

Bair Hugger* Model 750 Temperature Management Unit

750 Operator's Manual

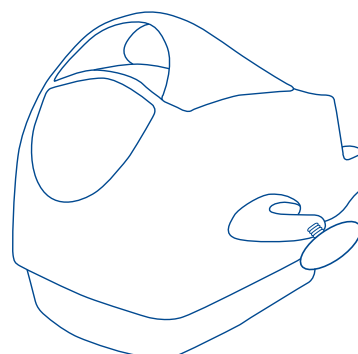


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Introduction

Description of the Total Temperature Management System

The Bair Hugger brand Total Temperature Management system consists of a Model 750 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 750 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 750 temperature management unit. For information about using Bair Hugger blankets, Bair Paws gowns, or the 241 blood/fluid warming set with the Model 750 temperature management unit, refer to the “Instructions for Use” included with each of these disposable components.

Indications for Use

The Bair Hugger Model 750 Total Temperature Management system is intended to prevent and treat hypothermia and to provide warmth to cold or shivering patients. In addition, this system should be used whenever conditions exist that could cause patients to become cold.

Contraindication

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 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 skin-surface warming therapy.
- Do not use a forced-air warming device over transdermal medication. Increased drug delivery and patient injury or death may occur.
- Do not provide warming therapy when an intra-aortic balloon pump is in use; thermal injury may occur if heat is applied to ischemic limbs.
- The Model 750 temperature management unit has been designed to operate safely 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.

- Do not continue temperature management therapy if the red *Over-temp* indicator light flashes and the alarm sounds. Thermal injury may result. Unplug the unit, and contact a qualified service technician.
- Do not continue 241 blood/fluid warming therapy if the red *Over-temp* indicator light flashes 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.
- Do not allow the temperature management unit hose to contact the patient's skin during warming therapy. Thermal injury may result.
- Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.
- EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics.

Precautions

- Monitor the patient's temperature and vital signs regularly according to institutional protocol. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician immediately of vital sign instability.
- Do not initiate temperature management therapy unless the Model 750 unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
- The Model 750 temperature management unit meets the international electronic interference requirements of EN 60601-1-2 and EN 55011. However, if radio frequency interference with monitoring equipment should occur, connect the unit to a different power source.
- 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.

Proper Use and Maintenance

Arizant Healthcare Inc. assumes no responsibility for the reliability, performance, or safety of the temperature management unit if the following events occur:

- Modifications or repairs are performed by unqualified personnel.
- The unit is used in a manner other than that described in the Operator's or Service Manual.
- The unit is installed in an environment that does not meet the appropriate electrical and grounding requirements.

Read Before Servicing Equipment

All repair, calibration, and servicing of the temperature management unit require the skill of a qualified, medical equipment service technician who is familiar with good practice for medical device repair. If service does not require the manufacturer's attention, the Model 750 Service Manual provides the technical information needed to service the unit, or Arizant Healthcare Inc. will provide that information on request. Perform all repairs and maintenance in accordance with the instructions in the Service Manual.

Overview and Operation

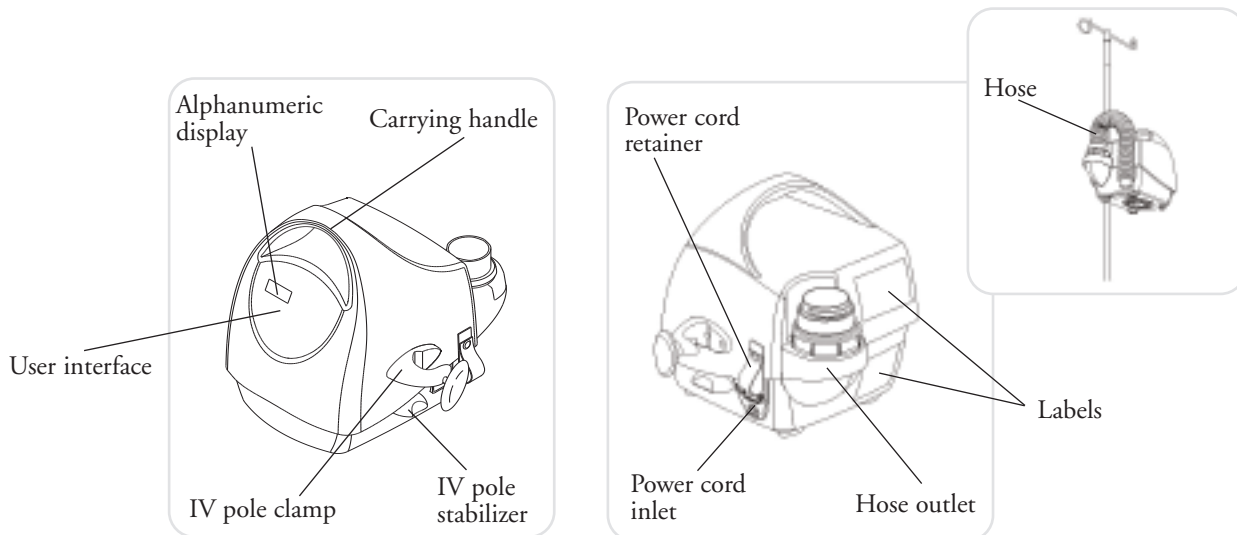


Figure A. Model 750 temperature management unit – front view

Figure B. Model 750 temperature management unit – rear view

Unit Power-On-Reset

The Model 750 temperature management unit proceeds through the following power-on-reset sequence after you connect the unit to a grounded power source:

- Performs all self-test functions.
- Illuminates indicator lights and all pixels in the alphanumeric display momentarily.
- Displays the text “BH 750” and the software revision level in the alphanumeric display.
- Sounds the alarm (three low-level clicks).
- Enters the *Standby* mode.

If the temperature management unit loses power for less than 1 second, the unit's software will return the unit to the operating mode you selected prior to the power loss. However, if the temperature management unit loses power for longer than 1 second, the unit's software will reset when you restore power. The unit will then enter the *Standby* mode.

Overview of Control Panel

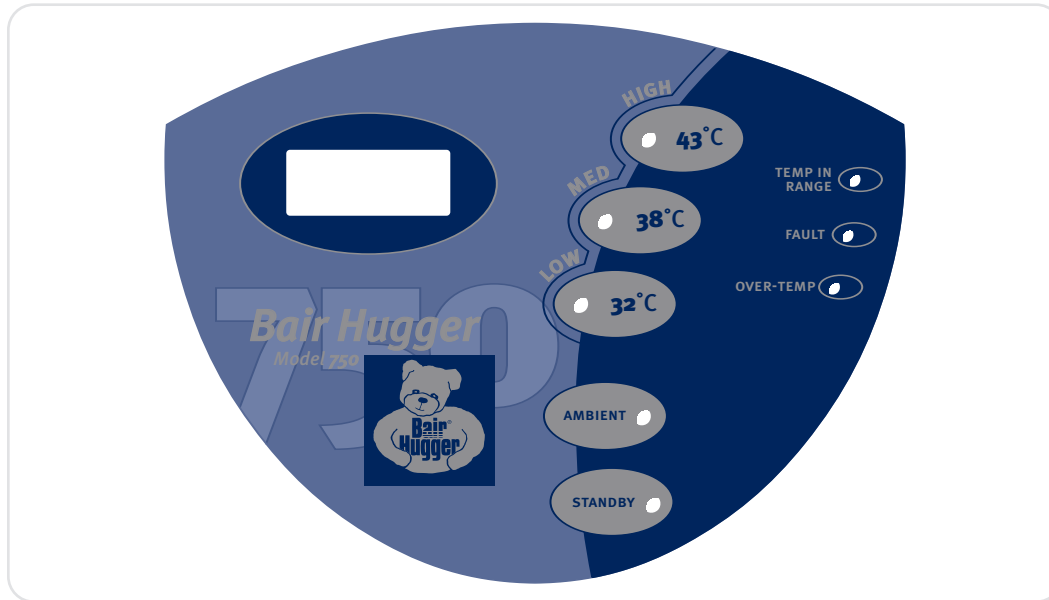


Figure C. Model 750 temperature management unit control panel

ALPHANUMERIC DISPLAY

The alphanumeric display shows the temperature at the blanket or gown end of the temperature management unit hose in degrees Celsius.

TEMPERATURE MODES

- Press the **Low** (32°C), **Med** (38°C), or **High** (43°C) button to select the desired temperature.
- Press the **Ambient** button to supply room temperature air.

When you select a temperature mode, the following events occur:

- Corresponding indicator light illuminates.
- Blower operates.
- Temperature at the blanket or gown end of the hose appears in the alphanumeric display.
- Heater activates except in *Ambient* mode.
- Temperature mode timer activates (or resets itself if changing from one temperature mode to another).

STANDBY

When the unit is in *Low*, *Medium*, *High*, or *Ambient* mode, press the **Standby** button to place the unit in *Standby* mode.

When you select the *Standby* mode, the following events occur:

- *Standby* indicator light illuminates.
- Blower and heater are turned OFF.
- Alphanumeric display deactivates.
- Alarm and fault detection functions remain active.
- Operating timer pauses.

TEMP IN RANGE INDICATOR LIGHT

The *Temp in Range* indicator light illuminates when the temperature at the blanket or gown end of the hose is $\pm 1.5^{\circ}\text{C}$ of the selected setting; this indicator light does not illuminate in the *Ambient* mode.

FAULT INDICATOR LIGHT

When a system fault occurs, the amber *Fault* indicator light flashes and an alarm sounds.

Please refer to *What to Do in Case of a Fault Condition* on page 9 for additional information.

OVER-TEMP INDICATOR LIGHT

If the unit senses an over-temperature condition, the red *Over-temp* indicator light flashes and an alarm sounds.

Please refer to *What to Do in Case of an Over-Temperature Condition* on page 9 for additional information.

Mounting the Temperature Management Unit to an IV Pole

CAUTION

To prevent tipping, clamp the Model 750 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 14 in. (35.6 cm) radius wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and patient injury.

METHOD

To mount the Model 750 temperature management unit to an IV pole, simply turn the clamp handle clockwise to tighten the clamp on the IV pole and counterclockwise to release it. See Figure D.

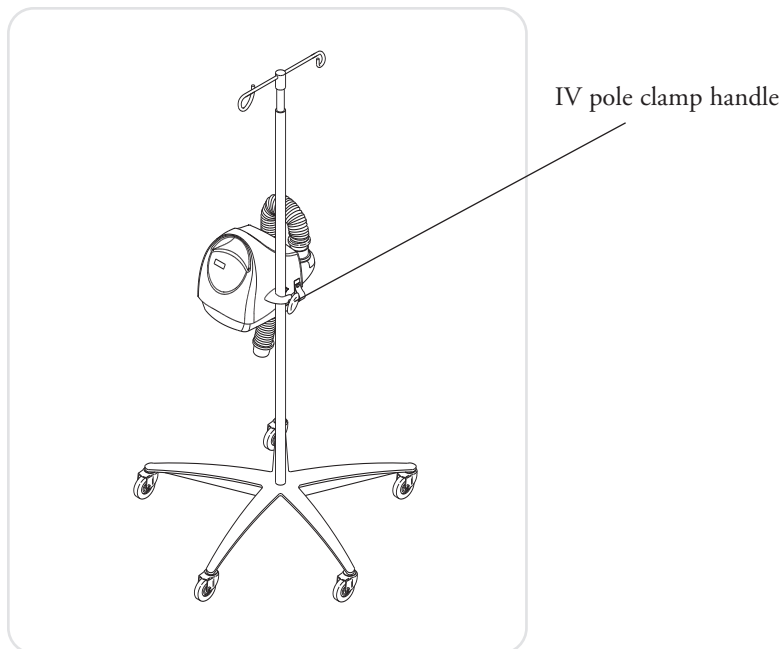


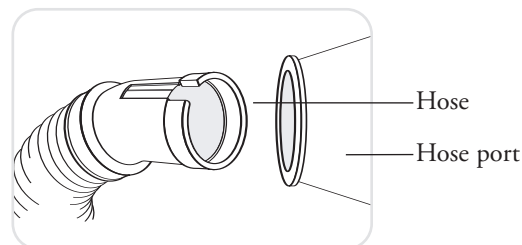
Figure D.

Instructions for Use

The instructions below describe how to operate the Model 750 temperature management unit. For information about using Bair Hugger blankets, Bair Paws gowns, or the 241 blood/fluid warming set with the Model 750 unit, refer to the Instructions for Use included with each of these disposable components.

1. If the Model 750 temperature management unit is not mounted on an IV pole or Bair Hugger rolling stand, place the unit on a flat, hard surface, such as a table, before beginning temperature management therapy. Do not place the unit on a soft or uneven surface, such as a bed, or the air intake may become blocked and cause the unit to overheat.

2. Insert the end of the temperature management unit hose into the hose port of a Bair Hugger blanket or Bair Paws gown. Use a twisting motion to ensure a snug fit.



3. Connect the temperature management unit to a properly grounded power source. The unit will be operating in *Standby* mode and the *Standby* indicator light will illuminate.
4. Press the appropriate button to select the desired temperature. When the unit reaches the selected temperature, the *Temp in Range* indicator light will illuminate; this indicator light does not illuminate in the *Ambient* mode.
5. Monitor the patient's temperature at least every 10 to 20 minutes, and adjust the temperature setting of the temperature management unit as required.
6. Press the *Standby* button when temperature management therapy is complete and discard disposable components.
7. Unplug the temperature management unit to disconnect it from the power source.

Viewing the Temperature Mode Timer

The temperature mode timer records the amount of time the temperature management unit has been operating in the selected temperature mode. The timer resets itself every time you select a different temperature mode.

To view the temperature mode timer, press the button for the current temperature mode, and hold it for 2 seconds. The alphanumeric display will show the temperature mode time, then go back to showing the temperature mode setting.

What to Do in Case of an Over-Temperature Condition

If an over-temperature condition occurs, the red *Over-temp* indicator light flashes and an alarm sounds. The unit automatically turns the heater, blower, and operating mode indicator lights OFF. The control panel will not respond to commands, but pressing any button will silence the alarm.

If an over-temperature condition occurs:

1. Discontinue all temperature management therapy. If you are using the 241 blood/fluid warming system, immediately stop fluid flow and discard the blood/fluid warming set.
2. Unplug the temperature management unit.
3. Contact a qualified service technician.

What to Do in Case of a Fault Condition

The Model 750 temperature management unit's software recognizes several non-hazardous conditions and reports those conditions as faults. When a system fault occurs, the software stores the fault code in memory, the amber *Fault* indicator light flashes, and an alarm sounds. The control panel will not respond to commands, but pressing any button will silence the alarm.

If a fault condition occurs:

1. Unplug the temperature management unit and wait for 5 minutes.
2. Reconnect the temperature management unit to a grounded power source. The unit will perform the normal power-on-reset sequence and then enter the *Standby* mode.
3. Reselect the temperature setting.
4. If the unit does not return to normal operation, contact a qualified service technician.

General Maintenance

Cleaning the Cabinet and Hose

WARNING

Do not immerse the cabinet or hose while cleaning. Moisture will damage the components, and thermal injury may result.

PRECAUTIONS

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

METHOD

1. Disconnect the temperature management unit from the power source before cleaning.
2. Wipe the cabinet and the outside of the hose with a damp, soft cloth and a mild detergent or antimicrobial spray.
3. Dry with a separate soft cloth.

Technical Support and Customer Service

USA, Worldwide

TEL:

800-733-7775

952-947-1200

FAX:

800-775-0002

952-947-1400

Within Europe

TEL:

+49-4154-9934-0

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

0800-877-077 (Toll-free in Switzerland)

FAX:

+49-4154-9934-20

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

0800-877-088 (Toll-free in Switzerland)

When You Call for Technical Support

We will need to know the serial number of your Bair Hugger temperature management unit when you call us. The serial number label is located on the back or side of the Bair Hugger temperature management unit.



In-Warranty Repair and Exchange

USA

Call Arizant Healthcare customer service if your Model 750 temperature management unit requires factory service. A customer service representative will give you a Return Authorization (RA) number. Please use this RA number on all correspondence concerning your temperature management unit. Your customer service representative will also send a shipping carton to you at no charge, if needed. Call your local supplier or sales representative to inquire about borrowing a temperature management unit while we service your unit. For more detailed instructions on returning units for service, please refer to the Model 750 service manual.

Worldwide

Contact your local distributor concerning in-warranty repair and exchange.

Specifications

Physical Characteristics

DIMENSIONS	12" high x 13.5" deep x 10" wide 30 cm high x 34 cm deep x 25 cm wide
WEIGHT	15.5 lb (7kg)
RELATIVE NOISE LEVEL	55 dBA
HOSE	Flexible, compatible with the Bair Hugger brand 241 blood/fluid warming system.
FILTRATION SYSTEM	0.2 μ m air filter
RECOMMENDED FILTER CHANGE	Every 500 hours of use.
MOUNTING	Can be clamped to an IV pole, placed on a hard surface, or mounted to the rolling stand accessory.

Temperature Characteristics

RECOMMENDED OPERATING ENVIRONMENT	15°C-25°C
TEMPERATURE CONTROL	Electronically controlled.
HEAT GENERATED	1644 BTU/hr (average), 482 W (average)
OPERATING TEMPERATURES	Average temperatures at the end of the hose: HIGH: 43° ± 1.5°C 109.4° ± 2.7°F MED: 38° ± 1.5°C 100.4° ± 2.7°F LOW: 32° ± 1.5°C 89.6° ± 2.7°F

Safety System

THERMOSTAT	Independent electronic circuit; thermal cutoff shuts the heater OFF at preset high temperature of 53°C ± 3°C at the end of the hose, back-up over-temperature detection at hose inlet.
ALARM SYSTEM	Over-temperature (53° ± 3°C): red <i>Over-temp</i> indicator light flashes, alarm sounds, heater and blower shut down, operating indicator lights turn OFF, control panel becomes unresponsive. Fault: amber <i>Fault</i> indicator light flashes, alarm sounds.
OVERCURRENT PROTECTION	Dual input fused lines.







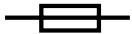






Specifications – Continued

Electrical Characteristics

HEATING ELEMENT	1400 W Resistive
LEAKAGE CURRENT	Meets UL 60601-1 and IEC 60601-1 requirements.
BLOWER MOTOR	Operating speed: approximately 4,000 rpm Airflow: up to 48 cfm or 23 L/s
POWER CONSUMPTION	Peak: 1550 W Average: 800 W
POWER CORD	15 ft., SJT, 3 cond., 13 A 15 ft., SJT, 3 cond., 15 A 4.6 m, HAR, 3 cond., 10 A
DEVICE RATINGS	110-120 VAC, 50/60 Hz, 11.7 A, or 220-240 VAC, 50/60 Hz, 7.2 A, or 100 VAC, 50/60 Hz, 15 A
FUSES	12 A (110 - 120 VAC) 8 A (220 - 240 VAC) 15 A (100 VAC)
CERTIFICATIONS	IEC 60601-1; EN 60601-1-2; UL 60601-1; CAN/CSA-C22.2, No. 601.1, EN 55011
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 and in accordance with Canadian/CSA C22.2, No. 601.1. Classified under the Medical Device (93/42/EEC) as a Class IIb device.
DIAGNOSTICS	A qualified service technician can perform over-temperature detection system testing, temperature output testing, operating temperature calibration, and fault code troubleshooting.

Definition of Symbols

The following symbols may appear on the product's labeling or exterior packaging.

	ON/STANDBY
	ON (used on isolation switch)
	OFF (used on isolation switch)
	ON/OFF push button switch
	Temperature control
	Equipotentiality plug (ground)
	Fuse
	Attention, consult appropriate documents
	Warning
	Nonexplosion proof
	Dangerous voltage
	Type BF equipment (patient applied)
	Voltage, alternating current (AC)



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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
TEL (44) 1924 200550 • FAX (44) 1924 200518

* Bair Hugger, Bair Paws, Arizant, Arizant Healthcare, bright ideas that work,
Total Temperature Management, 241 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.

May be covered by one or more of the following patents:
U.S. 6,355,915; 6,309,408; 6,309,409; 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; 6,126,681; 6,126,393;
6,129,936; 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; RE 38462
5,350,417; 5,336,250; 5,324,320; 5,300,102; 5,300,101; 5,184,612; 5,044,364;
Japan 2,561,326; Canada 1,325,484; EPO 0311336. Australia 756,900. UK 2,358,746B.
Other patents pending.