

JUL 9 2002

K001473

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344

Contact person: Scott Augustine, MD
Chief Executive Officer

Telephone: 952-947-1200

Fax: 952-947-1300

Device name

Trade name: Bair Hugger[®] temperature management system (Bair Hugger Series 200, 500, and 700 forced-air temperature management units used with Bair Hugger blankets) and Model 459 patient cooling set.

Common/usual name: Hyper/Hypothermia system

Classification name: System, Thermal, Regulating DWJ

Predicate Devices

1. Augustine Medical, Bair Hugger[®] Model 600 Hyper/hypothermia unit used with Bair Hugger blankets.
2. Seabrook Medical Systems, Tropi-Cool Hyper/hypothermia unit used with Temp-pad blankets.

Device Description

The Bair Hugger temperature management system consists of:

- a portable forced-air temperature management unit (200, 500, or 700 series),
- a disposable Bair Hugger forced-air blanket (various models), and
- the Model 459 patient cooling set (new disposable component of the system).

The temperature management unit delivers warmed or room-temperature air directly to a Bair Hugger blanket via a flexible hose, or it delivers room-temperature air to the Model 459 patient cooling set, which, when filled with common ice, cools the air before delivering it to a Bair Hugger blanket. Depending on the blanket model used, the blanket

Device Description (continued)

is placed around, over, or underneath the patient. Small perforations in the patient-side of the blanket disperse the air over the patient.

The new disposable Model 459 patient cooling set consists of an ice receptacle (flexible plastic bag) with an attached flexible hose assembly. The patient cooling set also has a handle to allow hanging it on an IV pole or similar stand near the temperature management unit.

The ice receptacle has:

- a hose port that accepts the hose of a Bair Hugger[®] temperature management unit,
- a resealable opening for adding and retaining ice,
- a valve for draining meltwater, and
- an integral divider that directs the flow of room-temperature air from the temperature management unit through the ice, which cools the air to a temperature ranging between 3.5°C and room temperature, as required.

Indications for use

The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Description of Safety and Effectiveness

Performance testing of the Model 459 patient cooling set was conducted to demonstrate the effectiveness of the component when used with the other Bair Hugger temperature management system components. The performance testing indicates that room-temperature air flowing from a temperature management unit through the ice-filled patient cooling set would be cooled to less than 10°C for about 1 hour. Ice may be added to the patient cooling set to prolong cooling therapy. A temperature management unit may also deliver ambient temperature air directly to a blanket for cooling therapy.

Because the modification to the device does not change any of the safety features of the device, testing was done only to determine the safety of temperatures delivered by the Model 459 patient cooling set, the new disposable component of the device.

The delivered temperatures are safe for two reasons: first, the temperature of air delivered to a Bair Hugger blanket is limited by the temperature and duration of the ice added to the Model 459 patient cooling set. Most ice in clinical settings is produced and stored in an icemaker at 0°C, and performance testing indicates that 15 pounds of ice will only deliver temperatures under 10°C for about an hour before the temperatures begin to rise. Second, tests show that if users add ice that has been stored below 0°C to the patient cooling set, the temperature of the delivered air might initially drop to close to 0°C, but it will quickly rise and stabilize between 5°C and 10°C, the standard temperature range for the device. The few minutes that a patient may be exposed to temperatures below 5°C are not harmful to the patient.

Substantial equivalence

The modified Bair Hugger[®] temperature management system (including the new Model 459 patient cooling set) is substantially equivalent to the predicate devices in safety and effectiveness. The modified device has the same intended use and patient population as the predicate devices. The warming modes of the previously cleared device(s) are not affected by the modification so the comparison of the device to predicate devices focuses on the substantial equivalence of the cooling modes of the devices.

Substantial equivalence to the Bair Hugger Model 600 hyper/hypothermia unit

The modified Bair Hugger temperature management system and the Bair Hugger Model 600 hyper/hypothermia unit (first predicate device) use the same technology to deliver air to forced-air blankets. The only significant difference between the two devices is that, in the cooling mode, the modified Bair Hugger temperature management system uses an external, ice-filled component (Model 459 patient cooling set) to cool the air before delivering it to a Bair Hugger blanket, and the predicate device has a thermoelectric heat exchanger that cools air and delivers it directly to a Bair Hugger blanket. This difference has no negative effect on the safety and effectiveness of the modified device because the temperatures delivered to the patient are similar.

Substantial equivalence to the Tropi-Cool hyper/hypothermia unit

The only significant difference between the modified Bair Hugger temperature management system (modified device) and the Tropi-Cool hyper/hypothermia unit (second predicate device) is that, in the cooling mode, the modified device uses an external, ice-filled component (Model 459 patient cooling set) to cool air before delivering it to a Bair Hugger forced-air blanket. The predicate device has a thermoelectric heat exchanger that cools water and delivers it directly to a Temp-pad water pad. This difference has no negative effect on the safety and effectiveness of the modified device because the temperatures delivered to the patient are similar.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Augustine Medical, Inc.
c/o Scott Augustine, MD
Chief Executive Officer
10393 West 70th Street
Eden Prairie, MN 55344

Re: K021473
Trade Name: Bair Hugger® Temperature Manager System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: May 7, 2002
Received: May 8, 2002

Dear Dr. Augustine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 - Scott Augustine, MD

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) number (Traditional): K021473

Device name: Augustine Medical, Inc. Bair Hugger® temperature management system

Indications for use: The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____

(Per 21 CFR 801-109)

[Signature]

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021473



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Augustine Medical, Inc.
c/o Scott Augustine, MD
Chief Executive Officer
10393 West 70th Street
Eden Prairie, MN 55344

Re: K021473
Trade Name: Bair Hugger® Temperature Manager System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II (two)
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Dated: May 7, 2002
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Page 2 - Scott Augustine, MD

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Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) number (Traditional): K021473

Device name: Augustine Medical, Inc. Bair Hugger® temperature management system

Indications for use: The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____

(Per 21 CFR 801-109)

[Signature]

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021473

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

May 08, 2002

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

510(k) Number: K021473
Received: 08-MAY-2002
Product: BAIR HUGGER
TEMPERATURE
MANAGEMENT SYSTEM

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.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. 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, International and Consumer Assistance (DSMICA) 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 (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh.ode/A02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. 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 DSMICA 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
Office of Device Evaluation
Center for Devices and Radiological Health

K 021973

Traditional 510(k) for Modified Device

Augustine Medical, Inc. Bair Hugger[®] Temperature Management System

Submitted May 7, 2002

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K021473

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INDICATIONS FOR USE

510(k) number (Traditional): _____

Device name: Augustine Medical, Inc. Bair Hugger[®] temperature management system

Indications for use: The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over the Counter Use _____

(Per 21 CFR 801-109)

TABLE OF CONTENTS

Cover Letter	1
Administrative Information	2
Request for Confidentiality	3
Truthful and Accurate Statement	4
Background Information	
<i>Reason for submission</i>	5
<i>Benefits of cooling therapy</i>	5
Description of the Modified Device	
<i>General description of the Bair Hugger[®] temperature management system</i>	7
<i>Modifications to the device components</i>	7
<i>Description of the Model 459 patient cooling set</i>	8
Substantial Equivalence	
<i>Substantial equivalence table</i>	10
<i>Comparison Summary</i>	13
Testing and Validation	
<i>General safety certification</i>	15
<i>Electromagnetic compatibility</i>	15
<i>Software validation</i>	15
<i>Hazard analysis– Model 459 patient cooling set</i>	15
<i>Biocompatibility statement</i>	15
<i>Sterilization statement</i>	16
<i>Performance testing – Model 459 patient cooling set</i>	16
510(k) Summary of Safety and Effectiveness	17

(continued)

TABLE OF CONTENTS (continued)

Product Labeling

<i>Proposed Instructions for Use – Model 459 patient cooling set</i>	<i>20</i>
<i>Revised labeling – Series 200 prescribing information</i>	<i>22</i>
<i>Revised labeling – Series 500 prescribing information</i>	<i>24</i>
<i>Revised labeling – Model 750 prescribing information</i>	<i>26</i>

Predicate Device Labeling

<i>Bair Hugger[®] Model 600 Hyper/hypothermia unit</i>	<i>Appendix A</i>
<i>Seabrook Medical Systems Tropi-Cool Hyper/hypothermia unit</i>	<i>Appendix B</i>
<i>Performance Test Report – Model 459 Patient Cooling Set.....</i>	<i>Appendix C</i>



May 7, 2002

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

Re: Traditional 510(k) Notification for Augustine Medical, Inc. Bair Hugger[®]
temperature management system *modification*, including addition of a disposable
component (Model 459 patient cooling set) to the temperature management system.

Pursuant to the regulations regarding 510(k) applications, Augustine Medical, Inc.,
intends to market the *modified* Bair Hugger Patient Warming System as part of the Bair
Hugger temperature management system. Augustine Medical regards this product to be
substantially equivalent to the following predicate devices:

1. Bair Hugger Model 600 hyper/hypothermia system (K950416), and
2. Seabrook Medical Systems Tropi-Cool Hyper/Hypothermia unit (K902756).

We consider our intent to market this device as confidential commercial information and
request that it be treated as such by the FDA.

The submission is provided in duplicate as required by regulation. If you have any
questions regarding this traditional 510(k) submission, please contact the undersigned at
952-947-1200 or by fax at 952-947-1300.

Sincerely,

A handwritten signature in black ink, appearing to read 'Scott D. Augustine, MD', with a small mark to the right.

Scott D. Augustine, MD
Chief Executive Officer

ADMINISTRATIVE INFORMATION

This is to notify you of the intention of Augustine Medical, Inc. to manufacture and market a *modified* medical device:

Product Classification Name and Code:	System, Thermal, Regulating DWJ
Common/Usual Name:	Hyper/Hypothermia system
Model Name/Number:	Bair Hugger [®] temperature management system (Bair Hugger Series 200, 500, and 700 forced-air temperature management units used with Bair Hugger blankets and new Model 459 patient cooling set).
Establishment Registration Number:	2183725
Device Class:	Class II, 870.5900
Classification Panel:	Cardiovascular
Performance Standard:	None available
Predicate Devices:	<ol style="list-style-type: none">1. Augustine Medical Bair Hugger[®] Model 600 Hyper/hypothermia unit used with Bair Hugger blankets. (K950416)2. Seabrook Medical Systems Tropi-Cool Hyper/hypothermia unit. (K902756)
Summary of Safety and Effectiveness:	Pursuant to the requirements of the SMDA of 1990, a summary of the safety and effectiveness information upon which the substantial equivalence determination is based is included with this submission.
Manufacturer:	Augustine Medical, Inc. 10393 West 70 th Street Eden Prairie, MN 55344 952-947-1200
Contact Person:	Scott D. Augustine, MD CEO and Medical Director Phone: 952-947-1200 Fax: 952-947-1300

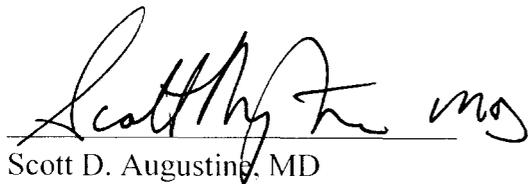
REQUEST FOR CONFIDENTIALITY

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.

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87(j))

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



Scott D. Augusting, MD
Chief Executive Officer
Augustine Medical, Inc.

5/7/02
Date

BACKGROUND INFORMATION

Reason for submission

The reason for this submission is to notify the FDA that Augustine Medical, Inc. plans to bring a *modified* device to market with additional indications for use and a new disposable component of the device.

Patient cooling will be added as an intended use for the Bair Hugger[®] temperature management system. Patient cooling is indicated for managing elevated body temperatures or hyperthermia in patients or for inducing hypothermia in or providing localized cooling for normothermic patients for whom induced hyperthermia or localized cooling would be therapeutic.

Reference list (continued)

3. Shiozake T, Sugimot H, Taneda M, et al. Effect of mild hypothermia on uncontrollable intracranial hypertension after severe head injury. *J Neurosurg.* 1992; 79.
4. Caruso CC, Hadley J, Shukla R, Frame P, Khoury J. Cooling effects and comfort of four cooling blanket temperatures in humans with fever. *Nurse Res.* 1992; 41(2): 68-72.
5. Harker J, Gibson P. Heat-stroke: a review of rapid cooling techniques. *Intensive Crit Care Nurs.* 1995; 11(4): 198-202.
6. Gronert GA, Schulman SR, Mott J. Malignant hyperthermia. In: Miller RD, ed. *Anesthesia.* 3rd ed. Churchill Livingstone Inc; 1990: 949.
7. Ogden W, Biser J, Akers K, Lytle C. *Constant cold therapy for total joint replacements.* Presented to the Piedmont Orthopaedic Society, May 1990.

DESCRIPTION OF THE MODIFIED DEVICE

General description of the Bair Hugger[®] temperature management system

The Bair Hugger temperature management system consists of:

- a portable forced-air temperature management unit (200, 500, or 700 series),
- a disposable Bair Hugger forced-air blanket (various models),
- a Model 459 patient cooling set (the new disposable component of the system).

The temperature management unit delivers warmed or ambient temperature air directly to a Bair Hugger blanket via a flexible hose, or it delivers room-temperature air to the model 459 patient cooling set, which, when filled with ice, cools the air before delivering it to a Bair Hugger blanket. Depending on the blanket model used, the blanket is placed either around, over, or underneath the patient. Small perforations in the patient-side of the blanket disperse the air over the patient.

Modifications to the device components

The following modifications have been made to the Bair Hugger temperature management system:

1. Series 200, 500, and 700 temperature management units (K873745 [200 series], K960167, K903360 [500 series], K001149 [700 series]) including all blankets.
 - Change intended use to include patient cooling, to be described as “patient temperature management.” Indications for use include hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold.

No physical changes to the components of the temperature management system have been made.

2. Model 459 patient cooling set
 - The patient cooling set is a new disposable component of the Bair Hugger temperature management system, which, when used with a 200, 500, or 700 series temperature management unit and a Bair Hugger blanket, provides patient cooling.

Description of the Model 459 patient cooling set

The Model 459 patient cooling set is used in conjunction with a Bair Hugger[®] Series 200, 500, or 700 forced-air temperature management unit and a Bair Hugger disposable blanket. The disposable patient cooling set consists of an ice receptacle (flexible plastic bag) with an attached hose assembly.

Figure A is a photograph of the patient cooling set without ice so that the construction of the cooling set can be seen.



Figure A. Model 459 Patient Cooling Set without ice.



Figure B. Model 459 Patient Cooling Set with ice.

- The ice receptacle has a hose port that accepts the hose of a Bair Hugger forced-air temperature management unit. The patient cooling set has a handle to allow hanging it on an IV pole or similar stand near the temperature management unit.
- The ice receptacle must be filled with common ice (frozen water). The ice receptacle has a resealable opening for filling the bag and retaining ice and a valve for draining meltwater from the receptacle. An integral divider in the ice receptacle directs the flow of room-temperature air from the temperature management unit through the ice, which cools the air to a temperature between 3.5°C and room temperature, as required.

Description of the Model 459 patient cooling set (continued)

- The cooled air exits the ice receptacle through the receptacle's attached hose assembly, which is connected to a Bair Hugger[®] blanket. See Figure C.

(b)(4)



Figure C.

- The Bair Hugger blankets, which are perforated on one side, deliver the cooled air generally or locally to the patient, depending on the blanket model used.
- A thermochromic liquid crystal temperature indicator is affixed to the hose assembly to measure and report the temperature of the air being delivered to the blanket.

SUBSTANTIAL EQUIVALENCE

Substantial equivalence table

Parameter	Modified Device: Augustine Medical, Inc. Bair Hugger® temperature management system (Series 200, 500, and 700 temperature management units, Model 459 patient cooling set, and Bair Hugger blankets)	Predicate Device: Augustine Medical, Inc. Bair Hugger Model 600 Hyper/Hypothermia unit used with Bair Hugger blankets	Predicate Device: Seabrook Medical Systems, Inc. Tropi-Cool Hyper/Hypothermia unit
Intended use	To warm or cool patients.	To warm or cool patients.	To warm or cool patients.
Indications for use	For the treatment of hyper- or hypothermia in adult and pediatric patients, or for normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold.	For the treatment of hyper- or hypothermia in adult and pediatric patients, or for normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated.	For the treatment of hyper- or hypothermia in adult and pediatric patients, or for normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated.
Settings for device use	All clinical settings, including: operating rooms, recovery rooms, intensive care units, obstetrical suites, emergency departments, or any other setting where patients require warming or cooling therapy.	All clinical settings, including: operating rooms, recovery rooms, intensive care units, obstetrical suites, emergency departments, or any other setting where patients require warming or cooling therapy.	Operating room, intensive care unit, and emergency room.
Blankets used	All Bair Hugger blankets.	All Bair Hugger blankets.	All Temp-pad blankets

Substantial equivalence table (continued)

Parameter	Modified Device: Augustine Medical, Inc. Bair Hugger [®] temperature management system (Series 200, 500, and 700 temperature management units, Model 459 patient cooling set, and Bair Hugger blankets)	Predicate Device: Augustine Medical, Inc. Bair Hugger Model 600 Hyper/Hypothermia unit used with Bair Hugger blankets	Predicate Device: Seabrook Medical Systems, Inc. Tropi-Cool Hyper/Hypothermia unit
Anatomical sites of use	General or various local regions of the body depending which model Bair Hugger blanket is used	General or various local regions of the body depending which model Bair Hugger blanket is used.	SMS-2236, SMS-2236V, SMS-2460V Temp-Pads: Can be placed over or under the patient.
Cooling/Heating System:			
Setpoint range	3.5°C to 43°C	10°C to 43°C	(water) 4°C to 42°C
Heating elements:	Resistive heating elements	Solid state, thermoelectric modules	250 watt cartridge type
Cooling elements:	Common ice contained in external disposable component (Model 459 patient cooling set)	Solid state, thermoelectric modules	Solid state, thermoelectric modules
Circulating system:			
Reservoir capacity:	Not applicable	Not applicable	2 quarts
Transfer media:	Filtered air	Filtered air	Distilled water
Flow rate:	16-30 cfm (with Model 459 patient cooling set)	30 cfm	18-20 gallons per hour

Substantial equivalence table (continued)

Parameter	Modified Device: Augustine Medical, Inc. Bair Hugger® temperature management system (Series 200, 500, and 700 temperature management units, Model 459 patient cooling set, and Bair Hugger blankets)	Predicate Device: Augustine Medical, Inc. Bair Hugger Model 600 Hyper/Hypothermia unit used with Bair Hugger blankets	Predicate Device: Seabrook Medical Systems, Inc. Tropi-Cool Hyper/Hypothermia unit
Safety characteristics	<p>The specific hazards that have been tested and shown to be appropriately protected against include:</p> <ul style="list-style-type: none"> • electric shock hazards • mechanical hazards • hazards of unwanted radiation • hazards of ignition of flammable anesthetic mixtures • excessive temperatures and other safety hazards • hazardous output • abnormal operation and fault conditions 	<p>The specific hazards that have been tested and shown to be appropriately protected against include:</p> <ul style="list-style-type: none"> • electric shock hazards • mechanical hazards • hazards of unwanted radiation • hazards of ignition of flammable anesthetic mixtures • excessive temperatures and other safety hazards • hazardous output • abnormal operation and fault conditions 	<p>Safety system includes:</p> <p>Warning lights:</p> <ul style="list-style-type: none"> • Add Water • High Limit • Low Limit • Back-up High Limit <p>Audible alarms:</p> <ul style="list-style-type: none"> • Add water • High Limit • Low Limit • Selection of "Patient Temp" mode without a probe connected • Remote probe temp. below 30°C • Malfunction of the water temperature sensor.

Comparison summary

Comparison of modified device to Bair Hugger® Model 600 hyper/hypothermia unit:

The modified Bair Hugger temperature management system, including the new Model 459 patient cooling set as a disposable component of the system, is substantially equivalent in safety and effectiveness in its intended use to the Bair Hugger Model 600 hyper/hypothermia unit (first predicate device). Both devices provide skin surface cooling and warming. Because the properties of the warming modes of the modified device have not changed since FDA initially cleared the device(s), the following comparison focuses strictly on the cooling modes of the devices.

The primary differences between the cooling modes for the devices are:

- The Bair Hugger Model 600 hyper/hypothermia unit has an internal thermoelectric heat exchanger that delivers cooled air directly to a Bair Hugger blanket. The modified device consists of a temperature management unit (200, 500, or 700 series) set in the *Ambient* mode that blows room-temperature air through an external, disposable, ice-filled bag (Model 459 patient cooling set), which delivers the cooled air to a Bair Hugger blanket.
- The Bair Hugger Model 600 hyper/hypothermia unit reports the temperature of the delivered air on the temperature management unit. The modified device displays the temperature of the cooled air on the Model 459 patient cooling set's hose assembly.
- The Bair Hugger Model 600 hyper/hypothermia unit will run indefinitely in the cooling mode. The Model 459 patient cooling set, used with a Bair Hugger temperature management unit, will cool air for about an hour before additional ice must be added to the receptacle of the cooling set.
- The Bair Hugger Model 600 hyper/hypothermia unit has a low temperature alarm to prevent prolonged patient cooling at undesirably low temperatures. The modified device has no low temperature alarm because the temperature of the delivered air is limited by the temperature of the common ice added to the Model 459 patient cooling set. Most ice that is made and used in clinical settings is from ice machines that produce and store ice at 0°C (32°F). If ice that has been stored below 0°C is used in the patient cooling set, the temperature of the delivered air quickly rises and stabilizes between 5°C and 10°C. See the Test Results in Appendix C for further discussion about ice temperature and delivered air temperatures.

Comparison of modified device to Tropi-Cool hyper/hypothermia unit:

The modified Bair Hugger[®] temperature management system, which includes the new Model 459 patient cooling set as a disposable component of the system, is substantially equivalent in safety and effectiveness in its intended use to the Tropi-Cool hyper/hypothermia unit (second predicate device). Both devices provide skin surface cooling and warming. Because the properties of the warming modes of the modified device have not changed since FDA initially cleared the device(s), the following comparison focuses strictly on the cooling modes of the devices.

The primary differences between the cooling modes for the devices are:

- The Tropi-Cool hyper/hypothermia unit has an internal thermoelectric heat exchanger that cools and delivers water to a Temp-pad blanket to provide patient cooling. The modified Bair Hugger temperature management system consists of a forced-air temperature management unit (200, 500, or 700 series) set in the *Ambient* mode that blows room-temperature air through an external, disposable, ice-filled bag (Model 459 patient cooling set), which delivers the cooled air to a Bair Hugger blanket to provide patient cooling.
- The Tropi-Cool hyper/hypothermia unit reports the temperature of the cooled water on the unit. The modified device displays the temperature of the cooled air on the Model 459 patient cooling set's hose assembly.
- The Tropi-Cool hyper/hypothermia unit will run indefinitely in the cooling mode. The Model 459 patient cooling set, used with a Bair Hugger temperature management unit, will cool air for about an hour before additional ice must be added to the receptacle of the cooling set.
- The Tropi-Cool hyper/hypothermia unit has a low temperature alarm to prevent prolonged patient cooling at undesirably low temperatures. The modified device has no low temperature alarm because the temperature of the delivered air is limited by the temperature of the common ice added to the Model 459 patient cooling set. Most ice that is made and used in clinical settings is from ice machines that produce and store ice at 0°C (32°F). If ice that has been stored below 0°C is used in the patient cooling set, the temperature of the delivered air quickly rises and stabilizes between 5°C and 10°C. See the Test Results in Appendix C for further discussion about ice temperature and delivered air temperatures.

TESTING AND VALIDATION

General safety certification

The modification to the Bair Hugger® series 200, 500, and 700 temperature management units is to the indications for use only and does not alter the mechanical functioning or safety features of the temperature management units.

The series 200, 500, and 700 temperature management units are certified to the requirements of the UL 2601 and EN 60601-1 safety standards. Test protocols and certification documents remain on file at Augustine Medical, Inc.

Electromagnetic compatibility

The modification to the Bair Hugger series 200, 500, and 700 temperature management units is to the indications for use only and does not alter the electromagnetic compatibility of the temperature management units.

The series 200, 500, and 700 temperature management units are certified to the requirements of EN 60601-1-1-2 (1993) and EN 55011 (1991); Corregendum-1996. Test protocols and certification documents remain on file at Augustine Medical, Inc.

Software validation

The modification to the Bair Hugger series 200, 500, and 700 temperature management units is to the indications for use only and does not alter the software validation of the temperature management units.

Software is controlled within the guidelines of the Augustine Medical, Inc., systems. A Software Requirements Specification has been previously documented and approved.

Hazard analysis

Standard design control processes were performed for the Model 459 patient cooling set (the new disposable component to be used with a Bair Hugger series 200, 500, or 700 temperature management unit), including hazard analyses that confirmed that the product meets safety requirements. Hazard analysis techniques include a (b)(4) (b)(4) Items identified as possible concerns were analyzed for corrective action and appropriate steps were taken to eliminate the concern or reduce the risk priority to an acceptable level.

Biocompatibility

Biocompatibility testing is not required because the Model 459 patient cooling set (the new disposable component to be used with a Bair Hugger series 200, 500, or 700 temperature management unit) does not contact the patient. The Model 459 patient cooling set is latex-free.

Sterilization

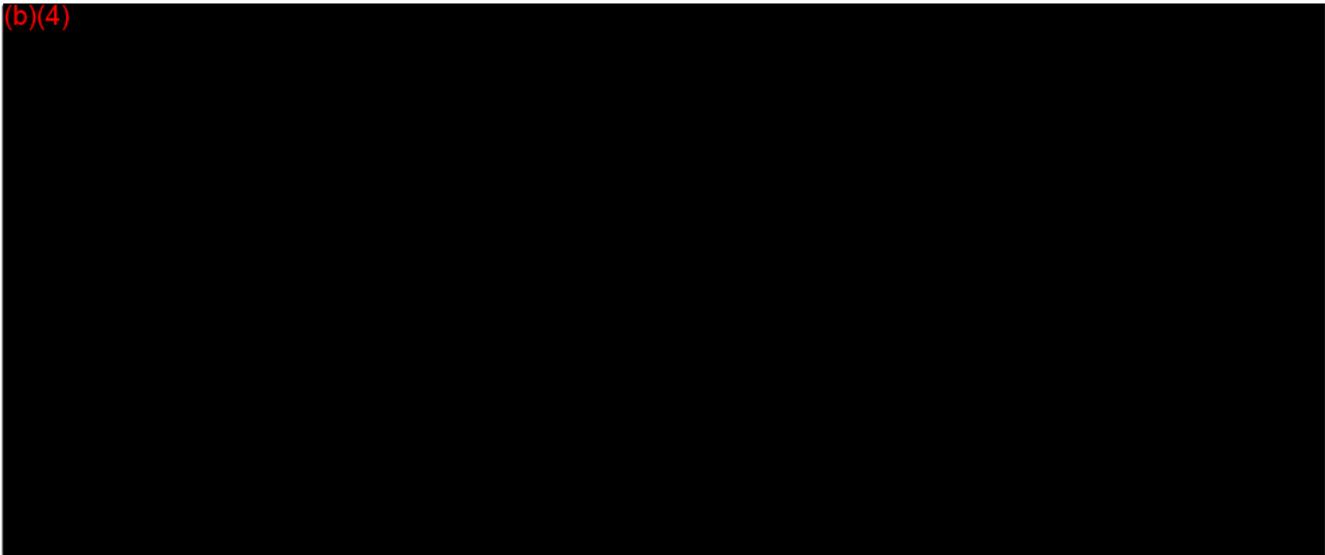
Sterilization testing is not required because the Model 459 patient cooling set (the new disposable component to be used with a Hugger series 200, 500, or 700 temperature management unit) is not sterile.

Performance testing

Series 200, 500, and 700 temperature management units

The modification to the Bair Hugger[®] series 200, 500, and 700 temperature management units is to the indications for use only and does not alter the performance of the temperature management units.

(b)(4)



See Appendix C for actual test results.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344

Contact person: Scott Augustine, MD
Chief Executive Officer

Telephone: 952-947-1200

Fax: 952-947-1300

Device name

Trade name: Bair Hugger[®] temperature management system (Bair Hugger Series 200, 500, and 700 forced-air temperature management units used with Bair Hugger blankets) and Model 459 patient cooling set.

Common/usual name: Hyper/Hypothermia system

Classification name: System, Thermal, Regulating DWJ

Predicate Devices

1. Augustine Medical, Bair Hugger[®] Model 600 Hyper/hypothermia unit used with Bair Hugger blankets.
2. Seabrook Medical Systems, Tropi-Cool Hyper/hypothermia unit used with Temp-pad blankets.

Device Description

The Bair Hugger temperature management system consists of:

- a portable forced-air temperature management unit (200, 500, or 700 series),
- a disposable Bair Hugger forced-air blanket (various models), and
- the Model 459 patient cooling set (new disposable component of the system).

The temperature management unit delivers warmed or room-temperature air directly to a Bair Hugger blanket via a flexible hose, or it delivers room-temperature air to the Model 459 patient cooling set, which, when filled with common ice, cools the air before delivering it to a Bair Hugger blanket. Depending on the blanket model used, the blanket

Device Description (continued)

is placed around, over, or underneath the patient. Small perforations in the patient-side of the blanket disperse the air over the patient.

The new disposable Model 459 patient cooling set consists of an ice receptacle (flexible plastic bag) with an attached flexible hose assembly. The patient cooling set also has a handle to allow hanging it on an IV pole or similar stand near the temperature management unit.

The ice receptacle has:

- a hose port that accepts the hose of a Bair Hugger[®] temperature management unit,
- a resealable opening for adding and retaining ice,
- a valve for draining meltwater, and
- an integral divider that directs the flow of room-temperature air from the temperature management unit through the ice, which cools the air to a temperature ranging between 3.5°C and room temperature, as required.

Indications for use

The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Description of Safety and Effectiveness

Performance testing of the Model 459 patient cooling set was conducted to demonstrate the effectiveness of the component when used with the other Bair Hugger temperature management system components. The performance testing indicates that room-temperature air flowing from a temperature management unit through the ice-filled patient cooling set would be cooled to less than 10°C for about 1 hour. Ice may be added to the patient cooling set to prolong cooling therapy. A temperature management unit may also deliver ambient temperature air directly to a blanket for cooling therapy.

Because the modification to the device does not change any of the safety features of the device, testing was done only to determine the safety of temperatures delivered by the Model 459 patient cooling set, the new disposable component of the device.

The delivered temperatures are safe for two reasons: first, the temperature of air delivered to a Bair Hugger blanket is limited by the temperature and duration of the ice added to the Model 459 patient cooling set. Most ice in clinical settings is produced and stored in an icemaker at 0°C, and performance testing indicates that 15 pounds of ice will only deliver temperatures under 10°C for about an hour before the temperatures begin to rise. Second, tests show that if users add ice that has been stored below 0°C to the patient cooling set, the temperature of the delivered air might initially drop to close to 0°C, but it will quickly rise and stabilize between 5°C and 10°C, the standard temperature range for the device. The few minutes that a patient may be exposed to temperatures below 5°C are not harmful to the patient.

Substantial equivalence

The modified Bair Hugger[®] temperature management system (including the new Model 459 patient cooling set) is substantially equivalent to the predicate devices in safety and effectiveness. The modified device has the same intended use and patient population as the predicate devices. The warming modes of the previously cleared device(s) are not affected by the modification so the comparison of the device to predicate devices focuses on the substantial equivalence of the cooling modes of the devices.

Substantial equivalence to the Bair Hugger Model 600 hyper/hypothermia unit

The modified Bair Hugger temperature management system and the Bair Hugger Model 600 hyper/hypothermia unit (first predicate device) use the same technology to deliver air to forced-air blankets. The only significant difference between the two devices is that, in the cooling mode, the modified Bair Hugger temperature management system uses an external, ice-filled component (Model 459 patient cooling set) to cool the air before delivering it to a Bair Hugger blanket, and the predicate device has a thermoelectric heat exchanger that cools air and delivers it directly to a Bair Hugger blanket. This difference has no negative effect on the safety and effectiveness of the modified device because the temperatures delivered to the patient are similar.

Substantial equivalence to the Tropi-Cool hyper/hypothermia unit

The only significant difference between the modified Bair Hugger temperature management system (modified device) and the Tropi-Cool hyper/hypothermia unit (second predicate device) is that, in the cooling mode, the modified device uses an external, ice-filled component (Model 459 patient cooling set) to cool air before delivering it to a Bair Hugger forced-air blanket. The predicate device has a thermoelectric heat exchanger that cools water and delivers it directly to a Temp-pad water pad. This difference has no negative effect on the safety and effectiveness of the modified device because the temperatures delivered to the patient are similar.

PRODUCT LABELING

Proposed Instructions for Use

Bair Hugger[®] Model 459 Patient Cooling Set

Intended Use/Indications for Use

To provide skin-surface cooling for adult and pediatric patients who are hyperthermic and for normothermic patients for whom induced hypothermia or localized temperature therapy is clinically indicated.

Contraindication

None.

Warnings

- Do not continue cooling therapy if the red warning light illuminates (steadily or flashing) and/or the alarm sounds. Thermal injury may result. Unplug the temperature management unit and contact qualified technical personnel.
- Do not use the Model 459 patient cooling set with any forced-air warming or cooling system other than a Bair Hugger temperature management unit with a Bair Hugger blanket.
- Do not use dry ice or other cooled substances in the Model 459 patient cooling set. Thermal injury may result. Use only common ice (frozen water) in the Model 459 patient cooling set.

Precautions

- Read the Operator's Manual for the Bair Hugger temperature management unit and the Instructions for Use for the Bair Hugger blanket before beginning cooling therapy with the Model 459 patient cooling set.
- Do not invert the Model 459 ice bag or raise it above the temperature management unit while the unit's hose is attached to the bag if the bag contains ice and/or water. Doing so may cause moisture to enter the temperature management unit and damage electrical components.

Instructions for Use (continued)

Bair Hugger® Model 459 Patient Cooling Set

- 1 Follow the Instructions for Use included with the Bair Hugger® blanket for placing and securing the blanket to the patient.
- 2 Add ice up to the fill line on the bag of the patient cooling set (about 15 pounds of ice) and seal the bag shut. Use only common ice (frozen water) in the cooling set. Do not use other types of ice, such as dry ice.
- 3 Hang the patient cooling set from a bed rail or a stable rolling stand near the Bair Hugger temperature management unit (TMU) at a height lower than the TMU.
- 4 Insert the end of the TMU's hose into the hose port on the ice bag.
- 5 Insert the end of the patient cooling set's hose into the hose port on the blanket.
- 6 If your TMU has an isolation switch on the back of the unit, turn the switch to the ON position. Turn the TMU ON and select the *Ambient* temperature setting.
- 7 Monitor the temperature on the cooling set's hose every 10 to 20 minutes. Shift the ice in the bag and drain meltwater as necessary to maintain airflow and optimum cooling effect. (Output temperature can vary depending on amount and position of ice.) Add additional ice to extend cooling therapy.

CAUTION: Disconnect the TMU's hose from the ice bag before moving the bag if you intend to move the patient cooling set to another location to add ice.

- 8 Monitor the patient's temperature every 10 to 20 minutes and discontinue cooling therapy when therapeutic goal is reached.
- 9 When cooling therapy is complete, disconnect the TMU's hose from the ice bag before discarding the patient cooling set and blanket.

NOTE: If you need to rewarm the patient after administering cooling therapy, remove the TMU's hose from the ice bag and connect the hose directly to the hose port on the blanket. Do not warm patients while the TMU is still connected to the Model 459 patient cooling set.

Revised Labeling

Series 200 Temperature Management Unit

Prescribing information excerpted from Operator's Manual:

Indications for Use

The Bair Hugger[®] temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Contraindications

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

Warnings

- Do not use the HIGH temperature setting on 200 series warming units when treating patients with the following conditions:
 - Significant peripheral vascular disease (occlusive or diabetic)
 - Low cardiac output
 - Total immobilization
 - Marginal cutaneous perfusion

Monitor the patient's temperature at least every 10 to 20 minutes. Risk of thermal injury is significant for this group of patients.

- Do not use 200 series warming units in operating rooms. Thermal injury and airborne contamination may result.
- Do not warm patients with the temperature management unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin-surface temperature management therapy.
- Use only Bair Hugger disposable components with 200 series temperature management units. This temperature management unit has been designed to operate safely with Bair Hugger disposable components. Use with other products may cause thermal injury. To the full extent permitted by law, the manufacturer and/or importer

declines all responsibility for thermal injury resulting from the unit being used in conjunction with non- Bair Hugger[®] forced-air temperature management blankets.

- Do not continue temperature management therapy if the red *Over Heat* indicator light illuminates and the alarm sounds. Thermal injury may result. Unplug the temperature management unit, and contact qualified service personnel.
- Do not allow the temperature management unit's hose to contact the patient's skin during warming therapy. Thermal injury may result.

Precautions

- Monitor the patient's temperature at least every 10 to 20 minutes, and monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician immediately of vital sign instability.

S1

Series 500 Temperature Management Units

Prescribing information excerpted from Operator's Manual:

Indications for Use

The Bair Hugger[®] temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Contraindication

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

Warnings

- Do not warm patients with the temperature management unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin-surface temperature management therapy.
- Use only Bair Hugger disposable components with the 500 series temperature management units. These temperature management units have been designed to operate safely with Bair Hugger disposable components. Use with other products may cause thermal injury. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the temperature management units being used in conjunction with non-Bair Hugger forced-air temperature management products.
- Do not continue temperature management therapy if the red *Over Heat* indicator light flashes and the alarm sounds. Thermal injury may result. If providing blood/fluid warming therapy, immediately stop fluid flow and discard the 241 blood/fluid warming set. Unplug the temperature management unit, and contact a qualified service technician.
- Do not allow the temperature management unit's hose to contact the patient's skin during warming therapy. Thermal injury may result.
- Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.

52

Precautions

- Monitor the patient's temperature at least every 10 to 20 minutes, and monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician immediately of vital sign instability.
- Do not initiate temperature management therapy unless the 500 series temperature management unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
- The 500 series temperature management units meet the international electronic interference requirements of EN 60601-1-2 and EN 55011. However, if radio frequency interference with monitoring equipment should occur, connect the temperature management unit to a different power source.

Model 750 Temperature Management Unit

Prescribing information excerpted from Operator's Manual:

Indications for Use

The Bair Hugger[®] temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Contraindication

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

Warnings

- Do not warm patients with the temperature management unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin-surface temperature management therapy.
- Use only Bair Hugger disposable components with the Model 750 temperature management unit. This temperature management unit has been designed to operate safely with Bair Hugger disposable components. Use with other products may cause thermal injury. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the unit being used in conjunction with non-Bair Hugger forced-air temperature management products.
- Do not continue temperature management therapy if the red *Over-temp* indicator light flashes and the alarm sounds. Thermal injury may result. If providing blood/fluid warming therapy, immediately stop fluid flow and discard the 241 blood/fluid warming set. Unplug the temperature management unit, and contact a qualified service technician.
- Do not allow the temperature management unit's hose to contact the patient's skin during warming therapy. Thermal injury may result.
- Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.

54

Precautions

- Monitor the patient's temperature at least every 10 to 20 minutes, and monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician immediately of vital sign instability.
- Do not initiate temperature management therapy unless the Model 750 temperature management unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
- The Model 750 temperature management unit meets the international electronic interference requirements of EN 60601-1-2 and EN 55011. However, if radio frequency interference with monitoring equipment should occur, connect the temperature management unit to a different power source.

SS'

Appendix A

Predicate Device Labeling

Bair Hugger[®] Model 600 Hyper/Hypothermia Unit

BAIR HUGGER OPERATION MANUAL

Model 600 PolarAir™
Hyper/Hypothermia Unit

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

Available in UK TEL: +44-19-24-200550

FAX: +44-19-24-200518

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 (for domestic shipments only).

When You Call for Technical Support

Remember, we will need to know the serial number of your Unit when you call us. On Model 600 Units, the serial number label is affixed to the back panel.

58

The Model 600 PolarAir™ unit is a self-contained, easily transportable forced-air patient cooling and warming device, designed for safe use in all clinical areas, including post anesthesia care units (PACU), recovery rooms, operating rooms, obstetrical suites, emergency departments, and intensive care areas.

The Model 600 Unit draws room air through a filter and warms or cools the air to a specified temperature range. It then delivers the thermally controlled air through a hose to the Bair Hugger® blanket over the patient.

When used properly, the Bair Hugger® blanket safely surrounds the patient in a thermally-controlled envelope of filtered air.

*Bair Hugger®
Total Temperature
Management® System*

This manual describes how to operate Model 600 PolarAir™ units, general maintenance, and specifications. More detailed information can be found in the instructions included with Bair Hugger® blankets.

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*Model 600 Limited Warranty**

6 Year Warranty

Augustine Medical, Inc. (the "Company") warrants to the original end user that the heat exchanger modules and blowers in the Model 600 PolarAir™ unit will be free from defects in materials and workmanship under normal use and service for six years¹.

1 Year Warranty

Augustine Medical, Inc. warrants to the original end user that all major electronic components will be free from defects in materials and workmanship under normal use and services for one year¹.

¹This warranty shall not apply to hose assemblies and filters. The warranty shall 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. The use of any cover or blanket not manufactured or approved by the Company with the Company's Model 600 Units invalidates the foregoing warranty.

²The Limited Warranty is valid only for Model 600 Forced Air Warming and Cooling Therapy. It does not apply to Bair Hugger Accessories.

The Buyer shall be obligated to return any defective product to the Company. Such return shall occur only pursuant to a Return Authorization issued by the Company. Customers should contact the Company in writing or by telephone at the following address to obtain a Return Authorization:

Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344 USA
1-800-733-7775
(612) 947-1200

Scott D. Augustine, M.D., Chief Executive Officer
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344 USA
1-800-733-7775
(612) 947-1200



60

Table of Contents

Precautionary Information	1
Contraindications	1
Warnings	1
Precautions	1
Important Information	2
Read Before Servicing Equipment	2
Hypothermia as a Clinical Problem or as a Desired Clinical Result	3
Blankets	4
Model 600 Unit	5
Control Panel	6
System Control ON/STANDBY	6
Temperature Indicators	6
Set UP/Set DOWN	6
Temperature Output at Hose End Display	6
°C/°F mode	6
Set Time / Minutes Display	6
Temperature Out of Range Indicator	6
Call for Service Indicator	6
Instructions for Use	7
Set Time Function	8
General Maintenance	9
Cabinet Cleaning	9
Error Codes	9
Specifications	10

List of Figures

Figure 1. Bair Hugger® blankets4
Figure 2. Model 600 PolarAir™ unit.....5
Figure 3. Control Panel.....6

62

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® units with any blanket or thermal cover other than Bair Hugger® blankets. Thermal injury may result.

Do not provide skin surface warming or cooling with the hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin surface temperature therapy.

Alarm Do not continue therapy if the red warning light illuminates and the audible alarm sounds. Thermal injury may result. Turn the Model 600 Unit off and contact qualified service personnel.

Precautions

Monitor temperature Monitor the patient's temperature at least every 10-20 minutes, and monitor patient vital signs regularly. Discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician immediately of vital sign instability.

Pediatric usage 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.

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

Patient safety Series 500 and Series 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 and Blanket instructions prior to use.

Important Information

Explosion hazard Do not use in the presence of flammable anesthetics.

Electrical shock hazard



Do not disassemble the Model 600 PolarAir™ unit; refer to an authorized service technician. There are electrically live parts within the Model 600 Unit when it is connected to the power source, even when the switches are in the STANDBY position.

Electrical interference

If radio frequency interference with monitoring equipment should occur, connect the Model 600 Unit to a different power source.

Read Before Servicing Equipment

The repair, calibration, and servicing of the Model 600 PolarAir 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 Bair Hugger® Model 600 PolarAir unit, and before returning the Model 600 Unit to service. A safety inspection should include a test of the operating temperatures (described in the Service Manual), the temperature 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 non-authorized 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.

Hypothermia as a Clinical Problem or as a Desired Clinical Result

Definition	<p>Hypothermia occurs when a patient's body temperature drops below 36°C (96.8°F).</p> <p>Adverse consequences of hypothermia include:</p> <ul style="list-style-type: none">• Coagulopathy.• Hemodynamic instability.• Immunal depression.• Shivering and patient discomfort.• Altered drug effect.• Post-operative nitrogen wasting.
Indications for Warming Therapy	<p>Sixty to eighty percent of all patients undergoing operative procedures become hypothermic and require warming therapy, such as that supplied by the Bair Hugger® Total Temperature Management® System.</p> <p>Indications for warming therapy can include:</p> <ul style="list-style-type: none">• Cold operating room environment.• Anesthetic drug effect.• The opening of the body cavity.
Indications for Cooling Therapy	<p>Hypothermia, however, is sometimes a desired clinical result.</p> <ul style="list-style-type: none">• Induced hypothermia is commonly used to reduce damage to ischemic neurologic tissue during surgical procedures.*• Induced hypothermia can produce a protective effect for high risk or protracted neurosurgical procedures.*• More routinely, feverish patients are treated by exposure to a contained, cooled environment, primarily for comfort.*
Polar Air™ Therapy	<p>The Model 600 PolarAir™ unit combines the ability to warm patients when hypothermia is an undesired condition, <u>with</u> the ability to induce mild hypothermia when clinically indicated, in a portable, easy-to-use, self-contained unit.</p>

* A complete bibliography is available upon request.

PolarAir™ Therapy

PolarAir™ Therapy consists of

a disposable **Bair Hugger®** blanket, and
a **Model 600 Unit**.

Bair Hugger® blankets

Bair Hugger blankets comprise long, tubular channels which deliver controlled air temperatures. The self-supporting Blanket is designed to “hug” the patient. Blankets are designed in various configurations for specific applications, as shown in Figure 1.

Follow the instructions provided with Bair Hugger blankets for specific information concerning their recommended use.

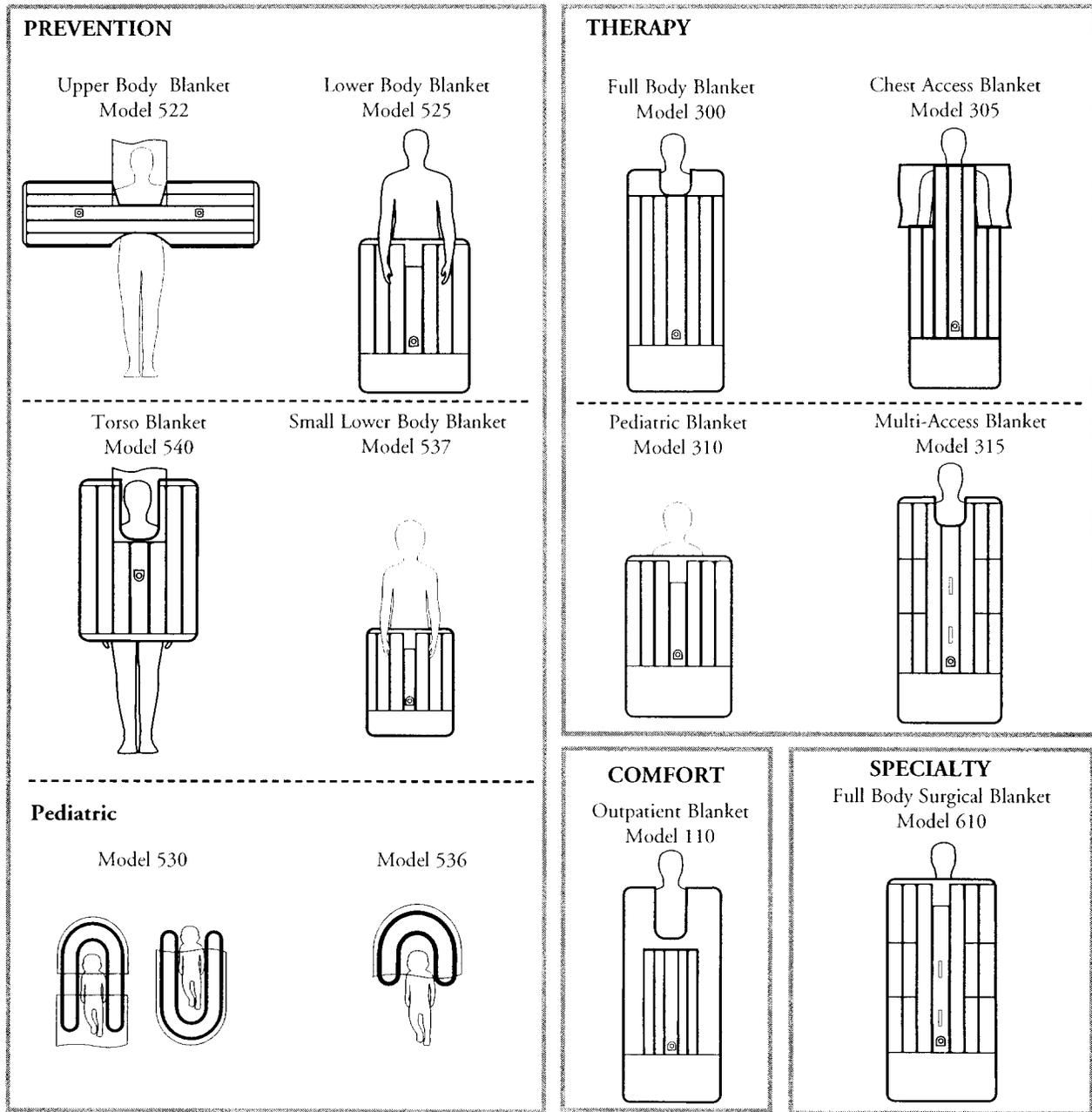


Figure 1. Bair Hugger® Blankets

Model 600 Unit The Model 600 PolarAir™ unit uses two high-efficiency blower motors, a thermoelectric heat exchanger, an AC to DC power converter, and a microprocessor-based temperature controller to create a continuous flow of warm or cool air to the Blanket.

The Model 600 PolarAir unit is designed for safe use in all clinical applications, including the operating room, post-anesthesia care unit, emergency room, and intensive care unit.

The Model 600 PolarAir unit is manufactured for Augustine Medical, Inc. by Zytac Corporation, Redwood Falls, MN 56283 USA.

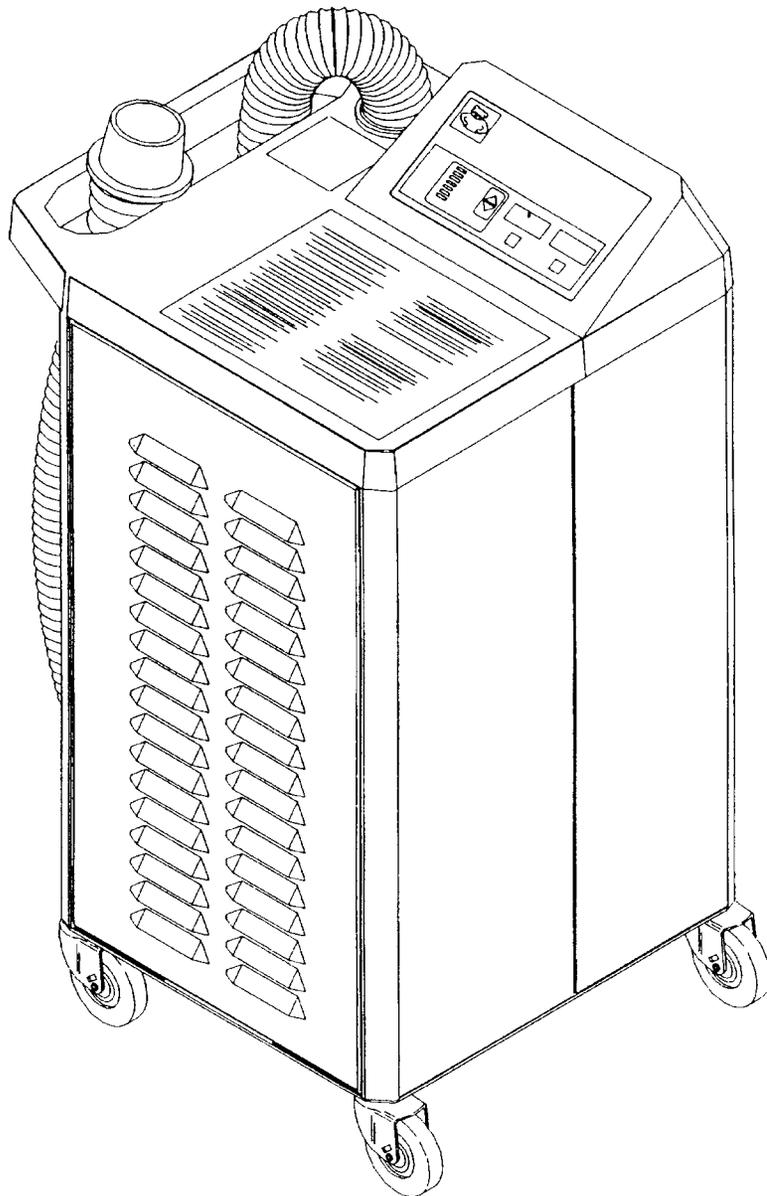


Figure 2. Model 600 PolarAir™ Unit

Control Panel	This section describes the features found on the Control Panel of the Model 600 PolarAir™ unit.
System ON/STANDBY	Push this button to turn the Model 600 either to ON or STANDBY. The MAIN POWER light illuminates when the Unit is plugged into a wall outlet.
Temperature Indicators	The seven temperature level LEDs display the selected temperature level. When the Model 600 PolarAir™ Unit is initially turned on, the AMBIENT (room) temperature level is automatically selected.
Temperature Selected	Push the Set UP button to increment the temperature to the desired setting. Push the Set DOWN button to decrement the temperature to the desired setting.
Temp Output at Hose End Display	The temperature at the hose end ($\pm 3^{\circ}\text{C}$) is digitally displayed. When the Model 600 Unit is initially turned on, the Celsius display is automatically selected.
$^{\circ}\text{C}/^{\circ}\text{F}$ mode	In Celsius mode, the hose output temperature displays in 3-digit format (one digit in tenths of a degree). In Fahrenheit mode, the hose output temperature displays in 3-digit format (no decimal display).
Set Time / Minutes Display	When the Model 600 PolarAir unit is initially turned on, the MINUTES display shows the software date code for 2 seconds, and then is inactive. After setting the desired temperature level, push the SET TIME button to increment the timer in 30-minute intervals up to 120 minutes. See SET TIME description on page 8 for more detail.
Temp Out of Range Indicator	This indicator illuminates and an audible alarm sounds when an over- or under-temperature condition is detected. To reset, turn the Unit off and then on, using the ON/STANDBY switch. (Also see the Warnings section of this manual.)
System Check	This indicator illuminates intermittently when the Model 600 is performing a routine check of all system functions. If this light remains illuminated, contact qualified service personnel and refer to the Error Codes section of this manual.

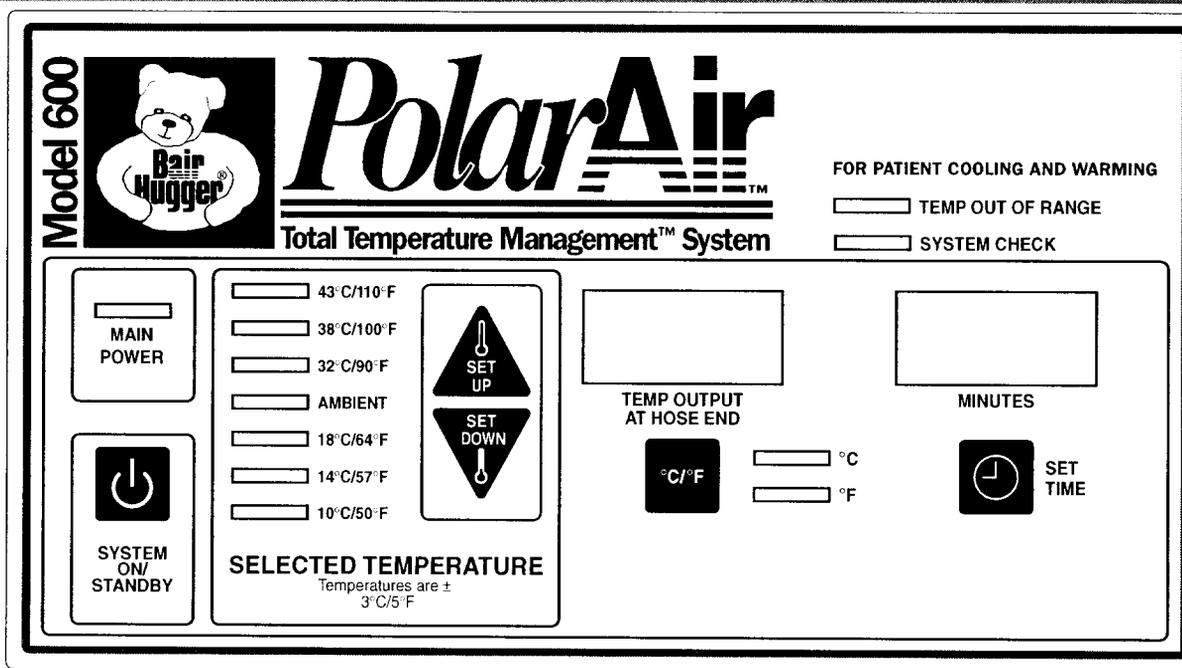
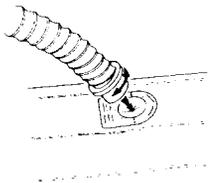


Figure 3. Control Panel

68

Instructions for Use

The Model 600 PolarAir™ unit is easy to set up and to use. Follow the instructions provided with each Blanket for specific information concerning blanket use.



1. Place the Bair Hugger® blanket on the patient with the perforated side (that is, with small holes) against the patient's skin.
2. Using a twisting motion, insert the hose of the Model 600 unit into the inlet port on the Blanket until it fits snugly.
3. Connect the Model 600 to a properly grounded power source.



CAUTION!

To disconnect the Model 600 from the power source, remove the power cord from the wall receptacle. Keep the area around the receptacle clear of obstructions.

4. Press the System ON/STANDBY button to turn the Unit ON.
5. Set the desired temperature output, using either the SET UP or SET DOWN buttons. Assuming ambient temperatures of 10 - 21°C (50 - 70°F), and relative humidity ≤60%, temperature output ranges are as follows:

°C	°F	
43±3	110±5	Temperatures reaching patient are approximately 2°C (3.6°F) lower.
38±3	100±5	
32±3	90±5	
Ambient	Ambient	
18±3	64±5	Temperatures reaching patient are approximately 2°C (3.6°F) higher.
14±3	57±5	
10±3	50±5	

NOTE

If the Model 600 unit is operated under environmental conditions outside the stated ranges, output cooling temperatures may be different than those listed above. In general, the Model 600 unit is capable of cooling to a maximum of 12°C below ambient.

6. To change the temperature display mode (°C or °F), press the °C/°F button.
7. To maintain the selected temperature for a limited time period, press the SET TIME switch. This switch advances the timer setting in 30-minute increments, up to a maximum of 120 minutes. (For more information, please refer to the Set Time section on page 8.)
8. Place a cloth blanket over the Bair Hugger® Blanket for maximum effectiveness.
9. Monitor the patient's temperature at least every 10 to 20 minutes and adjust the temperature setting of the Model 600 Unit as required.
10. When therapy is completed, turn the Model 600 Unit off before disconnecting from the power source. Failure to do so will result in an error condition when the system is restarted (see Error Codes, page 9).

Set Time Function The SET TIME function on your Model 600 PolarAir™ unit will maintain a desired temperature setting for 30, 60, 90, or 120 minutes.

1. When your Model 600 PolarAir™ unit is initially turned on, the MINUTES display is blank.
2. After selecting a temperature setting using the Set UP or Set DOWN buttons, press the SET TIME button to illuminate the MINUTES display.
Each time this button is pressed, the MINUTES display advances in 30-minute increments, up to a maximum of 120 minutes.
3. Five seconds after the timer has been set, it begins counting down, and the MINUTES display shows the minutes remaining until the timer will shut off.
4. While the timer is running, you may change the timer setting. Press the SET TIME button. The timer will reset to 000. Press again to increase the timer setting to the next 30-minute level.
5. When the set time has expired, the temperature control and blower will turn off. The MINUTES display will flash 000.
6. Press either of the set temperature buttons to select the desired temperature setting. The MINUTES display will return to blank.

**General
Maintenance**

This section describes general maintenance procedures.

Cabinet cleaning Disconnect the Model 600 Unit from the power source before cleaning.
Use a damp soft cloth and a mild detergent to clean the Model 600 cabinet. Dry with a separate soft cloth.

	<p>CAUTION!</p> <p>Do not use a dripping wet cloth to clean the cabinet. Moisture may seep into the electrical contacts and cause damage.</p> <p>Do not use alcohol or other solvents to clean the cabinet. Solvents may damage the labels and other plastic parts.</p>
---	--

Error Codes

If the System Check light remains illuminated, an error condition has occurred. To display the error code, press the Bair Hugger® logo on the control panel, which accesses a hidden switch. The error code is displayed in the Minutes display window. All error codes are listed below, with definitions.

Error Code	Definition
000	System left in diagnostic mode. Call for service.
001	RAM corruption error. Call for service.
002	Proper power shut-down sequence error. Turn system off before removing main power.
004	Missing HEPA filter error. Call for service.
008	Power supply heat sink overtemperature. Call for service.
016	Temperature sensor error. Call for service.
032	Heat exchanger overtemperature. Call for service.
064	Analog-to-digital converter error. Call for service.
128	Control voltage output error. Call for service.

Specifications

Physical Characteristics

Dimensions

17" deep x 19" wide x 34" high; 43 x 48 x 86 cm

Weight

140 lbs; 64 kg

Blower Motor

Airflow: 30 cfm

Safety System

Thermostat

Bi-metallic snap disc thermostat for cold; bulb-type variable thermostat for heat.

Over/Under Temperature Warning

If the temperature gets too high or too low, the Temp Out of Range light on the front panel will illuminate and the alarm will sound. The temperature controller will shut off the blower and the power to the thermoelectric modules.

High Temperature Thermostat

The thermostat interrupts power to the heater and activates the audible/visual alarm at a preset high temperature of 53°C (127.4°F) or less, at the end of the hose, as determined by the Augustine Medical, Inc. Temperature Test Kit.

Low Temperature Thermostat

The thermostat interrupts power to the cooling system and activates the audible/visual alarm at a preset low temperature of 2°C (35.6°F) or more, at the end of the hose, as determined by the Augustine Medical, Inc. Temperature Test Kit.

Classification

Classified under IEC 601-1 Guidelines as Class I, Type BF, Ordinary equipment, Continuous operation.

Temperature Characteristics

Air temperatures reaching the patient are within 2°C of the listed temperatures.

Operating Temperatures

Average temperature at the end of the hose, assuming the back pressure of a Blanket, or a Model 221 Temperature Test Kit.

Heating	43° ± 3°C	110° ± 5.4°F
	38° ± 3°C	100° ± 5.4°F
	32° ± 3°C	90° ± 5.4°F
Cooling	18° ± 3°C	64° ± 5.4°F
	14° ± 3°C	57° ± 5.4°F
	10° ± 3°C	50° ± 5.4°F

Electrical Characteristics

Current Leakage

Meets hospital and regulatory standards for leakage current.

Motors

Fractional horsepower, single phase.

Heating System

Thermoelectric cells, setpoint range at the machine output from ambient to 43°C (110°F).

Cooling System

Thermoelectric cells, setpoint range at the machine output from ambient to 10°C (50°F).

Circuit Breakers

- 17 Amps(115V Units)
- 8.0 Amps(220 - 240V Units)

Device Ratings

- 110 - 120VAC, 60Hz, 12 Amperes
- 220 - 240VAC, 50 Hz, 7.5 Amperes

72

Symbol Definitions



SET TIME



ON/STANDBY



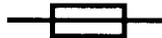
SET UP (Temperature setting control)



SET DOWN
(Temperature setting 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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(800) 733-7775 • TEL+1-612-947-1200 • FAX +1-612-947-1400

©1997 Augustine Medical, Inc. All rights reserved. 8/97
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.
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):
Augustine Medical Limited, Trinity House Borough Road, Wakefield WF1 3AZ,
United Kingdom • TEL (44) 1924 200550 • FAX (44) 1924 200518



Appendix B

Predicate Device Labeling

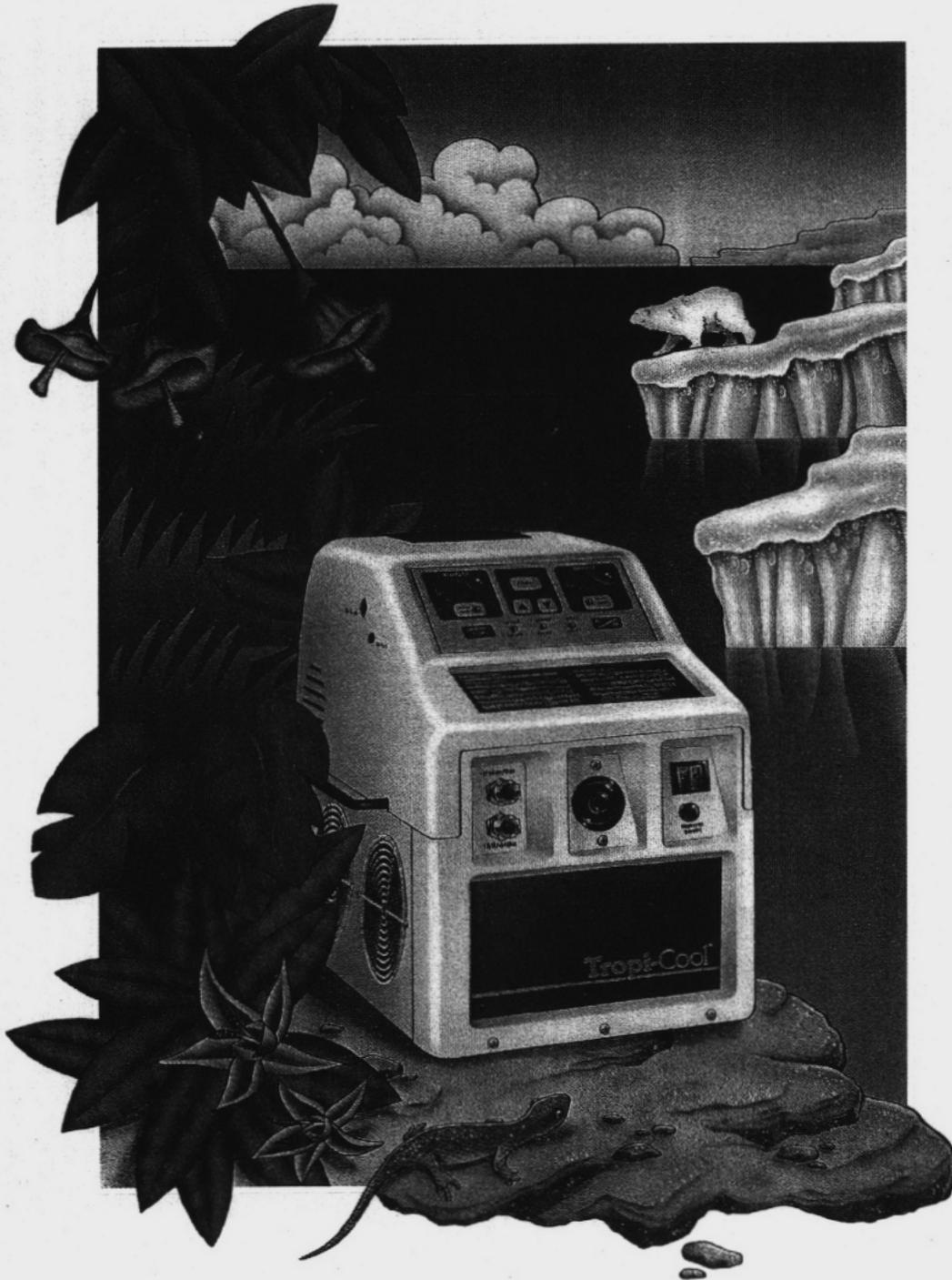
Tropi-Cool™ Hyper/Hypothermia Unit

FS'

PREDICATE DEVICE LITERATURE

TROPI-COOL™

HYPER/HYPOTHERMIA UNIT



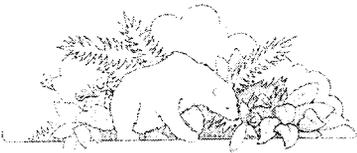
YOUR PARTNERS
IN THERMAL CARE

76

Baxter

 **Seabrook** Medical Systems Inc.

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



Display patient and/or water temperature in °C or °F.

Automatic mode requires a 400 Series-type esophageal/rectal probe.

Alerts operator of low water, high or low temperature limit conditions.

Silences audible alarm for five minutes while operator attempts to correct alarm condition.

Provides visual assurance of continuous water flow.

Foam insulated to prevent condensation on the floor; contains self-sealing, quick-connect couplings.

Available in pediatric/torso and full body sizes.



Considerably smaller and lighter than traditional hyper/hypothermia units, *Tropi-Cool* offers true portability. Its small size increases flexibility in the crowded operating room, intensive care unit and recovery room. *Tropi-Cool* glides easily on its mobile stand, featuring a storage compartment for pads and tray for hose, probe and probe cable.

Tropi-Cool utilizes the first major advance in cooling technology for hyper/hypothermia equipment in over thirty years — *thermoelectric modules* replace traditional Freon-based mechanical refrigeration systems. And because Freon is not used, there are no adverse environmental effects to the ozone layer.

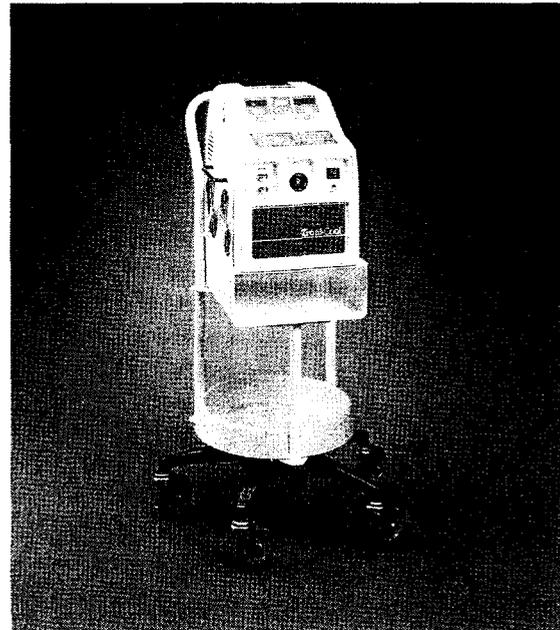
Tropi-Cool operates quietly, ensuring that hospital staff will hear important alarm signals from other equipment in use. And the patient is not disturbed by irritating noise.

Extremely Efficient

With a 400 Series-type thermistor probe, *Tropi-Cool* automatically monitors and controls patient body temperature for increased patient safety and nursing convenience. The technologically advanced thermoelectric modules and efficient cartridge heaters, combined with a high flow rate, produce effective cooling and heating.

Extremely Comfortable Pads

Our pads offer the high quality look of reusables coupled with the hygienic advantage of

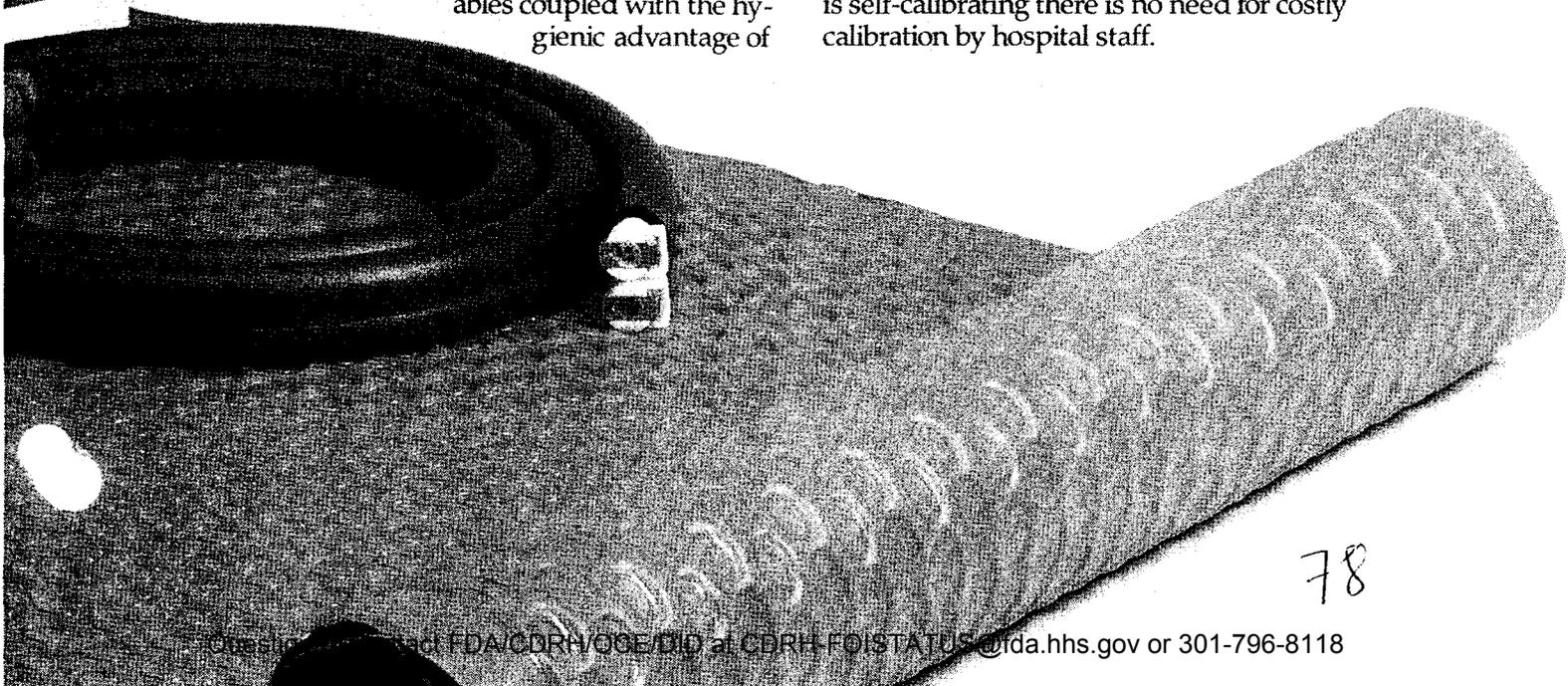


Tropi-Cool, the compact hyper/hypothermia unit, on its mobile stand, offers true portability.

disposables. The top vinyl surface is easy to clean, and the bottom foam surface (torso pad only) cushions the patient and keeps the pad securely in place on OR table or patient bed.

Extremely Affordable

Tropi-Cool offers all of these features at a price much lower than conventional hyper/hypothermia units. The absence of a mechanical refrigeration system means your maintenance costs can be minimized, and because *Tropi-Cool* is self-calibrating there is no need for costly calibration by hospital staff.



78

TROPI-COOL™ SYSTEM SPECIFICATIONS*

TROPI-COOL UNIT (SMS-5200)

Physical

Size 13.9"W X 15.5"H X 16.5"D
 Weight (dry) 61 lbs.
 Couplings Quick-Connect
 Case Material G.E. Noryl Plastic
 Case Color Light Gray

Control System

Type Microprocessor-based, Digital
 Accuracy ±.2°F (±.1°C)
 Self-Calibrating 60 Second Intervals
 Water Temp Display 7 Segment, 4 Digits
 Patient Temp Display 7 Segment, 4 Digits
 Display Range (Water) 32° to 122°F (0° to 50°C)
 Display Range (Patient) 86° to 122°F (30° to 50°C)

Cooling/Heating System

Setpoint Range (Water) 40° to 107°F (4° to 42°C)
 Setpoint Range (Patient) 86° to 104°F (30° to 40°C)
 Heating Elements (2 ea.) 250 Watts (Total 500 Watts),
 Cartridge Type

Cooling Unit Solid State, Thermoelectric
 Modules

Electrical System

Voltage 115V, 60 Hz
 Current 8.5 Amp (at 115V, 60 Hz)
 Circuit Breaker 10 Amp
 Power Cord 3 Conductor, 16 AWG, 12',
 Hospital Grade Plug
 Leakage Current Under 100 Microamperes

Safety System

Low Limit Alarm 38°F (3°C)
 High Limit Alarm 109°F (43°C)
 Back-up High Limit Alarm 110° to 116°F (43.3° to 46.6°C)
 Add Water Alarm Removes power from pump,
 cooling unit and heater
 Warning Lights "Add Water", "High Limit",
 "Low Limit", "Back-Up High
 Limit"
 Audible Alarms Add Water, High Limit, Low
 Limit; Selection of "Patient
 Temp" mode without a probe
 connected; Remote probe
 temperature below 86°F (30°C);
 Malfunction of the water
 temperature sensor.

Circulating System

Reservoir Capacity 2 Quarts
 Reservoir Fluid Distilled water
 Fill Cap Vented
 Flow Rate (through pad) 18-20 GPH
 Maximum Pressure 5.6 PSI

MOBILE STAND (SMS-A0450)

Material Steel, Powder Coated
 Casters Five (5), 4" Diameter, Rubber
 tread
 Dimensions Height - 42" ; Base Size - 22" Dia.
 Storage 4½" H shelf under unit for
 pad(s). Tray for hose, probe,
 and probe cable storage. Power
 cord wrap on back.

TEMP-PAD®

Material Vinyl/foam; All vinyl
 Pattern Elliptical design
 Duration of Use Single-patient use; Reusable
 Connectors Quick-connect, flow through
 Clamps Positive, one-hand application
 Sizes 22" x 36"; 24" x 60"

ORDERING INFORMATION

SMS-5200 TROPI-COOL Hyper/Hypothermia Unit
 (includes SMS-A0800 Hose and SMS-A0206
 Adapter)
 SMS-A0206 Adapter, Baxter K-Pad to Seabrook TEMP-
 HOSE™
 SMS-A0450 TEMP-STAND® Mobile Stand
 SMS-A0460 TEMP-PROBE™ 400 Series Type Thermistor
 Esophageal/Rectal Probe, Single-patient use,
 Sterile
 SMS-A0462 TEMP-PROBE 400 Series -type Thermistor
 Skin Probe, Single-patient use, Sterile
 SMS-A0461 Adapter Cable, Connects TEMP-PROBE to
 TROPI-COOL
 SMS-A0580 TEMP-HOSE 8' Insulated Connecting Hose
 SMS-A0582 TEMP-HOSE 8' Insulated Dual Pad Connect-
 ing Hose
 SMS-2236 TEMP-PAD (22" x 36") Vinyl/foam
 SMS-2236V TEMP-PAD (22" x 36") All vinyl
 SMS-2460V TEMP-PAD (24" x 60") All vinyl



Distributed by:

Baxter Healthcare Corporation
 I.V. Systems Division
 Route 120 and Wilson Road
 Round Lake, Illinois 60073
 (800) 423-3238

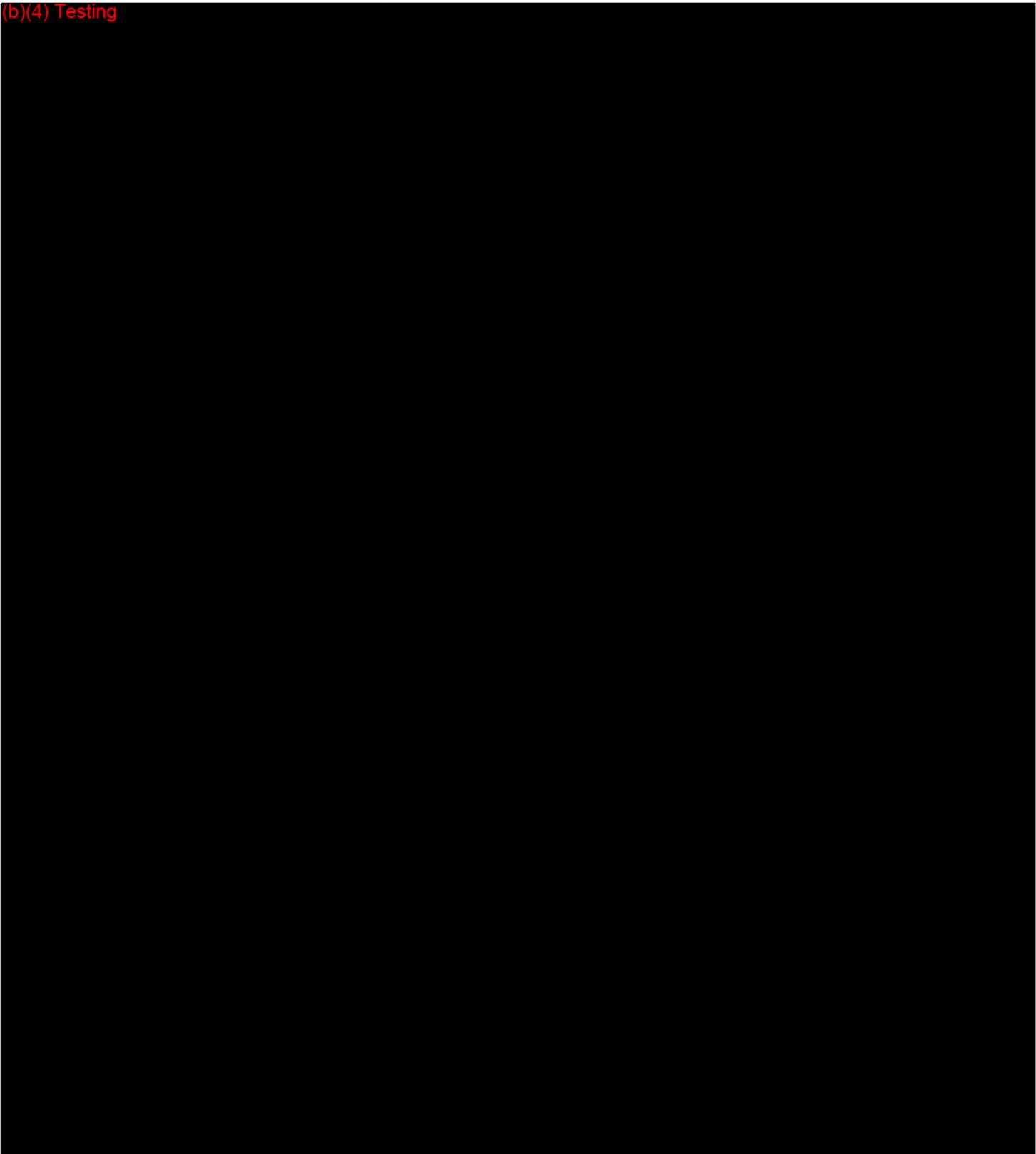
Manufactured by:

Seabrook Medical Systems, Inc.
 673 Wilmer Avenue
 Cincinnati, Ohio 45226

79

Test Report Summary

(b)(4) Testing



80

(b)(4) Testing



85

MEMORANDUM

Catherine

Date: July 2, 2002
From: Catherine Wentz – Engineer/Lead Reviewer
To: File: K021473 Augustine Medical Temperature Management System
Series 200, 500, and 700.
Subj: Original Application. Adding cooling indication to currently marketed series.
Action: Substantially Equivalent

SUMMARY

The sponsor has submitted an original, traditional 510(k) application to request marketing clearance for the Augustine Medical Series 200, 500, and 700 Temperature Management Systems. These series of forced air warming blankets are currently on the market without a cooling indication. This application will be modifying this series of products by adding a cooling unit (Model 459 cooling unit), and a cooling indication.

All the information presented by the sponsor is sufficient to make a determination of substantial equivalence. It should be noted that some of the required information was obtained through e-mail and voicemail correspondence. All correspondence is attached at the end of this memo.

RECOMMENDATION: Substantial Equivalence

6

REVIEW

Descriptive

The Augustine Medical Bair Hugger Temperature Management System Series 200, 500, and 700, are modifications to the currently marketed Augustine Medical Bair Hugger forced-air temperature management units with the same series numbers. The general modifications include a cooling indication and the addition of a disposable Model 459 patient cooling set.

The Temperature Management Systems are comprised of a forced air temperature management unit (200, 500, or 700 series blower/heater units), a disposable Bair Hugger forced-air blanket (various models), and a Model 459 disposable patient cooling set (consisting of an ice bag with an attached hose assembly, to be hung on an IV pole). In general, the operation of the system is the same: The electro-mechanical unit provides the power necessary to force air through tubing connected to a Bair Hugger Blanket. This air can be room temperature (ambient), or heated by the electro-mechanical unit. If the delivery of chilled air is indicated, then ambient air is forced through the tubing to the ice bag (Model 459 cooling set) and then through more tubing to the blanket. The cooling set only has the capability of providing cooled air for approximately 45 minutes, or until the ice melts. At which time, the ice bag would need to be refilled if necessary.

Predicate devices:

- Augustine Medical Bair Hugger Model 600 Hyper/hypothermia unit used with Bair Hugger Blankets (K950416)
- Seabrook Medical Systems Tropi-Cool Hyper/hypothermia unit (K902756)

Indications for Use:

"The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patients thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients."

It was clarified in an e-mail from the sponsor (dated 7/2/02, attached at the end of the memo) that operating specifications have not changed between the currently marketed 200, 500, 700 series, and the modified series with the new cooling indication.

Remaining Concerns: None.

7

Performance

The only performance requirement for this modification would be to demonstrate that the system can deliver cooled air through the blankets as stated. The sponsor performed this testing (b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing As such, the sponsor has sufficiently demonstrated that the delivery of cooled air will not be a safety concern.

Remaining Concerns: (b)(4)

(b)(4)

Biocompatibility

No new materials have been introduced into the patient contacting materials (blankets). As such, no new biocompatibility information is necessary.

Remaining Concerns: None

EMC

The new component added to the System is a non-mechanical unit – the ice bag for the delivery of cooled air. There are no new EMC related issues with this application.

Remaining Concerns: None

8

Software

No new software issues are introduced with the addition of the Model 459 ice bag component. The blower/heater temperature management unit introduces ambient air to the ice bag for the deliver of chilled air to the blanket. The delivery of ambient air to the blanket is currently an operating setting on the marketed 200, 500, and 700 series units.

Remaining Concerns: None.

Sterilization/Shelf-life/Packaging

No new sterilization issues are introduced with the new component since the Model 459 ice bag is provided non-sterile.

Shelf-life remains the same for the system. The Model 459 materials are the same as materials that are currently used in the blankets (see attached e-mail information). As such, the shelf-life will not change.

Packaging will be the same for the Model 459 component as for the blankets – e.g., plastic wrap.

Remaining Concerns: None.

Labeling

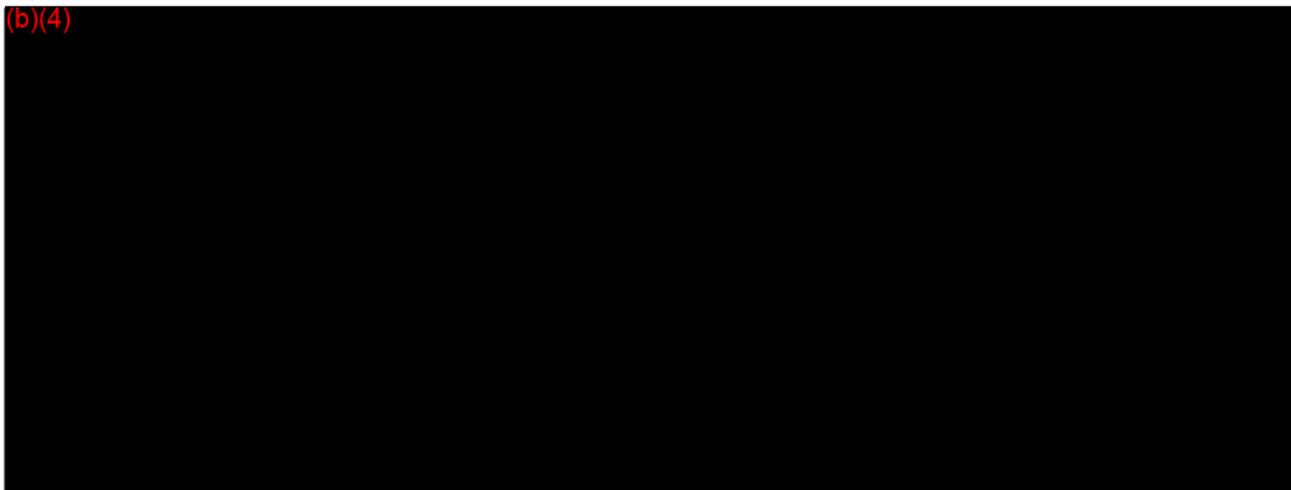
No promotional materials are included, but the body of the 510(k) indicates a list of

(b)(4)

This list of (b)(4) were forwarded to Neil Ogden's branch (neurology), and his e-mail regarding these "benefits" is provided at the end of this memo.

The predicate device (K950416 – Model 600) labeling included the following list under the heading (b)(4):

(b)(4)



FDA currently has a

number of IDE studies for intravascular cooling devices demonstrating management of the patient's core body temperature, and related benefits of cooling. In this application, the sponsor's device delivers temperature controlled air. (b)(4)

The sponsor was contacted via e-mail regarding the (b)(4) (as requested) will be used (see e-mail below).

Remaining Concerns: None.

Administrative

The sponsor provided a 510(k) summary, truthful and accurate statement, and indications for use form.

Remaining Concerns: None.

E-Mail to Neurology regarding list of "benefits of cooling" provided by sponsor:

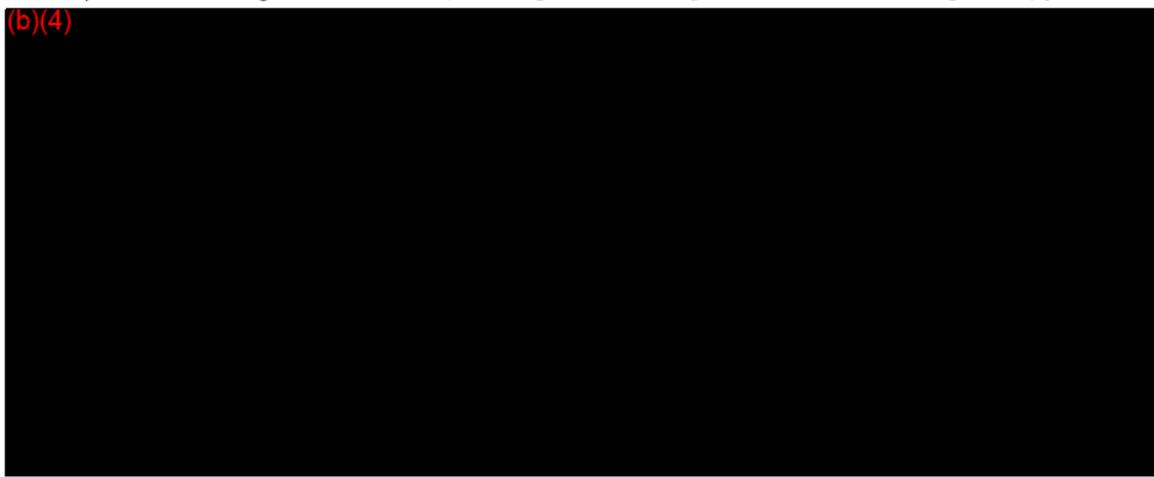
-----Original Message-----

From: Wentz, Catherine P.
Sent: Thursday, June 27, 2002 12:51 PM
To: Felten, Richard P.; Ogden, Neil
Cc: Fleischer, Dina J.
Subject: Cooling/Heating blankets

Dear Neil and Richard,

I have a 510(k) for a thermal regulating system (heating/cooling blankets using air as the temperature management medium), stating the following BENEFITS of cooling therapy:

(b)(4)



Predicate labeling includes similar "claims" that were cleared in 1995 based on animal studies, non-significant risk human studies, and literature. What do you think??

Catherine

Hi Catherine,

I'd like to see them stick to the exact indications/claims of the predicate in this case.

(b)(4)



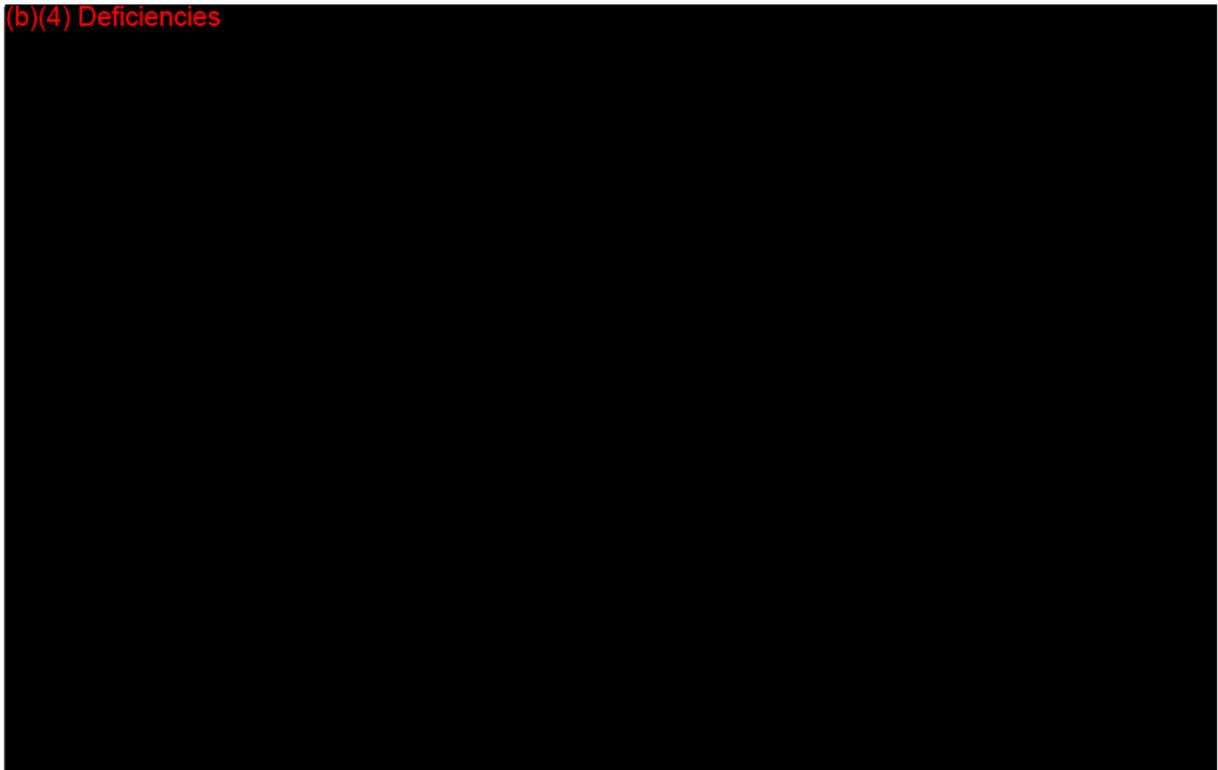
Neil

E-mail to Sponsor regarding labeling concerns (7/1/02):

Dear Mr. Westlin,

One last thing before I complete the review of your application..... Labeling.....

(b)(4) Deficiencies



Catherine Wentz
Chemical/Biomedical Engineer

E-mail from sponsor addressing (b)(4) concerns (7/2/02) and voicemail requests related to (b)(4) (b)(4) Model 459 (b)(4) to the (b)(4) (b)(4) marketed 200, 500 and 700 series units (7/2/02):

Catherine,

Attached are the responses to your questions. There is a new page 5 with the (b)(4) The second document includes responses to the other items that we have discussed.

Please let me know if this resolves the questions you have. I look forward to hearing from you.

Best regards,

David Westlin
Director of Regulatory Affairs and Quality Assurance
Augustine Medical Inc.

Bair Hugger Model 459 Patient Cooling Set

510(k) Number: K021473

July 1, 2002

Materials

The Model 459 patient cooling set is composed of (b)(4). These are the (b)(4), which have been previously FDA-cleared.

Packaging

The Model 459 patient cooling set will be packaged individually in sealed plastic bags and shipped in cardboard boxes. This is the same method currently used to package the Bair Hugger blankets.

Air output of Bair Hugger temperature management units

Attaching the Model 459 patient cooling set to the Bair Hugger temperature management units does not alter the performance specifications of the temperature management units.

Over Heat or Over-Temp indicator light and alarm

The Instructions for Use for the Model 459 patient cooling set include a warning statement with instructions to discontinue patient cooling if the red warning light illuminates and/or the alarm sounds. The warning light and alarm are existing safety features found on Bair Hugger temperature management units. Their purpose is to alert health care providers in the event of an over-temperature condition. This warning was retained in the Model 459 patient cooling set's Instructions for Use.

New Page 5:

BACKGROUND INFORMATION

Reason for submission

The reason for this submission is to notify the FDA that Augustine Medical, Inc. plans to bring a *modified* device to market with additional indications for use and a new disposable component of the device.

Patient cooling will be added as an intended use for the Bair Hugger® temperature management system. Patient cooling is indicated for managing elevated body temperatures or hyperthermia in patients or for inducing hypothermia in or providing localized cooling for normothermic patients for whom induced hyperthermia or localized cooling would be therapeutic.

510(k) Decision Making Documentation

1. IS THE PRODUCT A DEVICE? **Yes**

2. IS THE DEVICE SUBJECT TO 510(k)? **Yes**

3. IS THE NEW DEVICE COMPARED TO A LEGALLY MARKETED DEVICE? **Yes**

4. DOES THE NEW DEVICE HAVE THE SAME INDICATION STATEMENT? IF NO EXPLAIN.

Yes

5. DOES THE NEW DEVICE HAVE THE SAME TECHNOLOGICAL CHARACTERISTICS (E.G., DESIGN, MATERIALS, ETC.)? IF NO, EXPLAIN.

Yes

6. ARE THE DESCRIPTIVE CHARACTERISTICS ENOUGH TO DETERMINE EQUIVALENCE?

No. Additional performance data is required for this type of device before a determination can be made on safety, effectiveness and equivalence. See below.

7. ARE PERFORMANCE DATA AVAILABLE IN SUPPORT OF 1) SAFETY AND EFFICACY FOR THE DEVICE'S INTENDED USE, AND 2) SUBSTANTIAL EQUIVALENCE AS COMPARED TO PREDICATE DEVICE(S)?

YES. ALL SUPPORTING INFORMATION HAS BEEN PROVIDED.

8. DOES DATA DETERMINE EQUIVALENCE? **Yes**

RECOMMENDATION: Substantial Equivalence

**Catherine P. Wentz
Biomedical Engineer**

1.5

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
a. 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.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
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. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

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 #191-2 and Federal Register 90N0332, September 10, 1991.		

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	
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 over-the-counter 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

Memorandum

m: Reviewer(s) - Name(s) Catherine Wentz

Subject: 510(k) Number K 021473

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):

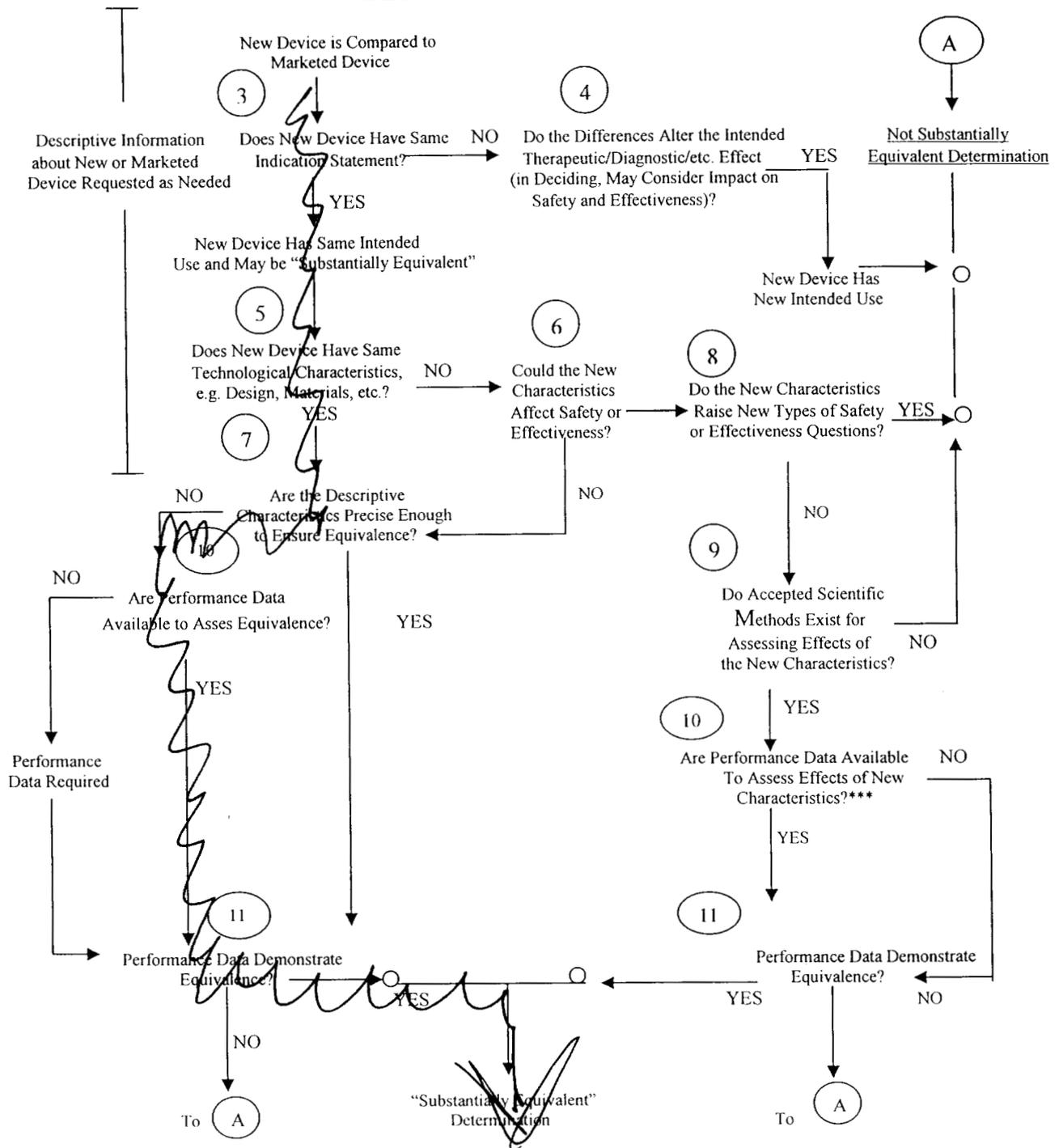
D05 / class II 24

Review: Dina Simuliu CSPB 7/8/02
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 7/9/02
(Division Director) (Date)

Revised: 8/17/99

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

S