

Veterinary Patient Warming System Controller User Manual

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INTRODUCTION

The Hot Dog Patient Warming System consists of two components: the Hot Dog Controller and the Hot Dog Warming Blanket. The Controller is pre-set to deliver a constant, efficacious temperature to help maintain normothermia in patients before, during, and after surgical procedures and to help prevent unintended hypothermia.

This manual includes maintenance instructions and specifications for the Hot Dog Patient Warming System. For information about using the Hot Dog Warming Blanket refer to the "Instructions for Use" provided with each of these components.

Veterinary Instructions for Use:

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.

CONTRAINDICATIONS

Do not warm patients with ischemic or non-perfused limbs; thermal injury may result.

WARNINGS

Do not layer multiple warming methods i.e. a hot dog blanket should not be used under a patient in combination with a heated surgical table or a hot water mattress.

EXPLOSION HAZARD - Do not use the Controller or Warming Blanket in the presence of flammable anesthetics or highly oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.

Inspect the Warming Blanket prior to use and cleaning 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 Warming Blanket until it is inspected by technical staff. Do not expose the inner heating element to fluids.

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

Pressure reduction

When a patient remains in a single position for an extended amount of time, ischemia can occur at points of elevated pressure which can lead to tissue necrosis. Warming

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ischemic tissue is contraindicated, therefore precautions should be taken when using the Hot Dog blankets under a patient. The Hot Dog warming blanket IS NOT a pressure reduction device.

When using blankets under a patient, ensure that adequate steps are taken to mitigate pressure.

Hard objects, should not be placed between the patient and the blanket.

If a rigid cautery ground plate is used, ensure that adequate steps are taken to mitigate pressure. Do not place the cautery plate on the sensor area of the blanket. The cautery plate must not be larger than the patient, i.e. the patient must completely cover the cautery plate.

PRECAUTIONS

Monitor the patient's vital signs regularly during warming according to institutional protocol. If vital sign instability occurs, notify the clinician.

Do not use the highest heat setting on or under patients with poor perfusion.

Use over-body warming instead of under body warming on patients with multiple risk factors such as short hair, poor circulation, severe illness that may impact circulation, or long duration procedures (> 2 hours).

Do not expose the warming blanket to a continuous exchange of cold irrigation fluids.

INSTRUCTIONS FOR USE

When using the Hot Dog Blanket above patient

Use on warmest setting appropriate to the patient condition and procedure for maximum effectiveness.

Place blanket directly on the patient with the sensor in contact with the patient.

When using the Hot Dog Blanket under patient or wrapped around patient

Do no use the highest heat setting unless you have a towel placed between the patient and the warming blanket.

The sensor should be in contact with the patient. A towel between the sensor and patient is acceptable.

Ensure that adequate steps are taken to mitigate pressure.

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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 13). Augustine Biomedical + Design 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 Instructions for Use manuals.
- The Controller is installed in an environment that does not meet the appropriate electrical and grounding requirements.

INITIAL SETUP & ASSEMBLY

Contents

The following components are included in the Hot Dog Patient Warming System box:

- Hot Dog Controller
- Mains power cord
- Warming Blanket power cord
- IFU

Reusable Hot Dog Warming Blankets are sold separately.

Assembly Procedure

- 1. Remove all items from the box and discard packaging per institutional protocol.
- 2. Firmly insert the mains power cord into the receptacle on the back of the Controller.

For controllers with the Optional Cord Retainer:

- 3. Loosen and remove the two cord retainer screws and the cord retainer (the cord retainer is located 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 Fig. 1)

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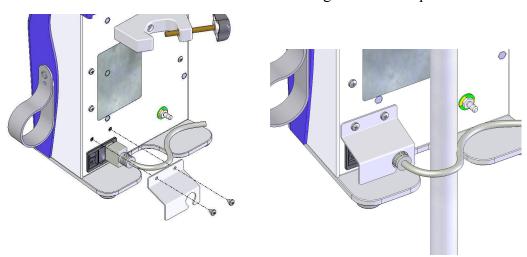


Figure 1. With Optional Cord Retainer

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. To remove the Controller from the IV pole, turn the clamp handle counterclockwise until the unit releases. (See Figure 2.)

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

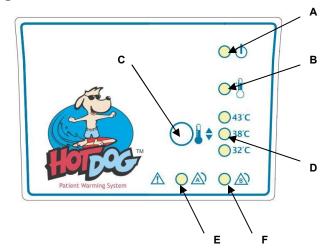


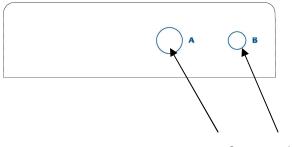
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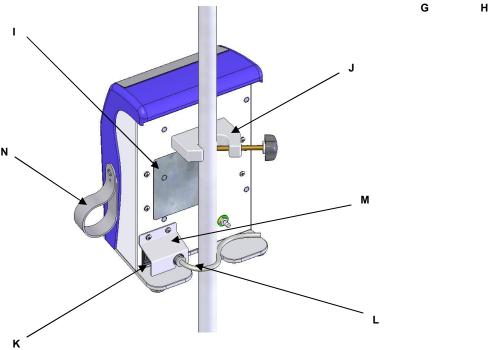
Overview of Control Panel Features & Operating Modes

Figure 4: Hot Dog Control Panel

- A. ON-OFF Power LED
- B. Temperature In Range LED
- C. Temperature Adjust Button
- D. Temperature Setting Indicator (3)
- E. Alarm Port A LED
- F. Alarm Port B LED
- G. Port A Outlet (Warming Blanket)
- H. Port B Outlet (Accessory Option)
- I. Serial Label
- J. IV Pole Clamp
- K. Mains Power Switch
- L. Power Plug and Inlet (fuses inside)
- M. Cord Retainer (optional)
- N. Cord Strap







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Mains Power Switch / ON Power Light

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, the Controller will beep and all lights will illuminate briefly. The Mains Power ON light will illuminate and the Controller will remain idle until a temperature is selected with the Temperature Adjust Button. If there is a loss of power to the Controller, the unit will return to ON when power is returned. When the unit is ON and idle (i.e., no Temperature Setting lights are illuminated), no power is applied to the Warming Blanket and no alarm conditions are indicated.

Temp Adjust Button / Temp Setting Lights

Press the Temperature Adjust Button until the desired high (43°C), medium (40°C), or low (37°C) temperature is selected, as indicated by the illuminated Temperature Setting light. The designated warming temperature will be reached within 5 minutes.

Temp in Range Light

The green Temperature in Range light will illuminate when the temperature of the Warming Blanket is $+ 1^{\circ}$ C of the selected temperature setting.

Port A

Port A is used only for Hot Dog Warming Blanket connection. When plugging a Warming Blanket into the Controller, an audible beep indicates that the control and over temperature sensors (safety device) are present and functioning properly.

Alarm Port A

If the Warming Blanket exceeds one degree above nominal (including tolerances) or other fault conditions exist, an audible alarm sounds and the Alarm Port A light illuminates red. The Controller will automatically discontinue power to the Warming Blanket. When the operating temperature is regained, the alarm will shut off and normal function will be restored. If the Alarm Port A light illuminates steadily and the alarm continues to sound, turn the Mains Power Switch to the OFF position and disconnect the Warming Blanket from the Controller.

• If Alarm Port A occurs when connecting a Warming Blanket to the Controller, disconnect the Warming Blanket and replace it with another Warming Blanket.

Port B (Optional)

Port B is a 48V output for Hot Dog accessories.

Alarm Port B (Optional)

If the accessory attached to Port B exceeds the pre-set current threshold, an audible alarm sounds and the Alarm Port B light illuminates red. Power is removed from the port. Disconnect the accessory from Port B to reset alarm.

- If Alarm Port B occurs when connecting an accessory to the Controller, disconnect the accessory and replace it with another accessory.
- If Alarm Port B occurs during use and the Alarm Port B light illuminates steadily, disconnect the accessory from the Controller and replace with another accessory.

INSTRUCTIONS FOR USE

The instructions below describe how to operate the Hot Dog Controller. For information about the Hot Dog Warming Blanket, refer to the Warming Blanket Instructions for Use.

- 1. Mount the Hot Dog Controller on an IV pole if desired.
- 2. Insert the Hot Dog Controller power plug into a properly-grounded hospital-grade electrical outlet.
- 3. Turn on the Mains Power Switch and ensure that the green mains Power ON light illuminates. When power is applied to the controller an audible beep and the visual alarm indicator should flash upon start up indicating that the over temperature alarm circuit is working satisfactorily.
- 4. Position the Hot Dog Warming Blanket as desired (refer to the Hot Dog Warming Blanket Instructions for Use).
- 5. Connect the Hot Dog Warming Blanket into Port A on the Hot Dog Controller. When plugging a warming blanket into the controller an audible beep indicates that the control sensor and over temperature thermistor are present and functioning properly.
- 6. Press the Temperature Adjust button until the desired high (43°C), medium (40°C), or low (37°C) temperature is set, as indicated by the Temperature Setting light. The designated warming temperature will be reached within 3 to 5 minutes, as indicated by illumination of the green Temperature in Range light.
- 7. Monitor the patient's temperature regularly. Adjust the temperature setting of the Hot Dog Controller as necessary to maintain the desired patient temperature.
- 8. When patient warming therapy is complete, turn off the Mains Power Switch to turn the Hot Dog Controller off.

MAINTENANCE

Testing of Indicator Light Function

Method

- 1. Confirm that the Controller is connected to mains and that NO cables or devices are connected to Port A or Port B.
- 2. Turn the Mains Power Switch to ON and carefully observe for the following proper start-up sequence:
- a. All lights illuminate briefly.
- b. The Mains Power ON light remains illuminated while the other lights illuminate one by one in the following order:
 - 1. Temperature in Range
 - 2. Alarm A
 - 3. Alarm B
 - 4. 43°
 - 5. 40°
 - 6. 37°
- c. All of the lights will illuminate simultaneously, and then the unit will emit an audible tone.
- d. After the sequence completes, only the Mains Power ON light remains illuminated.

If this sequence varies or is incomplete, contact Technical Support (see page 13).

Cleaning of the Controller

Frequency

As needed.

Tools/Equipment

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

Warning

Do not use a dripping wet cloth and do not immerse Hot Dog components in liquid. Moisture will damage internal 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.

Method

- 1. Disconnect the patient warming 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.

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.

USA and Worldwide:

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DEFINITION OF PRODUCT SYMBOLS

\triangle	Attention, consult accompanying documents	<u> </u>	Heating Area
†	BF Patient Applied Part according to IEC60601-1.	REF	Reference Number
LOT	Lot Number	SN	Serial Number
1	Temperature in Range	₩	Manufacture Date
*	Temperature Adjustment	1	Transport and storage temperature range
(h)	Main's Power On Indicator	%	Transport and storage humidity range
\rightarrow \right	Equipotential		Alarm
\Box	Fuse	X	Return to Authorized Representative
c (NATED) US	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.	*	Keep Dry

ACCESSORIES

Cables for Use with the Hot Dog Patient Warming System

Part Number	Description
1272	Cable for Hot Dog Warming Blankets, 2.5m (10ft)

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SPECIFICATIONS

Physical Characteristics			
Dimensions	29.2 cm high x 14.0 cm deep x 19.7 cm wide		
	11.5" high x 5.5" deep x 7.75" wide		
Weight	3.6 kg (8.0 lb)		
Mounting	Can be clamped to an IV pole		
Temperature Characteristics			
Temperature Control	Micro-processor		
Operating Temperatures	Average temperature at the Warming Blanket:		
	High 43° ± 1.0°C 109.4° ± 1.8°F		
	Medium 40° ± 1.0°C 104° ± 1.8°F		
	Low 37° ± 1.0°C 98.6° ± 1.8°F		
Safety System			
Primary Over-temp Alarm	Alarm sounds at 44°C + 1°C		
Secondary Over-temp Alarm	Independent electronic circuit shuts the heater off if the Warming Blanket temperature reaches $46^{\circ}\text{C} \pm 1^{\circ}\text{C}$.		
Over-current Monitoring			
- Port A	12 amps max.		
- Port B	1.7 amps max.		
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	Peak 580 W		
Power Cord	4.6 m (15 ft.)		
Device Ratings	Input: 100-240 VAC, 50/60 Hz, 600VA		
	Output A: 48 VDC, 500 VA Max		
	Output B: 48 VDC, 80 VA Max		
Fuses	T6.3AL250V (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
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

The Hot Dog Patient Warming System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual

Warning

- 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, the Hot Dog Patient Warming System should be observed to verify normal operation in the configuration in which it will be used.

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.

	Т	T
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
Harmonic emissions IEC 61000-3-2	Class A	establishments other than domestic and those directly connected to the public low-voltage power supply
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	network that supplies buildings used for domestic purposes.

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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	$<5\%\ U_{\rm T}$ $(>95\%\ dip\ in\ U_{\rm T})$ for 0,5 cycle $40\%\ U_{\rm T}$ $(60\%\ dip\ in\ U_{\rm T})$ for 5 cycles $70\%\ U_{\rm T}$ $(30\%\ dip\ in\ U_{\rm T})$ for 25 cycles $<5\%\ U_{\rm T}$ $(>95\%\ dip\ in\ U_{\rm T})$ for 5 sec	$<5\%\ U_{\rm T}$ $(>95\%\ dip\ in\ U_{\rm T})$ for 0,5 cycle $40\%\ U_{\rm T}$ $(60\%\ dip\ in\ U_{\rm T})$ for 5 cycles $70\%\ U_{\rm T}$ $(30\%\ dip\ in\ U_{\rm T})$ for 25 cycles $<5\%\ U_{\rm T}$ $(>95\%\ dip\ in\ U_{\rm T})$ 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
			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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d=0.35\sqrt{P}$ 80 MHz to 800 MHz $d=0.7\sqrt{P}$ 800 MHz to 2,5 GHz
			where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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 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.

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	Separation distance according to frequency of transmitter m			
power of transmitter W	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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Basic Troubleshooting

If a system alarm occurs, the following steps will help identify which system component is malfunctioning. Once a malfunctioning device has been identified, or for additional troubleshooting support, contact <u>Customer Service at 866-484-3505</u>.

- 1. Turn off the controller and unplug all blankets and cables. Let the blanket cool to room temperature. Complete the following steps IN ORDER.
- 2. Turn the mains power switch on the controller to ON and ensure that the controller successfully completes the brief diagnostic check (all lights illuminate sequentially, followed by a short audible beep).
 - a. If the startup sequence varies or is incomplete, the controller is malfunctioning.
- 3. Plug one end of the cable into the temperature controller.
 - a. If the controller alarms, the cable is malfunctioning.
- 4. Plug the other end of the cable into a blanket.
 - a. If the controller alarms immediately upon attaching a blanket, the blanket or the cable may be malfunctioning.
 - b. If a second cable is available, swap cables. If the alarm resolves, the original cable is malfunctioning.
 - c. If a second blanket is available, swap blankets. If the alarm resolves, the original blanket is malfunctioning.
- 5. Select the highest temperature setpoint.
 - a. If the controller alarms immediately upon selecting a temperature setpoint, the blanket or the cable may be malfunctioning.
 - b. If a second cable is available, swap cables. If the alarm resolves, the original cable is malfunctioning.
 - c. If a second blanket is available, swap blankets. If the alarm resolves, the original blanket is malfunctioning.
- 6. Place the blanket black (heated) side down on a thermally insulated surface (such as several layers of blankets or towels, or another warming blanket of similar or larger size) and let it run.
 - a. Observe the "Temperature In Range" indicator. If the controller alarms approximately 10 minutes after warming was initiated, but the temperature

- in range indicator did not indicate that set point temperature had been achieved, the blanket may be malfunctioning.
- b. If the Temperature In Range indicator indicates that set point has been achieved, and the controller then alarms, the controller or the blanket may be malfunctioning.

<u>Note:</u> The controller has a 6-hour shut down alarm indicated by 3 audible beeps after which the alarm LED will flash continuously. This alarm condition occurs if a blanket is left on for 6 hours with no user intervention. Selecting a temperature set point will clear this alarm condition.

Manufactured by:

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