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The Bair Hugger® Total Temperature Management® System was developed by an anesthesiologist to

prevent and/or treat the common but significant problem of hypothermia. Examples of current

applications for Bair Hugger Total Temperature Management Systems are post anesthesia care units

Bair Hugger® Total Temperature Management System

(PACU), recovery rooms, operating rooms, emergency departments, obstetrical suites, and intensive

care areas. The warming unit draws ambient air through a filter and warms the air to the specified

temperature. It then delivers the warmed air through a hose to the Bair Hugger blanket which is

placed over the patient. When used properly, the Bair Hugger blanket distributes the warm air around

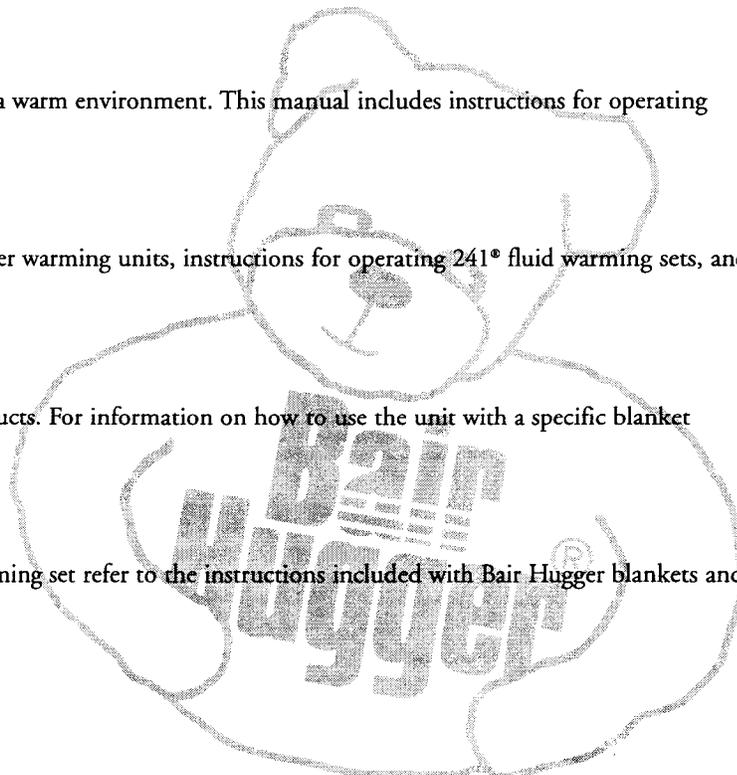
the patient's body, creating a warm environment. This manual includes instructions for operating

and maintaining Bair Hugger warming units, instructions for operating 241® fluid warming sets, and

specifications for both products. For information on how to use the unit with a specific blanket

model or the 241 fluid warming set refer to the instructions included with Bair Hugger® blankets and

241 fluid warming sets.



Technical Service and Order Placement

Technical Service

USA

TEL: 1-612-947-1200

1-800-733-7775

FAX: 1-612-947-1400

GERMANY

TEL: +49-8441-496734

FAX: +49-8441-496735

Order Placement

USA

TEL: 1-612-947-1200

1-800-733-7775

FAX: 1-612-947-1400

In-Warranty Repair and Exchange

Replacement parts to correct a problem are delivered at no charge. To return a device to Augustine Medical, Inc. for service, first obtain a Return Authorization (RA) number from a technical service representative. Please use this number on all correspondence when returning a device for service. A shipping carton will be delivered to you at no charge, if needed. Call your local supplier or sales representative to inquire about loaner devices while your device is being serviced.

When You Call for Technical Support

Remember, we will need to know the serial number of your unit when you call us. On Model 505 units, the serial number label is affixed to the rear panel. On the Model 500/OR unit the serial number label is affixed to the galvanized pan on the underside of the unit.

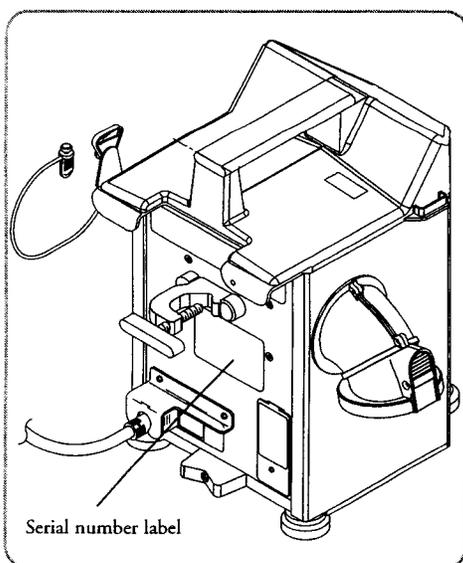


Figure A. Serial number label on Model 505

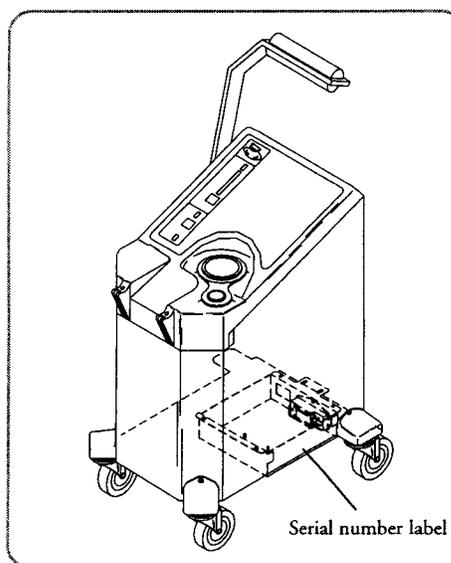


Figure B. Serial number label on Model 500/OR

Bair Hugger® Therapy Warranty

5 Year Limited Warranty*

Augustine Medical, Inc. (the "Company") warrants to the original end user that each Bair Hugger® warming unit will be free from defects in materials and workmanship under normal use and service for 5 years from the date of shipment.¹

¹The warranty period for hose assemblies in the warming unit expires one (1) year from the date of shipment, and this warranty does not apply to fuses and filters. The warranty does not apply to any item in which parts other than replacement parts made or approved by the Company have been used if such parts are the cause of failure. The Company shall have no obligation under this warranty to make repairs or replacements necessitated in whole or in part by accidents, fault or negligence of the user.

NOTE: The above warranty applies only to the original end user and is valid only for the use of Bair Hugger warming units with Bair Hugger warming blankets. The use of any blanket not manufactured or approved by the Company with the Company's warming units invalidates the foregoing limited warranty. Use of warming units in a manner not specified in the instructions for use invalidates the foregoing warranty.

* The Limited Warranty is valid only for Bair Hugger Forced Air Warming Therapy. It does not apply to the 241® Fluid Warming System or Bair Hugger Accessories.

Warranty on Parts for Units Produced After March 31, 1997

PART	WARRANTY PERIOD (FROM THE DATE OF SHIPMENT TO THE END USER)
Filters	N/A
Hoses	1 Year
Cords	1 Year
Caster	N/A
Labels	1 Year

NOTE:

- Distributors are not end users unless they have purchased a unit for their sales representative's use.
- Refurbished units have a 2 year warranty from the date of shipment to the end user.



Scott D. Augustine, M.D., Chief Executive Officer

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Hypothermia: A Common Problem in Patient Care

Description

Hypothermia occurs when a patient's body temperature drops below 36°C (96.8°F). Sixty to eighty percent of all patients undergoing operative procedures become hypothermic.

Contributing Factors

Factors contributing to hypothermia include:

- Cold operating room environment
- Anesthetic drug effect
- Administration of cold intravenous fluids
- The opening of the body cavity
- Cold exposure
- Drowning
- Spinal trauma
- Geriatric thermoregulatory processes

Adverse Consequences

Adverse consequences of hypothermia include:

- Coagulopathy
- Hemodynamic instability
- Immunodepression
- Shivering and patient discomfort
- Altered drug effect
- Postoperative nitrogen wasting
- Cardiac dysfunction

Indications for Bair Hugger® Warming Therapy

Examples of indications for the Bair Hugger® Total Temperature Management® system include:

- Body temperature drops below 36°C (96.8°F)
- Patient exhibits shivering
- Patient complains of being uncomfortably cold

Also, to prevent hypothermia, the Bair Hugger Total Temperature Management system should be used whenever conditions exist that could cause patients to become cold.

Precautionary Information

Contraindications

Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

Warnings

- Do not use Bair Hugger® warming units with any forced-air blanket or cover other than Bair Hugger blankets. Thermal injury may result.
- Do not warm patients with the warming unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin surface warming therapy.

- Do not use the 241® fluid warming set with any forced air warming system other than the 500 Series Bair Hugger system equipped with a fluid warming hose. Fluid temperature outside the indicated range or damage to the warming device may result.
- Do not continue therapy if the Over Heat warning light illuminates and the audible alarm sounds. Thermal injury may result. Turn the warming unit OFF and contact qualified technical personnel. If using 241 fluid warming, immediately stop fluid flow, and discard the fluid warming set.
- Do not initiate therapy unless the Model 505 warming unit is securely mounted or injury may result.
- Do not administer fluids if air is in the 241 set tubing. Introduction of air to the patient may result.

Precautions

- Monitor the patient's temperature at least every 10 to 20 minutes, and monitor the patient's vital signs regularly. Reduce air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician immediately of vital sign instability.
- To prevent suffocation from misuse, do not leave children or infants unattended when administering Bair Hugger® therapy.
- Except for specific blanket models, Bair Hugger blankets are not sterile and all are intended for single patient use only. Placing a sheet between the Bair Hugger blanket and the patient does not prevent contamination of this product.
- The 241® fluid warming set fluid path is sterile and non-pyrogenic in an unopened, undamaged package. Do not use the 241 fluid warming set if any part is damaged, distorted, or contaminated, or if end caps are not in place.
- Series 500 and 600 blankets meet an international standard for flammability IEC 695-2-2, and the Consumer Product Safety Commission's flammable fabric regulation, 16 CFR 1610; however, follow standard safety protocols when using high intensity heat sources.
- The blanket's clear plastic drape may cause visual distortion. Lift the plastic drape to view the patient's head clearly.
- See CONTRAINDICATIONS and WARNINGS before administering therapy. Read this Operation Manual, blanket instructions and 241 fluid warming set package instructions before use.

Important Information

EXPLOSION HAZARD

Do not use in the presence of flammable anesthetics.

ELECTRICAL SHOCK HAZARD

Do not disassemble the warming unit; refer to authorized technical personnel. There are electrically live parts within the warming unit when it is connected to the power source, even when the switches are in the OFF position.

ELECTRICAL INTERFERENCE

If radio frequency interference with monitoring equipment should occur, connect the warming unit to a different power source.



Read Before Servicing Equipment

The repair, calibration, and servicing of the warming unit requires the skill of qualified technical personnel who are familiar with good practice for medical device repair. If service is designated as not requiring the manufacturer's attention, the technical information is provided in the Service Manual or will be provided, upon request, by Augustine Medical, Inc.

REFER TO SERVICE MANUAL

Perform all repairs and maintenance in accordance with the instructions in the Service Manual.

SAFETY INSPECTION

Perform a safety inspection after making repairs to the warming unit, and before returning the warming unit to service. A safety inspection must include a test of the operating temperatures (described in the Service Manual), the Over Heat Alarm system, as well as a leakage current test.

PROPER USE AND MAINTENANCE

Augustine Medical, Inc. assumes no responsibility for the reliability, performance, or safety of the equipment if:

- Modifications or repairs are performed by unauthorized personnel.
- The equipment is used in a manner other than that described in the Operation or Service Manuals.
- The equipment is installed in an environment that does not meet the relevant grounding requirements.

Setup and Operation

The Bair Hugger® Total Temperature Management® System is easy to set up and to use. Follow the instructions provided with each blanket for specific information.

- 1) Place the Bair Hugger blanket on the patient with the perforated side (the side with small holes) against the patient's skin.

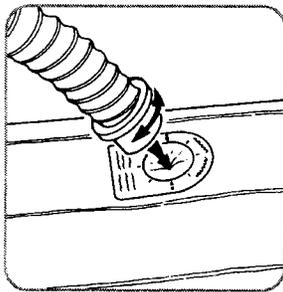


Figure C.

- 2) Insert the hose of the warming unit in the inlet port on the blanket. Use a twisting motion to ensure a snug fit (see Figure C).
- 3) Connect the warming unit to a properly grounded power source.
- 4) If so equipped, turn the Isolation Switch to the ON position (see the section titled Isolation Switch).
- 5) Press the System ON/OFF button to turn the warming unit ON and select the appropriate temperature setting.
- 6) Place a cotton blanket over the Bair Hugger blanket for maximum effectiveness.
- 7) Monitor the patient's temperature at least every 10 to 20 minutes and adjust the temperature setting of the warming unit as required.

Bair Hugger® Total Temperature Management® System

The Bair Hugger Total Temperature Management System consists of a disposable blanket and a warming unit. Bair Hugger warming therapy can also include 241® fluid warming therapy, described under *Warming Fluids Using the 241 Fluid Warming Set*.

Bair Hugger® Blankets

Bair Hugger blankets are made up of long, tubular channels which deliver controlled warmth. The blanket is designed to “hug” the patient. Blankets are designed in various configurations for specific applications. Follow the instructions provided with Bair Hugger blankets for specific information concerning their recommended use.

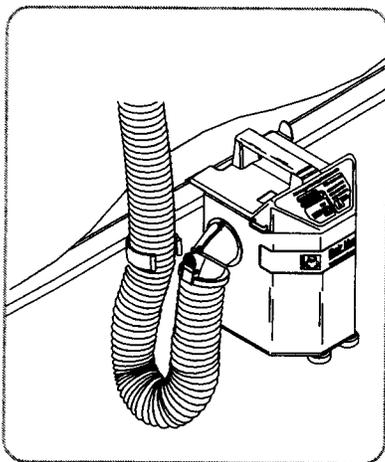


Figure D. Model 505 warming unit

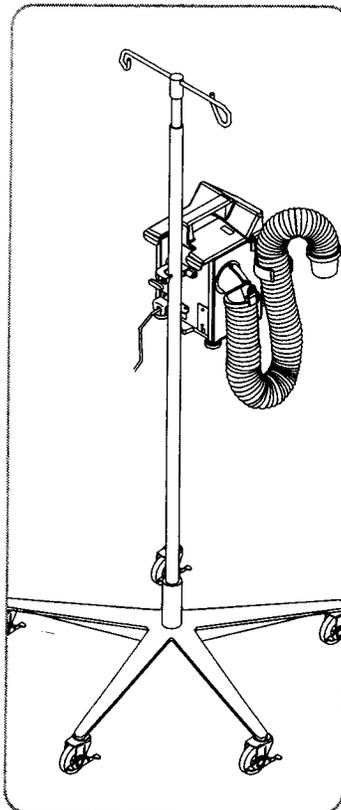


Figure E. Model 505 warming unit attached to an I.V. pole

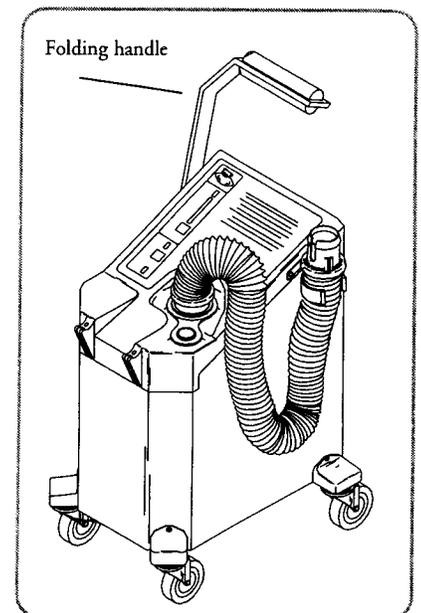


Figure F. Model 500/OR and Model 500/OR,E warming unit

Warming Units

The warming unit uses a high-efficiency motor, a heating element, and a solid-state temperature control to create a continuous flow of warm air to the blanket. Models 500/OR, 500/OR,E and 505 are designed for safe use in all areas, including the operating room.

The folding handle on the Model 500/OR, 500/OR,E warming units can be placed in two positions. The handle is moved forward and down for the folded position; it is pushed up and back for the upright position. In the folded position the warming unit can be rolled out of the way (for example, under the operating table) during warming therapy, and it can be stored more conveniently when warming therapy is completed. The upright position allows the warming unit to be easily transported between clinical areas.

The Model 505 warming unit can be attached to an I.V. pole or to the railing on a bed.

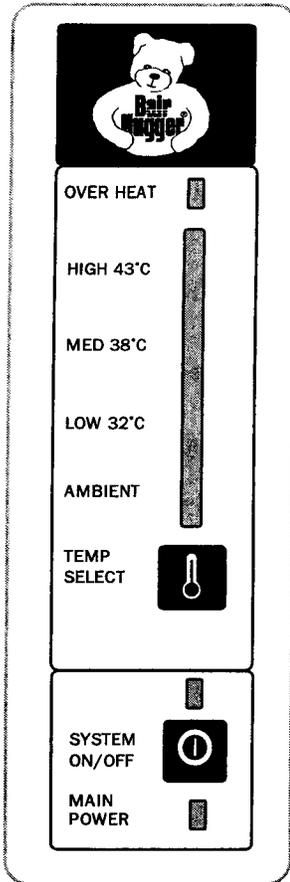


Figure G. Control panel of the Model 500/OR and 500/OR,E warming unit

Control Panel Features of the Model 500/OR and 500/OR,E Warming Unit

OVER HEAT INDICATOR

The Over Heat Indicator illuminates and an audible alarm sounds when an over-temperature condition is detected. To reset, turn the warming unit OFF and then ON, either by the System ON/OFF button (see Figure G), or by the Isolation Switch (see the section titled *Isolation Switch*). Also refer to the Warnings section of this manual.)

TEMPERATURE INDICATORS

The indicator bar illuminates up to the selected temperature level. When the warming unit is initially turned on, the AMBIENT temperature level is automatically selected.

TEMPERATURE SELECT

Push this button to increase the temperature setting level by level to the desired setting. When the temperature setting is at HIGH, push the button again to return the setting to AMBIENT.

SYSTEM ON/OFF

Push this button to turn the warming unit either ON or OFF. The indicator directly above the switch illuminates when the warming unit is ON.

MAIN POWER INDICATOR

The main power indicator illuminates when main power is applied to the warming unit and the Isolation Switch is in the ON position (see the section titled *Isolation Switch*). This indicator must be illuminated for any functions to operate.

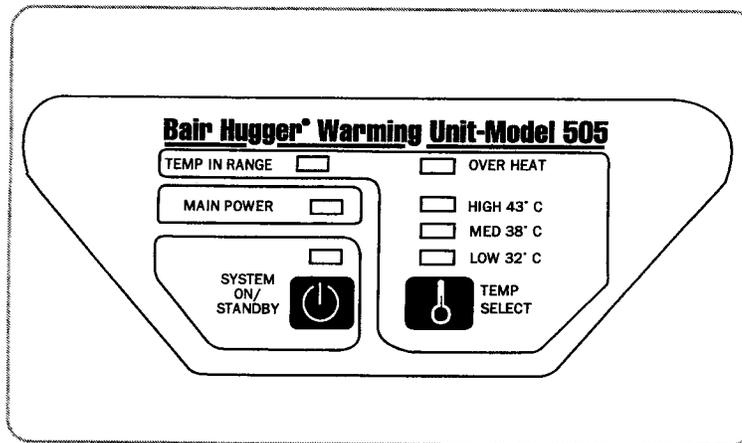


Figure H. Control panel of the Model 505 warming unit

Control Panel Features of the Model 505 Warming Unit

TEMPERATURE IN RANGE INDICATOR

The temperature in range indicator illuminates when the output air temperature is within the range of the selected level.

MAIN POWER INDICATOR

The main power indicator illuminates when the warming unit is connected to a power source. This indicator must be illuminated for any functions to operate.

SYSTEM ON/STANDBY

Push this button to turn the warming unit either ON or OFF. The indicator directly above the switch illuminates when the warming unit is ON.

OVER HEAT INDICATOR

The Over Heat Indicator illuminates and an audible alarm sounds when an over-temperature condition is detected. To reset, turn the warming unit OFF and then ON, using the System ON/STANDBY button. (Also refer to the Warnings section of this manual.)

TEMPERATURE INDICATORS

The temperature indicators illuminate up to the selected temperature level. When the warming unit is initially turned on, none of these indicators are illuminated and ambient air will be delivered.

TEMPERATURE SELECT

Push this button to increase the temperature setting level by level to the desired setting. When the temperature setting is at HIGH, push the button again to return to delivery of ambient air.

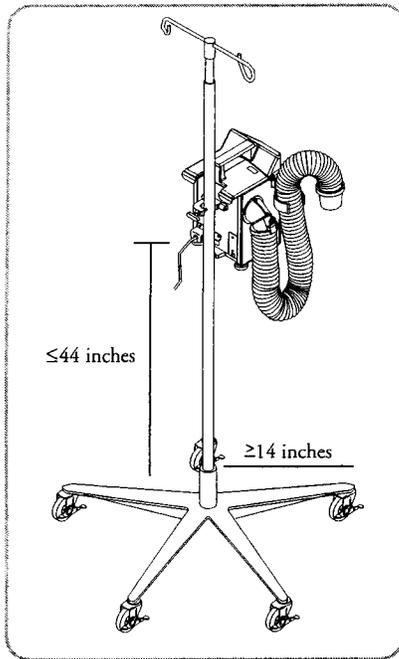


Figure I. Model 505 warming unit attached to an I.V. pole

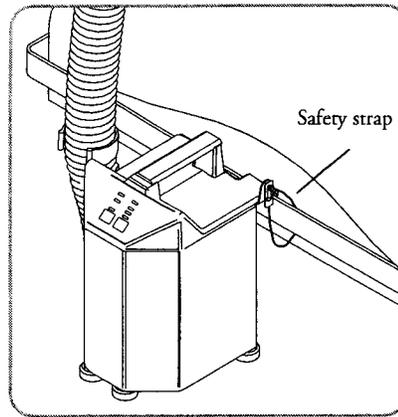


Figure J. Model 505 warming unit attached to a bed rail

Mounting the Model 505 Warming Unit

USING AN I.V. POLE

The Model 505 warming unit clamps easily to an I.V. pole (see figure I). Simply turn the handle clockwise to tighten the clamp onto an I.V. pole, counterclockwise to release.



WARNING: To prevent tipping, clamp the Model 505 warming unit to an I.V. pole at a height that provides stability. We recommend clamping the unit no higher than 44" (112 cm) on an I.V. pole with a minimum 14" (35.6 cm) radius wheelbase. Failure to do so may result in I.V. pole tipping, catheter site trauma, and patient injury.

USING A BED RAIL

The Model 505 warming unit can also hang on the edge of a bed. The safety strap is designed to loop around the bed rail, keeping the Model 505 unit safely suspended even if the unit is inadvertently dislodged from the bed rail (see figure J).

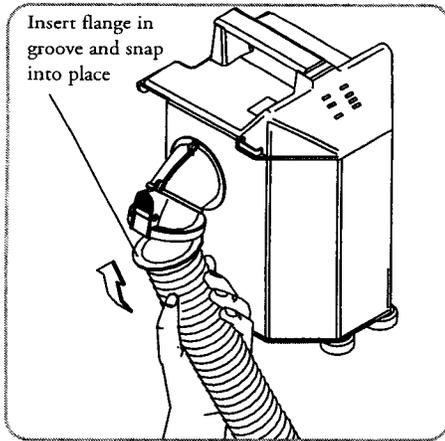


Figure K. Attaching the Model 505 unit hose

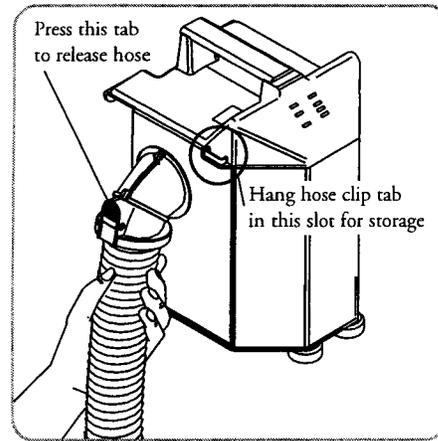


Figure L. Storing the Model 505 unit hose

Attaching and Storing the Model 505 Warming Unit Hose

The Model 505 unit has a unique “snap-fit” hose. This extended length, swivel hose, adapted for 241° fluid warming, attaches by inserting the flange end at a 45° angle in the grooved blower outlet, then by “snapping” the hose into place.

Press the white tab on the blower outlet to release the hose.

When storing the Model 505 unit, insert the hose clip tab in the hanger slot near the blower outlet.

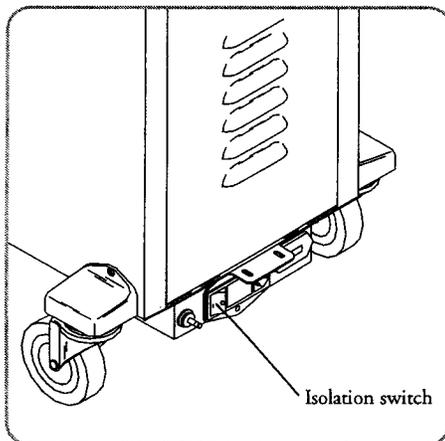


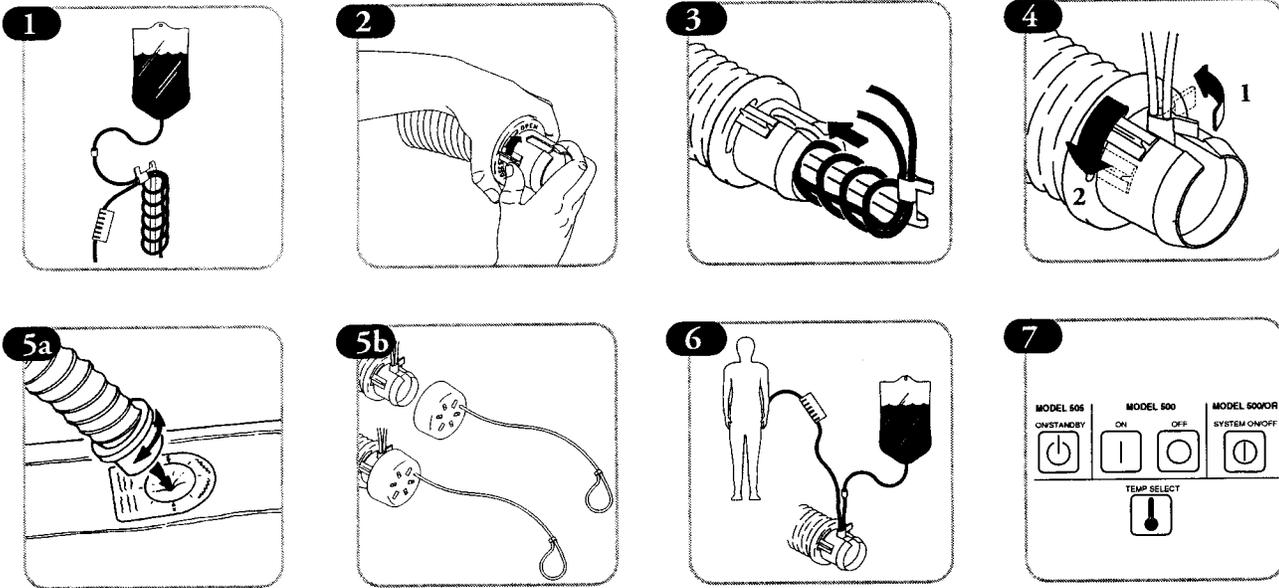
Figure M. Isolation Switch on Model 500/OR and 500/OR,E units

Isolation Switch

The isolation switch allows you to disconnect the warming unit from the power source without removing the power cord from the wall receptacle. The isolation switch is located on the back of Model 500/OR and 500/OR,E warming units. The isolation switch must be in the ON position before the warming unit will operate. The Model 505 unit does not have an isolation switch.



CAUTION: To disconnect the Model 505 unit from the power source, remove the power cord from the wall receptacle. Keep the area around the receptacle clear of obstructions.

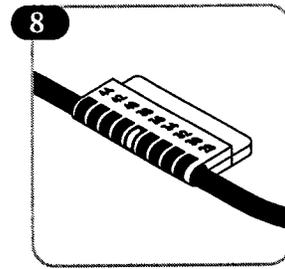


Warming Fluids Using the 241® Fluid Warming Set

Series 500 warming units are equipped with a special hose for 241 fluid warming. This allows the Bair Hugger® Total Temperature Management® system to warm blood and intravenous fluids delivered through a Bair Hugger 241 fluid warming set at infusion rates up to 3,000 ml/hr.

Before initiating fluid warming therapy, read the package insert for the 241 fluid warming set. The 241 fluid warming set is latex-free.

- 1) Connect the 241 fluid warming set to the fluid source using the end of tubing without the temperature indicator. Thoroughly prime all tubing.
- 2) Push the tab to open the notch on the hose end.
- 3) Slide the coil completely into the hose until the lever on the 241 fluid warming set reaches the base of the notch.
- 4) Rotate the lever (1) of the fluid warmer towards the hose collar until it is parallel with the hose collar. Push the tab (2) to close the notch on the hose end.
- 5a) To perform fluid warming with skin surface warming: Insert the end of the hose in the opening for the hose on a Bair Hugger blanket. Use a twisting motion to ensure a snug fit.
- 5b) To perform fluid warming alone: Attach the hose cap to end of hose. Direct the hose end away from patient.
- 6) Make patient connection. Do not entrap air.
- 7) Press the System ON/OFF (ON/STANDBY) button to turn the Series 500 Bair Hugger® unit ON, and select the appropriate temperature setting. Tuck the outlet and extension tubing between the blanket channels to insulate.
- 8) Begin infusion. Use the temperature indicator to monitor the fluid temperature. The green square indicates fluid temperature.



Fluid Warming Specifications

The average fluid output temperatures during normal operation of the 241 fluid warming set with the warming unit set on HIGH are as follows:

INFUSION RATE	OUTPUT TEMPERATURE
500 ml/hr	34.9°C
1000 ml/hr	36.8°C
1500 ml/hr	36.1°C
2000 ml/hr	34.7°C
2500 ml/hr	33.2°C
3000 ml/hr	31.9°C

Fluid input temperature: 20°C. Increase fluid temperature by an average of 3°C by tucking the outlet tubing in Bair Hugger blanket channels.

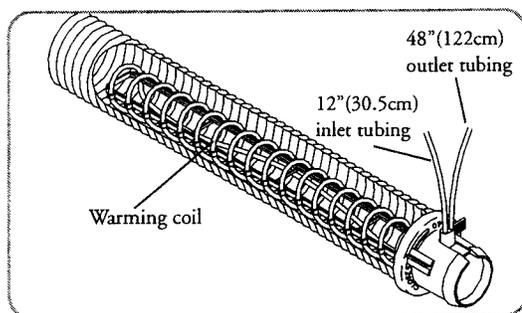


Figure N. Fluid warming set inside warming unit hose

Optional Features

This section discusses optional features for Bair Hugger® warming units. For more details about these features, please call Augustine Medical or your local distributor.

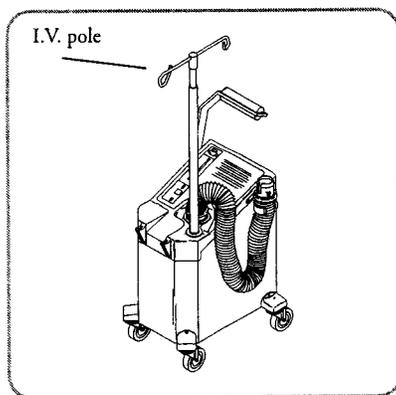


Figure O. Warming unit with I.V. pole option

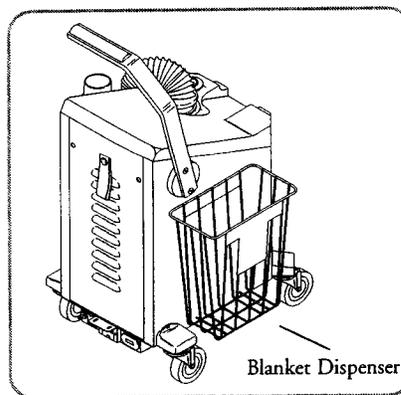


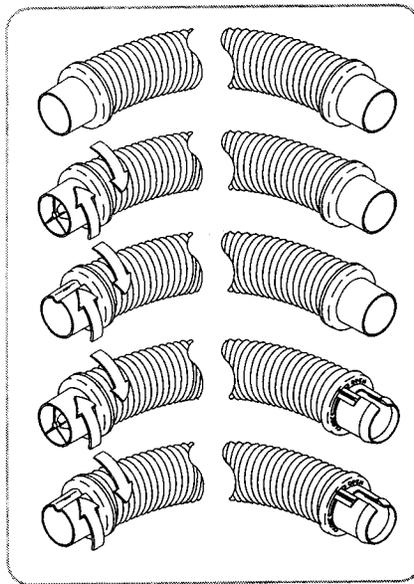
Figure P. Warming unit with blanket dispenser

I.V. POLE

Model 500/OR and 500/OR,E warming units have a port that accommodates an Augustine Medical, Inc. I.V. pole.

BLANKET DISPENSER

The blanket dispenser is available for use on all warming units, except the Model 505 unit. This dispenser attaches to the warming unit and can store several Bair Hugger blankets. See the package instructions for details.



Standard length without swivel option
(replacement only)

Standard length with swivel option
(replacement only)

Extended length with swivel option
(note keyway)

Standard length 241 fluid warming hose
(replacement for 500 series only)

Extended length 241 fluid warming hose
(note keyway) (standard for 500 series only)

Figure Q. Hose assemblies

HOSE ASSEMBLIES

Warming unit hose assemblies are available in five options. The keyway on the extended length hose matches a keyway on warming units specifically calibrated for the extended length hose option, to ensure the delivery of proper temperature to the patient.

Model 505 units are only available with a snap-fit, extended length 241® fluid warming hose assembly, described in *Attaching and Storing the Model 505 warming unit hose*.

General Maintenance

Cabinet Cleaning

- 1) Disconnect the warming unit from the power source before cleaning.
- 2) Use a damp soft cloth and a mild detergent to clean the warming unit cabinet. Dry with a separate soft cloth.



CAUTION

- Do not use a dripping wet cloth to clean the cabinet. Moisture may seep into the electrical contacts, damaging the components.
- Do not use alcohol or other solvents to clean the cabinet. Solvents may damage the labels and other plastic parts.

Specifications

500/OR

Physical Characteristics

DIMENSIONS

24 in. high x 16 in. deep x 14 in. wide
61 cm high x 41 cm deep x 36 cm wide

WEIGHT

43 lb; 19.5 kg

505

Physical Characteristics

DIMENSIONS

13 in. high x 10 in. deep x 11 in. wide
33 cm high x 25 cm deep x 28 cm wide

WEIGHT

11.5 lb; 5.2 kg

500/OR

MOUNTING
Supplied with swivel casters; floor use only

RELATIVE NOISE LEVEL
52 decibels

HOSE
Detachable, flexible, washable; compatible with Bair Hugger 241® fluid warming system

FILTRATION SYSTEM
0.2µM level

RECOMMENDED FILTER CHANGE
Every 6 months or 500 hours of use

Temperature Characteristics

TEMPERATURE CONTROL
Electronically controlled using a thermocouple sensor

HEAT GENERATED
1800 BTUs (average)

SYSTEM TIME TO 100°F (37.7°C)
~35 secs

OPERATING TEMPERATURES
Air temperatures reaching the patient are approximately 2°C lower than the listed temperatures.

Average temperatures at the end of the hose, assuming the back pressure of an Augustine Medical, Inc. warming blanket, or an Augustine Medical, Inc. temperature test unit:

HIGH: 43° ± 3°C	109.4° ± 5.4°F
MED: 38° ± 3°C	100.4° ± 5.4°F
LOW: 32° ± 3°C	89.6° ± 5.4°F

Safety System

THERMOSTAT
Independent bulb and capillary

OVERCURRENT PROTECTION
Dual fused input lines

ALARM SYSTEM
Over-heat: flashing red light with audible alarm; heater shuts down

CERTIFICATIONS
UL 544, CSA C22.2 No. 125, IEC 601-1, IEC 601-1-2, EN55014, AS 3200.1990

CLASSIFICATION
Classified under IEC 601-1 Guidelines as Class I, Type BF, Ordinary equipment, Continuous operation

Electrical Characteristics

BLOWER MOTOR
Operating speed: 2650 rpm
Airflow: 28-30 cfm

POWER CONSUMPTION
Peak: 1000W
Average: 500W

505

MOUNTING
IV pole clamp, bed rail hook with safety strap; can be placed on hard surface

RELATIVE NOISE LEVEL
53 decibels

HOSE
Detachable, flexible, washable; compatible with Bair Hugger 241® fluid warming system

FILTRATION SYSTEM
0.2µM level

RECOMMENDED FILTER CHANGE
Every 6 months or 500 hours of use

Temperature Characteristics

TEMPERATURE CONTROL
Electronically controlled using a thermocouple sensor

HEAT GENERATED
1800 BTUs (average)

SYSTEM TIME TO 100°F (37.7°C)
~17 secs

OPERATING TEMPERATURES
Air temperatures reaching the patient are approximately 2°C lower than the listed temperatures.

Average temperatures at the end of the hose, assuming the back pressure of an Augustine Medical, Inc. warming blanket, or an Augustine Medical, Inc. temperature test unit:

HIGH: 43° ± 3°C	109.4° ± 5.4°F
MED: 38° ± 3°C	100.4° ± 5.4°F
LOW: 32° ± 3°C	89.6° ± 5.4°F

Safety System

THERMOSTAT
Independent bulb and capillary

OVERCURRENT PROTECTION
Dual fused input lines

ALARM SYSTEM
Over-heat: flashing red light with audible alarm; heater shuts down

CERTIFICATIONS
UL 544, CSA C22.2 No. 125, IEC 601-1, IEC 601-1-2, EN55014, AS 3200.1990

CLASSIFICATION
Classified under IEC 601-1 Guidelines as Class I, Type BF, Ordinary equipment, Continuous operation

Electrical Characteristics

BLOWER MOTOR
Operating speed: 3150 rpm
Airflow: 28-30 cfm

POWER CONSUMPTION
Peak: 1000W
Average: 450W

500/OR

LEAKAGE CURRENT
<100µA

HEATING ELEMENT
850W Resistive

POWER CORD
15-foot, SJT, 3 cond., 10A
4.6 meter, HAR, 3 cond., 10A

DEVICE RATINGS
110-120VAC, 60Hz, 9.5 Amperes, or
220-240VAC, 50Hz, 4.5 Amperes, or
100VAC, 50/60 Hz, 10 Amperes

FUSES
10A, 200mA and 500mA (110 - 120 VAC Units)
6.3A, 100mA and 500mA (220 - 240 VAC Units)
10A, 160mA and 400mA (100VAC Units)

DIAGNOSTICS
Over-heat test can be performed by the bio-
medical group.

505

LEAKAGE CURRENT
<100µA

HEATING ELEMENT
850W Resistive

POWER CORD
15-foot, SJT, 3 cond., 10A
4.6 meter, HAR, 3 cond., 10A

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Definition of Symbols



ON/STANDBY



ON (used on isolation switch)



OFF (used on isolation switch)



ON/OFF push button switch



Temperature Control



Equipotentiality plug (Ground)



Fuse



Warning/Caution (see appropriate documents)



Non Explosion-Proof



Dangerous Voltage



Type BF Equipment (patient applied)



Voltage, Alternating Current (AC)