# Table of Contents

3 **Introduction**

3 Description of the Total Temperature Management* System

3 Indications for Use

3 Contraindications

3 Warnings

3 Precautions

3 Important Information

4 Read Before Servicing Equipment

4 **Setup and Operation**

5 Temperature Management Units

6 Control Panel Features of the Model 500/OR Temperature Management Unit

7 Control Panel Features of the Model 505 Temperature Management Unit

8 Mounting the Model 505 Temperature Management Unit

9 Attaching and Storing the Model 505 Hose

9 Isolation Switch

10 Optional Features

11 **General Maintenance**

11 Cabinet Cleaning

11 **Technical Service and Order Placement**

12 **Specifications**

14 **Definition of Symbols**
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.

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.

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.
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.
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 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).
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.

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.

**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 Hugger blankets. See the package instructions for details.

**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.
Specifications

<table>
<thead>
<tr>
<th>500/OR</th>
<th>505</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Characteristics</strong></td>
<td><strong>Physical Characteristics</strong></td>
</tr>
<tr>
<td><strong>DIMENSIONS</strong></td>
<td><strong>DIMENSIONS</strong></td>
</tr>
<tr>
<td>24 in. high x 16 in. deep x 14 in. wide</td>
<td>13 in. high x 10 in. deep x 11 in. wide</td>
</tr>
<tr>
<td>61 cm high x 41 cm deep x 36 cm wide</td>
<td>33 cm high x 25 cm deep x 28 cm wide</td>
</tr>
<tr>
<td><strong>WEIGHT</strong></td>
<td><strong>WEIGHT</strong></td>
</tr>
<tr>
<td>43 lb; 19.5 kg</td>
<td>13.6 lb; 6.2 kg</td>
</tr>
<tr>
<td><strong>MOUNTING</strong></td>
<td><strong>MOUNTING</strong></td>
</tr>
<tr>
<td>Supplied with swivel casters; floor use only</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><strong>RELATIVE NOISE LEVEL</strong></td>
</tr>
<tr>
<td>52 decibels</td>
<td>53 decibels</td>
</tr>
<tr>
<td><strong>HOSE</strong></td>
<td><strong>HOSE</strong></td>
</tr>
<tr>
<td>Detachable, flexible, washable; compatible with Bair Hugger 241 fluid warming system</td>
<td>Detachable, flexible, washable; compatible with Bair Hugger 241 fluid warming system</td>
</tr>
<tr>
<td><strong>FILTRATION SYSTEM</strong></td>
<td><strong>FILTRATION SYSTEM</strong></td>
</tr>
<tr>
<td>0.2µM level</td>
<td>0.2µM level</td>
</tr>
<tr>
<td><strong>RECOMMENDED FILTER CHANGE</strong></td>
<td><strong>RECOMMENDED FILTER CHANGE</strong></td>
</tr>
<tr>
<td>Every 6 months or 500 hours of use</td>
<td>Every 6 months or 500 hours of use</td>
</tr>
<tr>
<td><strong>Temperature Characteristics</strong></td>
<td><strong>Temperature Characteristics</strong></td>
</tr>
<tr>
<td><strong>TEMPERATURE CONTROL</strong></td>
<td><strong>TEMPERATURE CONTROL</strong></td>
</tr>
<tr>
<td>Electronically controlled using a thermocouple sensor</td>
<td>Electronically controlled using a thermocouple sensor</td>
</tr>
<tr>
<td><strong>HEAT GENERATED</strong></td>
<td><strong>HEAT GENERATED</strong></td>
</tr>
<tr>
<td>1800 BTUs (average)</td>
<td>1800 BTUs (average)</td>
</tr>
<tr>
<td><strong>SYSTEM TIME TO 100°F (37.7°C)</strong></td>
<td><strong>SYSTEM TIME TO 100°F (37.7°C)</strong></td>
</tr>
<tr>
<td>~35 secs</td>
<td>~17 secs</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Temperature Level</th>
<th>Temperature (°C)</th>
<th>Temperature (°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>43° ± 3°C</td>
<td>109.4° ± 5.4°F</td>
</tr>
<tr>
<td>Medium</td>
<td>38° ± 3°C</td>
<td>100.4° ± 5.4°F</td>
</tr>
<tr>
<td>Low</td>
<td>32° ± 3°C</td>
<td>89.6° ± 5.4°F</td>
</tr>
</tbody>
</table>

Safety System

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>THERMOSTAT</td>
<td>Independent bulb and capillary</td>
</tr>
<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>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLOWER MOTOR</td>
<td>Operating speed: 2650 rpm, Airflow: 28-30 cfm</td>
</tr>
<tr>
<td>POWER CONSUMPTION</td>
<td>Peak: 1000W, Average: 500W</td>
</tr>
<tr>
<td>LEAKAGE CURRENT</td>
<td>&lt;100µA</td>
</tr>
<tr>
<td>HEATING ELEMENT</td>
<td>850W Resistive</td>
</tr>
<tr>
<td>POWER CORD</td>
<td>15-foot, SJT, 3 cond., 10A, 4.6 meter, HAR, 3 cond., 10A</td>
</tr>
<tr>
<td>DEVICE RATINGS</td>
<td>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</td>
</tr>
<tr>
<td>FUSES</td>
<td>10A, 200mA and 500mA (110 - 120 VAC Units), 6.3A, 100mA and 500mA (220 - 240 VAC Units), 10A, 160mA and 400mA (100 VAC Units)</td>
</tr>
<tr>
<td>DIAGNOSTICS</td>
<td>Over-heat test can be performed by the biomedical group.</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Temperature Level</th>
<th>Temperature (°C)</th>
<th>Temperature (°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>43° ± 3°C</td>
<td>109.4° ± 5.4°F</td>
</tr>
<tr>
<td>Medium</td>
<td>38° ± 3°C</td>
<td>100.4° ± 5.4°F</td>
</tr>
<tr>
<td>Low</td>
<td>32° ± 3°C</td>
<td>89.6° ± 5.4°F</td>
</tr>
</tbody>
</table>

Safety System

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>THERMOSTAT</td>
<td>Independent bulb and capillary</td>
</tr>
<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>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLOWER MOTOR</td>
<td>Operating speed: 3150 rpm, Airflow: 28-30 cfm</td>
</tr>
<tr>
<td>POWER CONSUMPTION</td>
<td>Peak: 1000W, Average: 450W</td>
</tr>
<tr>
<td>LEAKAGE CURRENT</td>
<td>&lt;100µA</td>
</tr>
<tr>
<td>HEATING ELEMENT</td>
<td>850W Resistive</td>
</tr>
<tr>
<td>POWER CORD</td>
<td>15-foot, SJT, 3 cond., 10A, 4.6 meter, HAR, 3 cond.,10A</td>
</tr>
<tr>
<td>DEVICE RATINGS</td>
<td>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</td>
</tr>
<tr>
<td>FUSES</td>
<td>10A, 200mA and 500mA (110 - 120 VAC Units), 6.3A, 100mA and 500mA (220 - 240 VAC Units), 10A, 160mA and 400mA (100 VAC Units)</td>
</tr>
<tr>
<td>DIAGNOSTICS</td>
<td>Over-heat test can be performed by the biomedical group.</td>
</tr>
</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)
- Non Explosion-Proof
- Dangerous Voltage
- Type BF Equipment (patient applied)
- Voltage, Alternating Current (AC)
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

©2003-2004 Arizant Healthcare Inc. All rights reserved. 10393 West 70th Street, Eden Prairie, MN 55344 USA TEL 800-733-7775 • 952-947-1200 • FAX 800-775-0002 • 952-947-1400 www.arizanthealthcare.com

*Bair Hugger, 241, Total Temperature Management and the Bair Hugger and Arizant logos are trademarks of Arizant Healthcare Inc., registered or pending in the U.S. Patent & Trademark Office and in other countries.

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.

200977A  01/04