

Bair Hugger* Model 505 and Model 500/OR **Temperature Management Units**

Operator'sManual

Betriebshandbuch für Bair Hugger Temperaturmanagement-Geräte Modell 505 und 500 OR

Manuel de l'utilisateur pour les appareils de gestion de la température Bair Hugger modèle 505 et modèle 500/OR

Manuale d'uso delle unità di gestione della temperatura Bair Hugger modello 505 e modelli della serie 500

Manual del usuario para las unidades de control de temperatura Bair Hugger, modelos 505 y 500/OR

Manual do utilizador das unidades de gestão de temperatura Bair Hugger Modelo 505 e Modelo 500/OR

Bair Hugger Temperatuurregelunits model 505 en model 500/OR Gebruikshandleiding

Brugsanvisning til Bair Hugger temperaturreguleringsenheder, Model 505 og Model 500/OR

Bruksanvisning till Bair Hugger modell 505 och 500/OR temperaturstyrenhet

Brukerhåndbok for Bair Hugger-temperaturbehandlingsenhet, modell 505 og 500/OR

Bair Hugger -lämpötilansäätölaitteen mallit 505 ja 500/OR käyttäjän opas



Bair Hugger Model 505 and Model 500/OR Temperature Management Units

Operator'sManual

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Introduction

Description of the Total Temperature Management System

The Bair Hugger brand Total Temperature Management System consists of a Bair Hugger forced-air temperature management unit (with available rolling stand and sheet clip) and Bair Hugger disposable components, including forced-air blankets and the 241* blood/fluid warming set. The system is intended for use in all clinical settings including the operating room.

This manual includes operating instructions and unit specifications for the Model 505 and Model 500/OR forced-air temperature management units. For information about using Bair Hugger blankets or the 241 blood/fluid warming set with Bair Hugger units, refer to the "Instructions for Use" included with each of these disposable components.

Indications for Use

The Bair Hugger brand Total Temperature Management System is intended to prevent and treat hypothermia and to provide warmth to cold or shivering patients. In addition, the system should be used whenever conditions exist that could cause patients to become cold.

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 units with any forced-air blanket or cover other than Bair Hugger blankets. Thermal injury may result.
- Do not warm patients with the Bair Hugger unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin surface warming therapy.
- Do not continue therapy if the Over Heat warning light illuminates and the audible alarm sounds. Thermal injury may result. Turn the temperature management 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 temperature management unit is securely mounted or injury 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.
- 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 temperature management unit; refer to authorized technical personnel. There are electrically live parts within the 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 temperature management unit to a different power source.

Read Before Servicing Equipment

The repair, calibration, and servicing of the temperature management 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 Arizant Healthcare 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 temperature management unit and before returning the 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

Arizant Healthcare 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.

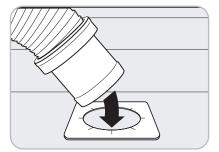


Figure C.

2) Insert the hose of the temperature management unit in the hose port on the blanket. Use a twisting motion to ensure a snug fit (see Figure C).

- 3) Connect the 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 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 unit as required.

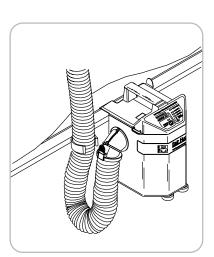


Figure D. Model 505 temperature management unit

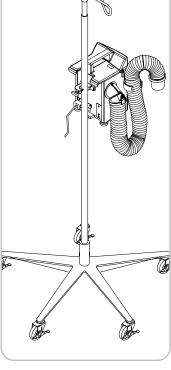


Figure E. Model 505 unit attached to an IV pole

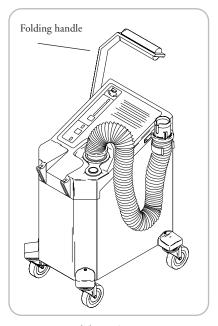


Figure F. Model 500/OR temperature management unit

Temperature Management Units

The temperature management 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 and 505 are designed for safe use in all areas, including the operating room.

The folding handle on the Model 500/OR unit 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 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 unit to be easily transported between clinical areas.

The Model 505 temperature management unit can be attached to an IV pole or to the railing on a bed.

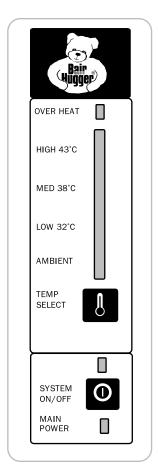


Figure G. Control panel of the Model 500/OR temperature management unit

Control Panel Features of the Model 500/OR Temperature Management 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 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 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 unit either ON or OFF. The indicator directly above the switch illuminates when the unit is ON.

MAIN POWER INDICATOR

The main power indicator illuminates when main power is applied to the 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.

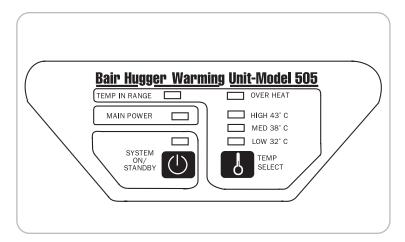


Figure H. Control panel of the Model 505 unit

Control Panel Features of the Model 505 Temperature Management 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 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 unit either ON or OFF. The indicator directly above the switch illuminates when the 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 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 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

remperature setting is at HIGH, push the button again to return to delivery of ambient air.

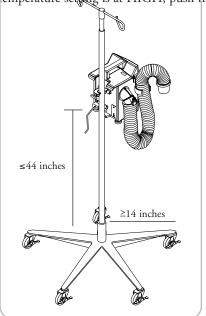


Figure I. Model 505 unit attached to an IV pole

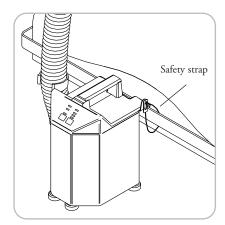


Figure J. Model 505 unit attached to a bedrail

Mounting the Model 505 Temperature Management Unit

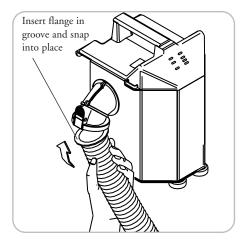
USING AN IV POLE

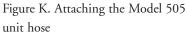
The Model 505 unit clamps easily to an IV pole (see Figure I). Simply turn the handle clockwise to tighten the clamp onto an IV pole, counterclockwise to release.

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

USING A BEDRAIL

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





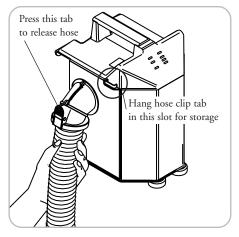


Figure L. Storing the Model 505 unit hose

Attaching and Storing the Model 505 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 and "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.

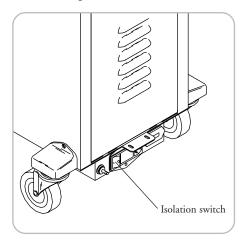


Figure M. Isolation Switch on the Model 500/OR unit

Isolation Switch

The isolation switch allows you to disconnect the temperature management unit from the power source without removing the power cord from the wall receptacle. The isolation switch is located on the back of the Model 500/OR unit. The isolation switch must be in the ON position before the 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.

Optional Features

This section discusses optional features for Bair Hugger temperature management units. For more details about these features, please call Arizant Healthcare Inc. or your local distributor.

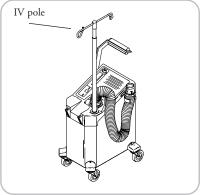


Figure N. Temperature management unit with IV pole option

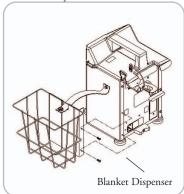


Figure O. Temperature management unit with blanket dispenser

IV POLE

Model 500/OR unit has a port that accommodates an Arizant Healthcare IV pole.

BLANKET DISPENSER

The blanket dispenser is available for use on the Series 500 units. This dispenser attaches to the unit and can store several Bair Hossger Mankets. See the package instructions for details.

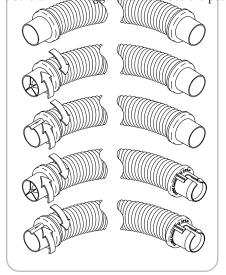


Figure P. Hose assemblies

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)

HOSE ASSEMBLIES

Temperature management hose assemblies are available in five options. The keyway on the extended length hose matches a keyway on 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 temperature management unit from the power source before cleaning.
- 2) Use a damp soft cloth and a mild detergent to clean the 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.

Technical Service and Order Placement

USA, WORLDWIDE

TEL: 1-952-947-1200 FAX: 1-952-947-1400

1-800-733-7775

WITHIN EUROPE

TEL: +49-4154-9934-0 FAX: +49-4154-9934-20

0800-100-1236 (Toll-free in Germany) 0800-100-1324 (Toll-free in Germany)

In-Warranty Repair and Exchange

Replacement parts to correct a problem are delivered at no charge. To return a device to Arizant Healthcare 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.

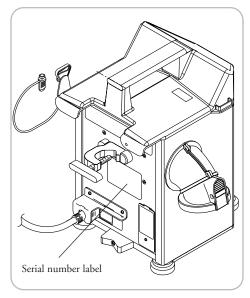


Figure A. Serial number label on Model 505

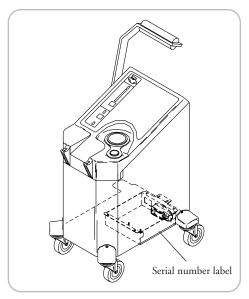


Figure B. Serial number label on Model 500/OR

Specifications

HEAT GENERATED

~35 secs

1800 BTUs (average)

SYSTEM TIME TO 100°F (37.7°C)

500/OR	505
Physical Characteristics	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	DIMENSIONS 13 in. high x 10 in. deep x 11 in. wide 33 cm high x 25 cm deep x 28 cm wide
WEIGHT 43 lb; 19.5 kg	WEIGHT 13.6 lb; 6.2 kg
MOUNTING Supplied with swivel casters; floor use only	MOUNTING IV pole clamp, bedrail hook with safety strap; can be placed on hard surface
RELATIVE NOISE LEVEL 52 decibels	RELATIVE NOISE LEVEL 53 decibels
HOSE Detachable, flexible, washable; compatible with Bair Hugger 241 fluid warming system	HOSE Detachable, flexible, washable; compatible with Bair Hugger 241 fluid warming system
filtration system 0.2μM level	FILTRATION SYSTEM 0.2μM level
RECOMMENDED FILTER CHANGE Every 6 months or 500 hours of use	RECOMMENDED FILTER CHANGE Every 6 months or 500 hours of use
Temperature Characteristics	Temperature Characteristics
TEMPERATURE CONTROL Electronically controlled using a thermocouple sensor	TEMPERATURE CONTROL Electronically controlled using a thermocouple sensor

HEAT GENERATED

~17 secs

1800 BTUs (average)

SYSTEM TIME TO 100°F (37.7°C)

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 a Bair Hugger warming blanket, or an Arizant Healthcare 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

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CLASSIFICATION

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Electrical Characteristics

BLOWER MOTOR

Operating speed: 2650 rpm Airflow: 28-30 cfm

POWER CONSUMPTION Peak: 1000W Average: 500W

Leakage current $<100\mu A$

HEATING ELEMENT 850W Resistive

POWER CORD

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

DEVICE RATINGS

110-120 VAC, 60 Hz, 9.5 Amperes, or 220-240 VAC, 50 Hz, 4.5 Amperes, or 100 VAC, 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 (100 VAC Units)

DIAGNOSTICS

Over-heat test can be performed by the biomedical group.

Electrical Characteristics

BLOWER MOTOR

Operating speed: 3150 rpm

Airflow: 28-30 cfm

POWER CONSUMPTION

Peak: 1000W Average: 450W

LEAKAGE CURRENT

 $<100\mu A$

HEATING ELEMENT 850W Resistive

POWER CORD

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

DEVICE RATINGS

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

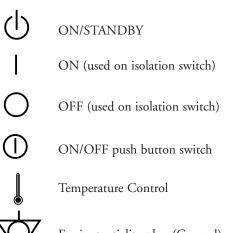
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DIAGNOSTICS

Over-heat test can be performed by the biomedical group.

Definition of Symbols





Equipotentiality plug (Ground)



Fuse



Attention (see appropriate documents)



Non Explosion-Proof



Dangerous Voltage



Type BF Equipment (patient applied)



Voltage, Alternating Current (AC)



(€ 0470

Authorized Representative in the European Community (as defined in Article 14 of the Medical Device Directive: 93/42/EEC): Actamed Limited, Calder Island Way, Wakefield, WF2 7AW, United Kingdom • TEL + 44 1924 200550 • FAX + 44 1924 200518

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Bair Hugger temperature management products may be covered by one or more of the following patents: US 6,355,915; 6,309,409; 6,309,408; 6,290,716; 6,287,327; 6,254,337; 6,241,755; 6,228,107; 6,210,428; 6,203,567; 6,176,870; 6,168,612; 6,146,412; 6,129,936; 6,126,681; 6,126,393; 6,036,722; 5,997,572; 5,968;084; 5,964,792; 5,928,274; 5,824,025; 5,800,489; 5,773,275; 5,733,318; 5,697,963; 5,674,269; 5,658,325; 5,620,482; 5,545,194; 5,405,371; 5,350,417; 5,336,250; 5,324,320; 5,300,102; 5,300,101; 5,184,612; 5,044,364; 4,572,188. Japan 2,561,326. Canada 1,325,484. EPO 0,311,336. Australia 756,900. Other patents pending.

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