User & Technical Manual

HotDog Veterinary Patient Warming System

Temperature Management Controller

Model WC71V Single Port Controller

Model WC77V Multiport Controller

www.vetwarming.com

Manufactured by:
Augustine Temperature Management
6581 City West Parkway
Eden Prairie, MN 55344 USA
TEL 952.465.3500
FAX 952.465.3501
EMAIL: cs@augsurg.com

EU Authorized Representative:
EC REP
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands
TEL (31) (0) 70 345-8570
FAX (31) (0) 70 346-7299

CE 2797

HOTDOG VETERINARY CONTROLLER – USER AND TECHNICAL MANUAL

Contents

Customer Service Contact

Phone: +1-952-465-3500

Email: CS@AugSurg.com

INTRODUCTION

Device Description

The HotDog Veterinary Patient Warming System (System) consists of a Temperature Management Controller and a reusable Warming Blanket.

Controller: Allows you to select the temperature for your Warming Blankets. There are 2 Controller options available:

- WC71V-The Single Port Controller operates 1 Blanket.
- WC77V-The Multiport Controller operates up to 4 Blankets at a time.

Warming Blankets: Blankets are available in several sizes; select the proper size.

Model Number	Warming Blanket Size	Primary Patient Use
V101	X-Small 10” X 12” (25.4 x 30.5 cm)	Mice and rats in research
V102	Small 10” X 23” (25.4 x 58.4 cm)	Exotics or pocket pets
V103	Medium 16” X 22” (40.6 x 55.9 cm)	An average-size cat
V104	Large 22” X 31” (55.9 x 78.7 cm)	An average-size dog
V106	Extra Large 27” X 47” (68.6 x 119.4 cm)	Bigger dogs

It is the responsibility of the clinician to determine whether warming is appropriate for each patient. The System should not be used when clinical considerations indicate that warming is not advisable.

INDICATIONS FOR USE

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

CONTRAINDICATIONS

Do not warm ischemic or non-perfused tissue; thermal injury may result. Examples include tissue distal to aortic cross clamping, severe dehydration, or when vasoconstrictive drugs would lead to severe, prolonged vasoconstriction.

Do not warm patients receiving transdermal medication as increased drug delivery may occur.

WARNINGS

Explosion hazard - Do not use 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, nicks, or cuts are evident, remove the Blanket from service.

Discontinue use of the System if the over-temperature indicator and/or any other Alarm continues to sound after reset. See Error Codes: Alerts and Alarms section.

To avoid risk of electric shock, the Controller must only be connected to a supply mains with protective earth grounding.

Do not use the Blanket beyond the expiration date marked on the yellow cable.

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 a clinician.
- Do not use the System with other warming modalities, i.e. Blankets should not be used in combination with a heated surgical table or any other warming modality.
- Do not continue to use the System if a safety Alarm sounds after reset. See Page 13 & 14, Error Codes: Alerts & Alarms for detailed troubleshooting information. Do not open the Controller. There are no user-serviceable parts. If service is required, contact Customer Service. The limited warranty is invalidated if:
    - The Controller is disassembled or serviced by an unauthorized person.
    - The System is used in a manner other than described in the User and Technical Manual.
    - The Controller is installed in an environment that does not meet the appropriate electrical and grounding requirements.
    - The Controller is grounded and attached to an un-grounded table intended for use with a hyfrecator or equivalent devices.

INITIAL SETUP & ASSEMBLY

Contents

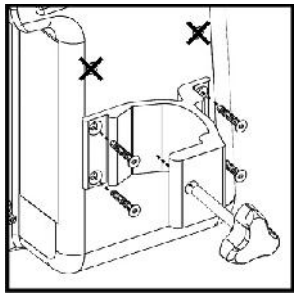
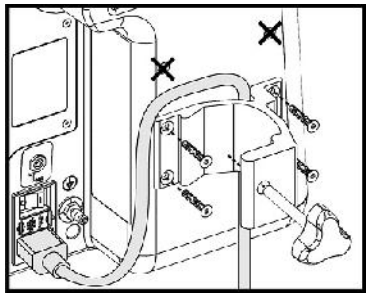
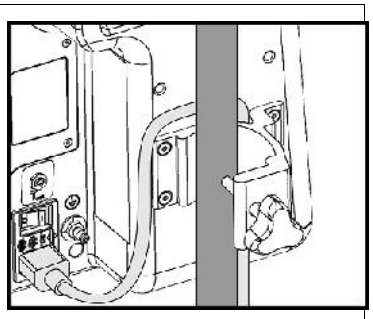
The following components are included with the Controller shipping carton:

- 1—Controller Model WC7X
- 1—Main power cord
- 1—IV pole clamp, clamp knob, and mounting hardware
- 1—Warming Blanket Cable (P/N A101)
- Remove the Controller and all components (including the yellow cable, gray power cord, clamp, clamp knob, and mounting hardware) from the shipping carton. Retain the shipping carton and packaging for future use.
- Place the Controller on a table or install IV pole clamp and knob, following the instructions provided. Be sure the power cord is in the clamp slot to provide strain relief. (Figure 1.)

Caution

To prevent the IV pole from tipping, attach the Controller at a height that provides stability. Use an IV pole with a minimum wheelbase radius of 35.6 cm (14 in) and mount the Controller no higher than 112 cm (44 in) from the floor. Failure to properly mount the Controller may cause the IV pole to tip, possibly resulting in injury.

Figure 1: Controller Mounted on an IV Pole

		
Line up the mounting clamp with bottom two sets of screw holes. Note: the clamp will not fit on the top two sets of screw holes.	Ensure the power cable is in the clamp slot to strain-relief cable. Tighten screws using supplied Allen wrench.	Mount the Controller to IV pole and tighten the clamp

The back of the Controller features a standard VESA 75mm x 75mm interface, allowing for additional mounting options, when using top and bottom holes. The provided IV pole clamp only works with the bottom four holes.

Rotate the clear cable-retention loop down on the side of the Controller. Use to assist with cable management when mounted to an IV pole.

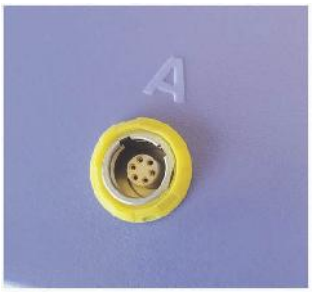
How to Operate the Controller

(For information about Warming Blankets, refer to the Warming Blanket Instructions for Use.)

1. Plug the gray power cord into the Controller and the electrical outlet.
2. Turn the Controller on. The power switch is located on the back of the Controller.
3. Watch “Getting Started” and “Overview” on the Controller. (Blanket must not be connected.)
4. Temperatures may be displayed in Celsius or Fahrenheit. The Controller defaults to Fahrenheit. To change, access Settings>Temperature Graph>Celsius/Fahrenheit. The selection will illuminate.
5. Remove the Blanket from the shipping carton. The serial number and 2-year expiration date are written on the yellow cable extending from the Blanket.
6. Connect the yellow cable to the short yellow cable off the side of the Blanket by aligning both red dots and pushing straight in. Do not twist!
7. Position and secure the Blanket.
8. Insert the Blanket’s connecting cable into the proper port on the Controller. Do not twist! (Figure 2.)

WC71V- Single Port	WC77- Multiport	Port Color	Device
A	A, B, C, D	Yellow	Warming Blanket

Figure 2: Controller Ports

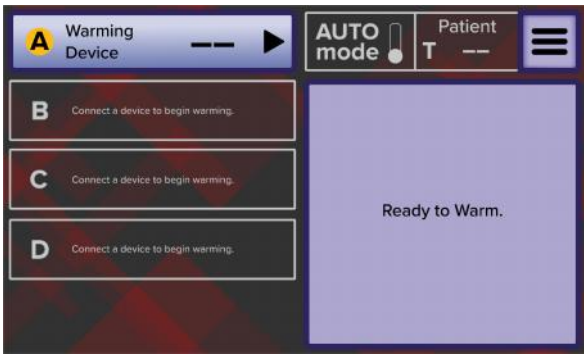
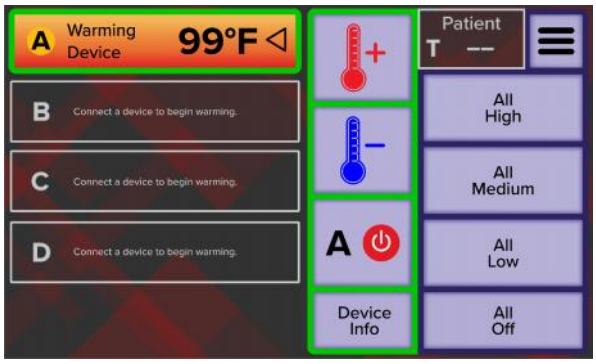
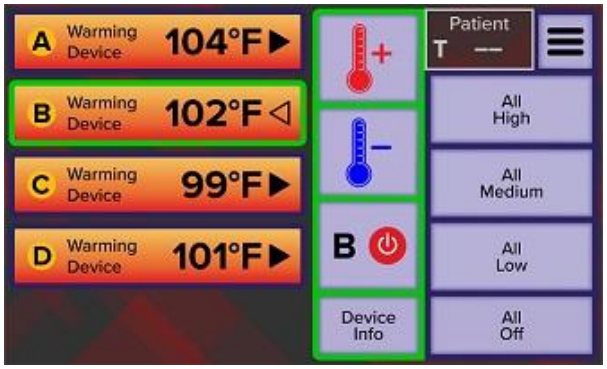


Port A on front of Controller

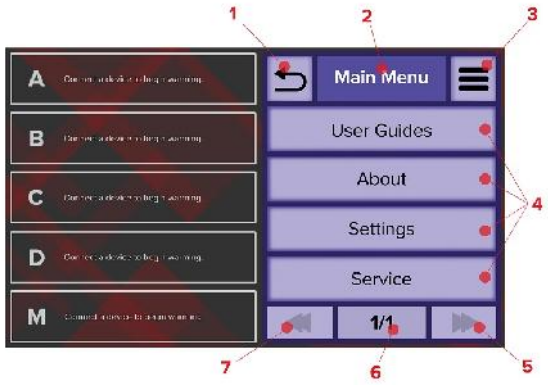
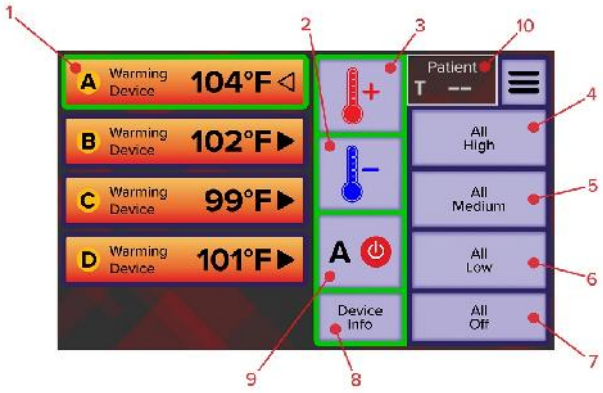
This is the only port available on a Single Port Controller, Model-WC71V

Ports B, C, and D on back of Controller.

Only available on a Multiport Controller, Model-WC77V

	1. Plug in Port A for a single Warming Blanket. (With Multiport Controller, use other ports as needed. When the cable is properly inserted into Controller, an audible sound indicates that the Blanket is properly connected and the port icon illuminates on the screen.
	2. Touch the illuminated icon to activate.
	3. The Blanket highlighted in green is the currently selected device. To the select Blanket temperature, use the + thermometer to increase the temperature or the – thermometer to decrease the temperature. Turn off highlighted port at the red power icon.
	4. Each connected Blanket can be adjusted separately. Other icons to the right adjust all port temperatures simultaneously: • All High • All Medium • All Low • All Off

CONTROL SCREEN OVERVIEW

	1. Back 2. Menu Title 3. Main Menu 4. Submenu 5. Next Page 6. Pages 7. Previous Page
	1. Currently Selected Blanket (green border) 2. Decrease Selected Device Temperature 3. Increase Selected Device Temperature 4. Set All Devices to High Temperature 5. Set All Devices to Medium Temperature 6. Set All Devices to Low Temperature 7. Turn Off All Devices 8. View Selected Device Info 9. Turn off Selected Device 10. Core Temperature Display (Coming Soon)

GENERAL INSTRUCTIONS

USE UNDER THE DIRECT SUPERVISION OF A CLINICIAN.

1. Select the Warming Blanket size that is the best fit for your patient, covering as much of your patient as possible.

2. Position the Blanket under, over, or around patient as desired, with the black side facing the patient. Make sure the patient is in contact with the sensor. Refer to Precautions and Pressure Reduction for guidance.

3. If desired, use the included strap to help conform the Blanket to the patient.

4. Connect the yellow cable to the short yellow cable off the side of the Blanket by aligning both red dots and pushing straight in. Do not twist!

5. Connect the opposite end of the yellow cable to the Controller by inserting it into a yellow port with the red dot on the cable facing up.

6. Turn the Controller on to begin warming and select the desired temperature on the Controller. The Blanket will take approximately 3 minutes to reach the selected temperature.

7. Monitor the temperature of the patient frequently during each case. Increase or decrease the Blanket temperature gradually to maintain normothermia.

GUIDELINES FOR TEMPERATURE SELECTION

Start by using the 40°C/104°F temperature setting. If the patient is becoming normothermic, there is no need to increase the temperature. If you are not getting the desired results, you may increase the temperature, following all precautions.

	Celsius Display	Fahrenheit Display
LOW	37	99
	38	101
MED	39	102
	40	104
	41	106
HIGH	42	108
	43	110

Use over-body warming instead of under-body warming on patients with any risk factors such as dehydration, bony prominences, poor circulation, lack of perfusion, or any illness that may impact circulation. For dental procedures, see Page 10.

PRESSURE REDUCTION

- The Warming Blanket is not a pressure-reduction device. Steps must be taken to mitigate heat-on-pressure situations when the Blanket is under the patient on hard surfaces, surgery tables, or dental grates. Use a pressure-reduction device (such as the HotDog Pressure Reduction Pad) or a soft pad, thick blanket, or thick towel between the Blanket and the hard surface.
- Longer duration procedures (approximately two hours or more) create greater risks. 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. Eliminate pressure points from occurring by appropriate pressure reduction.
- Closely monitor the temperature selection. Start by using the 40°C/104°F temperature setting. If the patient is becoming normothermic, there is no need to increase the temperature. If you are not getting the desired results, you may increase the temperature, following all precautions.
- Use over-body warming instead of under-body warming on patients with any risk factors ("Risk Factors") such as dehydration, bony prominences, poor circulation, lack of perfusion, or any illness that may impact circulation. (Note: for dental procedures, see below.)
- 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.

DENTAL PROCEDURES

Although the System is particularly useful in dental procedures, clinicians should take a few extra precautions to protect the patient:

- Most importantly, ensure that the patient is in contact with the sensor at all times during the case. Follow the temperature selection and pressure-reduction guidelines.
- Place a towel under the patient's mouth/head to absorb dental fluids and to reduce drainage onto the Warming Blanket. Make certain that the patient's body is not lower than the head.
- Do not place a sheet, towel, or other barrier between the patient and the Blanket.
- You may wrap the Blanket around the patient. However, when the Blanket is under the patient, do not select a temperature above 40°C/104°F.
- Use over-body warming instead of under-body warming on patients with any risk factors such as dehydration, bony prominences, poor circulation, lack of perfusion, or any illness that may impact circulation.
- The Blanket is not a pressure-reduction device. Steps must be taken to mitigate heat-on-pressure situations when the Blanket us under the patient on hard surfaces, surgery tables, or dental grates. Use a pressure-reduction device (such as the HotDog Pressure Reduction Pad) or a soft pad, thick blanket, or thick towel between the Blanket and the hard surface.

CLEANING THE CONTROLLER

Warnings

- Do not immerse the Controller 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 the Controller.
- Do not expose to hydrogen peroxide.

Frequency

- Per institutional protocols.

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 the Controller with a moistened sponge or soft cloth; avoid pushing fluids into any openings.
3. Dry with a separate soft cloth.

CONTROLLER OUTLINE

Main Menu

1. User Guides
2. About
3. Settings
4. Service

1. User Guides
    1. In-service slideshows
       Note: This information is unavailable if a blanket is connected and temperature selected. You must turn the blanket off to access the User Guides.
       a. Overview - Introduction to HotDog Patient Warming
       b. Getting Started - Explanation of how to use HotDog Patient Warming.

    1.2 Troubleshooting

    1.3 FAQ- Frequently Asked Questions

    1.4 Research Summary

    1.5 Getting Started

1.6 Auto Mode Guide Currently unavailable for Veterinary Use.

1.7 Positioning Guides

1.8 Cleaning Guide

1.9 Temperature Monitor Guide Currently unavailable for Veterinary Use.

2. About (Company and Device Information)

3. Settings

3.1 Temperature Graph

3.1.1 Select Celsius or Fahrenheit. Fahrenheit is the default.

3.2 Brightness

3.3 Volume

3.4 Audible Feedback When enabled, a tone sounds each time the screen is touched.

3.5 Automatic Shutoff Timer

3.6 Mode Vet mode is the default. The word “Vet” will illuminate green. Do not change.

4.0 Service

4.1 Diagnostic Test

4.2 Technical Support

4.3 Troubleshooting

FAQ- Frequently Asked Questions

1. How does HotDog warming work? HotDog Warming Blankets use a conductive polymer ThermAssure fabric. A low voltage DC current flows over this light, flexible fabric, and the resistance generates even warmth. Blankets do not contain carbon fiber or ink, which could break and create hot spots.
2. Why is HotDog warming safe? HotDog’s controller is really a microprocessor with many built-in safety features. It monitors connected warming devices at the patient and will automatically stop operation if readings are outside of safe parameters. The Blankets use a low-voltage, floating, isolated DC current to warm. The flexible conductive polymer fabric generates uniform heat with no hot spots.
3. Why do HotDog Blankets expire? Over time, the electric current flowing over the conductive polymer fabric oxidizes it, changing its resistance and the time it needs to reach temperature. When new, it only takes a few minutes to reach the set temperature. After 24 months of use, the Blanket will take longer to reach the set temperature. We have no data to support the use of the devices beyond 24 months.
4. Are the Blankets difficult to clean? Cleaning takes 30 seconds or less. Blankets can be cleaned by wiping with an approved cleaner. Do not use cleaners that contain

hydrogen peroxide. Do not use abrasive cleaners. The non-porous outer shell contains an anti-microbial, and the edges are heat-sealed to eliminate crevices.

5. What cleaners are approved? The following may be used: Alcohol, Sodium Hypochlorite (bleach), Chlorhexidine Gluconate, and Ammonium Chloride-based solutions. Follow your facility's cleaning protocols. Do not use Hydrogen Peroxide-based cleaners. Do not use cleaning products that are abrasive.
6. How do I get the best warming results? BODY SURFACE AREA: Warm as much surface area as possible. Warming the core is more effective than the periphery. SENSOR CONTACT: Ensure that the sensor is in contact with the patient.
7. What temperature should I select? Start by using the 40°C/104°F temperature setting. Monitor the temperature of your patient frequently during each case. Increase or decrease the blanket temperature gradually to maintain patient normothermia. Do not use any temperature above 40C/104F when the HotDog Blanket is positioned under or around the patient.
8. What type of barrier should I use? No barrier between the patient and the Blanket is necessary.
9. How do I manage pressure reduction? See Pressure Reduction on page 10 Ensure that pressure is mitigated for patients with any risk factors such as dehydration, bony prominences, poor circulation, lack of perfusion, or any illness that may impact circulation. Use a pressure-reduction device (such as the HotDog Pressure Reduction Pad) or a soft pad, thick blanket, or thick towel between the Blanket and the hard surface.
10. How do I select Blanket size? See page 3. There are 5 Blanket sizes. Select the size that is best fits the patient. Cover the most surface area of the patient.
11. How do I position the Blanket? The Blanket can be positioned over, under, or wrapped around the patient. However, when the Blanket is under the patient, do not select a temperature above 40°C/104°F. Cover the most surface area of the patient without interfering with the procedure area. The patient should always be in contact with the sensor on the black side of the Banket. Use the Blanket strap to secure.
12. Can the HotDog system be used in x-ray? Yes. The heater fabric is completely radiolucent. However, the Blanket has parallel busbars that run along the long edges. These can be seen on x-ray. The area around the sensor is also radio opaque. Position the Blanket so that the imaging area does not contain the sensor or busbar.

ERROR CODES: Alerts & Alarms

If an Alarm or Alert condition occurs, the associated error code will remain on the display until the condition is resolved.

After the Alarm or Alert condition has been displayed, the display will return to the main operating screen where the error code will still be present on the screen in place of the temperature set point.

To resolve an Alarm, follow the on-screen instructions. Blanket will not be active when an Alarm is occurring.

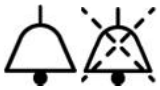
NOTE: BLANKET WILL STOP WARMING IF AN ALARM CONDITION APPEARS

Error Codes	Error Description	Problem Solving Steps
E1	Over-Temperature	When the temperature exceeds one degree above the set point, the Alarm sounds and power is removed from the Warming Blanket. Unplug the Blanket to reset the Alarm. Wait 5 minutes and then reconnect the Blanket. Turn the Controller on and select the temperature. If the Alarm occurs again, stop using the Blanket and contact technical support.
E2	Failure To Reach Temp	When the Warming Blanket does not reach the temperature set point within 10 minutes, the Alarm sounds, and power is removed from the Blanket. Check to make sure the Blanket is in contact with a patient and the sensor area is touching the patient. Unplug the Blanket and reconnect to reset. If the Alarm occurs again, stop using the Blanket and contact technical support.
E3	Port Current Reached	If the electrical current in the Warming Blanket exceeds the allowable limit, the Alarm sounds and power is removed from the Blanket. This may indicate and electrical problem with the Blanket. Unplug the Blanket from the Controller and reconnect to reset. If the Alarm occurs again, stop using the Blanket and contact technical support.
E4	Sensor or Cable Failure	If the Controller loses communication with the sensor in the Warming Blanket, an Alarm sounds, and power is removed from the Blanket. This may be caused by an electrical problem in the Blanket or in the Controller. Swap the cables and Blanket with known good product to isolate the problem if possible. If the problem continues, stop using the Blanket or cable and contact technical support
E5	Blanket Fold Detection	This Error Code does not apply to Veterinary blankets.
E7	Auto Mode Disengaged	The temperature sensor has exceeded 46° C/ 114.8°F. Disconnect the Warming Blanket and contact technical support.
E8	Over-Temperature Sensor (Secondary)	The temperature sensor has exceeded 46° C. Disconnect the Warming Blanket and contact technical support.
EA, EC, EF, EH or EP	Hardware Failure	Please turn off the Controller, wait one minute, then restart. If the problem persists contact technical support.

Contact Technical Support @ 952.465.3500 or CS@augsurg.com

Automatic Shutoff Timer - This feature prevents the System from unintentionally being left on. The System is not intended for use without a clinician present. The System defaults to a 6-hour shutoff. If there is no interaction with the Controller within 6 hours, it will automatically shut off.

DEFINITION OF PRODUCT SYMBOLS

	See IFU for Warnings and Precautions		See information for use at the provided website.		Measured temperature (invalid patient temperature)
	Natural Rubbber Latex Free		Not Sterile	T 37.0°C	Valid Patient Temperature (example)
	Attention; consult accompanying documents		Reference Number		Lot Number
	BF Patient Applied Part according to IEC60601-1.		Serial Number		Manufacture Date
	Do not use after YYYY-MM-DD		Transport and storage temperature range		Manufacturer
	Keep Dry		Transport and storage humidity range		Fuse
	Equipotential	EC REP	EU Authorized Representative		Return to Authorized Representative
	Temperature Sensor		Device Temperature Increase Button +1°C (When gray, device is at maximum temperature.)		Device Temperature Decrease Button -1°C (When gray, device is at minimum temperature.)
	Main Menu Button		Back Button		Next/Previous Page Graph Scroll Left/Right
	Confirm/Yes Button		Cancel/No Button		Increase Setting Button (Volume, Brightness, Etc.)
	Decrease Setting Button (Volume, Brightness, Etc.)		Graph Zoom in Button		Graph Zoom out Button
	Slideshow Play/Pause Button (Outline indicates pause)		Slideshow Volume Button		Alarm Mute Button (X indicates alarm is muted.)
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.				
CE 2797	Conforms to Medical Device Regulation (OJ No L 117/1 of 2017-05-05)				
C ETL US Intertek	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.				

TECHNICAL MANUAL

Do not open the Controller. There are no user-serviceable parts. For technical assistance, contact Customer Service. Perform all maintenance activities in accordance with the instructions in this Technical Manual. Approved personnel: unplug device before servicing internal components.

TESTING

Diagnostic Testing

Frequency

This test should be completed upon initial equipment check-in and once every 24 months (or more frequently if required by hospital guidelines).

Method

Place the Controller in Diagnostic Test mode by navigating to the Service Menu (Main Menu>Service>Diagnostic Test). To run the Diagnostic Test, select the green checkmark button.

> NOTE: All Warming Blankets need to be disconnected from the Controller to perform this check.

The system will check the internal components to ensure complete functionality. Upon completion of the test, a beep sound followed by a yellow blinking light will occur. The word “Passed” will appear in green if the Controller passes. The Word “Fail” will appear if the Controller does not pass. If a failure occurs contact Technical Support.

Per IEC 2-35: Test verifies that the independent thermal cut-out (i.e. secondary over-temperature sensor) is operational

Current Leakage Test

Frequency

This test should be completed per institutional protocols.

Tools/Equipment

- Warming Blanket Cable (A101)
- Leakage current tester
- HotDog Warming Blanket

Method

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 Controller may be used as a grounding point for these tests. Equipotential stud is for ease of attaining ground connection during electrical safety testing. Clip to stud during test. IEC Standard, Reference 60601-1 8.6.7

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

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), or clamped to an IV pole.
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
Safety System All alarm conditions are classified as Medium Priority Technical Alarms		
Auditory Alarms		Minimum SPL of 65 dB(A) at 3m (from front of controller) with a back ground SPL not to exceed 55dB(A)
Primary Over-temp Alarm		Ports A, B, C, D (Warming Blanket) Medium Priority Alarm sounds when temperature sensor is at set point + 1°C
		Port M (Warming Mattress) Medium Priority Alarm sounds when temperature sensor at set point + 1°C
Secondary Over-temp Alarm		Ports A, B, C, D (Warming Blanket) Independent electronic circuit shuts the heater off if the Warming Blanket temperature sensor reaches set point + 3°C. (46°C) Medium Priority Alarm sounds. Port M (Warming Mattress) Independent electronic circuit shuts the heater off if the Warming Mattress temperature sensor reaches set point ± 2.5°C (41.5°C) Medium Priority Alarm sounds.
Over-current limits		Port A: 10 amps max Port B: 10 amps max Port C: 10 amps max Port D: 10 amps max Port M: 7 amps max Port T Trucore: XXXX amps max System: 14.6 amps

	Medium Priority Alarm sounds
System Over-current Protection	Dual input fused lines. Medium Priority Alarm sounds
Electrical Characteristics	
Leakage Current	Meets UL 60601-1 and IEC 60601-1 requirements for Class I, Type BF equipment.
Power Consumption	850W maximum
Power Cord	4.6 m (15 ft) - May vary by country and region per local requirements and regulations.
Device Ratings	Input: 100-240 VAC, 50/60 Hz, 850VA Output A, B, C, D: 48 VDC, 480 VA Max each Output M: 336 VA Max
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%
Technical Description of PCLCS (physiologic closed-loop control system) – AUTO mode -- per IEC 60601-1-10 ed. 1.1	
Accompanying Information From Table C.3	Details necessary for the safe use of a DISTRIBUTED PCLCS 6.4: NA - Not a distributed PCLCS Summary of the PCLC modes of operation and specification of PCLCS responses 8.2.2.6: See Table 1 in IFU Means to check responses of the PCLCS 8.2.2.6: If patient temperature is outside a normal range, AUTO mode is disengaged and E7 alert is initiated.
Classification and Standards	
Certifications	IEC 60601-1; EN 60601-1-2; UL 60601-1; CAN/CSA-C22.2, No. 601.1, EN 55011 CE 2797 ETL Intertek
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.
Essential Performance	**1. If the applied part cannot reach set point within 10 minutes, the warming device shall turn off and a medium 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 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:

Time (s)	Temperature (C)
10000	43.5
6000	44
3300	44.5
1990	45
1000	45.5
600	46
350	46.5
225	47
110	47.5
80	48
60	48.5
38	49
28	49.5
22	50
17	50.5

ELECTROMAGNETIC COMPATIBILITY (EMC)

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

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The HotDog™ Patient Warming System is intended for use in the electromagnetic environment specified below. The customer or user of the HotDog 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 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	The HotDog 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 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	±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 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	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 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	3 Vrms 150 kHz to 80 MHz 10 V/m	3 V 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,

IEC 61000-4-3	80 MHz to 2,5 GHz		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.

Customer Service Contact Phone: +1-952-465-3500 Email: CS@AugSurg.com

3489 Rev A (07/2020)