

K060865

## **SMDA Summary— Special 510(k) Modified Product Labeling**

**Submitted by:**

Arizant Healthcare Inc.  
10393 West 70<sup>th</sup> Street  
Eden Prairie, MN 55344  
Telephone: 952-947-1200

APR 24 2006

**Contact person:**

David Westlin  
Senior Director, Regulatory Affairs and Quality Assurance

**Summary date:**

March 31, 2006

**Device name/trade name:**

Bair Paws<sup>®</sup> Temperature Management System

**Common/usual name:**

Hyper/Hypothermia System

**Classification name:**

System, Thermal, Regulating, DWJ

**Equivalent marketed device:**

Bair Hugger<sup>®</sup> Temperature Management System (K053645)

**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 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.

**Comparison of the Technological Characteristics of the  
New Device and Predicate Devices**

The Bair Paws<sup>®</sup> Temperature Management System is substantially equivalent to the Bair Hugger<sup>®</sup> Temperature Management System (K053645).

**Comparison of Technological Features**

<b>Features</b>	<b>Bair Paws Temperature Management System</b>	<b>Bair Hugger Temperature Management System</b>
Method of operation	The Bair Paws warming unit has a blower motor and a heating element. The warming unit delivers warmed air through a hose that is connected to a port in a Bair Paws gown.	The Bair Hugger warming unit has a blower motor and a heating element. The warming unit delivers warmed air through a hose that is connected to a port in a Bair Hugger blanket or Bair Paws gown.
Alarms	Over-temperature: color indicator light illuminates, heater and blower shut down.	Over-temperature: red light illuminates with audible alarm, heater and blower shut down.
Areas for device use	Pre-op, intensive care unit, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients.	Pre-op, intensive care unit, operating room, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients.
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Patient Position	Stationary	Stationary
Device positioning	Can be set on table, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail; or attached to the wall using a wall mount bracket.	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail.
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length, washable, 1.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 24 2006

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

Re: K060865  
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: March 29, 2006  
Received: March 30, 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 Federal Register.

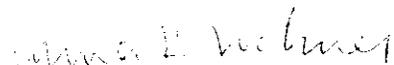
Page 2 - Mr. David Westlin

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 <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

Enclosure

### Indications for Use

510(k) Number (if known): K060865

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)

*Patricia P. [Signature]*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number   K060865  

Page 1 of 1



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 24 2006

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

Re: K060865  
Bair Hugger® Temperature Management System  
Regulation Number: 21 CFR 870.5900  
Regulation Name: Thermal Regulating System  
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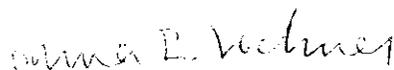
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Page 2 - Mr. David Westlin

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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): K060865

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    
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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)

*William P. [Signature]*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K060865

Page 1 of 4

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

March 30, 2006

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

510(k) Number: K060865  
Received: 30-MAR-2006  
Product: BAIR PAWS  
TEMPERATURE  
MANAGEMENT SYSTEM  
MODEL 850

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](http://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

K060865

Please direct this submission to Catherine Wentz

K24

SP

## Special 510(k):

# Bair Paws<sup>®</sup> Temperature Management System

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

FOOD AND DRUG ADMINISTRATION

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

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission March 24, 2006	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 70 <sup>th</sup> 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 E-mail Address dwestlin@arizant.com		
Contact Title Senior Director, Regulatory Affairs and Quality Assurance			

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

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

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (specify):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	K053645	2		3	
4		5		6	
7		8		<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

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

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

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
 Bair Paws Temperature Management System

Trade or Proprietary or Model Name for This Device	Model Number
1 Bair Paws Temperature Management Systems	1 Model 850
2	2
3	3
4	4
5	5

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

1 K873745	2 K903360	3 K960167	4 K001149	5 K021473	6 K041686
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 DWJ	C.F.R. Section (if applicable) 870.5900	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> 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**

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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					
2					
3					
4					
5					
6					
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

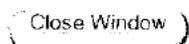
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (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:					
<ol style="list-style-type: none"> <li>1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.</li> <li>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.</li> <li>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.)</li> <li>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.)</li> <li>5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <a href="http://www.fda.gov/cdrh/mdufma/faqs.html#3a">http://www.fda.gov/cdrh/mdufma/faqs.html#3a</a>. You are responsible for paying all fees associated with wire transfer.</li> <li>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.</li> </ol>					
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: <a href="http://www.fda.gov/dc/mdufma">http://www.fda.gov/dc/mdufma</a> )  <table border="0"> <tr> <td> <b>Select an application type:</b>  <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party  <input type="checkbox"/> Biologics License Application (BLA)  <input type="checkbox"/> Premarket Approval Application (PMA)  <input type="checkbox"/> Modular PMA  <input type="checkbox"/> Product Development Protocol (PDP)  <input type="checkbox"/> Premarket Report (PMR)         </td> <td> <b>3.1. Select one of the types below</b>  <input checked="" type="checkbox"/> Original Application  <b>Supplement Types:</b>  <input type="checkbox"/> Efficacy (BLA)  <input type="checkbox"/> Panel Track (PMA, PMR, PDP)  <input type="checkbox"/> Real-Time (PMA, PMR, PDP)  <input type="checkbox"/> 180-day (PMA, PMR, PDP)         </td> </tr> </table>				<b>Select an application type:</b> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	<b>3.1. Select one of the types below</b> <input checked="" type="checkbox"/> Original Application <b>Supplement Types:</b> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> 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. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> 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).)  <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)		(b)(4)			

03-Mar-2006

Form FDA 8601 (08/2005)





March 31, 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: Special 510(k) Notification: Bair Paws<sup>®</sup> Temperature Management System**

Pursuant to the regulations regarding Special 510(k) applications, Arizant Healthcare Inc., intends to market the Bair Paws Temperature Management System. Arizant Healthcare regards this device to be substantially equivalent to existing devices currently on the market.

The Bair Hugger systems have been cleared for use by the FDA in the following submissions: K053645, 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](mailto:dwestlin@arizant.com).

Sincerely,

David Westlin  
Senior Director, Regulatory Affairs and Quality Assurance

**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: 3-29-06

### 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)

Page 1 of \_\_\_\_\_

### **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.

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### Administrative Information

This is to notify you of the intention of Arizant Healthcare Inc. to manufacture and market a *modified* medical device:

Product Classification Name and Code:	<b>System, Thermal, Regulating DWJ</b>
Common/Usual Name:	<b>Hyper/Hypothermia system</b>
Model Name/Number:	<b>Bair Paws<sup>®</sup> Temperature Management System</b>
Establishment Registration Number:	<b>3004542876</b>
Device Class:	<b>Class II, 870.5900</b>
Classification Panel:	<b>Cardiovascular</b>
Performance Standard:	<b>None available</b>
Predicate Devices:	<b>Bair Hugger<sup>®</sup> Temperature Management System K053645</b>
Summary of Safety and Effectiveness:	<b>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.</b>
Manufacturer:	<b>Arizant Healthcare Inc. 10393 West 70<sup>th</sup> Street Eden Prairie, MN 55344 952-947-1200</b>
Contact Person:	<b>David Westlin Senior Director, Regulatory Affairs and Quality Assurance Phone: 952-947-1277 Fax: 952-918-5277</b>

## **Description of the Modification**

### **Bair Paws® Warming System**

The Bair Paws Warming System is a modification of the Bair Hugger Temperature Management System [510(k) clearance K053645].

The Bair Hugger Temperature Management System consists of a warming unit and disposable warming blankets that disperse the warmed air to the patient. The Bair Paws Warming System consists of a disposable gown that has the warming blanket (insert) attached in the front of the gown and a modified warming unit designed to provide lower volume warming. The gown is designed to be used with the Bair Hugger warming units or the Bair Paws warming units.

A brief description of the system changes and similarities follow:

- The safety and control systems have not changed; the temperature range is the same as the predicate devices.
- The Bair Hugger warming units have 2.5-inch diameter hose; the Bair Paws warming unit includes a smaller (1.5-inch) diameter hose.
- No changes were made to the internal control mechanisms.
- The minimum required air volume and pressure have been reduced to accommodate the volume and pressure required by the comfort warming gown. Blower capacity is between 8 cfm and 42 cfm depending upon the warming device used. This is within the predicate device range, which is up to 48 cfm on other Bair Hugger units.
- In case of an over-temperature event, the warming units shut off to eliminate any safety hazard. The indicator light on the warming unit will illuminate. The operator will need to turn the warming unit off and turn it on again to reset it. The devices reaction to a fault condition is the same as the predicate device.

### **Forced-Air Warming Gown**

The patient gown is a modification of the forced-air warming technology used in the Bair Hugger Model 300 warming blanket (K873745) and Model 520/522 Upper Body warming blanket (K903360). The dual air-channel insert attaches to the front region of a disposable warming gown that enables the gown to be connected to a Bair Hugger series 500 or 700 temperature management unit or a Series 800 warming unit. The warming gown can be used for prewarming, in the operating room, and in any clinical settings that use Bair Hugger units instead of or in addition to Bair Paws warming units. The design has been tested for safety and efficacy with the three warming unit models. The mean contact surface temperature (MCST) with each design and each warming unit is within established specifications for forced-air warming devices. All Bair Paws gowns include the following features and functions:

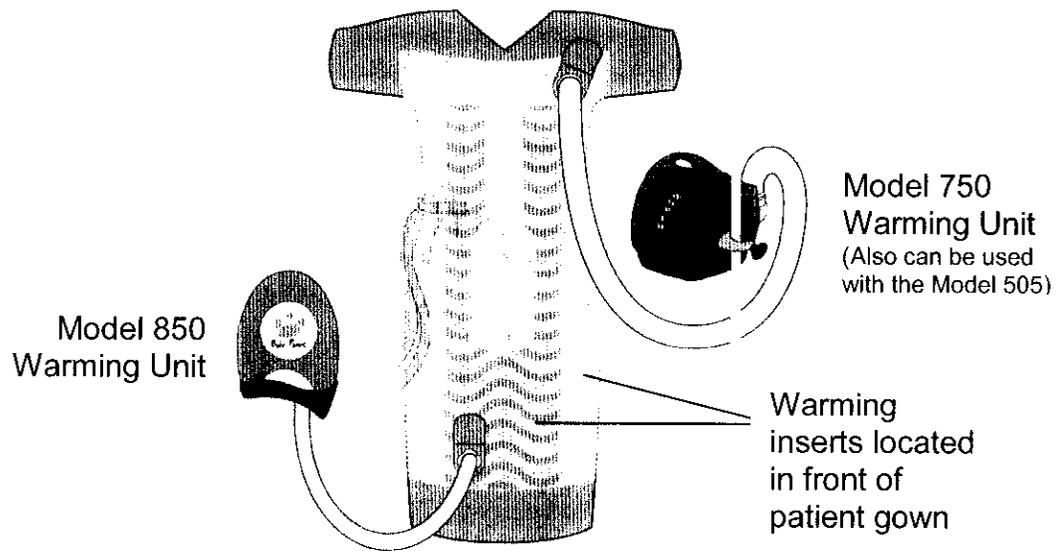
- A panel of perforated air-channels on the inside front of the gown—equivalent to the forced-air blanket technology used in the Bair Hugger Model 300 forced-air warming blanket (K873745) and in the Bair Hugger Model 520/522 forced-air warming blanket (K903360).
- Lower hose port on the outside front of the gown to connect it to the 800 Series warming unit.
- Upper hose port on the outside front of the gown to connect it to the Model 505 and 750 warming units.
- Non-sterile and single-use.
- Made of polyester (b)(4) material from (b)(4) Nonwovens—(b)(4) fabric.
- Tie strips for closure at the neck and waist.
- Hook-and-loop fasteners on the shoulder for clinicians' access to the patient.

### **Model 850 Warming Device**

The Bair Paws Model 850 warming device was modified to be used with the forced-air patient warming gown as follows:

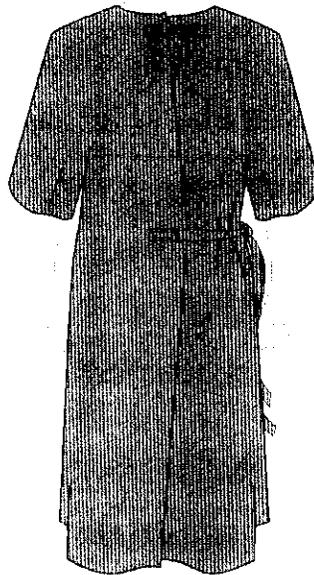
- Functional modifications include a reduction in the delivered air pressure and volume to match the characteristics required by the warming gown, and a continuously variable air temperature up to 40°C that can be controlled by the patient or clinician. The pressure, volume, and temperatures are all within the ranges of the previously cleared predicate devices. The safety and control systems have not changed.
- A temperature controller with temperature control knob and an ON/OFF switch replaces the various user interfaces of the other model warming units.

### Front of the Bair Paws<sup>®</sup> Gown



**Note:** Only one warming unit can be used at a time.

### Back of the Bair Paws<sup>®</sup> Gown



# BAIR PAWS SYSTEM

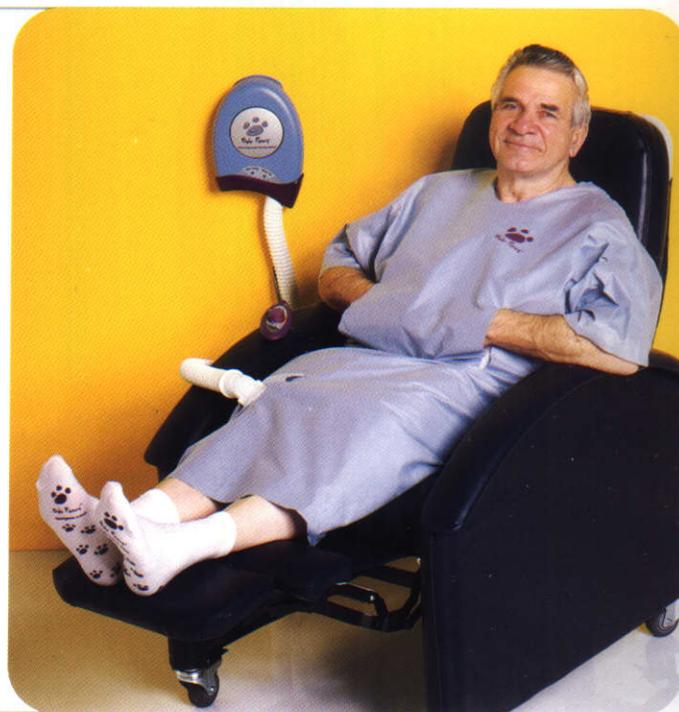
## ONE PATIENT. ONE GOWN. CONTINUOUS WARMTH.

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.

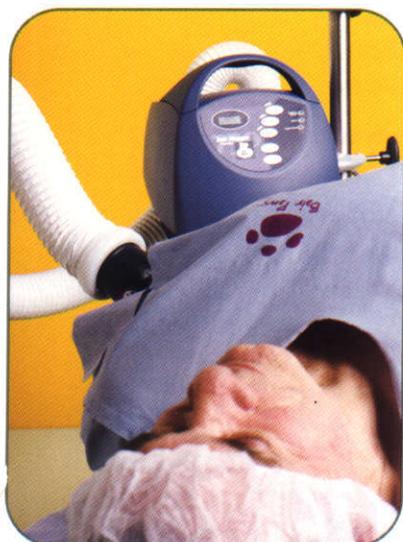
The Bair Paws gown provides patient-controlled comfort warming in the pre-op and post-op setting. The same gown offers effective clinical warming during surgery involving the head, neck, knees, or extremities. The Bair Paws gown can also be used anytime a patient gown is needed.

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.

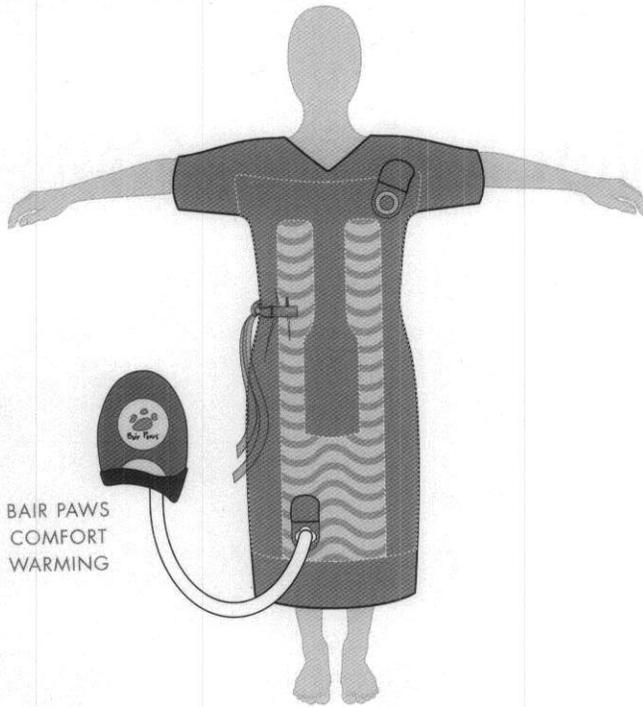
- **The soft, thick, opaque material is both comfortable and covering.** Patient modesty concerns are a thing of the past.

- **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.<sup>1</sup> The Bair Paws system directly addresses this major patient issue, and satisfied patients can boost the bottom line<sup>2</sup>.

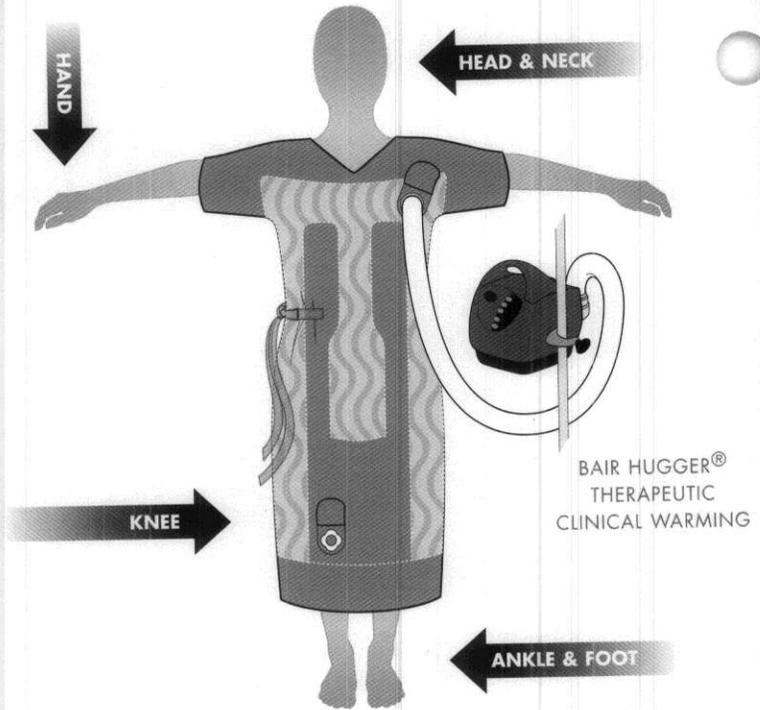
- **Give your patients control.** The Bair Paws system's hand-held controller puts the ability to regulate warmth where it belongs – with the patient.

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).



BAIR PAWS  
COMFORT  
WARMING



BAIR HUGGER®  
THERAPEUTIC  
CLINICAL 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](http://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.



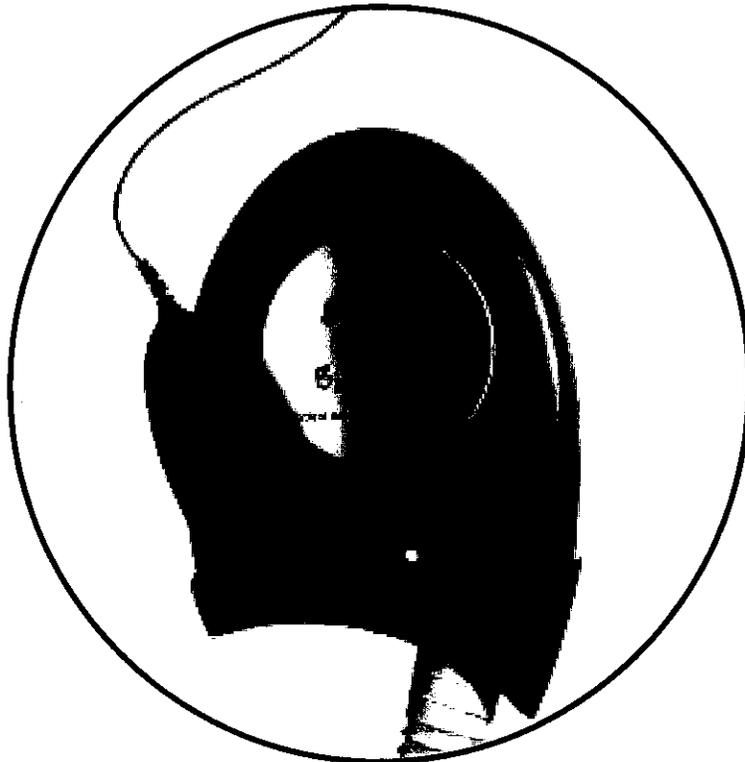
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 10393 West 70th St., Eden Prairie, MN 55344 USA

TEL 800-733-7775 • 952-947-1200 • FAX 800-775-0002 • 952-947-1400 • [www.arizanthealthcare.com](http://www.arizanthealthcare.com)

6

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# Bair Paws® Model 850 Warming Unit



## Operator's Manual



**Bair Paws®**

Patient Adjustable Warming System

by Bair Hugger® Therapy

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## Introduction to the Bair Paws Patient Adjustable Warming System

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The Bair Paws patient adjustable warming system consists of the Model 850 forced-air warming unit and disposable warming gowns. The Bair Paws warming system can provide warmth and comfort to patients in multiple pre- and post-operative settings.

This manual includes operating instructions and unit specifications for the Model 850 warming unit. Please refer to the Instructions for Use included with the Bair Paws warming gown for more information about the gown.

### Bair Paws Model 850 Warming Unit

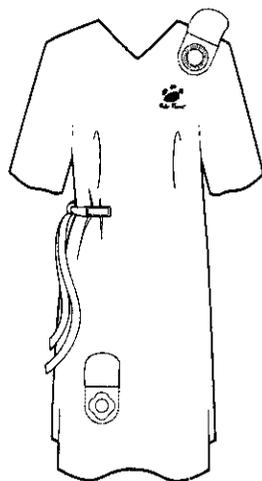
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The Bair Paws Model 850 warming unit has a blower motor, a heating element, and a hand-held temperature controller. The warming unit delivers warmed air through a hose that is connected to a port in a Bair Paws gown. The patient can adjust the air temperature using the temperature controller.

### Bair Paws Warming Gowns

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The Bair Paws single-use warming gown has an integral, channeled insert that delivers warm air through small perforations to warm the patient. The front of the gown has two ports. The lower port accepts the hose of a Bair Paws Model 850 warming unit to provide comfort warming. The shoulder port is sized to accept the hose of a Bair Hugger® 500 or 700 series temperature management unit, which the clinician may choose to provide clinical warming. The gown also has Velcro® fastener strips on each shoulder that provide easy access to the patient's arms and chest. The Bair Paws warming gowns are latex-free.

VELCRO is a registered trademark of Velcro Industries B.V.



## Bair Paws® Model 850 Warming Unit

# Important Information about the Model 850 Warming Unit

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### Indications/Intended Use

The Model 850 warming unit is indicated for patient thermal comfort. This warming unit has been designed for use with the Bair Paws warming gowns in all preoperative and post-operative settings. The Model 850 warming unit is not intended for use in the operating room.

### Contraindication

Do not apply heat to ischemic limbs. Thermal injury may result.

### Warnings

- Do not warm patients with the warming unit's hose alone. Thermal injury may result. Always connect the hose to a Bair Paws warming gown before providing patient warming.
- Do not use a forced-air warming device over transdermal medications; increased drug delivery and patient death or injury may occur.
- Use only Bair Paws warming gowns with the Model 850 warming unit. This warming unit has been designed to operate safely with Bair Paws warming gowns; use with other products may cause thermal injury. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the unit being used in conjunction with products other than Bair Paws warming gowns.
- Do not allow the warming unit's hose to contact the patient's skin during patient warming. Thermal injury may result.
- Position the temperature controller cord and the hose away from the patient's neck or shoulders to avoid entanglement or injury.
- EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics.

### Precautions

- Do not initiate patient warming unless the Model 850 warming unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
- The Model 850 warming unit meets the international electronic interference requirements of EN 60601-1-2 and EN 55011. However, if radio frequency interference with monitoring equipment occurs, connect the warming unit to a different power source.



## **Proper Use and Maintenance**

Arizant Healthcare Inc. assumes no responsibility for the reliability, performance, or safety of the unit if:

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

## **Read Before Servicing Equipment**

All repair, calibration, and servicing of the Model 850 warming unit must be performed by qualified, medical equipment service technicians who are familiar with good practice for medical device repair. If the warming unit does not require the manufacturer's attention, Arizant Healthcare Inc. will ship replacement parts to your location. Perform all repairs and maintenance in accordance with the instructions provided with the replacement parts.



## Bair Paws® Model 850 Warming Unit

### Preparing the Model 850 Warming Unit for Use

Before you begin using the warming unit, make sure that it is safely placed on a flat, hard surface such as a table, or securely mounted on a wall, IV pole, or bedrail.

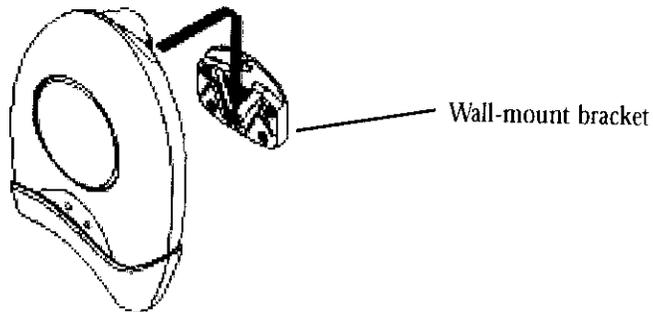
**CAUTION:** Do not place the warming unit on a soft or uneven surface, such as a bed, or the air intake may become blocked.

A wall-mount bracket is shipped with every warming unit; the brackets for mounting the warming unit to an IV pole or a bedrail are available separately. Please contact your local sales representative or call Arizant Healthcare® customer service at 1-800-733-7775 for more information about ordering mounting brackets.

The following instructions for mounting the warming unit assume that the brackets have already been attached to the wall or to the warming unit.

#### **Placing the Warming Unit on the Wall-Mount Bracket**

1. Slide the V-shaped bracket on the back of the warming unit into the groove of the wall-mount bracket.
2. Lift the warming unit straight up to remove it from the wall-mount bracket.

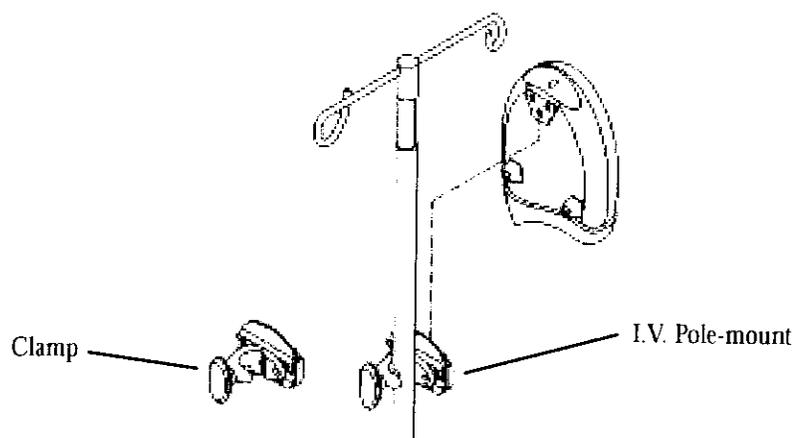




## Mounting the Warming Unit on an IV Pole

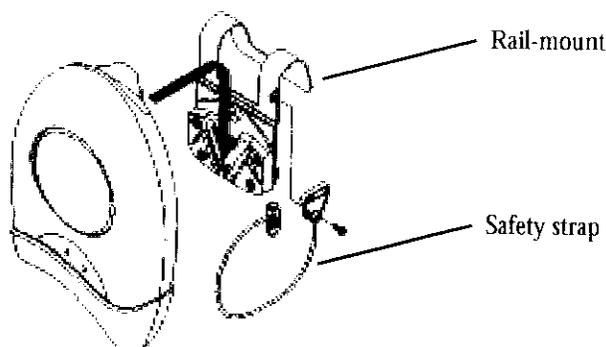
**CAUTION:** To prevent tipping, mount the Model 850 warming unit on an IV pole at a height that provides stability. We recommend mounting the warming unit no higher than 44 in. (112 cm) from the floor on an IV pole with a minimum 14 in. (35.6 cm) radius wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and patient injury.

1. Position the warming unit at the desired height on the IV pole, and turn the clamp handle on the pre-attached pole-mount clockwise to tighten the clamp to the pole.



## Mounting the Warming Unit on a Bedrail

1. Hang the Model 850 warming unit on a bedrail by the hooks on the rail-mount that has been pre-attached to the back of the unit.
2. Wrap both ends of the safety strap around the bedrail and connect the ends to the fasteners on the rail-mount. The safety strap will prevent the warming unit from falling if the unit is inadvertently dislodged from the bedrail.





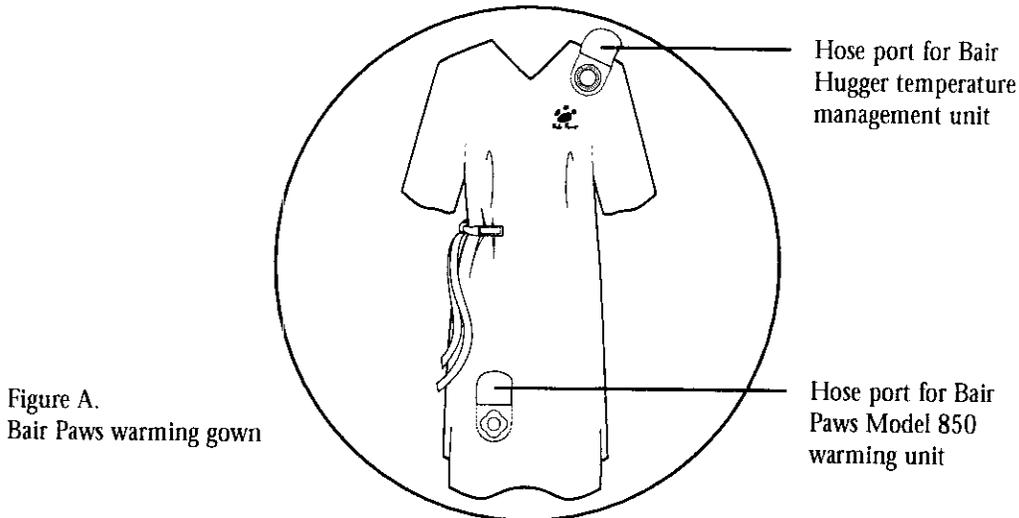
## Bair Paws® Model 850 Warming Unit

### Operating Information

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#### Instructions for Use

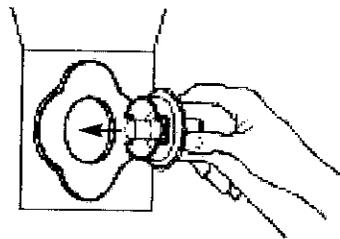
The instructions below describe how to use the Bair Paws Model 850 warming unit with a Bair Paws gown. For more information about the Bair Paws warming gowns, refer to the Instructions for Use that is shipped with the warming gowns.



1. Instruct your patient to put the warming gown on so the opening is in the back and it ties on the side and at the neck. The gown should be tied loosely to help warm air to circulate in the gown insert.

- 
2. Connect the warming unit hose to the lower hose port on the warming gown:

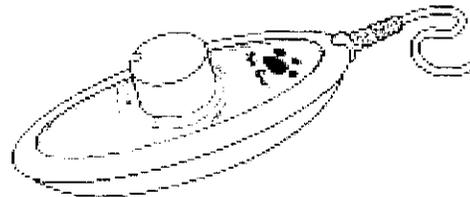
- squeeze and hold the 2 buttons on the sides of the hose nozzle,
- insert the nozzle into the open hose port in the warming gown,
- release the buttons to lock the hose nozzle in place.





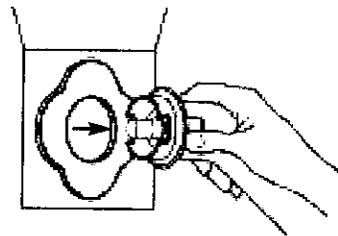
3. Connect the warming unit to a properly grounded power source.
- 

4. Turn the knob on the temperature controller clockwise to turn the warming unit ON. When you turn the warming unit on, the heater and blower activate.
- 



5. Allow the patient to adjust the temperature to a comfortable level. The temperature is adjusted by turning the knob on the temperature controller. The temperature adjustment varies from ambient to  $40 \pm 3^\circ\text{C}$ .
- 

6. To disconnect the hose nozzle from the warming gown, press the 2 buttons on the sides of the nozzle and withdraw the nozzle from the hose port.
- 



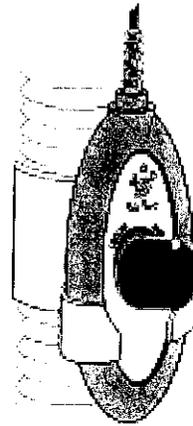


## Bair Paws® Model 850 Warming Unit

### Using the Hand-held Temperature Controller Holder

The controller holder helps to prevent cord clutter around the patient or accidental damage to the controller.

1. Press the holder onto the warming unit hose so it is within the patient's reach.
2. Slide the temperature controller into the holder. It should fit securely with the dial facing the patient.



### What to Do if the Over-Temperature Indicator Light Illuminates

If the *Over-temperature* indicator light illuminates, it means that the warming unit is delivering air at a temperature that is higher than the unit is calibrated to deliver. When an over-temperature condition occurs, the heater and blower will automatically turn off. You should perform the following steps:

1. Discontinue patient warming.
  - Disconnect the warming unit hose from the Bair Paws warming gown.
  - Turn the warming unit OFF.
2. Unplug the warming unit from the power source and wait 5 minutes.
3. Reconnect the warming unit to the grounded power source.
4. Turn the warming unit ON and select the temperature setting.
5. Allow the warming unit to run for at least 5 minutes, then:
  - if the *Over-temperature* light illuminates again, return the warming unit to Arizant Healthcare for service.
  - if the *Over-temperature* light does not illuminate again, reconnect the warming unit hose to the Bair Paws gown to resume patient warming.



## General Maintenance

---

### Calibrating the Operating Temperatures

Operating temperature calibration should be verified every 6 months and after performing service procedures. In addition, if the ambient temperature where the warming unit will be used is higher than 24°C (75°F), the unit should be recalibrated before it is placed in service. You will need a Bair Paws Model 90055 temperature test kit to perform the calibration. Calibration instructions are included with the test kit.

### Replacing the Filter

Replace the filter every 6 months or sooner if necessary. To order a replacement filter, contact Arizant Healthcare customer service at the phone numbers listed on page 10. Instructions for replacing the filter will be included with the replacement filter.

### Cleaning the Warming Unit

#### WARNING

Do not immerse any part of the warming unit while cleaning it. Moisture will damage the components, and thermal injury may result.

#### PRECAUTIONS

- Do not use a dripping wet cloth to clean the warming unit. Moisture may seep into the electrical contacts and damage the components.
- Do not use harsh solvents to clean the warming unit.\* Solvents may damage the labels and other plastic parts.

### Method

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

\* WINDEX® multi-use liquid cleaner, ENVIROCIDE® disinfectant and ALCONOX® industrial cleaner are three products that can be used to clean the equipment, as well as 3% household bleach, isopropanol, ethanol, ammonia or other phosphate-based glass cleaning solutions.

WINDEX is a registered trademark of S.C. Johnson & Son, Inc.  
ENVIROCIDE is a registered trademark of Metrex Research Corporation  
ALCONOX is a registered trademark of Alconox, Inc.



## Bair Paws® Model 850 Warming Unit

### Technical Support and Customer Service

#### U.S. Customer Service

TEL:  
800-733-7775  
952-947-1200

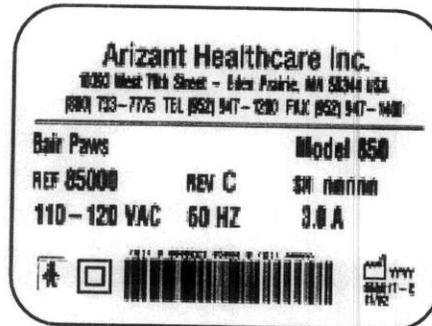
FAX:  
800-775-0002  
952-947-1400

#### When You Call for Technical Support

Please be ready to give the Technical Support Representative the serial number of your Bair Paws warming unit. The serial number is located on the back of the unit. See figure below.

#### Repair and Exchange

Call Arizant Healthcare customer service if your Model 850 warming unit requires service. A customer service representative will give you a Return Authorization (RA) number. Please use this RA number on all correspondence concerning your warming unit. Your customer service representative will also send a shipping carton to you at no charge, if needed.





## Bair Paws Warming Unit Limited Warranty

### **Two-Year Limited Warranty<sup>a, c</sup>**

Arizant Healthcare Inc. ("Company") warrants to the original end-user (User)<sup>a</sup> that each Bair Paws warming unit (Unit)<sup>b</sup> will be free from defects in materials and workmanship under normal use and service for two years<sup>c</sup> from the date of shipment. **THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES APPLICABLE TO THE UNITS, SUCH AS WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY THE COMPANY.** Some jurisdictions may not allow the disclaimer of implied warranties, so the above limitations may not apply to you.

### **Limitation of Remedies**

If, during the limited warranty period, a Unit or part is found to be defective because of defects in materials and workmanship under normal use and service, it will be repaired or replaced without charge. Defective Units or parts must be returned to Arizant Healthcare Inc., 10393 West 70<sup>th</sup> Street, Eden Prairie, MN 55344. Repair or replacement of a Unit or part under the terms of this limited warranty in no way lengthens the limited warranty period.

User's exclusive remedy, **IN LIEU OF ALL INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING FOR NEGLIGENCE**, is limited to repair or replacement of a defective Unit or part under the terms and conditions of this limited warranty. Company will bear no other expenses. Some jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so this limitation may not apply to you.

This limited warranty does not apply to certain of the parts listed below or to any Unit in which parts other than replacement parts made or approved by the Company have been used if such parts are the cause of failure. Company shall have no obligation under this limited warranty to make repairs or replacements necessitated in whole or in part by accidents, fault, or negligence of User.

<u>PART</u>	<u>WARRANTY PERIOD (from the date of shipment to User)</u>
Filters	N/A
Fuses	N/A
Hose	1 year
Cords	1 year
Labels	1 year
Temperature controller	1 year
Mounting brackets	1 year

This limited warranty applies only to User and is valid only for the use of Units with Bair Paws gowns. The use of any gowns or other products not manufactured or approved by Company for use with Units invalidates this limited warranty. Use of Units in a manner not specified in the instructions for use invalidates this limited warranty. This limited warranty is non-transferable.

This limited warranty gives you specific legal rights, and you may also have other rights which vary from jurisdiction to jurisdiction.

- a. Distributors are not end-users unless they have purchased a unit for their sales representatives' use.
- b. This limited warranty is valid only for Bair Paws warming units. It does not apply to Bair Paws gowns or accessories or any other product.
- c. Refurbished Units have a one-year limited warranty from the date of shipment to User. As indicated below, this limited warranty does not apply to certain parts and other parts have a one-year limited warranty from the date of shipment to User.



**Bair Paws® Model 850 Warming Unit**

**Technical Specifications**

**Physical Characteristics**

DIMENSIONS OF WARMING UNIT	11 in. high x 2.5 in. deep x 7.7 in. wide 27.9 cm high x 6.4 cm deep x 19.6 cm wide
DIMENSIONS OF TEMPERATURE CONTROLLER	2.5 in. wide x 5.8 in. long 6.4 cm wide x 14.7 cm long
WEIGHT OF WARMING UNIT	6.3 lb; 2.9 kg.
MOUNTING OPTIONS	Wall mount bracket, IV pole clamp, and rail-mount bracket with safety strap.
HOSE	Detachable, flexible, and washable. 78 in. long x 1.5 in. wide; 198 cm long x 3.8 cm wide
FILTRATION SYSTEM	Dust filter included.
RECOMMENDED FILTER CHANGE	Change at least every 6 mo.

**Temperature Characteristics**

TEMPERATURE CONTROL	Electronically controlled using integrated circuit sensor.
HEAT GENERATED	750 BTU/hr (average)
AVERAGE OPERATING TEMPERATURES AT THE END OF THE HOSE	Variable: ambient to 40° ± 3°C ambient to 104° ± 5.4°F

**Safety System Characteristics**

THERMOSTAT	Independent electronic and heater (electromechanical)
OVERCURRENT PROTECTION	Fused input line.
SAFETY FEATURE	Over-temperature: color indicator light illuminates, heater and blower shut down.
CERTIFICATIONS	IEC 601-1: UL 60601-1; CAN/CSA-C22.2, No. 601.1; EN 60601-1-2; EN 55011
CLASSIFICATIONS	Classified under EN 60601-1 Guidelines (and other national versions of the Guidelines) as Class II, Type BF, Ordinary equipment, Continuous operation. Not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601.1 and in accordance with Canadian/CSA C22.2, No. 601.1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.





## Technical Specifications - Continued

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### Electrical Characteristics

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BLOWER MOTOR	Airflow: 8-10 cfm
POWER CONSUMPTION	Peak: 290W    Average: 150W
LEAKAGE CURRENT	Meets IEC 601-1 and UL 2601-1 requirements
HEATING ELEMENT	285W Resistive
POWER CORD	15-foot, SJT, 3 cond., 10A
DEVICE RATINGS	110-120 VAC, 60 Hz, 3.0 A
FUSES	3.0 A
TEMPERATURE CONTROLLER CORD	32" from hose collar, 4 cond., Max. voltage: 5V



## Bair Paws® Model 850 Warming Unit

### Definition of Symbols

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The following symbols may appear on the product, on the exterior packaging, or in the product labeling.

	ON/STANDBY
	Temperature control
	Equipotentiality plug (ground)
	Fuse
	Attention, consult accompanying documents
	Nonexplosion proof
	Dangerous voltage
	Type BF equipment (patient applied)
	Voltage, alternating current (AC)
	Protective earth ground
	Ground
	Class II Equipment



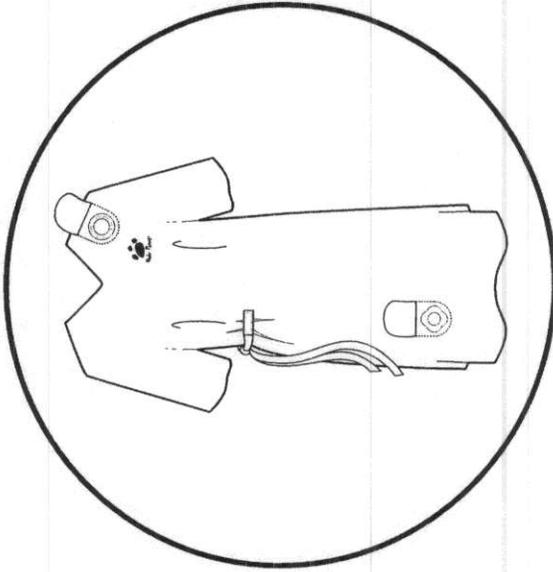
Arizant Healthcare Inc., 10393 West 70th Street, Eden Prairie, MN 55344 USA  
TEL 800-733-7775 • 952-947-1200 • FAX 800-775-0002 • 952-947-1400  
[www.bairpaws.com](http://www.bairpaws.com)

Bair Hugger, Bair Paws, Arizant, Arizant Healthcare, bright ideas that work,  
and the Bair Paws and Arizant logos are trademarks of Arizant Healthcare Inc.,  
registered or pending in the U.S. Patent & Trademark Office  
and in other countries.

U.S. Patent 6,876,884; D485,338. Other patents pending.

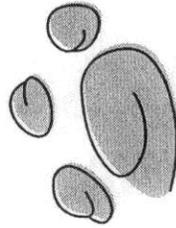
©2003-2005 Arizant Healthcare Inc. All rights reserved.  
200744D 04/05

# Bair Paws® Warming Gown



### Warming gown features:

- Velcro® strips provide quick access to the arms and chest.
- Side ties ensure full and secure coverage, even in the back.
- Dual air-channel insert and 2 hose ports enable comfort warming with a Bair Paws 800 series warming unit or clinical warming with a Bair Hugger® 500 or 700 series temperature management unit.
- Longer gown length provides added coverage.
- Thick, soft material means greater personal comfort.



**Bair Paws®**

**Patient Adjustable Warming System**  
by Bair Hugger® Therapy



**NOT STERILE**

### Caution

Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.

**Arizant  
Healthcare**  
bright ideas that work

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



Authorized Representative in the European Community  
(as defined in Article 14 of the Medical Device Directive: 93/42/EEC):  
Actamed Limited, Calder Island Way, Wakefield, WF2 7AW, United Kingdom  
TEL (44) 1924 200550 FAX (44) 1924 200518

Bair Paws, Arizant, bright ideas that work, Bair Hugger, and the Arizant and Bair Paws logos are trademarks of Arizant Healthcare Inc., registered or pending in the U.S. Patent & Trademark Office and in other countries.

Velcro is a registered trademark of Velcro Industries B.V.

Patents pending.

800065C 06/05

### Indications for Use

The Bair Paws® patient adjustable warming system provides forced-air warming when conditions exist that could cause patients to feel cold. The gown can be connected to a Bair Paws 800 series warming unit to provide comfort warming, such as in pre-op and post-op settings where the patient is able to adjust the temperature setting to their personal comfort level. During a surgical procedure, the gown can be connected to a Bair Hugger® 500 or 700 series temperature management unit. These units provide clinical warming, and temperatures are controlled and monitored by a clinician. The Bair Paws warming gown can also be used any time a gown is needed.

### Contraindications

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

### Warnings

1. Do not use this gown with any device other than a Bair Paws 800 series warming unit or Bair Hugger 500 or 700 series temperature management unit; thermal injury may result.
2. Do not use a forced-air warming device over transdermal medication. Increased drug delivery and patient injury or death may occur.
3. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions; thermal injury may result.
4. Do not provide warming therapy when an intra-aortic balloon pump is in use; thermal injury may occur if heat is applied to ischemic limbs.
5. Do not allow the gown to cover the patient's head or airway. Interference with ventilation and patient injury may occur.
6. Do not treat patients with the warming unit hose alone; thermal injury may result. Always attach the hose to Bair Paws gown before providing therapy.
7. Do not allow the patient to lie on the warming unit hose or allow the hose to contact the patient's skin during patient warming; thermal injury may result.
8. Do not connect the gown to a warming unit if the fabric has been cut; air channels could be damaged and thermal injury may result.
9. Do not continue therapy if the warming unit's warning light illuminates or an audible alarm sounds; thermal injury may result. Turn the warming unit OFF and contact qualified technical personnel.

### Precautions

1. Rolling, gathering, or bunching the air-channel insert of the gown can occlude airflow and prevent warming of the patient. Extend the insert to its full length when connected to a warming unit.
2. This gown is not sterile and is intended for single patient use only.
3. This product meets the Consumer Products Safety Commission's

flammable fabric regulation, 16 CFR 1610; however, always follow standard safety protocols when using high intensity heat sources.

4. During warming therapy using a Bair Hugger temperature management unit, monitor the patient's temperature and vital signs regularly according to institutional protocol. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.

### Instructions for Use

Instruct your patient to put the warming gown on so the opening is in the back and ties at the right side and at the neck. When tied, the gown should fit loosely enough that the air channels are not restricted.

### For comfort warming with a Bair Paws warming unit (800 series)

1. Connect the Bair Paws warming unit hose to the gown's lower hose port.
2. Connect the warming unit hose to the warming gown (Figure 1):
  - squeeze and hold the 2 buttons on the sides of the hose nozzle,
  - insert the nozzle into the open hose port in the warming gown,
  - release the buttons to lock the hose nozzle in place.

Figure 1

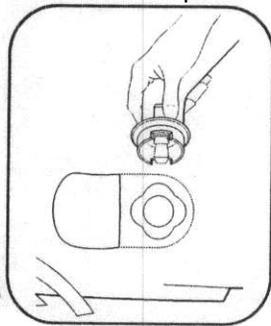


Figure 2

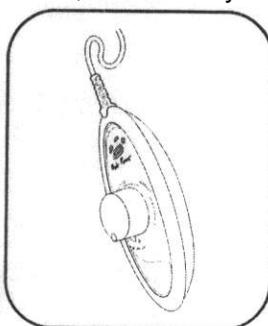
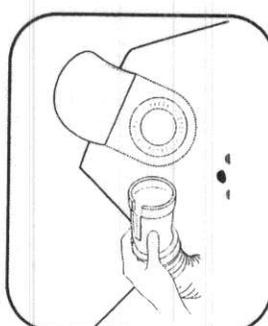


Figure 3



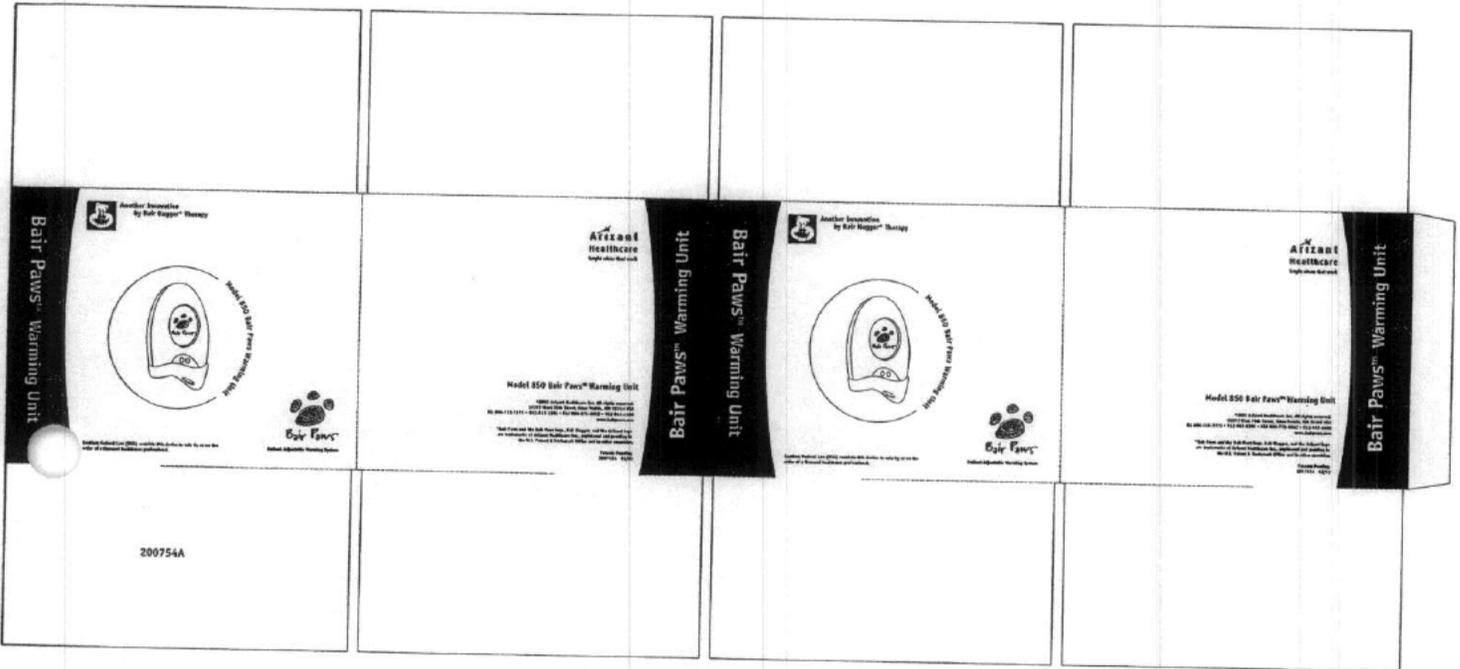
3. Turn the knob on the temperature controller clockwise to turn the warming unit on (Figure 2).
4. Allow the patient to adjust the temperature to a comfortable level. The temperature is adjusted by turning the knob on the temperature controller.
5. To disconnect the hose nozzle from the warming gown, press the 2 buttons on the sides of the nozzle and withdraw the nozzle from the hose port.

### For clinical warming with a Bair Hugger temperature management unit (500 or 700 series)

**WARNING:** Do not cut the gown; thermal injury may result if an air channel is cut.

1. Insert the end of the Bair Hugger unit hose in the gown's shoulder hose port (Figure 3).
2. Turn the Bair Hugger unit on and select the appropriate temperature setting.
3. Monitor the patient's temperature regularly according to institutional protocol and adjust the temperature setting of the Bair Hugger unit as required.

# Instructions For Use



NOTES:  
 • PRINT COLORS: PMS 2627C

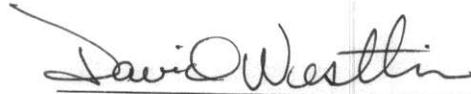
Arizant Healthcare		10200 WEST 20th STREET EDEN PRairie, MN 55344 TEL (952) 947-3200 FAX (952) 947-3400	
ACTIVITY	(b)(4)	DATE	
DESCRIPTION	(b)(6)	TIME	CARTON, SHIPPING, MODEL 850
QTY	1	SCALE	UNIT NO. 200745 (b)
SCALE		SHEET	2 of 2

### **Currently Marketed Device**

The predicate legally-marketed device is the Bair Hugger temperature management system, including forced-air warming units and disposable warming blankets (K053645, K041686, K021473, K001149, K960167, K903360, and 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.

## Substantial Equivalence

The Bair Paws<sup>®</sup> Model 850 Warming System is substantially equivalent in safety and effectiveness to the predicate device, the Bair Hugger Temperature Management System (K053645).

### **Bair Paws Temperature Management System and Bair Hugger Temperature Management System**

#### **Summary of Similarities**

- Both systems have the same intended use.
- The Bair Paws Temperature Management System has similar mechanical characteristics; it uses the same type of heater and blower unit.
- Both warming units can be set on table, shelf or other hard surface, attached to an I.V. pole, or bed rail.
- Both can be used in intensive care unit, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients.
- Both have visual alarms.
- The Bair Paws Temperature Management System is for comfort and clinical warming, while the Bair Hugger Temperature Management System provides comfort warming and clinical warming.

#### **Summary of Differences**

- The Bair Paws Temperature Management System unit provides less airflow.
- The primary temperature sensor for the Bair Paws Temperature Management System is set to a maximum of  $40\pm 3^{\circ}\text{C}$ . The primary sensor for the Bair Hugger Temperature Management System is set to a maximum of  $43\pm 3^{\circ}\text{C}$ .
- The Bair Paws warming unit can not be used in the operating room.

## Substantial Equivalence Matrix

### Bair Paws Temperature Management System and Bair Hugger Temperature Management System

	<b>Bair Paws Temperature Management System</b>	<b>Bair Hugger Temperature Management System</b>
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.	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.
Areas for device use	Pre-op, intensive care unit, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients.	Pre-op, intensive care unit, operating room, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients.
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Patient position	Stationary	Stationary
Device positioning	Can be set on table, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail; or attached to the wall using a wall mount bracket.	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail.
Dimensions	11" x 2.5" x 7.7"	Max: 13" x 14" x 11"
Weight	6.3 lbs	Max: 16 lbs
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length, washable, 1.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter
Recommended filter change	Every 6 months	Every 500 hours of use or every 6 months
Temperature sensor	Shuts the heater off if damaged	Shuts the heater off if damaged
Temperature range (maximum at nozzle)	40°C±3°C	43°C±3°C
Heat generated	750 BTU/h (avg.)	1644 BTU/h (avg.)
Electrical requirements	20 Amps fused circuit	20 Amps fused circuit
Power cable	15' hospital grade	15' hospital grade
Airflow at comparable operating pressure	Up to 10 cfm (4.7 L/s)	Up to 48 cfm (22.6 L/s)

**Bair Paws Model 850 Warming Unit and  
Bair Hugger Model 505 and 750 Warming Unit**

	<b>Bair Paws Model 850 Warming Unit</b>	<b>Bair Hugger Model 505 Warming Unit</b>	<b>Bair Hugger Model 750 Warming Unit</b>
Power consumption at 20°C ambient temperature	Peak: 290W Average: 150W	Peak: 1000W Average: 450W	Peak: 1650W Average: 800W
Diagnostics	Over-temperature and temperature output testing and calibration can be performed by biomedical technician.	Over-temperature and temperature output testing and calibration can be performed by biomedical technician.	Over-temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician. Upon power-up and mode change, the software performs self-test functions.
Over-temperature detection	Independent thermistor. Thermal cutoff shuts the heater off at preset high temperature of 53°C or lower, at the end of the hose.	Independent bulb and capillary. Thermal cutoff shuts the heater off at a preset high temperature of 53±3°C, at the end of the hose.	Independent electronic circuit; thermal cut-off shuts the heater off at preset high temperature of 53±3°C at the end of the hose, back-up over-temperature detection at hose inlet.
Over current protection	Fused input line	Dual input fused lines	Dual input fused lines
Alarm system	Over-temperature: color indicator light illuminates, heater and blower shut down.	Over-temperature: red light illuminates with audible alarm, heater and blower shut down.	Over-temperature: red light flashes, alarm sounds, heater and blower shut down, operating indicator lights turn off, control panel becomes unresponsive.
Control circuitry	Analog	Analog	Microprocessor-based
Blankets/ Gowns Used	All Bair Paws gowns	All Bair Hugger blankets and Bair Paws gowns	All Bair Hugger blankets and Bair Paws gowns
Motor	23 watts, AC	Fractional horsepower, single-phase, AC	40 watt, DC
Heater	285W resistive	850W resistive	1600W resistive
Leakage current	Meets IEC 601-1 and UL 2601-1 requirements	Meets EN 60601-1 and UL 2601-1 requirements	Meets EN 60601-1 and UL 2601-1 requirements

### **Design Control Activities**

The FDA Quality System Regulation § 820.30 Design Control states “Each manufacturer of any class III or class II device shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

The Bair Paws System was subjected to Arizant Healthcare Inc. design control system requirements, which meets the following requirements of section § 820.30:

- § 820.30(b) Design and Development Planning
- § 820.30(c) Design Input
- § 820.30(d) Design Output
- § 820.30(e) Design Review
- § 820.30(f) Design Verification
- § 820.30(g) Design Validation
- § 820.30 (h) Design Transfer
- §820.30(i) Design Changes
- § 820.30 (j) Design History File

Risk analysis and safety activities are described in the Summary of Safety and Effectiveness.

## Summary of Safety and Effectiveness

Arizant Healthcare Inc. has assessed safety and effectiveness through its risk management system, which is based upon the ISO 14971 standard – Application of risk management to medical devices. Through the risk management system, the safety and effectiveness of the device is assessed through development, production and post-production.

As part of the design control process, multiple hazard/risk analyses were performed. The purpose was to identify inherent risks of the system, and eliminate the risk, if possible. The risk/benefit to the patient is analyzed when determining possible adverse effects of the device and deciding what constitutes an acceptable risk. In instances where the risk could not be eliminated, the objective was to reduce the risk to the furthest extent possible, provide protection appropriate to the risk, and/or provide to the user information relative to the risks that remained. All remaining risks are reviewed and approved by executive management before product release. These documented risk/hazard analysis reports are on file at Arizant Healthcare Inc.

The Bair Paws system has been subjected to performance and safety testing within Arizant Healthcare Inc. and was tested by independent third party testing laboratories to ensure the device performs as intended and is effective in treating the conditions identified as intended uses.

The Bair Paws Model 850 meets the electrical safety requirements of IEC 60601-1, IEC 60601-1-2, UL 2601, and CAN/CSA-C22.2 No.601.1-M90. Compliance with these medical electrical general requirements reduce the risk of flammability/explosion, fluid leaks into or out of the device, and electrical, mechanical or thermal hazards. Complete test results are on file at Arizant Healthcare Inc.

The complete line of Bair Paws gowns have been extensively tested with the Model 505, 750 and 850 warming units for compatibility and to ensure its safety and effectiveness when used according to the instructions for use. When used in the combinations described in the instructions for use, the system is compatible with every component of the system with which it interacts and does not adversely affect the performance of the system or individual components of the system. Test reports verifying the device's compatibility, performance and safety are on file with Arizant Healthcare Inc.

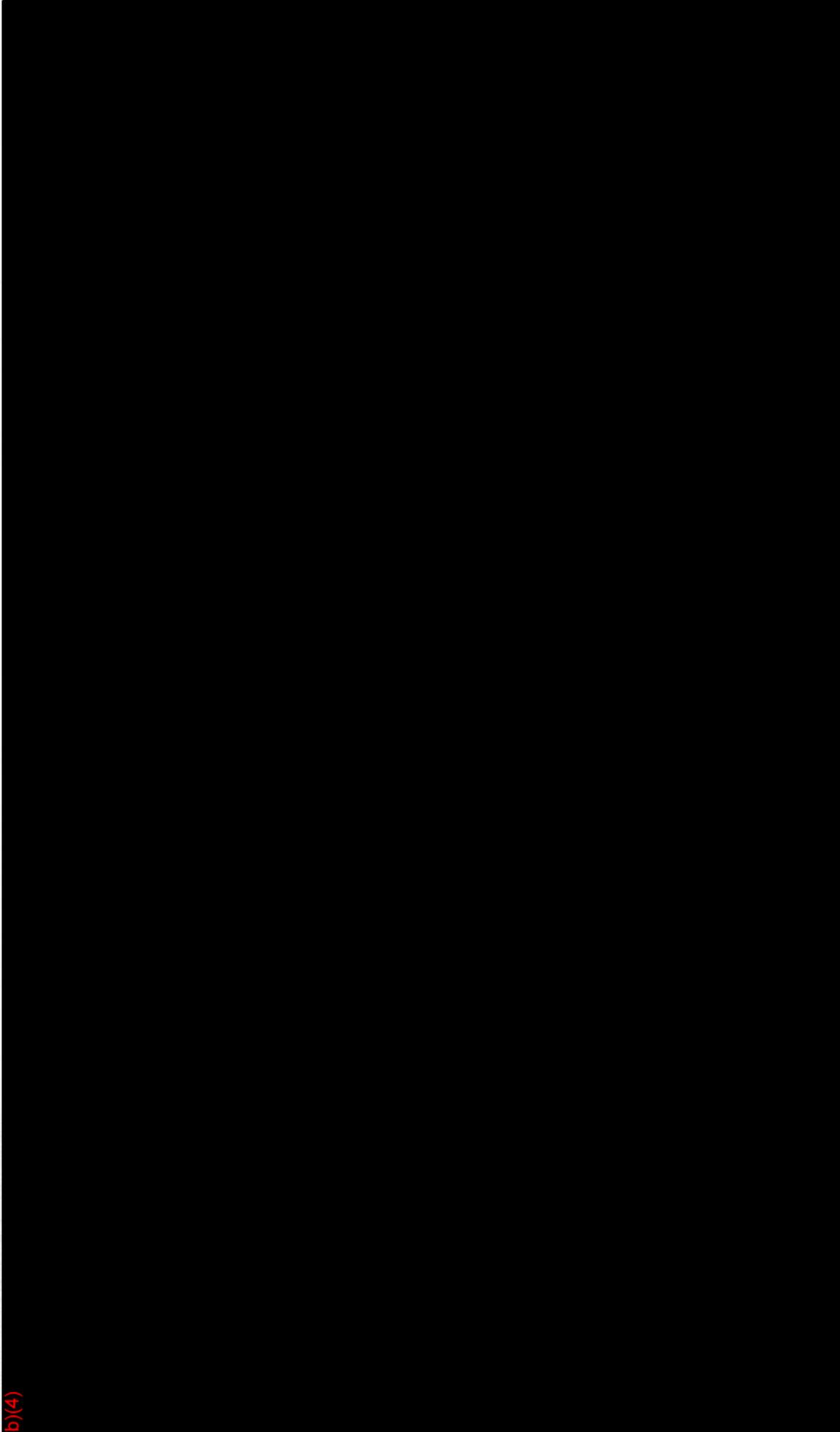
Forced-air warming, as demonstrated by over 15 years of successful commercial use, is an inherently safe system when used according to the instructions for use. The only known hazards of the Bair Hugger and Bair Paws systems are product misuse. These hazards are identified in the operator's manuals for each device as well as the corresponding instructions for use of the gowns.

**Hazard Analysis Worksheet**

**Product/Process Analyzed: OR Bair Paws**

**Date of Analysis: 11/11/2004**

(b)(4)







**Final Hazard Analysis Worksheet**

(b)(4) Hazard Analysis



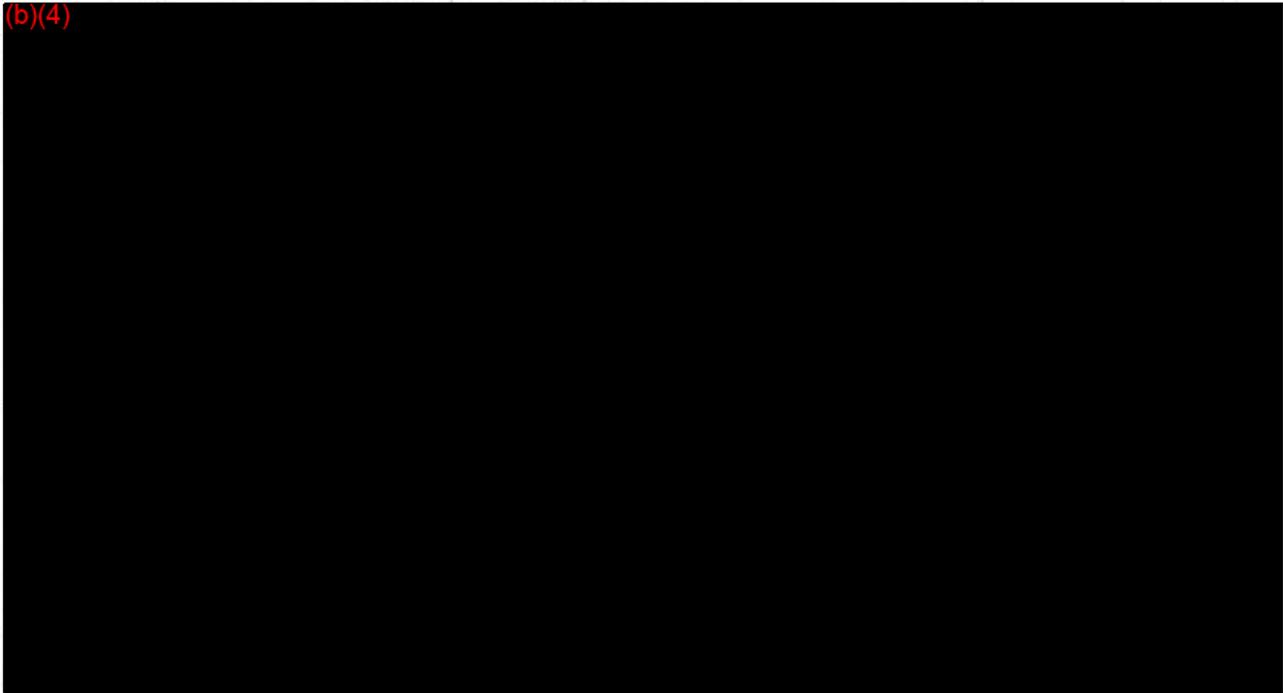




April 20, 2006

**Follow-up to Hazard Analysis performed on Model 850 Warming Unit**

(b)(4)



(b)(6)



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Project Manager Research and Development

(b)(6)



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Regulatory Affairs Manufacturing Engineer

(b)(6)

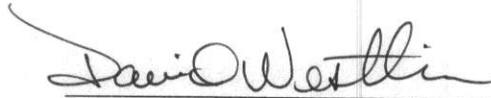


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(b)(6) ng Other

### Declaration of Conformity

1. Verification and validation activities were performed by Arizant Healthcare Inc. in accordance 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 Inc. 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 70<sup>th</sup> Street  
Eden Prairie, MN 55344  
Telephone: 952-947-1200

**Contact person:**

David Westlin  
Senior Director, Regulatory Affairs and Quality Assurance

**Summary date:**

March 31, 2006

**Device name/trade name:**

Bair Paws<sup>®</sup> Temperature Management System

**Common/usual name:**

Hyper/Hypothermia System

**Classification name:**

System, Thermal, Regulating, DWJ

**Equivalent marketed device:**

Bair Hugger<sup>®</sup> Temperature Management System (K053645)

**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 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.

**Comparison of the Technological Characteristics of the  
New Device and Predicate Devices**

The Bair Paws® Temperature Management System is substantially equivalent to the Bair Hugger® Temperature Management System (K053645).

**Comparison of Technological Features**

<b>Features</b>	<b>Bair Paws Temperature Management System</b>	<b>Bair Hugger Temperature Management System</b>
Method of operation	The Bair Paws warming unit has a blower motor and a heating element. The warming unit delivers warmed air through a hose that is connected to a port in a Bair Paws gown.	The Bair Hugger warming unit has a blower motor and a heating element. The warming unit delivers warmed air through a hose that is connected to a port in a Bair Hugger blanket or Bair Paws gown.
Alarms	Over-temperature: color indicator light illuminates, heater and blower shut down.	Over-temperature: red light illuminates with audible alarm, heater and blower shut down.
Areas for device use	Pre-op, intensive care unit, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients.	Pre-op, intensive care unit, operating room, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients.
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Patient Position	Stationary	Stationary
Device positioning	Can be set on table, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail; or attached to the wall using a wall mount bracket.	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail.
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length, washable, 1.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Catherine Wentz  
Subject: 510(k) Number K060865  
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: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

DWT / Class II

Review: M. G. Hillebrand CS PB 4/21/2006  
(Branch Chief) (Branch Code) (Date)

Final Review: Dennis R. Lochner for BD2 4/22/06  
(Division Director) (Date)

Records processed under FOIA Request # 2016-0012, Date 08-30-2016  
**SPECIAL 510(k) Device Modification**  
**ODE Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K060865

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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: **Bair Hugger Temperature Management System K053645.**
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED (p. 27)** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as 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 (p. 27)**.  
**This change was for a new blanket and blower model to include a warming blanket fashioned into a robe. Other design modifications to accommodate this additional model include 1) a reduced diameter hose (from 2.5" to 1.5"), 2) a reduction in the delivered air volume and pressure to accommodate the volume and pressure characteristics of the warming gown, 3) cannot be used in the operating room as the Bair Hugger Units can, and 4) the primary temperature sensor for the Bair Paws Temperature Management System is set at 40+3°C down from 43+3°C for the Bair Hugger Temperature Management System.** The warming pad is placed in a pocket in the FRONT of the gown only. This is so that the patient can not sit on an active warming surface. The Bair Paws Robe insert is indicated for use with the Bair Hugger 850 warming unit, as well as the 505 and 750 Model Warming Units. The sponsor states that all compatibility testing has been performed and demonstrates safe use with these units.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and operating specifications. The only differences are noted above, and are **1) a reduced diameter hose (from 2.5" to 1.5"), 2) a reduction in the delivered air volume and pressure to accommodate the volume and pressure characteristics of the warming gown, 3) cannot be used in the operating room as the Bair Hugger Units can, and 4) the primary temperature sensor for the Bair Paws Temperature Management System is set at 40+3°C down from 43+3°C for the Bair Hugger Temperature Management System.**
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
  - 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
  - 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.**



8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	x		If NO = Request Data
11. Data Demonstrate Equivalence?	x		Final Decision: <b>Substantial Equivalence</b>

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:

"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."

2. Device Description: The Bair Paws Temperature Management System is part of the Bair Hugger Family Temperature Management Systems, and consists of a warming blanket, warming unit, and connecting hose. The Bair Paws System differs from other Bair Hugger systems in that this system is intended to be fashioned into a robe (heating is in the front only) for greater mobility for the patient.

**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: **Compatibility testing with current blower/heater units needs to be performed. The sponsor stated that this testing was performed and demonstrates compatibility with warming units 850, 750, and 505 (all Bair Hugger Units).**
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: Compatibility testing with current blower/heater units needs to be performed. The sponsor stated that this testing was performed and demonstrates compatibility with warming units 850, 750, and 505 (all Bair Hugger Units).
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

## *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: \_\_\_\_\_

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

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

\*\* - Required for Class III devices, only.

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

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

	Present	Inadequate or Missing
Name and 510(k) number of the 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.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

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

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

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

	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.

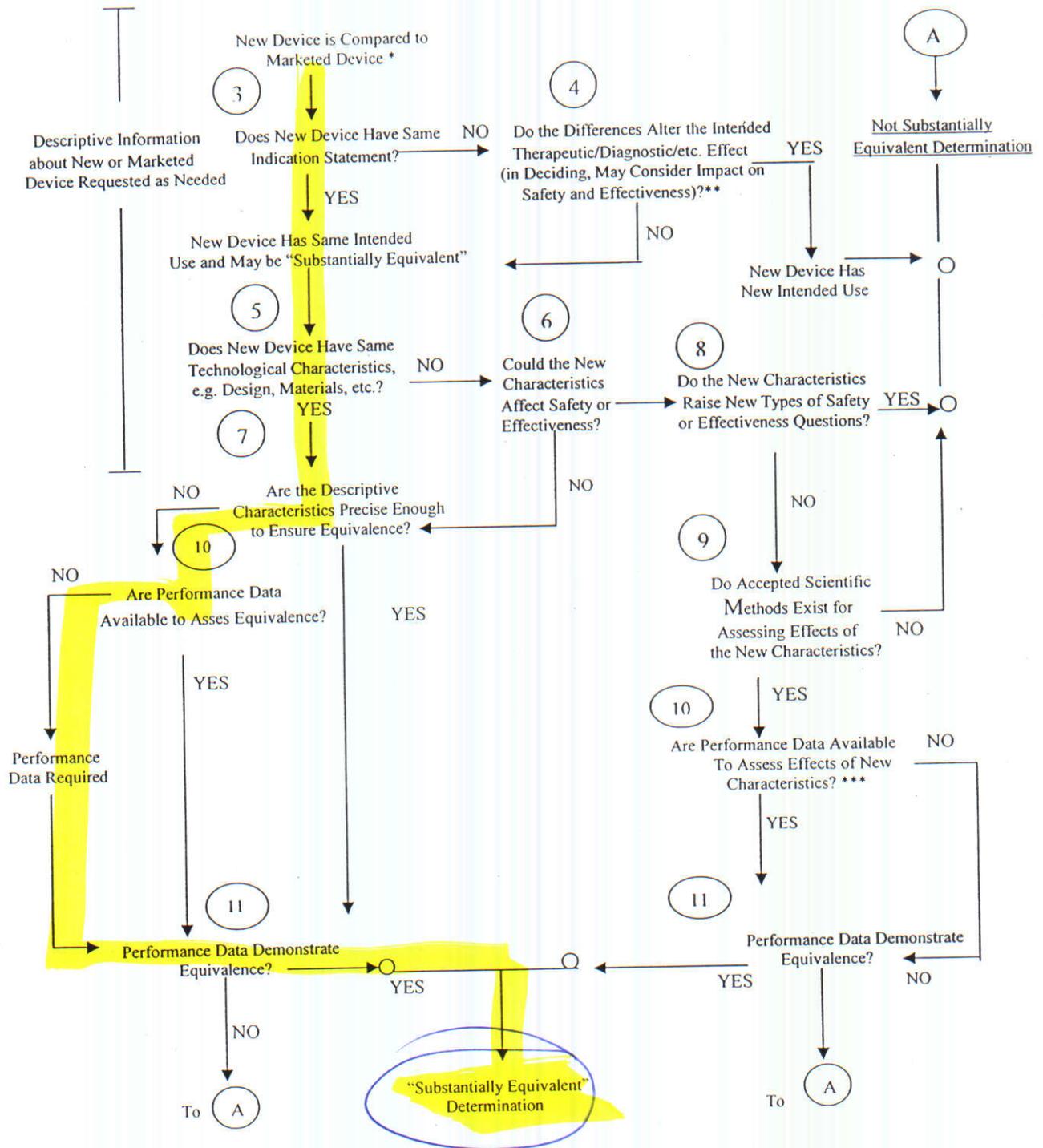
1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does 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.