

3M

Bair Hugger™

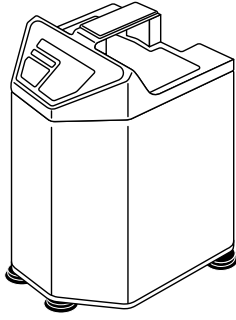
Temperature Management Unit
Model 505

Operator's Manual

- Ⓜ Temperature management unit Model 505
Operator's manual
- Ⓜ Manuel de l'utilisateur pour les appareils de gestion de la température Modèle 505
- Ⓜ Betriebshandbuch für Temperaturmanagement-Geräte Modell 505
- Ⓜ Manuale d'uso delle unità di gestione della temperatura Modello 505
- Ⓜ Manual del usuario para las unidades de control de temperatura, Modelo 505
- Ⓜ Temperatuurregelunit Model 505 Gebruikshandleiding
- Ⓜ Bruksanvisning till Modell 505 temperaturstyrenhet
- Ⓜ Brugsanvisning til temperaturreguleringsenheder, Model 505
- Ⓜ Brukerhåndbok for temperatur-behandlingsenhet, Modell 505
- Ⓜ Lämpötilansäätölaitteen Malli 505 käyttäjän opas
- Ⓜ Manual do utilizador das unidades de gestão de temperatura Modelo 505
- Ⓜ Εγχειρίδιο Χρήσης Μονάδα διαχείρισης θερμοκρασίας, Μοντέλο 505
- Ⓜ Instrukcja Obsługi Dmuchawy Model 505 - urządzenia do aktywnego przeciwdziałania hipotermii
- Ⓜ 505 sz. Modell hőmérséklet-szabályozó egység használati utasítása
- Ⓜ Návod k obsluze jednotky regulace teploty typ 505
- Ⓜ Operatoriaus Vadovas Modelis 505 Temperatūros reguliavimo prietaisas
- Ⓜ Руководство по эксплуатации Модель 505 Устройство управления температурой
- Ⓜ Çalıştırma El Kitabı Vücut Isısı Yönetim Ünitesi Model 505
- Ⓜ 操作员手册 505型温度管理仪
- Ⓜ دليل المشغل وحدة التحكم في درجة الحرارة طراز 505



Total Temperature Management™ System



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Bair Hugger

Temperature Management Unit

Model 505

Operator's Manual

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Introduction

Description of the Total Temperature Management™ System

The 3M™ 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, 3M™ Bair Paws™ patient warming gowns, and the 3M™ 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.







The Bair Hugger warming unit is attached to the blanket or gown by means of a flexible hose. Warm air is generated in the unit and flows through the hose and into the blanket or gown. Depending on the model, the blanket or gown is placed either around, over, or underneath the patient. Small perforations on the blanket or gown allow the warm air to be dispersed over the patient. For fluid warming applications, the Model 241 blood/fluid warming set is inserted in the warming unit hose. When the unit is turned ON and a temperature setting is selected, warm air flows over the Model 241 tubing and warmed fluid exits from the distal end of the tubing. For additional information on Bair Hugger blankets, Bair Paws gowns, the 241 warming set, or other accessories visit us online at bairhugger.com or bairpaws.com.

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. The Bair Hugger system should only be used by trained medical professionals.

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.

Definition of Symbols

	ON/STANDBY
	ON (used on isolation switch)
	OFF (used on isolation switch)
	ON/OFF push button switch
	Temperature Control
	An equipotentiality plug (grounded) conductor other than a protective earth conductor or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation. Please consult IEC 60601-1; 2005 for requirements.



Fuse



CAUTION



Dangerous Voltage



Type BF Equipment (patient applied)



Voltage, Alternating Current (AC)



This system is subject to European WEEE Directive 2002/96/EC. This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.



Protective earth ground



No free hosing



Date of manufacture



Manufacturer



Consult instructions for use



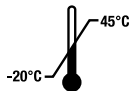
Follow instructions for use



Recycle to avoid environmental contamination. This product contains recyclable parts. For information on recycling, please contact your nearest 3M Service Center for advice.



Keep dry



Temperature limit

Explanation of Signal Word Consequences

**WARNING:**

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

**CAUTION:**

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.


NOTICE:

Indicates a situation which, if not avoided, could result in property damage only.

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 3M Patient Warming 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-3M Patient Warming 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 (the side 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-temp 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.
9. Reusable 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 safely ONLY with Bair Hugger blankets and Bair Paws gowns.
10. Do not connect a Bair Hugger blanket, 241 blood/fluid warmer, or Bair Paws gown to the warming unit if it has been cut or damaged; thermal injury may result.
11. Do not use a Bair Hugger blanket to transfer or move the patient; injury may result. To reduce the risks associated with hazardous voltage and fire:

- keep power cord visible and accessible at all times. The plug on the power cord serves as the disconnect device. The wall socket outlet shall be as close as practical and shall be easily accessible.
 - use only the power cord specified for this product and certified for the country of use.
 - do not allow the power cord to get wet.
 - do not use the warming unit when it appears the warming unit, power cord or any component is damaged. Contact 3M Patient Warming Technical Support at 1-800-733-7775.
 - this equipment must only be connected to a supply mains with protective earth.
12. To reduce the risks associated with exposure to biohazards always perform the decontamination procedure prior to returning the warmer for service and prior to disposal.
 13. Do not retain the patient using a warming blanket alone, as injury may result. Use a draw, sheet safety strap, or other means to retain the patient.
 14. Do not modify this equipment without authorization of the manufacturer.
 15. To ground the Bair Hugger warming unit, only connect to receptacles marked “Hospital Only,” “Hospital Grade,” or a reliable grounded outlet.



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 free from mechanical damage and is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
5. To prevent tipping, clamp the Model 775 temperature management 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 28" (71 cm) diameter wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and 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.
7. To reduce the risks associated with environmental contamination follow applicable regulations when disposing of this device or any of its electronic components.

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 avoid Bair Hugger warming unit damage:
 - do not immerse the Bair Hugger warming unit or warming unit parts or accessories in any liquid or subject them to any sterilization process.
 - do not use solvents such as acetone or thinner to clean the warming unit; avoid abrasive cleaners.
 - clean warming unit exterior with soft cloth using plain water or a mild, all-purpose or nonabrasive cleaner.

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 3M Patient Warming.

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

3M Patient Warming 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 Operator's or Service Manuals.
- The equipment is installed in an environment that does not meet the appropriate electrical and 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/STANDBY 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.

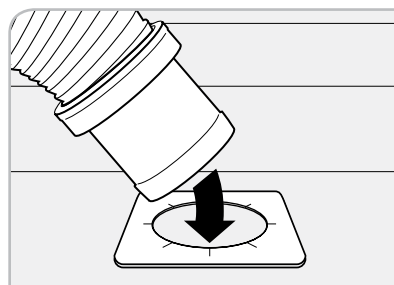


Figure A.

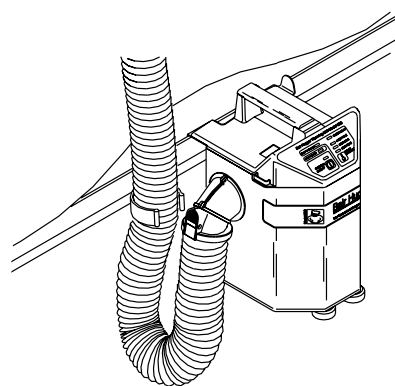


Figure B. Model 505 unit attached to a bedrail

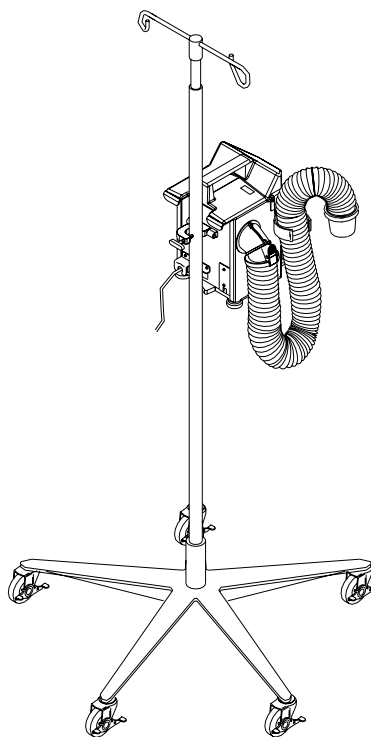


Figure C. Model 505 unit attached to an IV pole

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 (see Figures B and C).

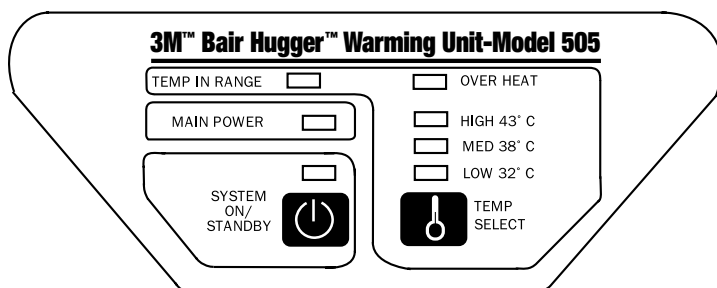


Figure D. Control panel of the Model 505 unit

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.

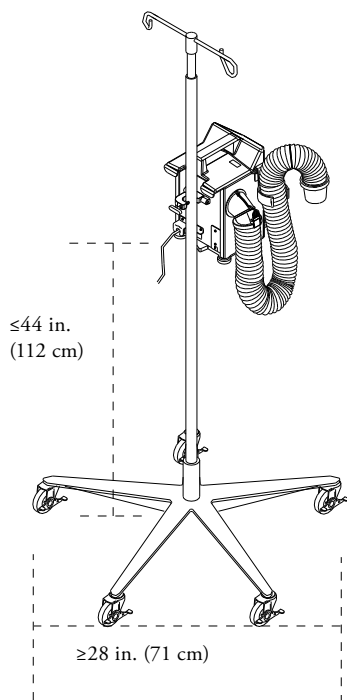


Figure E. Model 505 unit attached to an IV pole

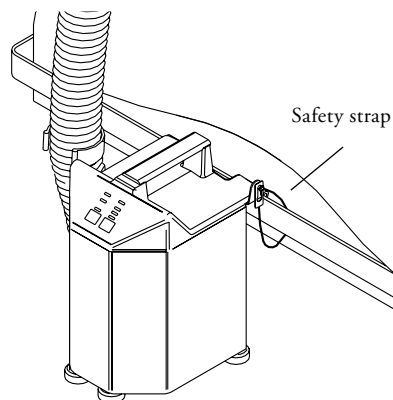


Figure F. Model 505 unit attached to a bedrail

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 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).

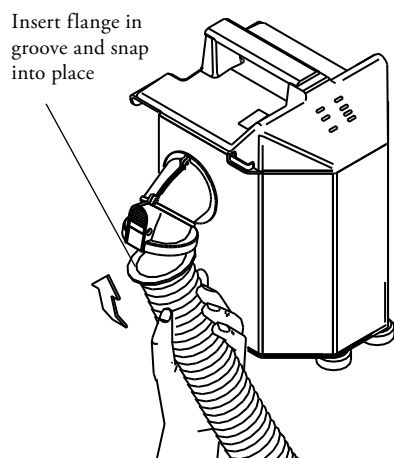


Figure G. Attaching the Model 505 unit hose

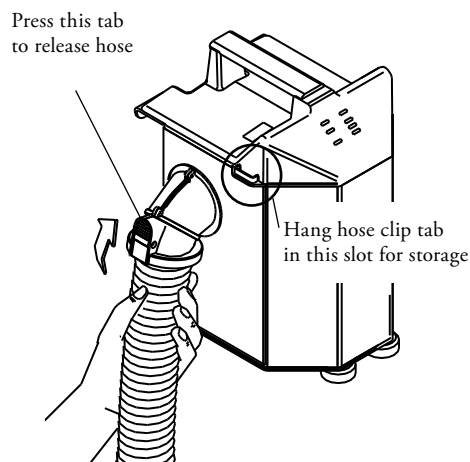


Figure H. Storing the Model 505 unit hose

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 blood/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: 1-800-228-3957

In-Warranty Repair and Exchange

Replacement parts to correct a problem are delivered at no charge. To return a device to 3M Patient Warming 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.

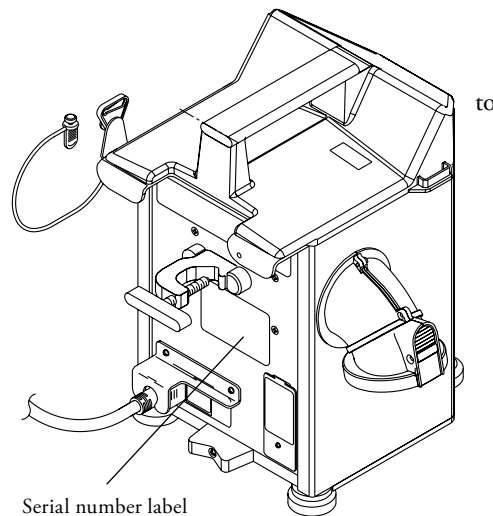


Figure J. Serial number label on Model 505

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 blood/fluid warming system
FILTRATION SYSTEM	0.2µm level
RECOMMENDED FILTER CHANGE	Every 12 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; IEC/EN 60601-1-2; UL 60601-1; CAN/CSA-C22.2, No.601.1; EN 55011; EN 80601-2-35.
CLASSIFICATION	 <p>MEDICAL — GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1; CAN/CSA-C22.2, No.601.1; ANSI/AAMI ES60601-1:2005 CSA-C22.2 No. 60601-1:08; EN 80601-2-35; Control No.4HZ8</p> <p>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, EN 80601-2-35 and in accordance with Canadian/CSA C22.2, No. 601.1. Classified under the Medical Device Directive as a Class IIb device.</p>

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.




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