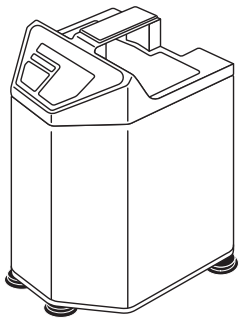
Bair Hugger*

Temperature Management Unit
Model 505



Operator's Manual

Betriebshandbuch für Bair Hugger* Temperaturmanagement-Geräte Modell 505

Manuel de l'utilisateur pour les appareils de gestion de la température Bair Hugger* Modèle 505

Manuale d'uso delle unità di gestione della temperatura Bair Hugger* Modello 505

Manual del usuario para las unidades de control de temperatura Bair Hugger*, Modelo 505

Manual do utilizador das unidades de gestão de temperatura Bair Hugger* Modelo 505

Bair Hugger* Temperatuurregelunit Model 505 Gebruikshandleiding

Brugsanvisning til Bair Hugger* temperaturreguleringsenheder, Model 505

Bruksanvisning till Bair Hugger* Modell 505 temperaturstyrenhet

Brukerhåndbok for Bair Hugger*-temperatur-behandlingsenhet, Modell 505

Bair Hugger* -lämpötilansäätölaitteen Malli 505 käyttäjän opas

Εγχειρίδιο Χρήσης Bair Hugger* Μονάδα διαχείρισης θερμοκρασίας, Μοντέλο 505

取扱説明書 ベアーハガーモデル505体温管理装置

Instrukcja Obsługi Dmuchawy Bair Hugger* Model 505 - urządzenia do aktywnego przeciwdziałania hipotermii

Bair Hugger* 505 sz. Modell hőmérséklet-szabályozó egység használati utasítása

Návod k obsluze jednotky regulace teploty Bair Hugger* typ 505

Operatoriaus Vadovas „Bair Hugger"* Modelis 505 Temperatūros reguliavimo prietaisas

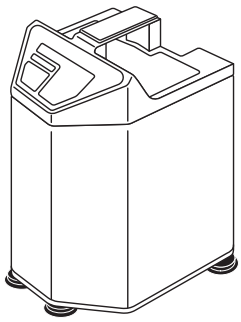
Руководство по эксплуатации Bair Hugger* Модель 505 Устройство управления температурой

操作员手册 505型
Bair Hugger* 温度管理仪

Total Temperature Management System

Bair Hugger*

Temperature Management Unit
Model 505



Operator's Manual

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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 disposable components, including Bair Hugger forced-air blankets, Bair Paws* patient warming gowns, and the 241* blood/fluid warming set. You can use the Model 505 temperature management unit in all clinical settings including the operating room to provide patient temperature management.

This manual includes operating instructions and unit specifications for the Model 505 forced-air temperature management unit. For information about using Bair Hugger blankets, Bair Paws gowns, 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

The Bair Hugger Temperature Management system is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management system can be used with adult and pediatric patients.

Contraindications

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

Warnings

1. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.
2. The Bair Hugger temperature management unit has been designed to operate safely ONLY with Arizant Healthcare* disposable components. Use with other products may cause thermal injury. (To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the unit being used in conjunction with non-Arizant Healthcare products.)
3.  Do not warm patients with the temperature management unit hose alone. Thermal injury may result. Always connect the hose to a Bair Hugger blanket or Bair Paws gown before providing therapy.
4. Do not place the non-perforated side of the blanket on the patient. Thermal injury may result. Always place the perforated side (that is, with small holes) towards the patient.
5. Do not continue temperature management therapy if the over-temp indicator light illuminates and the alarm sounds. Thermal injury may result. Unplug the unit, and contact a qualified service technician.
6. Do not continue 241 blood/fluid warming therapy if the over-heat indicator light illuminates and the alarm sounds. Immediately stop fluid flow, and discard the blood/fluid warming set. Unplug the temperature management unit, and contact a qualified service technician.
7. Do not use a forced-air warming device over transdermal medication. Increased drug delivery and patient injury or death may occur.
8. Do not allow the patient to lie on the warming unit hose or allow the hose to directly contact the patient's skin during patient warming; thermal injury may result. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
9. Resuable blankets made from woven fabric, or blankets without discrete, visible holes, can cause the safety system of this unit to fail, which may result in serious thermal injury. This warming unit has been designed to operate safety ONLY with Bair Hugger blankets or Bair Paws gowns.

Cautions

1. Except for specific blanket models, Bair Hugger blankets are not sterile and are all intended for single patient use ONLY. Placing a sheet between the Bair Hugger blanket and the patient does not prevent contamination of this product.
2. Monitor the temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling every 10-20 minutes or according to institutional protocol. Monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.
3. Do not leave pediatric patients unattended during therapy.
4. Do not initiate temperature management therapy unless the temperature management unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
5. To prevent tipping, clamp the Model 505 temperature management unit to an IV pole at a height that provides stability. We recommend clamping the unit no higher than 44 in. (112 cm) from the floor on an IV pole with a minimum 28 in. (71 cm) diameter wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and the patient injury.

6. Electrical shock hazard. Do not disassemble the temperature management unit unless you are a qualified service technician. There are electrically live parts with in the unit when it is connected to a power source, even when the unit is in Standby mode.

Notices

1. The Bair Hugger temperature management unit meets medical electronic interference requirements. If radio frequency interference with other equipment should occur, connect the unit to a different power source.
2. Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.
3. To reliably ground this Bair Hugger warming unit, only connect to receptacles marked "Hospital Only" or "Hospital Grade".

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.

Set up and Operation

The Bair Hugger brand Total Temperature Management system is easy to set up and to use. Follow the instructions provided with each Bair Hugger blanket or Bair Paws gown for specific information.

1. Place the blanket or gown on the patient with the perforated side (the side with small holes) against the patient's skin.
2. Insert the hose of the temperature management unit in the hose port on the blanket or gown. Use a twisting motion to ensure a snug fit (see Figure A).
3. Connect the unit to a properly grounded power source.
4. Press the System ON/OFF button to turn the unit ON and select the appropriate temperature setting.
5. You may place a cotton blanket over the blanket or gown for maximum effectiveness.

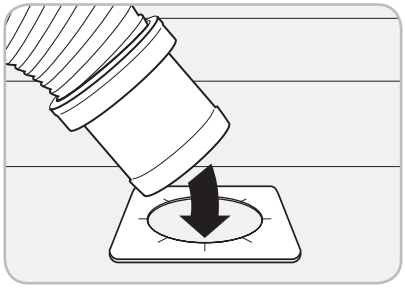

Figure A.

6. Monitor the temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling every 10-20 minutes or according to institutional protocol. Monitor the patient's vital signs regularly.

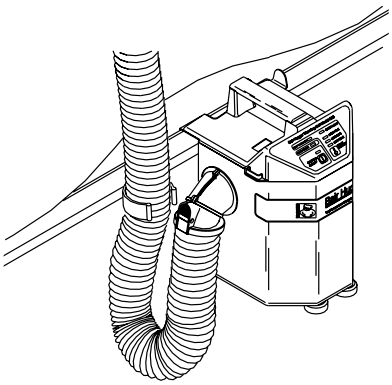

Figure B. Model 505 unit attached to a bedrail

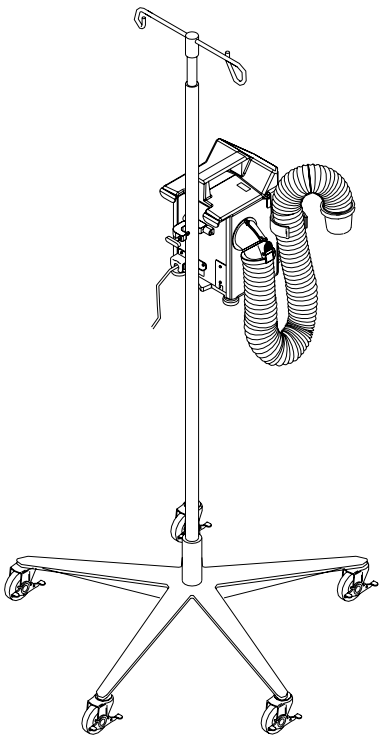

Figure C. Model 505 unit attached to an IV pole

Temperature Management Unit

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 or gown. It is designed for safe use in all areas, including the operating room.

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

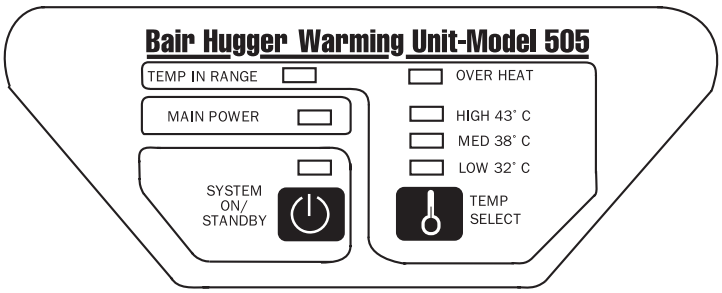

Figure D. Control panel of the Model 505 unit

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

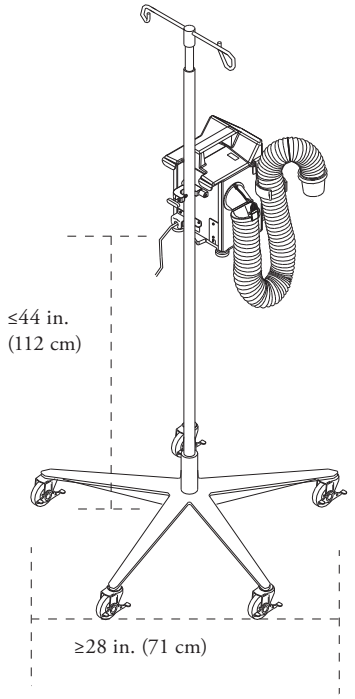

Figure E. Model 505 unit attached to an IV pole

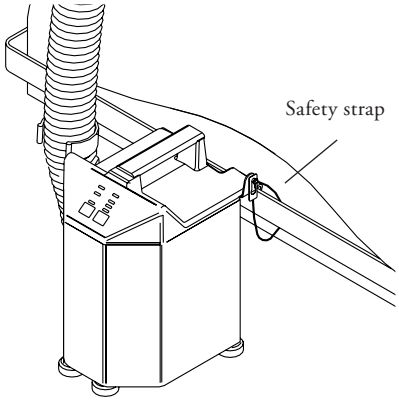

Figure F. Model 505 unit attached to a bedrail

Mounting the Model 505 Temperature Management Unit

USING AN IV POLE

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

Warning: To prevent tipping, clamp the Model 505 temperature management unit to an IV pole at a height that provides stability. We recommend clamping the unit no higher than 44 in. (112 cm) from the floor on an IV pole with a minimum 28 in. (71 cm) diameter wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and the 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 F).

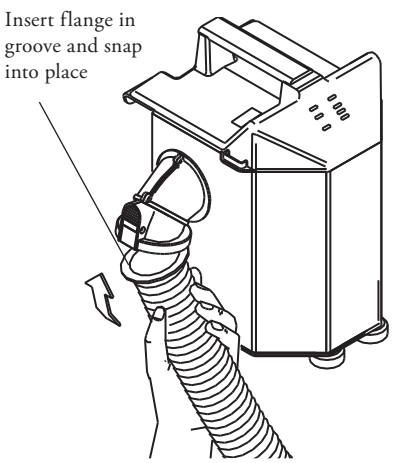

Figure G. Attaching the Model 505 unit hose

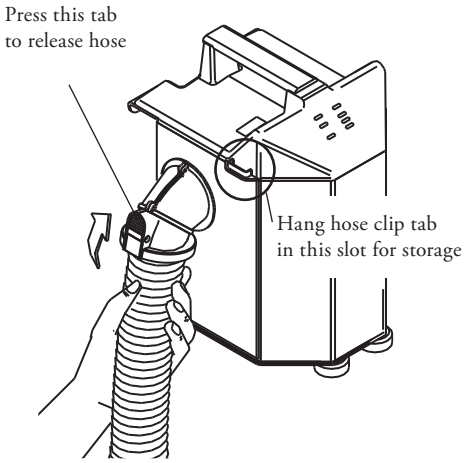

Figure H. Storing the Model 505 unit hose

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.

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 1-800-733-7775	Fax:	1-952-947-1400

WITHIN EUROPE

Tel:	+49-4154-9934-0 0800-100-1236 (Toll-free in Germany)	Fax:	+49-4154-9934-20 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.

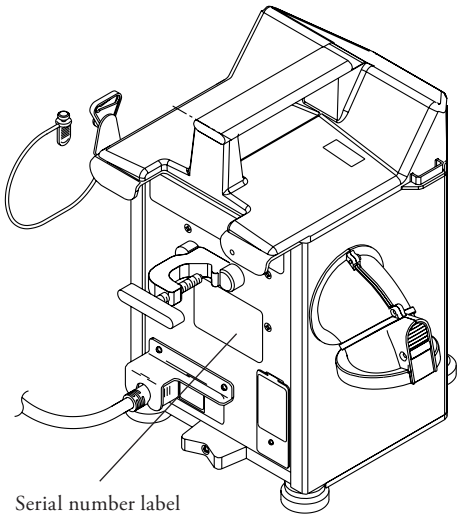

Figure J. Serial number label on Model 505

Specifications

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	13.6 lb; 6.2 kg
MOUNTING	IV pole clamp, bedrail hook with safety strap; can be placed on hard surface
RELATIVE NOISE LEVEL	53 decibels
HOSE	Detachable, flexible, washable; compatible with the 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: HIGH: 43°C ± 3°C 109.4°F ± 5.4°F MED: 38°C ± 3°C 100.4°F ± 5.4°F LOW: 32°C ± 3°C 89.6°F ± 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	IEC 60601-1; EN 60601-1-2; UL 60601-1; CAN/CSA-C22.2, No. 601.1, EN 55011; ASTM F2196-02
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 the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1, ASTM F2196-02, and Canadian/CSA C22.2, No. 601.1.

Electrical Characteristics

BLOWER MOTOR	Operating speed: 3150 rpm Airflow: 28-30 cfm
POWER CONSUMPTION	Peak: 1000W Average: 450W
LEAKAGE CURRENT	<100µA
HEATING ELEMENT	850W Resistive
POWER CORD	15-foot, SJT, 3 cond., 10A 4.6 meter, HAR, 3 cond., 10A
DEVICE RATINGS	110-120 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 (110 - 120 VAC Units) 6.3A, 100mA (220 - 240 VAC Units) 15A, 160mA (100 VAC Units)
DIAGNOSTICS	Over-heat test can be performed by the biomedical group.

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


Attention (see appropriate documents)


Dangerous Voltage


Type BF Equipment (patient applied)

Voltage, Alternating Current (AC)


Special Refuse, discard separately


Protective earth ground


No free hosing