MAR 9 2006

K053645

SMDA Summary— Special 510(k) Modified Product Labeling

Submitted by:
Arizant Healthcare Inc.
10393 West 70th Street
Eden Prairie, MN 55344
Telephone: 952-947-1200

Contact person:
David Westlin
Senior Director, Regulatory Affairs and Quality Assurance

Summary date:
December 30, 2005

Device name/trade name:
Bair Hugger family of Temperature Management System

Common/usual name:
Hyper/Hypothermia System

Classification name:
System, Thermal, Regulating, DWJ

Equivalent marketed device:
Bair Hugger temperature management system (K041686).

Device description:
The Bair Hugger family of temperature management systems consist of a portable forced-air temperature management unit, disposable Bair Hugger forced-air blankets, and disposable Bair Paws warming gowns.

Intended use of the device

The Bair Hugger temperature management systems are 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 systems 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 systems can be used with adult and pediatric patients.

Technological characteristics

The technological characteristics of the cleared devices do not change with this modification to product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2006

Arizant Healthcare, Inc.
c/o Mr. David Westlin
Senior Director of Regulatory Affairs and Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K053645
Bair Hugger® Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (Two)
Product Code: DWJ
Dated: February 14, 2006
Received: February 17, 2006

Dear Mr. Westlin:

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

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 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K053645

Device Name: Bair Hugger® Temperature Management System

The Bair Hugger family of temperature management systems consist of portable forced-air temperature management units, disposable Bair Hugger forced-air blankets and Bair Paws® warming gowns.

Indications For Use:

The Bair Hugger family of temperature management systems are 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 temperature management systems can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management systems can be used with adult and pediatric patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Jachmen
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053645

Page 1 of 1

K053645/A1

Westlin, Dave

From: Westlin, Dave
ent: Tuesday, January 10, 2006 9:20 AM
.o: 'Wentz, Catherine P.'
Subject: K053645 Follow-up - Arizant

Importance: High

Date: January 10, 2006

To: Catherine Wentz
FDA, CDRH

From: David Westlin
Arizant Healthcare

Subject: Follow-up Information Request (K053645)

Dear Ms. Wentz,
As requested, enclosed are copies of the affected labeling referenced in 510(k) submission K053645.
If you have additional questions or comments, please feel free to contact me.
Sincerely,

David Westlin
Senior Director of Regulatory Affairs and Quality Assurance
Compliance Officer
rizant Inc.
10393 West 70th Street
Eden Prairie, Minnesota 55344
Direct Telephone: 952-947-1277
Direct Fax: 952-918-5277
e-mail: dwestlin@arizant.com

BH Brochure.pdf 601777B.pdf

K23

BAIR PAWS® SYSTEM

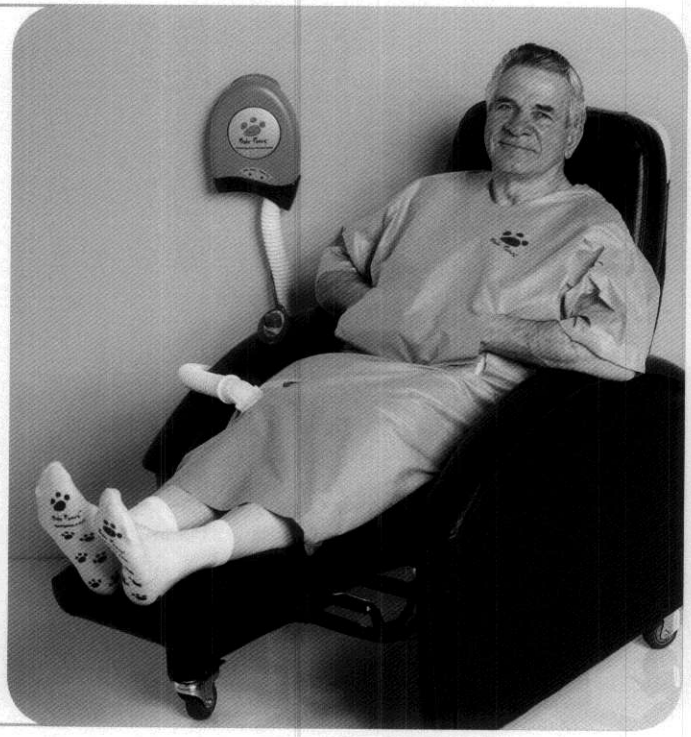
ONE PATIENT. ONE GOWN. CONTINUOUS WARMTH.

Recognized as the world's first temperature-adjustable gown, the Bair Paws system now offers the ease and efficiency of forced-air warming throughout the perioperative process – including the operating room.

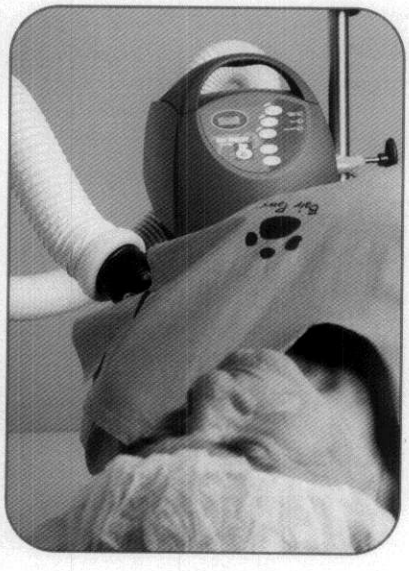
The Bair Paws gown provides patient-controlled comfort warming in the pre-op and post-op setting. The same gown offers effective clinical warming during surgery involving the head, neck, knees, or extremities. The Bair Paws gown can also be used anytime a patient gown is needed.

The Bair Paws system moves away from cotton gowns and blankets into more versatile, practical ways of being covered, comfortable, and clinically warmed.

THE BAIR PAWS WARMING SYSTEM



In and Out of the OR – Comfort, Convenience and Efficiency that Cotton Just Can't Match



- **The Bair Paws system brings versatility.** One single-use gown covers the entire perioperative experience, from comfort warming before the induction of anesthesia through clinical warming in the OR and PACU.

- **An effective, affordable alternative to warmed cotton blankets.** The Bair Paws system can reduce patient warmth complaints and save valuable nursing time.

- **The soft, thick, opaque material is both comfortable and covering.** Patient modesty concerns are a thing of the past.

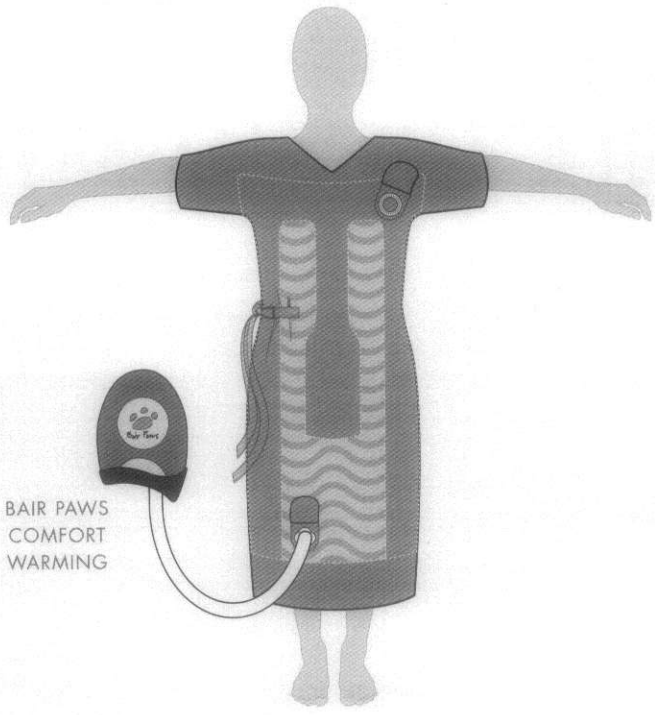
- **Temperature management ranks at the top of patient concerns,** according to a 2003 survey that found warmth to be the most cited patient comfort complaint.[1] The Bair Paws system directly addresses this major patient issue, and satisfied patients can boost the bottom line[2].

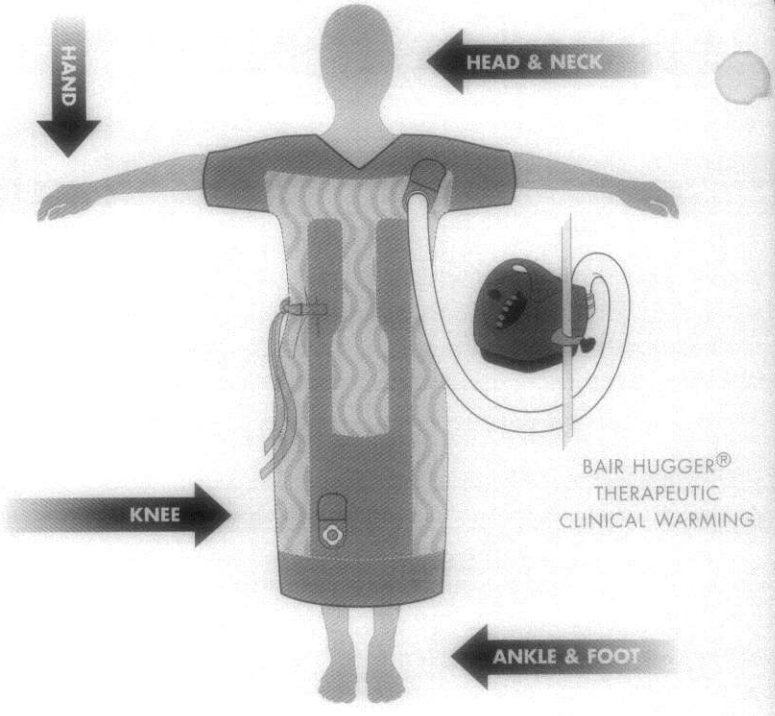
- **Give your patients control.** The Bair Paws system's hand-held controller puts the ability to regulate warmth where it belongs – with the patient.

1. Wilson, Linda; Kolcaba, Katharine. Practical Application of Comfort Theory in the Perianesthesia Setting. *Journal of PeriAnesthesia Nursing.* June 2004; 164-173.

2. Press I. Patient Satisfaction: Defining, Measuring and Improving the Experiences of Care. (Chicago Health Administration Press, 2002).

HOW THE BAIR PAWS GOWN PROVIDES WARMING





- **Ideal for extremity surgeries**
- **Efficient for short duration surgeries because the gown is already on the patient**

FOR BEST RESULTS, MAXIMIZE THE SURFACE AREA OF THE WARMING INSERT.

PRODUCT SPECIFICATIONS

Bair Paws Warming Gown Sizes

Standard
51" long; 64" sweep

X-Large
51" long; 110" sweep

Model 850 Patient Warming Unit

Temperature:	ambient to 40° +/-3°C
Alarms:	over-temperature
Power:	110-120 VAC
Weight:	6.3 lbs
Mounting options:	wall, bedrail, IV pole, flat surface

ORDERING INFORMATION

For more information about the Bair Paws patient adjustable warming system, please contact your Arizant Healthcare Inc. representative or call 1-800-733-7775. Or visit us at www.bairpaws.com.

Patient Warming Gown

81001 Standard	30/case
81201 X-Large	20/case

Patient Warming Gown with Booties

83001 Standard	30/case
83201 X-Large	20/case

Patient Warming Gown Kit

84001 Standard	30/case
84201 X-Large	20/case

Kit includes patient warming gown, bonnet, booties, personal belongings bag and shoe bag.

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Arizant Healthcare

10393 West 70th St., Eden Prairie, MN 55344 USA
TEL 800-733-7775 • 952-947-1200 • FAX 800-775-0002 • 952-947-1400 • www.arizanthealthcare.com

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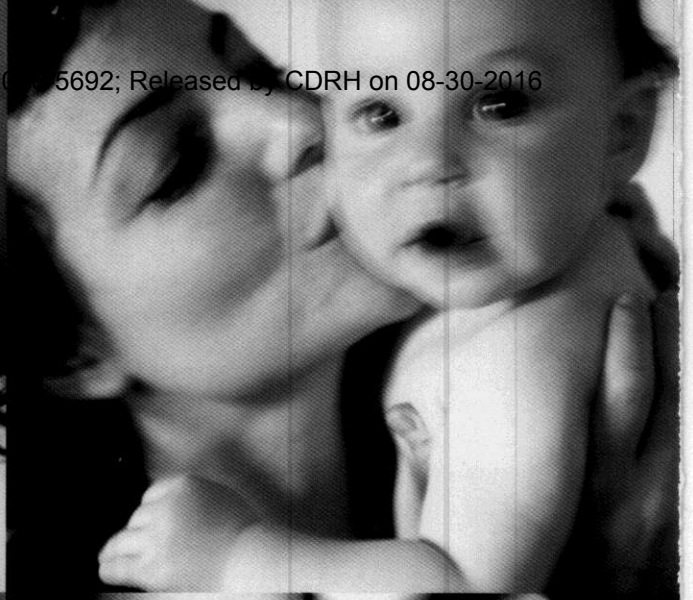

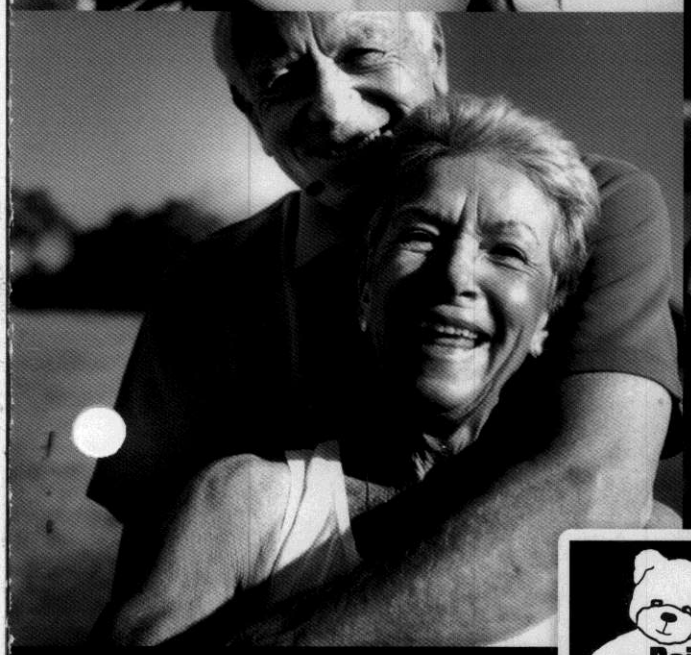

Bair Hugger®

EVERYONE DESERVES A **HUGG**

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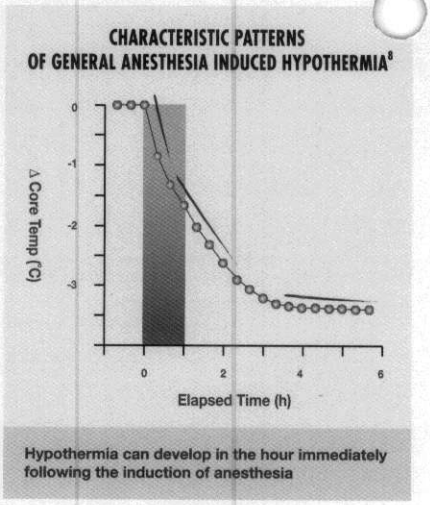
DID YOU KNOW PATIENTS CAN BECOME HYPOTHERMIC IN LESS THAN 1 HOUR?

Patients under general anesthesia are unable to regulate their temperature. Core hypothermia can develop rapidly in the hour immediately following the induction of anesthesia. Research has shown that during the first hour of general anesthesia, unwarmed surgical patients can lose up to 1.6°C.[1]

Even patients undergoing regional anesthesia are often at risk of unintended hypothermia. Why? Core temperature is seldom monitored during spinal and epidural anesthesia, and patients rarely feel cold because of the blocked areas. Patients may actually feel warm in spite of becoming hypothermic because the body incorrectly evaluates skin temperature in the blocked area.



Hypothermia can develop in the hour immediately following the induction of anesthesia

UNINTENDED HYPOTHERMIA: RISKS WORTH AVOIDING

Unintended hypothermia is associated with adverse outcomes such as:

- increased rate of wound infection[5]
- increased hospital length of stay[7]
- higher mortality rates[3]

The good news is that unintended hypothermia is easily prevented.

"Normothermia should be a goal during emergence and recovery. When available, forced-air warming systems should be used for treating hypothermia."

– Practice Guidelines for Postanesthetic Care. American Society of Anesthesiologists. March 2002.

UNINTENDED HYPOTHERMIA: WHY RISK IT?

More than 100 scientific papers have been written about the benefits of forced-air warming and the prevention of hypothermia. Studies have found forced-air warming to be the most effective warming method in general for preventing and treating unintended hypothermia. Maintaining normothermia with forced-air warming has been shown to reduce the risk of complications and the costs associated with them. It's no wonder on average a Bair Hugger blanket is used every 4 seconds in hospitals worldwide!

OUTCOMES

Studies have suggested that maintaining normothermia in some general type surgeries may yield positive results such as:

- Reduction in the rate of postoperative wound infections
- Decreased likelihood of postoperative myocardial infarction
- Decreased ICU time
- Shortened hospital length of stay
- Lowered mortality rates
- Reduction in the use of blood products
- Decreased likelihood of mechanical ventilation
- Reduced probability of needing a transfusion

Savings can range from $2,500-$7,000* per patient

AFFORDABLE PREVENTION AT LESS THAN $10

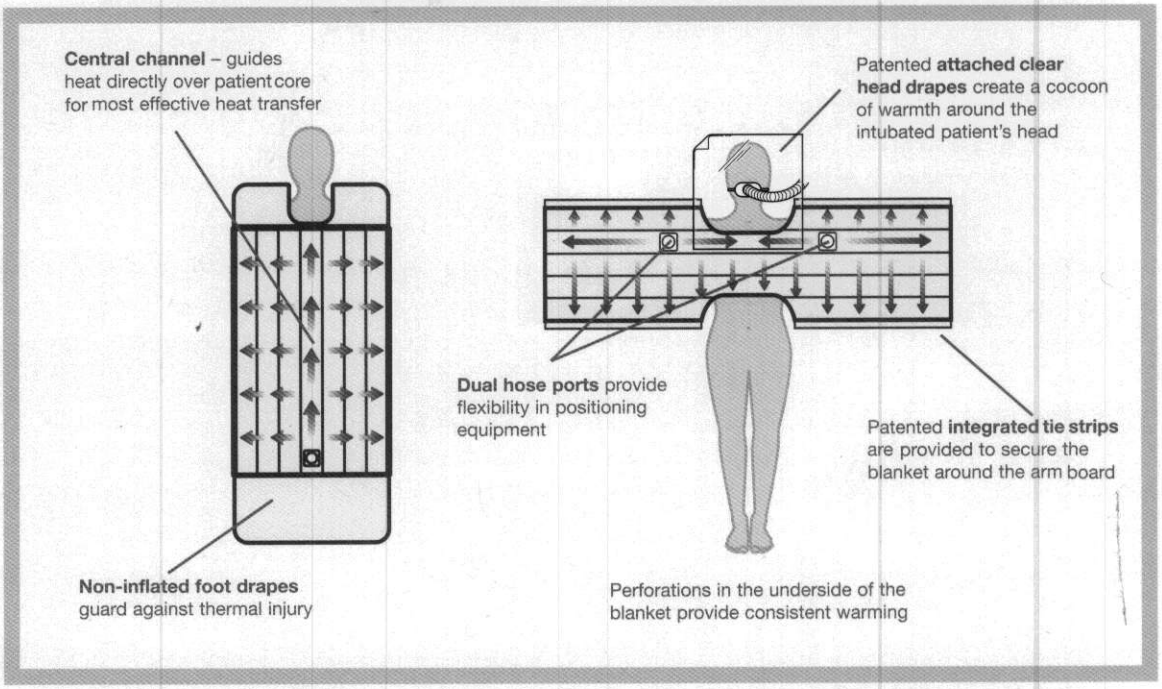
eventing these negative outcomes is affordable — the average price of a forced-air warming blanket is less than $10. For the cost of a movie ticket, all anesthetized patients can enjoy the benefits of forced-air warming.

BAIR HUGGER® THERAPY

The makers of Bair Hugger therapy created forced-air warming and continue to fine-tune every aspect of the system to deliver optimum warming.

The Bair Hugger system is scientifically engineered to deliver consistent, even patient warming by optimizing the airflow through the blanket's patented air channel and perforation pattern. And the Bair Hugger blanket design provides maximum warming areas for a variety of procedures. Only Bair Hugger therapy offers 23 blanket styles for all patient warming needs from pediatrics to geriatrics, from brief outpatient procedures to complex cardiac procedures.

UNIQUE FEATURES OFFERED BY BAIR HUGGER THERAPY



The central channel of the Bair Hugger blanket is an important design feature that guides the heat directly over the core of the body where heat transfer is most effective. Perforation patterns on the underside of the blanket are specifically designed to optimize heat transfer and provide even and consistent warming across the entire blanket.

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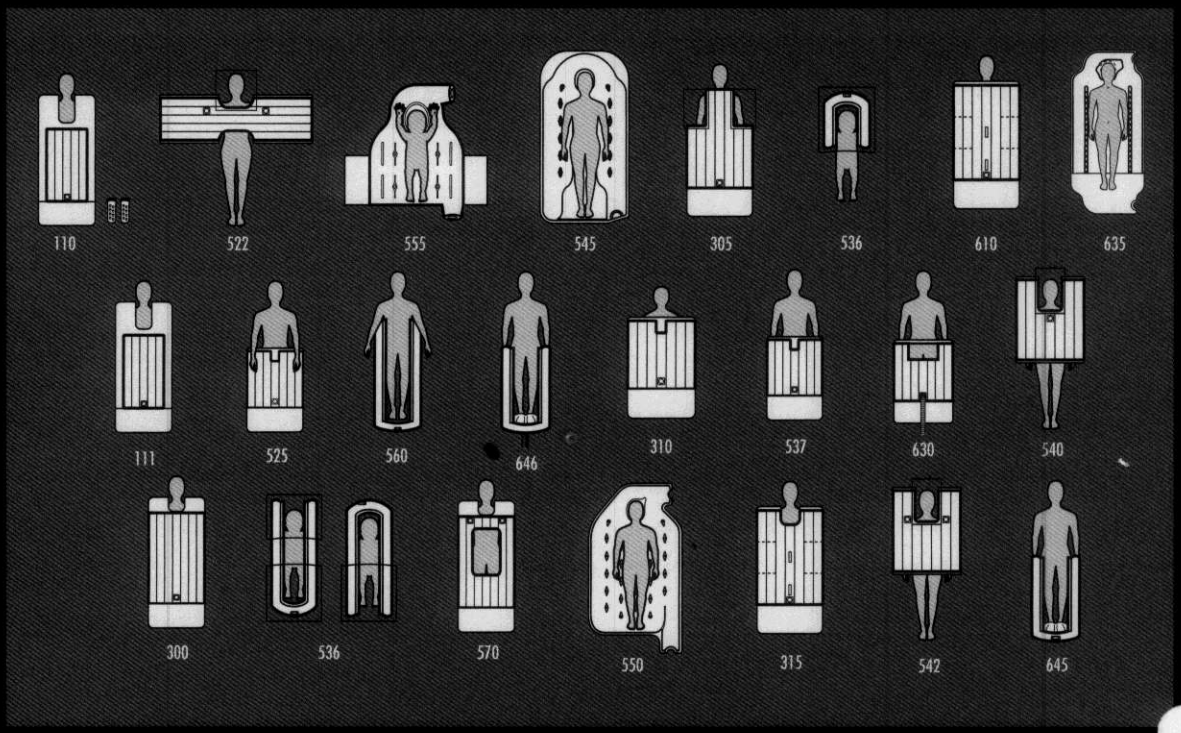
Blankets are available for all your warming needs from pediatrics to geriatrics, from brief outpatient procedures to complex cardiac procedures.



Call 1-800-733-7775 or visit
www.bairhugger.com for more information

1. Matsukawa T, Sessler DI, Sessler A. Heat flow and distribution during induction of general anesthesia. *Anesth* 1995; 82: 662-673.
2. Sessler DI, Current concepts: mild perioperative hypothermia. *N Eng J Med* 1997; 336: 1730-1737.
3. Tryba M, Leban J, et al. Does active warming of severely injured trauma patients influence perioperative morbidity? *Anesthesiology* 1996; 85: A283.
4. Mahoney CB, et al. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. *AANA J.* April 1999. Vol. 67, No. 2: 155-164.
5. Barie, PS. Surgical Site Infections: Epidemiology and Prevention. *Surgical Infections.* Vol 3, Supplement 2002; S-9 – S-21.
6. Sessler, et al. Optimal Duration and Temperature of Prewarming. *Anesthesiology.* Mar 1995. Vol 82. No 3; 674-680.
7. Jeran L. American Society of PeriAnesthesia Nurses Development Panel. Clinical Guideline for the Prevention of Unplanned Perioperative Hypothermia. *Journal of PeriAnesthesia Nursing* Oct. 2001:Vol 16(5): pp 305-314.
8. Kurz A, Sessler DI, Christensen R, Dechert M. Heat balance and distribution during the core-temperature plateau in anesthetized humans. *Anesthesiology* 83:491, 1995

601463A

36°C

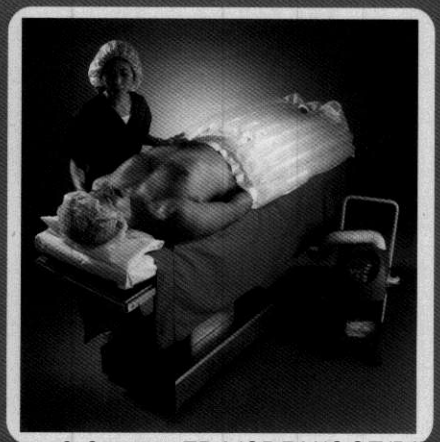
ARE YOUR PATIENTS AT RISK OF UNINTENDED HYPOTHERMIA?

Unintended perioperative hypothermia is not an uncommon occurrence in major surgery. Unintended hypothermia is not just a risk for frail, elderly patients or those undergoing lengthy procedures.

- Heat loss research on healthy volunteers demonstrates that patients receiving general or regional anesthesia are at risk for unintended hypothermia.

- Also demonstrated was that within the first hour of anesthesia, patients can lose 1.6°C due to temperature redistribution.[1]

Fortunately, there is a proven, effective and affordable way to prevent unintended hypothermia and its associated risks: forced-air warming.



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"There is no longer a question whether maintenace of normal core body temperature is important for decreasing the incidence of SSI (surgical site infections); the answer is unequivocally **yes.**"[5]

HYPOTHERMIA PREVENTION FACTS & TIPS

- The average price of a Bair Hugger® blanket is less than $10.
- Induction of anesthesia is the single greatest contributor to unintended hypothermia, resulting in 81% of total heat loss due to heat redistribution.[6]
- Unwarmed surgical patients lose approximately 1.6°C during the first hour of surgery.[1]
- Patients under regional anesthesia are often at greater risk of undetected hypothermia.[2]
- Internal redistribution of body heat is the major cause of unintended hypothermia during the first hour of anesthesia.[1]
- 90% of all heat loss is through the skin.[2]
- The American Society of Perianesthesia Nurses has adopted a patient temperature guideline which indicates that signs and symptoms of unintended hypothermia should be assessed and active warming measures should be instituted to maintain a patient core temperature of 36°C-38°C (96.8°F-100.4°F) intraoperatively.[7]
- Bair Hugger therapy offers 23 blankets styles for all of your warming needs.
- On average, a Bair Hugger blanket is used every 4 seconds in hospitals worldwide.

Special 510(k):

Labeling Modification

Submitted by:
Arizant Healthcare Inc.
10393 West 70th Street
Eden Prairie, MN 55344

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2006

Arizant Healthcare, Inc.
c/o Mr. David Westlin
Senior Director of Regulatory Affairs and Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K053645
Bair Hugger® Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (Two)
Product Code: DWJ
Dated: February 14, 2006
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.

Sincerely yours,

Donna R. Zuckerman

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

Indications for Use

510(k) Number (if known): K053645

Device Name: Bair Hugger® Temperature Management System

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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Jackson
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053645

Page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

Arizant Healthcare, Inc.
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10393 West 70th Street
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Re: K053645
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Dated: December 30, 2005
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Dear Mr. Westlin:

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

(b)(4)

[redacted]

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

19

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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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

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

If you have any questions concerning the contents of the letter, please contact Catherine Wentz at (301) 443-8262 ext. 164, or e-mail at catherine.wentz@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anna R. Lechner

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

JAN 19 2006

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c/o Mr. David Westlin
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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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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

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

If you have any questions concerning the contents of the letter, please contact Catherine Wentz at (301) 443-8262 ext. 164, or e-mail at catherine.wentz@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

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

Prepared by:CWentz:att/1/18/06

FILE COPY

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
450	Wentz	1/18/06						
HFZ450	Fernstr	1-19-06						

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 30, 2005

ARIZANT HEALTHCARE INC.
10393 WEST 70TH ST.
EDEN PRAIRIE, MN 55344
ATTN: DAVID WESTLIN

510(k) Number: K053645
Received: 30-DEC-2005
Product: MODIFICATION TO:BAIR HUGGER TEMPERATURE MANAGEMENT SYSTEMS

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

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 one above 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 regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, 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
Supervisory Consumer Safety Officer
Office of Device Evaluation

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K053645

Please direct this submission to Catherine Wentz

423 CV A

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
December 30, 2005	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Arizant Healthcare Inc.		Establishment Registration Number *(if known)*: 3004542876	
Division Name *(if applicable)*		Phone Number *(including area code)*: (952) 947-1277	
Street Address: 10393 West 70th Street		FAX Number *(including area code)*: (952) 918-5277	
City: Eden Prairie	State / Province: MN	ZIP/Postal Code: 55344	Country: USA
Contact Name: David Westlin			
Contact Title: Senior Director, Regulatory Affairs and Quality Assurance		Contact E-mail Address: dwestlin@arizant.com	

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: N/A			
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )	
Street Address		FAX Number *(including area code)*: ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:
  Additional description of product benefits. No change in Indication or Intended Use.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	K041686	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

ɾrmation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K041686	1	Bair Hugger Temperature Management System	1	Arizant Healthcare Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Bair Hugger Temperature Management Systems

	Trade or Proprietary or Model Name for This Device		Model Number
1	Bair Hugger Temperature Management Systems	1	Various
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K021473	2 K001149	3 K960167	4 K903360	5 K873745	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
DWJ	870.5900	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular

Indications *(from labeling)*

The Bair Hugger family of temperature management systems are 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 temperature management systems can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management systems can be used with adult and pediatric patients.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
eet Address		FAX Number *(including area code)* ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1					
	Standards No.	Standards Organization	Standards Title	Version	Date
2					
	Standards No.	Standards Organization	Standards Title	Version	Date
3					
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Form Approved: OMB No. 0910-512 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) (b)(4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ARIZANT HEALTHCARE INC
10393 WEST 70TH STREET
EDEN PRAIRIE MN 55344
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
371455959

2. CONTACT NAME
David Westlin

2.1 E-MAIL ADDRESS
dwestlin@arizant.com

2.2 TELEPHONE NUMBER (include Area code)
952-947-1277

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
952-918-5277

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4)
07-Dec-2005

Form FDA 8601 (08/2003)

Close Window

60 50

Arizant Inc.
Arizant Healthcare Inc.
Augustine Medical, Inc. • 10393 West 70th Street • Eden Prairie, MN 55344 USA

159422

Inv Date	Invoice	Reference	Invoice Amt	Discount	Net Amount
12/07/2005	(b)(4)		(b)(4)	$0.00	(b)(4)

12/08/2005	(b)(4)	Page 1 of 1	(b)(4)	$0.00	(b)(4)

THIS DOCUMENT HAS A COLORED BACKGROUND, AN ULTRAVIOLET INK FEATURE AND A SIMULATED WATERMARK ON THE BACK

Arizant

Arizant Inc.
Arizant Healthcare Inc.
Augustine Medical, Inc.
10393 West 70th Street • Eden Prairie, MN 55344 USA

(b)(4)

(b)(4)

December 8, 2005

(b)(4)

DATE

NOT VALID AFTER 180 DAYS

AMOUNT

(b)(4)

PAY TO THE ORDER OF: Food & Drug Administration
US Bank
Attn: Govt Lockbox (b)(4)
Saint Louis MO 63101

(b)(6)

(b)(4)

(b)(4)

Two Signatures required for checks $25,000 and above

51

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Arizant
Healthcare
bright ideas that work

December 30, 2005

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

Re: Special 510(k) Notification: Bair Hugger® Temperature Management System

Pursuant to the regulations regarding Special 510(k) applications, Arizant Healthcare Inc., intends to modify its product labeling for the Bair Hugger temperature management systems to include results and recommendations regarding the benefits of forced-air warming from published studies. No other changes to labeling indications for use, contraindications, warnings or precautions are required or being made in relation to this modification.

The Bair Hugger systems have been cleared for use by the FDA in the following submissions: K041686, K021473, K001149, K960167, K903360, and K873745.

We consider our intent to market this device with additional benefit data as confidential commercial information and request that it be considered as such by the FDA.

The submission is provided in duplicate as required by regulation. If you have any questions regarding this Special 510(k) submission, please contact the undersigned at 952-947-1277, by fax at 952-918-5277, or by e-mail at dwestlin@arizant.com.

Sincerely,

David Westlin
Senior Director, Regulatory Affairs and Quality Assurance

10393 West 70th Street, Eden Prairie, MN 55344 USA
952-947-1200 800-800-4346 fax 952-947-1300
www.arizant.com

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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))

I certify in my capacity as Senior Director of Regulatory Affairs and Quality Assurance for Arizant Healthcare Inc. that, to the best of my knowledge, all data and information submitted in this Special 510(k) are truthful and accurate and that no material fact has been knowingly omitted.

David Westlin
Senior Director, Regulatory Affairs and Quality Assurance
Arizant Healthcare Inc.
Date: 12-29-2005

Indications for Use

510(k) Number (if known): _____

Device Name: Bair Hugger® Temperature Management System

The Bair Hugger family of temperature management systems consist of portable forced-air temperature management units, disposable Bair Hugger forced-air blankets and Bair Paws® warming gowns.

Indications For Use:

The Bair Hugger family of temperature management systems are 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 temperature management systems can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management systems can be used with adult and pediatric patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Statement of Confidentiality

Arizant Healthcare Inc. considers the information in this submission to be confidential commercial information. We ask that this notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

Table of Contents

Administrative Information

This is to notify you of the intention of Arizant Healthcare Inc. to *modify the product labeling* for our cleared medical device:

Product Classification Name and Code:	**System, Thermal, Regulating** **DWJ**
Common/Usual Name:	**Hyper/Hypothermia system**
Model Name/Number:	**Bair Hugger family of temperature management system includes warming unit, forced-air warming blankets, and Bair Paws® warming gowns.**
Establishment Registration Number:	**3004542876**
Device Class:	**Class II, 870.5900**
Classification Panel:	**Cardiovascular**
Performance Standard:	**None available**
Predicate Devices:	**Bair Hugger temperature management system** **K041686**
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:	**Arizant Healthcare Inc.** **10393 West 70th Street** **Eden Prairie, MN 55344** **952-947-1200**
Contact Person:	**David Westlin** **Senior Director,** **Regulatory Affairs and Quality Assurance** **Phone: 952-947-1277** **Fax: 952-918-5277**

Description of the Modification to Product Labeling

The currently marketed device is the Bair Hugger temperature management system (K041686, K021473, K001149, K960167, K903360, K873745).

The modifications to product labeling consist of adding language to the labeling that describes the benefits of keeping patients warm and preventing unintended hypothermia, a practice recognized as being advantageous in clinical studies. There are no changes in the intended use of the Bair Hugger family as a result of the modification.

The information listed below provides evidence that:

- Warming makes patients more comfortable
- Studies suggest that patients may experience a reduction in anxiety

Supporting Documents Include:

Arizant Summary Report Describing Product Benefits. August 2005.

Reference Studies

Wagner, et al. Effects of Comfort Warming in Preoperative Patients.

Sessler, et al. Optimal Duration and Temperature of Prewarming. *Anesthesiology.* Mar 1995. Vol 82. No 3; 674-680.

Fossum S, Hays J, Henson M. A Comparison Study on the Effects of Prewarming Patients in the Outpatient Surgery Setting. *Journal of PeriAnesthesia Nursing* June 2001:Vol 16(3): pp 187-194.

O'Brien D, et al. Final Report – Comfort, Satisfaction, and Anxiolysis in Surgical Patients Using a Patient-Adjustable Comfort Warming System: A Prospective Randomized Clinical Trial. Dec. 2004.

Request for additional Bair Paws®/Bair Hugger® forced-air system claims
Arizant Healthcare
August 8, 2005

Anxiety is a "a persistent feeling of dread, apprehension, and impending disaster."[1] The level of anxiety is categorized as either moderate, described as "a painful or apprehensive uneasiness of mind usually over an impending or anticipated ill," or severely pathological, "characterized by an abnormal and overwhelming sense of apprehension and fear often marked by physiological signs (as sweating, tension, and increased pulse), by doubt concerning the reality and nature of the threat, and by self-doubt about one's capacity to cope with it."[2] Anxiety that derives from the outlook of a durably pessimistic personality to the vicissitudes of life is referred to as trait-anxiety. Anxiety that results from the perception of a transient threat is referred to as state-anxiety.

Most surgical patients are beset by state-anxiety.[3] If the patient's anxiety is severe enough, anesthetic induction, recovery, and satisfaction may be adversely affected. For these reasons, several types of anxiolysis are used routinely in the perioperative setting, including, drugs, disclosure, distraction, imaging, and relaxation techniques. Prediction of preoperative anxiety is difficult primarily because it seems to depend on individual personality traits and not on less abstract characteristics.[4] Interestingly, as a group, anesthesiologists are not very good at assessing preoperative anxiety.[3]

A quantitative analysis of anxiety depends on a validated test instrument. The two most common instruments used to assess anxiety are the Visual Analog Scale (VAS) and the Spielberger State-Trait Anxiety Inventory (STAI). Several studies have confirmed a significant correlation between the STAI and VAS scores; however, the STAI is able to discriminate between state and trait anxiety, but the VAS cannot.[5]

Comfort is the opposite of anxiety. A theory of human comfort in hospital patients has been developed and is the basis for nursing interventions in perioperative care.[6] Nursing standards identify patient comfort as an important characteristic that can and should be assessed and managed. Comfort is defined as the "immediate state of being strengthened through having the human needs for relief, ease, and transcendence met in the four contexts of experience (physical, psychospiritual, sociocultural, and environmental."[7] The three types of comfort (relief, ease, and transcendence) describe distinct levels of fulfillment that range from mere mitigation to a state of serene wholeness, irrespective of external circumstances. Fully-realized comfort depends on the satisfaction of both concrete and abstract characteristics, but the fulfillment of a single context can also have a synergistic effect on the experience of total comfort.[7] Unfortunately, the vast majority of anxiolytic therapy is driven by the desire for clinical efficiency and not by the individual requirements of patients.[8]

The environmental conditions necessary to maintain the comfort of the workers in an institutional setting such as a hospital place patients at a thermal disadvantage.[9, 10] The thermal insulation of the clinician's clothing, combined with the metabolic heat produced by a relatively high level of work, requires a lower environmental temperature to produce thermal comfort for the clinician. On the other hand, muscular inactivity and the absence of clothing, combined with relatively low ambient temperatures, produce a sensation of thermal discomfort in many patients. The thermoregulatory response to cold can enhance the sensation of anxiety by increasing the level of cortisol and other vasoactive amines.[11]

While nurses may be able to address the need for transcendence as it applies to the patient's abstract emotional needs in less-than-ideal settings, the need for physical transcendence, especially as it concerns the establishment of thermal comfort, requires an intervention that establishes and maintains a preferred rate of heat loss in the patient.[12]

The thermal needs of conscious patients are considerably different from those in patients under the influence of anesthesia. Thermal comfort in normothermic individuals always requires the establishment of a preferred rate of steady-state heat loss, which depends on balancing the metabolic heat production with cutaneous heat loss.[13, 14] In hypothermic patients, however, perception of thermal comfort is determined by the skin surface temperature and not the mean body temperature.[15] For this reason, the use of forced-air warming systems can produce thermal comfort even in subjects who are hypothermic.[16]

The Arizant Healthcare Bair Paws and Bair Hugger warming systems are comprised of an electrical warming unit that delivers temperature-conditioned air to either an inflatable blanket or a disposable gown that contains an integral thermal warming pad. In the case of the Bair Paws warming system, the warming unit has a tethered temperature control that allows the patient to adjust the operating temperature to a setting that is comfortable.

The temperature of the Bair Paws warming system may be easily adjusted by the patient to produce a comfortable rate of heat loss. Moreover, the Bair Paws system allows patients to exercise at least some control over another context of comfort: their thermal environment.

(b)(4) Testing

[redacted]

The results (attached) from several surveys confirm that a majority of patients prefer to set their own temperature to establish a preferred rate of heat loss. Moreover, many morbidly obese patients reported that they were able to produce states of thermal comfort by operating the Bair Paws warming system on its ambient temperature setting. This feature allows morbidly obese patients to remain fully covered by the gown and still enjoy complete thermal comfort. Also, a majority of patients reported that the Bair Paws gown was partially responsible for helping them achieve transcendence in the sociocultural context of comfort. Most of the patients surveyed in these studies also reported that the Bair Paws gown contributed significantly to their overall satisfaction.

Perioperative Anxiety and Thermal Comfort - Summary

Bair Hugger forced-air warming therapy provides relief, ease, and transcendence in the physical and environmental contexts of comfort (see attached survey data). The satisfaction of the needs in these contexts reduces anxiety. Bair Paws forced-air warming therapy provides relief, ease, and transcendence in the physical and environmental contexts and sociocultural contexts of comfort. The satisfaction of needs in several contexts of comfort produces a synergistic improvement in patient comfort. Data from two studies and several surveys indicate that patients treated with forced-air warming report less anxiety than subjects in the comparison groups.[17, 20]

On the basis of these studies and mechanistic explanations, we are requesting that the FDA permit Arizant Healthcare to make the following claim concerning the perioperative use of the Bair Hugger therapy and Bair Paws gown systems:

1. **Forced-air warming reduces patient anxiety.**

References:

1. NLM. Medical Subject Headings Vocabulary.
2. Merriam-Webster Inc. *Merriam-Webster's collegiate dictionary*. 10th ed. Springfield, Mass., U.S.A.: Merriam-Webster; 1993.
3. Badner NH, Nielson WR, Munk S, Kwiatkowska C, Gelb AW. Preoperative anxiety: detection and contributing factors. *Can J Anaesth*. May 1990;37(4 Pt 1):444-447.
4. Domar AD, Everett LL, Keller MG. Preoperative anxiety: is it a predictable entity? *Anesth Analg*. Dec 1989;69(6):763-767.
5. Kindler CH, Harms C, Amsler F, Ihde-Scholl T, Scheidegger D. The visual analog scale allows effective measurement of preoperative anxiety and detection of patients' anesthetic concerns. *Anesth Analg*. Mar 2000;90(3):706-712.
6. Wilson L, Kolcaba K. Practical application of comfort theory in the perianesthesia setting. *J Perianesth Nurs*. Jun 2004;19(3):164-173; quiz 171-163.
7. Kolcaba K, Wilson L. Comfort care: a framework for perianesthesia nursing. *J Perianesth Nurs*. Apr 2002;17(2):102-111; quiz 111-103.

8. Mitchell M. Patient anxiety and modern elective surgery: a literature review. *J Clin Nurs.* Nov 2003;12(6):806-815.
9. Smith RM, Rae A. Thermal comfort of patients in hospital ward areas. *J Hyg (Lond).* Feb 1977;78(1):17-26.
10. Fanger PO. *Thermal Comfort: Analysis and Applications in Environmental Engineering.* Copenhagen: Danish Technical Press; 1970.
11. Frank SM, Higgins MS, Breslow MJ, et al. The catecholamine, cortisol, and hemodynamic responses to mild perioperative hypothermia. A randomized clinical trial. *Anesthesiology.* Jan 1995;82(1):83-93.
12. Choi JJ. A compassionate view of patient warming. *Outpatient Surgery Magazine*; 2004:88.
13. Fanger PO, McNall PE, Nevins RG. Predicted and measured heat losses and thermal comfort conditions for human beings. Paper presented at: Symposium on Thermal Problems in Biotechnology, 1968.
14. Topliff ED, Livingstone SD. Thermal comfort in relation to mean skin temperature. *Can J Physiol Pharmacol.* Feb 1970;48(2):98-101.
15. Sessler DI, Moayeri A. Skin-surface warming: heat flux and central temperature. *Anesthesiology.* Aug 1990;73(2):218-224.
16. Summers S, Dudgeon N, Byram K, Zingsheim K. The effects of two warming methods on core and surface temperatures, hemoglobin oxygen saturation, blood pressure, and perceived comfort of hypothermic postanesthesia patients. *J Post Anesth Nurs.* Oct 1990;5(5):354-364.
17. Wagner DP, Byrne MJ, Kolcaba K. Effects of comfort warming in preoperative patients: a in press. 2005, Kennasaw.
18. Sessler DI, Schroeder M, Merrifield B, Matsukawa T, Cheng C. Optimal duration and temperature of prewarming. *Anesthesiology.* Mar 1995;82(3):674-681.
19. Fossum S, Hays J, Henson MM. A comparison study on the effects of prewarming patients in the outpatient surgery setting. *J Perianesth Nurs.* Jun 2001;16(3):187-194.
20. O'Brien D, Greenfield MVH, Anderson JE, Smith B, Morris M. Comfort, satisfaction, and anxiolysis in surgical patients using a patient-adjustable comfort warming system: A prospective randomized trial: a in press. 2004, Ann Arbor.

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Optimal Duration and Temperature of Prewarming

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Background: **Core hypothermia developing immediately after induction of anesthesia results largely from an internal core-to-peripheral redistribution of body heat. Although difficult to treat, redistribution can be prevented by prewarming. The benefits of prewarming may be limited by sweating, thermal discomfort, and efficacy of the warming device. Accordingly, the optimal heater temperature and minimum warming duration likely to substantially reduce redistribution hypothermia were evaluated.**

Methods: **Sweating, thermal comfort, and extremity heat content were evaluated in seven volunteers. They participated on two study days, each consisting of a 2-h control period followed by 2 h of forced-air warming with the heater set on "medium" (≈40°C) or "high" (≈43°C). Arm and leg tissue heat contents were determined from 19 intramuscular needle thermocouples, ten skin temperatures, and "deep" foot temperature.**

Results: **Half the volunteers started sweating during the second hour of warming. None of the volunteers felt uncomfortably warm during the first hour of heating, but many subsequently did. With the heater set on "high," arm and leg heat content increased 69 kcal during the first 30 min of warming and 136 kcal during the first hour of warming, representing 38% and 75%, respectively, of the values observed after 2 h of warming. The increase was only slightly less when the heater was set to "medium."**

Conclusions: **Neither sweating nor thermal discomfort limited heat transfer during the first hour of warming. Thirty minutes of forced-air warming increased peripheral tissue heat content by more than the amount normally redistributed during the first hour of anesthesia. The large increase in arm and leg heat content during prewarming thus explains the observed efficacy of prewarming. (Key words: Anesthetic techniques: prewarming. Heat: balance; distribution. Temperature, measurement: muscle; skin; tympanic membrane. Thermoregulation: vasoconstriction; vasodilation.)**

CORE hypothermia developing immediately after induction of general[1] and regional[2] anesthesia results largely from an internal core-to-peripheral redistribution of body heat. Under test conditions, 81% of the observed 1.6°C reduction in core hypothermia during the first hour of general anesthesia represented redistribution and resulted from a flow of 46 kcal from the trunk to extremities. In contrast, only 17 kcal was redistributed during the subsequent 2 h of anesthesia.[3]

It is difficult to *treat* redistribution hypothermia both because the internal flow of heat is large and—more importantly—because heat applied to the skin surface requires considerable time to reach the core thermal compartment. However, redistribution can be *prevented* by prewarming. Cutaneous warming before induction of anesthesia has little effect on core temperature (which remains well regulated).[4,5] It does increase peripheral tissue temperature and reduce the normal core-to-peripheral temperature gradient. Subsequent induction of anesthesia then produces little redistribution hypothermia because heat can only flow down a temperature gradient.[4,6,7] The efficacy of prewarming is thus determined by the extent to which treatment increases peripheral thermal compartment (*i.e.*, extremity) tissue temperature and heat content.

Several factors potentially limit the speed and maximum efficacy of prewarming. (1) Sweating is a remarkably effective thermoregulatory response,[8] easily dissipating more heat than is provided by even the best clinical warming devices. It is regulated by core and skin temperature and the rate of skin temperature change. Sufficiently aggressive cutaneous warming may thus trigger sweating and *reduce* net cutaneous heat transfer. (2) High skin temperatures—and especially rapid increases in skin temperature—provokes thermal discomfort. Such discomfort may limit the tolerable

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duration of aggressive warming. (3) Body heat content increases as the sum of metabolic heat production and environmental loss/gain. Resting metabolic rate is essentially constant, but noninvasive warmers differ significantly in their cutaneous heat transfer rates. Forced-air is the most effective clinically available warming method[5,9] and thus potentially increases tissue temperature most rapidly. Nonetheless, tissue heat transfer at the highest temperature settings may be restricted by sweating or thermal discomfort.

Previous studies demonstrating the benefits of prewarming on redistribution hypothermia have applied moderate heat intensities for 1.5–2 h.[4,6,7] Such prolonged prewarming is, however, impractical in most hospitals. Accordingly, we evaluated sweating, thermal comfort, and the rate at which peripheral tissue heat content increases during moderate and intense forced-air warming. Our purpose was to determine the optimal heater temperature and minimum warming duration likely to substantially reduce redistribution hypothermia.

Methods

With approval from the Committee on Human Research at the University of California, San Francisco and written informed consent, we studied seven male volunteers. None was obese, was taking medication, or had a history of thyroid disease, dysautonomia, or Raynaud's syndrome. Each participated on 2 study days in March 1994.

The volunteers' height was 176 ± 8 cm (mean ± SD), weight 84 ± 15 kg, and age 32 ± 6 yr. The percentage of body fat was 17 ± 3, as determined using infrared interactance[10] (Futrex 1000, Futrex, Hagerstown, MD). Ambient temperature was maintained at 21.3 ± 0.5°C and ambient relative humidity at 36 ± 5% during the study period (Model HX93 humidity and temperature transmitter, Omega Engineering, Stamford, CT).

Studies in two of the volunteers started at approximately 9:30 AM; studies in five others began near 5 PM. All started with 2 h of exposure to a typical operating room environment (control period), which was sufficient to trigger thermoregulatory vasoconstriction. The volunteers then were warmed for two h with a Bair Hugger forced-air heater (Model 200 blower, full-body cover, Augustine Medical, Eden Prairie, MN).[5] On 1 day, the blower was set to "high" (≈43°C), and on the other it was set to "medium" (≈40°C). In each case, two cotton blankets were superimposed on the covers.

Details of the measurement techniques are described in a companion manuscript[3] and previous publications. Most values were measured continuously, and recorded on a computer at 5-min intervals. Briefly, core temperature was measured at the tympanic membrane.[11] Peripheral tissue temperatures were measured using 10 cutaneous probes, foot "deep temperature,"[12,13] and 19 thermocouple needles inserted into arm and leg muscles.[3] Extremity heat content was calculated by fitting local skin and tissue temperatures to parabolic regressions and integrating over volume.[14]

Mean skin-surface temperature and cutaneous heat transfer were calculated from measurements at 15 area-weighted sites using thermocouples incorporated into thermal flux transducers.[1,3] These transducers record heat lost *via* radiation, conduction, and convection; however, they do not detect evaporative loss. Sweating on the chest was quantified by passing anhydrous oxygen through a ventilated capsule. Cutaneous water loss was calculated from the gas flow rate, gas temperature, and relative humidity, as previously described.[15,16] As in previous studies, we considered a sweating rate of 40 $g \cdot m^{-2} \cdot h^{-1}$ as significant.

Oxygen consumption was measured using a canopy-based metabolic monitor (Deltatrac, SensorMedics, Yorba Linda, CA). The system was calibrated daily using a known mixture of gases, and additionally calibrated numerous times by burning ethanol. Measurements were averaged over 5-min epochs. Metabolic heat production was calculated from oxygen consumption, as previously described.[17]

Left forearm blood flow was quantified using strain-gauge plethysmography.[18] Instead of a mercury-in-rubber gauge, we used a capacitance-based "extensometer."[19] Strain-gauge plethysmography is often used to measure cutaneous capillary blood flow, in which case arteriovenous shunts in the hand or foot are isolated by an arterial tourniquet.[20] In this study, however, we avoided a distal arterial tourniquet because we were interested in total extremity blood flow. Arteriovenous shunt flow in the finger was evaluated using volume plethysmography. Capillary vasodilation was estimated using laser Doppler flowmetry (Periflux 3, Perimed, Piscataway, NJ) with an integrating multi-probe ("wide-band" setting) positioned on the right lateral forearm.[21,22]

Vasodilation in leg capillaries was estimated using laser Doppler flowmetry with a standard fiberoptic

probe ("narrow-band" setting) positioned on the right lateral calf. Vascular tone also was evaluated on the second toe using the perfusion index, which is derived, using the same principle as in pulse oximeters, from absorption of two different infrared wave lengths. The index is calculated from the combined absorption of the two intensities.[24]

Thermal comfort was evaluated at 15-min intervals, as previously described,[24] using a 100-mm visual analog scale (VAS). Zero was defined as the coldest imaginable sensation and 100 mm defined as the warmest imaginable sensation; 50 mm identified thermal comfort.

Changes in extremity heat content also were calculated from overall heat balance. Specifically, the change was calculated as the sum of metabolic heat production, cutaneous heat gain, and the change in core temperature multiplied by the weight of the trunk (and head) and the specific heat of humans (0.83 kcal · $kg^{-1}°C^{-1}$).[25] Trunk and head weight was estimated by subtracting the calculated weight of the extremities (from the radial integration) from the total weight of each subject. Calculated changes in arm and leg heat content were compared with directly measured values using two-tailed, unpaired *t* tests.

We considered measured arm and leg heat contents maximal at the end of 2 h warming with the heater set to "high." Time-dependent changes were evaluated using repeated-measure ANOVA; values were compared with those recorded at time zero (start of warming) with Dunnett's test. Differences between the treatments ("medium" and "high" heater setting) were evaluated using paired *t* tests. Results are expressed as mean ± SD; differences were considered statistically significant when $P < 0.01$.

Results

In all volunteers, vasoconstriction was observed throughout the control period. Vasodilation occurred soon after forced-air warming started, and the volunteers remained vasodilated for the rest of the study. Forearm blood flow increased significantly from 3.3 ± 3.8 ml · min^{-1} · 100 g^{-1} to 9.6 ± 5.2 ml · min^{-1} · 100 g^{-1} when it was set to "high." Consistent with this increase, finger (arteriovenous shunt) flow increased from 0.1 ± 0.1 ml/min to ≈0.9 ml/min. Forearm capillary flow doubled on the "medium" and tripled on the "high" settings. Leg vasodilation was dramatic, with both the perfusion index on the toe and capillary flow on the calf (as evaluated using laser Doppler flowmetry) increasing significantly (table 1).

Metabolic heat production, which was nearly constant at ≈100 W before induction of anesthesia, decreased slightly during forced-air heating. Cutaneous heat loss was ≈97 W before warming was started. In contrast, the first 40 min of active warming transferred 7 ± 12 W through the skin surface on the "medium" setting, and 21 ± 15 W when the heater was set to "high." As the skin and subcutaneous tissues warmed, heat transfer subsequently decreased ≈7 and ≈17 W, respectively, at each setting. No sweating was observed during the control period or for the first hour of warming. However, the increases in core temperature during the second hour of active warming triggered detectable sweating in about half the volunteers (fig. 1).

After an initial 0.1°C increase, core temperatures gradually increased an additional ≈0.1°C during the control period. During the first 30 min of forced-air heating, core temperatures decreased ≈0.2°C at each temperature setting. Subsequently, core temperatures increased ≈0.3°C when the warmer was set on "medium" and ≈0.4°C when it was set to "high" (fig. 2). Mean skin temperature, which was ≈32°C at the beginning of the study, decreased ≈0.4°C during the control period. Subsequently, it increased to 36.7 ± 0.2°C when the forced-air warmer was set to "medium" and 37.1 ± 0.2°C when it was set to "high."

Estimated mass of the thighs and lower legs (including feet) were 20 ± 9 kg and 8 ± kg, respectively. Consequently, the legs represented ≈35% of our volunteers' total mass. Similarly, estimated mass of the upper and forearms (including hands) were 4 ± 2 kg and 3 ± 1 kg, respectively. Consequently, the arms represented ≈10% of our volunteers' total mass. The

Table 1. Extremity Blood Flow

	Control	Medium	High
Extensometer/arm (ml · min^{-1} · 100 g^{-1})	3.3 ± 3.8	9.6 ± 5.2	8.6 ± 3.5
Finger flow (ml/min)	0.1 ± 0.1	0.8 ± 0.3	1.0 ± 0.3
Laser Doppler/forearm (units)	6.0 ± 2.8	13.8 ± 3.5	16.9 ± 5.4
Laser Doppler/calf (units)	0.0 ± 0.1	3.5 ± 1.8	6.2 ± 5.6
Perfusion index/toe (units)	0.2 ± 0.2	1.1 ± 0.4	1.3 ± 0.9

There were no statistically significant differences between the control periods on the "medium" and "high" days; consequently, these results were combined. All values differed significantly from control during "medium" and "high" heating. Absolute laser Doppler values on the calf and forearm should not be compared because of differences in the probes used and instrument settings.

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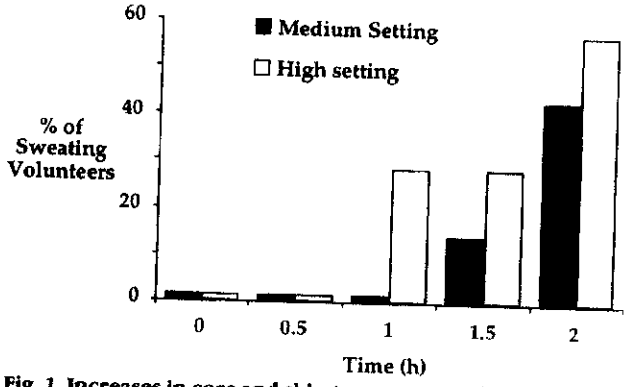

Fig. 1. Increases in core and skin temperatures during the second hour of active warming triggered sweating in about half the volunteers. Elapsed time zero identifies the beginning of forced-air warming.

parabolic regression correlation coefficients for extremity skin and tissue temperatures were generally excellent (*i.e.*, $r^2 > 0.95$).

Initial extremity heat content (at −2 elapsed hours) averaged 1393 kcal and decreased ≈50 kcal during the control period. Both arm and leg heat contents increased significantly during forced-air warming. However, leg heat content increased three times as much as that in the arms (fig. 3). With the heater set on "high," total (arm and leg) heat content increased ≈69 kcal during the first 30 min of warming and ≈136 kcal during the first hour of warming, representing 38% and

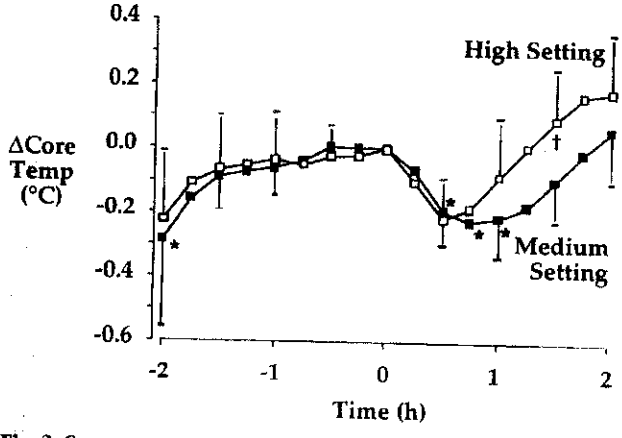

Fig. 2. Core temperatures increased ≈0.2°C during the control period, decreased ≈0.2°C during the first 30 min of forced-air heating, and then increased ≈0.3°C when the warmer was set on "medium" and ≈0.4°C when it was set to "high." Elapsed time zero identifies the beginning of forced-air warming. *Value differs significantly from time zero. †A significant difference between the heater settings.

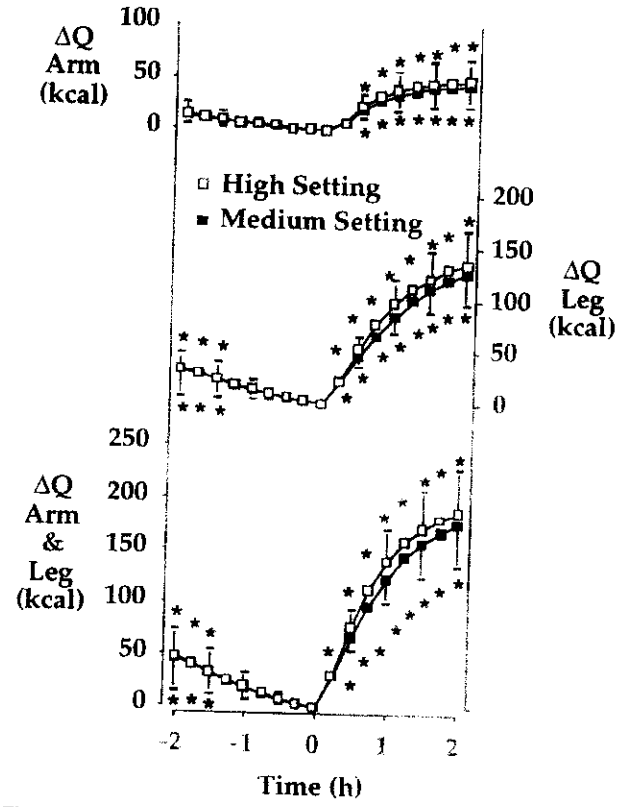

Fig. 3. Heat content of the arms and legs increased at virtually the same rate during forced-air warming with the heater set at "medium" and "high." The increase in the legs was three times as great in the arms. With the heater set on "high," total (arm and leg) heat content increased ≈69 kcal during the first 30 min of warming and ≈136 kcal during the first hour of warming, representing 38% and 75%, respectively, of the values observed after 2 h of warming. Elapsed time zero identifies the beginning of forced-air warming. *Value differs significantly from time zero.

75%, respectively, of the values observed after 2 h of warming. Extremity heat content increased only slightly faster when the forced-air warmer was set to "high" than when it was set to "medium," and maximum content was only slightly greater at the higher temperature (tables 2 and 3).

The volunteers felt slightly cool when the study started, and the cold sensation increased during the control period. Forced-air warming rapidly produced an intense warm sensation; however, none of the volunteers felt uncomfortably warm during the first hour of active heating. Subsequently, many of the volunteers were uncomfortably warm when the forced-air heater was set to "medium," and all were excessively hot when the heater was set to "high" (fig. 4).

Table 2. Extremity Heat Content with Forced-air Warmer Set on "Medium"

Time (h)	Calculated Δ Content (kcal)	Measured Δ Content (kcal)	Measured Δ Content (kcal/kg)	Fraction of Measured Maximum (%)
0.5	51 ± 9	61 ± 13	0.7 ± 0.1	33 ± 7
1.0	97 ± 15	118 ± 22	1.4 ± 0.2	65 ± 12
2.0	171 ± 23	172 ± 40	2.1 ± 0.2	94 ± 22

Total arm and leg tissue heat content increased substantially with forced-air warming set on "medium." Changes in calculated and measured extremity heat contents did not differ significantly. Changes are referenced to elapsed time zero when forced-air warming started. Maximum was defined by leg heat content after 2 h of warming with the heater set to "high." Most warming occurred within 1 h.

Table 3. Extremity Heat Content with Forced-air Warmer Set on "High"

Time (h)	Calculated Δ Content (kcal)	Measured Δ Content (kcal)	Measured Δ Content (kcal/kg)	Fraction of Measured Maximum (%)
0.5	53 ± 12	69 ± 14	0.8 ± 0.1	38 ± 5
1.0	104 ± 23	136 ± 28	1.6 ± 0.2	75 ± 7
2.0	191 ± 38	182 ± 41	2.2 ± 0.2	100

Total arm and leg tissue heat content increased dramatically with forced-air warming set on "high." Changes in calculated and measured extremity heat contents did not differ significantly. Changes are referenced to elapsed time zero when forced-air warming started. Maximum was defined by leg heat content after 2 h of warming with the heater set to "high." Most warming occurred within 1 h.

Discussion

The amount of heat redistributed during the first hour of anesthetic-induced vasodilation is ≈46 kcal, with an additional core-to-peripheral transfer of ≈17 kcal in the subsequent 2 h.[3] Redistribution is not the only cause of intraoperative core hypothermia. However, under test conditions (undressed volunteers in an ≈22°C environment), 65% of the hypothermia observed after 3 h of anesthesia results from redistribution.[3] Forced-air warming (even at the "medium" setting) increased peripheral tissue heat content by this amount within 30 min. After 1 h of warming ("high" setting), measured extremity heat content had increased 136 ± 28 kcal, explaining why prewarmed patients remain normothermic even after 3 h of major surgery.[6]

Among the factors potentially limiting efficacy of prewarming is thermoregulatory sweating provoked by high skin temperature[26] and/or a rapid increase in skin temperature.[27] There was little sweating during the first hour of prewarming, and by the end of the 2-h warming period, only about half the volunteers started to sweat. However, sweating apparently did not significantly impede transfer of heat to peripheral tissues, because extremity heat content calculated from metabolic rate, cutaneous thermal flux, and change in trunk temperature was comparable to that determined by direct measurement. More importantly, the increase in extremity heat content already was substantial by the time sweating was first detected.

All the volunteers were uncomfortably cool during the control period and appreciated forced-air warming for the first 30–60 min, even when the heater was set to "high." Subsequently, most felt excessively warm especially at the higher air temperature. However, peripheral compartment heat content was increased by clinically important amounts within 30–60 min of warming at either temperature setting. Based on these data, we predict that adequate prewarming can be administered without engendering thermal discomfort. In practice, the forced-air warmer can be set to "high" for long as patients wish. Blower temperature[28] can be decreased as necessary to maintain a comfortable sense of warmth.

Cutaneous heat loss during the control period was similar to that we have reported at ambient temperatures near 21°C.[1] The efficacy of convective warming

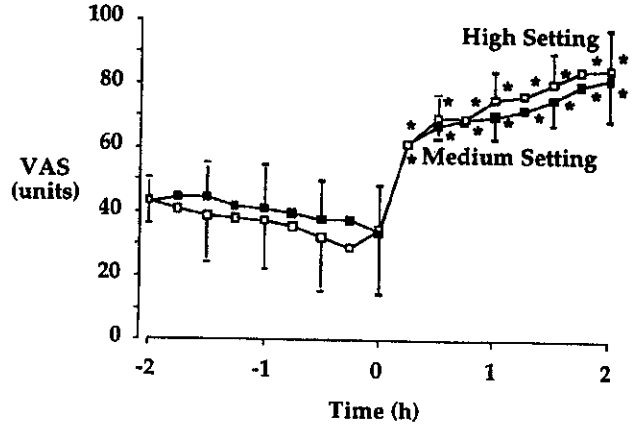

Fig. 4. Forced-air warming rapidly produced an intense warm sensation; however, none of the volunteers felt uncomfortably warm during the first hour of active heating. Thermal comfort was rated on a 100-mm visual analog scale (VAS), with zero indicating intense cold and 100 mm representing intense heat. Elapsed time zero identifies the beginning of forced-air warming. All values after induction of anesthesia differed significantly from time zero; however, there were no significant differences between the groups.

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also was similar to that we reported previously.[5] Even greater rates of cutaneous heat transfer during forced-air warming were reported by Giesbrecht *et al.*[28] There were, however, two major differences between that study and ours. First, ambient temperature was ≈25°C: High ambient temperature reduces cutaneous flux during the control period[29] but also increases heat transfer during active warming (there is less cooling within the forced-air cover). Second, the head was not included in those measurements. Eliminating the head similarly decreases loss during the control period but increases apparent heat transfer during warming (calculated on a per person basis). After ≈40 min of active warming, cutaneous heat transfer gradually decreased ≈7 and ≈17 W, respectively, at each setting. Heat transfer during forced-air warming is roughly proportional to the skin-air gradient (at constant air velocity). This decrease thus simply reflects the progressive increase in skin and tissue temperature as peripheral thermal compartment heat content increased.

As previously described,[14] our direct tissue heat content estimates are limited by extrapolations from a limited number of temperature measurement sites and various assumptions of tissue homogeneity and symmetry. Measured extremity heat content increased somewhat more rapidly than did calculated arm and leg heat content. However, the values never differed significantly, and after 2 h of warming, each method provided similar estimates. It is, therefore, unlikely that the increase in peripheral compartment heat content was much less impressive than reported here. In any case, even quite large underestimates would not change our conclusion that 30–60 min of prewarming substantially increases body heat content and, therefore, reduces the potential for redistribution hypothermia.

Our volunteers had minimal peripheral tissue heat content when active warming started because they had already been vasoconstricted in a cool environment for 2 h. Body heat content would likely be greater (and the core-to-peripheral temperature gradient less) in most surgical patients because they will be better covered and usually maintained in a preinduction environment warmer than the one we used. Effective prewarming would require even less time in such patients.

After an initial 0.1°C increase, core temperature remained relatively constant during the control period, increasing only an additional 0.1°C. Nearly constant core temperatures were consistent with the relatively small decrease in mean skin temperature during this period. Active cutaneous warming then triggered dramatic arteriovenous shunt[30] and capillary[31] vasodilation. Dilation likely was mediated both by cutaneous thermal input to the central regulatory system[32] and by increase in local skin temperature.[33] This vasodilation decreased core temperature ≈0.2°C during the first 30–45 min of forced-air warming. However, during the last hour of warming, redistribution was no longer able to accommodate the increase in body heat content, and core temperature again increased. The interthreshold range is defined by core temperatures (at constant skin temperature) *not* triggering thermoregulatory responses.[34] Consistent with previous reports,[35] the range of core temperatures observed before onset of sweating was ≈0.2°C.

Extremity heat content decreased ≈50 kcal during the 2-h control period. Heat content in the current volunteers presumably decreased because thermoregulatory vasoconstriction constrained metabolic heat to the core,[14] further augmenting the normal core-to-peripheral tissue temperature gradient. In contrast, arm and leg heat content remained nearly constant during the control period in a similar study.[3] The studies, however, differed in two important ways. First, most of the current studies were started in the evening, whereas all the previous ones started in the morning. It is likely that the muscular activity associated with locomotion increases leg content over the course of the day. Second, the current investigation was conducted in March, when San Francisco was considerably warmer than in January, when most of the previous studies were done. It is thus likely that vasoconstriction was already present in volunteers in the previous studies when they arrived in the laboratory, and they thus had nearly minimal extremity temperature and heat content. Under these conditions, heat content would not decrease further during the control exposure. Consistent with this theory, initial tissue heat content was 16% (189 kcal) greater in the March volunteers than in the previous ones. These differences in the response to a standard set of laboratory conditions illustrate the importance of initial conditions and sufficiently long control periods in thermoregulatory studies.

Acute inhibition of tonic thermoregulatory vasoconstriction initiates a core-to-peripheral redistribution of body heat that is the major cause of hypothermia during the first hour of anesthesia.[1] Although arms are considerably smaller than legs, both contribute comparably to redistribution hypothermia.[3] During active warming, however, the larger leg mass absorbed considerably more heat than the arms. These results suggest that re-

distribution accesses only a fraction of the peripheral thermal compartment's potential capacity.

To minimize volunteer risk, we did not induce general anesthesia and specifically quantify redistribution hypothermia. However, the mechanism by which redistribution reduces core temperature,[1] the magnitude of heat flow,[3] and the efficacy of prewarming[4,6] are all well established. We thus can predict with reasonable certainty that redistribution hypothermia in surgical patients will be markedly reduced by 30 min of forced-air warming and virtually eliminated if active heating is maintained for an hour.

We only studied men; the specific amounts of heat absorbed during prewarming would differ somewhat in women. However, the amount required also would be less because women usually are smaller than men. It is thus likely that our general conclusions would apply comparably to women.

In summary, half the volunteers started sweating during the second hour of forced-air warming. None of the volunteers felt uncomfortably warm during the first hour of heating, but many subsequently did. With the heater set on "high," arm and leg heat content increased 69 kcal during the first 30 min of warming and 136 kcal during the first hour of warming, representing 38% and 75%, respectively, of the values observed after 2 h of warming. The increase was only slightly less when the heater was set to "medium." Neither sweating nor thermal discomfort limited heat transfer during the first hour of warming. Thirty minutes of forced-air warming increased peripheral tissue heat content by more than the amount typically redistributed from core to peripheral tissues. The large increase in extremity heat content during prewarming explains why prewarmed patients remain normothermic even after several hours of major surgery.

References

1. Sessler DI, McGuire J, Moayeri A, Hynson J: Isoflurane-induced vasodilation minimally increases cutaneous heat loss. ANESTHESIOLOGY 74:226–232, 1991

2. Hynson J, Sessler DI, Glosten B, McGuire J: Thermal balance and tremor patterns during epidural anesthesia. ANESTHESIOLOGY 74: 680–690, 1991

3. Matsukawa T, Sessler DI, Sessler AM, Schroeder M, Ozaki M, Kurz A, Cheng C: Heat flow and distribution during induction of general anesthesia. ANESTHESIOLOGY 82:662–673, 1995

4. Hynson JM, Sessler DI, Moayeri A, McGuire J, Schroeder M: The effects of pre-induction warming on temperature and blood pressure during propofol/nitrous oxide anesthesia. ANESTHESIOLOGY 79:219–228, 1993

5. Sessler DI, Moayeri A: Skin-surface warming: Heat flux and central temperature. ANESTHESIOLOGY 73:218–224, 1990

6. Just B, Trévien V, Delva E, Lienhart A: Prevention of intraoperative hypothermia by preoperative skin-surface warming. ANESTHESIOLOGY 79:214–218, 1993

7. Glosten B, Hynson J, Sessler DI, McGuire J: Preanesthetic skin-surface warming reduces redistribution hypothermia caused by epidural block. Anesth Analg 77:488–493, 1993

8. Buono MJ, Sjoholm NT: Effect of physical training on peripheral sweat production. J Appl Physiol 65:811–814, 1988

9. Kurz A, Kurz M, Poeschl G, Faryniak B, Redl G, Hackl W: Forced-air warming maintains intraoperative normothermia better than circulating-water mattresses. Anesth Analg 77:89–95, 1993

10. Conway JM, Norris KH, Bodwell CE: A new approach for the estimation of body composition: Infrared interactance. Am J Clin Nutr 40:1123–1130, 1984

11. Støen R, Sessler DI: The thermoregulatory threshold is inversely proportional to isoflurane concentration. ANESTHESIOLOGY 72:822–827, 1990

12. Fox RH, Solman AJ, Isaacs R, Fry AJ, MacDonald IC: A new method for monitoring deep body temperature from the skin surface. Clin Sci 44:81–86, 1973

13. Kobayashi T, Nemoto T, Kamiya A, Togawa T: Improvement of deep body thermometer for man. Ann Biomed Eng 3:181–188, 1975

14. Belani K, Sessler DI, Sessler AM, Schroeder M, McGuire J, Washington D, Moayeri A: Leg heat content continues to decrease during the core temperature plateau in humans. ANESTHESIOLOGY 78: 856–863, 1993

15. Washington D, Sessler DI, Moayeri A, Merrifield B, Prager M, McGuire J, Belani K, Hudson S, Schroeder M: Thermoregulatory responses to hyperthermia during isoflurane anesthesia in humans. J Appl Physiol 74:82–87, 1993

16. Lopez M, Ozaki M, Sessler DI, Valdes M: Physiological responses to hyperthermia during epidural anesthesia and combined epidural/enflurane anesthesia in women. ANESTHESIOLOGY 78:1046–1054, 1993

17. Hynson JM, Sessler DI, Moayeri A, McGuire J: Absence of nonshivering thermogenesis in anesthetized humans. ANESTHESIOLOGY 79: 695–703, 1993

18. Whitney RJ: The measurement of volume changes in human limbs. J Physiol 121:1–27, 1953

19. Brimacombe JR, Macfie AG, McCrirrick A: The extensometer: Potential applications in aneaesthesia and intensive care. Anaesthesia 46:756–761, 1991

20. Wyss CR, Brengelmann GL, Johnson JM, Rowell LB, Silverstein D: Altered control of skin blood flow at high skin and core temperatures. J Appl Physiol 38:839–845, 1975

21. Holloway Jr GA, Watkins DW: Laser Doppler measurement of cutaneous blood flow. J Invest Dermatol 69:306–309, 1977

22. Sessler DI, Olofsson CI, Rubinstein EH: The thermoregulatory threshold in humans during nitrous oxide-fentanyl anesthesia. ANESTHESIOLOGY 69:357–364, 1988

23. Ozaki M, Sessler DI, Lopez M, Walter K: Pulse oximeter-based flow index correlates well with fingertip volume plethysmography (abstract). ANESTHESIOLOGY 79:A542, 1993

24. Sessler DI, Ponte J: Shivering during epidural anesthesia. ANESTHESIOLOGY 72:816–821, 1990

25. Burton AC: Human calorimetry: The average temperature of the tissues of the body. J Nutr 9:261–280, 1935

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26. Bothorel B, Dewasmes G, Hoeft A, Candas V: Leg skin temperature and thigh sweat output: Possible central influence of local thermal inputs. Eur J Appl Physiol 62:405–409, 1991

27. Libert JP, Candas V, Vogt JJ: Effect of rate of change in skin temperature on local sweating rate. J Appl Physiol 47:306–311, 1979

28. Giesbrecht GG, Ducharme MB, McGuire JP: Comparison of forced-air patient warming systems for perioperative use. ANESTHESIOLOGY 80:671–679, 1994

29. Sessler DI, Moayeri A, Støen R, Glosten B, Hynson J, McGuire J: Thermoregulatory vasoconstriction decreases cutaneous heat loss. ANESTHESIOLOGY 73:656–660, 1990

30. Hales JRS: Skin arteriovenous anastomoses, their control and role in thermoregulation, Cardiovascular Shunts: Phylogenetic, Ontogenetic and Clinical Aspects. Edited by Johansen K, Burggren W. Copenhagen, Munksgaard, 1985, pp 433–451

31. Rowell LB: Active neurogenic vasodilation in man, Vasodilatation. Edited by Vanhoutte PM, Leusen I. New York, Raven, 1981, pp 1–17

32. Benzinger TH, Pratt AW, Kitzinger C: The thermostatic control of human metabolic heat production. Proc Natl Acad Sci USA 47: 730–739, 1961

33. Hales JRS, Jessen C, Fawcett AA, King RB: Skin AVA and capillary dilatation and constriction induced by local skin heating. Pflugers Arch 404:203–207, 1985

34. Sessler DI: Perianesthetic thermoregulation and heat balance in humans. FASEB J 7:638–644, 1993

35. Lopez M, Sessler DI, Walter K, Emerick T, Ozaki M: Rate and gender dependence of the sweating, vasoconstriction, and shivering thresholds in humans. ANESTHESIOLOGY 80:780–788, 1994

A Comparison Study on the Effects of Prewarming Patients in the Outpatient Surgery Setting

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Maintenance of core body temperature in surgical patients presents a challenge to perioperative nurses. Core temperatures less than 36°C are associated with multiple adverse outcomes postoperatively. Internal redistribution of heat from the body core to the colder periphery results in core temperature decreases of 0.5°C to 1.5°C in the first 30 minutes after induction of anesthesia. The purpose of this study was to determine if there was a difference in arrival temperatures to the PACU between surgical patients who had been warmed preoperatively with a forced warm air blanket and those patients warmed with cotton blankets. One hundred patients were randomly assigned to receive prewarming by using a forced-air warm blanket (n = 50) or a cotton blanket (n = 50). Temperatures were monitored every 15 minutes throughout the preoperative and postoperative periods. Patients in the forced warm air group had significantly higher temperatures on arrival to the PACU from the OR than did patients in the warm blanket group (P = .000). Patients in the forced warm air group exhibited a change in temperature of 0.0067°C (± .52) compared with a decrease of 0.22°C (± .48) for patients in the control group.

MAINTENANCE OF core body temperature in surgical patients undergoing general anesthesia presents a challenge to perioperative nurses. Normal core body temperature varies between 36.5°C and 37.5°C. Previous studies have shown that general anesthesia can impair thermoregulatory responses, causing mild hypothermia.[1] Temperatures less than 36°C are associated with multiple adverse postoperative outcomes. Even mild hypothermia, defined as temperatures between 33°C to 35°C, can prolong drug action,[2,3] reduce resistance to surgical wound infections,[4] and impair platelet[5] and clotting cascade function.[6,7] Hypothermia, defined as a temperature less than 36°C, can increase morbid myocardial outcomes,[8] trigger postanesthetic shivering, and lead to patient discomfort.[9,10]

Internal redistribution of heat results in core temperature decreases of 0.5°C to 1.5°C in the first 30 minutes after induction of general anesthesia, the majority of which is caused by anesthesia-induced vasodilation and redistribution of heat

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from the body core to the colder periphery.[11,12] Matsukawa[12] reported that core temperatures can drop an average of 1.6°C within the first hour after induction of general anesthesia.

PURPOSE

The primary purpose of this study was to determine the effect of prewarming with forced warm air versus warmed cotton blankets on the core body temperature of surgical patients. The following research questions were specifically addressed:

1. What effect does the method of prewarming have on surgical patients' ability to maintain core body temperature throughout the perioperative experience?
2. What effect does the prewarming method have on surgical patients' self-report of thermal comfort?
3. What effect does the prewarming method have on postoperative shivering?
4. Is there a difference in the incidence of postoperative nausea and vomiting (PONV) and/or the need for postoperative pain medication between patients prewarmed with forced warm air and warmed cotton blankets?

LITERATURE REVIEW

Although limited data exist on the effects of prewarming preoperative patients, numerous studies document the effects of hypothermia on patient outcomes,[13-15] the importance of monitoring temperatures perioperatively,[16,17] and the need for warming techniques during surgery and postoperatively.[15,18-20] At this institution, the accepted standard of practice during the preoperative process is to place a warmed cotton blanket on a patient after he/she has put on his/her hospital gown and is situated on the gurney. Blankets are obtained from a blanket warmer whose thermostatic control is set at 66°C as per the manufacturer's requirements. Most patients welcome the warmth from the application of this warm blanket and express positive statements to this effect. As part of the preoperative process, core temperatures (tympanic) are taken. Clinical observations by the researchers have noted that these temperatures often register below 36°C.

Sessler and Schroeder[21] reported that in addition to giving patients the perception of warmth, warmed blankets can reduce heat loss more than unwarmed ones, but the benefit dissipates within approximately 10 minutes. In 2 separate studies conducted on volunteers in a laboratory setting,[21,22] results showed the positive effects of prewarming with warm forced air. Results from these 2 studies concluded that after 20 to 30 minutes of forced air warming, there was an increase in peripheral heat content that reduced the potential for redistribution hypothermia

According to Durel and Durel,[23] the core body temperature usually drops 0.5°C to 1.5°C during the first hour after the induction of general anesthesia. This is explained by the redistribution of heat from the core to the periphery. This redistribution is potentiated by the vasodilation induced by anesthetic agents. After this initial redistribution of heat, the core body temperature continues to decrease over the next 2 to 3 hours in a slow linear fashion.

The most current research by Sessler[24] reinforces the notion that redistribution of body heat is the major initial cause of hypothermia seen in patients undergoing anesthesia. With limited information on the results of prewarming patients in the clinical setting, it was evident that further research was necessary.

METHODS

Design

A pretest/posttest experimental design was used. Surgical patients were randomly assigned to either the control group or the treatment group. Patients in the control group were provided with one warmed cotton blanket. Patients in the treatment group received forced air prewarming. This study was conducted at a major Northern California academic medical center over a 7-month period. Approval for this study was given by the University Human Subjects Institutional Review Board, and all patients gave informed consent.

Sample

A total of 100 patients were enrolled in this study. The sample included men and women who were 18+ years of age and who were undergoing a surgical procedure that required general anesthesia. For control purposes, the patients were limited to those who were undergoing gynecological, orthopedic, or urological surgical procedures. All patients had an American Society of Anesthesiol-

ogy classification of I, II, or III. General anesthesia was provided via endotracheal intubation, nasal intubation, or with a laryngeal mask airway. Patients who were accepted into this study had a minimum anesthesia time of 1 hour to a maximum anesthesia time of 3 hours. These procedures were all performed at an outpatient surgery center.

Exclusion Criteria

Patients under 18 years of age and those patients whose anesthesia time was less than 1 hour or more than 3 hours were excluded from the study. These criteria were chosen because pediatric patients and length of anesthesia time may reflect other causes for hypothermia (A. Ayyalapu, personal communication, October 1999). Patients who were unable to have tympanic temperatures taken were excluded from the study. Two patients who subsequently required forced air warming in the OR were dropped from the study. In the view of the anesthesia provider, these patients' temperatures dropped and warranted treatment with forced warm air in the OR. Patients being treated for hypothyroidism were not excluded from the study. Subjects with a central nervous system impairment (ie, paraplegic, quadriplegic) were excluded because of vasomotor instability and the potential inability to feel hot or cold.

Variables

Variables of interest included the effects of prewarming on (1) arrival temperatures to the PACU, (2) the incidence of PONV, (3) the need for postoperative pain medication, (4) the patient's self-report of thermal comfort on arrival to the PACU, and (5) postoperative shivering.

Measurement

Pre- and postoperative core body temperatures were measured with a tympanic membrane thermometer (Model #2090; IVAC Corp, San Diego, CA). Core tympanic temperatures were obtained by inserting the thermometer according to manufacturer's instructions, depressing the button and holding for 3 seconds or until the green light blinked, and recording the digital temperature readout. Staff members were inserviced on this technique before beginning the study. Thermometers were calibrated before the study and every 2 months thereafter by the clinical engineering department.

Patients assigned to the treatment group were warmed with a forced warm air unit (Bair Hugger Model #505; Augustine Medical Inc, Eden Prairie, MN) set at a medium operating temperature of 38°C ± 3°C. The forced warm air blanket used was the Bair Hugger Pre-op and Outpatient Care Blanket (Model #110; Augustine Medical Inc, Eden Prairie, MN), with a single cotton sheet placed over it. Patients in the control group were warmed with a single layer cotton blanket. Blankets were warmed in a Continental Metal Products blanket warmer (Model #SW1AE-24; Continental Medical Products Company Inc, Woburn, MA) set at 66°C.

Subjective data to evaluate patient pain level were obtained by using a Likert pain scale, with 0 representing no pain and 10 representing the worst pain. Patients' self-report of thermal comfort was described by using a similar 10-point Likert scale, with 0 representing most comfortable and 10 representing extremely uncomfortable (either hot or cold).

A data collection form was designed to record demographic data and other variables, including preoperative and postoperative temperatures, thermal comfort levels, the use and amount of pain medication given, shivering, and PONV. This form was pilot tested on 5% of the patients to determine usability and clarity. A group of PACU nurses (n = 6), who were specifically trained in the use of this form, reviewed it for content validity.

Data Collection Procedure

Before the study was initiated, PACU nurses, OR staff, and anesthesia providers in the outpatient surgery setting participated in an inservice to be informed about the study. After informed consent was obtained by the investigators, patients were randomly assigned to one of the 2 groups. Fifty sealed packets contained a blue dot (control group) and 50 sealed packets contained a red dot (treatment group). These packets were shuffled before the patients' consent and randomly chosen by the investigator consenting the patient. The treatment group had a forced warm air blanket placed over them; the control group had a warmed cotton blanket placed over them, which was replaced at patients' request. In the preoperative holding area, both groups were prewarmed for a minimum of 45 minutes before being transported to the OR. Data collection was initiated in the preoperative holding

area of the outpatient surgery center. An admission tympanic core temperature was taken as part of the routine preoperative assessment before prewarming. Core temperatures were measured and recorded every 15 minutes during each patient's stay in the preoperative holding area. The same ear was used throughout the perioperative stay. Immediately before transfer to the OR, a final temperature was obtained along with each patient's self-report of thermal comfort.

On return to the PACU from the OR, warming measures were instituted on all patients. Patients in the control group received warmed cotton blankets; the patients in the treatment group had the forced warm air blanket reapplied and turned on to a medium setting. Tympanic temperatures for both groups were recorded every 15 minutes on the data collection sheet. Warming measures were continued until the patient was ready for discharge or discontinued at the patient's request. Patient observations, clinical status, and nursing interventions that occurred in the PACU were recorded. On discharge, the data collection sheet was returned to the designated receptacle for the investigators.

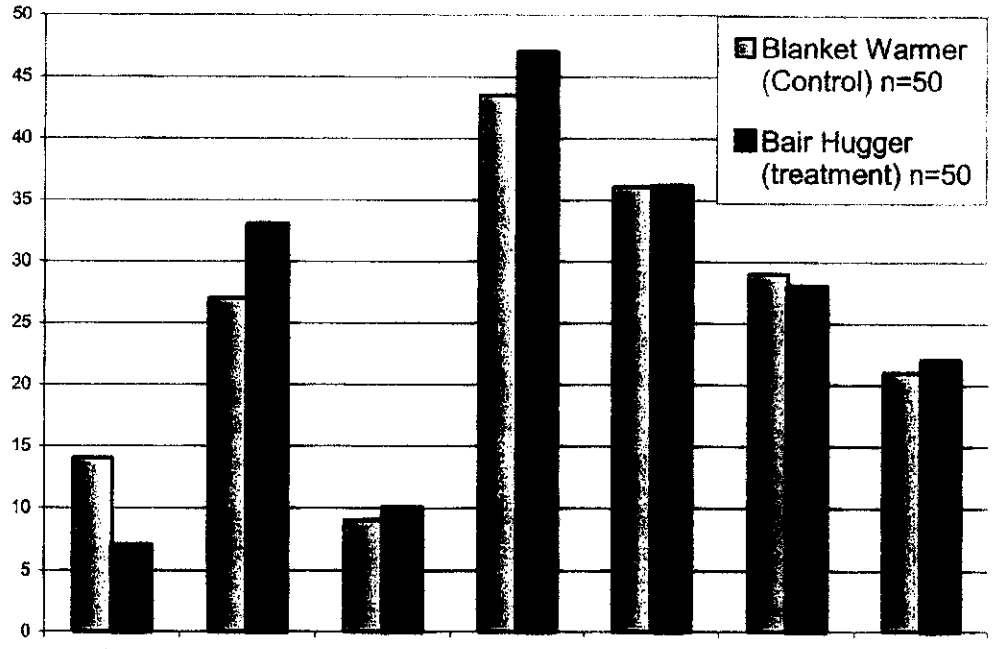
RESULTS

Data analysis was performed by using the Statistical Package for the Social Sciences (SPSS) software (version 9.0 for Windows; SPSS Inc, Chicago, IL). Descriptive statistics including frequencies, means, and standard deviations were analyzed. Inferential statistics included t tests of between-group differences. Nonparametric tests were used for analysis of categorical variables. Significance level was set at $P < .05$.

A total of 100 patients were enrolled in this study, with 50 patients enrolled in each group. There were 57 men and 43 women enrolled in the study. The mean age of the patients was 45.2 ± 14.2 years. There were no significant differences between groups on the following variables: age, gender, type of surgery, ASA classification, and initial temperature (Fig 1).

Maintenance of Core Body Temperature

Patients in the treatment group had a statistically significant increase in temperature during the preoperative stay as compared with patients in the control group (.45°C ± .38 v .17°C ± .51, respec-



	Gyn Surgery (n=)	Ortho Surgery (n=)	Urology Surgery (n=)	Age (Mean/StdDev)	Initial Temp (Mean/Std Dev)	Male (n=)	Female (n=)
Control (n=50)	14	27	9	43.5/±12.10	36.118/±.5029	29	21
Treatment (n=50)	7	33	10	46.96/±15.94	36.456/±.5092	28	22

Fig 1. Patient Demographics.

tively), ($t = -3.1$, $P = .002$). In addition, patients in the treatment group maintained significantly higher mean temperatures (35.97°C ± .52) on arrival to the PACU from the OR than did patients in the control group (35.54°C ± .50) ($t = -4.15$, $P = .000$). Also of interest was that patients in the treatment group were better able to maintain core body temperature throughout the perioperative period than were patients in the control group. Patients in the treatment group exhibited a change in temperature of .0067°C (± .52) compared to a decrease of .22°C (± .48) for patients in the control group (Fig 2).

Thermal Control/Shivering

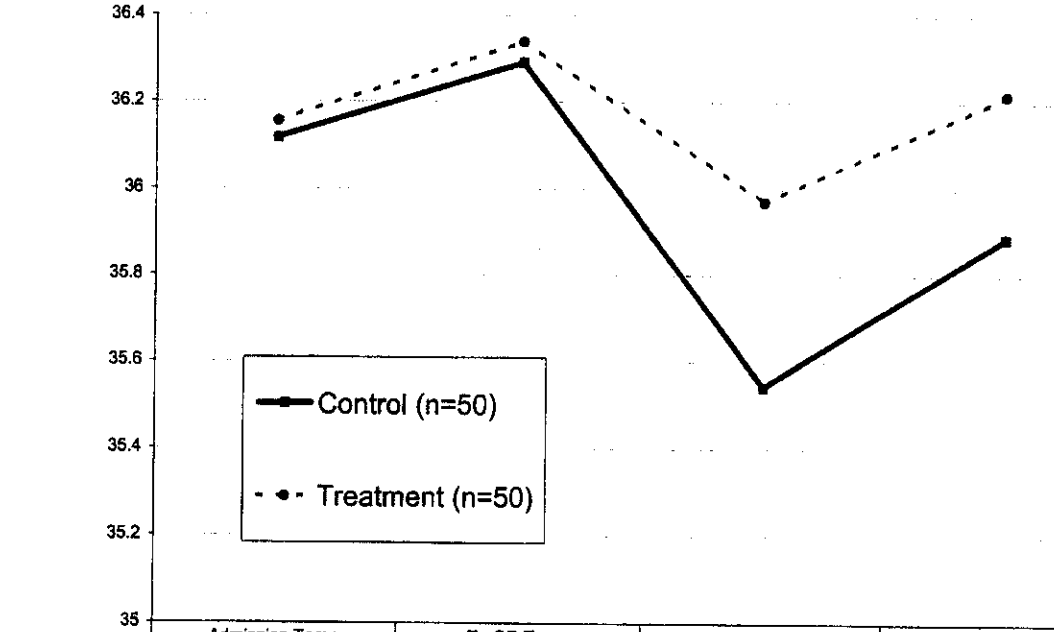
Patients in the treatment group were significantly more likely to self-report thermal comfort than were patients in the control group ($\chi^2 = .369$, $P = .000$). Patients were not questioned regarding thermal comfort until they were able to respond to verbal stimuli. As to the question of postoperative shivering, there were no statistically significant differences in complaints of shivering between patients in the control group and patients in the treatment group. Of interest was the finding of a significant, although small, correlation between age and complaints of shivering ($r = -2.5$, $P = .013$). This is consistent with the significant, although small, inverse correlation found between age and initial postoperative temperature ($r = -.21$, $P = .00$). The older the patient, the lower his/her initial postoperative temperature. Conversely, patients who complained of shivering were more likely to be younger (36 ± 10.6 years *v* 46.6 ± 14.2 years). As expected, there was a significant inverse correlation between complaints of shivering and reported thermal comfort for patients while in the PACU ($r = -.500$, $P < .01$). In other words, the less the patients complained of shivering, the more likely they were to report thermal comfort.

PONV and Complaints of Pain

No differences were noted between groups on the incidence of nausea and/or vomiting ($z = -.434$, $P = .664$). In addition, there were no differences between groups on complaints of pain ($t = .38$, $P = .415$).

DISCUSSION

This study was conducted to determine the effect of prewarming with forced warm air versus



	Admission Temp	To OR Temp	Adm to Pacu Temp	Discharge Temp
Control (n=50)	36.118	36.292	35.542	35.8878
Treatment (n=50)	36.156	36.34	35.97	36.2163

Fig 2. Comparison of Temperature Trends.

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warmed cotton blankets on surgical patients' core body temperature. Kelly et al[25] state that the application of forced warm air devices in the preoperative holding area may be beneficial.

The findings from this study support the use of forced warm air to prewarm surgical patients preoperatively. Results showed that patients arrived preoperatively with similar initial admission temperatures. Although the temperatures of both the control group and the treatment group rose during the preoperative stay, the temperatures of the treatment group were warmer. The patients in the treatment group arrived to the PACU with significantly higher temperatures than the control group (Table 1). Ten percent (n = 5) of the control group arrived to the PACU with a temperature less than 35°C, and 72% arrived with a temperature less than 36°C. Of the patients in the treatment group, 56% arrived with a temperature above 36°C. The correlation found between age and initial postoperative temperature was not surprising and supports the opinion that the geriatric population is at greater risk for developing hypothermia.[26] Patients in both groups who were 60+ years (n = 13) arrived to the PACU from the OR with an average temperature of 35.6°C.

Forty-six percent of the control group were discharged from the PACU with a temperature less than 36°C; 6% were discharged home with a temperature less than 35°C. Those patients discharged home were awake with stable vital signs. Sixty-eight percent of the treatment group were discharged home with temperatures 36°C or greater.

Table 1. Comparison of Patient Temperatures, Thermal Comfort Levels, and Outcome Variables

	Treatment Group (n = 50) Mean (±SD)	Control Group (n = 50) Mean (±SD)	*P* Value
Temperatures			
Initial	36.2°C (±.5)	36.1°C (±.5)	.70
Pre-op	36.6°C (±4)	36.3°C (±.5)	.001
Initial PACU	36°C (±.5)	35.5°C (±.5)	.000
Discharge	36.2°C (±.52)	35.9°C (±.5)	.002
Thermal comfort			
Pre-op	1.2 (±2.1)	1.8 (±2.4)	.19
Post-op	1.8 (±3.1)	3.3 (±3.4)	.03
Outcome variables			
Initial pain score	3.34	3.56	.745
Pain score on discharge	2.1	1.8	.415

Abbreviations: Pre-op, preoperative; Post-op, postoperative.

Patients in the treatment group (n = 50) expressed more positive feelings toward temperature than did patients in the control group. When patients were consented for the study and both methods of prewarming were discussed, most patients expressed a desire to be in the group being prewarmed with the forced warm air and were disappointed if they were not randomized to this group. Patients who were randomized to the forced warm air group expressed positive comments about feeling warm and comfortable. Patients randomized to the control group verbalized negative comments about being cold. Before transport from the preoperative area to the OR, comfort level was assessed in both groups. Twenty-two percent (n = 11) of the control group verbalized feeling cold with a comfort level (cold) of 5 or greater before transport to the OR, whereas 8% of the control group stated they were feeling cold with a comfort level above 8 on a scale of 0 to 10. Sixty-six percent (n = 33) of the treatment group verbalized a comfort level of 0, with 0 being the most comfortable and 10 the most uncomfortable. None of the patients in the treatment group self-reported discomfort of being cold. These findings clearly indicate that the application of forced warm air preoperatively provides positive feelings of comfort for patients. Along with these positive feelings of comfort, patients also expressed that they were less anxious, although the reason for this is not clear. This is a patient satisfaction issue

Fourteen percent (n = 14) of the entire sample (n = 100) arrived to the PACU shivering. Statistics showed that as patients' complaints of shivering increased, their satisfaction with their comfort level decreased. Of the patients who shivered (n = 14), 79% (n = 11) complained of being cold.

There was no statistical significance noted between groups in relation to nausea and complaints of pain on arrival to the PACU. Thirty patients (60%) in both the control group and treatment group had complaints of pain on arrival to the PACU. Of those patients in the treatment group, 42% (n = 21) had complaints of 5 or greater on the Likert pain scale. Forty-eight percent (n = 24) of the control group arrived to the PACU with complaints of 5 or greater on the same pain scale.

Thirty percent (n = 30) of the total sample (n = 100) arrived to the PACU with complaints of

nausea. Thirty-two percent (n = 16) of the patients in the treatment group arrived with nausea to the PACU, whereas 28% (n = 14) of the control group complained of nausea on arrival. A surprising result to the investigators was the relatively low percentage of patients who experienced nausea in the PACU. Because of past clinical observations, our perception has been that a higher number of patients experience nausea in the PACU, but this was not validated in this study.

NURSING IMPLICATIONS

Temperature plays a key role in a patient's perception of comfort during the perioperative experience. As the nurse places the warm blanket on the patient preoperatively, he/she frequently hears the statement "This is the best part about surgery. I love the warm blankets," or "I remember being so cold after surgery and shivering." Thermal comfort is a memorable part of the surgical process whether it is negative or positive in nature. To continually increase patient satisfaction, we as nurses and patient advocates need to be mindful of those positive aspects of thermal comfort.

Based on the results of this study, the investigators recommend the use of forced air prewarming for all surgical patients. The geriatric population may especially benefit from prewarming as evidenced by the fact that all 13 patients over the age of 60 arrived from the OR to the PACU with an average temperature of less than 35.6°C. Within our unit, the investigators discovered that nurses were inconsistent in the discharge criteria they used for temperature. Serious consideration needs to be given to standardizing temperature criteria for discharge from the PACU.

STUDY LIMITATIONS

Length of stay was one of the variables that we intended to evaluate in this study. Results were inconclusive because of extraneous variables such as boarding time in PACU for bed availability, delay in ride home, and staffing issues. The investigators would suggest tighter controls on these variables to better evaluate the effect of prewarming on length of stay.

Because of limitations in patient population, length of anesthesia time, and types of surgeries performed, this study cannot be generalized to all institutions and populations. Future studies might include different surgical procedures with longer anesthesia times.

ACKNOWLEDGMENT

The authors would like to thank the University Surgery Center PACU nurses, OR staff, and anesthesia team for their assistance and cooperation with this study. Appreciation is expressed to Carol Robinson, Director of Nursing, and the Center for Nursing Research at the University of California Davis Health System for financial support to conduct the study. A special thanks to Peggy Hodge, RN, EdD, Clinical Nurse Scientist, for her assistance with the statistical analysis. We wish to thank Augustine Medical for providing the equipment used to conduct this study and the financial support needed to disseminate results.

REFERENCES

1. Sessler DI, Sessler AM: Experimental determination of heat flow parameters during induction of general anesthesia. Anesthesiology 89:657-665, 1998

2. Heier T, Caldwell JE, Sessler DI, et al: Mild intraoperative hypothermia increases duration of action and spontaneous recovery of vecuronium blockade during nitrous oxide-isoflurane anesthesia in humans. Anesthesiology 74:815-819, 1991

3. Leslie K, Sessler DI, Bjorksten AR, et al: Mild hypothermia alters propofol pharmacokinetics and increases duration of action of atracurium. Anesth Analg 80:1007-1014, 1995

4. Kurz, Sessler DI, Lenhardt RA: Study of wound infections and temperature group: Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. N Engl J Med 334:1209-1215, 1996

5. Valeri CR, Khabbaz K, Khuri SF, et al: Effect of skin temperature on platelet function in patients undergoing extracorporeal bypass. J Thorac Cardiovasc Surg 104:108-116, 1992

6. Reed L, Johnston TD, Hudson JD, et al: The disparity between hypothermic coagulopathy and clotting studies. J Trauma 33:465-470, 1992

7. Staab DB, Sorensen VJ, Fath JJ, et al: Coagulation defects resulting from ambient temperature–induced hypothermia. J Trauma 36:634-638, 1994

8. Frank SM, Fleisher LA, Breslow MJ, et al: Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: A randomized clinical trial. JAMA 227:1127-1134,1997

9. Kurz A, Sessler DI, Narzt E, et al: Postoperative hemodynamic and thermoregulatory consequences of intraoperative core hypothermia. J Clin Anesth 7:359-366, 1995

10. Sessler DI: Perioperative hypothermia. N Engl J Med 336:1730-1737, 1997

11. Sessler DI, Rubenstein EH, Moayeri A: Physiological responses to mild perianesthetic hypothermia in humans. Anesthesiology 75:594-610, 1991

12. Matsukawa T, Sessler DI, Sessler AM, et al: Heat flow

and distribution during induction of general anesthesia. Anesthesiology 82:662-673, 1995

13. Shah JB, Hudson JC, Keenan RL, et al: Hypothermia and its impact in the postanesthesia care unit. Anesthesiology 77:A1057, 1992 (abstr, suppl)

14. Uebelen R, Schultze K, Muller D, et al: Unintended decreasing body temperature: A stepchild of perioperative care and outcome consequence. Br J Anaesth 80:A26, 1998 (abstr, suppl)

15. Mahoney CB, Odom J: Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. American Association of Nurse Anesthetists Journal 67:155-164, 1999

16. Cory M, Fossum S, Donaldson K, et al: Constant temperature monitoring: A study of temperature patterns in the postanesthesia care unit. J PeriAnesth Nurs 13:292-300, 1998

17. Sessler DI: A proposal for new temperature monitoring and thermal management guidelines. Anesthesiology 89:1298-1300, 1998

18. Sessler DI: Consequences and treatment of perioperative hypothermia. Anesthesiology Clinics of North America 12:425-456, 1994

19. Kurz A, Kurz M, Poeschl G, et al: Forced air warming maintains intraoperative normothermia better than circulating air mattresses. Anesth Analg 77:89-95, 1993

20. Ouellette RG: Comparison of four intraoperative warming devices. Journal of American Association of Nurse Anesthetists 61:394-396, 1993

21. Sessler DI, Schroeder M: Heat loss in humans covered with cotton hospital blankets. Anesth Analg 77:73-77, 1993

22. Sessler DI, Schroeder M, Merrifield B, et al: Optimal duration and temperature of prewarming. Anesthesiology 82:674-681, 1995

23. Durel YP, Durel JB: A comprehensive review of thermoregulation and intraoperative hypothermia. Current Reviews in Nurse Anesthesia 22:249-260, 2000

24. Sessler DI: Perioperative heat balance. Anesthesiology 92:578-596, 2000

25. Kelly JA, Doughty JK, Hasselbeck AN, et al: The effect of arthroscopic irrigation fluid warming on body temperature. J PeriAnesth Nurs 15:245-252, 2000

26. Morrison RC: Hypothermia in the elderly. Int Anesthesiol Clin 26:124-133, 1988

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

Proposed Labeling

Bair Hugger labeling will state:

- Warming makes patients more comfortable.
- Studies suggest that patients may experience a reduction in anxiety.

Currently Marketed Device

The predicate legally-marketed device is the Bair Hugger temperature management system, including forced-air warming units and disposable warming blankets (K041686, K021473, K001149, K960167, K903360, K873745).

The intended use and indications for use of the temperature management system as described in its labeling have not changed.

The fundamental scientific technology of the device has not changed.

David Westlin
Senior Director, Regulatory Affairs and Quality Assurance
Arizant Healthcare Inc.

Design Control Activities

No additional design control activities are required for modification of product labeling.

Declaration of Conformity

1. Verification and validation activities were performed by Arizant Healthcare Inc. with previous device submissions, and the results demonstrated that the predetermined acceptance criteria were met. No additional activities are required relevant to the proposed product labeling modifications.

2. The Arizant Healthcare manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Records are available for review.

David Westlin
Senior Director, Regulatory Affairs and Quality Assurance
Arizant Healthcare Inc.

SMDA Summary— Special 510(k) Modified Product Labeling

Submitted by:
Arizant Healthcare Inc.
10393 West 70th Street
Eden Prairie, MN 55344
Telephone: 952-947-1200

Contact person:
David Westlin
Senior Director, Regulatory Affairs and Quality Assurance

Summary date:
December 30, 2005

Device name/trade name:
Bair Hugger family of Temperature Management System

Common/usual name:
Hyper/Hypothermia System

Classification name:
System, Thermal, Regulating, DWJ

Equivalent marketed device:
Bair Hugger temperature management system (K041686).

Device description:
The Bair Hugger family of temperature management systems consist of a portable forced-air temperature management unit, disposable Bair Hugger forced-air blankets, and disposable Bair Paws warming gowns.

Intended use of the device

The Bair Hugger temperature management systems are 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 systems 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 systems can be used with adult and pediatric patients.

Technological characteristics

The technological characteristics of the cleared devices do not change with this modification to product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Catherine

Subject: 510(k) Number K053645/S1

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

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☒ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☐ NO 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: DWT / Class II

Additional Product Code(s) with panel (optional):

Review: [signature] 3-3-06
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] for Bill 3/8/06
(Division Director) (Date)

Revised:4/2/03

4

MEMORANDUM

Catherine W 3/1/06

FROM: **Catherine Wentz – Engineer/lead reviewer**
FILE: **K053645/S1**
SPONSOR: **Arizant Healthcare**
DEVICE: **All Bair Hugger Temperature Management Systems**
CLS/CODE: **DWJ**
870.5900 – Thermal Regulating System
Comb. Prod. **N**
SUBJECT: **Response to 1/19/06 AI Letter**
ACTION: **Substantial Equivalence**

AWF 3-3-06

SUMMARY

The sponsor has responded to FDA's January 19, 2006 additional information letter regarding additional "patient comfort" and "possible reduction of anxiety" claims related to their thermal regulating systems. The application was submitted as a special (only these labeling changes were being proposed), but there were a few items that needed to be addressed before making a final determination. This is the second round for this Special 510(k), and all of the items in the January 19, 2006 letter have been sufficiently addressed.

Of special note was item #2 in the 1/19/06 letter. In the sponsor's application, a device, manufactured by the sponsor, was mentioned in a brochure. Since I am the primary reviewer for thermal regulating system's I was pretty sure that the mentioned device had not been cleared under a 510(k). It was a patient robe that contained a portable heater and warming blanket. I requested the 510(k) number from the sponsor, and they stated that there was none, due to the companies determination that this change in design would not require the submission of a 510(k) for marketing. After reviewing this with a collegue (who also reviews these type of devices), and my Branch Chief, Ann Ferriter, it was determined that a 510(k) would in fact be needed for this change in design/technology. As such, since this does not directly affect the determination for the subject application, this application will be cleared, and the sponsor will be notified by phone that a 510(k) will be necessary for this portable system.

Recommendation: Substantial Equivalence

(b)(4) Deficiencies

[redacted]

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

Catherine P. Wentz
Chemical/Biomedical Engineer

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.

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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

Internal Administrative Form

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

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

Subject: 510(k) Number K053645

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

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

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

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

Final Review: _____
(Division Director) (Date)

Revised:4/2/03

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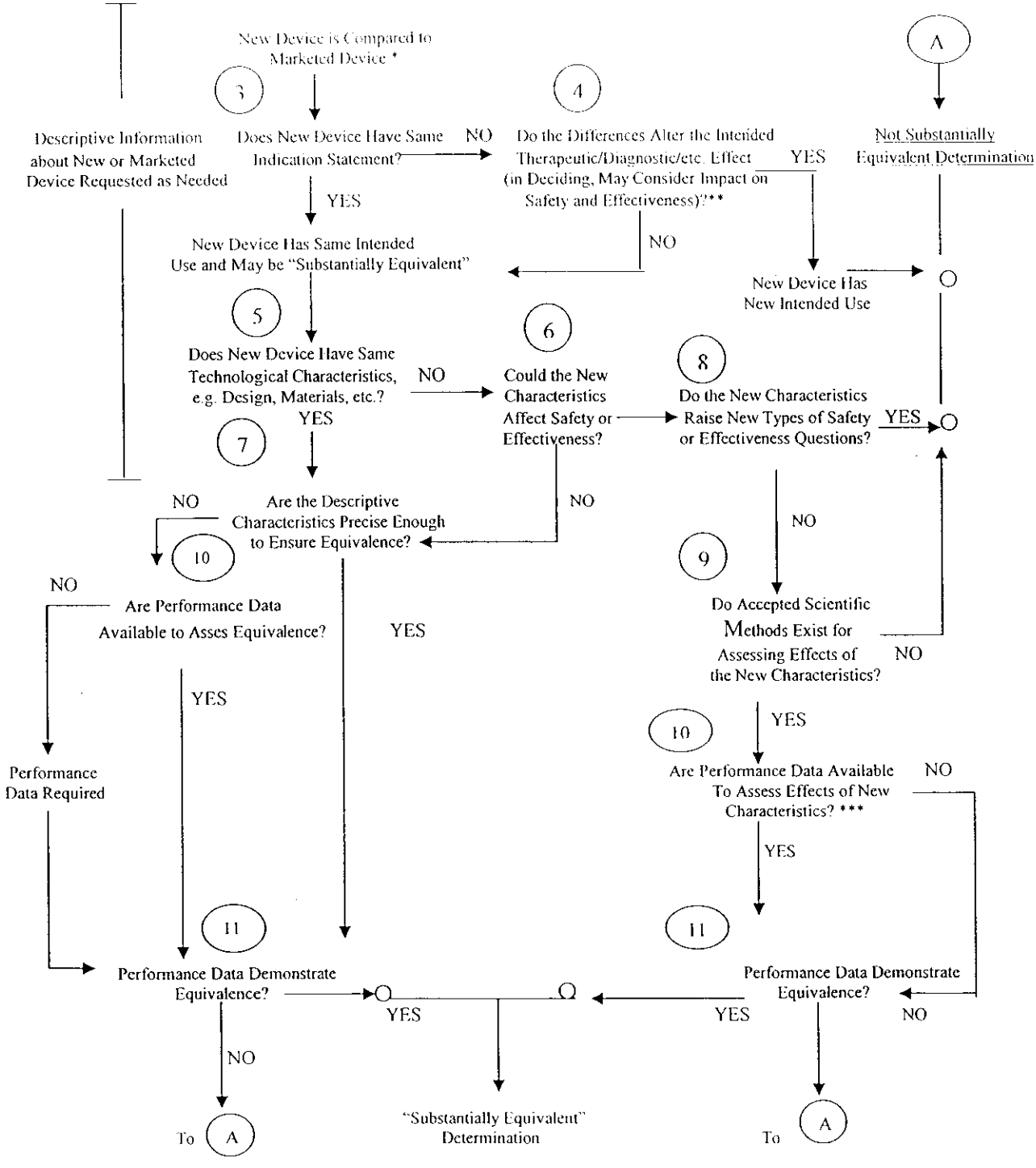
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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.

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SPECIAL 510(k) Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER **K053645**

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: K041686; K021473; K001149; K960167; K903360; and K873745.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are the reason for this special 510(k), but they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for additional labeling changes to include claims of "warming makes patients more comfortable" and "studies suggest that patients may experience a reduction in anxiety". The submission included literature in support these "claims".
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device. ONLY THE LABELING HAS BEEN MODIFIED. So, only the labeling was provided. No other modifications have been made to the intended use, physical characteristics, operating characterists, functionality, etc. HOWEVER, (b)(4) [redacted]. The (b)(4) [redacted]
5. A **Design Control Activities Summary** which includes:
   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. NONE REQUIRED for the proposed labeling changes.
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied. NONE REQUIRED for the proposed labeling changes.
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure.**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the

design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Catherine P. Quesenberry 1/18/06

(Reviewer's Signature) (Date)

Comments

PLEASE SEE ATTACHED INFORMATION. These labeling changes were the subject of several e-mails and informal reviews prior to being submitted here in this formal Special 510(k) – all relevent e-mails are attached). FINAL LABELING WAS NOT PROVIDED.

revised:8/1/03

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

K053645

Reviewer: Catherine Wentz

Division/Branch: DCD / CSPB

Device Name: Bair Hugger Temperature Management System

Product To Which Compared (510(K) Number If Known): K041686; K021473; K001149; K960167; K903360; and K873745.

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

11. Data Demonstrate Equivalence?			Final Decision: **AI**

(b)(4) Deficiencies

[redacted]

1. Intended 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."

THESE INDICATIONS ARE IDENTICAL TO K021473 PREDICATE.

2. Device Description: This System is a thermal regulating system comprised of blankets and a temperature control unit that provides forced cool or warm air to the patient via the blankets.

Catherine,
Thanks for responding. I apologize for being so confusing with the second question. I think your response answered my question.
What I was wondering was (b)(4)
(b)(4)
Any additional response?
Thanks again for the follow-up
Dave

-----Original Message-----
From: Wentz, Catherine P. [mailto:CXW@CDRH.FDA.GOV]
Sent: Tuesday, November 29, 2005 7:10 AM
To: Westlin, Dave
Cc: Wentz, Catherine P.
Subject: RE: Question

Good morning Dave. In answer to your questions:

(b)(4)

Catherine

-----Original Message-----
From: Westlin, Dave [mailto:dwestlin@arizant.com]
Sent: Monday, November 28, 2005 4:00 PM
To: Wentz, Catherine P.
Subject: RE: Question

Catherine,
I have a couple follow-up questions since our phone conversation. (b)(4)
(b)(4)
Any feedback you can provide would be much appreciated.

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Thanks again for your (and other's) assistance.
Dave

952-947-1277. I'm here now and have no meetings planned.

-----Original Message-----
From: Wentz, Catherine P. [mailto:CXW@CDRH.FDA.GOV]
Sent: Monday, November 28, 2005 1:49 PM
To: Westlin, Dave
Subject: RE: Question

Dave,
What is your phone number? I would like to call you....
Catherine

-----Original Message-----
From: Westlin, Dave [mailto:dwestlin@arizant.com]
Sent: Friday, November 18, 2005 3:42 PM
To: Wentz, Catherine P.
Subject: RE: Question

Catherine,
Attached are the [redacted] you asked for.
(b)(4)

Thanks for working with us on these issues.

Dave

-----Original Message-----
From: Wentz, Catherine P. [mailto:CXW@CDRH.FDA.GOV]
Sent: Thursday, November 03, 2005 1:40 PM
To: Westlin, Dave
Subject: RE: Question

Dave,
Can you send us electronic copies of references 17, 18, 19, and 20?
Catherine

-----Original Message-----
From: Westlin, Dave [mailto:dwestlin@arizant.com]
Sent: Wednesday, November 02, 2005 8:28 AM
To: Wentz, Catherine P.
Subject: RE: Question

Catherine,
A number of months ago (many months actually) we corresponded about the

(b)(4)
(b)(4) (I included the previous thread to remind you about our communications). We put together a document to address each of those items. I have attached that document for informal review. We let this sit for an extended time, so I know this was not on your schedule. But, at your convenience, would you please provide your feedback? Thanks, Dave

David Westlin
Senior Director of Regulatory Affairs and Quality Assurance Compliance Officer Arizant Inc. 10393 West 70th Street Eden Prairie, Minnesota 55344
Direct Telephone: 952-947-1277 Direct Fax: 952-918-5277
e-mail: dwestlin@arizant.com

-----Original Message-----
From: Wentz, Catherine P. [mailto:CXW@CDRH.FDA.GOV]
Sent: Monday, May 02, 2005 9:19 AM
To: Westlin, Dave
Cc: Fleischer, Dina J.
Subject: RE: Question

Hi Dave,

OK. Could you please send in (informally - via e-mail) your (b)(4)
(b)(4)
for our review? Once we determine what is appropriate I will have you send in the information formally as a 510(k). OK?

Catherine

-----Original Message-----
From: Westlin, Dave [mailto:dwestlin@arizant.com]
Sent: Wednesday, April 27, 2005 10:31 AM
To: Wentz, Catherine P.
Subject: RE: Question

Catherine,
(b)(4)

-----Original Message-----
From: Wentz, Catherine P. [mailto:CXW@CDRH.FDA.GOV]
Sent: Wednesday, April 27, 2005 9:22 AM
To: Westlin, Dave
Subject: RE: Question

Dear David,
Please don't spend any time right now putting things together. A simple answer to my question will help us make a determination as to whether this
(b)(4)
wait until we can make some kind of general decision before you spend any time putting information together.

Thanks

Catherine

-----Original Message-----
From: Westlin, Dave [mailto:dwestlin@arizant.com]
Sent: Wednesday, April 27, 2005 9:43 AM
To: Wentz, Catherine P.
Cc: Fleischer, Dina J.
Subject: RE: Question

Thanks for the follow-up Catherine.
I will have our clinical director assemble the available information. Dave

-----Original Message-----
From: Wentz, Catherine P. [mailto:CXW@CDRH.FDA.GOV]
Sent: Tuesday, April 26, 2005 7:31 PM
To: Westlin, Dave
Cc: Fleischer, Dina J.
Subject: RE: Question

Thanks for asking... Good question... Do you have (b)(4) [redacted] this?

Catherine

-----Original Message-----
From: Westlin, Dave [mailto:dwestlin@arizant.com]
Sent: Tuesday, April 26, 2005 2:36 PM
To: Wentz, Catherine P.
Subject: Question

Hello Catherine,
We have not had any communications lately. I hope all is well with you. I am writing to get your opinion about something. With our (b)(4) [redacted]

(b)(4) [redacted] Would you have any specific concerns with this? Dave

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Internal Administrative Form

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

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

510(k) Number: K053645

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 or Adequate	Missing or Inadequate
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.	✓	
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).]	N/A	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - 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:

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	Present	Inadequate or Missing
Name and 510(k) number of the submitter'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 submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
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.**]		

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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 not 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 and 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		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" 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

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:

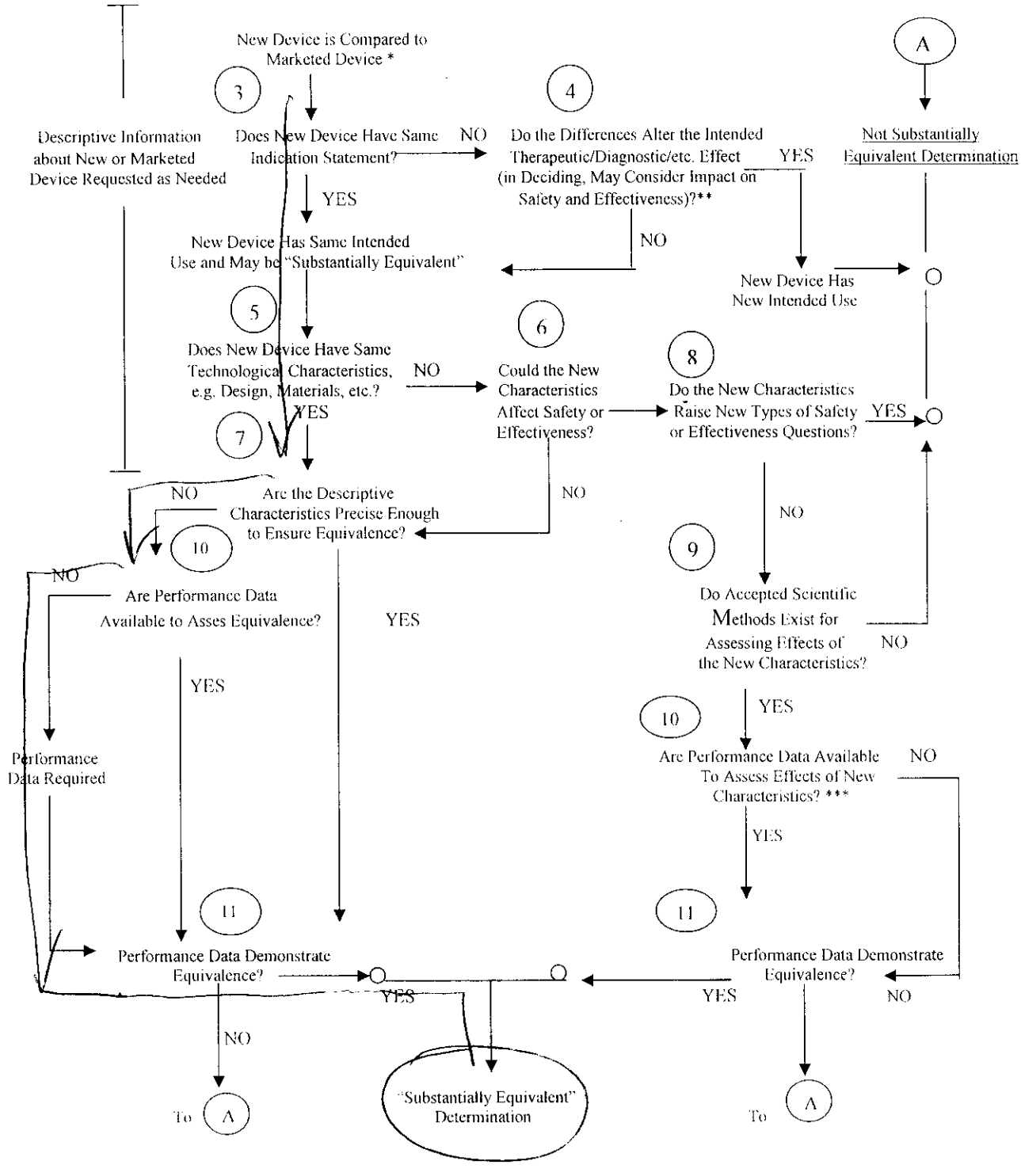
9. Explain why existing scientific methods can not be used:

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

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

February 17, 2006

ARIZANT HEALTHCARE INC.
10393 WEST 70TH ST.
EDEN PRAIRIE, MN 55344
ATTN: DAVID WESTLIN

510(k) Number: K053645
Product: MODIFICATION TO:BAIR HUGGER TEMPERATURE MANAGEMENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. 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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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

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K053645 / S1

927

Arizant Healthcare

bright ideas that work

February 14, 2006

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

Re: Response to Request for Additional Information
Special 510(k) Notification: Bair Hugger® Temperature Management System
K053645

As requested on January 19, 2006, the items listed provide additional information regarding 510(k) K053645.

(b)(4) Deficiencies

[redacted]

The submission is provided in duplicate as required by regulation. If you have any questions regarding this Special 510(k) submission, please contact the undersigned at 952-947-1277, by fax at 952-918-5277, or by e-mail at dwestlin@arizant.com.

Sincerely,

David Westlin

David Westlin
Senior Director, Regulatory Affairs and Quality Assurance

K26

10393 West 70th Street, Eden Prairie, MN 55344 USA
952-947-1200 800-800-4346 fax 952-947-1300
www.arizant.com

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Bair Hugger® Back-to-Basics Brochure Copy

Cover

Everyone deserves a hugg.

Introduction

"There is no longer a question whether maintenance of normal core body temperature is important for decreasing the incidence of SSI (surgical site infections); the answer is unequivocally yes."[1]

Hypothermia Prevention Facts & Tips

- The average price of a Bair Hugger blanket is less than $10.
- Induction of anesthesia is the single greatest contributor to unintended hypothermia, resulting in 81% of total heat loss due to heat redistribution.[2]
- Unwarmed surgical patients lose approximately 1.6°C during the *first hour* of surgery.[3]
- Patients under regional anesthesia are often at greater risk of undetected hypothermia.[4]
- Internal redistribution of body heat is the major cause of unintended hypothermia during the first hour of anesthesia.[3]
- 90% of all heat loss is through the skin.[4]
- The American Society of Perianesthesia Nurses has adopted a patient temperature guideline which indicates that signs and symptoms of unintended hypothermia should be assessed and active warming measures should be instituted to maintain a patient core temperature of 36°C-38°C (96.8°F-100.4°F) intraoperatively.[5]
- Bair Hugger therapy offers 23 blankets styles for all of your warming needs.
- On average, a Bair Hugger blanket is used every 4 seconds in hospitals worldwide.

Did You Know Patients Can Become Hypothermic in Less Than 1 Hour?

Patients under general anesthesia are unable to regulate their temperature. Core hypothermia can develop rapidly in the hour immediately following the induction of anesthesia. Research has shown that during the first hour of general anesthesia, unwarmed surgical patients can lose up to 1.6°C. [3]

Even patients undergoing regional anesthesia are often at risk of unintended hypothermia. Why? Core temperature is seldom monitored during spinal and epidural anesthesia and patients rarely feel cold because of the blocked areas. Patients may actually feel warm in spite of becoming hypothermic because the body incorrectly evaluates skin temperature in the blocked area.

Insert Characteristic Patterns of General Anesthesia Induced Hypothermia[6] graph.

Unintended Hypothermia: Risks Worth Avoiding

Unintended hypothermia is associated with adverse outcomes such as

- increased rates of wound infection[1]
- increased hospital length of stay[5]
- higher mortality rates[7].

The good news is that unintended hypothermia is easily prevented.

"Normothermia should be a goal during emergence and recovery. When available, forced-air warming systems should be used for treating hypothermia."
– Practice Guidelines for Postanesthetic Care. American Society of Anesthesiologists. March 2002.

Unintended Hypothermia: Why Risk It?

More than 100 scientific papers have been written about the benefits of forced-air warming and the prevention of hypothermia. Studies have found forced-air warming to be the most effective warming method in general for preventing and treating unintended hypothermia. Maintaining normothermia with forced-air warming has been shown to reduce the risk of complications and the costs associated with them. Forced-air warming can provide comfort warming and pre-warming during the entire perioperative experience. In addition, recent studies suggest that forced-air warming may result in a reduction in the perioperative anxiety of the surgical patient. It's no wonder on average a Bair Hugger blanket is used every 4 seconds in hospitals worldwide!

Outcomes[8]

Studies have suggested that maintaining normothermia in some general type surgeries may yield positive results such as:

- Reduction in the rate of postoperative wound infections
- Decreased likelihood of postoperative myocardial infarction
- Decreased ICU time
- Shortened hospital length of stay
- Lowered mortality rates
- Reduction in the use of blood products
- Decreased likelihood of mechanical ventilation
- Reduced probability of needing a transfusion

Savings can range from $2500 - $7000 per patient

Affordable Prevention

Preventing these negative outcomes is affordable — the average price of a forced-air warming blanket is less than $10. For the cost of a movie ticket, all anesthetized patients can enjoy the benefits of forced-air warming.

Bair Hugger® Therapy

The makers of Bair Hugger therapy created forced air warming and continue to fine-tune every aspect of the system to deliver optimum warming.

The Bair Hugger system is scientifically engineered to deliver consistent, even patient warming by optimizing the airflow through the blanket's patented air channel and perforation pattern. And the Bair Hugger blanket design provides maximum warming areas for a variety of procedures. Only Bair Hugger therapy offers 23 blanket styles for all patient warming needs from pediatrics to geriatrics, from brief outpatient procedures to complex cardiac procedures.

The central channel of the Bair Hugger blanket is an important design feature that guides the heat directly over the core of the body where heat transfer is most effective. Perforation patterns on the underside of the blanket are specifically designed to optimize heat transfer and provide consistent, even warming across the entire blanket.

Callouts with Upper and Full Body Graphics:

- **Central channel** guides heat directly over core for most effective heat transfer
- **Dual hose ports** provide flexibility in positioning equipment
- Patented **integrated tie strips** are provided to secure the blanket around the arm board
- **Non-inflated foot drapes** guard against thermal injury
- **Patented attached clear head drapes** create a cocoon of warmth around the intubated patient's head
- **Perforations** in the underside of the blanket provide consistent warming

CLOSE WITH: Blankets are available for all your warming needs from pediatrics to geriatrics, from brief outpatient procedures to complex cardiac procedures.

Call 1-800-733-7775 or visit www.bairhugger.com for more information

[1] Barie, PS. Surgical Site Infections: Epidemiology and Prevention. *Surgical Infections.* Vol 3, Supplement 2002; S-9 – S-21.
[2] Sessler, et al. Optimal Duration and Temperature of Prewarming. *Anesthesiology.* Mar 1995. Vol 82. No 3; 674-680.
[3] Matsukawa T, Sessler DI, Sessler A. Heat flow and distribution during induction of general anesthesia. *Anesth* 1995; 82: 662-673.
[4] Sessler DI, Current concepts: mild perioperative hypothermia. *N Eng J Med* 1997; 336: 1730-1737.
[5] Jeran L. American Society of PeriAnesthesia Nurses Development Panel.Clinical Guideline for the Prevention of Unplanned Perioperative Hypothermia. *Journal of PeriAnesthesia Nursing* Oct. 2001: Vol 16(5): pp305-314.
[6] Kurz A, Sessler DI, Christensen R, Dechert M. Heat balance and distribution during the core-temperature plateau in anesthetized humans. *Anesthesiology* 83:491, 1995.
[7] Tryba M, Leban J, et al. Does active warming of severely injured trauma patients influence perioperative morbidity? Anesthesiology 1996; 85: A283.
[8] Mahoney CB, et al. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. AANA J. April 1999. Vol. 67, No. 2: 155-164.

Bair Paws® System

One Patient. One Gown. Continuous Warmth.

Recognized as the world's first temperature-adjustable gown, the Bair Paws system now offers the ease and efficiency of forced-air warming throughout the perioperative process – including the operating room.

The Bair Paws gown provides patient-controlled comfort warming and pre-warming during the entire perioperative experience. The same gown offers effective clinical warming during surgery involving the head, neck, knees, or extremities. The Bair Paws gown can also be used anytime a patient gown is needed.

The Bair Paws system moves away from cotton gowns and blankets into more versatile, practical ways of being covered, comfortable, and clinically warmed. In addition, recent studies suggest that forced-air warming may result in a reduction in the perioperative anxiety of the surgical patient.

In and Out of the OR – Comfort, Convenience and Efficiency that Cotton Just Can't Match

- **The Bair Paws system brings versatility.** One single-use gown covers the entire perioperative experience, from comfort warming before the induction of anesthesia through clinical warming in the OR and PACU.
- **An effective, affordable alternative to warmed cotton blankets.** The Bair Paws system can reduce patient warmth complaints and save valuable nursing time.
- **The soft, thick, opaque material is both comfortable and covering.** Patient modesty concerns are a thing of the past.
- **Temperature management ranks at the top of patient concerns,** according to a 2003 survey that found warmth to be the most cited patient comfort complaint.[1] The Bair Paws system directly addresses this major patient issue, and satisfied patients can boost the bottom line.[2]
- **Give your patents control.** The Bair Paws system's hand-held controller puts the ability to regulate warmth where it belongs – with the patient.

How the Bair Paws Gown Provides Warming

- Ideal for extremity surgeries
- Efficient for short duration surgeries because the gown is already on the patient
- For best results, maximize the surface area of the warming insert.

Insert illustrations of comfort and clinical warming.

Product Specifications
Bair Paws Warming Gown Sizes

Standard
51" long; 64" sweep

X-Large
51" long; 110" sweep

Model 850 Patient Warming Unit

Temperature:	ambient to 40°± 3°C
Alarms:	over-temperature
Power:	110-120 VAC
Weight:	6.3 lbs
Mounting options:	wall, bedrail, IV pole, flat surface

Ordering Information
For more information about the Bair Paws patient adjustable warming system, please contact your Arizant Healthcare Inc. representative or call 1-800-733-7775. Or visit us at www.bairpaws.com.

Patient Warming Gown

81000 Standard	30/case
81200 X-Large	20/case

Patient Warming Gown with Booties

83000 Standard	30/case
83200 X-Large	20/case

Patient Warming Gown Kit

84000 Standard	30/case
84200 X-Large	20/case

Kit includes patient warming gown, bonnet, booties, personal belongings bag and shoe bag.

[1] Wilson, Linda; Kolcaba, Katharine. Practical Application of Comfort Theory in the Perianesthesia Setting. *Journal of PeriAnesthesia Nursing.* June 2004; 164-173.
[2] Press I. Patient Satisfaction: Defining, Measuring and Improving the Experiences of Care. (Chicago Health Administration Press, 2002).