Operator’s Manual

Betriebsanleitung 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* Temperaturregelunit 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温度管理装置
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
操作員手冊 505型
Bair Hugger* 温度管理仪

Total Temperature Management System
# Operator’s Manual

<table>
<thead>
<tr>
<th>Language</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>1</td>
</tr>
<tr>
<td>Deutsch</td>
<td>15</td>
</tr>
<tr>
<td>Français</td>
<td>29</td>
</tr>
<tr>
<td>Italiano</td>
<td>43</td>
</tr>
<tr>
<td>Español</td>
<td>57</td>
</tr>
<tr>
<td>Português</td>
<td>71</td>
</tr>
<tr>
<td>Nederlands</td>
<td>85</td>
</tr>
<tr>
<td>Dansk</td>
<td>99</td>
</tr>
<tr>
<td>Svenska</td>
<td>113</td>
</tr>
<tr>
<td>Norsk</td>
<td>127</td>
</tr>
<tr>
<td>Sumoi</td>
<td>141</td>
</tr>
<tr>
<td>Ελληνικά</td>
<td>155</td>
</tr>
<tr>
<td>日本語</td>
<td>169</td>
</tr>
<tr>
<td>Polski</td>
<td>183</td>
</tr>
<tr>
<td>Magyar</td>
<td>197</td>
</tr>
<tr>
<td>Česky</td>
<td>211</td>
</tr>
<tr>
<td>Lietuvių Kalba</td>
<td>225</td>
</tr>
<tr>
<td>Русскийй</td>
<td>237</td>
</tr>
<tr>
<td>英语</td>
<td>249</td>
</tr>
</tbody>
</table>
# Table of Contents

**Introduction** .................................................. 3  
Description of the Total Temperature Management* System .......... 3  
Indications ......................................................... 3  
Contraindications ................................................ 3  
Warnings .......................................................... 4  
Cautions .......................................................... 4  
Notices ............................................................ 5  
Read Before Servicing Equipment .................................... 5  

**Set up and Operation** ............................................. 6  
Temperature Management Unit ..................................... 7  
Control Panel Features of the Model 505 Temperature Management Unit .... 7  
Mounting the Model 505 Temperature Management Unit ............. 8  
Attaching and Storing the Model 505 Unit Hose ....................... 9  

**General Maintenance** ........................................... 10  

**Technical Service and Order Placement** .......................... 10  
In-Warranty Repair and Exchange ................................ 10  
When You Call for Technical Support ................................ 10  

**Specifications** .................................................. 11  

**Definition of Symbols** .......................................... 13
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. Resusable 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 within 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.

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.
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.

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.
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).
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 |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>WEIGHT</strong></td>
<td>13.6 lb; 6.2 kg</td>
</tr>
<tr>
<td><strong>MOUNTING</strong></td>
<td>IV pole clamp, bedrail hook with safety strap; can be placed on hard surface</td>
</tr>
<tr>
<td><strong>RELATIVE NOISE LEVEL</strong></td>
<td>53 decibels</td>
</tr>
<tr>
<td><strong>HOSE</strong></td>
<td>Detachable, flexible, washable; compatible with the 241 fluid warming system</td>
</tr>
<tr>
<td><strong>FILTRATION SYSTEM</strong></td>
<td>0.2µM level</td>
</tr>
<tr>
<td><strong>RECOMMENDED FILTER CHANGE</strong></td>
<td>Every 6 months or 500 hours of use.</td>
</tr>
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### Temperature Characteristics

<table>
<thead>
<tr>
<th><strong>TEMPERATURE CONTROL</strong></th>
<th>Electronically controlled using a thermocouple sensor</th>
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<tbody>
<tr>
<td><strong>HEAT GENERATED</strong></td>
<td>1800 BTUs (average)</td>
</tr>
<tr>
<td><strong>SYSTEM TIME TO 100°F (37.7°C)</strong></td>
<td>~17 secs</td>
</tr>
<tr>
<td><strong>OPERATING TEMPERATURES</strong></td>
<td>Air temperatures reaching the patient are approximately 2°C lower than the listed temperatures.</td>
</tr>
<tr>
<td><strong>HIGH:</strong></td>
<td>43°C ± 3°C 109.4°F ± 5.4°F</td>
</tr>
<tr>
<td><strong>MED:</strong></td>
<td>38°C ± 3°C 100.4°F ± 5.4°F</td>
</tr>
<tr>
<td><strong>LOW:</strong></td>
<td>32°C ± 3°C 89.6°F ± 5.4°F</td>
</tr>
</tbody>
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Safety System

<table>
<thead>
<tr>
<th>THERMOSTAT</th>
<th>Independent bulb and capillary</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVERCURRENT PROTECTION</td>
<td>Dual fused input lines</td>
</tr>
<tr>
<td>ALARM SYSTEM</td>
<td>Over-heat: flashing red light with audible alarm; heater shuts down</td>
</tr>
<tr>
<td>CERTIFICATIONS</td>
<td>IEC 60601-1; EN 60601-1-2; UL 60601-1; CAN/CSA-C22.2, No. 601.1, EN 55011; ASTM F2196-02</td>
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<tr>
<td>CLASSIFICATION</td>
<td>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.</td>
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Electrical Characteristics

<table>
<thead>
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<th>BLOWER MOTOR</th>
<th>Operating speed: 3150 rpm</th>
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<tbody>
<tr>
<td></td>
<td>Airflow: 28-30 cfm</td>
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<tr>
<td>POWER CONSUMPTION</td>
<td>Peak: 1000W</td>
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<tr>
<td></td>
<td>Average: 450W</td>
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<tr>
<td>LEAKAGE CURRENT</td>
<td>&lt;100µA</td>
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<tr>
<td>HEATING ELEMENT</td>
<td>850W Resistive</td>
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<tr>
<td>POWER CORD</td>
<td>15-foot, SJT, 3 cond., 10A</td>
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<tr>
<td></td>
<td>4.6 meter, HAR, 3 cond., 10A</td>
</tr>
<tr>
<td>DEVICE RATINGS</td>
<td>110-120 VAC, 60 Hz, 9.5 Amperes, or</td>
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<td></td>
<td>220-240 VAC, 50 Hz, 4.5 Amperes, or</td>
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<tr>
<td></td>
<td>100 VAC, 50/60 Hz, 10 Amperes</td>
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<tr>
<td>FUSES</td>
<td>10A, 200mA (110 - 120 VAC Units)</td>
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<td></td>
<td>6.3A, 100mA (220 - 240 VAC Units)</td>
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<tr>
<td></td>
<td>15A, 160mA (100 VAC Units)</td>
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<td>DIAGNOSTICS</td>
<td>Over-heat test can be performed by the biomedical group.</td>
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</tbody>
</table>


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