K033021

NOV 12 2003

p 1/2

Section 14

Premarket Notification [510(k)] Summary

1. **Submitted by:**

Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076

Contact Person: Richard V. Wolfe
Manager, Regulatory Affairs

Telephone: (770) 587-8208
Facsimile: (770) 587-7761
e-mail: richard.wolfe@kcc.com

Date Prepared: September 25, 2003

2. **Device Name**

Trade / Proprietary Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads
Common / Usual name: Hypo / Hyperthermia System
Classification Name: System, Thermal Regulating (per 21CFR 870.5900)

3. **Predicate Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is substantially equivalent to the MediVance Inc. ARTIC SUN™ Temperature Management System – Model 100 Control Unit and Energy Transfer Pads cleared under 510(k) # K002577.

4. **Intended Use of the Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Clinical applications of this device include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required. This would include, but not be limited to, medical, surgical, febrile, accidental hypothermia, or heat stroke patients.

5. **Description of the Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is a device used to monitor and control patient temperature. It consists of single-use heat transfer pads, which are adhered to areas of the patient's skin, and a control module that circulates temperature-controlled water. The control module is connected to the pads by flexible tubing. A commercially available probe connected to the control module senses the patient's core temperature. The system can control the patient's core temperature by altering the temperature of the circulating water.

Section 14

Premarket Notification [510(k)] Summary *(Continued)*

6. Summary of the technological characteristics of the device compared to the predicate device

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is identical in design to MediVance's Artic Sun™ Temperature Management System which obtained FDA clearance on October 26, 2000 under 510(k) number K002577 Kimberly-Clark acquired all product rights related to the patient warming business from MediVance, Inc. on May 27, 2003

7. Testing

Testing of the Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads [under MediVance's 510(k) # K002577], included: biocompatibility testing in accordance with ISO 10993-1 and / or USP, electrical safety testing in accordance with IEC601 and functional safety and performance testing.

8. Conclusions

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is the exact same medical device as MediVance's Artic Sun™ Temperature Management System which obtained FDA clearance on October 26, 2000. Therefore, no new safety or effectiveness issues exist.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

Kimberly-Clark Corporation
c/o Mr. Richard V. Wolfe
1400 Holcomb Bridge Road
Roswell, GA 30076

Re: K033021
Kimberly-Clark Patient Warming System – Model 100
Control Unit and Energy Transfer Pads
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: September 25, 2003
Received: September 26, 2003

Dear Mr. Wolfe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set 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 (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Section 15

Indications For Use

Applicant: Kimberly-Clark Corporation

510(k) Number: K033021

Device Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads

Indications for Use: The KIMBERLY-CLARK* Patient Warming System is intended for monitoring and controlling patient temperature. The indications for use of the device include any condition where patient temperature control within the range covering mild hypothermia to normothermia is required.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033021

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

Kimberly-Clark Corporation
c/o Mr. Richard V. Wolfe
1400 Holcomb Bridge Road
Roswell, GA 30076

Re: K033021
Kimberly-Clark Patient Warming System – Model 100
Control Unit and Energy Transfer Pads
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: September 25, 2003
Received: September 26, 2003

Dear Mr. Wolfe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set 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 (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Section 15

Indications For Use

Applicant: Kimberly-Clark Corporation

510(k) Number: K033021

Device Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads

Indications for Use: The KIMBERLY-CLARK* Patient Warming System is intended for monitoring and controlling patient temperature. The indications for use of the device include any condition where patient temperature control within the range covering mild hypothermia to normothermia is required.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033021

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 26, 2003

KIMBERLY-CLARK CORP.
1400 HOLCOMB BRIDGE RD.
ROSWELL, GA 30076
ATTN: RICHARD V. WOLFE

510(k) Number: K033021
Received: 26-SEP-2003
Product: KIMBERLY-CLARK
PATIENT WARMING
SYSTEM - MODEL 100
CONTROL UNIT AND

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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

Sincerely yours,

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

K033021

ORIGINAL

September 25, 2003

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

FDA/CDRH/OCE/DID
2003 SEP 26 A 8:30

Re: Traditional Premarket Notification 510(k):

Kimberly-Clark Patient Warming System -
Model 100 Control Unit and Energy Transfer Pads

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, Kimberly Clark Corporation is submitting a Premarket Notification of our intent to market a Kimberly-Clark Patient Warming System - Model 100 Control Unit and associated Energy Transfer Pads.

The Kimberly-Clark Patient Warming System is indicated for monitoring and controlling patient temperature. This device is identical in design to MediVance's Artic Sun™ Temperature Management System which obtained FDA clearance on October 26, 2000 under 510(k) number K002577. Kimberly-Clark acquired all product rights related to the patient warming business from MediVance, Inc. on May 27, 2003. This includes the Artic Sun™ Model 100 Control Unit and related Artic Sun™ Energy Transfer Pads.

This Premarket Notification contains written authorization from MediVance, Inc. that allows Kimberly-Clark to reference all information contained in their cleared 510(k), therefore specific information required for Kimberly-Clark's Premarket Notification is provided by reference in lieu of inclusion. We respectfully request that all material marked "Confidential" not be provided with any Freedom of Information requests regarding this Premarket Notification.

Kimberly-Clark Corporation in accordance with the "Medical Device User Fee and Modernization Act of 2002" has submitted payment in the amount of $ (b) (4) to the FDA for processing this Premarket Notification. A copy of the "Medical Device User Fee Cover Sheet (Form FDA 3601)" can be found in ***Section 1*** of the Premarket Notification.

It is expected that you will find this submission complete and well organized. If there are any questions or clarification required during the review process, please contact us.

Sincerely,

(b) (6)

Richard V. Wolfe
Manager, Regulatory Affairs
Kimberly-Clark Health Care
Phone: (770) 587-8208
Fax: (770) 587-7761
E-Mail: richard.wolfe@kcc.com

CV II

SK 19

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Table of Contents

Premarket Notification [510(k)]

Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)

Write the Payment Identification Number on your check.

See Instructions Before Completing This Cover Sheet

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: http://www.fda.gov/oc/mdufma.The following three actions must be taken to properly submit your premarket application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. *(Note: In no case should payment be submitted with the premarket application.)* Also remember that the Payment Identification Number must be written on the check. If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to: US Bank, 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.)
3. Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration at either the CBER or CDRH Document Mail Center.

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

KIMBERLY-CLARK CORPORATION
1400 HOLCOMB BRIDGE ROAD
ROSWELL, GA 30076-2199
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) (4)

2. CONTACT NAME
RICHARD WOLFE

2.1 E-MAIL ADDRESS
richard.wolfe@kcc.com

2.2 TELEPHONE NUMBER (Include area code)
770-587-8208

2.3 FACSIMILE (FAX) NUMBER (Include area code)
770-587-7761

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

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologic License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☑ NO, I am not a small business

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

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologic application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$ (b) (4)

(b)(4), Payment Invoice and Check

Section 2

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR §807.87(j)]

Kimberly-Clark Patient Warming System -
Model 100 Control Unit and Energy Transfer Pads

I certify that, in my capacity as Manager, Regulatory Affairs for Kimberly-Clark Corporation, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6)

Richard V. Wolfe
Manager, Regulatory Affairs

September 25, 2003
Date

Premarket Notification 510(k) Number

Section 3

Background Information on Kimberly-Clark's purchase of MediVance"s Artic Sun™ Temperature Management System – Model 100 Control Unit and Energy Transfer Pads

On May 27, 2003 Kimberly-Clark Corporation acquired all products related to the patient warming business from MediVance, Inc., Louisville, CO. A joint announcement from Kimberly-Clark Health Care and MediVance Inc., regarding this purchase was issued on June 2, 2003 ***(see page 3-2)***.

The Artic Sun Temperature Management System – Model 100 Control Unit and Energy Transfer Pads at the present time (b) (4) by (b) (4) (b) (4) at (b) (4) under the following registrations.

Company Name / Address:	(b) (4)
Establishment Registration #:	
510(k) #:	K002577
Device Classification:	"Thermal regulating system" (21CFR§870.5900)
Product Code:	DWJ
Device Listing #:	B093414

CONFIDENTIAL

MediVance has retained ownership of their 510(k) number K002577 as that premarket notification supports their 510(k) number K010338 for their patient cooling product line.

Kimberly-Clark Health Care is submitting this premarket notification using information provided by MediVance to establish our own cleared 510(k) for our patient warming business. In this premarket notification the only changes from MediVance's cleared 510(k) number K002577 will be with respect to the following:

- **Product Labeling:** Change in company name and product name as follows:
  - **From:** MediVance Artic Sun™ Temperature Management System – Model 100 Control Unit and Energy Transfer Pads
  - **To:** Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads
- **Manufacturing location:** Change in manufacturing location as follows:

  Model 100 Control Unit – The manufacture of the Model 100 Control Unit (b) (4)

  Energy Transfer Pads– The manufacture of the Energy Transfer Pads (b) (4) (b) (4)

Kimberly-Clark

June 2, 2003

Dear Arctic Sun Customer:

We are pleased to inform you that effective May 27, 2003, Kimberly-Clark Health Care has acquired all products related to the warming business from Medivance Inc. This includes the ARCTIC SUN® Model 100 and related ARCTIC SUN Energy Transfer Pads™ currently in use in your operating room.

Medivance sales representatives and clinical specialists will become Kimberly-Clark employees and continue to provide you with uninterrupted service. For the time being, you will continue to place all purchase orders with Medivance, and all catalog numbers and product information will remain unchanged. Within the next four weeks Kimberly-Clark will provide detailed information on a new process for submitting orders directly with Kimberly-Clark.

Medivance is pleased that a company with Kimberly-Clark's presence and reputation for quality, support and service has purchased this business and can continue to provide you with the same high quality of service provided by Medivance. Since 2001, the Arctic Sun 100 has been used in nearly 10,000 procedures. This acquisition further emphasizes the success of the ARCTIC SUN and the commitment to this business for the long term. This represents an exciting step in Kimberly-Clark's ongoing plans to offer an expanding array of customer-preferred products to the health care industry. The ARCTIC SUN patient warming product line fits well with Kimberly-Clark's philosophy of utilizing patented technology to deliver superior clinical performance.

Medivance will continue to operate and market the ARCTIC SUN Model 2000 to induce therapeutic hypothermia in critical care applications. The ARCTIC SUN 2000 and related ARCTIC SUN Energy Transfer Pads are used solely for human cooling purposes and are not interchangeable with the warming ARCTIC SUN 100. The ARCTIC SUN 2000 and related Energy Transfer Pads should continue to be ordered directly through Medivance Customer Service.

We believe this change in ownership will be positive for you and your staff. If you have any questions about any of these changes, your sales representative or clinical specialist will be in touch with you shortly.

Sincerely,

(b) (6)

Joanne Bauer
President
Kimberly-Clark Health Care

(b) (6)

Robert Kline
President and CEO
Medivance Inc.

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Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, Georgia 30076 (770) 587-8000

Section 4

Basic 510(k) Elements

Device Name

Classification Name: System, Thermal Regulating

Common / Usual Name: Hypo / Hyperthermia System

Trade / Proprietary Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads

Establishment Registration Number & Device Listing Number

- **Kimberly-Clark Patient Warming System** – Kimberly-Clark Corporation is the owner of the Kimberly-Clark Patient Warming System and manages / oversees all activities from the following location:

  Company Name / Address: Kimberly-Clark Corporation
  1400 Holcomb Bridge Road
  Roswell, GA 30076

  Establishment Registration #: 1033422 (Specification Developer)

  The manufacture of the Model 100 Control Unit and the manufacture of the Energy Transfer Pads is conducted at the following facilities:

- **Model 100 Control Unit** - (b) (4) Kimberly Clark Patient Warming System – Model 100 Control Unit. Applicable information is as follows:

  Company Name / Address: (b) (4)

  Establishment Registration #:

  Device Listing #:

- **Energy Transfer Pads** – (b) (4) Energy Transfer Pads (b) (4) facility:

  Company Name / Address: (b) (4)

  Establishment Registration #:

  Device Listing #:

Section 4

Basic 510(k) Elements (Continued)

Device Classification

The Kimberly Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads falls under the following device classification:

CFR Section:	21CFR§870.5900 "Thermal regulating system"
Identification:	A thermal regulating system is an external system consisting of a device that is placed in contact with the patient, and a temperature controller for the device.
Classification:	Class II (performance standards)
Product Code:	DWJ

Performance Standards

No mandatory performance standards applicable to thermal regulating systems have been established under Section 514 of the Federal Food Drug and Cosmetic Act, as amended. In addition, no specific guidance documents exist for thermal regulating systems as defined in 21CFR§870.5900. MediVance followed, where applicable, the following standards:

- **Electrical Safety**: IEC-60601-1, "Medical Electrical Equipment – Part 1: General Requirements for Safety".
- **Biological Testing**: ANSI/AAMI/ISO 10993-1, "Biological Evaluation of Medical Devices" was used to select the appropriate biocompatibility testing for the short term (< 30 days) surface contacting materials used in the Energy Transfer Pads.
- **Software**: FDA's May 29, 1998 " Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

Right to Reference MediVance's 510(k) # K002577

Based upon e-mail correspondence with the FDA's PreMarket Notification [510(k)] Staff and CDRH Office of Device Evaluation that confirms the acceptability of referencing MediVance's 510(k) # K002577 in lieu of providing that same information in this Premarket Notification ***(see pages 4-3 and 4-4),*** Kimberly-Clark has elected to do so. When a reference is made to Medivance's 510(k) in support of this Premarket Notification it is specifically called out by the section and page number(s) from MediVance's 510(k).

Medivance, Inc. has provided a formal written authorization allowing the FDA to reference all information contained in their cleared 510(k) # K002577 in support of Kimberly-Clark's Premarket Notification for our Patient Warming System, Model 100 Control Unit and Energy transfer Pads. A copy of this authorization letter is included ***(see page 4-5)***.

Wolfe, Richard

From: Garcia, Diane [DMP@CDRH.FDA.GOV]
Sent: Tuesday, September 16, 2003 11:51 AM
To: Shulman, Marjorie G.
Cc: Wentz, Catherine P.; 'richard.wolfe@kcc.com'
Subject: RE: Request for Advice on 510(k) filing

Hi,
If this 510k is a transfer of ownership and you have a copy of the previous 510k, you could simply make a copy and submit it with your new 510k. Though, I don't think that's absolutely necessary. As long as the transfer information is clear in the 510k you plan to submit, I don't see any potential problems with referencing the data.

Diane Garcia
Public Health Advisor
CDRH/ODE/POS
301-594-1190 ext. 157
HFZ-404

-----Original Message-----
From: Shulman, Marjorie G.
Sent: Monday, September 15, 2003 5:03 PM
To: Garcia, Diane
Subject: FW: Request for Advice on 510(k) filing

Hi Diane,

Did you get a change to get back with this person? Thanks.

Marjorie Shulman
Premarket Notification (510(k)) Staff
(301) 594-1190 x 144

-----Original Message-----
From: Wolfe, Richard [mailto:Richard.Wolfe@kcc.com]
Sent: Friday, September 12, 2003 11:10 AM
To: 'Wentz, Catherine P.'
Cc: Shulman, Marjorie G.
Subject: RE: Request for Advice on 510(k) filing

Dear Ms. Wentz:

Thank you for forwarding this request for advice to Ms. Shulman. I am currently preparing the 510(k) with a submission planned prior to October 1, 2004, when new user fees take effect.

Best regards,
Dick Wolfe
Regulatory Affairs
Kimberly-Clark Health Care
(770) 587-8208

E mail: richard.wolfe@kcc.com
-----Original Message-----
From: Wentz, Catherine P. [mailto:CXW@CDRH.FDA.GOV]
Sent: Thursday, September 11, 2003 11:05 AM
To: Shulman, Marjorie G.
Cc: 'Wolfe, Richard'
Subject: FW: Request for Advice on 510(k) filing

Sorry, I forgot to include Mr. Wolfe's e-mail. Please copy him on your response.

Thank you!

Catherine

-----Original Message-----
From: Wolfe, Richard [mailto:Richard.Wolfe@kcc.com]
Sent: Thursday, September 11, 2003 8:22 AM
To: 'cxw@cdrh.fda.gov'
Cc: '(b) (6)
Subject: Request for Advice on 510(k) filing

CONFIDENTIAL

Dear Ms. Wentz:

(b) (6), MediVance's Manager of Regulatory Affairs and Quality Assurance recommended that I contact you regarding a 510(k) filing question. I am the Manager, Regulatory Affairs at Kimberly-Clark Health Care in Roswell, GA. On May 27, 2003 Kimberly-Clark purchased all rights to MediVance's patient warming business, which included their ARTIC SUN(tm) Model 100 Control Unit and Energy Transfer Pads, a Class 2 medical device that was cleared for marketing under 510(k) # K002577. MediVance has retained ownership of this 510(k) as it was referenced by and supports their 510(k) K010338 for another product for their patient cooling business.

Kimberly-Clark has decided to submit their own 510(k) for the ARTIC SUN(tm) Model 100 Control Unit and Energy Transfer Pads using all of the information contained in MediVance's cleared 510(k). MediVance is willing to provide a letter giving Kimberly-Clark permission to reference all of the supportive information in their 510(k). The only changes that Kimberly-Clark will be making are as follows:

Product Name: The product name in all labeling will be changed to a Kimberly-Clark brand name.

Manufacturing Location: The Model 100 Control Unit (b) (4)
(b) (4)
facility. The manufacture of the Energy Transfer Pads (b) (4)
(b) (4)

My question is does Kimberly-Clark need to re-submit all of the MediVance supportive information in our 510(k) or can we make reference to MediVance's 510(k) for that information? I would appreciate it if you could recommend a date and time that I could call you to discuss this subject, or feel free to respond to my question by e-mail. I will appreciate your guidance on this issue.

Best regards,
Dick Wolfe
Regulatory Affairs
Kimberly-Clark Health Care
(770) 587-8208
E mail: richard.wolfe@kcc.com

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Medivance
INCORPORATED

500 S. Arthur Avenue, Suite 100
Louisville, Colorado 80027

Tel: 303 926 1917
Fax: 303 926 1924
800#: 877 267 2314

www.medivance.com

September 22, 2003

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

Re: **Authorization to Reference 510(k) # K002577**

Dear Sir/Madam:

Medivance, Inc. authorizes Kimberly-Clark Corporation to reference any and all information included in the 510(k) premarket notification for the Medivance Arctic Sun Model 100 and Energy Transfer Pads (K002577), for use in support of the premarket notification for the Kimberly-Clark Patient Warming System.

Sincerely,

(b) (6)

Manager, Regulatory Affairs and Quality Assurance

cc: Richard Wolfe, KCC

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Section 5

Labeling

The following 'Draft" labeling is applicable to the Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads:

- **Model 100 Control Unit** – Control Unit labeling consists of the following major items.
  - **Operator's Manual** *(Attachment 5A)*
  - **Usage Guide** *(Attachment 5B)*
  - **Label on Control Unit** *(Attachment 5C)*

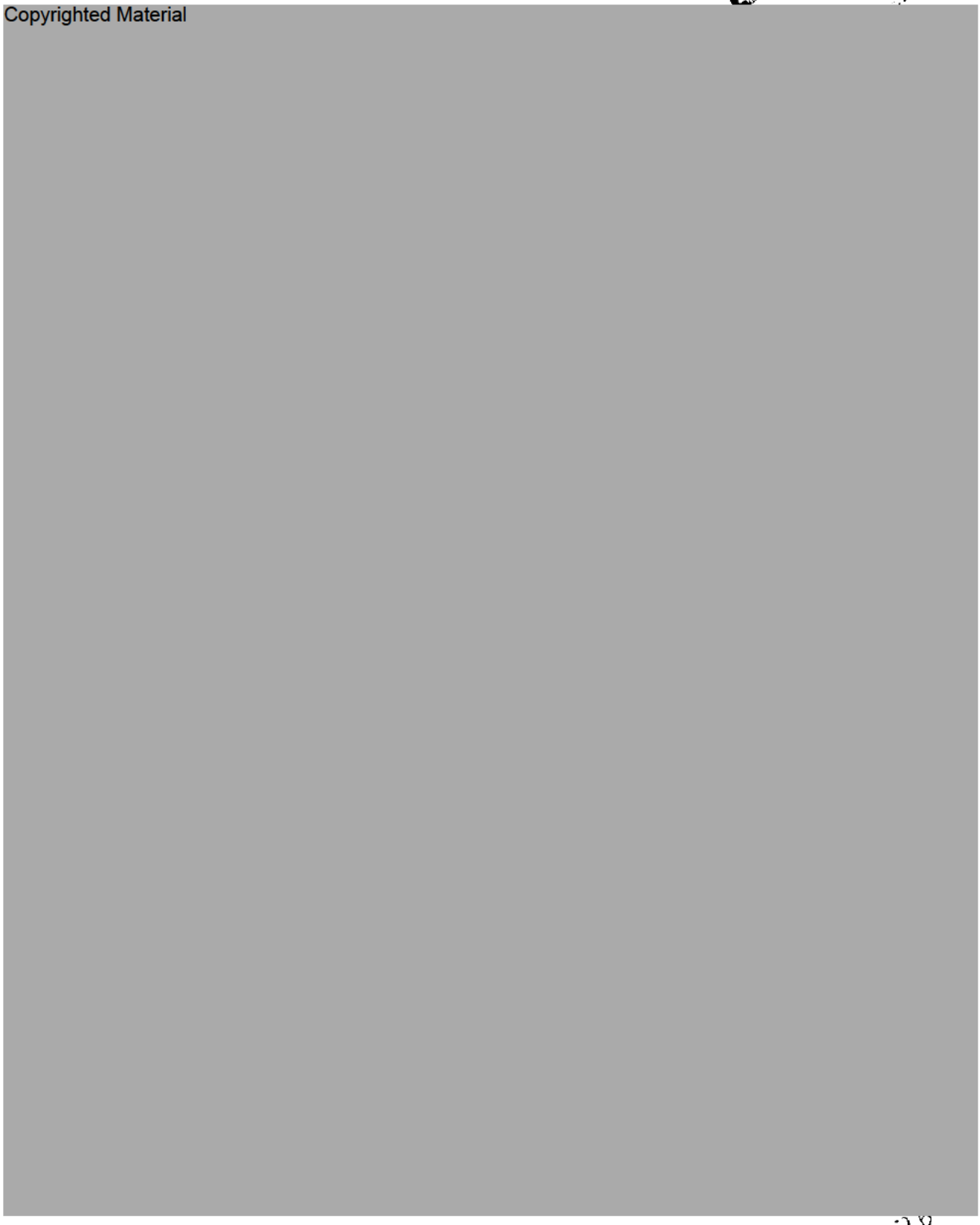
  The Operator's Manual and Quick Reference Guide depict the screen printed product name that appears on the Control Unit as well as the labeling of all functional displays and commands.

- **Energy Transfer Pads** – Energy Transfer Pads are provided in several configurations (e.g. split torso [small, medium, large]; universal pad [small, large]; thigh pad [small. large]; etc.). Labeling for the Energy Transfer Pads consist of an outer label that identifies the specific Energy Transfer Pad, and a Universal Insert used with all pads which provides Directions for use.
  - **Energy Transfer Pad Outer Label** – Split Torso / Medium configuration used as an example. *(Attachment 5D)*
  - **Indications / Instructions for Use** – Applicable to all Energy Transfer Pads *(Attachment 5E)*

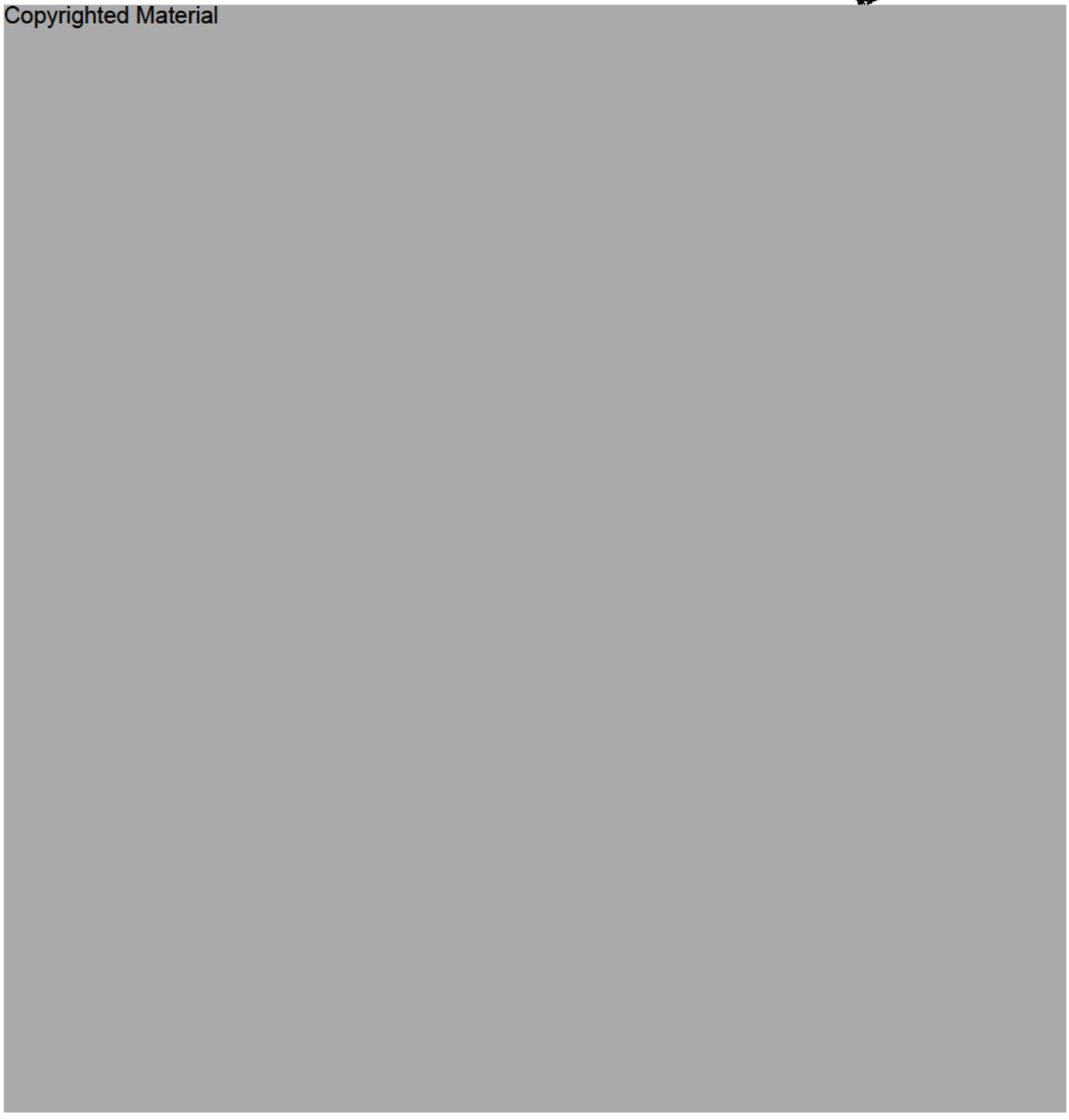
Operator's Manual

Protection. For life. Kimberly-Clark

KIMBERLY-CLARK* Patient Warming System

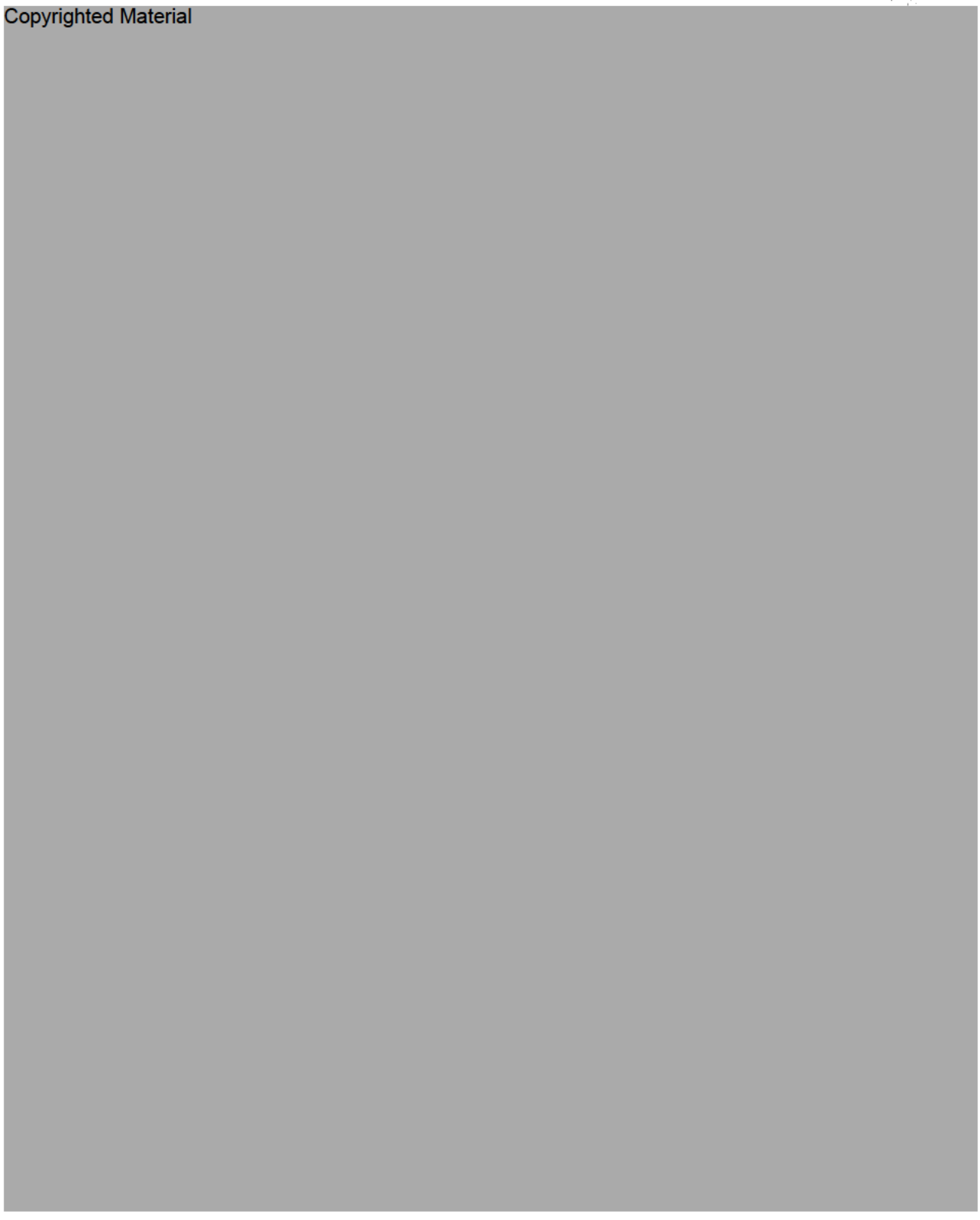


Precautions



Symbols and Standards

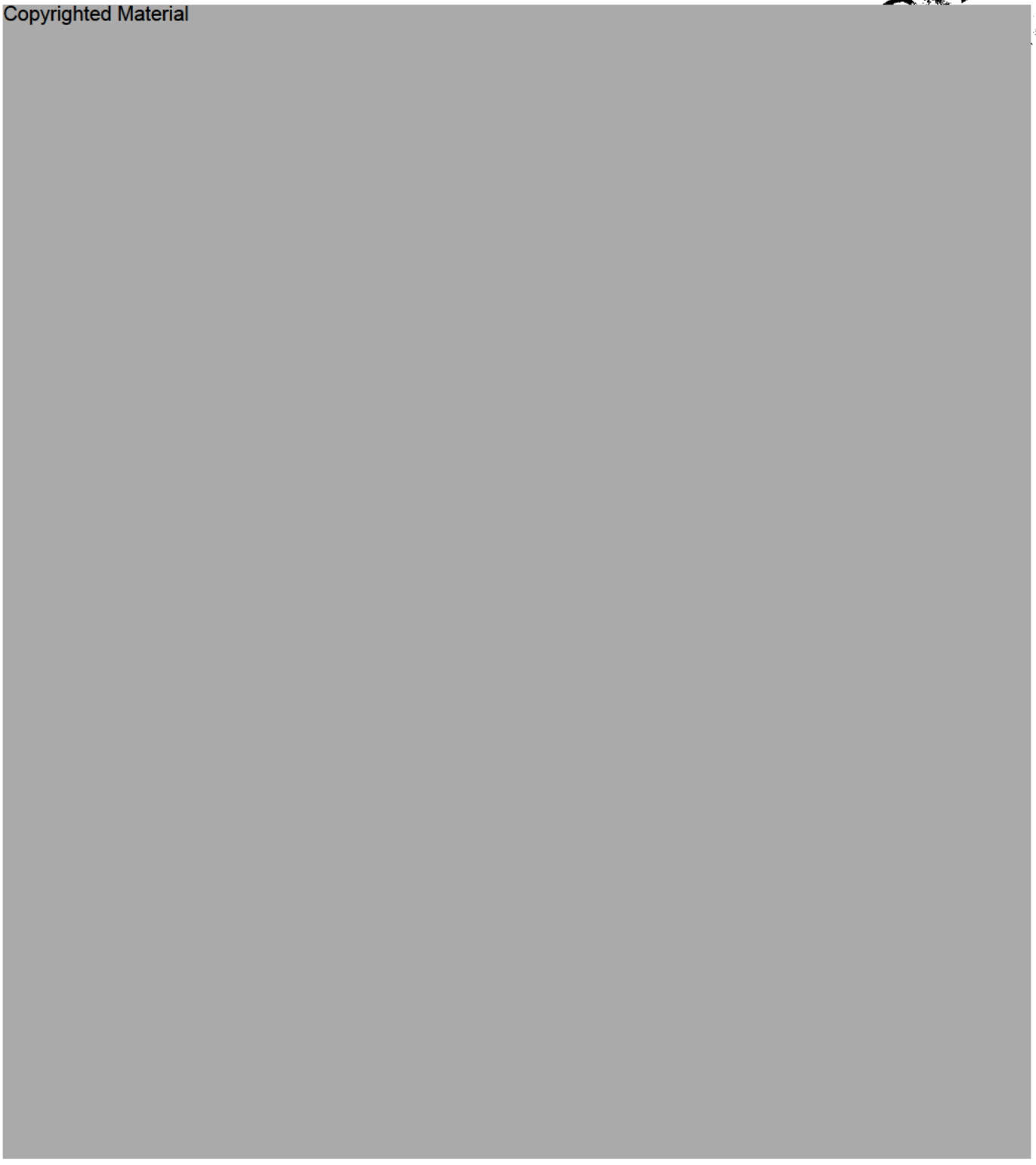
1.0. SYSTEM OVERVIEW



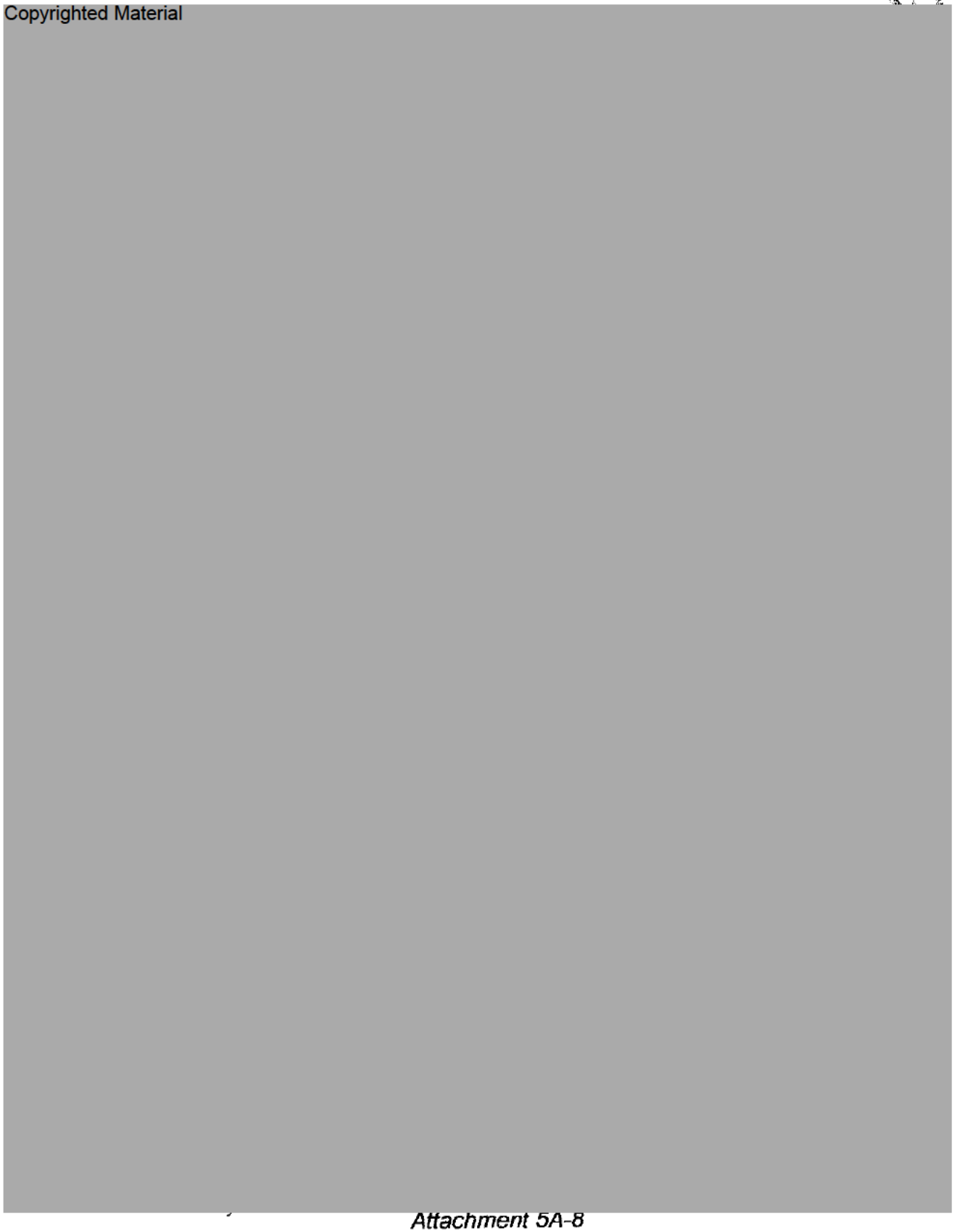
Attachment 5A-5

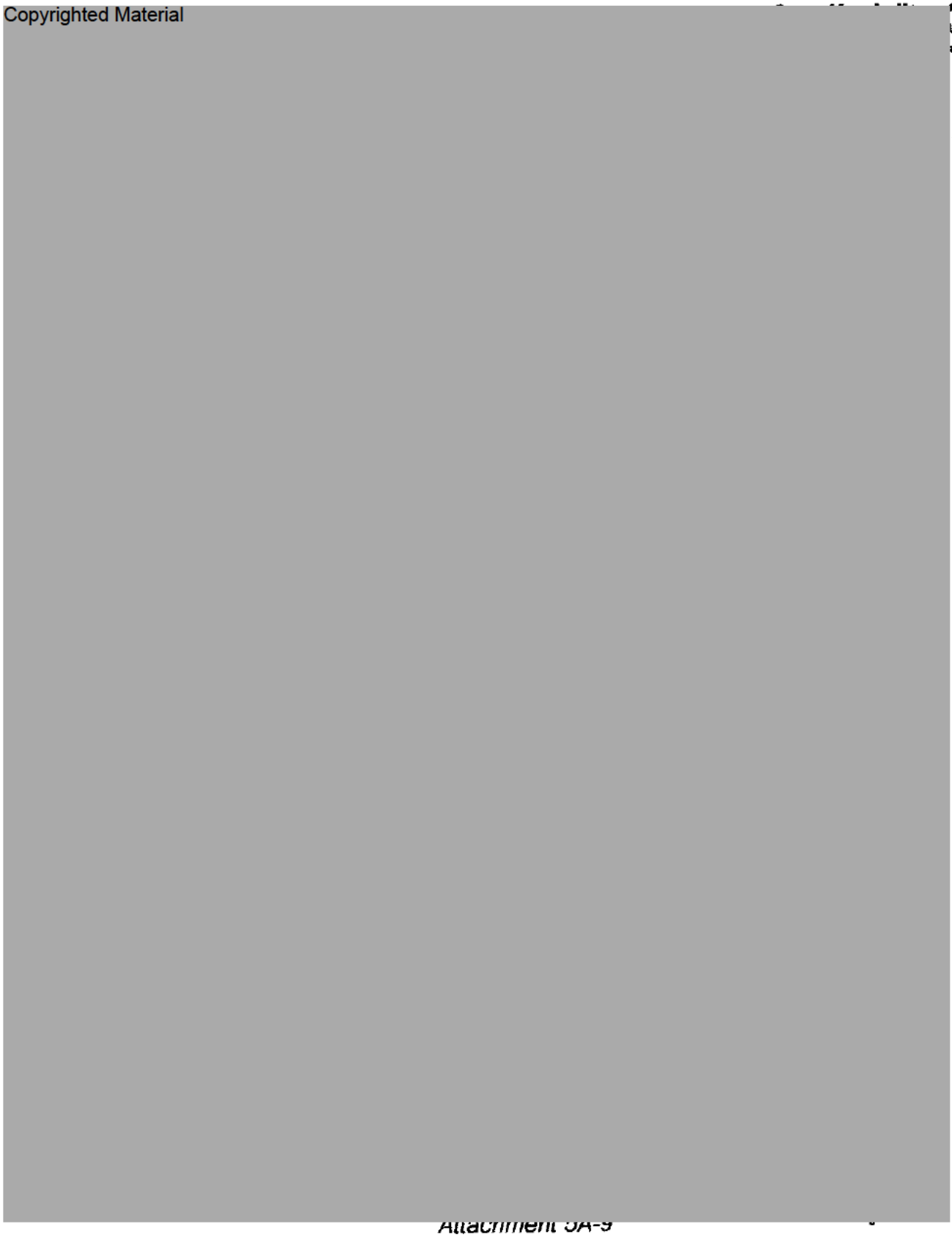
2.0. USING THE CONTROL UNIT

Kimberly-Clark* Patient Warming System Control Unit



Attachment 5A-7

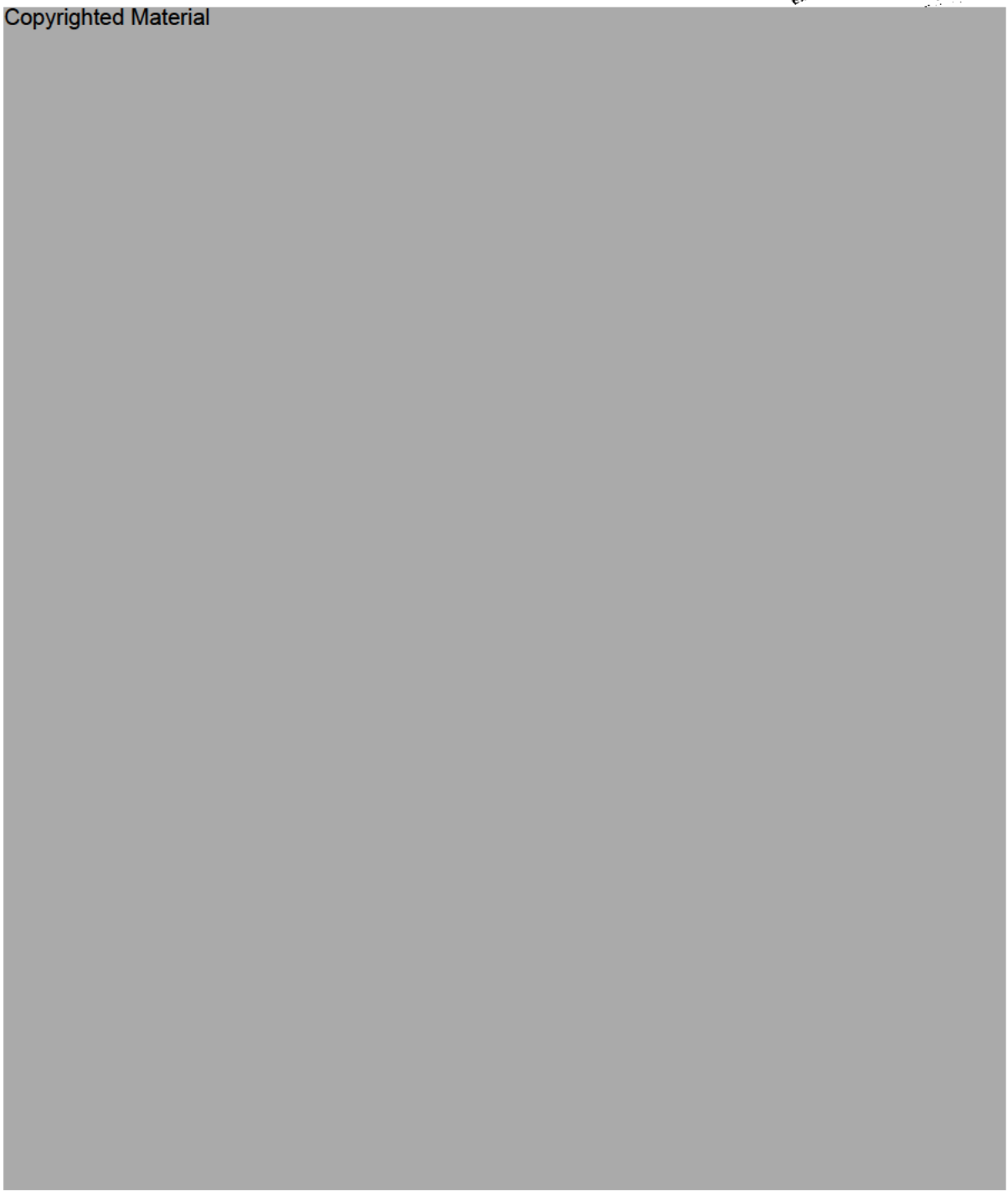


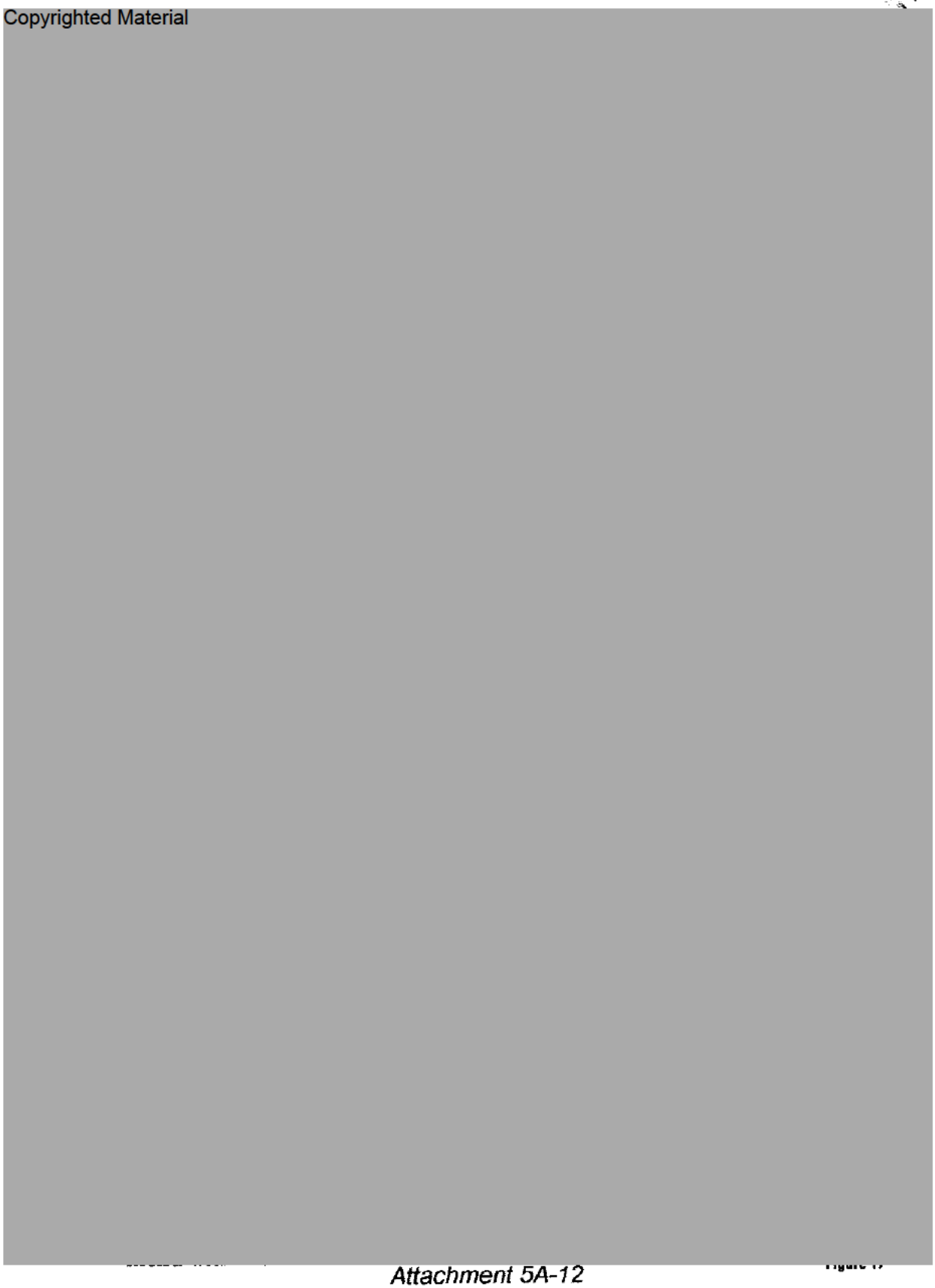


Copyrighted Material

3.0. GETTING STARTED:

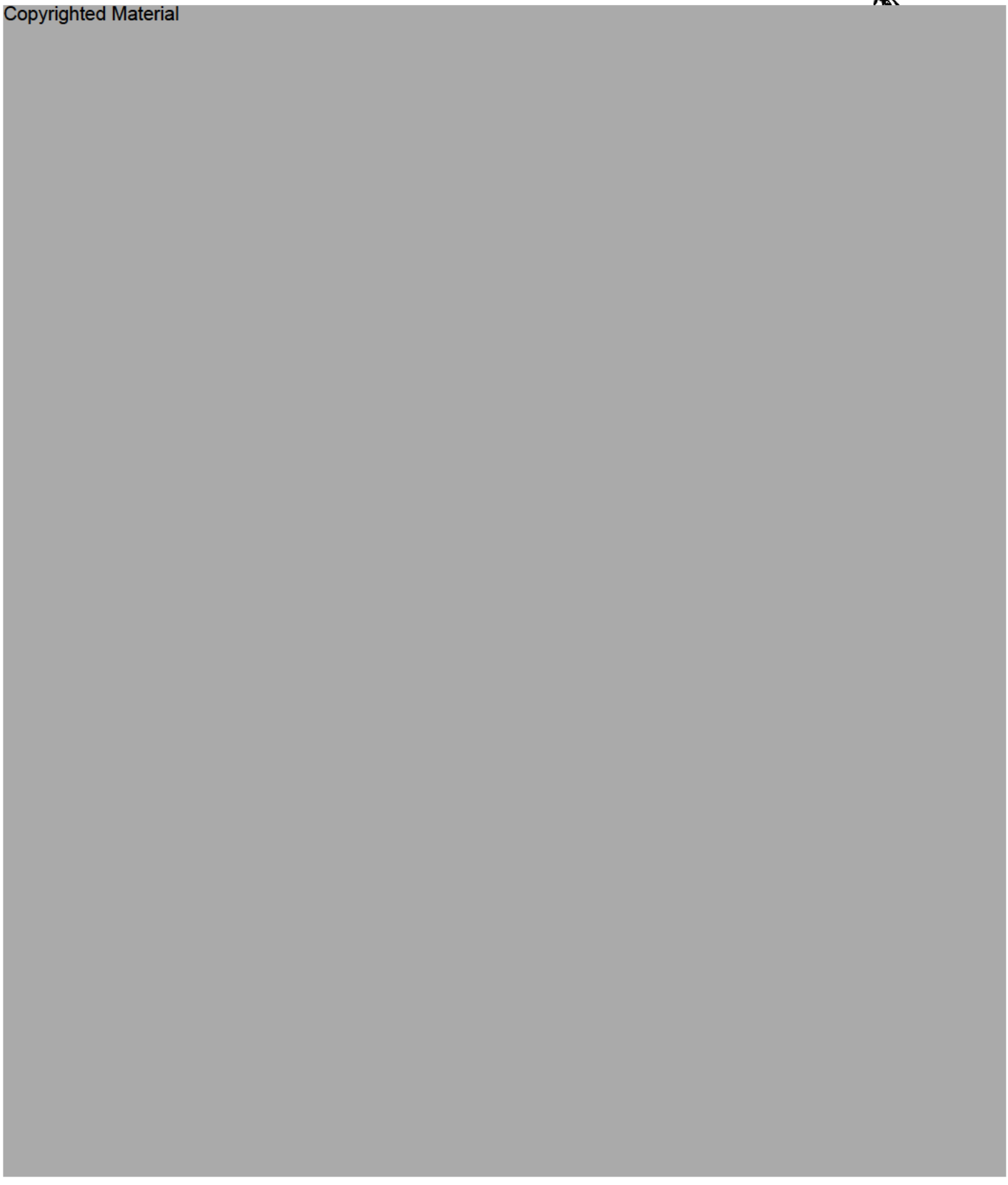
Copyrighted Material

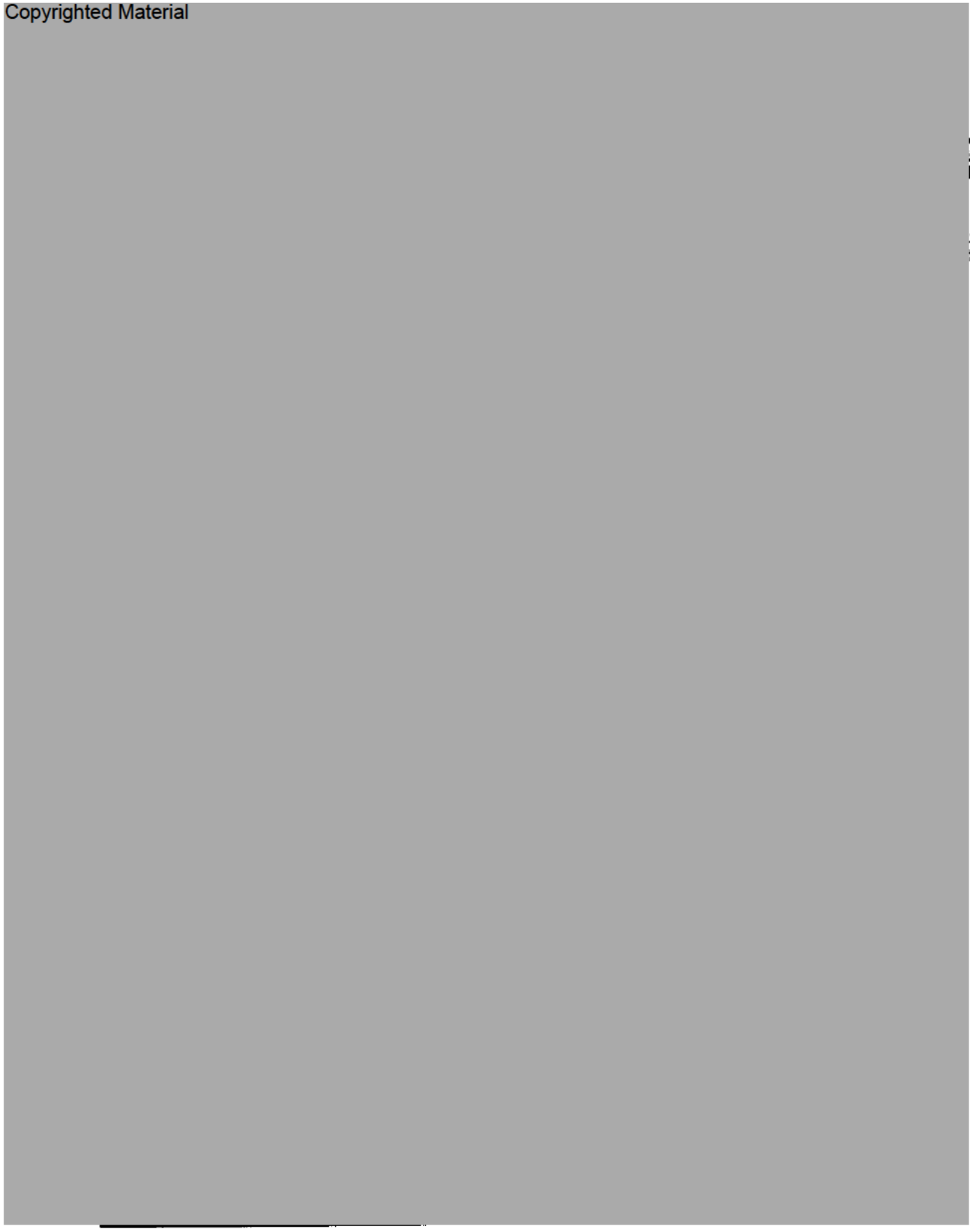




Attachment 5A-12

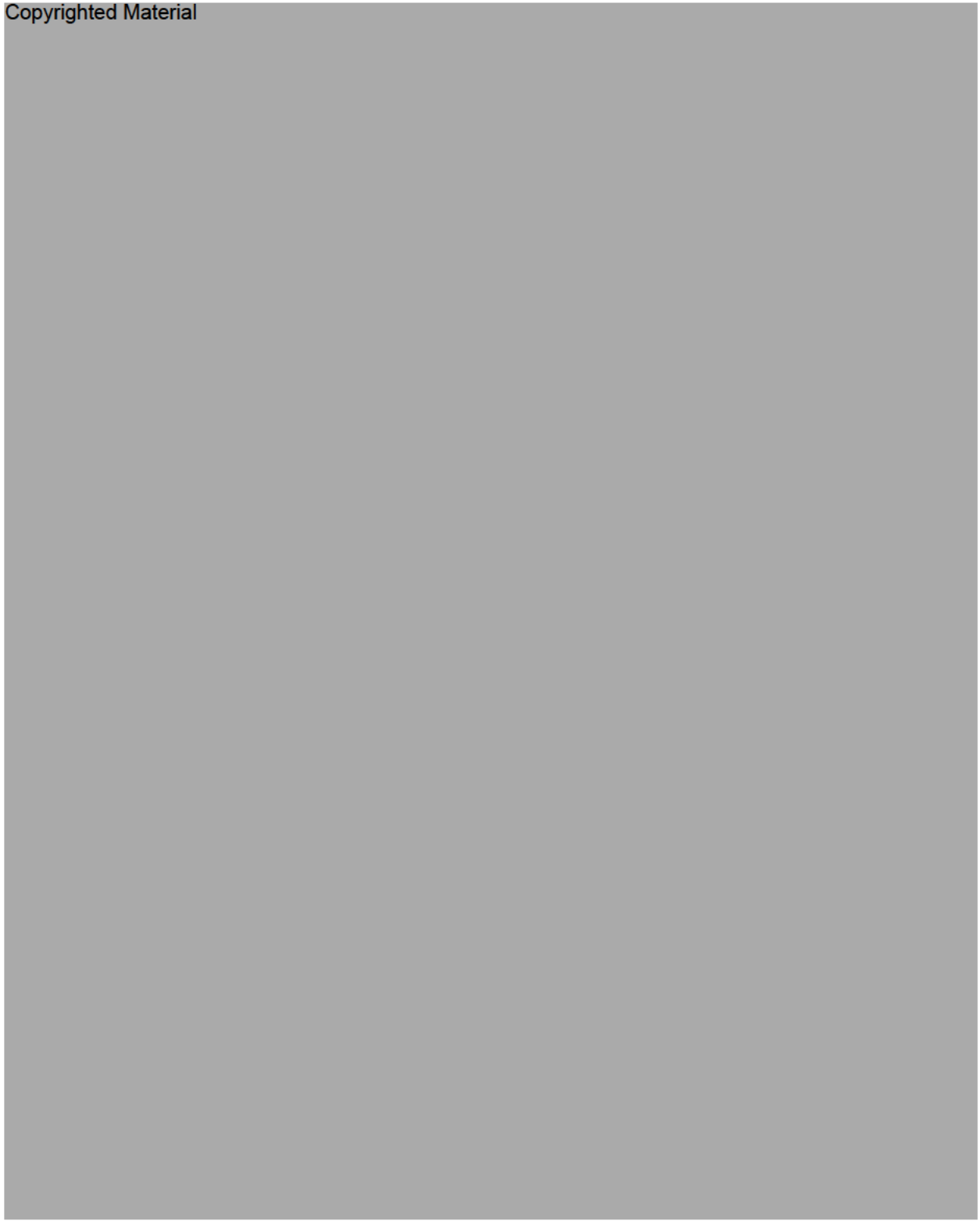
4. 0. TREATING THE PATIENT



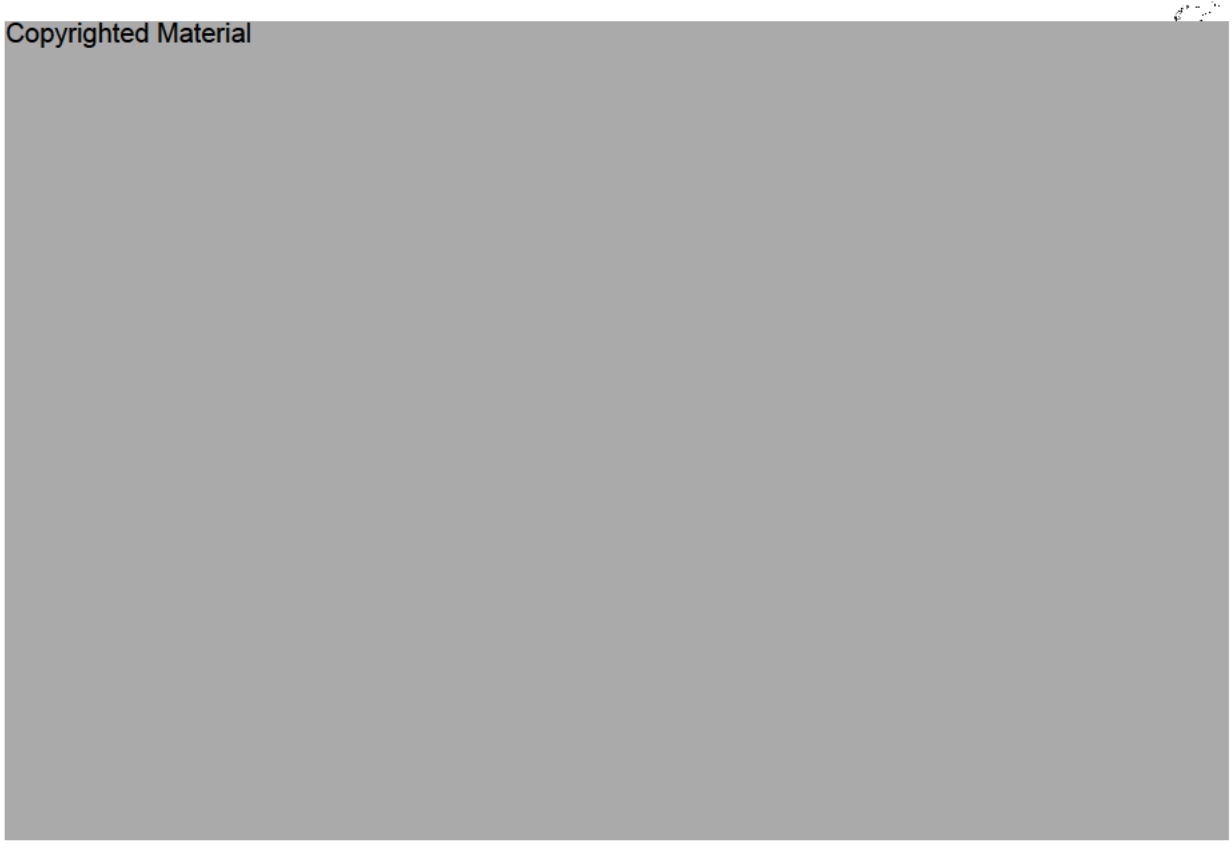


Attachment 5A-15

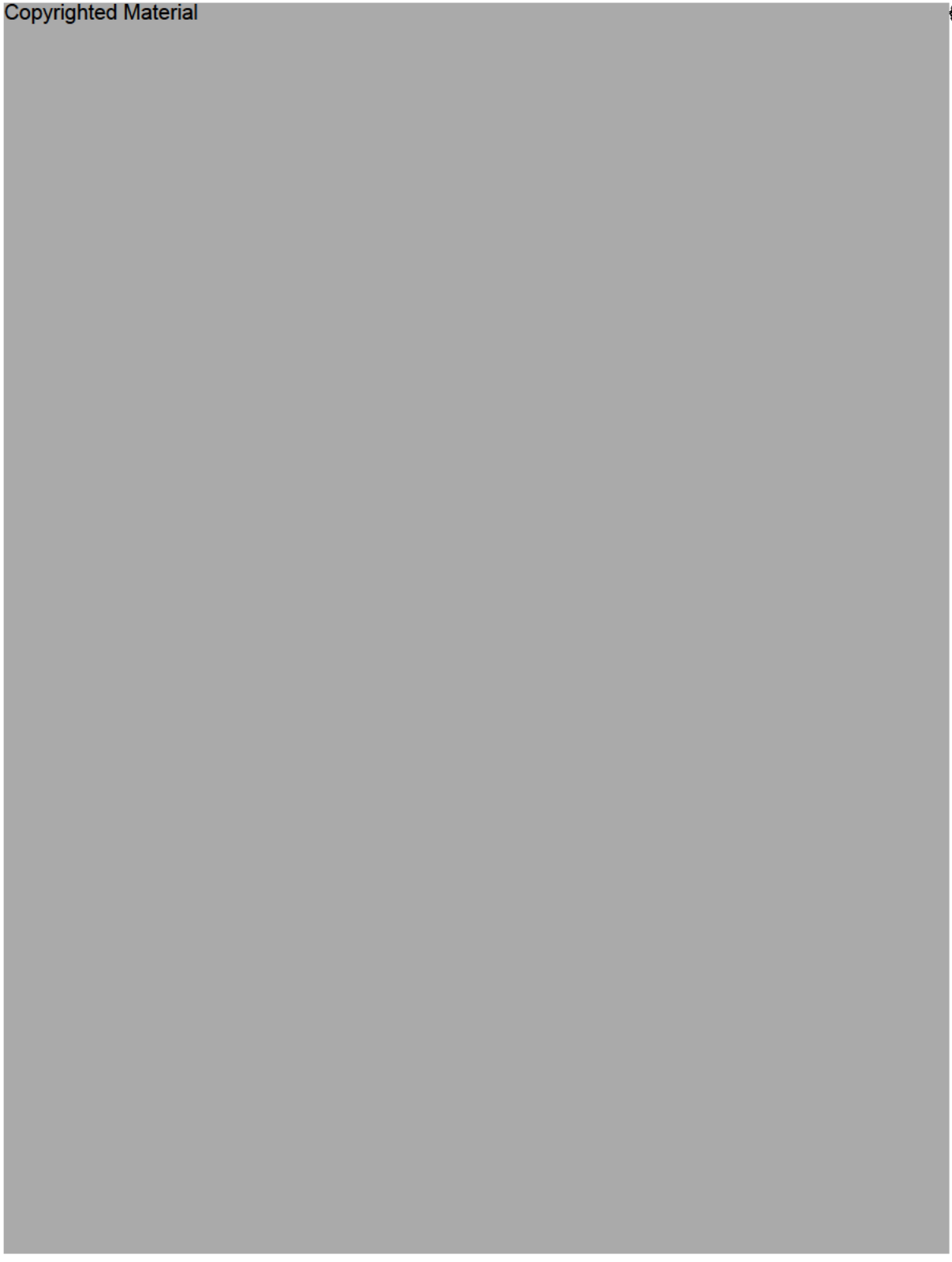
5.0. SPECIAL FEATURES:



6.0. ALARMS AND ALERTS

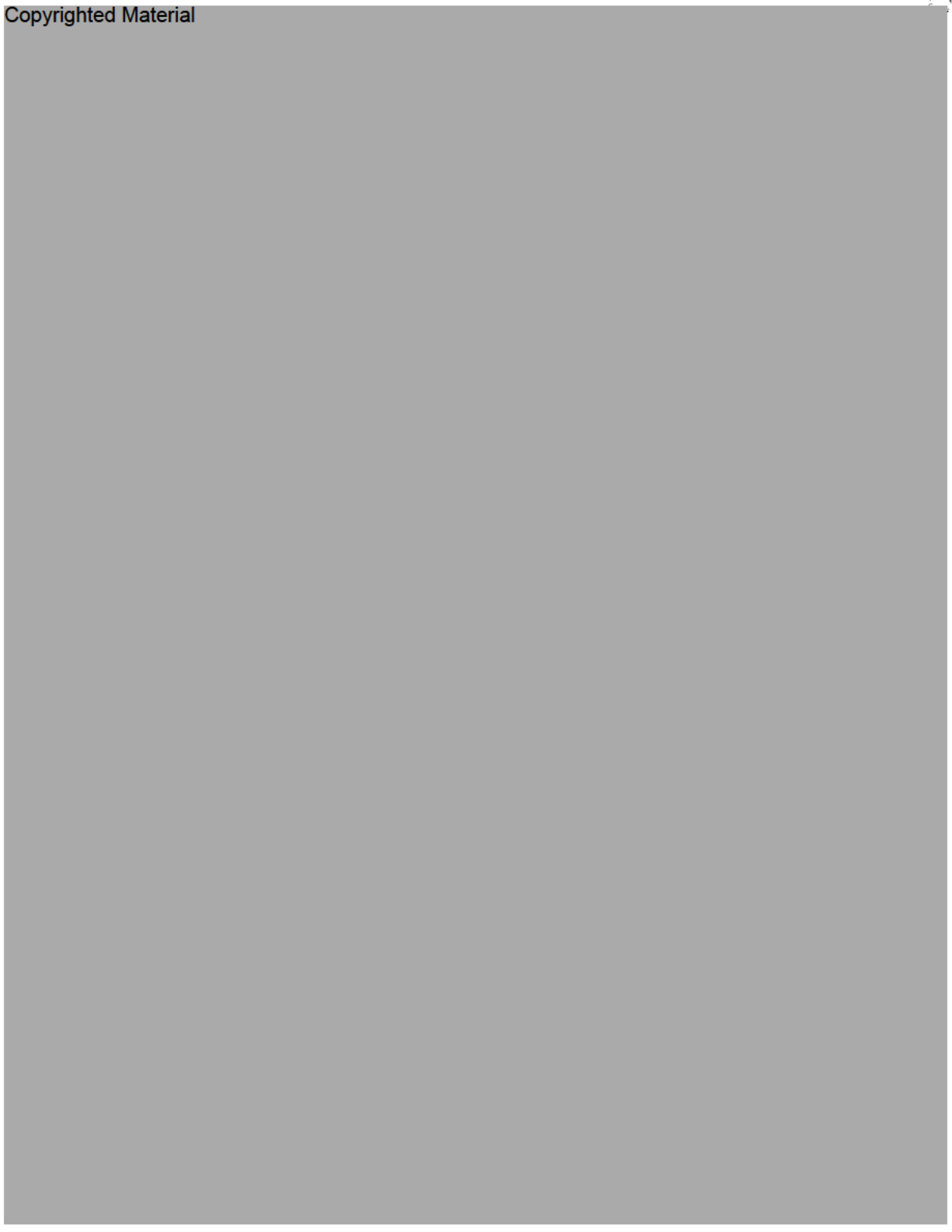


ALARMS/ALERTS:



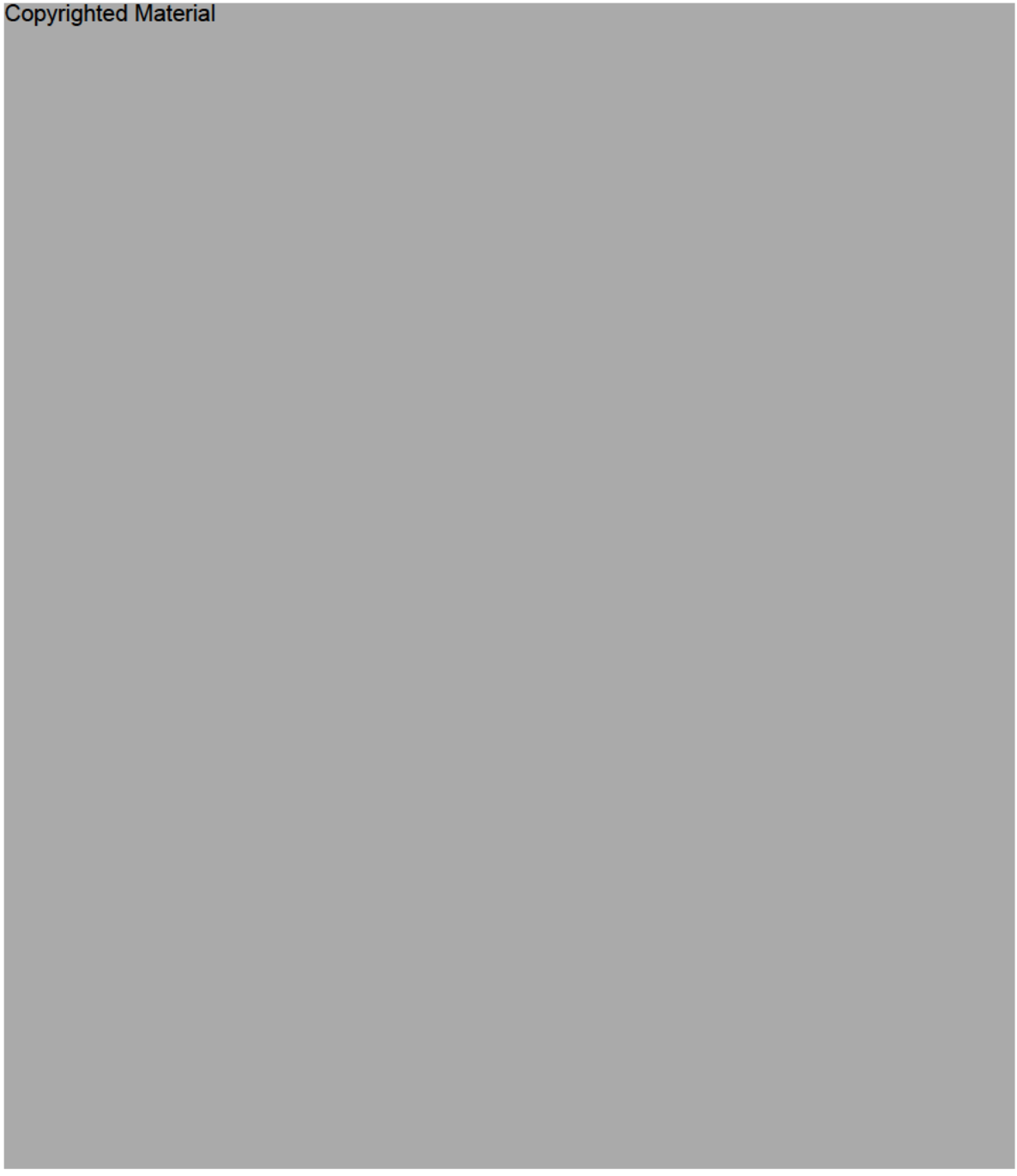
Attachment 5A-19

ALARMS/ALERTS: (con't.)



Attachment 5A-20

ALARMS/ALERTS: (con't.)



7.0. COMPLETING THE PROCEDURE – PURGING THE PADS

8.0. RECORDING DATA

10.0. MAINTENANCE

Copyrighted Material

Copyrighted Material

11.0. CUSTOMER SUPPORT

Copyrighted Material

11.1. Product Returns

Copyrighted Material

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KLM-XXX HXXXX 14-60-052-0-00

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Attachment 5A-26

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TEMPERATURE MANAGEMENT SYSTEM

KIMBERLY-CLARK® Patient Warming System

Model 100 Control Unit Usage Guide

Please refer to the Operator's Manual for full instructions on the use of the Kimberly-Clark* Patient Warming System.

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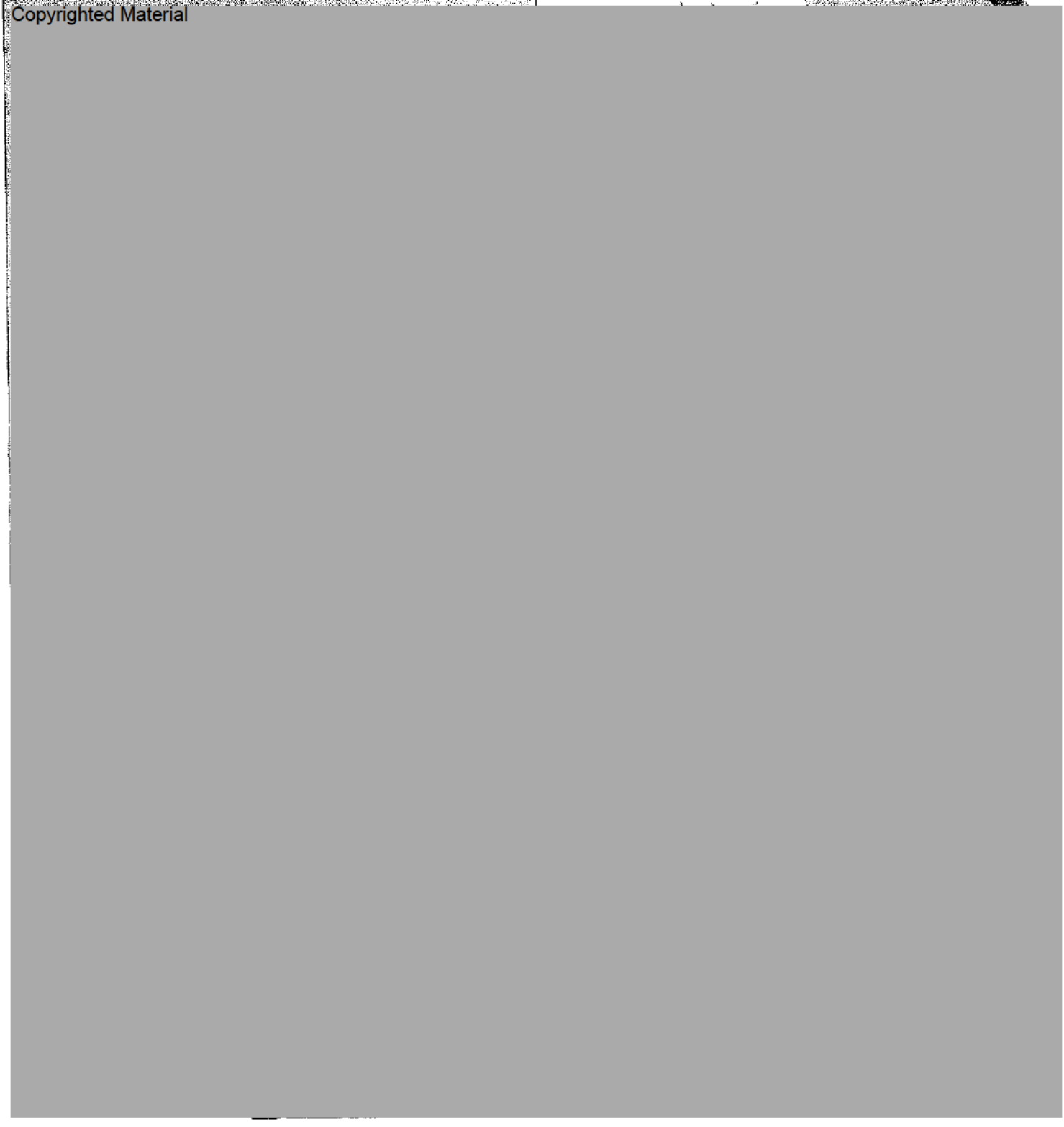
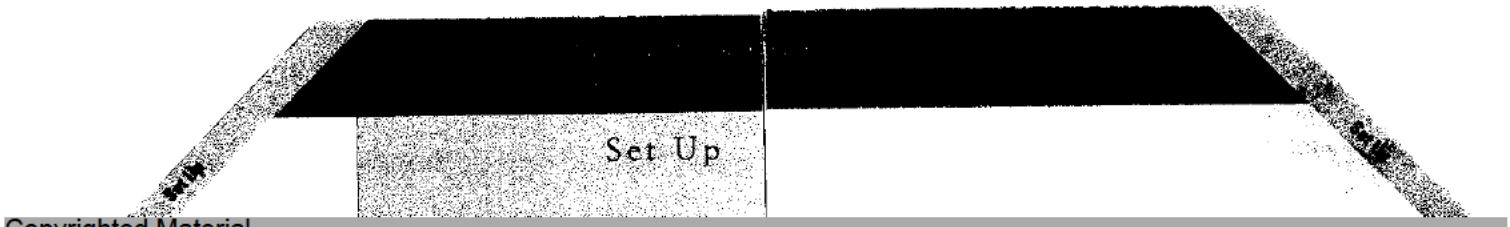
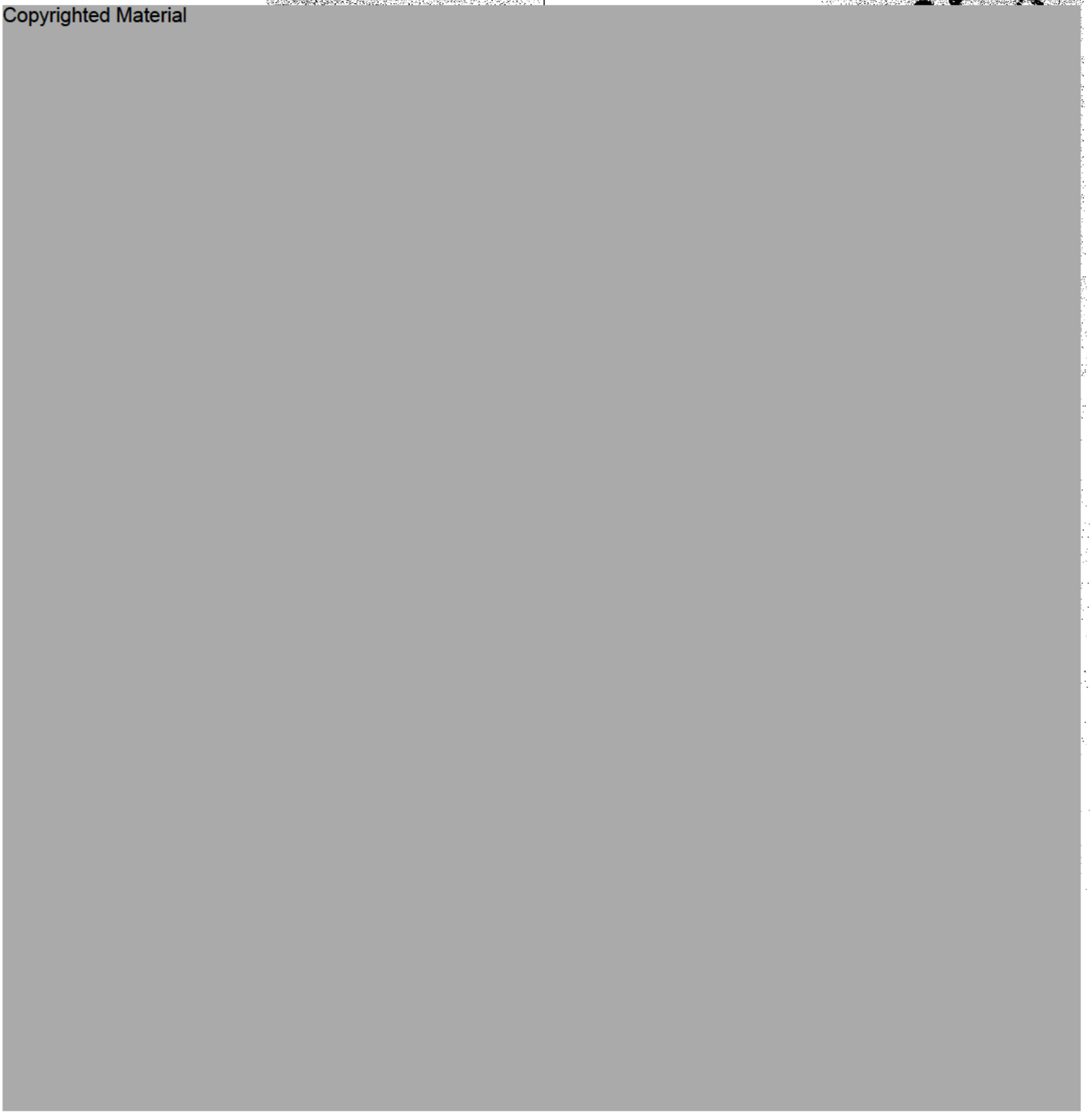
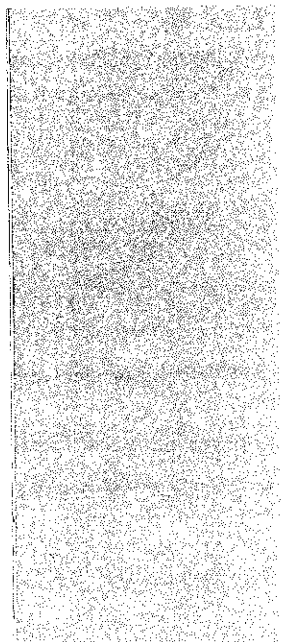
Attachment 5B-1

Filling the Control Unit









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14-60-053-0-00

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Kimberly-Clark*

REF 00101-03

Patient Warming System

S/N	Mfg Date	

Model 100 CSA / 115 V ~ , 50/60 Hz, 5A

Risk Class 2 Standard/Norme C22.2, No. 125

DANGER – Risk of explosion if used in the presence of flammable anesthetics.

US C entela Certified

Kimberly-Clark Manufactured for Kimberly-Clark, Roswell, GA 30076 USA
Distributed in the U.S. by Kimberly-Clark Global Sales, Inc., Roswell, GA 30076 USA
Comments? Suggestions? Call 1-800-KCHELPS · www.kchealthcare.com

8/22/03
Preprinted Unit Label
20-62-147-0-00
4" x 6"
Prints Black

Attachment 5C-1

8.5"

3.66"

Attachment 5D-1

Patient Warming System
Energy Transfer Pad
Split Torso / Medium

1 Set

Expiration Date

(01) 1 06 80651 334715

Surgical Application
For use only with KIMBERLY-CLARK* Patient Warming System
Natural Rubber Latex Free
Non-sterile
Store Flat
Avoid excessive heat > 40° C (104° F)

Single Use Only

R_x Only

REF **00315-05**

LOT

8/27/03
Thermal Pouch Label
8.5" x 3.66"

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Attachment 5E-1

Kimberly-Clark

Patient Warming System
Energy Transfer Pads

Indications

The KIMBERLY-CLARK* Patient Warming System is intended for monitoring and controlling patient temperature within a range of 33° C to 37° C (91.4° F to 98.6° F).

The indications include any condition where patient temperature control within a range from mild hypothermia to normothermia is required.

Contraindications
There are no known contraindications for the use of a thermoregulatory system.

Do not place KIMBERLY-CLARK* Energy Transfer Pads on skin that has signs of ulcerations, burns, hives or rash.

While there are no known allergies to hydrogel materials, caution should be exercised with any patient with a history of skin allergies or sensitivities. Some pad styles include medical grade adhesive edge tapes to minimize the chance of solutions pooling between the pad and skin. Do not apply the adhesive tape to patients with a history of sensitivity to adhesive tape.

Cautions
Federal law restricts this device to sale by or on the order of a physician.

This product is to be used by or under the supervision of trained, qualified medical personnel.

The clinician is responsible for determining the appropriateness of use of this device and the user-settable parameters, including water temperature, for each patient.

Due to underlying medical or physiological conditions, some patients are more susceptible to skin damage from pressure and heat or cold. Patients at risk include those with poor tissue perfusion or poor skin integrity due to diabetes, peripheral vascular disease, poor nutritional status or steroid or high dose vasopressor therapy.

If accessible, examine the patient's skin under the Energy Transfer Pads often; especially those patients at higher risk of skin injury.

Skin injury may occur as a cumulative result of pressure, time and temperature. Do not place bean bags or other firm positioning devices under the Energy Transfer Pads. Do not place any positioning devices under the pad manifolds or pad fluid lines.

Do not allow antibacterial agents to pool underneath the Energy Transfer Pads. Excess antibacterial agents can absorb into the pad adhesive and cause chemical burns and loss of pad adhesion.

Do not place an Energy Transfer Pad directly over an electrosurgical grounding pad. The combination of heat sources may result in skin injury.

Carefully remove Energy Transfer Pads from the patient's skin at the completion of use. Aggressive removal of the pad or edge tape adhesive from the patient's skin may result in skin injury.

The Energy Transfer Pads are non-sterile for single patient use only. Do not place pads in the sterile field. If used in a sterile environment, pads should be placed according to the physician's directions, prior to either the sterile preparation or to sterile draping.

Do not reprocess or sterilize.

Do not allow water to contaminate the surgical field when pad lines are disconnected.

9/1/03
14-60-051-0-00
Insert Front
5.5" x 8..5"
Prints PMS 299 Blue and Black

Kimberly-Clark

Patient Warming System
Energy Transfer Pads

Directions for use

1. KIMBERLY-CLARK* Energy Transfer Pads are only for use with a KIMBERLY-CLARK* Control Unit. See Operator's Manual for detailed instructions on system use.
2. Select the proper number, size and style pad for the patient size and clinical indication. However, the rate of temperature change and potentially the final achievable temperature is affected by pad surface area, patient size, pad placement and water temperature range.
3. For patient comfort, the pads may be pre-warmed using Water Temperature Control Mode (manual) prior to application.
4. Place the pads on healthy, clean skin only. Remove any creams or lotions from patient's skin before pad application. Remove the release liner from each pad and apply to the appropriate area. The pads may be overlapped or folded adhesive-to-adhesive to achieve proper placement. The pads may be removed and reapplied if necessary. The pad surface must contact the skin for optimal energy transfer efficiency.
5. Attach the pad connector to the fluid delivery line. Begin circulating water through the pads using either Patient Temperature Control Mode (automatic) or Water Temperature Control Mode (manual). If the pads fail to prime, or a significant continuous air leak is observed in the pad return line, check connections. If needed, replace the leaking pad.
6. Once all the pads are primed, assure the flow rate displayed on the control panel is appropriate for the number of pads connected. (See Operators Manual)

Minimum Flow Rates

Number of Pads	1	2	3	4
Flow Rate (lpm)	0.8	1.5	2.1	2.6

7. When finished, purge water from pads. Slowly remove pads from the patient and discard.

Natural Rubber Latex Free

Kimberly-Clark

Manufactured for Kimberly-Clark, Roswell, GA 30076 USA
Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076 USA
Comments? Suggestions? Please call 1-800-KCHELPS · www.kchealthcare.com

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Insert Back
5.5" x 8..5"
Prints PMS 299 Blue and Black

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Section 6

Substantial Equivalence Comparison

Predicate Device:	MediVance's Artic Sun™ Temperature Management System – Model 100 Control Unit and Energy Transfer Pads.
510(k) #:	K002577
Device Classification:	"Thermal Regulation System" (21CFR870.5900)
Product Code:	DWJ
Identification:	A thermal regulating system is an external system consisting of a device that is placed in contact with the patient, and a temperature controller for the device.
Classification:	Class II (performance standards)

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is the exact same medical device as the predicate device that is currently marketed by MediVance, Inc. As previously stated, on May 27, 2003 Kimberly-Clark acquired all product rights related to MediVance's patient warming business. This specifically includes the stated predicate device which is being renamed as a Kimberly-Clark product.

See Substantial Equivalence Comparison on ***page 6-2.***

Section 6

Substantial Equivalence Comparison (Continued)

Comparison of Kimberly-Clark Patient Warming System To MediVance ARTIC SUN™ Temperature Management System

	MediVance ARTIC SUN™ Temperature Management System	Kimberly-Clark Patient Warming System
Intended Use	For monitoring and controlling patient temperature	Same
Clinical Applications	OR, Recovery, Medical/Surgical, ER, ICU	Same
Thermal Systems		
Cooling Source	(b) (4)	Same
Heater Size		Same
Refrigerant Used		Same
Microprocessor Controlled?		Same
Data Collection		Same
Calibration		Same
Circulating Fluid		Same
Flow Rate		Same
Reservoir Capacity		Same
Monitor Patient Temperature?		Same
Probe Used		Same
Patient Temp. Display Range (°C)		Same
Modes	Patient Temperature, Water temperature, Purge, Stop	Same
Setpoint Ranges		
Circulating Fluid (°C)	(b) (4)	Same
Patient Temperature (°C)		Same
Electrical		
Characteristics		Same
Current Leakage		Same
Alarm Limits		
Heating (°C)		Same
Cool (°C)		Same

Section 6

Substantial Equivalence Comparison (Continued)

Comparison of Kimberly-Clark Patient Warming System To MediVance ARTIC SUN™ Temperature Management System

	MediVance ARTIC SUN™ Temperature Management System	Kimberly-Clark Patient Warming System
Independent Backup		
Heat (°C)	(b) (4)	Same
Cool (°C)		Same
Alarms: A= Audio; V = Visual		
High Water Temperature Limit		Same
Low / Empty Water		Same
Patient Probe		Same
Water Sensor		Same
Patient Temperature Hi/Low Limit		Same
Patient Pads	Energy Transfer Pads	Same
Type	Single-Patient, Non-sterile	Same
Material	(b) (4)	Same

Section 7

Description and Principles of Operation

Please refer to following information contained in MediVance's cleared 510(k) # K002577:

- Section 6.0 titled "Description and Principles of Operation", pages 100-108.
- MediVance's October 11, 2000 letter with respect to the design of the Energy Transfer Pads.

Section 8

Software

Please refer to following information contained in MediVance's cleared 510(k) # K002577:

- Section 7.0 titled "Software", pages 109-191.
- MediVance's October 17, 2000 letter with respect to software hazard analysis.

Section 9

Performance Data

Please refer to following information contained in MediVance's cleared 510(k) # K002577:

- Section 8.0 titled "Performance Data", pages 192-198.
- MediVance's October 11, 2000 letter with respect to performance testing of the Energy Transfer Pads.
- MediVance's October 17, 2000 letter with respect to performance testing of the Model 100 Control Unit and Energy Transfer Pads.
- MediVance's October 20, 2000 letter with respect to performance testing of the Energy Transfer Pads.

Section 10

Biocompatability

Please refer to following information contained in MediVance's cleared 510(k) # K002577:

- Section 9.0 titled "Biocompatibility", page 199.
- MediVance's October 20, 2000 letter with respect to Biocompatibility Testing.

Section 11

Sterility

NOT APPLICABLE. The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads are provided non-sterile.

Section 12

Color Additives

NOT APPLICABLE. Kimberly-Clark does not add any color additives to the Model 100 Control Unit or Energy Transfer Pads during their manufacture.

Section 13

Kits, Packs or Trays

NOT APPLICABLE.

Section 14

Premarket Notification [510(k)] Summary

1. **Submitted by:**

Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076

Contact Person: Richard V. Wolfe
Manager, Regulatory Affairs

Telephone: (770) 587-8208
Facsimile: (770) 587-7761
e-mail: richard.wolfe@kcc.com

Date Prepared: September 25, 2003

2. **Device Name**

Trade / Proprietary Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads
Common / Usual name: Hypo / Hyperthermia System
Classification Name: System, Thermal Regulating (per 21CFR 870.5900)

3. **Predicate Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is substantially equivalent to the MediVance Inc. ARTIC SUN™ Temperature Management System – Model 100 Control Unit and Energy Transfer Pads cleared under 510(k) # K002577.

4. **Intended Use of the Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Clinical applications of this device include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required. This would include, but not be limited to, medical, surgical, febrile, accidental hypothermia, or heat stroke patients.

5. **Description of the Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is a device used to monitor and control patient temperature. It consists of single-use heat transfer pads, which are adhered to areas of the patient's skin, and a control module that circulates temperature-controlled water. The control module is connected to the pads by flexible tubing. A commercially available probe connected to the control module senses the patient's core temperature. The system can control the patient's core temperature by altering the temperature of the circulating water.

Section 14

Premarket Notification [510(k)] Summary *(Continued)*

6. Summary of the technological characteristics of the device compared to the predicate device

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is identical in design to MediVance's Artic Sun™ Temperature Management System which obtained FDA clearance on October 26, 2000 under 510(k) number K002577. Kimberly-Clark acquired all product rights related to the patient warming business from MediVance, Inc. on May 27, 2003.

7. Testing

Testing of the Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads [under MediVance's 510(k) # K002577], included: biocompatibility testing in accordance with ISO 10993-1 and / or USP, electrical safety testing in accordance with IEC601 and functional safety and performance testing.

8. Conclusions

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is the exact same medical device as MediVance's Artic Sun™ Temperature Management System which obtained FDA clearance on October 26, 2000. Therefore, no new safety or effectiveness issues exist.

Section 15

Indications For Use

Applicant: Kimberly-Clark Corporation

510(k) Number:

Device Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads

Indications for Use: The KIMBERLY-CLARK* Patient Warming System is intended for monitoring and controlling patient temperature. The indications for use of the device include any condition where patient temperature control within the range covering mild hypothermia to normothermia is required.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

CDRH SUBMISSION COVERSHEET

Date of Submission: Septembre 25 2003 **FDA Document Number:**

Section A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ☑ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B **Applicant or Sponsor**

Company/Institution Name: Kimberly-Clark Corporation	Establishment registration number: 1033432
Division Name (if applicable):	Phone number (include area code): (770) 587-8208
Street Address: 1400 Holcomb Bridge Road	Fax number (include area code): (770) 587-7761

City:	State/Province:	Zip code:	Country:
Roswell	GA	30076	USA

Contact Name: Richard V Wolfe

Contact Title:	Contact e-mail address:
Manager, Regulatory Affairs	Richard.Wolfe@KCC.com

Section C **Submission Correspondent (if different from above)**

Company/Institution Name: Same as above	Establishment registration number:
Division name (if applicable)	Phone number (include area code):
Street Address:	Fax number (include area code):

City:	State/Province:	Zip Code:	Country

Contact Name:

Section D1 **Reason for Submission – PMA,PDP, or HDE**

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Licensing Agreement
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Location Change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Processing Change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Labeling Change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other (specify below)_
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post Approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Change in Ownership
- ☐ Change in correspondent
- ☐ Other Reason (specify):

Section D2 **Reason for Submission - IDE**

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 **Reason for Submission – 510(k)**

- ☐ New Device
- ☐ Additional or expanded indications
- ☑ Other reason (specify):
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

Change in ownership of product. MediVance retains ownership of 510(k) # K002577

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 data:
1 DWJ	2	3	4	☑ 510(k) summary attached
5	6	7	8	☐ 510(k) statement

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 K002517	1 Artic Sun Temperature Management System	1 Medivance, Inc.
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name:

Trade or proprietary or model name	Model Number
1 Kimberly-Clark Patient Warming System	1 Model 100
2	2
3	3
4	4
5	5

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

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: DWJ	C.F.R. Section 21 CFR 870.5900	Device Class: ☐ Class I ☑ Class II ☐ Class III ☐ Unclassified
Classification Panel:	Cardiovascular	

Indications (from labeling):

For monitoring and controlling patient Temperature

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

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

(b) (4)

☐ Add ☐ Delete ☐ Contract Manufacturer ☐ Repackager/relabeler

Company/Institution name:	Establishment registration number:		
Division name (if applicable):	Phone number (include area code):		
Street address:	FAX number (include area code):		
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title	Contact e-mail address:		

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
with Reference to K002577

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

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

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.]**		N/A
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:	N/A	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:	*	

* Reference made to K003577

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

Passed Screening _____Yes _____No
Reviewer:_____
Concurrence by Review Branch:_____

Date:_____

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

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

Subject: 510(k) Number K033021

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?	(b) (4)	
Special 510(k)?		
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/A

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

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

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

Predicate Product Code with class: DWJ / Class II 74

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

Review: Dina Kruerlu CDRH 11/6/03
(Branch Chief) (Branch Code) (Date)

Final Review: for DZ Lieberman 11/10/03
(Division Director) (Date)

Revised: 4/2/03

MEMORANDUM

Catherine

FROM: Catherine Wentz – Engineer/lead reviewer
FILE: k033021.kimberlyclark arctic sun
SPONSOR: Kimberly-Clark Corporation
DEVICE: Kimberly-Clark Patient Warming System
CLS/CODE: DWJ/870.5900/Class II
SUBJECT: Original 510(k) Application
ACTION: Substantially Equivalent

Summary

Kimberly-Clark has acquired all product rights related to the patient warming business from MediVance, Inc. on May 27, 2003. A joint announcement was issued on June 2, 2003 (included in submission).

MediVance has retained ownership of the 510(k) K002577 (MediVance Arctic Sun Temperature Management System – Model 100 Control Unit and Energy Transfer Pads), while pursuing other indications with this system for patient cooling. As such, Kimberly-Clark has submitted this premarket notification to establish their own cleared 510(k) for this product. This will permit them to make changes to the system for their own patient warming needs.

The sponsor has indicated that the systems are currently identical with the following exceptions:

1. Labeling will be changed to identify Kimberly-Clark as the company and product name;
2. Manufacturing location for the energy transfer pads (b) (4)
(b) (4)

A copy of the review performed for K002577 (MediVance submission) is attached.

The indications for use are consistent with the indications for use under K002577:

"The Kimberly-Clark Patient Warming System is intended for monitoring and controlling patient temperature. The indications for use of the device include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required."

RECOMMENDATION: Substantially Equivalent

Catherine Wentz 11/3/03

Dina Fleischer

Review K002577

The sponsor has submitted an application for a thermal regulating system (21 CFR 870.5900 – DWJ). The application contains all the elements required for a 510(k) submission, and the information supports substantial equivalence as compared to similar predicate devices.

Indications for use:

> *The Arctic Sun™ Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature.*

Identified Predicate Devices:

Allon 2001 System	*K001546*
Model RK K-Thermia System	*K882442*
MediTherm System	*K912051*
Blanketrol II System	*K811742*
TropiCool Unit	*K902756*

Description

The Arctic Sun Temperature Management System is a thermal regulating system comprised of a hardware control module and disposable non-sterile pads. The control module is connected to the pads with tubing. Circulating water is used as the cooling/warming medium, and the water is controlled within a range of 15-42°C. The water is circulated through the pads using a positive displacement pump in the control module that creates a negative pressure within the pads minimizing accidental water leakage. The system has alarms for patient and water over-temperature and under-temperature, and even a shutdown mechanism for certain conditions.

Up to 4 pads can be connected to the control unit at one time. The pads have a thin adhesive applied to the patient contacting side to aid in secure placement and heat transfer. The adhesive is a "skin compatible hydrogel adhesive" that has demonstrated itself to be non-irritating through non-significant risk clinical studies with the device, as well as biocompatibility testing. The adhesive is only a light adhesive that aids in secure placement of the device and can be repositioned, but will not leave a residue or pull hair or skin when removed. The adhesive has also been identified on a similar product – electrosurgical return pads (K822572). The pads can be used during surgery, and the labeling has clearly stated that the pads cannot be used in the sterile field.

Specifications:

Water flow rate (total) ranges from 0.5 – 8.0 liters/minute.
Alarms:
Water temperature high 42.5 C
Patient Temperature High 38C
Patient Temperature Lo 32C

The operating specifications all fall within the same ranges as for the identified predicate devices.

Performance

The sponsor has performed a series of tests to demonstrate safety, effectiveness and substantial equivalence for the Arctic Sun Device. Number of devices tested was as follows:

(b) (4)

Functional Testing included:

(b) (4)

(b) (4)

Clinical Experience

The sponsor also reports on experience (b) (4)
(b) (4) The sponsor stated that (b) (4)
(b) (4)

(b) (4) This was requested of the sponsor via e-mail. The sponsor responded (attached) with additional testing demonstrating (b) (4)
(b) (4)

Biocompatibility

The sponsor provided results of biocompatibility testing for the pads (specifically, the hydrogel adhesive material). The tests performed included cytotoxicity, irritation, and sensitization tests. The testing was performed in accordance with ISO 10993, and all tests indicate that the material is non-toxic/non-irritant/no reaction.

Software

The sponsor provided software information in accordance with the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" May 29, 1998, for a device of Minor Level of Concern. The sponsor was contacted via e-mail and requested to discuss how they came up with a minor level of concern – i.e., malfunction would not cause injury to the patient. If it is possible for a burn to develop on the patient's skin during a malfunction, then this device should be considered Moderate Level of Concern.*

*The sponsor responded in an e-mail (attached) and explained that the device

(b) (4)

This response is satisfactory. A minor level of concern for the device is justified.

The elements included in the software description were 1) level of concern (minor), 2) software description, 3) device hazard analysis, 4) architecture design chart, 5) validation, verification and testing, and 6) release version number.

Remaining Concerns: The information appears complete and no further questions arise regarding the software.

Labeling

The sponsor provided their labeling as well as the labeling for the predicate devices. The labeling appears clear, includes a table of all alarms/alerts and required actions for each one, as well as maintenance and service information. The indications for use printed within the labeling are consistent with those provided in the IFU Form.

Remaining Concerns: NONE

SMDA

The sponsor has provided the Indications for Use Form, Truthful and Accurate Statement, and a 510(k) summary.

Remaining Concerns: NONE

510(k) Decision Making Documentation

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

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

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

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

   Yes

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

   Yes

6. ARE THE DESCRIPTIVE CHARACTERISTICS ENOUGH TO DETERMINE EQUIVALENCE?

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

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

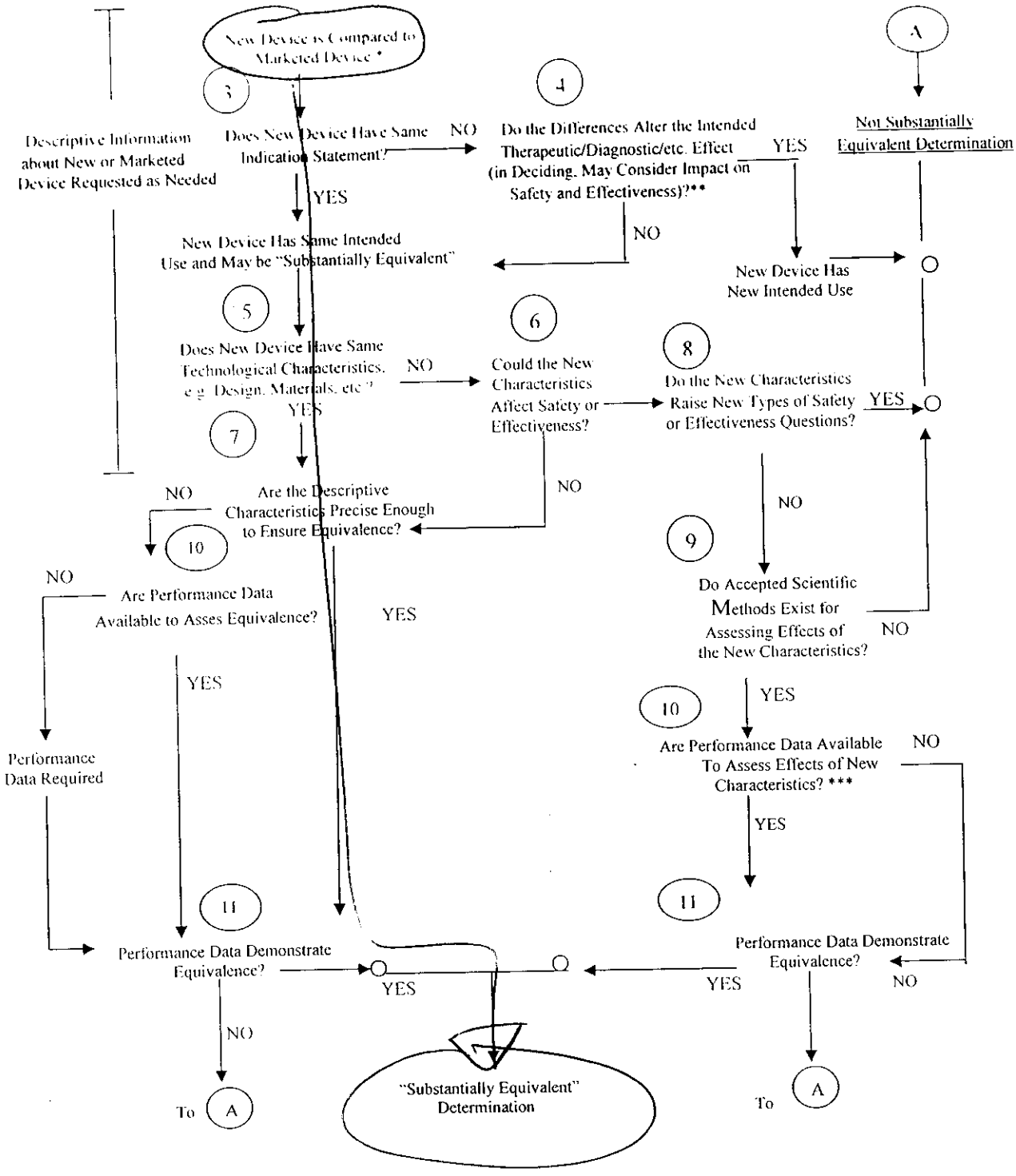
   YES. ALL SUPPORTING INFORMATION HAS BEEN PROVIDED.

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

RECOMMENDATION: Substantial Equivalence

Catherine P. Wentz
Biomedical Engineer

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.