

SEP - 6 2000

K001149

D. Substantial Equivalence

The Bair Hugger® Model 750 Total Temperature Management® system is substantially equivalent in safety and effectiveness to the predicate device, the Model 505 Total Temperature Management system (K960167), currently manufactured and marketed by Augustine Medical, Inc.

Bair Hugger Model 750 Warming Unit and Bair Hugger Model 505 Warming Unit

Summary of Similarities

- Both devices have the same intended use and patient populations.
- The Model 750 unit has similar mechanical characteristics; it uses the same type of heater and blower unit.
- The output temperature ranges at each temperature setting are the same (the tolerances are tighter on the Model 750 unit).
- The over temperature safety system provides visible and audible warnings.
- Both devices are designed for use with all of the current Bair Hugger blankets and the 241® fluid warming set. No modifications have been made to the blankets or the 241 set.
- Both warming units can be used as a shelf, floor or table model, or attached to an I.V. pole or bed rail. In addition, the Model 750 unit can be attached to a rack or stand.

Summary of Differences

- The Model 750 unit incorporates software as part of the primary temperature control system.
- The Model 750 unit provides greater airflow.
- The Model 750 unit measures the temperature at the distal end of the warming unit hose and displays it on the control panel; the Model 505 unit calculates this temperature. Because of this, the Model 750 unit uses a different warming unit hose.
- The Model 750 control panel includes independent switches for *Standby* mode and each temperature setting; the Model 505 control panel has one temperature select switch which, when pressed, changes the temperature setting to the next setting in the sequence.
- The Model 750 control panel includes an LCD window that displays error codes; because it lacks software, the Model 505 unit does not have an error code feature.
- The primary over temperature sensor for the Model 750 unit is set to $47 \pm 2^{\circ}\text{C}$ and the secondary over temperature sensor is set to $53 \pm 3^{\circ}\text{C}$. The primary sensor for the Model 505 unit is set to $53 \pm 3^{\circ}\text{C}$.
- The Model 750 unit can include a collapsible or non-collapsible warming unit hose with a variety of storage options.

Substantial Equivalence Table

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Patient warming	Patient warming
Clinical areas for device use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Device positioning	Can be set on table, floor, shelf or other hard surface; attached to a rack or stand; clamped to an I.V. pole; or hung on a bed rail	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail
Dimensions	13.5" x 9.5" x 10.5"	13" x 10" x 11"
Weight	@12.5 lbs	@11.5 lbs.
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length or collapsible, washable, 2.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter
Recommended filter change	Every year	Every 6 months or 500 hours of use
Temperature sensor	Shuts the heater off if damaged	Shuts the heater off if damaged
Temperature range (at nozzle)	Ambient to 45 degrees	Ambient to 46 degrees
Heat generated	1644 BTU/h (avg.)	1112 BTU/h (avg.)
Electrical requirements	20 Amp fused circuit	20 Amp fused circuit
Power cable	15' hospital grade	15' hospital grade
Airflow at comparable operating pressure	Up to 48 cfm (22.6 L/s)	Up to 30 cfm (14.2 L/s)
Air filter	HEPA	0.2µM
Motor	40 watt DC	Fractional horsepower, single-phase, AC
Heater	1600W resistive	850W resistive
Leakage current	Meets requirements of UL 2601 and EN 60601-1	Meets requirements of UL 2601 and EN 60601-1
Power consumption at 20°C ambient condition	Peak: 1650W Avg.: 800W	Peak: 1000W Avg.: 450W
Diagnostics	Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician. Upon power-up and mode change, the software performs self-test functions	Over temperature and temperature output testing and calibration can be performed by biomedical technician

Substantial Equivalence Table (cont.)

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Over temperature detection	Independent electronic circuit. Thermal cutoff shuts the heater off at preset high temperature of 47±2°C, measured at the end of the hose, plus an independent electronic system that reacts in the same manner and at the same set points as the SE device	Independent bulb and capillary. Thermal cutoff shuts the heater off at a preset high temperature of 53°C±3°C (127.4°F±3.6°F), measured at end of the hose.
Overcurrent protection	Dual input fused lines	Dual input fused lines
Alarm system	Over temperature: flashing red light with audible alarm, heater and blower shut down. Error condition: audible alarm, unit goes into <i>Standby</i> mode, error code displays in LCD window	Over temperature: flashing red light with audible alarm, heater shuts down.
Control circuitry	Microprocessor-based	Analog
Blankets Used	All Bair Hugger blankets (see next page for details)	All Bair Hugger blankets (see next page for details)
Blood/Fluid Warming System that can integrate with warming unit	Augustine Medical Model 241 system (see next page for details)	Augustine Medical Model 241 system (see next page for details)



Bair Hugger® Blankets- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same blankets as found in the predicate device, the Model 505 Total Temperature Management system. These blankets, listed below, are currently manufactured and marketed by Augustine Medical.

- Model 522 Upper body blanket (K903360)
- Model 525 Lower body blanket (K903360)
- Model 540 Torso blanket (K921165)
- Model 537 Small lower body blanket (K950416)
- Model 300 Full body blanket (K873745)
- Model 536 (K920432)
- Model 530 (K913734)
- Model 305 Chest access blanket (K920265)
- Model 315 Multi-access blanket (K950416)
- Model 310 (K950416)
- Model 650 (K952864)
- Model 655 (K952864)
- Model 610 Full body surgical (K950432)
- Model 110 Outpatient (K960167)
- Model 630 Sterile cardiac access (K964673)
- Model 645 cardiac (K913734)
- Model 555 pediatric full access (K913734) ✓
- International white blankets: Models 42268 (K903360), 42568 (K903360), 40068 (K873745), and 44068 (K921165)

Model 241 Fluid Warming Set- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same 241® Fluid Warming Set (K933726) as found in the predicate device, the Model 505 Total Temperature Management system. The 241 Fluid Warming Set is currently manufactured for and marketed by Augustine Medical.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Augustine Medical
c/o David Westlin
Director of Regulatory Affairs and
Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K001149
The Bair Hugger® Model 750 Total Temperature
Management® System
Regulatory Class: II Two
Product Code: DWJ
Dated: July 19, 2000
Received: July 21, 2000

Dear Mr. Westlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

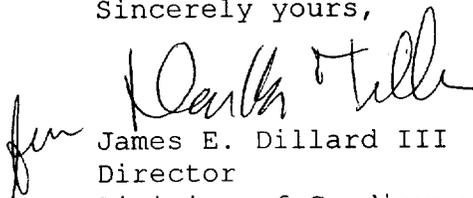
Page 2 - Mr. David Westlin

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

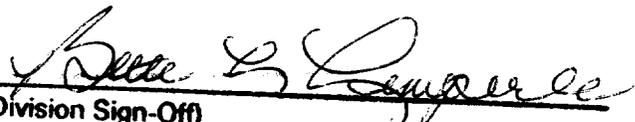
Enclosure

Indications for Use

510(k) number: Not known

Device name: The Bair Hugger[®] Model 750 Total Temperature Management[®] System

Indications for use: The Bair Hugger[®] Model 750 Total Temperature Management[®] System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the Bair Hugger[®] Model 750 Total Temperature Management[®] System should be used whenever conditions exist that could cause patients to become cold.


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001149

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801-109)

or Over the Counter Use



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Augustine Medical Inc.
c/o Mr. David Westlin
Director of Regulatory Affairs and Quality Assurance
10393 West 70th Street
Eden Prairie, Minnesota 55344

SEP - 9 2002

Re: K001149/A003
Device Name: Bair Hugger® Model 750 Total Temperature Management® System
Dated: August 20, 2002
Received: August 21, 2002

Dear Mr. Westlin:

We have reviewed the information dated August 20, 2002, regarding the 510(k) notification K001149 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SEP - 9 2002

Augustine Medical Inc.
c/o Mr. David Westlin
Director of Regulatory Affairs and Quality Assurance
10393 West 70th Street
Eden Prairie, Minnesota 55344

Re: K001149/A003
Device Name: Bair Hugger® Model 750 Total Temperature Management® System
Dated: August 20, 2002
Received: August 21, 2002

Dear Mr. Westlin:

We have reviewed the information dated August 20, 2002, regarding the 510(k) notification K001149 previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2

Page 2 - Mr. David Westlin Department of Health & Human Services

cc: HFZ-450 (DCD)

HFZ-401 DMC

Prepared by: Deborah Ramdat 9/3/02

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-450	K. Fly	9-5-02			
450	Jumbam	9-6-02			



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: September 5, 2002

To: File

From: Keith Foy *Keith Foy*
Materials/Mechanical Engineer

Re: Document Control Number: K001149/A3

Applicant: Augustine Medical Inc.
10393 West 70th Street
Eden Prairie, Minnesota 55344

Contact: David Westlin, Director of Regulatory Affairs and Quality Assurance
Telephone: (952) 947-1277
Fax: (952) 918-5277

Common Name: Warming unit, §870.5900

Device Name: Bair Hugger® Model 750 Total Temperature Management® System

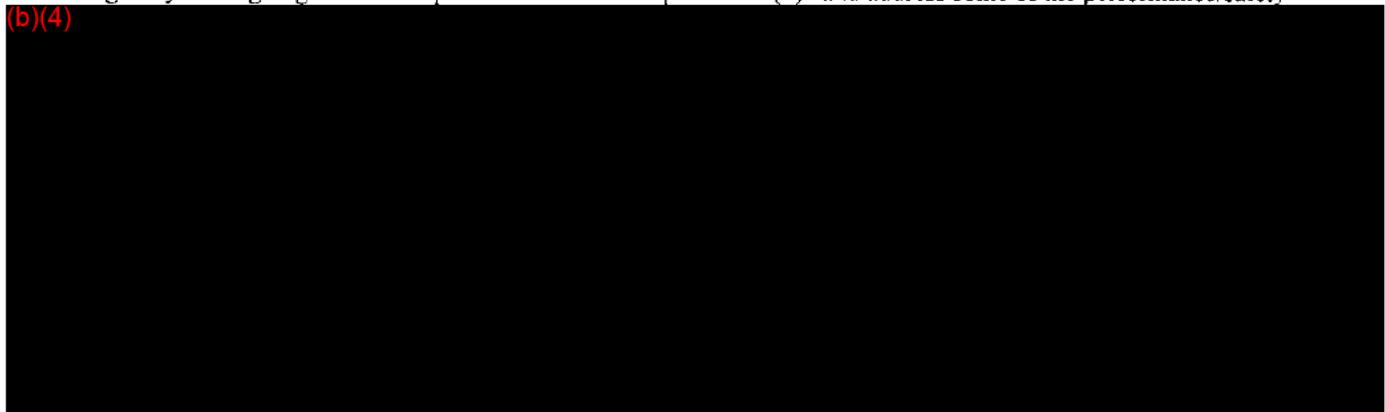
Purpose of review:

The sponsor has notified FDA of a change in the temperature "set point" of their device. The pages provide some clarification of the proposed change and ask whether a 510(k) is necessary.

Phone conversation (September 5, 2002):

Originally I was going to ask the sponsor to submit a "Special 510(k)" and address some of the performance/safety

(b)(4)



With this information, I agree that this change doesn't change the status of the 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 8-21-02

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K001149/A3

To: Division Director: CV/DCD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

Additional information requires a new 510(k); please process [This information will be made into a new 510(k)]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Kett 77

Date: ~~8/28/02~~ 9/5/02

Draft #2 : 9/8/99
Draft #3: 1/3/00

DMC
9/9

5

1001149/A3



August 20, 2002

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland
20850

RECEIVED
AUG 21 11 26 AM '02
FDA/CDRH/OCE/DMC

Subject: **Is a 510(k) Necessary?**
(Reference 510(k) number **K 001149**)

To Whom it May Concern,

Augustine Medical is requesting that a determination be made concerning the need to provide a 510(k) submission for the modifications described in the attached documents.

This request is being submitted in duplicate similar to a 510(k) notification. If only one copy is needed please destroy the second copy.

If there are any questions regarding this request, please contact me at the provided addresses and/ or telephone numbers.

Sincerely,

David Westlin
Director of Regulatory Affairs and Quality Assurance
Augustine Medical Inc.
Direct Telephone: 952-947-1277
Fax: 952-918-5277
e-mail: dwestlin@augmed.com

SK102

6

Submitter's name and address

Augustine Medical Inc.
10393 West 70th Street
Eden Prairie, Minnesota
55344

Contact person

David Westlin
Director of Regulatory Affairs and Quality Assurance
Direct Telephone: 952-947-1277
Direct Fax: 952-918-5277
e-mail: dwestlin@augmed.com

Establishment registration number of submitter

2183725

Device name

The Bair Hugger[®] Model 750 Total Temperature Management[®] System

Device classification

Class II, 870.5900

510(k) number

K001149

Predicate device for original submission

Augustine Medical Bair Hugger Model 505 Warming Unit (K960167)

Description of Modification

Augustine Medical would like to make a modification to a specific parameter identified the original submission for the Bair Hugger[®] Model 750 Total Temperature Management[®] System, 510(k) number K001149. The modified parameter falls within the range between the settings allowed for the predicate device and the submission for the model 750 warming unit, so it is felt that a new submission is not needed. But, in an effort to assure compliance with FDA guidelines and interpretations we are requesting a decision from FDA regarding the need for a new submission.

The parameter that is being changed is the reported set point of the over-temperature back-up system. The over-temperature back-up system is intended to react to fault conditions that could allow the temperature of the warming unit to rise beyond a safe level. If the output air temperature rises to this activation point the back-up system turns off the heater at a level that assures continued safety, even in a fault condition.

In the original submission for the Model 750 unit, the activation temperature was identified at 47°C, ± 2°C. The detection point for the predicate device is 53°C, ± 3°C. The change will allow the over-temperature detection point to be set at 51°C, ± 3°C. Temperatures are measured at the end of the warming unit hose in all cases.

Maximum temperatures allowed for:

- Predicate device (K96017) 56°C
- Original submission (K001149) 49°C
- Modified specification 54°C

The reason for the modification is to allow for (b)(4)

(b)(4)

When an over-temperature condition is detected the (b)(4)

(b)(4)

(b)(4)

The other variation is in the (b)(4)

(b)(4)

The warming unit detection points have not been changed. The only difference is in the (b)(4) (b)(4). The variations noted here include all worse case conditions combined. Even in this instance, the device is still within the limitations defined by the predicate device.

This modification in temperatures will provide continuous safety (at a point even safer than the predicate device) while allowing for an accurate description within the test methodology.

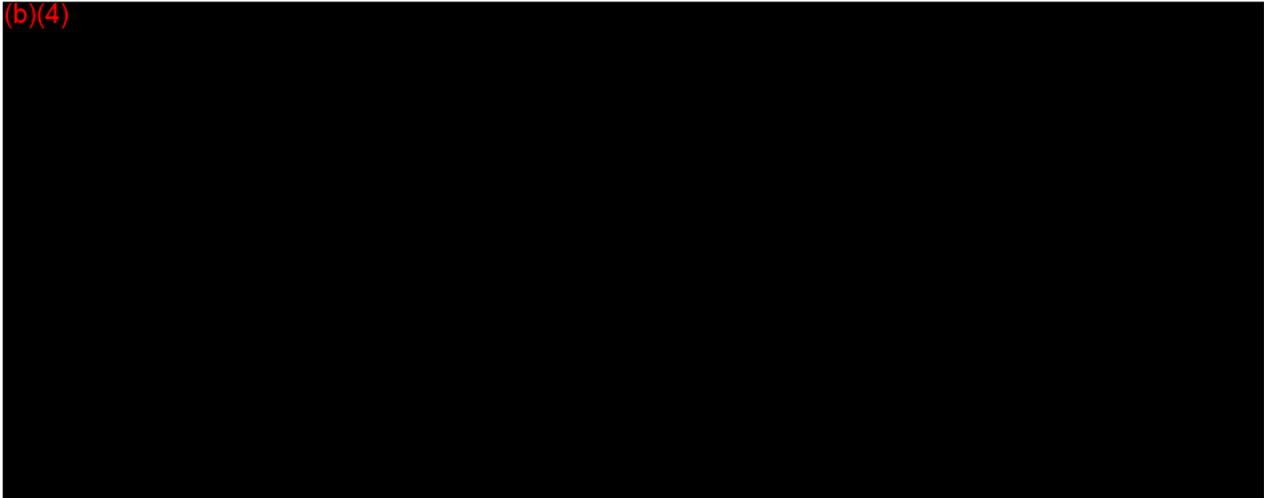
A graphical description of the set points can be found on the following page.

8

Overtemperature Detection Set Points

Preset Detection Ranges (with tolerance included) are shown in red.

(b)(4)



The model 750 has two back-up systems, while the predicate device has one back-up system. This is done to provide redundant safety if there were a condition that could render the operating and initial back-up system useless. The modification described here includes the worse case scenarios of the primary and secondary back-up system.

Summary:

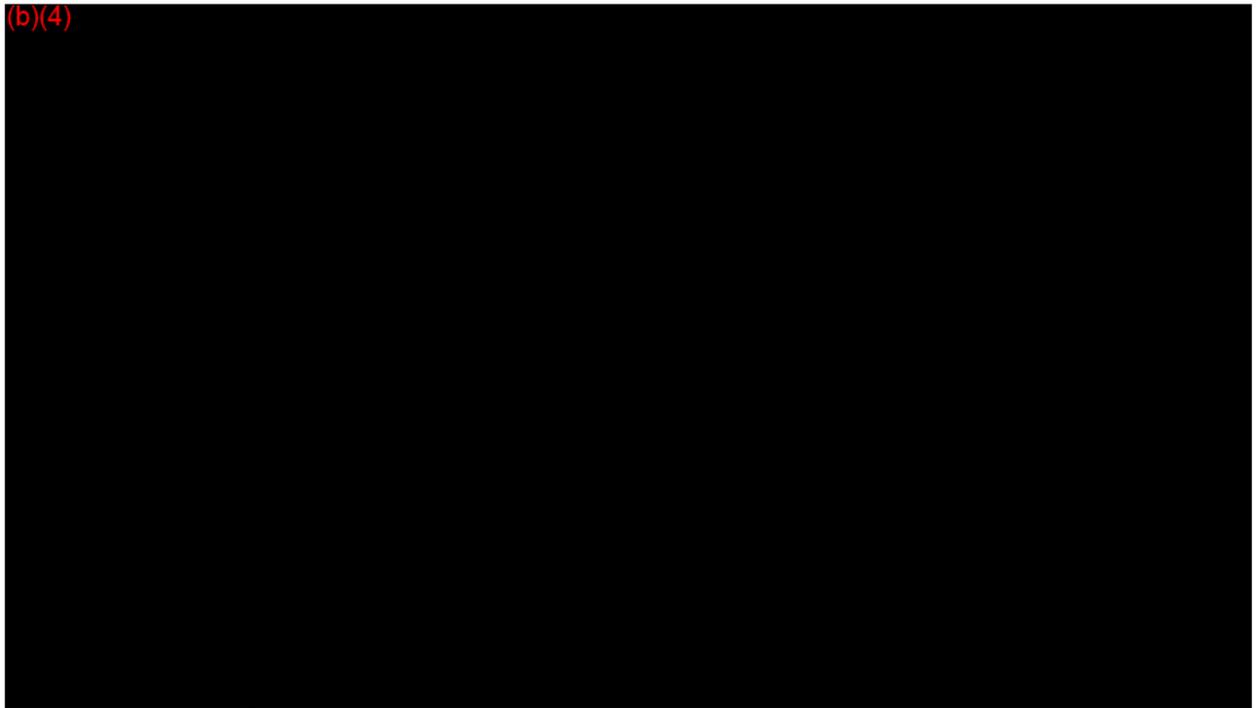
The modification to the over-temperature set point still maintains the detection point at a level that is lower (safer) than the predicate device. There have been no reports of patient injury for the predicate device in conditions where an over-temperature fault was detected. The modification to the set point parameter provides increased safety levels over the predicate device. As such, the modification will continue to assure safety under all conditions.

Reference Information

*Safety Feature page of the Original submission (K001149)
With the original detection point highlighted*

Safety Features of the Model 750 Warming Unit

(b)(4)



The user must reselect the temperature setting to return the unit to operational mode. If the over temperature fault condition persists, the unit will return to alarm status.

All temperature and safety controls are designed to meet the requirements of UL 2601, IEC 601-1 and EN 60601-1.

3. Error Mode

In an error condition, the audible alarm sounds and the LCD window displays the error code. The user silences the alarm by pressing the *Standby/Reset* button.

Reference Information

*Safety Feature page
With the modified detection point highlighted*

Safety Features of the Model 750 Warming Unit

(b)(4)



The user must reselect the temperature setting to return the unit to operational mode. If the over temperature fault condition persists, the unit will return to alarm status.

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In an error condition, the audible alarm sounds and the LCD window displays the error code. The user silences the alarm by pressing the *Standby/Reset* button.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Augustine Medical
c/o David Westlin
Director of Regulatory Affairs and
Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K001149
The Bair Hugger® Model 750 Total Temperature
Management® System
Regulatory Class: II Two
Product Code: DWJ
Dated: July 19, 2000
Received: July 21, 2000

Dear Mr. Westlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

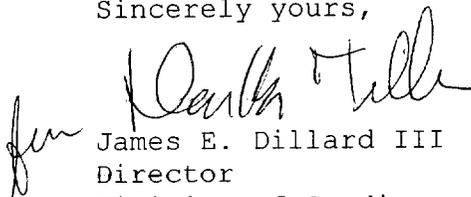
Page 2 - Mr. David Westlin

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number: Not known

Device name: The Bair Hugger® Model 750 Total Temperature Management® System

Indications for use: The Bair Hugger® Model 750 Total Temperature Management® System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the Bair Hugger® Model 750 Total Temperature Management® System should be used whenever conditions exist that could cause patients to become cold.


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001149

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801-109)

or Over the Counter Use _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) J. R. [Signature]

Subject: 510(k) Number K001149/51

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed (required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

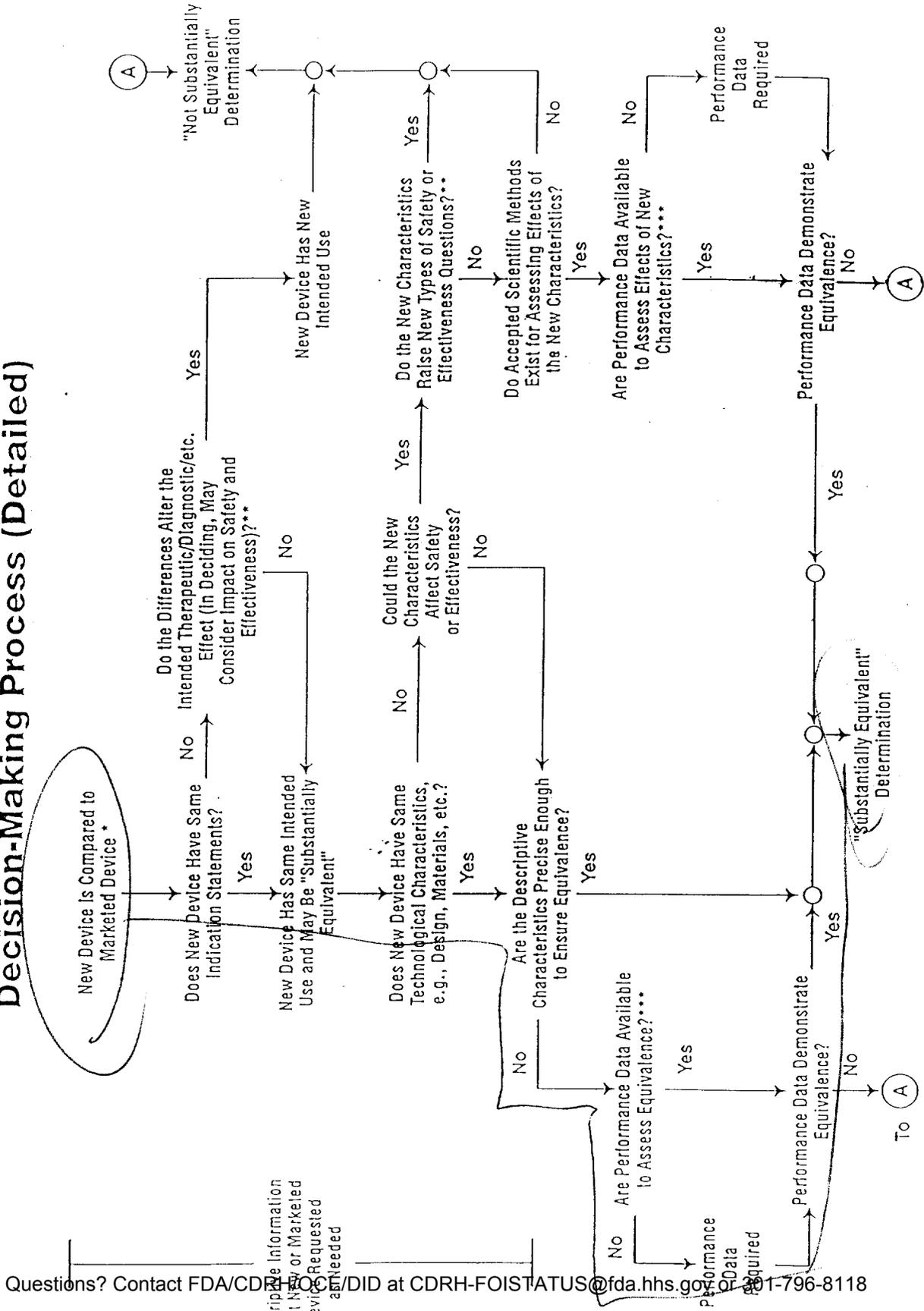
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: [Signature] 31 Aug '00
(Branch Code) (Date)

Final Questions? Contact [Signature] at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
(Division Director) (Date)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



** This Decision is Normally Based on Descriptive Information Alone, But Limited to Information Sometimes Required.
 *** Data from 510(k), Other 510(k), The Center's Classification Files, or the Literature.

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices is Unclear.

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 21, 2000

AUGUSTINE MEDICAL, INC.
10393 WEST 70TH ST.
EDEN PRAIRIE, MN 55344
ATTN: SCOTT D. AUGUSTINE

510(k) Number: K001149
Product: AUGUSTINE
MEDICAL BAIR
HUUGER, MODEL
750 TOTAL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Office of Device Evaluation

MEMORANDUM

Date: August 21, 2000
From: Joydeb Roy *JR*
Physicist (DCRND/CSPG)
To File: File (K001149)/S1
Sponsor: Augustine Medical Inc.
Device: Bair Hugger Model 750
Predicate: Bair Hugger Model 505 (K960167)
Review: Traditional 90Day
Recommendation: Substantially Equivalent (SE)

30/10
3/15/00

The requested information on (b)(4) was faxed by the company on August 18, 2000.

(b)(4)

The response is satisfactory.

(b)(4)

The response is satisfactory

Based on the information provided, the device is judged to be substantially equivalent (SE) to the predicate device.

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION
(To be attached to the SE Review Memo)

510K #: K001149

Reviewer: J.Roy

Division/Branch:DCRD/CSPG

Device Name: Augustine Medical Bair Hugger Model 750

Product To Which Compared (510(K) Number If Known):_K960176 (Bair Hugger Model 505)

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?		X	If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: In addition to completing the form on the LAN, "YES" responses to questions 4, 6, 8, and 11, and every "NO" response requires an explanation.

- Intended Use:** The device is intended to prevent and treat hypothermia and provide warmth to cold and shivering patients. In addition, the device should be used whenever conditions exist that could cause patient to become cold.

2. **Device Description:** Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The device consists of a portable forced air warming unit. It will be used with a Bair Hugger blanket and also a fluid warming warming system.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. **Explain why not a device:**
2. **Explain why not subject to 510(k):**
3. **How does the new indication differ from the predicate device's indication:**
4. **Explain why there is or is not a new effect or safety or effectiveness issue:**
5. **Describe the new technological characteristics:**
6. **Explain how new characteristics could or could not affect safety or effectiveness:**
7. **Explain how descriptive characteristics are not precise enough:**
Several clarifications (i.e., test results) were needed.
8. **Explain new types of safety or effectiveness questions raised or why the questions are not new:**
9. **Explain why existing scientific methods can not be used:**
10. **Explain what performance data is needed:**
Temperature data, hazard analysis and software information.
11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**
The performance of the subject and the predicate are similar.

ATTACH ADDITIONAL SUPPORTING INFORMATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Office of Device Evaluation

MEMORANDUM

Date: August 7, 2000
From: Joydeb Roy 
Physicist (DCRND/CSPG)
To File: File (K001149)/S1
Sponsor: Augustine Medical Inc.
Device: Bair Hugger Model 750
Predicate: Bair Hugger Model 505 (K960167)
Review: Traditional 90 Day
Recommendation: Additional Information (AI)

Additional Information:

(b)(4)

(b)(4)

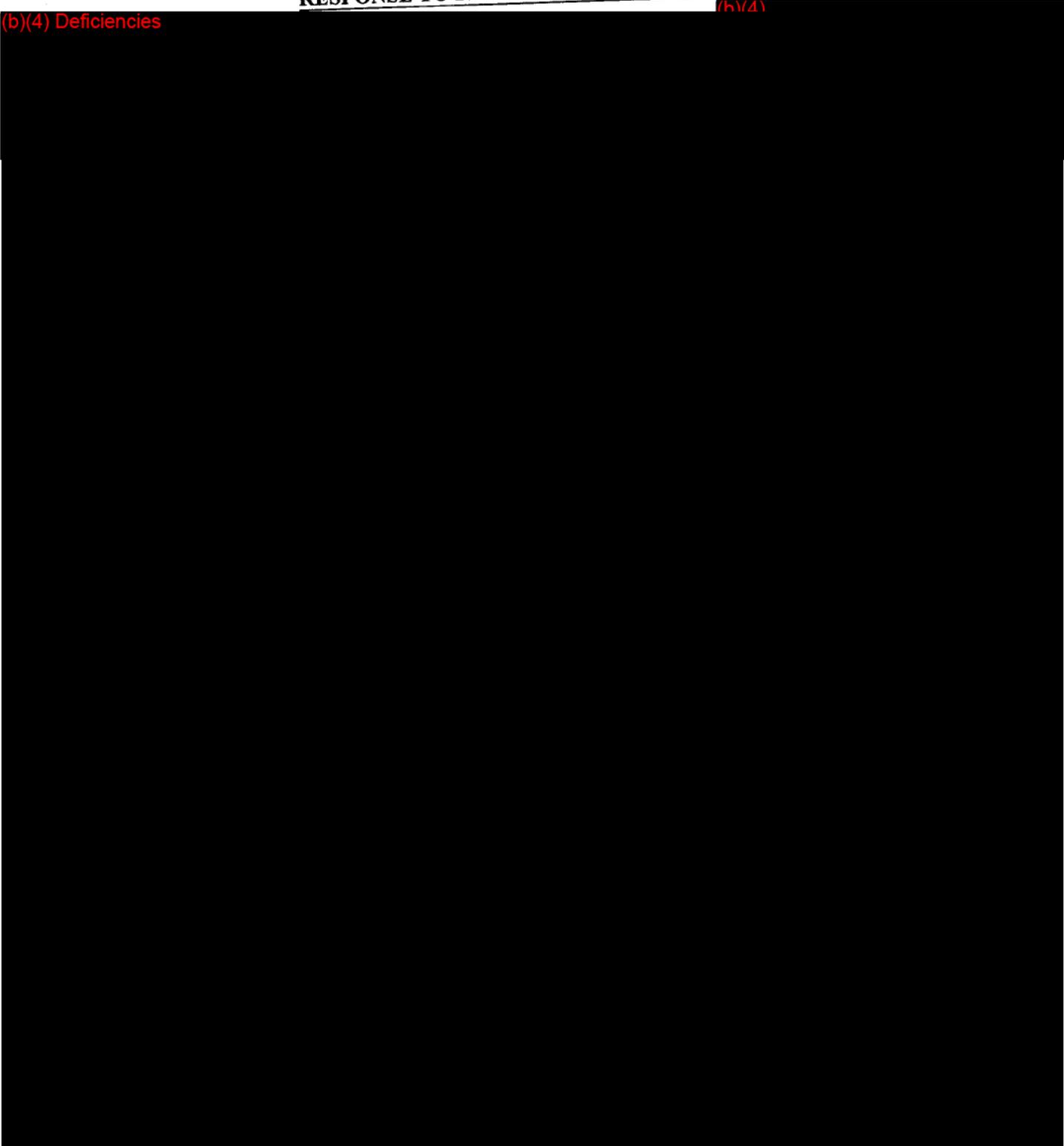
7,2000 and requested the information.

To save time, I called the company on August

RESPONSE TO FDA LETTER OF JULY 6, 2000

(b)(4) Deficiencies

(b)(4)



//

~~FAX~~



ATTN: MR. JOYDEB ROY

301-827-4351

August 18, 2000

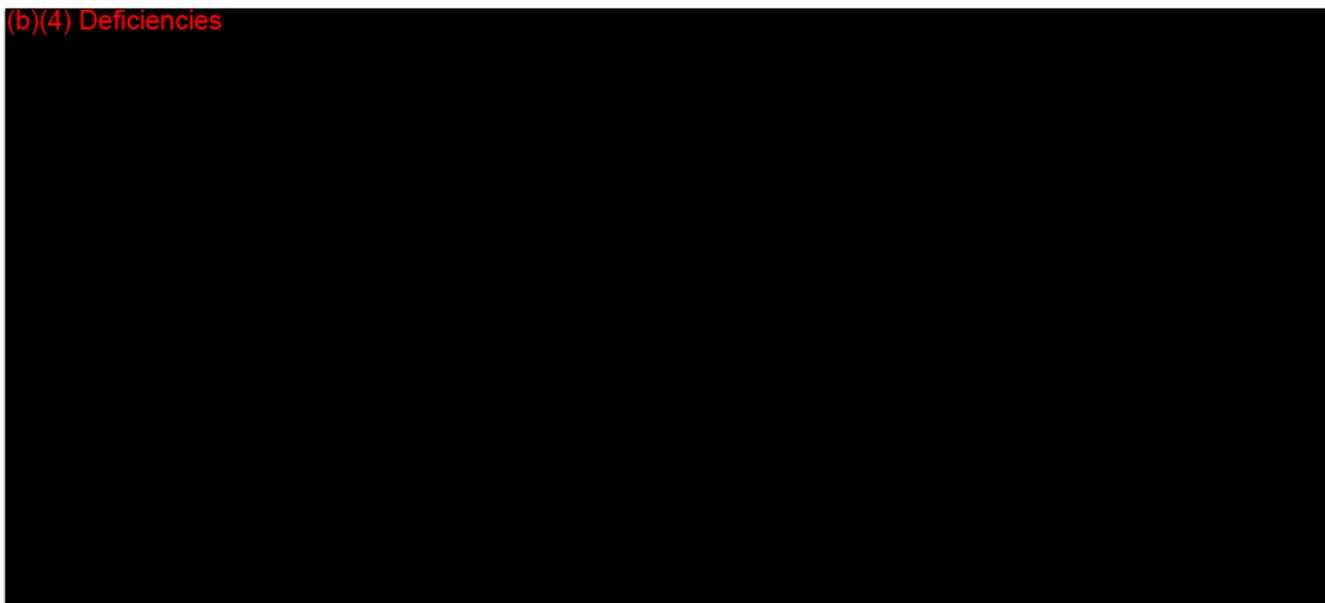
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Response to request for additional information
510(k) number **K001149**

To Whom It May Concern:

I am providing the following clarifications to Items 3 and 4 as listed in FDA's request for additional information dated July 6, 2000. A response was provided by Augustine Medical on July 19, and additional clarification was requested by telephone on August 16.

(b)(4) Deficiencies

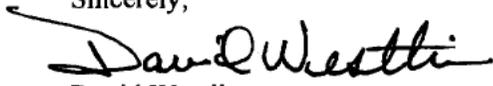


(b)(4) Deficiencies



Please feel free to call if there are questions regarding these responses.

Sincerely,



David Westlin
Director of Regulatory Affairs and Quality Assurance
for Scott Augustine, MD, CEO

K001149-51



July 19, 2000

Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Response to request for additional information
510(k) number **K001149**

To Whom It May Concern:

Enclosed is the response to the request for additional information regarding 510(k) submission **K001149** submitted by Augustine Medical Inc. Two copies are included, as was requested in the letter.

The responses are identified as Items 1-4, respectively, in the same order as the questions in the request for information.

Please feel free to call if there are questions regarding these responses.

Sincerely,

David Westlin
Director of Regulatory Affairs and Quality Assurance
for Scott Augustine, MD, CEO

RECEIVED
21 JUN 00 13 11
FDA/CDRH/OCE/DHG

AK
520



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scott D. Augustine, M.D.
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344

JUL 6 2000

Re: K001149
Bair Hugger Model 750
Dated: April 5, 2000 and June 1, 2000
Received: April 10, 2000

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4) Deficiencies

(b)(4) Deficiencies

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market

Page 2 - Scott D. Augustine, M.D.

the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

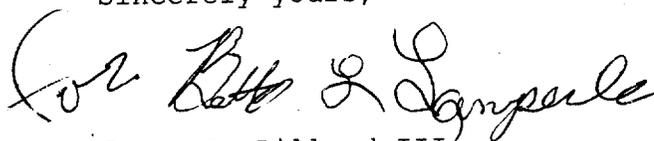
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Roy Joydeb at (301) 443-8262. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Scott D. Augustine, M.D.
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344

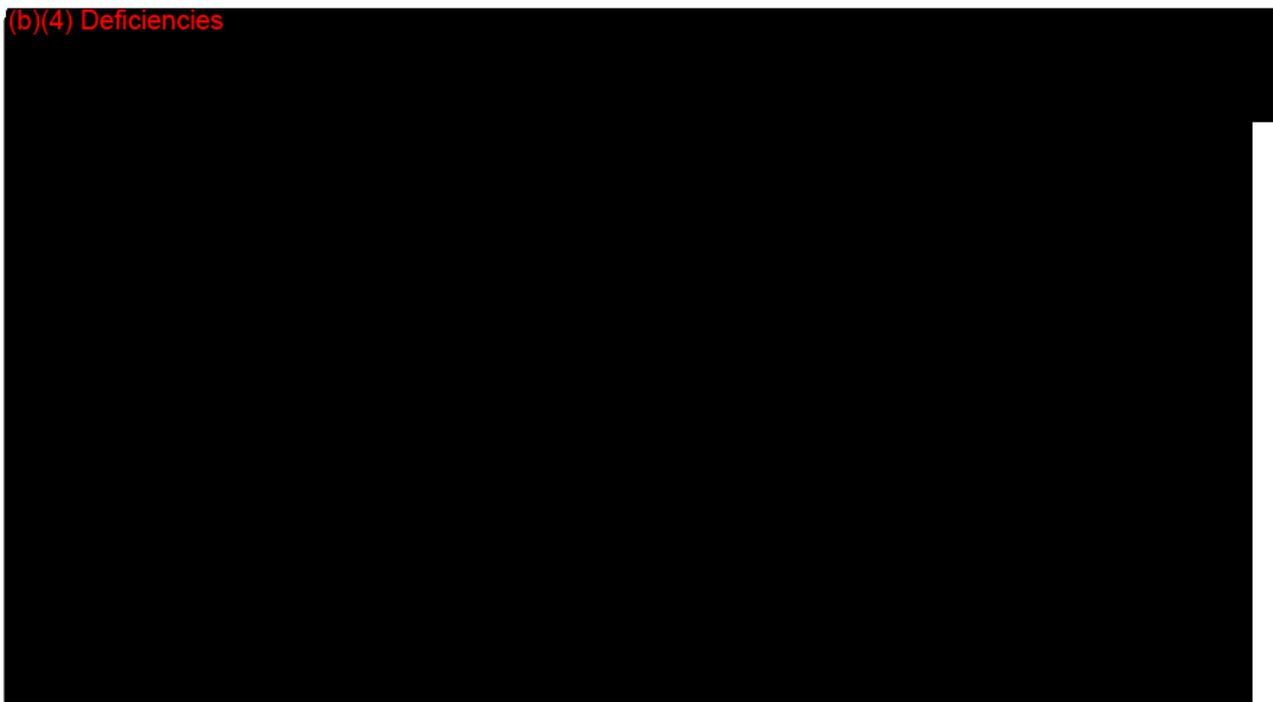
JUL 6 2000

Re: K001149
Bair Hugger Model 750
Dated: April 5, 2000 and June 1, 2000
Received: April 10, 2000

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4) Deficiencies



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Page 2 - Scott D. Augustine, M.D.

the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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9200 Corporate Boulevard
Rockville, Maryland 20850

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Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 3 - Scott D. Augustine, M.D.

cc: HFZ-401 DMC
 HFZ-404 510(k) Staff
 HFZ-450 Division
 D.O.

Prepared by: JRoy:ecf:06/21/00

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-450	JR	6/26/00						
HFZ-450	TXN	26 June						
450	Rampers	26 June						

U.S. GPO 1986-169-089

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) J.R.z

Subject: 510(k) Number K001149

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

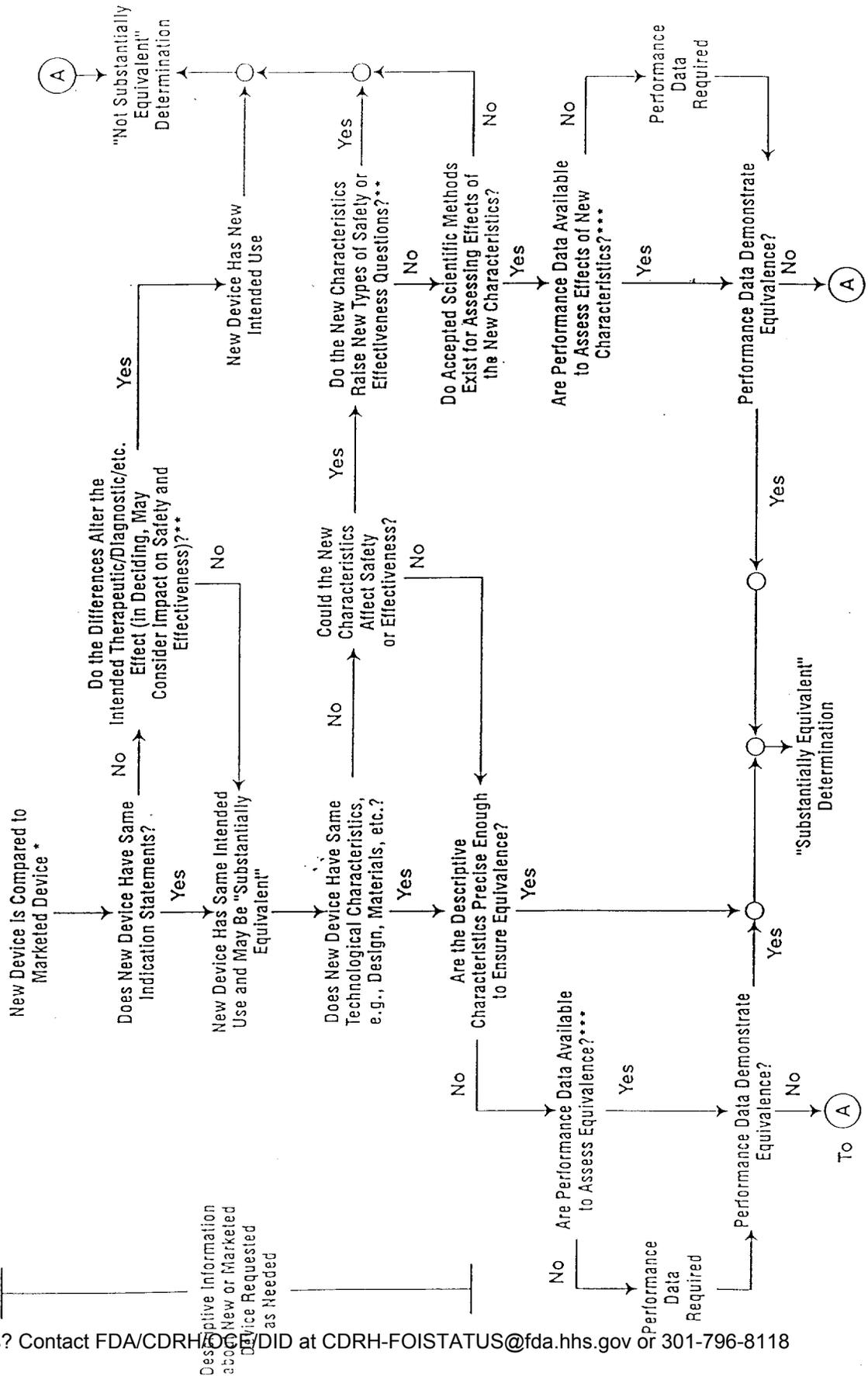
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: _____ (Branch Chief) CSTG (Branch Code) _____ (Date)

Final Review: Mark N. Mulherson (Division Director) 6/28/00 (Date)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH FOI DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendment) Devices is Unclear.

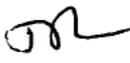
** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May include the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Office of Device Evaluation

MEMORANDUM

Date: June 15, 2000
From: Joydeb Roy 
Physicist (DCRND/CSPG)
To File: File (K001149)
Sponsor: Augustine Medical Inc.
Device: Bair Hugger Model 750
Predicate: Bair Hugger Model 505 (K960167)
Review: Traditional 90Day
Recommendation: Additional Information (AI)

Additional Information:

The company has submitted additional information recently (June 1,2000) stating that HEPA filters for this device cannot be obtained from the supplier. Instead of HEPA filter, a filter similar to and substantially equivalent to the predicate will be used.

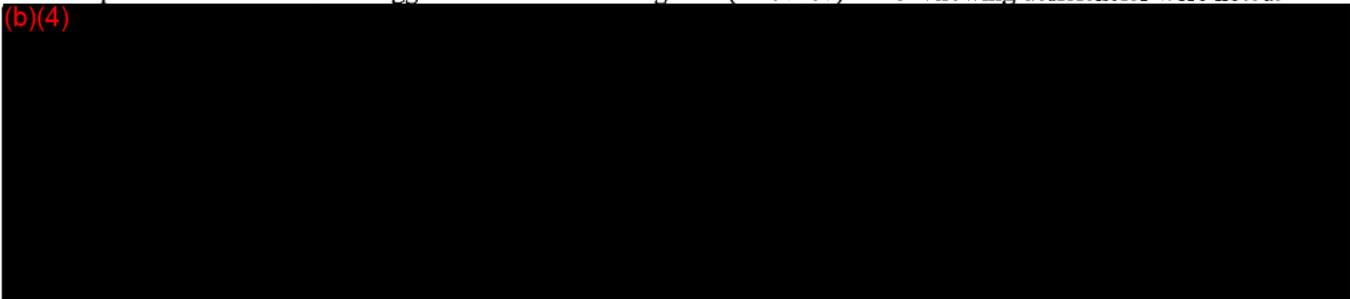
This filter is currently being used by the company in all of its cleared devices. Hence, with this amendment, the filters in Model 505 (predicate), and Model 750 (subject) will all be 0.2 micron filters. The company has provided modifications necessary to the pages affected by this change.

This is satisfactory.

SUMMARY OF FINDING:

This is a **Thermal Regulating System** intended for treating hypo and hyperthermia patients, both adults and pediatrics. The predicate device is Bair Hugger Model 505 Warming Unit (K960167). The following deficiencies were noted:

(b)(4)



Additional information will be required. A deficiency letter is being prepared.

Review Elements

1. Administrative Information:

Special (S), Abbreviated (A), or Traditional (T)	(T)
Truthful and Accurate Statement:	Yes
Indications for Use Statement:	Yes
Summary of SE (S) or Statement (ST):	S
Class III Certification/Summary	N/A
Predicate Device:	Bair Hugger Model 505 (K960167)
Panel Code/ Class/CFR:	DWJ/74/II/870.5900
Reason for Submission:	New

Missing Information: No

2. Indications for Use:

The Bair Hugger Model 750 Total Temperature Management System (subject device) is intended to prevent and treat hypothermia and provide warmth to cold and shivering patients. In addition, the device should be used whenever conditions exist that could cause patient to become cold.

The predicate device Augustine Medical Bair Hugger Model 505 Warming Unit (K960167) is indicated for hypothermia patients both adults and pediatric.

The device indication appears to be consistent with the predicate use.

Missing Information: No

3. Labeling:

Labeling information provided in Appendix A. The information includes operator's manual, device labels, marketing brochure, warning, contraindications, etc. Product literature, and labeling information provided for the predicate device.

The information is satisfactory.

Missing Information: No

4. Description:

(b)(4)

An error code display is included in the subject device. The predicate has no error code display. The primary over temperature sensor for the device is set to $47^{\circ}\text{C}\pm 2^{\circ}\text{C}$ and the secondary over temperature sensor is set to $53^{\circ}\pm 3^{\circ}\text{C}$. The primary sensor for the predicate unit is set to $53^{\circ}\text{C}\pm 3^{\circ}\text{C}$.

The average heat generated is 1644 BTU/h in the device and 1112 BTU/h in the predicate. The airflow is up to 48CFM (22.6 L/s) in the device and up to 30CFM (14.2L/s) in the predicate. The air filter is HEPA for the device and 0.2micro meter in the predicate. The heater is 1600W resistive in the device and 850W resistive in the predicate. The peak power consumption at 20°C is 1650W in the device and 1000W in the predicate.

The device has diagnostic features (b)(4). The predicate does not use microprocessor. Over temperature protection is available in both devices, but additional features such as, error correction is included only in the subject device. So while, general device features and technology are similar, the device seems to have several new and improved features overall.

Note: The comparison table (b)(4).

The information is not satisfactory.

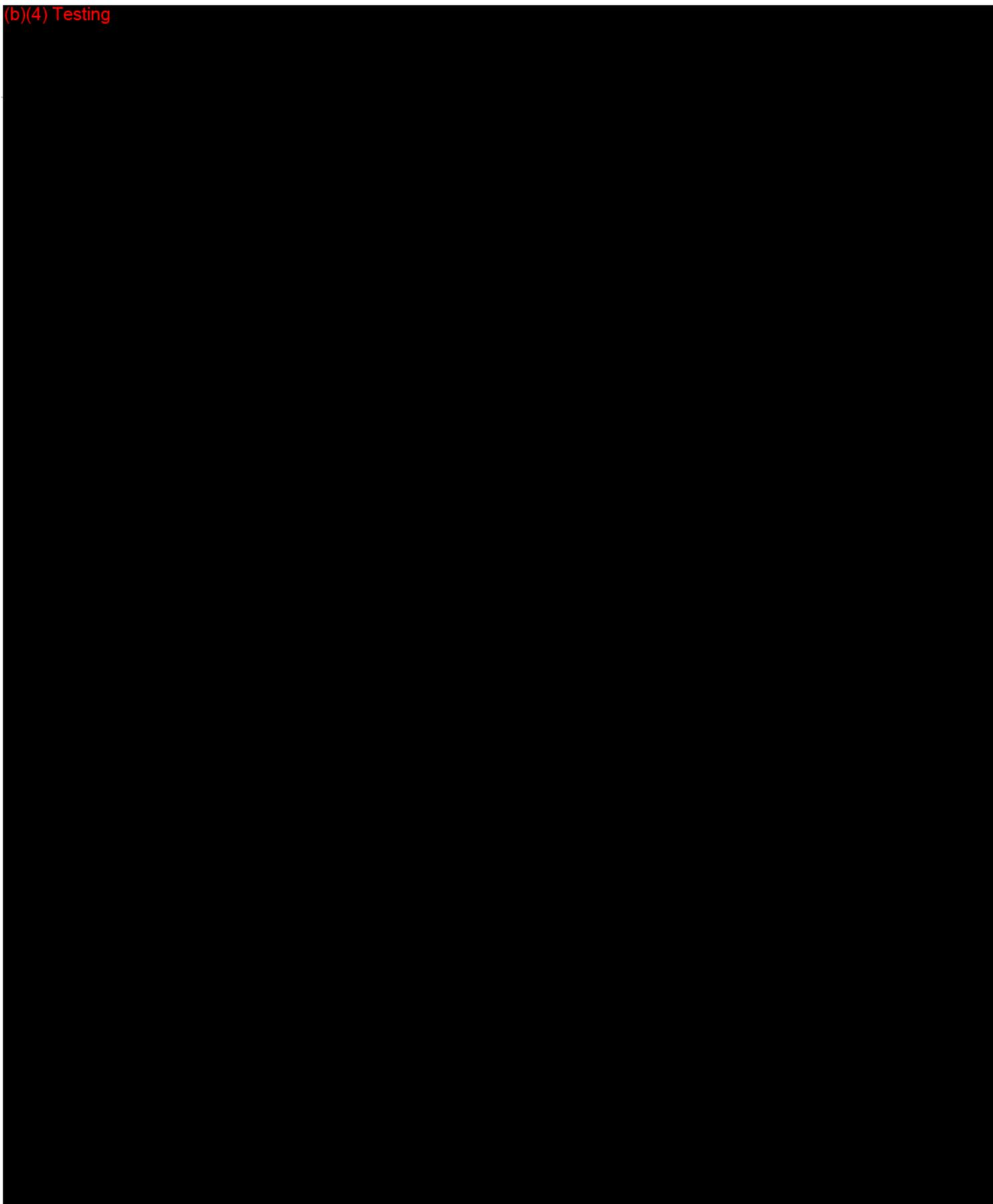
Missing Information:

(b)

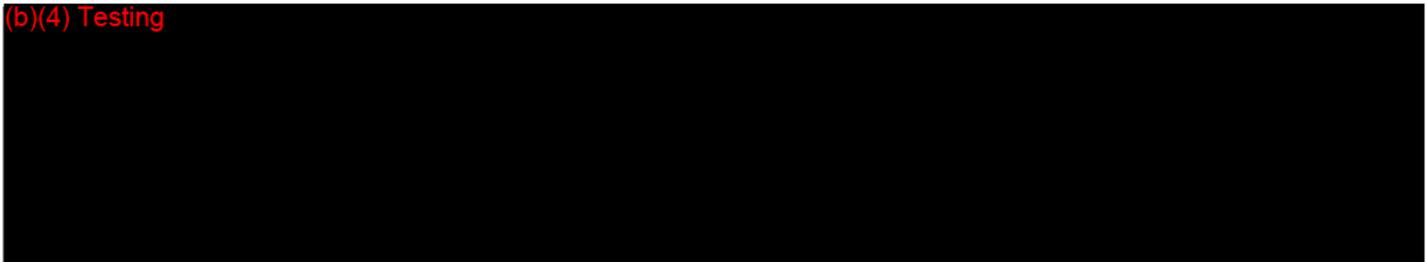
6. Performance Testing (In-Vitro):

(b)(4)

(b)(4) Testing



(b)(4) Testing



Missing Information:

Yes

7. Clinical Study :

N/A

Missing Information:

NONE

8. Animal Study:

N/A

Missing Information:

NONE

9. Biocompatibility Testing:

No biocompatibility test results are included. No biocompatibility tests were performed as no new patient contact materials are involved. All blankets are approved.

This is acceptable.

Missing information:

No

10. Sterility, Packaging and Shelf life:

No sterility information provided. The blankets are all approved.

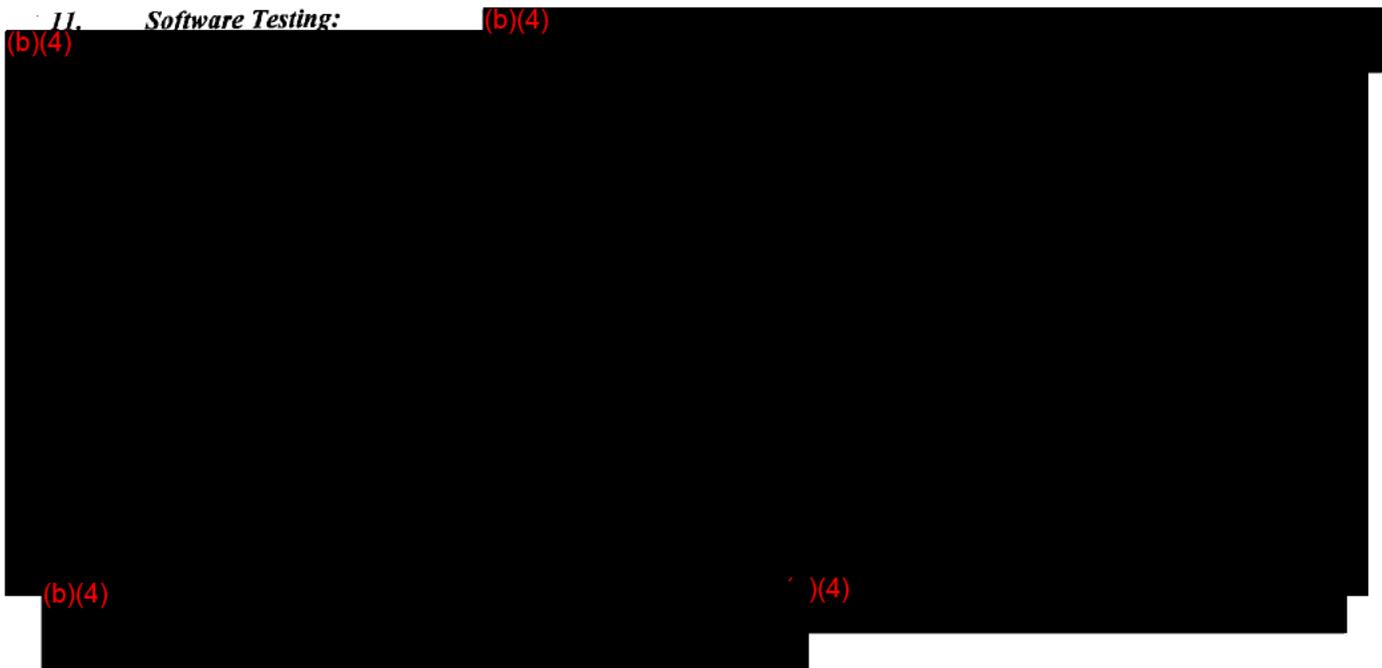
Missing Information:

No

11. Software Testing:

(b)(4)

(b)(4)



(b)(4)

(b)(4)

Hazard Analysis: The product has been determined to be a moderate level of concern, based upon its

application and the independent safety system built into the device Hazard Analysis have been performed but no data or information provided. (b)(4) (b)(4) were performed. No data or information provided.

NOTE: (b)(4)

Missing Information

Yes

12. Recommendation: AI

K-3
CANNOT DETERMINE EQUIVALENCY LETTER
- NEED MORE INFORMATION

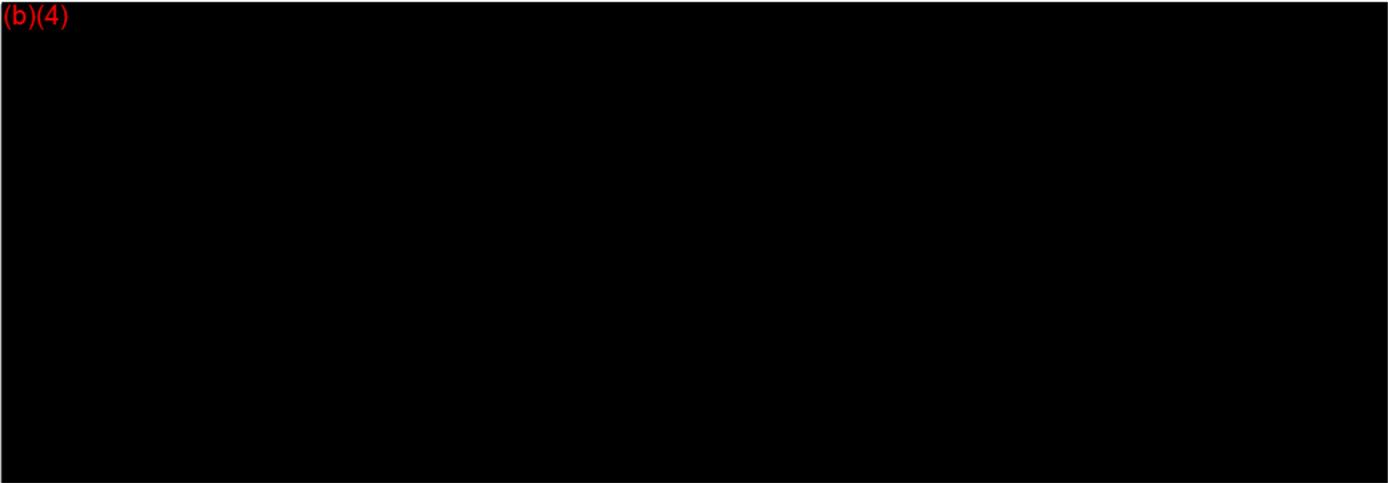
Scott D. Augustine, M.D.
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344

Re: K001149
Trade Name: Bair Hugger Model 750
Dated: April 5, and June 1, 2000
Received: April 16, and June 2, 2000

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration

Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact [DIVISION REPRESENTATIVE] at (301) 594-[]. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

[Division Director]

Office of Device Evaluation
Center for Devices and
Radiological Health

cc:

HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

K001149/A1



June 1, 2000

Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
Document Control Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re.: Amendment to 510(k) K 001149

Reviewer: Mr. Joydeb Roy

Dear Mr. Roy:

Augustine Medical would like to make an amendment to the above listed 510(k) that is currently in review. The modification is not significant relative to the submission, but the device would be better described with the amendment in place.

In the 510(k) submission, the air filter is described as a HEPA filter. Our plan has been to offer a HEPA filter as a marketing advantage. There are no problems with the filter in our current (SE device) units that caused us to consider the HEPA filter; it was simply added as a marketing tool.

The basis for the requested amendment is the fact that we cannot obtain the new, higher efficiency HEPA filter media from our supplier at this time. With this new media, we are able to maintain the device air volume described in the 510(k). But because we cannot get this HEPA filter media now, we want to have the option to use our current filter characteristics.

We want to amend the 510(k) to include a filter that is substantially equivalent to the filter currently being used in all of our cleared devices. The description of this filter will be the same, but the physical size will be slightly smaller. With this amendment, the filters in our currently cleared devices (including the SE device Model 505) and the Model 750 will all be 0.2 micron filters.

The change to add the filter with the SE device characteristics will not affect the test results described in the 510(k) submission as the device outputs are matched to the design criteria, which are maintained with either filter.

I have included the pages that need to be changed to accommodate the requested amendment. There are only four pages that need to be replaced. Those pages are:

- Page 11, Section D, Substantial Equivalence Table
- Page 30, 510(k) Summary
- Page 35, Appendix A, Product Claims Model 750
- Page 13 of Model 750 Operation Manual, Appendix A

I have included two copies of each of the amended pages for your files. I have also included reduced size copies of the original pages with the changes highlighted for your convenience.

RECEIVED
2 JUN 08 14 14
FDA/CDRH/OCE/DID

Handwritten initials/signature

If you have additional questions or comments, please feel free to contact me. Thank you, in advance, for your cooperation with this amendment.

Sincerely,

A handwritten signature in cursive script that reads "David Westlin". The signature is written in black ink and is positioned to the right of the word "Sincerely,".

David Westlin
Director of Regulatory Affairs and Quality Assurance
(for Scott D. Augustine, MD, CEO)

April 5, 2000

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device, System Thermal Regulating 74 DW1, Patient Warming System called the Bair Hugger® Total Temperature Management® System - Model 750 Warming Unit. The predicate device is the Bair Hugger® Patient Warming System, Model 505 Warming Unit.

1. Summary of Safety:

- A. Injuries to tissue:** Cutaneous burns. Thermal injury is determined by a combination of temperature and time. Patients with ischemic limbs or extremely poor perfusion are especially susceptible to thermal injuries.
- Prevention:** The Bair Hugger® Model 750 maximum heat output (range of 43 to 45°C) does not provide temperatures high enough to cause burns to tissue when used as directed. Performance testing demonstrated that by the time the air leaves the Bair Hugger warming unit, flows through the hose and is circulated through the inflatable blanket placed over the patient, temperatures have dropped to an average of 36.9°C to 41.8°C. These temperatures are well within the range of safety.^{1,2}
- Over-temperature safety system:** Bair Hugger warming unit overtemperature detection systems are independent electrical and mechanical systems, which use sensors to detect an over temperature condition. The system triggers audible and visual alarms and deactivates the heater and blower when an over-temperature condition is detected.
- Labeling:** Labels affixed to each Bair Hugger blanket at the inlet port and packaged with each Bair Hugger blanket read as follows:
Contraindications:
Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury to ischemic limbs may occur.
- B. Hyperthermia:** Warming treatment continued past the point of the patient reaching normothermia may eventually produce hyperthermia.
Prevention: Instructions packaged with each Bair Hugger® blanket instruct the user to "Monitor the patient's temperature at least every 10-20 minutes."
- C. Other Possible Safety Concerns:**
Contamination: Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.
 Prevention of airborne contamination: All Bair Hugger® blankets designed for use in the operating room feature a tape barrier which prevents air from migrating toward the surgical site. Additionally, air is filtered through a HEPA filter. Two studies have concluded that the Bair Hugger® 500 Series Units do not increase the incidence of microbial or wound contamination.^{4,5} The Model 750 filter is more effective than the Model 505 filter.

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Page 30, 510(k) Summary

Substantial Equivalence Table

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients
Clinical areas for device use	Adult and pediatric patients	Adult and pediatric patients
Intended patient population	Can be set on table, floor, shelf or other hard surface; attached to a rack or stand; clamped to an I.V. pole, or hung on a bed rail	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole, or hung on a bed rail
Device positioning	13.5" x 9.5" x 10.5"	13" x 10" x 11"
Dimensions	@12.5 lbs	@11.5 lbs
Weight	Plastic/metal	Plastic/metal
Materials	Detachable, flexible, fixed length or collapsible, washable, 2.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter
Warming unit hose	Every year	Every 6 months or 500 hours of use
Recommended filter change	Shuts the heater off if damaged	Shuts the heater off if damaged
Temperature sensor	Ambient to 45 degrees	Ambient to 46 degrees
Temperature range (at nozzle)	1644 BTU/h (avg.)	1112 BTU/h (avg.)
Heat generated	20 Amp fused circuit	20 Amp fused circuit
Electrical requirements	15' hospital grade	15' hospital grade
Power cable	Up to 48 cfm (22.6 L/s)	Up to 30 cfm (14.2 L/s)
Airflow at comparable operating pressure	HEPA	HEPA
Air filter	40 watt DC	0.2uM
Motor	1600W resistive	Fractional horsepower, single-phase, AC
Heater	Meets requirements of UL 2601 and EN 60601-1	850W resistive
Leakage current	Peak: 1650W Avg.: 800W	Meets requirements of UL 2601 and EN 60601-1 Peak: 1000W Avg.: 450W
Power consumption at 20°C ambient condition	Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician. Upon power-up and mode change, the software performs self-test functions	Over temperature and temperature output testing and calibration can be performed by biomedical technician
Diagnostics		

11

Page 11, Section D, Substantial Equivalence

Copies of original pages with changes highlighted

Specifications

Physical Characteristics	
Dimensions	13.5 in. high x 9.5 in. deep x 9.5 in. wide 34 cm high x 24 cm deep x 24 cm wide
Weight	12.5 lbs.
Relative Noise Level	53 decibels
Hose	Detachable, flexible, washable; compatible with Bair Hugger® Model 241® Fluid Warming System
Filtration System	HEPA level
Recommended Filter Change	Once a year
Mounting	Has I.V. pole clamp and bed rail hook with safety strap; can be placed on hard surface
Temperature Characteristics	
Recommended Operating Environment	15°C-25°C
Temperature Control	Electronically controlled
Heat Generated	1644 btu/hr (average)
System Time to 38°C (@100°F)	5-10 secs in ambient temperature conditions
Operating Temperatures	
Average temperatures at the end of the hose, assuming the back pressure of an Augustine Medical, Inc. warming blanket, or an Augustine Medical, Inc. temperature test unit:	
HIGH:	43° ± 2°C 109.4° ± 3.6°F
MED:	38° ± 2°C 100.4° ± 3.6°F
LOW:	32° ± 2°C 89.6° ± 3.6°F
Safety System	
Thermostat	Independent electronic circuit. Thermal cutoff shuts the heater off at preset high temperature of 47°C at the end of the hose.
Overcurrent Protection	Dual input fused lines
Alarm System	
Over temperature: flashing red light with audible alarm; heaters and blower shut down; membrane keypad becomes unresponsive. Error: audible alarm, unit goes into standby mode, error code displays in LCD window.	
Certifications	
EN60601-1, EN 60601-1-2, UL 2601-1, CAN/CSA - C22.2, NO. 601-1	
Classification	
Classified under IEC 601-1 Guidelines as Class I, Type BF, Ordinary equipment, Continuous operation Classified under the Medical Device Directive (93/42/EEC) as class 1b.	
Electrical Characteristics	
Leakage Current	Meets UL 2601 and EN 60601-1 requirements
Heating Element	1600W Resistive
Blower Motor	Operating speed: approx. 4000 rpm up to 48 cfm Airflow: Power Consumption Peak: 1650W Average: 800W
Power Cord	15-foot, SJT, 3 cond., 15A 4.6 meter, HAR, 3 cond., 10A
Device Ratings	110-120VAC, 60Hz, 13 Amperes, or 220-240VAC, 50Hz, 8 Amperes, or 100VAC, 50/60 Hz, 16 Amperes
Fuses	13A (110 - 120 VAC Units) 8A (220 - 240 VAC Units) 16A (100VAC Units)
Diagnostics	Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician.

Augustine Medical, Inc.

Page 13, Model 750 Operation Manual, Appendix A

Model 750 Warming Unit Claims

- The Model 750 unit is lightweight and compact, making it easy to set up, transport and store.
- The Model 750 unit offers easy, flexible mounting options so the user can quickly find the optimum location for the unit.
- The Model 750 unit delivers up to 48 cubic feet/minute air flow, accommodating a wide range of Bair Hugger blanket performance needs.
- The Model 750 unit includes a HEPA filter.
- The Model 750 unit is quiet—the unit doesn't add to the noise in the busy operating room environment.
- The Model 750 unit delivers safe and effective output temperatures in all settings to help prevent and treat hypothermia.
- Hose end temperature sensing provides stable blanket temperatures regardless of ambient temperatures

Page 35, Appendix A, Product Claims Model 750

Copies of original pages with changes highlighted

Substantial Equivalence Table

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Patient warming	Patient warming
Clinical areas for device use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Device positioning	Can be set on table, floor, shelf or other hard surface; attached to a rack or stand; clamped to an I.V. pole; or hung on a bed rail	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail
Dimensions	13.5" x 9.5" x 10.5"	13" x 10" x 11"
Weight	@12.5 lbs	@11.5 lbs.
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length or collapsible, washable, 2.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter
Recommended filter change	Every year	Every 6 months or 500 hours of use
Temperature sensor	Shuts the heater off if damaged	Shuts the heater off if damaged
Temperature range (at nozzle)	Ambient to 45 degrees	Ambient to 46 degrees
Heat generated	1644 BTU/h (avg.)	1112 BTU/h (avg.)
Electrical requirements	20 Amp fused circuit	20 Amp fused circuit
Power cable	15' hospital grade	15' hospital grade
Airflow at comparable operating pressure	Up to 48 cfm (22.6 L/s)	Up to 30 cfm (14.2 L/s)
Air filter	0.2µM or HEPA	0.2µM
Motor	40 watt DC	Fractional horsepower, single-phase, AC
Heater	1600W resistive	850W resistive
Leakage current	Meets requirements of UL 2601 and EN 60601-1	Meets requirements of UL 2601 and EN 60601-1
Power consumption at 20°C ambient condition	Peak: 1650W Avg.: 800W	Peak: 1000W Avg.: 450W
Diagnostics	Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician. Upon power-up and mode change, the software performs self-test functions	Over temperature and temperature output testing and calibration can be performed by biomedical technician

June 1, 2000

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device, System Thermal Regulating 74 DWJ, Patient Warming System called the Bair Hugger® Total Temperature Management® System - Model 750 Warming Unit. The predicate device is the Bair Hugger® Patient Warming System, Model 505 Warming Unit.

1. Summary of Safety:

A. Injuries to tissue: Cutaneous burns. Thermal injury is determined by a combination of temperature and time. Patients with ischemic limbs or extremely poor perfusion are especially susceptible to thermal injuries.

Prevention: The Bair Hugger® Model 750 maximum heat output (range of 43 to 45°C) does not provide temperatures high enough to cause burns to tissue when used as directed. Performance testing demonstrated that by the time the air leaves the Bair Hugger warming unit, flows through the hose and is circulated through the inflatable blanket placed over the patient, temperatures have dropped to an average of 36.9°C to 41.8°C. These temperatures are well within the range of safety^{1,2}.

Over-temperature safety system: Bair Hugger warming unit overtemperature detection systems are independent electrical and mechanical systems, which use sensors to detect an over temperature condition. The system triggers audible and visual alarms and deactivates the heater and blower when an over-temperature condition is detected.

Labeling: Labels affixed to each Bair Hugger blanket at the inlet port *and* packaged with each Bair Hugger blanket read as follows:

Contraindications:

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

B. Hyperthermia: Warming treatment continued past the point of the patient reaching normothermia may eventually produce hyperthermia³.

Prevention: Instructions packaged with each Bair Hugger® blanket instruct the user to "Monitor the patient's temperature at least every 10-20 minutes."

C. Other Possible Safety Concerns:

Contamination: Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.

Prevention of airborne contamination: All Bair Hugger® blankets designed for use in the operating room feature a tape barrier which prevents air from migrating toward the surgical site. Additionally, air is filtered through a filter. Two studies have concluded that the Bair Hugger® 500 Series Units do not increase the incidence of microbial or wound contamination^{4,5}.

Model 750 Warming Unit Claims

- The Model 750 unit is lightweight and compact, making it easy to set up, transport and store.
- The Model 750 unit offers easy, flexible mounting options so the user can quickly find the optimum location for the unit.
- The Model 750 unit delivers up to 48 cubic feet/minute air flow, accommodating a wide range of Bair Hugger blanket performance needs.
- The Model 750 unit is quiet—the unit doesn't add to the noise in the busy operating room environment.
- The Model 750 unit delivers safe and effective output temperatures in all settings to help prevent and treat hypothermia.
- Hose end temperature sensing provides stable blanket temperatures regardless of ambient temperatures

Specifications

Physical Characteristics

Dimensions 13.5 in. high x 9.5 in. deep x 9.5 in. wide
34 cm high x 24 cm deep x 24 cm wide

Weight 12.5 lbs.

Relative Noise Level

53 decibels

Hose

Detachable, flexible, washable; compatible with Bair Hugger® Model 241® Fluid Warming System

Filtration System

0.2 µ M or HEPA level (optional)

Recommended Filter Change

Once a year

Mounting

Has I.V. pole clamp and bed rail hook with safety strap; can be placed on hard surface

Temperature Characteristics

Recommended Operating Environment

15°C-25°C

Temperature Control

Electronically controlled

Heat Generated

1644 btu/hr (average)

System Time to 38°C (@100°F)

5-10 secs in ambient temperature conditions

Operating Temperatures

Average temperatures at the end of the hose, assuming the back pressure of an Augustine Medical, Inc. warming blanket, or an Augustine Medical, Inc. temperature test unit:

HIGH:	43° ± 2°C	109.4° ± 3.6°F
MED:	38° ± 2°C	100.4° ± 3.6°F
LOW:	32° ± 2°C	89.6° ± 3.6°F

Safety System

Thermostat

Independent electronic circuit. Thermal cutoff shuts the heater off at preset high temperature of 47°C at the end of the hose.

Overcurrent Protection

Dual input fused lines

Alarm System

Over temperature: flashing red light with audible alarm; heaters and blower shut down; membrane keypad becomes unresponsive. Error: audible alarm, unit goes into standby mode, error code displays in LCD window.

Certifications

EN60601-1, EN 60601-1-2, UL 2601-1, CAN/CSA - C22.2, NO. 601-1

Classification

Classified under IEC 601-1 Guidelines as Class I, Type BF, Ordinary equipment, Continuous operation
Classified under the Medical Device Directive (93/42/EEC) as class 11b.

Electrical Characteristics

Leakage Current

Meets UL 2601 and EN 60601-1 requirements

Heating Element

1600W Resistive

Blower Motor

Operating speed:	approx. 4000 rpm
Airflow:	up to 48 cfm

Power Consumption

Peak:	1650W
Average:	800W

Power Cord

15-foot, SJT, 3 cond., 15A
4.6 meter, HAR, 3 cond., 10A

Device Ratings

110-120VAC, 60Hz, 13 Amperes, or
220-240VAC, 50Hz, 8 Amperes, or
100VAC, 50/60 Hz, 16 Amperes

Fuses

13A (110 - 120 VAC Units)
8A (220 - 240 VAC Units)
16A (100VAC Units)

Diagnostics

Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician.

Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name:						K						
Submitter (Company):												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D	T R A D I T I O N A L	✓ IF ITEM IS NEEDED AND IS MISSING			
YES		NO		YES		NO		YES		NO		
1. Cover Letter clearly identifies Submission as:						GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		
1. Cover Letter clearly identifies Submission as:												
a) "Special 510(k): Device Modification"												
b) "Abbreviated 510(k)"												
c) Traditional 510(k)												
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS								✓ IF ITEM IS NEEDED				
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES		NO		YES		
a) trade name, classification name (establishment registration) number, device class										✓		
b) OR a statement that the device is not yet classified						FDA may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA				✓		
d) compliance with Section 514 - performance standards						NA						
e) address of manufacturer										✓		
f) Truthful and Accurate Statement										✓		
g) Indications for Use enclosure										✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)										✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)										✓		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals										✓		
k) Proposed Labeling:										✓		
i) package labeling (user info)										✓		
ii) statement of intended use										✓		
iii) advertisements or promotional materials										✓		
i) MRI compatibility (if claimed)										✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:										✓		
i) Labeling										✓		
ii) intended use										✓		
iii) physical characteristics										✓		
iv) anatomical sites of use										✓		
v) performance (bench, animal, clinical) testing						NA				✓		
vi) safety characteristics						NA				✓		
m) If kit, kit certification										✓		
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR										* If no - STOP not a special		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*				* If no - STOP not a special
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							✓
i) component & material							✓
ii) identify patient-contacting materials							✓
iii) biocompatibility of final sterilized product							✓
b) Sterilization and expiration dating information:							✓
i) sterilization method							✓
ii) SAL							✓
iii) packaging							✓
iv) specify pyrogen free							✓
v) ETO residues							✓
vi) radiation dose							✓
c) Software validation & verification:							✓
i) hazard analysis							✓
ii) level of concern							✓
iii) development documentation							✓
iv) certification							✓

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 4/18/00
 Reviewer: William E. Hoban Jr
 Concurrence by Review Branch: _____

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

YES NO

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 11, 2000

AUGUSTINE MEDICAL, INC.
10393 WEST 70TH ST.
EDEN PRAIRIE, MN 55344
ATTN: SCOTT D. AUGUSTINE

510(k) Number: K001149
Received: 10-APR-2000
Product: AUGUSTINE MEDICAL
BAIR HUUGER, MODEL
750 TOTAL
TEMPERATURE

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

15 001149



April 5, 2000

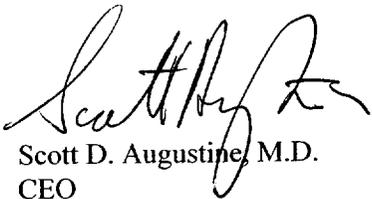
Office of Device Evaluation
Center for Biologics Evaluation and Research
Food and Drug Administration
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: 510(k) Notification: Bair Hugger® Model 750 Total Temperature Management System

Pursuant to the regulations regarding 510(k) applications, Augustine Medical, Inc. intends to market the Bair Hugger Model 750 Total Temperature Management System. Augustine Medical regards this device to be substantially equivalent to existing devices currently on the market. We consider our intent to market these devices as confidential commercial information and request that it be considered as such by FDA.

The submission and attachments are submitted in duplicate as required by regulation. If you have any questions regarding this 510(k) submission, please contact the undersigned at (952) 947-1200 or (952) 947-1400 fax.

Sincerely,


Scott D. Augustine, M.D.
CEO

FDA/CDRH/OCE/DNC
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Premarket Notification
Truthful and Accurate Statement
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as CEO and Medical Director of Augustine Medical, Inc., I believe to the best of my knowledge, that all data and information submitted in this 510(k) are truthful and accurate and that no material fact has been knowingly omitted.



Scott Augustine, M.D.
CEO, Augustine Medical, Inc.

Statement of Confidentiality

Augustine Medical, Inc. considers the information in this submission to be confidential commercial information. We have not, to our knowledge, released this information through advertising or any other manner to anyone outside the employ of Augustine Medical, Inc. Augustine Medical, Inc. has taken precautions to protect the confidentiality of this information under Section 807.95, Confidentiality of Information. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

Indications for Use

510(k) number: Not known

Device name: The Bair Hugger® Model 750 Total Temperature Management® System

Indications for use: The Bair Hugger® Model 750 Total Temperature Management® System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the Bair Hugger® Model 750 Total Temperature Management® System should be used whenever conditions exist that could cause patients to become cold.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801-109)

or

Over the Counter Use _____

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Bair Hugger®, Model 241®, and Total Temperature Management® are registered trademarks of Augustine Medical Inc.

A. Administrative Information

- A. Submitter's Name and Address
Augustine Medical, Inc. • 10393 W. 70th Street • Eden Prairie, MN 55344
• (952) 947-1200
- B. Contact Person
Scott D. Augustine, M.D. • CEO • phone: (952) 947-1200,
fax: (952) 947-1400
- C. Establishment Registration Number of Submitter
2183725
- D. Manufacturing Facility
Augustine Medical, Inc. • 10393 W. 70th Street • Eden Prairie, MN 55344
- E. Device Name
Proprietary Name: Augustine Medical Bair Hugger® Model 750 Total
Temperature Management® System- (Model 750 Warming Unit, Bair
Hugger Blankets, and Model 241 Fluid Warming Set)
 - Common Name: Patient Warming System
 - Classification Name: System, Thermal, Regulating
- F. Device Classification
Class II, 870.5900
- G. Action Taken to Comply with Section 514 of the Act
The Agency has recognized the EN standards EN 60601-1: Medical
electrical equipment, Part 1: General requirements for safety; EN 60601-1-
2: Collateral standard. Electromagnetic compatibility. Requirements and
tests.
- H. Reason for 510(k) Submission
Introduction of a new model: the Bair Hugger Model 750 Warming Unit
- I. Predicate Device
Augustine Medical Bair Hugger Model 505 Warming Unit (K960167)

B. Background

Intraoperative heat loss is a problem for 60-80% of all surgical patients. Surgical patients lose heat by five basic modalities:

- Conduction (e.g., skin contact on cool surfaces)
- Infusion of cold I. V. fluids
- Radiation (e.g., temperature difference between the patient and environment)
- Convection (e.g., high operating room airflow)
- Evaporation (e.g., open wounds, surgical prep solution)

Heat loss may occur in locations other than a hospital operating room from these and other environmental conditions. Heat loss can occur in settings outside the hospital due to:

- Cold exposure (e.g., frostbite, environmental hypothermia, drowning)
- Spinal trauma (e.g., sports-related or vehicular accidents)
- Older patients who have compromised temperature regulation (e.g., residents of long-term care facilities)
- Immobilized patients (e.g., sports-related or vehicular accidents)

Findings from a recent meta analysis¹ show that maintaining intraoperative normothermia (core temperature of 37°C) with Bair Hugger therapy can reduce hospitalization costs between \$2500 and \$7000 per surgical patient. Maintaining normothermia reduces costs by:

- Decreasing the rate of postoperative wound infections by 64%
- Decreasing the likelihood of postoperative myocardial infarction by 44%
- Decreasing ICU time by 43%
- Shortening hospital length of stay by 40%
- Lowering mortality rates by 55%
- Reducing the use of blood products - 86% less red blood cells, 79% less plasma, 78% less platelets
- Decreasing the likelihood of mechanical ventilation by 34%
- Reducing the probability of needing transfusion by 40%

Patients are at risk of becoming hypothermic with the induction of anesthesia. Consequently, the benefits of warming patients accrue even in procedures of one hour or less where patients are likely to drop only 1°C to 2°C in temperature. The cost of effectively warming patients to prevent perioperative hypothermia is insignificant compared with the enormous costs of complications brought on by hypothermia. The Bair Hugger Model 750 warming unit, when used with Bair Hugger blankets and, where appropriate, 241 fluid warming, has been designed to reduce or eliminate heat loss in patients.

1. Mahoney CB, Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. *AANA Journal*. 1999;67:155-164.

C. Description of the Device

Reason for Submission

The reason for this submission is to notify the FDA that Augustine Medical, Inc. plans to bring a new substantially equivalent patient warming unit to market. This device has not previously been submitted for market clearance by Augustine Medical.

General Description of the Model 750 Total Temperature Management System

The Model 750 Total Temperature Management system consists of:

- A portable forced air warming unit—the Model 750 warming unit
- A Bair Hugger blanket
- The Model 241 fluid warming system (if fluid warming is desired)

The Model 750 Total Temperature Management system effectively warms the patient through skin surface and, where appropriate, fluid warming, to prevent and treat hypothermia, or to provide thermal comfort. It is intended to be used for adult and pediatric patients.

Functional Description of the System

The system is made up of a warming unit and a warming blanket. The warming unit is attached to the blanket by means of a flexible hose. Warm air is generated in the unit and flows through the hose and into the blanket. Depending on the blanket model, the blanket is placed either around, over, or underneath the patient. Small perforations on the patient side of the blanket allow the warm air to be dispersed over the patient.

For fluid warming applications, the 241 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 241 tubing and warmed fluid exits from the distal end of the tubing.

The control circuitry of the warming unit maintains hose end operating temperatures at $43^{\circ}\pm 2^{\circ}\text{C}$ (High), $38^{\circ}\pm 2^{\circ}\text{C}$ (Medium), $32^{\circ}\pm 2^{\circ}\text{C}$ (Low), and Ambient. The unit has an over temperature warning system with both visual and audible alarms.

Temperatures are measured through use of (b)(4) on the system:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Although these temperatures are safe, a larger temperature tolerance must be built into the system. In the Model 750 unit, (b)(4)

The same opportunity to (b)(4)

In the case of the Model 750 unit, (b)(4)

(b)(4)

(b)(4) and provides safety control for the system. The software manages the following features:

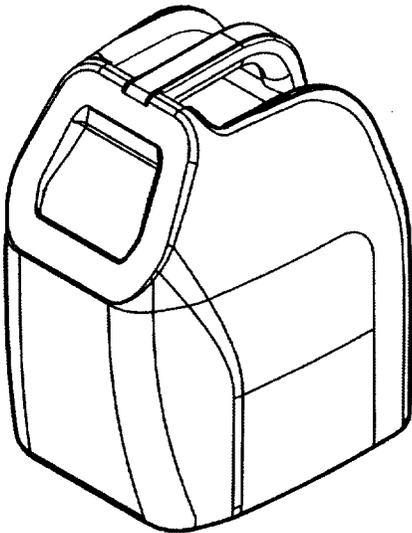
(b)(4)

Physical Description of the Warming Unit

The heating elements and electronics are housed in a plastic and metal case. A blower outlet on the unit is used to attach the warming hose to the unit. The warming unit can be used positioned on a table, floor, rack or stand, clamped to an IV pole, or hung on a bed rail. The unit plugs into a standard, hospital grade outlet. The warming unit is a reusable device.

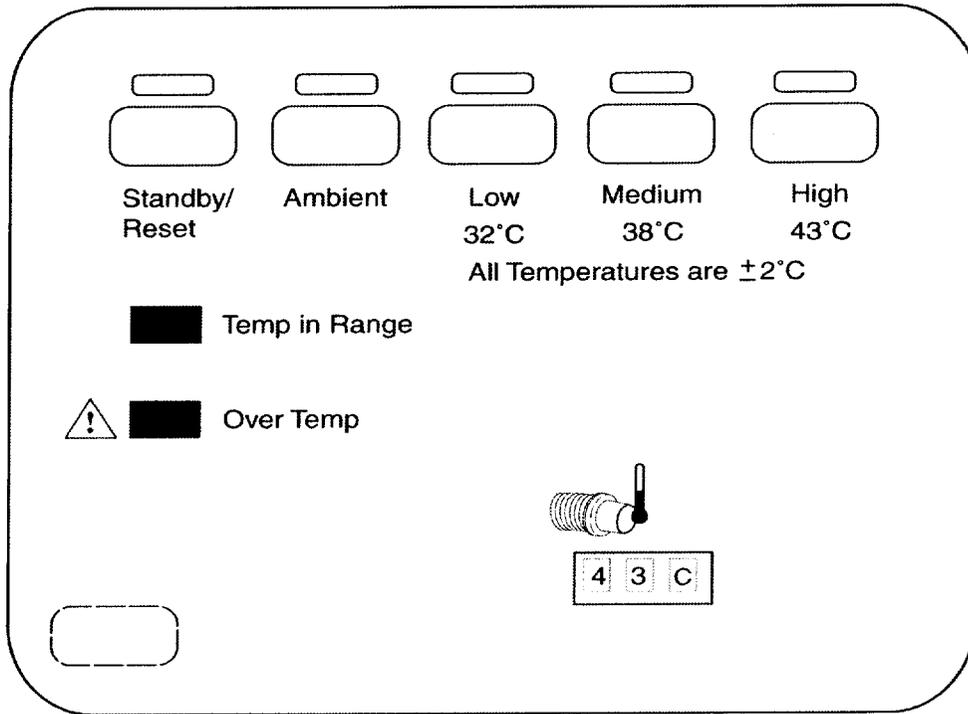
The user interface consists of a control panel that includes:

- Buttons with their respective LED indicators for High, Medium, Low and Ambient temperature settings and Standby/Reset mode
- LED indicators for temperature in range and over temperature conditions
- LCD window which displays the temperature at the distal end of the warming unit hose in °C
- Hidden alternative function key which allows the users to perform and confirm calibration, test the over temperature alarm, and view service information



The Model 750 Warming Unit

Description of Control Panel Features



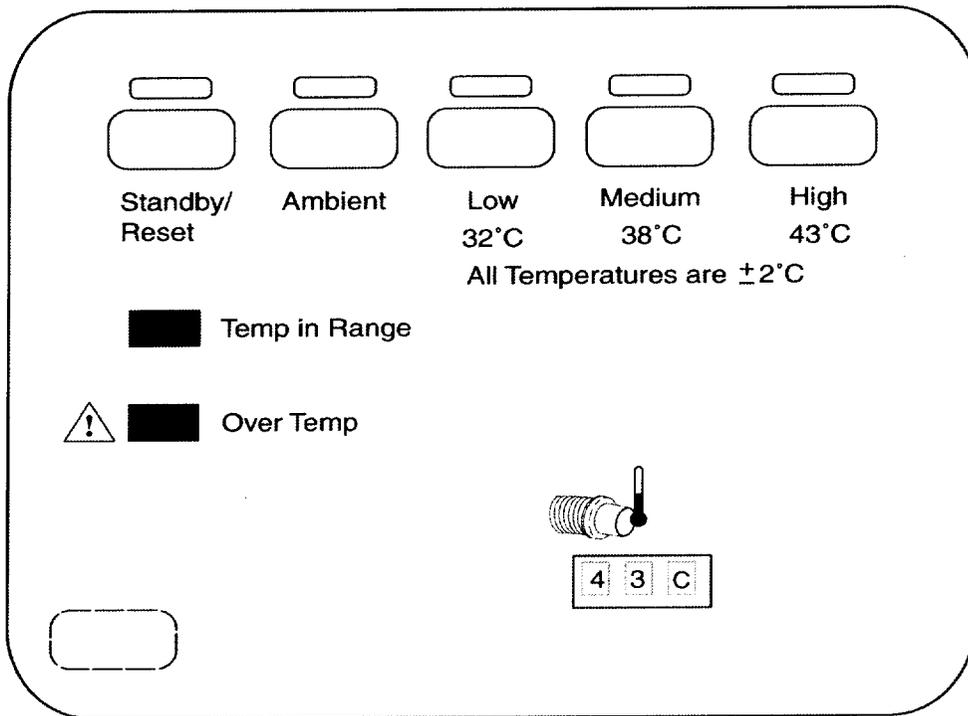
Standby Mode

- Standby/Reset LED continuously illuminated
- Blower, heater and LCD window are deactivated
- Operating time function does not begin incrementing
- Alarm and error functions remain active

"Ambient" Operating Mode

- Ambient LED continuously illuminated
- "Temp in Range" is not illuminated
- Blower is activated
- Heater is not activated
- Operating time function begins incrementing
- LCD window displays nozzle temperature

Description of Control Panel Features (cont.)



"Low" "Medium" and "High" Operating Modes

- Selected temperature mode (Low, Medium or High) LED continuously illuminated
- "Temp in Range" illuminates when nozzle temperature is maintained at the selected temperature setpoint
- Blower is activated
- Heater is activated
- Operating time function begins incrementing
- Hose end temperature is displayed in LCD window in °C

Alternative Function Key

- Allows biomed to perform and confirm calibration
- Allows biomed to test over temperature alarm function
- Allows biomed to view service information
- When key is pressed and held, selected operating mode keys are remapped with an alternative function
- When key is pressed a second time, warming unit returns to its operational mode

Safety Features of the Model 750 Warming Unit

1. Operating Temperature Sensor

A sensor is located in the distal end of the hose (blanket end). This nozzle sensor (b)(4)

(b)(4)

2. Over Temperature Safety Feature

In the event there is a fault condition that allows the temperature to increase above the operating range, an independent safety alarm system is activated. A second sensor is located in the distal end of the hose (blanket end). In the case of a fault condition, the software will detect an over temperature condition by constantly monitoring the temperature via this sensor. When the temperature reaches $47\pm 2^{\circ}\text{C}$, the over temperature alarm system is activated:

- Audible and visible alarms are activated
- The warming unit goes into *Standby* mode
- The heater and blower are turned off
- Nozzle temperature falls to ambient

The user must reselect the temperature setting to return the unit to operational mode. If the over temperature fault condition persists, the unit will return to alarm status.

All temperature and safety controls are designed to meet the requirements of UL 2601, IEC 601-1 and EN 60601-1.

3. Error Mode

In an error condition, the audible alarm sounds and the LCD window displays the error code. The user silences the alarm by pressing the *Standby/Reset* button.

Design Control and Quality Assurance

Augustine Medical Design Control Process. The design for the Bair Hugger® Model 750 warming unit was developed in accordance with Augustine Medical Design Control procedures. These procedures are in compliance with the QSR as well as ISO 9001 requirements.

Failure Mode Effect and Analysis are performed during various design stages.

Manufacturing Quality Assurance. The Bair Hugger Model 750 warming unit and all Bair Hugger blankets are manufactured at Augustine Medical, Inc., 10393 West 70th Street, Eden Prairie, MN, 55344, Establishment Registration Number 2183725.

Our quality processes include Supplier Quality Assurance, visual inspection, production testing for functionality, ongoing life testing, ongoing development, and product safety parameters. Detailed records are kept of all testing.

D. Substantial Equivalence

The Bair Hugger® Model 750 Total Temperature Management® system is substantially equivalent in safety and effectiveness to the predicate device, the Model 505 Total Temperature Management system (K960167), currently manufactured and marketed by Augustine Medical, Inc.

Bair Hugger Model 750 Warming Unit and Bair Hugger Model 505 Warming Unit

Summary of Similarities

- Both devices have the same intended use and patient populations.
- The Model 750 unit has similar mechanical characteristics; it uses the same type of heater and blower unit.
- The output temperature ranges at each temperature setting are the same (the tolerances are tighter on the Model 750 unit).
- The over temperature safety system provides visible and audible warnings.
- Both devices are designed for use with all of the current Bair Hugger blankets and the 241® fluid warming set. No modifications have been made to the blankets or the 241 set.
- Both warming units can be used as a shelf, floor or table model, or attached to an I.V. pole or bed rail. In addition, the Model 750 unit can be attached to a rack or stand.

Summary of Differences

- The Model 750 unit incorporates (b)(4)
- The Model 750 unit provides greater airflow.
- The Model 750 unit (b)(4)
- (b)(4)
- The Model 750 control panel includes independent switches for *Standby* mode and each temperature setting; the Model 505 control panel has one temperature select switch which, when pressed, changes the temperature setting to the next setting in the sequence.
- The Model 750 control panel includes an LCD window that displays error codes; because it lacks software, the Model 505 unit does not have an error code feature.
- The primary over temperature sensor for the Model 750 unit is set to $47 \pm 2^{\circ}\text{C}$ and the secondary over temperature sensor is set to $53 \pm 3^{\circ}\text{C}$. The primary sensor for the Model 505 unit is set to $53 \pm 3^{\circ}\text{C}$.
- The Model 750 unit can include a collapsible or non-collapsible warming unit hose with a variety of storage options.

Substantial Equivalence Table

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Patient warming	Patient warming
Clinical areas for device use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Device positioning	Can be set on table, floor, shelf or other hard surface; attached to a rack or stand; clamped to an I.V. pole; or hung on a bed rail	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail
Dimensions	13.5" x 9.5" x 10.5"	13" x 10" x 11"
Weight	@12.5 lbs	@11.5 lbs.
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length or collapsible, washable, 2.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter
Recommended filter change	Every year	Every 6 months or 500 hours of use
Temperature sensor	Shuts the heater off if damaged	Shuts the heater off if damaged
Temperature range (at nozzle)	Ambient to 45 degrees	Ambient to 46 degrees
Heat generated	1644 BTU/h (avg.)	1112 BTU/h (avg.)
Electrical requirements	20 Amp fused circuit	20 Amp fused circuit
Power cable	15' hospital grade	15' hospital grade
Airflow at comparable operating pressure	Up to 48 cfm (22.6 L/s)	Up to 30 cfm (14.2 L/s)
Air filter	HEPA	0.2µM
Motor	40 watt DC	Fractional horsepower, single-phase, AC
Heater	1600W resistive	850W resistive
Leakage current	Meets requirements of UL 2601 and EN 60601-1	Meets requirements of UL 2601 and EN 60601-1
Power consumption at 20°C ambient condition	Peak: 1650W Avg.: 800W	Peak: 1000W Avg.: 450W
Diagnostics	Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician. Upon power-up and mode change, the software performs self-test functions	Over temperature and temperature output testing and calibration can be performed by biomedical technician

Substantial Equivalence Table (cont.)

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Over temperature detection	Independent electronic circuit. Thermal cutoff shuts the heater off at preset high temperature of 47±2°C, measured at the end of the hose, plus an independent electronic system that reacts in the same manner and at the same set points as the SE device	Independent bulb and capillary. Thermal cutoff shuts the heater off at a preset high temperature of 53°C±3°C (127.4°F±3.6°F), measured at end of the hose.
Overcurrent protection	Dual input fused lines	Dual input fused lines
Alarm system	Over temperature: flashing red light with audible alarm, heater and blower shut down. Error condition: audible alarm, unit goes into <i>Standby</i> mode, error code displays in LCD window	Over temperature: flashing red light with audible alarm, heater shuts down.
Control circuitry	(b)(4)	(b)(4)
Blankets Used	All Bair Hugger blankets (see next page for details)	All Bair Hugger blankets (see next page for details)
Blood/Fluid Warming System that can integrate with warming unit	Augustine Medical Model 241 system (see next page for details)	Augustine Medical Model 241 system (see next page for details)

✓

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Bair Hugger® Blankets- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same blankets as found in the predicate device, the Model 505 Total Temperature Management system. These blankets, listed below, are currently manufactured and marketed by Augustine Medical.

- Model 522 Upper body blanket (K903360)
- Model 525 Lower body blanket (K903360)
- Model 540 Torso blanket (K921165)
- Model 537 Small lower body blanket (K950416)
- Model 300 Full body blanket (K873745)
- Model 536 (K920432)
- Model 530 (K913734)
- Model 305 Chest access blanket (K920265)
- Model 315 Multi-access blanket (K950416)
- Model 310 (K950416)
- Model 650 (K952864)
- Model 655 (K952864)
- Model 610 Full body surgical (K950432)
- Model 110 Outpatient (K960167)
- Model 630 Sterile cardiac access (K964673)
- Model 645 cardiac (K913734)
- Model 555 pediatric full access (K913734) ✓
- International white blankets: Models 42268 (K903360), 42568 (K903360), 40068 (K873745), and 44068 (K921165)

Model 241 Fluid Warming Set- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same 241® Fluid Warming Set (K933726) as found in the predicate device, the Model 505 Total Temperature Management system. The 241 Fluid Warming Set is currently manufactured for and marketed by Augustine Medical.

E. Summary of Testing and Validation

This section describes the testing, test results and certifications for the Augustine Medical Model 750 warming unit used with Bair Hugger blankets and the 241 blood/fluid warming set. Some of the items described are specific tests and test results while others are Design Control system techniques used in the design of the Model 750 warming unit.

General Safety Certifications

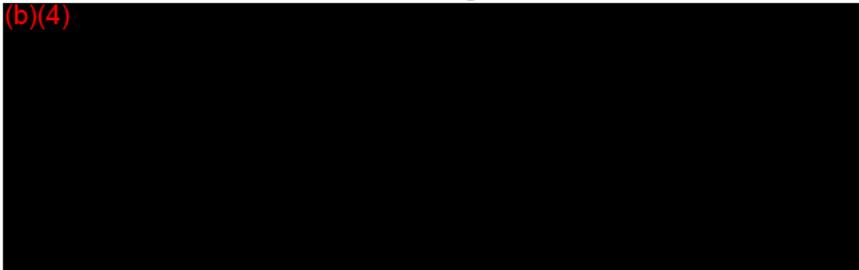
The Model 750 warming unit meets all the requirements of, and will be certified by third-party organizations to the safety standards UL 2601 and EN 60601-1. Test protocols and certification documents will remain on file at AMI.

Electromagnetic Compatibility

The Model 750 warming unit meets the requirements of:

- EN 60601-1-2(1993):
Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests First Edition
and
- EN 55011(1995); Corrigendum-1996:
Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment Second Edition;
Amendment 1-1996; Amendment 2-1996

These standards include the following tests:



The test protocols and pass/fail criteria are exactly the same as those for the predicate device, the Bair Hugger Model 505 Warming Unit (K960167).

Software Validation

Software is controlled within the guidelines of the Augustine Medical systems that are described and cleared for use in other Augustine Medical devices which incorporate software. (Reference Augustine Medical Model 600 Hyper/Hypothermia Unit, K950416 and Augustine Medical Model 68XXX, K963293.)

The product has been determined to be a moderate level of concern, based upon its application and the independent safety systems built into the product.

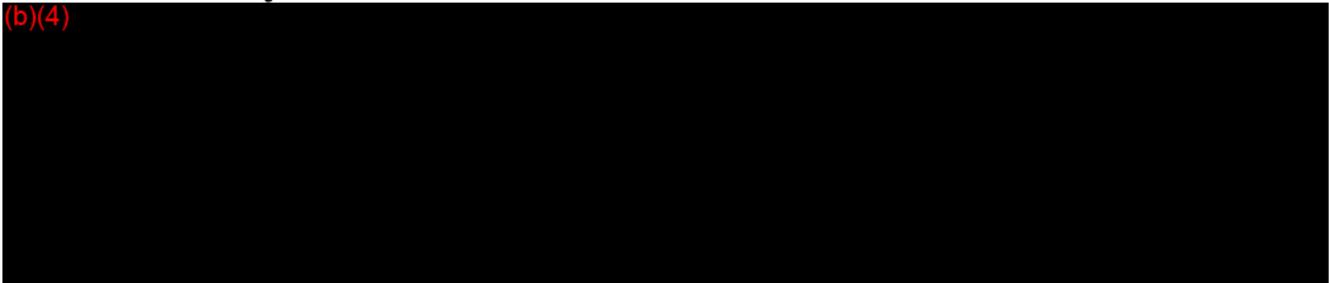
A Software Requirements Specification (SRS) is documented and approved. ✓

Standards and documents used as references include:

- FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (1998),
- EN 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety Section 1.4 Collateral Standard: General Requirements for Programmable Electrical Medical Systems
- FDA's Guidance for the General Principles of Software Validation – Draft Guidance (1997)
- IEEE Standard 1012-1986; IEEE Standard for Software Verification and Validation Plans
- IEEE Standard 1016-1987; IEEE Standard Practice for Software Design Descriptions

Hazard Analysis

(b)(4)



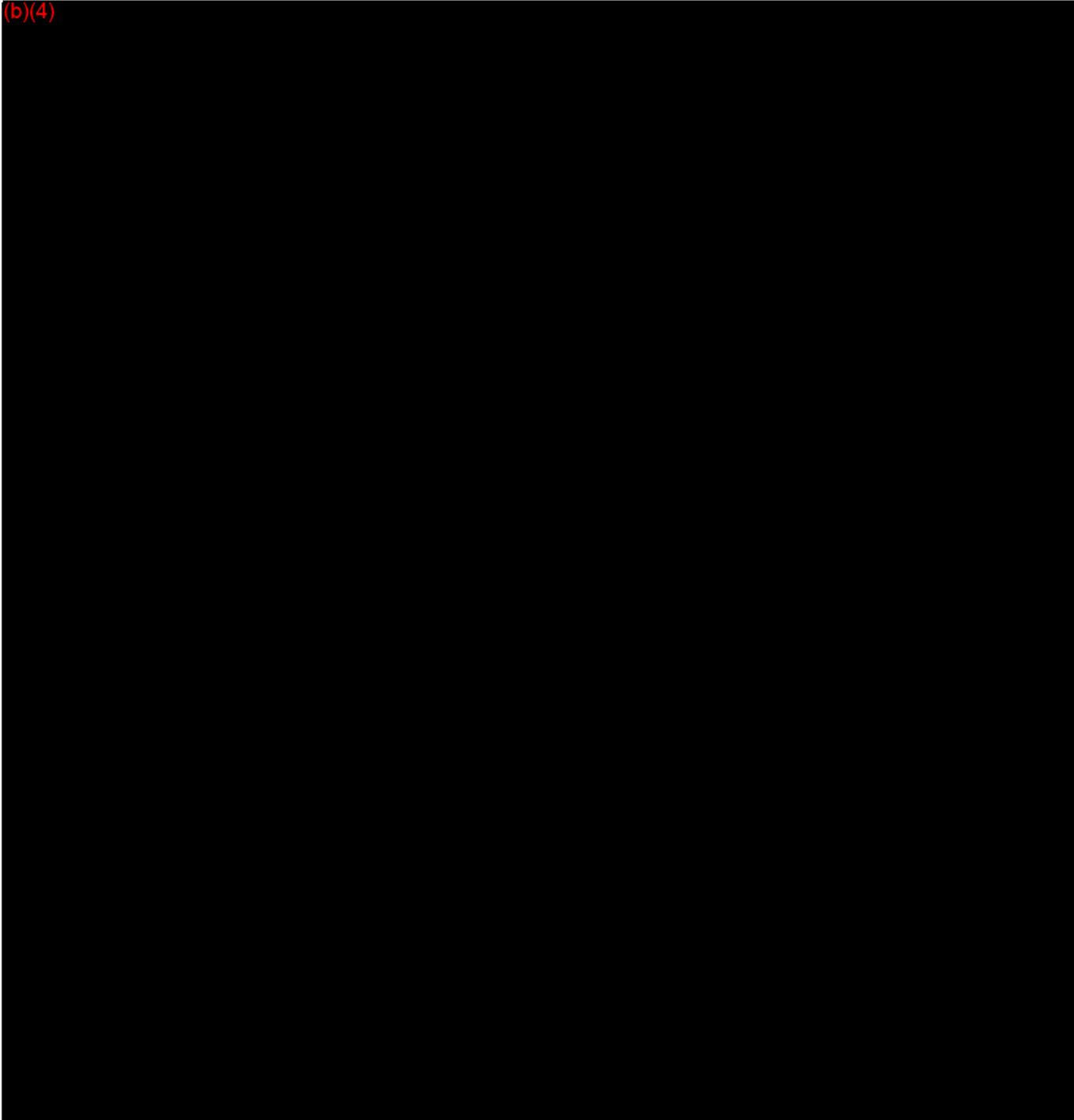
Biocompatibility

Biocompatibility is not required as none of the components of the model 750 warming unit contact the patient.

Performance Testing

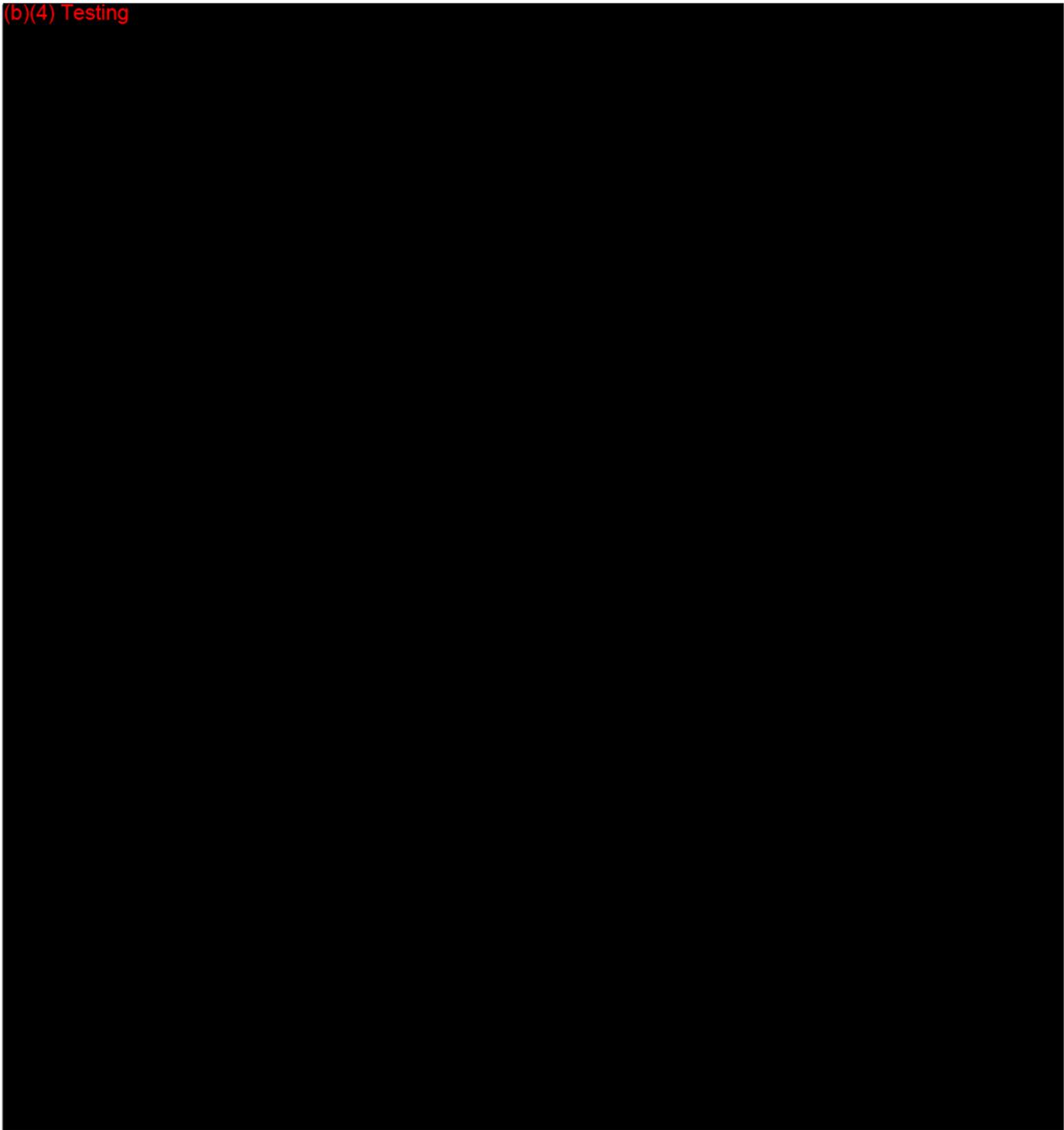
Operating and Over Temperature Testing- Blankets

(b)(4)



Performance Testing

(b)(4) Testing



April 5, 2000

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device, System Thermal Regulating 74 DWJ, Patient Warming System called the Bair Hugger® Total Temperature Management® System - Model 750 Warming Unit. The predicate device is the Bair Hugger® Patient Warming System, Model 505 Warming Unit.

1. Summary of Safety:

A. Injuries to tissue: Cutaneous burns. Thermal injury is determined by a combination of temperature and time. Patients with ischemic limbs or extremely poor perfusion are especially susceptible to thermal injuries.

Prevention: The Bair Hugger® Model 750 maximum heat output (range of 43 to 45°C) does not provide temperatures high enough to cause burns to tissue when used as directed. Performance testing demonstrated that by the time the air leaves the Bair Hugger warming unit, flows through the hose and is circulated through the inflatable blanket placed over the patient, temperatures have dropped to an average of 36.9°C to 41.8°C. These temperatures are well within the range of safety^{1,2}.

Over-temperature safety system: Bair Hugger warming unit overtemperature detection systems are independent electrical and mechanical systems, which use sensors to detect an over temperature condition. The system triggers audible and visual alarms and deactivates the heater and blower when an over-temperature condition is detected.

Labeling: Labels affixed to each Bair Hugger blanket at the inlet port *and* packaged with each Bair Hugger blanket read as follows:

Contraindications:

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

B. Hyperthermia: Warming treatment continued past the point of the patient reaching normothermia may eventually produce hyperthermia³.

Prevention: Instructions packaged with each Bair Hugger® blanket instruct the user to "Monitor the patient's temperature at least every 10-20 minutes."

C. Other Possible Safety Concerns:

Contamination: Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.

Prevention of airborne contamination: All Bair Hugger® blankets designed for use in the operating room feature a tape barrier which prevents air from migrating toward the surgical site. Additionally, air is filtered through a HEPA filter. Two studies have concluded that the Bair Hugger® 500 Series Units do not increase the incidence of microbial or wound contamination^{4,5}. The Model 750 filter is more effective than the Model 505 filter.

2. Summary of Effectiveness:

Performance data show that the Model 750 Total Temperature Management system delivers air temperatures in the warming mode within the same specifications as the Bair Hugger® Model 505 Total Temperature Management system, using the same Bair Hugger® blankets.

Bibliography on which the above summary is based:

1. Moritz AR, Henriques FC. *The Relative Importance of the Time and Surface Temperature in the Causation of Cutaneous Burns*. Am J Path 23:695-720, 1947.
2. Stoll AM, Greene LC. *Relationship Between Pain and Tissue Damage Due to Thermal Radiation*. J Apply Phys 14:373-382, 1959.
3. Genauer MB. *Postoperative Heat Stroke*. Anesthesiology 7:302-309, 1946.
4. Hall A. *Bair Hugger® Warmer Does Not Increase Microbial Contamination in the Operating Room*. Abstract presented at the Post Graduate Assembly, New York Society of Anesthesiologists, New York, NY, December 1991.
5. Zink RS. *Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room*. Anesthesiology 77:A1093, 1992 & Anesth Analg, 1993:76;50-3.
6. Eastland T, Van Duren A, Clay ME, *Effect of heat on stored red blood cells during non-flow conditions in a blood warming device*. Vox Sang 1999; 216-219

CONTACT PERSON: Scott D. Augustine

Appendix A.
Labeling and Product Information

Operators Manual

Device Labels

Marketing Claims

Operator Manual

Model 750



OPERATION MANUAL

Bair Hugger® Model 750 Warming Unit



Bair Hugger® Total Temperature Management® System

The Bair Hugger Total Temperature Management system was developed by an anesthesiologist to prevent and/or treat the common but significant problem of hypothermia.

Examples of current applications for the Bair Hugger Total Temperature Management system are post anesthesia care units (PACU), recovery rooms, operating rooms, emergency departments, obstetrical suites, and intensive care areas.

The warming unit draws ambient air through a filter and warms the air to the specified temperature. It then delivers the warmed air through a hose to the Bair Hugger blanket. When used properly, the Bair Hugger blanket distributes the warm air around the patient's body, creating a warm environment.

This manual includes instructions for operating and maintaining the Model 750 warming unit, instructions for operating 241® fluid warming sets, and specifications for both products. More detailed information can be found in the Service Manual, and instructions included with Bair Hugger blankets and 241 fluid warming sets.

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Hypothermia: A Common Problem in Patient Care

Description

Hypothermia occurs when body temperature drops below 36°C (96.8°F). Sixty to eighty percent of all patients undergoing operative procedures become hypothermic.

Contributing Factors

Factors contributing to hypothermia include:

- Cold operating room environment
- Anesthetic drug effect
- Administration of cold intravenous fluids
- The opening of the body cavity
- Cold exposure
- Drowning
- Spinal trauma
- Impaired thermoregulatory processes

Adverse Consequences

Adverse consequences of hypothermia include:

- Coagulopathy
- Hemodynamic instability
- Immunodepression
- Shivering and patient discomfort
- Altered drug effect
- Post-operative nitrogen wasting
- Cardiac dysfunction
- Increased rate of infection

Indications for Bair Hugger® Warming Therapy ✓

Examples of indications for the Bair Hugger® Total Temperature Management® system include:

- Body temperature drops below 36°C (96.8°F)
- Patient exhibits shivering
- Patient complains of being uncomfortably cold

Also, to prevent hypothermia, the Bair Hugger Total Temperature Management system should be used whenever conditions exist that could cause patients to become cold.

Precautionary Information

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® warming units with any forced-air blanket or cover other than Bair Hugger blankets. Otherwise, thermal injury may result.
- Do not warm patients with the warming unit hose alone. Otherwise, thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin surface warming.
- Do not use any fluid administration device other than the 241® fluid warming set with the Bair Hugger warming unit. Thermal injury or device damage may result.
- Do not use the 241 fluid warming set with any forced air warming system other than the 500 Series Bair Hugger System equipped with a fluid warming hose or a Model 750 warming unit. Fluid temperature outside the indicated range or damage to the warming device may result.
- Do not continue 241 fluid warming therapy if the *Over Temperature* LED illuminates and the audible alarm sounds. Immediately stop fluid flow and discard the fluid warming set. Unplug the unit and contact qualified technical personnel.
- Do not initiate therapy unless the Model 750 warming unit is securely mounted or injury may result.
- Do not administer fluids with a 241® Fluid warming set if air is in the tubing. Introduction of air to the patient 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.
- Bair Hugger blankets are intended for single patient use only. Placing a sheet between the Bair Hugger blanket and the patient does not prevent contamination of this product.
- The 241® fluid warming set fluid path is sterile and non-pyrogenic in an unopened, undamaged package. Do not use the 241 fluid warming set if any part is damaged, distorted, or contaminated, or if end caps are not in place.
- Series 500 and 600 Blankets meet an international standard for flammability, IEC 695-2-2, and the Consumer Product Safety Commission's flammable fabric regulation, 16 CFR 1610; however, follow standard safety protocols when using high intensity heat sources.
- 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.
- Do not disassemble the warming unit; refer to an authorized service technician. There are electrically live parts within the warming unit when it is connected to the power source, even when the unit is in *Standby* mode.
- If radio frequency interference with monitoring equipment occurs, connect the warming unit to a different power source.

Read Before Servicing Equipment

- The repair, calibration, and servicing of the warming unit requires the skill of a qualified Medical Equipment Service Technician who is familiar with good practice for medical device repair. If service is designated as not requiring manufacturer's attention, the technical information is provided in the Service Manual or will be provided, upon request, by Augustine Medical, Inc.
- Perform all repairs and maintenance in accordance with the instructions in the Service Manual.
- Perform a safety inspection after making repairs to the warming unit, and before returning the warming unit to service. A safety inspection must include a test of the operating temperatures, the Over Temperature alarm system and a leakage current test (described in the Service Manual).

Proper Use and Maintenance

Augustine Medical, 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.

Bair Hugger®

Total Temperature Management® System

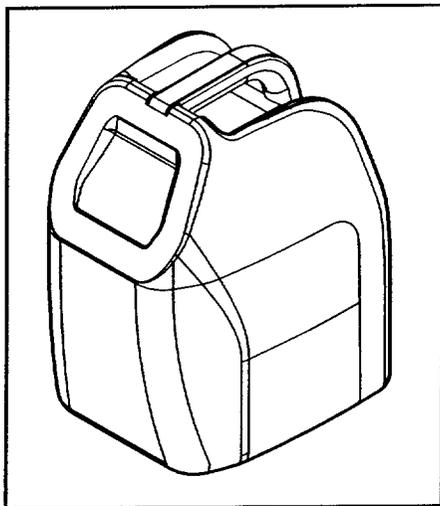
*The Bair Hugger Total Temperature Management system consists of a **warming unit** and a disposable **blanket**. Bair Hugger warming therapy can also include 241® fluid warming therapy, described under **Warming Fluids Using the 241 Fluid Warming Set**.*

Model 750 Warming Unit

The Model 750 unit is designed for safe use in all areas, including the operating room.

The warming unit can be placed on a table or the floor, or attached to an I.V. pole, rack or stand, a bed rail, or to the Bair Hugger rolling stand accessory.

Figure 1. Model 750 warming unit

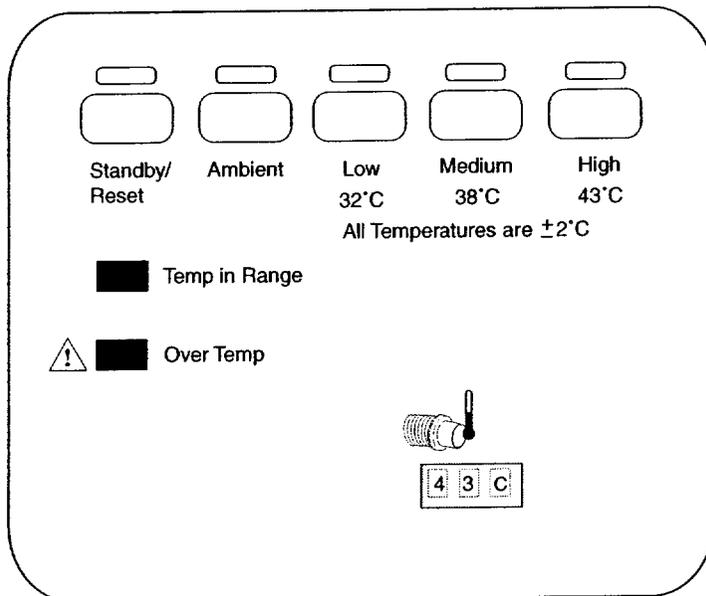


Bair Hugger Blankets

Bair Hugger blankets consist of tubular chambers that deliver controlled warm air. Blankets are designed in various configurations for specific applications. Follow the instructions provided with each Bair Hugger blanket for specific information concerning their recommended use.

Control Panel Features of the Model 750 Warming Unit

Figure 2. Control panel of the Model 750 warming unit



Standby/Reset

When the unit is in *Low*, *Medium*, or *High* mode, press the *Standby/Reset* button to place the unit in *Standby* mode. In *Standby* mode, the:

- *Standby* LED is lit
- Blower and heater are turned off
- LCD display is deactivated
- Operating time does not increment
- Alarm and error detection functions remain active

In case of an over temperature alarm condition, pressing the *Standby/Reset* button will turn off the warming unit blower, heater, overtemp light and alarm.

Temperature Settings

Press the *Low*, *Medium*, or *High* button to select the desired temperature. Press *Ambient* to supply ambient air.

Temperature In Range LED

The *Temperature in Range* LED illuminates when the output air temperature is within the range of the selected setting, except in the ambient mode.

Over Temperature LED

If the unit senses an over temperature condition, the *Over Temperature* LED flashes and an alarm sounds. The unit shuts off the heater.

LCD Window

During normal operation, the LCD window displays the temperature at the blanket end of the warming unit hose in °C. In an error mode, the window displays an error code. Error codes are listed in this manual under the section titled, *Error Codes*.

Mounting the Model 750 Warming Unit

Using an I.V. Pole

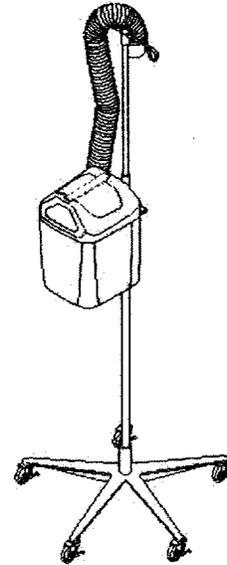
The Model 750 unit clamps easily to an I.V. pole. (See Figure 3.) Turn the handle *clockwise* to tighten the clamp onto an I.V. pole, *counterclockwise* to release.

WARNING: To prevent tipping, clamp the Model 750 warming unit to an I.V. pole at a height that provides stability. We recommend clamping the unit no higher than 44 inches (112 cm) from the floor on an I.V. pole with a minimum 14 inches (35.6 cm) radius wheelbase. Failure to do so may result in I.V. pole tipping, catheter site trauma, and patient injury.

Using a Bed Rail

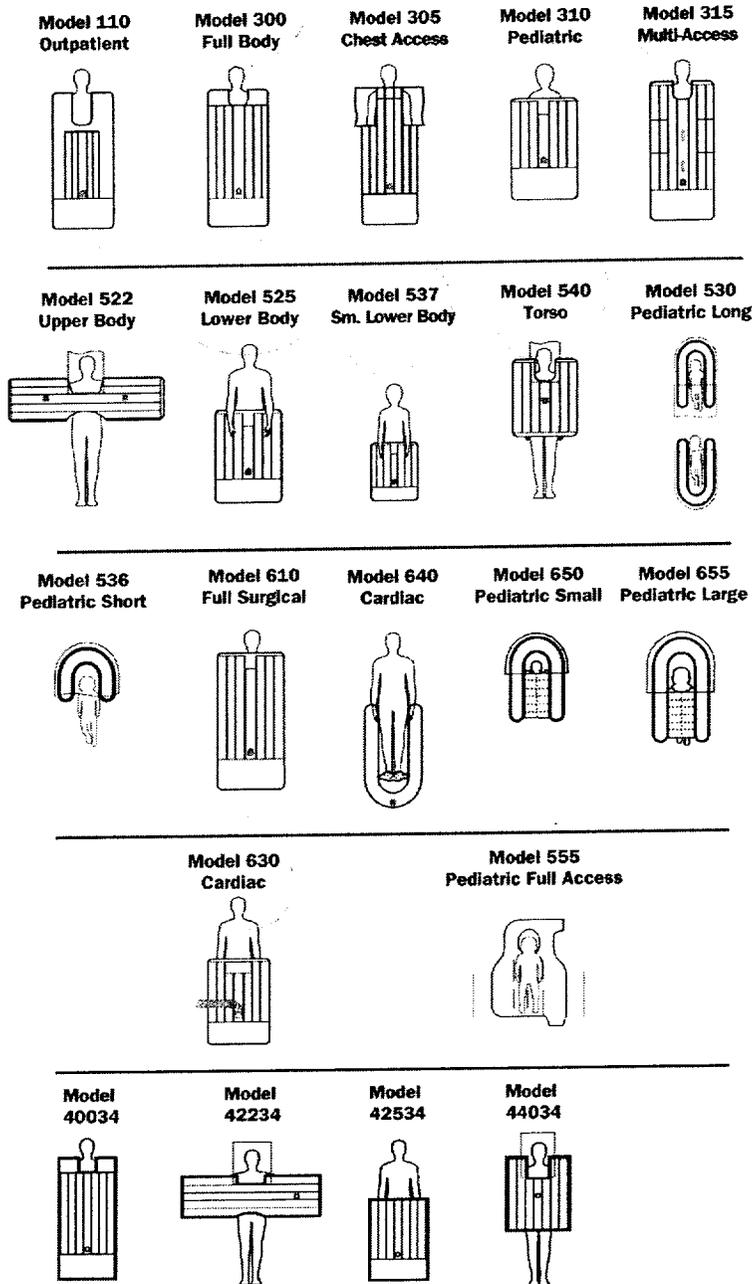
The Model 750 warming unit can also hang on the edge of a bed. The safety strap is designed to loop around the bed rail, keeping the Model 750 unit safely suspended even if the unit is inadvertently dislodged from the bed rail.

Figure 3. Model 750 warming unit attached to I.V. pole



Bair Hugger Blankets

Bair Hugger Blankets comprise long, tubular channels which deliver controlled warmth. The Blanket is designed to “hug” the patient. Blankets are designed in various configurations for specific applications (see Figure 2). Follow the instructions provided with Bair Hugger Blankets for specific information concerning their recommended use.



Setup and Operation

Follow the instructions provided with each blanket for specific information on blanket use.

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 end of the warming unit hose in the blanket hose port.
3. Connect the warming unit to a properly grounded power source. The unit will be operating in *Standby* mode.
4. Press the appropriate button to select the desired temperature or leave the unit in *Standby* mode. When the unit reaches the selected temperature, the *Temperature in Range* LED will come on, except in the ambient mode.
5. Place a cotton blanket over the Bair Hugger blanket for maximum effectiveness.
6. Monitor the patient's temperature at least every 10 to 20 minutes and adjust the temperature setting of the warming unit as required.
7. At the end of warming therapy, unplug the warming unit and discard the Bair Hugger blanket.

What to Do in Case of an Over Temperature Alarm

In rare circumstances, such as an obstruction at the hose end, the unit may detect an over temperature condition.

1. The *Over Temperature* LED flashes and an alarm sounds.
2. The unit turns the heater and blower off. The fan continues to run.
3. Press the *Standby/Reset* button to turn the fan, overtemp light and alarm off.
4. Reselect the temperature setting. If the unit has cooled down, it will resume normal operation. If the unit does not return to normal operation, contact technical personnel.

WARNING: Do not continue 241[®] fluid warming therapy if the *Over Temperature* LED illuminates and the audible alarm sounds. Immediately stop fluid flow and discard the fluid warming set. Unplug the unit and contact qualified technical personnel.

Error Codes

When a system error occurs, the LCD window displays the error code. In all cases, the user must unplug the unit and contact service (technical) personnel. All error codes are listed below with their definitions.

Error Code	Definition
01	Operating temperature sensor failure
02	Over temperature sensor failure
03	Power up failure
04	Memory failure
05	A/D failure
06	Watchdog timer failure

Warming Fluids Using the 241® Fluid Warming Set

The Model 750 warming unit is equipped with a special hose for 241 fluid warming. This allows the Bair Hugger® system to warm blood and intravenous fluids delivered through a Bair Hugger 241 fluid warming set at infusion rates up to 3,000 ml/hr.

Before initiating fluid warming therapy, read the package insert with the 241 fluid warming set.

Fluid Warming Specifications

The average fluid output temperatures during normal operation of the 241 fluid warming set with the warming unit set on HIGH and 10°C fluid input are as follows:

Infusion rate	Output temperature
500 ml/hr	40.9°C
1000 ml/hr	41.0°C
1500 ml/hr	39.3°C
2000 ml/hr	37.1°C
2500 ml/hr	34.9°C
3000 ml/hr	32.8°C

Fluid input temperature: 10°C.

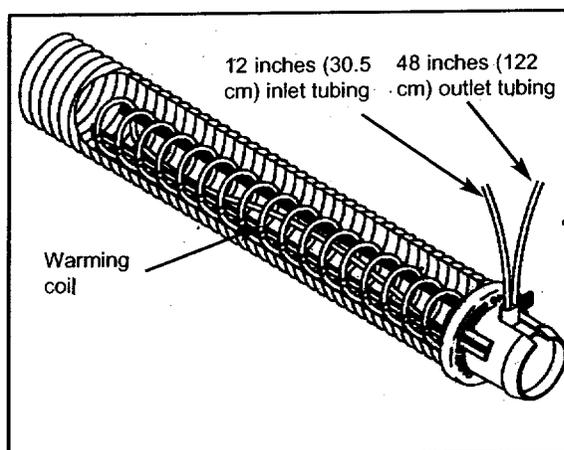


Figure 6. 241 fluid warming set inside warming unit hose

General Maintenance

Cabinet Cleaning

1. Disconnect the warming unit from the power source before cleaning.
2. Use a damp soft cloth and a mild detergent to clean the warming 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.

Specifications

Physical Characteristics

Dimensions 13.5 in. high x 9.5 in. deep x 9.5 in. wide
34 cm high x 24 cm deep x 24 cm wide

Weight 12.5 lbs.

Relative Noise Level

53 decibels

Hose

Detachable, flexible, washable; compatible with Bair Hugger® Model 241® Fluid Warming System

Filtration System

HEPA level

Recommended Filter Change

Once a year

Mounting

Has I.V. pole clamp and bed rail hook with safety strap; can be placed on hard surface

Temperature Characteristics

Recommended Operating Environment

15°C-25°C

Temperature Control

Electronically controlled

Heat Generated

1644 btu/hr (average)

System Time to 38°C (@100°F)

5-10 secs in ambient temperature conditions

Operating Temperatures

Average temperatures at the end of the hose, assuming the back pressure of an Augustine Medical, Inc. warming blanket, or an Augustine Medical, Inc. temperature test unit:

HIGH:	43° ± 2°C	109.4° ± 3.6°F
MED:	38° ± 2°C	100.4° ± 3.6°F
LOW:	32° ± 2°C	89.6° ± 3.6°F

Safety System

Thermostat

Independent electronic circuit. Thermal cutoff shuts the heater off at preset high temperature of 47°C at the end of the hose.

Overcurrent Protection

Dual input fused lines

Alarm System

Over temperature: flashing red light with audible alarm; heaters and blower shut down; membrane keypad becomes unresponsive. Error: audible alarm, unit goes into standby mode, error code displays in LCD window.

Certifications

EN60601-1, EN 60601-1-2, UL 2601-1, CAN/CSA - C22.2, NO. 601-1

Classification

Classified under IEC 601-1 Guidelines as Class I, Type BF, Ordinary equipment, Continuous operation
Classified under the Medical Device Directive (93/42/EEC) as class 11b.

Electrical Characteristics

Leakage Current

Meets UL 2601 and EN 60601-1 requirements

Heating Element

1600W Resistive

Blower Motor

Operating speed:	approx. 4000 rpm
Airflow:	up to 48 cfm

Power Consumption

Peak:	1650W
Average:	800W

Power Cord

15-foot, SJT, 3 cond., 15A
4.6 meter, HAR, 3 cond., 10A

Device Ratings

110-120VAC, 60Hz, 13 Amperes, or
220-240VAC, 50Hz, 8 Amperes, or
100VAC, 50/60 Hz, 16 Amperes

Fuses

13A (110 - 120 VAC Units)
8A (220 - 240 VAC Units)
16A (100VAC Units)

Diagnostics

Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician.

Customer Service 1-800-733-7775

Corporate Office 1-952-947-1200

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
	Warning / Caution See appropriate documents
	Non Explosion-Proof
	Dangerous Voltage
	Type BF Equipment (Patient applied)
	Voltage Alternating Current (AC)

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Device Labeling

Model 750

Device Labels

Model 750 **Bair Hugger®**
Total Temperature Management® System



Contraindications:

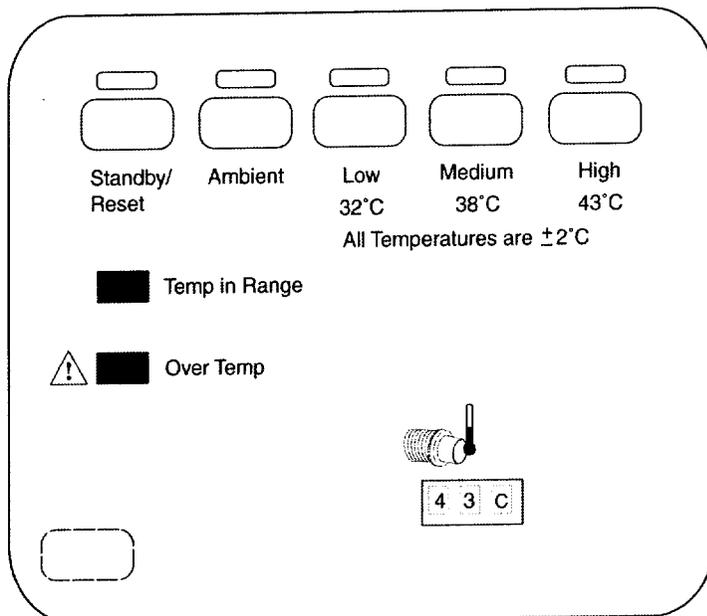
- Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

Warnings:

- Do not continue therapy if the Over Temp light illuminates and/or the audible alarm sounds. Thermal injury may result. Turn the unit off and contact technical personnel.
- Do not warm patients with the warming unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin surface warming.
- Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed health care professional.

Control panel



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Product Claims

Model 750

Model 750 Warming Unit Claims

- The Model 750 unit is lightweight and compact, making it easy to set up, transport and store.
- The Model 750 unit offers easy, flexible mounting options so the user can quickly find the optimum location for the unit.
- The Model 750 unit delivers up to 48 cubic feet/minute air flow, accommodating a wide range of Bair Hugger blanket performance needs.
- The Model 750 unit includes a HEPA filter.
- The Model 750 unit is quiet—the unit doesn't add to the noise in the busy operating room environment.
- The Model 750 unit delivers safe and effective output temperatures in all settings to help prevent and treat hypothermia.
- Hose end temperature sensing provides stable blanket temperatures regardless of ambient temperatures

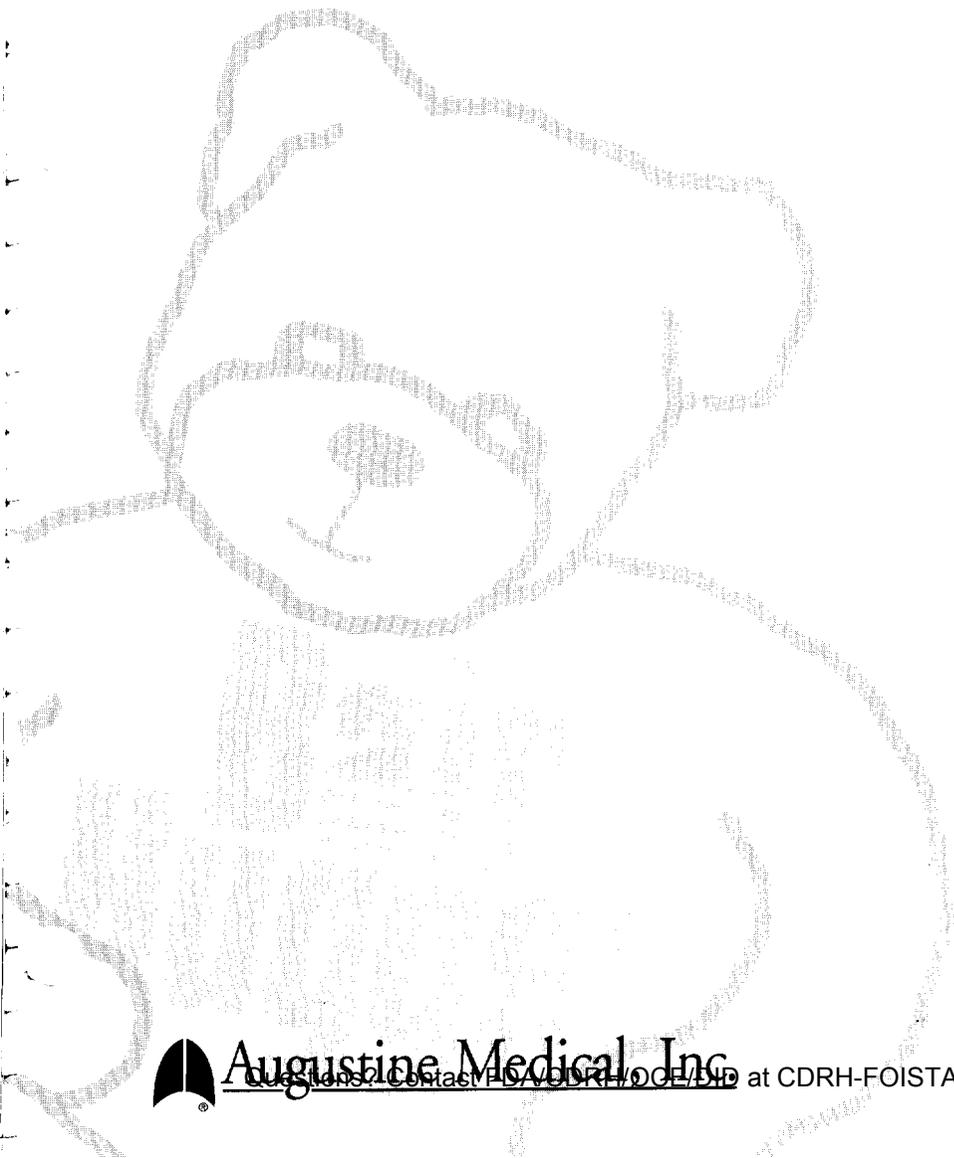
Operator Manual

Model 505 (Predicate Device)



OPERATION MANUAL

Bair Hugger® Model 500/OR and Model 505 Warming Units



Augustine Medical, Inc.

Questions? Contact FDA/CDRH/OCE/DIV at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CE 0123

Worldwide Technical Service and Order Placement

United States, Puerto Rico, Canada

Technical Service TEL: 1-612-947-1200
1-800-733-7775

Order Placement TEL: 1-612-947-1200
1-800-733-7775
FAX: 1-612-947-1400

Worldwide

Technical Service (USA) TEL: +1-612-947-1200
FAX: +1-612-947-1400

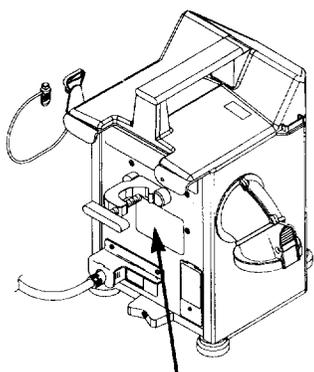
Order Placement (USA) FAX: +1-612-947-1400

In-Warranty Repair and Exchange

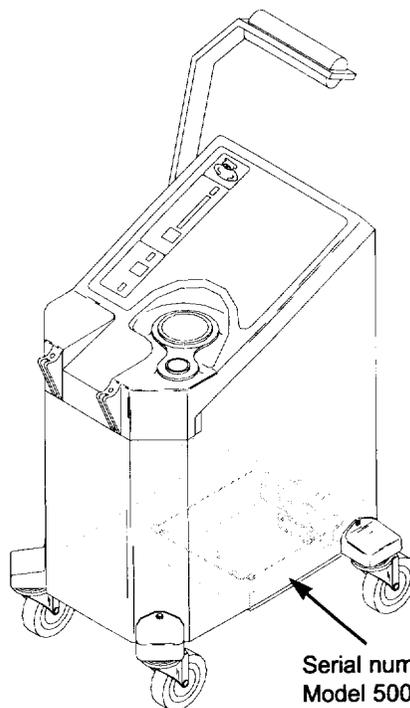
Replacement parts to correct a problem are delivered at no charge. To return a device to Augustine Medical, Inc. for service, first obtain a Return Authorization (RA) number from a technical service representative. Please use this number on all correspondence when returning a device for service. A shipping carton will be delivered to you at no charge, if needed. We will service and ship your device within five (5) working days of our receipt. 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.



Serial number label on Model 505 Unit



Serial number label on Model 500/OR Unit

Augustine Medical, Inc.
102306K

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Bair Hugger® Total Temperature Management® System



The Bair Hugger® Total Temperature Management® System was developed by an anesthesiologist to prevent and/or treat the common but significant problem of hypothermia.

Examples of current applications for Bair Hugger Total Temperature Management Systems are post anesthesia care units (PACU), recovery rooms, operating rooms, emergency departments, obstetrical suites, and intensive care areas.

The Warming Unit draws ambient air through a filter and warms the air to the specified temperature. It then delivers the warmed air through a hose to the Bair Hugger Blanket which is placed over the patient. When used properly, the Bair Hugger Blanket distributes the warm air around the patient's body, creating a warm environment.

This manual includes instructions for operating and maintaining Bair Hugger Warming Units, instructions for operating 241® Fluid Warming Sets, and specifications for both products. More detailed information can be found in the Service Manual, and instructions included with Bair Hugger Blankets and 241 Fluid Warming Sets.

Bair Hugger® Therapy Warranty

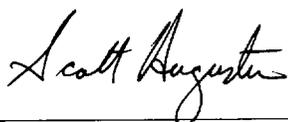
5 Year Limited Warranty*

Augustine Medical, Inc. (the "Company") warrants to the original end user that each Bair Hugger® Warming Unit will be free from defects in materials and workmanship under normal use and service for 5 years from the date of shipment.¹

① The warranty period for hose assemblies in the Warming Unit expires one (1) year from the date of shipment, and this warranty does not apply to fuses and filters. The warranty does not apply to any item in which parts other than replacement parts made or approved by the Company have been used if such parts are the cause of failure. The Company shall have no obligation under this warranty to make repairs or replacements necessitated in whole or in part by accidents, fault or negligence of the user.

NOTE: The above warranty applies only to the original end user and is valid only for the use of Bair Hugger Warming Units with Bair Hugger Warming Blankets. The use of any warming cover or blanket not manufactured or approved by the Company with the Company's Warming Units invalidates the foregoing limited warranty. Use of Warming Units in a manner not specified in the instructions for use invalidates the foregoing warranty.

* The Limited Warranty is valid only for Bair Hugger Forced Air Warming Therapy. It does not apply to the 241® Fluid Warming System or Bair Hugger Accessories.



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Tel: 612-947-1200
Fax: 612-947-1400

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Hypothermia: A Common Problem in Patient Care

Description

Hypothermia occurs when a patient's body temperature drops below 36°C (96.8°F). Sixty to eighty percent of all patients undergoing operative procedures become hypothermic.

Contributing Factors

Factors contributing to hypothermia include:

- Cold operating room environment
- Anesthetic drug effect
- Administration of cold intravenous fluids
- The opening of the body cavity
- Cold exposure
- Drowning
- Spinal trauma
- Geriatric thermoregulatory processes

Adverse Consequences

Adverse consequences of hypothermia include:

- Coagulopathy
- Hemodynamic instability
- Immunodepression
- Shivering and patient discomfort
- Altered drug effect
- Post-operative nitrogen wasting
- Cardiac dysfunction

Indications for Bair Hugger® Warming Therapy

Examples of indications for the Bair Hugger® Total Temperature Management® System include:

- Body temperature drops below 36°C (96.8°F)
- Patient exhibits shivering
- Patient complains of being uncomfortably cold

Also, to prevent hypothermia, the Bair Hugger Total Temperature Management System should be used whenever conditions exist that could cause patients to become cold.

Precautionary Information

Contraindications

Temperature

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

Warnings

Bair Hugger® Therapy

Do not use Bair Hugger® Warming Units with any forced-air blanket or cover other than Bair Hugger Blankets. Thermal injury may result.

Do not warm patients with the Warming Unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger Blanket before providing skin surface warming therapy.

Do not use any fluid administration device other than the 241® Fluid Warming Set with the Bair Hugger Warming Unit. Thermal injury or device damage may result.

Do not use the 241 Fluid Warming Set with any forced air warming system other than the 500 Series Bair Hugger System equipped with a fluid warming hose. Fluid temperature outside the indicated range or damage to the warming device may result.

Alarm

Do not continue therapy if the **Over Heat** warning light illuminates and the audible alarm sounds. Thermal injury may result. Turn the Warming Unit OFF and contact qualified service personnel. If using 241 Fluid Warming, immediately stop fluid flow, and discard the fluid warming set.

Model 505 Warming Unit

Do not initiate therapy unless the Model 505 Warming Unit is securely mounted or injury may result.

Purge 241 Fluid Warming Set

Do not administer fluids if air is in the tubing. Introduction of air to the patient may result.

Precautions

Monitor Temperature

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.

Pediatric Use

To prevent suffocation from misuse, do not leave children or infants unattended when administering Bair Hugger® Therapy.

Sterility

Blankets are not sterile and are intended for single patient use only. Placing a sheet between the Bair Hugger Blanket and the patient does not prevent contamination of this product.

The 241® Fluid Warming Set fluid path is sterile and non-pyrogenic in an unopened, undamaged package. Do not use the 241 Fluid Warming Set if any part is damaged, distorted, or contaminated, or if end caps are not in place.

Patient Safety

Series 500 and 600 Blankets meet an international standard for flammability, IEC 695-2-2, and the Consumer Product Safety Commission's flammable fabric regulation, 16 CFR 1610; however, follow standard safety protocols when using high intensity heat sources.

Visual Distortion

The Blanket's clear plastic drape may cause visual distortion. Lift the plastic drape to view the patient's head clearly.

Read Instructions

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 Warming Unit; refer to an authorized service technician. There are electrically live parts within the Warming 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 Warming Unit to a different power source.

Read Before Servicing Equipment

The repair, calibration, and servicing of the Warming Unit requires the skill of a qualified Medical Equipment Service Technician who is familiar with good practice for medical device repair. If service is designated as not requiring manufacturer's attention, the technical information is provided in the Service Manual or will be provided, upon request, by Augustine Medical, 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 Warming Unit, and before returning the Warming Unit to service. A safety inspection should 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

Augustine Medical, Inc. assumes no responsibility for the reliability, performance, or safety of the equipment if:

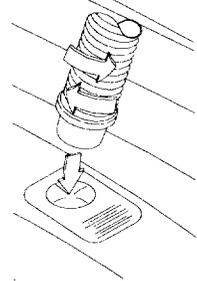
- Modifications or repairs are performed by unauthorized personnel.
- The equipment is used in a manner other than that described in the Operation or Service Manuals.
- The equipment is installed in an environment that does not meet the relevant grounding requirements.

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 Warming Unit in the inlet port on the Blanket. Use a twisting motion to ensure a snug fit (see Figure 1).
3. Connect the Warming 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 Warming 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 Warming Unit as required.

Figure 1.
Insert the
Hose in the
Inlet Port



Bair Hugger® Total Temperature Management® System

The Bair Hugger Total Temperature Management System consists of a disposable Blanket, and a Warming Unit. Bair Hugger Warming Therapy can also include 241® Fluid Warming Therapy, described under Warming Fluids Using the 241 Fluid Warming Set.

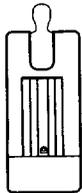
Bair Hugger Blankets

Bair Hugger Blankets comprise long, tubular channels which deliver controlled warmth. The Blanket is designed to “hug” the patient. Blankets are designed in various configurations for specific applications (see Figure 2). Follow the instructions provided with Bair Hugger Blankets for specific information concerning their recommended use.

**Figure 2.
Bair Hugger Blankets**

Outpatient Blanket

Outpatient
Model 110



PACU/ICU Blankets

Full Body
Model 300



Chest Access
Model 305



Pediatric
Model 310

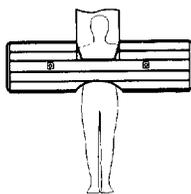


Multi-Access
Model 315

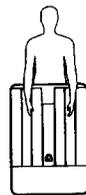


OR Blankets

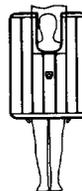
Upper Body
Model 522



Lower Body
Model 525



Torso
Model 540



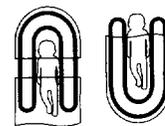
Small Lower Body
Model 537



Pediatric Short
Model 536



Pediatric Long
Model 530



Speciality Blankets

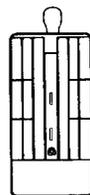
Pediatric Small
Model 650



Pediatric Large
Model 655



Full Body Surgical
Model 610



Cardiac Access
Model 640



Warming Units

The Warming 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, 500/OR,E and 505 are designed for safe use in all areas, including the operating room.

The folding handle on the Model 500/OR, 500/OR,E Warming Units 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 Warming 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 Warming Unit to be easily transported between clinical areas.

The Model 505 Warming Unit can be attached to an I.V. pole or to the railing on a bed.

Figure 3. Model 500/OR and Model 500/OR,E Warming Unit

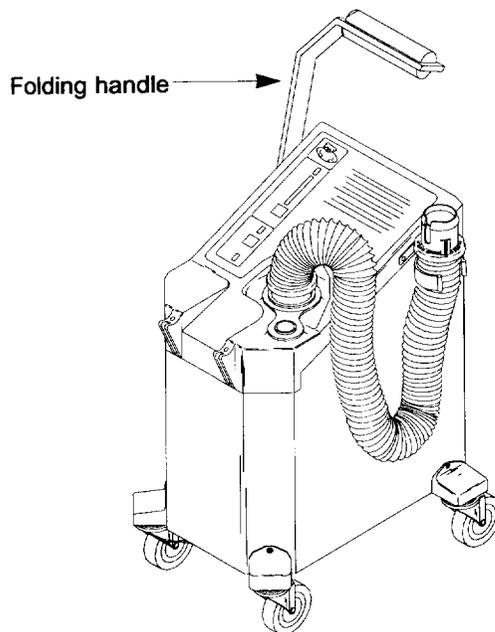
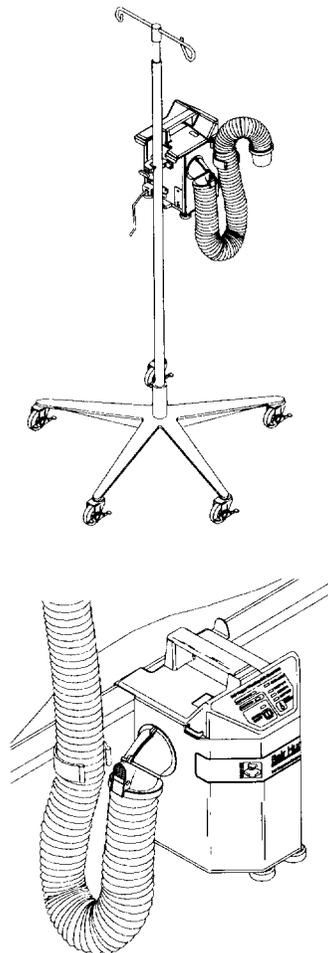


Figure 4. Model 505 Warming Unit



Control Panel Features of the Model 500/OR and 500/OR,E Warming 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 Warming Unit OFF and then ON, either by the System ON/OFF button (see Figure 5), 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 Warming 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.

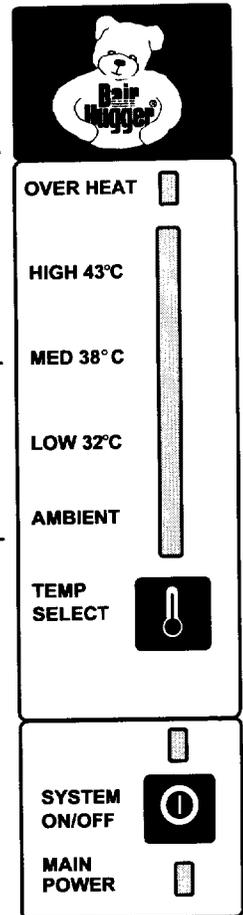
System ON/OFF

Push this button to turn the Warming Unit either ON or OFF. The indicator directly above the switch illuminates when the Warming Unit is ON.

Main Power Indicator

The main power indicator illuminates when main power is applied to the Warming 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.

Figure 5.
Control Panel of
the Model
500/OR and
Model 500/OR,E
Warming Unit



Control Panel Features of the Model 505 Warming 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 Warming 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 Warming Unit either ON or OFF. The indicator directly above the switch illuminates when the Warming 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 Warming Unit OFF and then ON, using the System ON/OFF button. (Also refer to the *Warnings* section of this manual.)

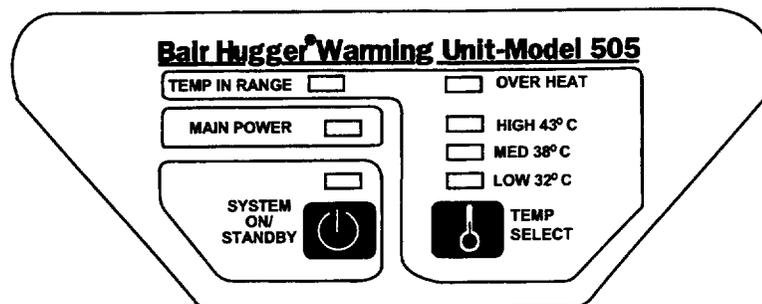
Temperature Indicators

The temperature indicators illuminate up to the selected temperature level. When the Warming 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 6. Control Panel of the Model 505 Warming Unit



Mounting the Model 505 Warming Unit

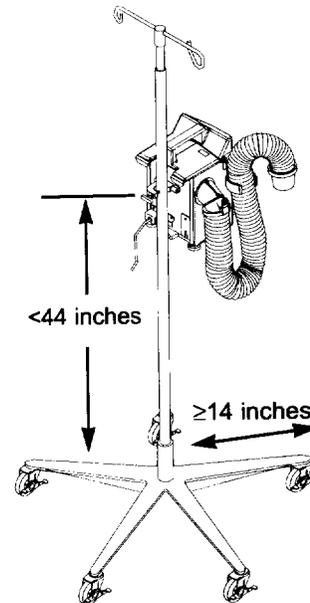
Using an I.V. Pole

The Model 505 Warming Unit clamps easily to an I.V. pole. (See Figure 7.) Simply turn the handle *clockwise* to tighten the clamp onto an I.V. pole, *counterclockwise* to release.



WARNING: To prevent tipping, clamp the Model 505 Warming Unit to an I.V. pole at a height that provides stability. We recommend clamping the Unit no higher than 44" (112 cm) on an I.V. pole with a minimum 14" (35.6 cm) radius wheelbase. Failure to do so may result in I.V. pole tipping, catheter site trauma, and patient injury.

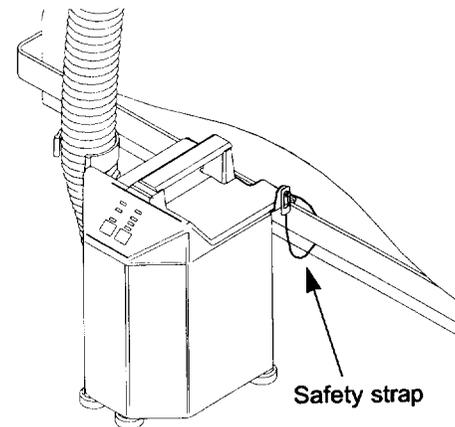
Figure 7. Model 505 Warming Unit Attached to I.V. Pole



Using a Bed Rail

The Model 505 Warming Unit can also hang on the edge of a bed. The safety strap is designed to loop around the bed rail, keeping the Model 505 Unit safely suspended even if the unit is inadvertently dislodged from the bed rail. (See Figure 8.)

Figure 8. Model 505 Warming Unit Attached to Bed Rail



Attaching and Storing the Model 505 Warming 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, then by “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.

Figure 9. Attaching the Model 505 Unit Hose

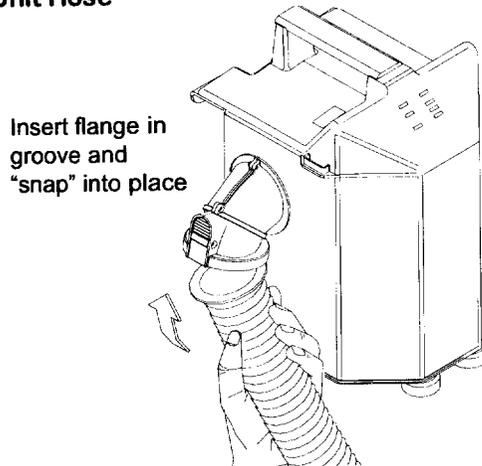
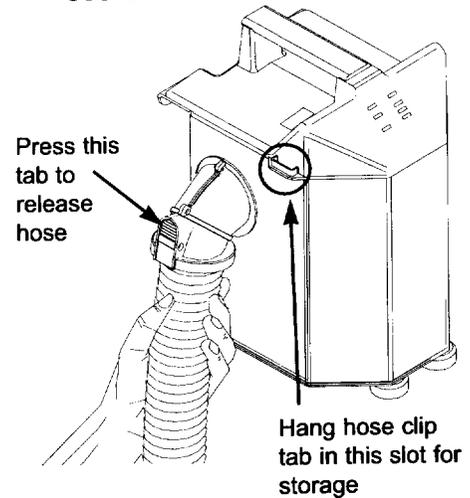


Figure 10. Storing the Model 505 Unit Hose



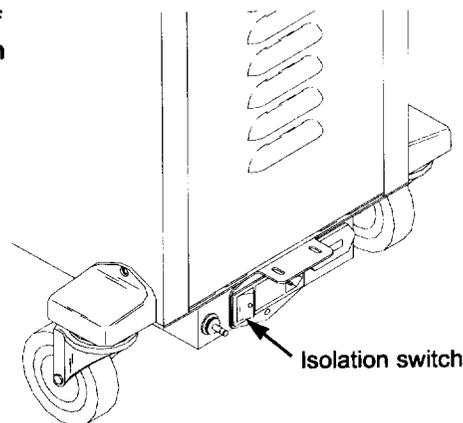
Isolation Switch

The Isolation Switch allows you to disconnect the Warming Unit from the power source without removing the power cord from the wall receptacle. The Isolation Switch is located on the back of Model 500/OR and 500/OR,E Warming Units. The Isolation Switch must be in the ON position before the Warming 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.

Figure 11. Location of the Isolation Switch on Model 500/OR and 500/OR,E Warming Units



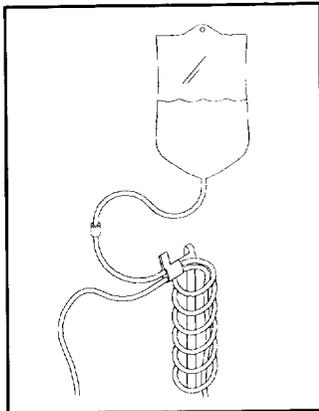
Warming Fluids Using the 241® Fluid Warming Set



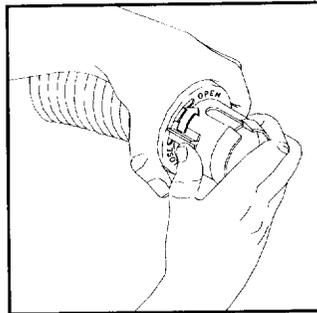
Series 500 Warming Units are equipped with a special hose for 241 Fluid Warming. This allows the Bair Hugger® Total Temperature Management® System to warm blood and intravenous fluids delivered through a Bair Hugger 241 Fluid Warming Set at infusion rates up to 3,000 ml/hr.

Before initiating fluid warming therapy, read the package insert for the 241 Fluid Warming Set.

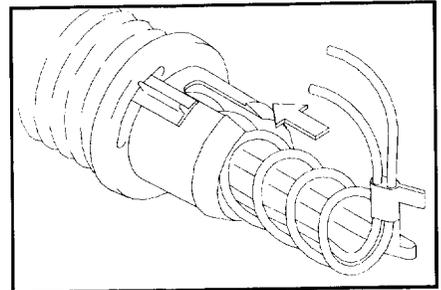
1. Connect the 241 Fluid Warming Set to the fluid source using the end of tubing without the temperature indicator. Thoroughly prime all tubing.



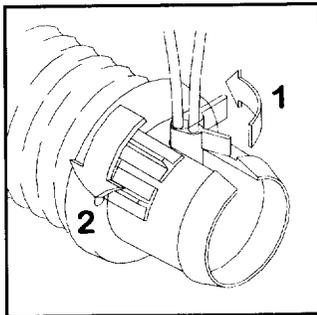
2. Push the tab to open the notch on the hose end.



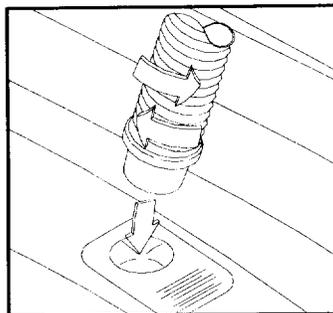
3. Slide the coil completely into the hose until the lever on the 241 Fluid Warming Set reaches the base of the notch.



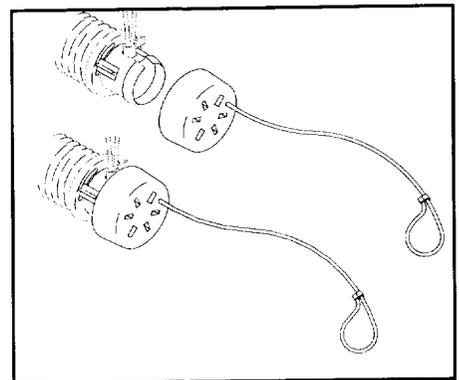
4. Rotate the lever (1) of the Fluid Warmer towards the hose collar until it is parallel with the hose collar. Push the tab (2) to close the notch on the hose end.



5a. To perform fluid warming with skin surface warming: Insert the end of the hose in the opening for the hose on a Bair Hugger Blanket. Use a twisting motion to ensure a snug fit.

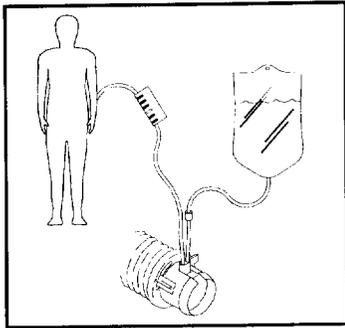


5b. To perform fluid warming alone: Attach the Hose Cap to end of hose. Direct the hose end away from patient.

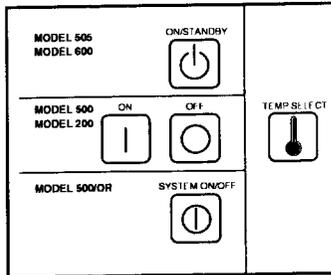


Fluid Warming Using the 241 Fluid Warming Set

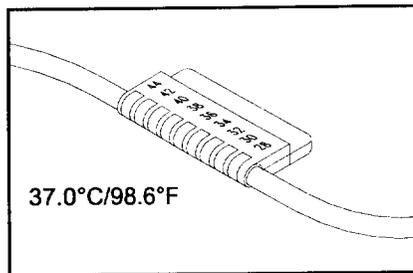
6. Make patient connection.
Do not entrap air.



7. Press the System ON/OFF (ON/STANDBY) button to turn the Series 500 Bair Hugger® Unit ON, and select the appropriate temperature setting. Tuck the outlet and extension tubing between the Blanket channels to insulate.



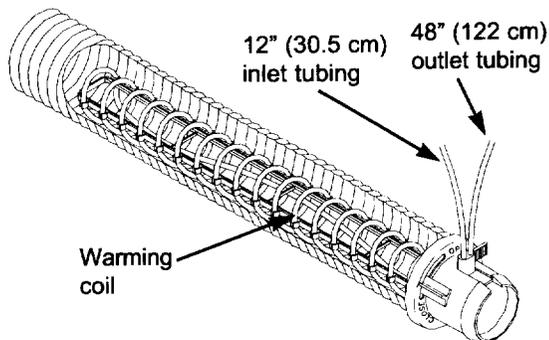
8. Begin infusion. Use the temperature indicator to monitor the fluid temperature. The green square indicates fluid temperature.



Fluid Warming Specifications

The average fluid output temperatures during normal operation of the Bair Hugger Fluid Warming Set with the Warming Unit set on HIGH are as follows:

Figure 12. 241 Fluid Warming Set Inside Warming Unit Hose



Infusion rate	Output temperature
500 ml/hr	34.9°C
1000 ml/hr	36.8°C
1500 ml/hr	36.1°C
2000 ml/hr	34.7°C
2500 ml/hr	33.2°C
3000 ml/hr	31.9°C

Fluid input temperature: 20°C.
Increase fluid temperature by an average of 3°C by tucking the outlet tubing in Bair Hugger Blanket channels.

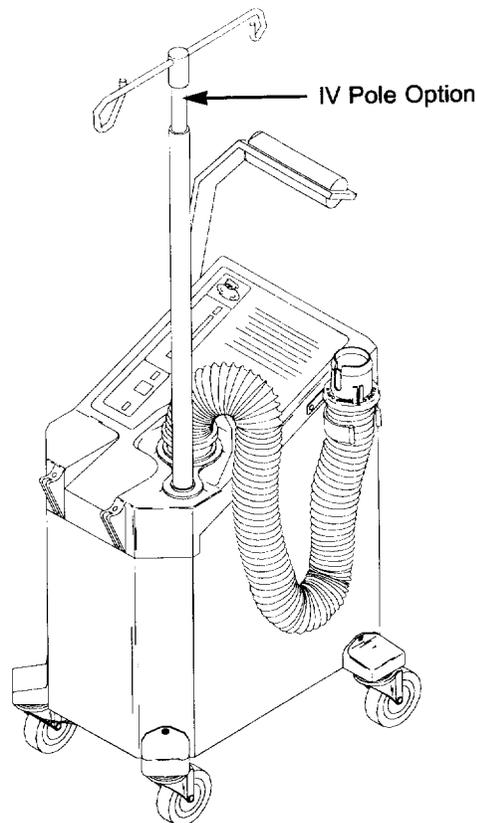
Optional Features

This section discusses available optional features for Bair Hugger® Warming Units. For more details about these features, please call Augustine Medical or your local distributor.

I.V. Pole

Model 500/OR and 500/OR,E Warming Units have a port that accommodates an Augustine Medical, Inc. I.V. pole.

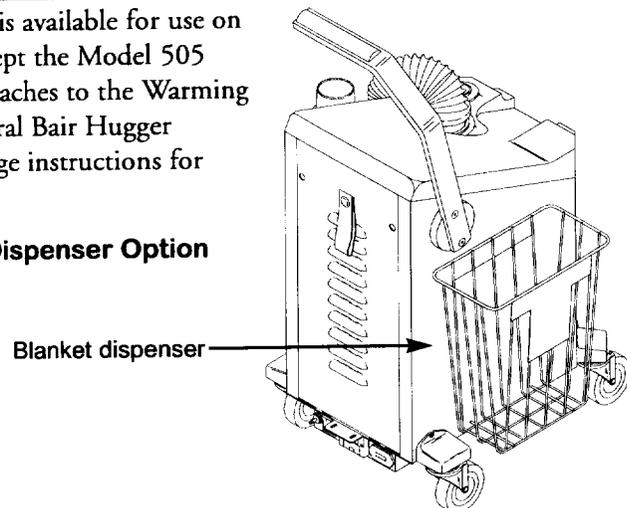
Figure 13. Warming Unit with I.V. Pole Option



Blanket Dispenser

The Blanket Dispenser is available for use on all Warming Units, except the Model 505 Unit. This dispenser attaches to the Warming Unit and can store several Bair Hugger Blankets. See the package instructions for details.

Figure 14. Blanket Dispenser Option



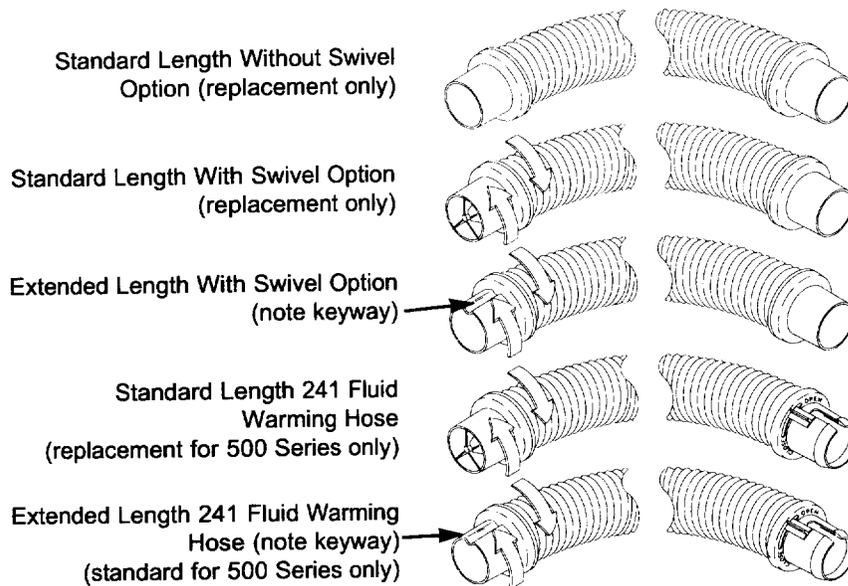
Optional Features

Hose Assemblies

Warming Unit Hose Assemblies are available in five options (see Figure 15). The keyway on the extended length hose matches a keyway on Warming 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*.

Figure 15. Warming Unit Hose Assembly Options



General Maintenance

This section describes cabinet cleaning. Please refer to the Service Manual for additional maintenance procedures.

Cabinet Cleaning

1. Disconnect the Warming Unit from the power source before cleaning.
2. Use a damp soft cloth and a mild detergent to clean the Warming 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.

Specifications

Physical Characteristics

500/OR

Dimensions 24 in. high x 16 in. deep x 14 in. wide
61 cm high x 41 cm deep x 36 cm wide

Weight 43 lb; 19.5 kg

505

Dimensions 13 in. high x 10 in. deep x 11 in. wide
33 cm high x 25 cm deep x 28 cm wide

Weight 11.5 lb; 5.2 kg

Relative Noise Level

500/OR: 52 decibels 505: 53 decibels

Hose

Detachable, flexible, washable; compatible with Bair Hugger® Model 241® Fluid Warming System

Filtration System

0.2µM level

Recommended Filter Change

Every 6 months or 500 hours of use

Mounting

500/OR: Supplied with swivel casters; floor use only
505: IV pole clamp, bed rail hook with safety strap; can be placed on hard surface

Temperature Characteristics

Temperature Control

Electronically controlled using a thermocouple sensor

Heat Generated

1800 BTUs (average)

System Time to 100°F (37.7°C)

500/OR: ~35 secs

505: ~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, assuming the back pressure of an Augustine Medical, Inc. Warming Blanket, or an Augustine Medical, Inc. Temperature Test Unit:

Model 500/OR, 505

HIGH:	43° ± 3°C	109.4° ± 5.4°F
MED:	38° ± 3°C	100.4° ± 5.4°F
LOW:	32° ± 3°C	89.6° ± 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

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

Leakage Current

<100µA

Heating Element

850W Resistive

Blower Motor

	500/OR	505
Operating speed:	2650 rpm	3150 rpm
Airflow:	28-30 cfm	28-30 cfm

Power Consumption

	500/OR	505
Peak:	1000W	1000W
Average:	500W	450W

Power Cord

15-foot, SJT, 3 cond., 10A
4.6 meter, HAR, 3 cond., 10A

Device Ratings

110-120VAC, 60Hz, 9.5 Amperes, or
220-240VAC, 50Hz, 4.5 Amperes, or
100VAC, 50/60 Hz, 10 Amperes

Fuses

10A, 200mA and 500mA (110 - 120 VAC Units)
6.3A, 100mA and 500mA (220 - 240 VAC Units)
10A, 160mA and 400mA (100VAC Units)

Diagnostics

Over-heat test can be performed by the biomedical group.

Ordering Information

Description	Part #	Units Per Case
Bair Hugger® Units		
Bair Hugger Model 500/OR Warming Unit	502	1 Unit
Bair Hugger Model 505 Warming Unit	505	1 Unit
Outpatient Blanket—Before...		
Outpatient Blanket	110	10
OR Blankets—During...		
Upper Body Blanket	522	10
Lower Body Blanket	525	10
Pediatric Blanket Long	530	10
Pediatric Blanket Short	536	10
Small Lower Body Blanket	537	10
Torso Blanket	540	10
PACU/ICU Blankets—After...		
Full Body Blanket	300	10
Chest Access Blanket	305	10
Pediatric Blanket	310	10
Multi-Access Blanket	315	10
Specialty Blankets		
Full Body Surgical Blanket	610	10
Pediatric Blanket Small	650	5
Pediatric Blanket Large	655	5
Cardiac Access Blanket	640	5
Fluid Warming		
Bair Hugger 21® Fluid Warming Set	24100	10
Accessories		
Model 505 Hose	90003	1 each
Series 500 Hose, Std. Length/Swivel Hose Flange	90004	1 each
Series 500 Hose, Ext. Length	90005	1 each
Filter for Model 500/OR-high efficiency 0.2µM	90008	1 each
Filter for Model 505-high efficiency 0.2µM	90009	1 each
Blanket Dispenser	90015	1 each
Sheet Clip	90016	1 each
Hose Clip	90017	1 each
Temperature Test Unit	22110	1 each
I.V. Pole (base not included)	90018	1 each
21® Fluid Warming Set Hose Cap	90026	12

Customer Service 1-800-733-7775

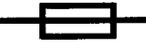
Corporate Office 1-612-947-1200

Augustine Medical, Inc.

102306K

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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
	Warning / Caution See appropriate documents
	Non Explosion-Proof
	Dangerous Voltage
	Type BF Equipment (Patient applied)
	Voltage, Alternating Current (AC)



©1996 Augustine Medical, Inc. All rights reserved.
U.S. Patent Numbers 4,572,188; 4,777,802; 5,106,373; 5,184,612; 5,300,101;
5,300,102; 5,324,320; 5,336,250; 5,350,417; 5,405,371; 5,545,194.
European Patent Number 0311336. Other patents pending.

Augustine Medical's Authorized Representative in the European Community
(as defined in Article 14 of the Medical Device Directive: 93/42/EEC):
Actamed Limited, Trinity House, Borough Road, Wakefield WF1 3AZ,
United Kingdom • TEL + 44 1924 200550 • FAX + 44 1924 200518



12/96
102306K

Device Labeling

Model 505 (Predicate Device)



Bair Hugger®
Model 505
 For Patient Warming

Augustine Medical™
 Bright ideas...that work

CONTRAINDICATIONS

1. Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury to ischemic limbs may result.
2. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.

PRECAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed health care professional.

Total Hours of Unit Operation

WARNINGS

1. Do not use this Unit with any blanket or warming cover other than Bair Hugger® Blankets. Thermal injury may result.
2. Do not provide therapy with the Warming Unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger® Blanket before providing therapy.
3. Do not continue therapy if the OVER HEAT warning light illuminates and/or the audible alarm sounds. Thermal injury may result. Turn the Warming Unit OFF and discontinue use. Contact qualified service personnel.
4. Do not initiate therapy until Warming Unit is securely mounted or injury may result.

AUGUSTINE MEDICAL, INC.
 PART NO. 51 68G

Bair Hugger® Warming Unit – Model 505

TEMP IN RANGE

MAIN POWER

SYSTEM ON/STANDBY

OVER HEAT

HIGH 43°C

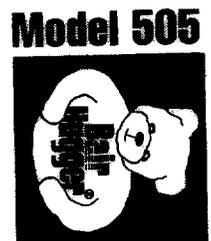
MED 38°C

LOW 32°C

TEMP SELECT

Risk Class 2G LR 86382 C22.2 6011-M90	 LISTED 84U1 MEDICAL EQUIPMENT	 MADE IN USA	Provide Unit serial number with all service or parts requests. TEL (612) 947-1200 • (800) 733-7775 FAX (612) 947-1400 • Augustine Medical, Inc. 10393 West 70th St., Eden Prairie, MN 55344 USA
WARNING: To prevent tipping, clamp the Model 505 Warming 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.			To reliably ground this Bair Hugger®, only connect to receptacles marked HOSPITAL ONLY or HOSPITAL GRADE .
OVER HEAT ALARM TEST PANEL WARNING! Removal of this panel will automatically place the Warming Unit in an over heat alarm self-test mode. Do not use for patient therapy without this panel securely positioned. See Service Manual for complete instructions.			Explosion hazard. Do not use in the presence of flammable anesthetics. Risque d'explosion. Ne pas utiliser en présence de produits anesthésiques inflammables.

120V
 60HZ



Bair Hugger®
 Total Temperature Management® System

OVER HEAT ALARM TEST PANEL

WARNING!
 Removal of this panel will automatically place the Warming Unit in an over heat alarm self-test mode. Do not use for patient therapy without this panel securely positioned. See Service Manual for complete instructions.

WARNING!
OVER HEAT ALARM TEST IN PROGRESS
 Do not provide patient therapy without over heat alarm test panel securely positioned. See Service Manual for complete instructions.

2X
 T10A, 250V
 REPLACE FUSE AS MARKED

1500mA 250V
 REPLACE FUSE AS MARKED

1200mA 250V
 REPLACE FUSE AS MARKED

Product Literature

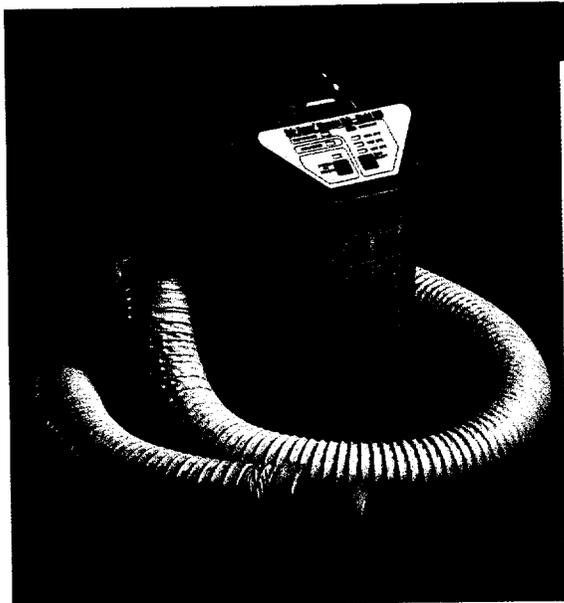
Model 505 (Predicate Device)

and

241 Fluid Warming

Warming units

Bair Hugger® warming units are the foundation of our forced air warming therapy. Each warming unit is individually tested to ensure years of safe, reliable and effective operation.



Model 505

The standard of excellence in forced air warming units, the Bair Hugger model 505 provides safe, quiet and effective warming to patients around the world.

- Small size gives you more useable work space
- Light weight makes transport and setup a breeze
- Freestanding, or easily attached to IV pole, bedrail or optional rolling stand
- Built-in hour meter makes it easy to monitor usage for preventive maintenance
- Unique snap-fit hose swivels at three points for easy blanket attachment and positioning
- Compatible with 241® blood/fluid warming set — provides two warming therapies with one machine



Specifications

Dimensions:

13" h x 10" w x 11" d (33 x 25 x 28 cm)

Weight:

11.5 lb (5.2 kg)

Operating Temperatures:

High: 43° ± 3°C 109.4° ± 5.4°F

Med: 38° ± 3°C 100.4° ± 5.4°F

Low: 32° ± 3°C 89.6° ± 5.4°F

Leakage Current:

Meets hospital and regulatory standards for leakage current.

Filter:

High-efficiency 0.2 µm filter

Device Ratings:

110-120 VAC, 60 Hz, 9.5 Amperes;

100 VAC, 50/60 Hz, 9.5 Amperes;

220-240 VAC, 50 Hz, 4.5 Amperes



Blood/Fluid Warming Set

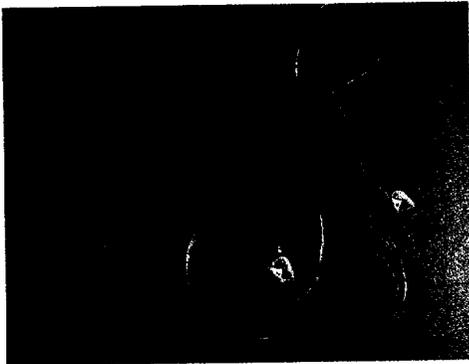
The 241 blood/fluid warming set allows you to use two warming modalities with one piece of equipment. It's ideal for low-flow situations (KVO to 3,000 mL/hr).

- Works with any Bair Hugger series 500 warming unit
- Gives you more work space, less equipment clutter
- In-line liquid crystal temperature display on outlet tubing makes it easy to monitor temperature
- Meets all American Association of Blood Bank (AABB) guidelines for blood warming

Specifications

- Natural latex-free fluid pathway
- Sterile (for single use only)
- Recommended for flow rates from KVO to 3,000 mL/hr
- Non-pyrogenic
- 34-mL priming volume
- In-line liquid crystal temperature display on outlet tubing

Model 241
Fluid Warming



Reusable Hose Cap

- Allows you to use the 241 blood/fluid warming set without a Bair Hugger blanket attached to the hose

