
Safety System		
Primary Over-temp Alarm		Ports A and B (Warming Blanket) Alarm sounds at set point + 1°C
		Port C (Warming Mattress) Alarm sounds at set point + 1°C
Secondary Over-temp Alarm		Ports A and B (Warming Blanket) Independent electronic circuit shuts the heater off if the Warming Blanket temperature reaches set point ± 3°C. Port C (Warming Mattress) Independent electronic circuit shuts the heater off if the Warming Mattress temperature reaches set point ± 2.5°C
Time out timer		If warming device does not reach set temperature within 10 minutes the controller will alarm
Six hour timer		If a warming device is left at a steady setting for six hours the controller will discontinue power to warming device.
Over-current limits		Port A: 10 amps max Port B: 10 amps max Port C: 5 amps Port D: 3 amps Port E: 3 amps System: 14.6 amps
System Over-current Protection		Dual input fused lines.

Electrical Characteristics		
Leakage Current		Meets UL 2601-1 and IEC 60601-1 requirements for Class I, Type BF equipment.
Power Consumption		850W maximum
Power Cord		4.6 m (15 ft)
Device Ratings		Input: 100-240 VAC, 50/60 Hz, 850VA Output A & B: 48 VDC, 480 VA Max each Output C: 240 VA Max Output D & E: 48 VDC, 144 VA Max each
Fuses		T10AL250V (2 x 5x20mm)
Environmental Conditions		
Environmental Conditions for Transport and Storage		Temperature: -20°C to 60°C Humidity: 20% to 80% Keep Dry
Environmental Conditions for Use		Temperature: 15°C to 25°C Humidity: 20% to 80%
Classification and Standards		
Certifications		IEC 60601-1; EN 60601-1-2; UL 60601-1; CAN/CSA-C22.2, No. 601.1, EN 55011 CE 0086 ETL C INTERTEK LISTED US
Classification		Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class I, Type BF, Ordinary equipment, Continuous operation. Not suitable for use in presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. 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. Classified under the Canadian Medical Device Regulation as Class II.
Diagnostics		A qualified technician can perform general system testing. The Controller has no user serviceable parts.
Important Information		This device complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in the close proximity of the device since this could influence the performances of the device. Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment and similar so that, e.g., the HF-cables are not routed on or near the device. If in doubt, contact a qualified technician or your local representative.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The Hot Dog Patient Warming 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

- **Use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the Hot Dog Patient Warming System.**
- **The Hot Dog Patient Warming System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, carefully observe the Hot Dog Patient Warming System to verify that it operates normally in this configuration.**

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Hot Dog™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or user of the Hot Dog Patient Warming System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions, CISPR 11	Group 1	The Hot Dog 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	The Hot Dog Patient Warming System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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 Hot Dog™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or the user of the Hot Dog 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % 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 Hot Dog Patient Warming System requires continued operation during power mains interruptions, it is recommended that the Hot Dog Patient Warming System be powered from an uninterruptible power supply or a battery.
Power frequency 50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 Hot Dog™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or the user of the Hot Dog 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	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Hot Dog 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: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	

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 Hot Dog Patient Warming System is used exceeds the applicable RF compliance level above, the Hot Dog 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 Hot Dog 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 Hot Dog Patient Warming System

The Hot Dog™ 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 Hot Dog Patient Warming System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hot Dog Patient Warming 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.

