U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(szs)
FOLDER:	K072845 - 2155 pages
COMPANY:	VAPOTHERM, INC. (VAPOTHERM)
PRODUCT:	HUMIDIFIER, RESPIRATORY GAS, (DIRECT PATIENT INTERFACE) (BTT)
SUMMARY:	Product: PRECISION FLOW
DATE REQUESTED:	Sep 22, 2011
DATE PRINTED:	Sep 22, 2011
Note:	Printed

K072845

510(k) SUMMARY

Vapotherm, Inc.'s Precision Flow™

JUL 17 2008

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

Phone: 410-604-3977
Facsimile: 410-604-3978

Contact Person: Gregory A. Whitney

Date Prepared: April 15, 2008

Name of Device and Name/Address of Sponsor

Precision Flow™
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

A. Common or Usual Name

Humidifier, Respiratory Gas (Direct Patient Interface)

B. Classification Name

Humidifier, Respiratory Gas (Direct Patient Interface)
Anesthesiology Panel (868.5450)
Class II

C. Product Code

BTT

D. Predicate Devices

Vapotherm, Inc.	2000i& 2000h	K000401, K0142245, K042245
Medtec	Oxygen Sensor	K063488
Bird Products	Air-Oxygen Blender	K911962

E. Intended Use / Indications for Use

The Precision Flow™ is intended to be used for adding warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

F. Technological Characteristics

The Precision Flow™ consists of two parts:

The **main unit** which contains all the electrical and electronic components including the electronic blender and flow controllers. All the sensors are located in the main unit. The main unit has no water pathways and the gas pathway contains only dry gas at room temperature, and consequently does not need internal cleaning or disinfection.

The **disposable components** comprising the disposable water module, vapor transfer cartridge and heated delivery tube. Conditions in the circulating water and gas streams are sensed remotely via the interface between the main unit and the disposable module.

1. Main unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow of each needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

- Firmware running in the main unit uses sensors to monitor gas pressure, water level and water temperature, and to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed. An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

K072845

2. Disposable components:

- Vapor Transfer Cartridge. In the cartridge blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- Triple-lumen heated delivery tube. The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize rain-out. A proprietary short nasal cannula is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- Disposable module. The module houses a water reservoir, pump, connections for the cartridge and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the Vapor Transfer Cartridge where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the water bag to replace evaporative losses in the Vapor Transfer Cartridge. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

3. Summary of Non-Clinical Performance Data

The following table lists the non-clinical Performance Testing Data that was performed on the Precision Flow™:

Number	Test Description
1	Biocompatibility – Murine Local Lymph Node Assay (LLNA) (Sensitization)
2	Biocompatibility – ISO Intracutaneous Reactivity Test (Irritation)
3	Biocompatibility – MEM Elution (Cytotoxcity)
4	Volatile Organic Compounds (VOC), EPA Compendium Method TO-15
5	Particulate Matter, NIOSH Method 0500
6	EMC Test
7	Emissions Test
8	Safety Inspection Test
9	IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety
10	IEC 60601-1-4, Medical Electrical Equipment Part 1-4 – Collateral Standard: Programmable Electrical Medical Systems

Number	Test Description
11	IEC 60601-1-8, Medical electrical equipment, General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
12	Bio Burden, 30 Day Comparative Use Testing
13	Ximedica TRP 1097, "Vapotherm Precision Flow Hyperthermic Humidification System, System Software Verification & Validation Test Plan"
14	TRP 1071 "System Software Test" (Black Box)
15	Unit Test Case Listing – 3VAP1004/TRP 1092 (White Box)
16	Thermal Stability
17	Blender Comparison Performance

- Bio Burden, 30 Day Comparative Use Testing: After a thirty day comparative use testing, there were no detectible bacteria in any water condensation samples from the Precision Flow® devices either initially (3 days) or after 30 days of operation.
- The Precision Flow™ software was verified and validated in accordance with applicable FDA guidance documents.
- The Volatile Organic Components and Particulate Mater tests were performed to recognized standards.

Substantial Equivalence

The Precision Flow™ is as safe and effective as the Vapotherm 2000i and 2000h, the Bird Mircoblender, and the Medtec Oxygen Sensor. The Precision Flow™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Precision Flow™ and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Precision Flow™ is as safe and effective as the predicate devices. Thus, the Precision Flow™ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vapotherm, Incorporated
C/O Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington DC 20004

JUL 17 2008

Re: K072845
Trade/Device Name: Precision Flow™
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: June 27, 2008
Received: June 30, 2008

Dear Mr. Kahan:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

~~Sincerely~~ yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K072845

Device Name: Precision Flow™

Indications for Use:

Precision Flow™ is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates **may be from 1 to 40 liters per minute via nasal cannula**.

Precision Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The counter Use ____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of __

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072845

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vapotherm, Incorporated
C/O Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington DC 20004

JUL 17 2008

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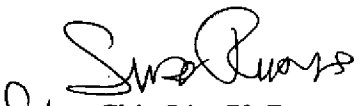
~~Sincerely yours,~~



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
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Enclosure

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Will Maly for M. Hasbani Page __ of __

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072845

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vapotherm, Incorporated
C/O Mr. Johnathan S. Kahan
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

APR -1 2008

Re: K072845
Trade Name: Precision Flow™
Dated: February 21, 2008
Received: February 26, 2008

Dear Mr. Kahan:

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

1. Please contact Kimberly Love at (240) 276-4251 or via email at kimberly.love@fda.hhs.gov upon receipt of this letter in order to schedule a teleconference to discuss the issues presented below.

2. (b)(4)

ii. (b)(4)

iii.

b. (b)(4)

3. (b)(4)

4.

b. (b)(4)

5. (b)(4)

c. (b)(4)

6. (b)(4)

7.

8.

9. (b)(4)

10.

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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.
The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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

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

If you have any questions concerning the contents of the letter, please contact Ms. Kimberly Love at (240) 276-4251. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
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C/O Mr. Johnathan S. Kahan
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Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DA
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HFZ-482	Patel	3/31/08						

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 11, 2007

VAPOTHERM, INC.
C/O HOGAN&HARTSON L.L.P
555 THIRTEENTH STREET, NW
WASHINGTON, DC 21666
ATTN: JONATHAN S. KAHN

510(k) Number: K072845
Device: PRECISION FLOW

Extended Until: 06-MAY-2008

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

1578

VAPOTHERM

December 7, 2007

By Federal Express and Electronic Copy

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

RE: Request for an Extension of Time Regarding 510(k) K072845
Trade Name: Precision Flow™
Response to FDA's Letter Dated November 8, 2007

Dear Sir or Madam:

The purpose of this letter is to request that the Food and Drug Administration ("FDA" or "the agency") grant Vapotherm, Inc. ("Vapotherm" or the "company") a one hundred and twenty (120) day extension, until March 7, 2008, to gather the information and complete all required tests necessary to respond to FDA's request for additional information regarding its letter to the company dated November 8, 2008, concerning the 510(k) premarket notification for the Precision Flow™ (K072845) device. Vapotherm has reviewed the content of FDA's request for additional information and has concluded that the company will need the additional time to complete all testing and fully respond to all of the requested information. The company will certainly submit the additional information to FDA before the end of the requested extension of time (March 7, 2008), if the test results become available sooner than expected.

145

1579

Document Mail Center (HFZ-401)
December 7, 2007

Thank you for your consideration regarding this request. Please contact me at (410) 604-3977, extension 109, or at (b)(6), if you have any questions concerning this request.

Sincerely,

(b)(6)

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

Cc: Jonathan S. Kahan, Esq., Hogan & Hartson L.L.P.
W. Robert Storey, President and CEO, Vapotherm, Inc.
Chiu Lin, Ph.D., Director FDA, Office of Device Evaluation
Kimberly Love, FDA

1580

VAPOTHERM

December 7, 2007

By Federal Express and Electronic Copy

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

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1581

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Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

Cc: Jonathan S. Kahan, Esq., Hogan & Hartson L.L.P.
W. Robert Storey, President and CEO, Vapotherm, Inc.
Chiu Lin, Ph.D., Director FDA, Office of Device Evaluation
Kimberly Love, FDA

1582

VAPOTHERM

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Response to FDA's Letter Dated November 8, 2007

Dear Sir or Madam:

The purpose of this letter is to request that the Food and Drug Administration ("FDA" or "the agency") grant Vapotherm, Inc. ("Vapotherm" or the "company") a one hundred and twenty (120) day extension, until March 7, 2008, to gather the information and complete all required tests necessary to respond to FDA's request for additional information regarding its letter to the company dated November 8, 2008, concerning the 510(k) premarket notification for the Precision Flow™ (K072845) device. Vapotherm has reviewed the content of FDA's request for additional information and has concluded that the company will need the additional time to complete all testing and fully respond to all of the requested information. The company will certainly submit the additional information to FDA before the end of the requested extension of time (March 7, 2008), if the test results become available sooner than expected.

1583

Document Mail Center (HFZ-401)
December 7, 2007

Thank you for your consideration regarding this request. Please contact me at (410) 604-3977, extension 109, or at (b)(6) if you have any questions concerning this request.

Sincerely,

(b)(6)

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

Cc: Jonathan S. Kahan, Esq., Hogan & Hartson L.L.P.
W. Robert Storey, President and CEO, Vapotherm, Inc.
Chiu Lin, Ph.D., Director FDA, Office of Device Evaluation
Kimberly Love, FDA

1584

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 - 2007

Vapotherm, Incorporated
C/O Mr. Johnathan Kahan
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

Re: K072845
Trade Name: Precision Flow™
Dated: October 2, 2007
Received: October 4, 2007

Dear Mr. Kahan:

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

1. (b)(4)

2.

3.

1585

i. (b)(4)
ii.

4. (b)(4)

5.

(b)(4)

6.

7.

8.

9.

10. (b)(4)

a. (b)(4)

b.

c.

d.

e.

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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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

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

If you have any questions concerning the contents of the letter, please contact Ms. Kimberly Love at (240) 276-4251. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Vapotherm, Incorporated
C/O Mr. Johnathan Kahan
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

Re: K072845
Trade Name: Precision Flow™
Dated: October 2, 2007
Received: October 4, 2007

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1. (b)(4)
2.
3.

i. (b)(4)
ii.

4. (b)(4)

5. (b)(4)

(b)(4)

6.

7.

8.

9.

10. (b)(4)

a. (b)(4)

b.

c.

d.

e.

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.

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

If you have any questions concerning the contents of the letter, please contact Ms. Kimberly Love at (240) 276-4251. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DA
HFZ-480	Kahan	11/7/07						

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.
F/T: HFZ-480-KGL - IXW 11/7/07

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-40
9200 Corporate Blvd.
Rockville, Maryland 20850

October 05, 2007

VAPOTHERM, INC.
C/O HOGAN&HARTSON L.L.P
555 THIRTEENTH STREET, NW
WASHINGTON, DC 21666
ATTN: JONATHAN S. KAHN

510(k) Number: K072845
Received: 04-OCT-2007
Product: PRECISION FLOW

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federa Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited abov Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you whe the processing of your 510(k) 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.

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 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actio 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 variou 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 (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry an FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an origin submission for a Traditional or Abbreviated 510(k). 3)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.

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In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/" If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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

K072845

Vapotherm, Inc.

510(k) Premarket Notification

Precision Flow™

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland
211666

AM
II

TABLE OF CONTENTS
Section

MEDICAL DEVICE USER FEE

1620

Confirmation

YOUR PAYMENT IDENTIFICATION NUMBER IS: (b)(4)

Your Cover Sheet has been submitted electronically. You must print and sign the hard copies. Include one in each copy of your application and include a copy with your payment.

Create Another Cover Sheet

Coversheet

Medical Device User Fee and Modernization Act

Print/View Final Coversheet 1 Fee: $3,404.00

Total:$3,404.00

Applicant Information

Applicant: VAPOTHERM INC
(b)(4)

Applicant Contact Information

Submitter: (b)(4)
VAPOTHERM INC
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville,MD 21044
UNITED STATES

Create Another Cover Sheet

2. CDRH Premarket Review Submission Cover Sheet

The Company's biocompatibility statement is included in this section of the submission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (*if known*)
10 - 3 -07	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (120 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other (*specify*):
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission ☐ Amendment ☐ Supplement	☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	☐ 513(g) ☐ 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	Establishment Registration Number (*if known*)		
Vapotherm, Inc.	1125759		
Division Name (*if applicable*)	Phone Number (*including area code*) (b)(6)		
Street Address 198 Log Canoe Circle	FAX Number (*including area code*) (b)(6)		
City Stevensville	State / Province Maryland	Zip/Postal Code 21666	Country USA
Contact Name William Robert Storey			
Contact Title President & CEO	Contact E-mail Address (b)(4)		

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

Company/ Institution Name Hogan & Hartson L.L.P.	Establishment Registration Number (*if known*) N/A		
Division Name (*if applicable*)	Phone Number (*including area code*) (b)(4)		
Street Address 555 Thirteenth Street, NW	FAX Number (*including area code*) (b)(4)		
City Washington	State / Province DC	Zip/Postal Code 20004	Country USA
[redacted]ntact Name Jonathan S. Kahan			
[redacted]ntact Title Regulatory Counsel	Contact E-mail Address (b)(4)		

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

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site
- [ ] Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other (*specify below*)
- [ ] Response to FDA correspondence:
- [ ] Change in design, component, or specification;
  - Software/ Hardware
  - Color Additive
  - Material
  - Specifications
  - Other (*specify below*)
- [ ] Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other (*specify below*)
- [ ] Location change:
  - Manufacturer
  - Sterilizer
  - Packager
- [ ] Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment
- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

SECTION D2 — REASON FOR APPLICATION – IDE

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

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded indications
- [ ] Change in Technology
- Other Reason (*specify*):

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SECTION E — ADDITIONAL INFORMATION ON 510(k) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	BTI	2	BTT	3	BTT	4	BZR
5	CCL	6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510(k) summary attached
☐ 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	K013486	Vapotherm 2000h	Vapotherm, Inc.
2	K000401	Vapotherm 2000i	Vapotherm, Inc.
3	K042245	Vapotherm 2000i and 2000h	Vapotherm, Inc.
4	K911962	Bird Blender	Bird Products
5	K063488	Maxtec	Oxygen Sensor

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Respiratory gas humidifier and/or breathing gas mixer

	Trade or Proprietary or Model Name for This Device		Model Number
1	Precision Flow™	1	Precision Flow™
		2	

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

1	2	3	4	5	6

Data Included in Submission ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section (*if applicable*)	Device Class
BTT	868.5450	☐ Class I ☒ Class II
BZR	868.5330	☐ Class III ☐ Unclassified

Classification Panel

Anesthesiology

Indications (*from labeling*)

Precision Flow™ is intended to add moisture to and to warm breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

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[redacted]e: Submission of this information does not affect the need to submit a 2891 [redacted]891 a Device Establishment Registration form.	FDA Document Number (*if known*)

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

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name Vapotherm, Inc.		Establishment Registration Number: 1125759
Division Name (*if applicable*)		Phone Number (*including area code*) (410) 604-3977
Street Address 198 Log Canoe Circle		FAX Number (*including area code*) (410) 604-3978
City Providence Stevensville,		State / Province Maryland
		ZIP Code 02907 21666
		Country USA USA
Contact Name William Robert Storey	Contact Title President and CEO	Contact E-mail Address (b)(4)

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name [redacted]n Group		Establishment Registration Number
Division Name (*if applicable*) (b)(4)		Phone Number (*including area code*) (b)(4)
Street Address (b)(4)		FAX Number (*including area code*) (b)(4)
City (b)(4)		State / Province Rhode Island
		ZIP Code 02907
		Country USA
Contact Name (b)(4)	Contact Title Division Manger	Contact E-mail Address (b)(4)

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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 Code Country
[redacted]ontact Name	Contact Title	Contact E-mail Address

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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.					
1	Standards No. IEC 60601-1	Standards Organization: IEC	Standards Title: General Requirements for Safety	Version	Date 1988
2	Standards No. EN 60601-1-2, Group 1, Class A	Standards Organization: EN	Standards Title:	Version	Date
3	Standards No. IEC 60601-1-8	Standards Organization: IEC	Standards Title: General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.	Version	Date 2003
4	Standards No.	Standards Organization	Standards Title:	Version	Date
5	Standards No.	Standards Organization	Standards Title:	Version	Date

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

1627

3. 510(k) Cover Letter

The Company's 510(k) Cover Letter for the Precision Flow™ is provided in this section of the submission.

VAPOTHERM

October 2, 2007

K-44

FDA CDRH DMC

OCT 0 4 2007

Received

By Messenger

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

Attention: **Document Mail Clerk**

Re: 510(k) Premarket Notification for Vapotherm, Inc.'s Precision Flow™

Dear Charles HO, Ph. D. (HFZ-450)

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), Vapotherm, Inc. ("Vapotherm" or the "Company") is submitting the attached premarket notification ("510(k) Notification") for its Precision Flow™ ("Device") for use in adding warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

The Vapotherm Precision Flow™ is a Class II Respiratory Gas Humidifier, Regulatory Class II (two). The device consists of the following components and accessories:

- Main Unit;
- Disposables: Water module, Vapor Transfer Cartridge, Delivery Tube, Cannula; and
- Accessories: Air/Oxygen Hoses, Water Trap, Oxygen Sensor, Power Cord, and Mounting Stand

In addition, the Vapotherm Precision Flow™ is identical to the Vapotherm Models 2000i and 2000h (K000401, K013486, and K042245), which have already been cleared for the treatment of any patient utilizing high flow supplemental air or air/oxygen mixtures in which humidification would be beneficial except for some minor technological differences. The primary changes are the addition of an integrated air/oxygen blender, an integrated oxygen sensor, and a disposable water module.

To conform with the Food and Drug Administration's ("FDA" or the "Agency") August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, the principal factors concerning the design and use of the Precision Flow™ are set forth in the following table of FDA questions.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

As explained in more detail in the attached 510(k) notice, the Precision Flow™ is also substantially equivalent to the Maxtec Oxygen Sensor (K063488), and the Bird Microblender (K911962) that the Food and Drug Administration ("FDA") has already cleared for the treatment of any patient utilizing high flow supplemental air or air/oxygen mixtures in which humidification would be beneficial. Vapotherm, Inc. is the primary application submitter for the Precision Flow™.

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Vapotherm, Inc. has submitted the required application fee of $3,404.00. A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

Vapotherm considers its intent to market the Precision Flow™ as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employers, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in the 510(k) notice is sufficient for FDA to find the Precision Flow™ substantially equivalent to its predicate devices for the listed indication. If you have any additional questions regarding the 510(k) notice, please contact me at the above number or (b)(4). Upon clearance of the device, please fax the substantial equivalence letter to me at (410) 604-3978.

Sincerely,

(b)(6)

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666
410.604.3977 Ext. 109

Attachments

ccs: Jonathan S. Kahan, Partner, Hogan & Hartson LLP
(b)(4), Hogan & Hartson LLP
William Robert Storey, President & CEO, Vapotherm, Inc.

4. INDICATIONS FOR USE STATEMENT

The Company's Indications for Use Statement for the Precision Flow™ is provided in this section of the submission.

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Precision Flow™

Indications for Use:

Precision Flow™ is intended use to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

5. 510(K) SUMMARY

The Company's 510(k) Summary is provided is provided in this section of the submission.

510(k) SUMMARY

Vapotherm, Inc.'s Precision Flow™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

Phone: 410-604-3977
Facsimile: 410-604-3978

Contact Person: Gregory A. Whitney

Date Prepared: October 2, 2007

Name of Device and Name/Address of Sponsor

Precision Flow™

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

A. Common or Usual Name

Humidifier, Respiratory Gas (Direct Patient Interface)

B. Predicate Devices

Vapotherm, Inc.	2000i & 2000h	K000401, K0142245, K042245
Maxtec	Oxygen Sensor	K063488
Bird Products	Air-Oxygen Blender	K911962

C. Intended Use / Indications for Use

The Precision Flow™ is intended to add moisture to and to warm breathing gases from an external source for administration to

neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

D. Technological Characteristics

The Precision Flow™ consists of two parts:

The **main unit** which contains all the electrical and electronic components including the electronic blender and flow controllers. All the sensors are located in the main unit. The main unit has no water pathways and the gas pathway contains only dry gas at room temperature, and consequently does not need internal cleaning or disinfection.

The **disposable components** consist of the disposable water module, vapor transfer cartridge and heated delivery tube. Conditions in the circulating water and gas streams are sensed remotely via the interface between the main unit and the disposable module.

1. Main unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow of each needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

  Firmware running in the main unit uses sensors to monitor gas pressure, water level and water temperature, and to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed. An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

2. Disposable components:

- Vapor Transfer Cartridge. In the cartridge blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses

as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- Triple-lumen Heated Delivery Tube. The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize rain-out. A proprietary short nasal cannula is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- Disposable Module. The module houses a water reservoir, pump, connections for the cartridge and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the Vapor Transfer Cartridge where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the water bag to replace evaporative losses in the Vapor Transfer Cartridge. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

E. Substantial Equivalence

The Precision Flow™ is as safe and effective as the Vapotherm 2000i and 2000h, the Bird Microblender, and the Maxtec Oxygen Sensor. The Precision Flow™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Precision Flow™ and its predicate devices raise no new issues of safety or effectiveness. Performance data will demonstrate that the Precision Flow™ is as safe and effective as the predicate devices. Thus, the Precision Flow™ is substantially equivalent.

6. TRUTHFUL AND ACCURATE STATEMENT

The Company's signed Truthful and Accurate statement is included in this section of the submission.

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 C.F.R. § 807.87(k))

I certify that, in my capacity as President and CEO of Vapotherm, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the Precision Flow™ are truthful and accurate and that no material fact has been omitted.

(b)(6)

(Signature)

William Robert Storey — President and CEO, Vapotherm, Inc.
(Typed Name and Title)

Vapotherm, Inc. — October 2, 2007
(Company) (Date)

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7. PREMARKET NOTIFICATION

CLASS III CERTIFICATION AND SUMMARY

(As Required by 21 CFR § 807.94)

The proposed device, Vapotherm Precision Flow, is not claiming equivalence to a Class III device, therefore the summary and certification is not required.

8. FINANCIAL DISCLOSURES

Vapotherm is not submitting clinical data in support of this 510(k) notice. For this reason, FDA's regulation regarding clinical investigators' financial interests and arrangements, i.e., 21 C.F.R. § 54.4, do not apply. Thus, the Company is not providing a disclosure or certification to the absence of any disclosable financial interests or arrangements.

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

The Company's Declarations of Conformity and Summary Reports are included in this section of the submission.

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

No performance standards or special controls have been developed under Section 514 of the FDC Act for Humidifier, Respiratory Gas (Direct Patient Interface). No special controls apply.

Consistent with FDA's guidance document entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000), Vapotherm has included this statement that the Precision Flow™ will comply with the following recognized consensus standards instead of providing the test reports demonstrating compliance with these standards:

ISO 8185-1; Requirements for Medical Humidifiers with exceptions:

- Section 1: Canister or wick type humidifier not applicable
- No external temperature sensors
- Section 6: Anesthetic mixtures not applicable
- Section 8.1: Water temperature is monitored, not gas temperature
- Section 8.2: Water temperature may deliver gas temperature up to 43° C
- Section 10: Delivery tube not applicable

IEC 60601-1; General Requirements for Safety with exceptions:

- Section 5: Device can not produce hazardous radiation
- Section 6: Anesthetic mixtures not applicable

EN 60601-1-2, Group 1, Class A

IEC60601-1-8, General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

UL 2601-1

CSA 22.2

IEC 529; IPX1 Drip Proof

ISO 9703-1, Anesthesia and respiratory care alarm signals – Part 1: Visual alarm signals

ISO 9703-2, Anesthesia and respiratory care alarm signals – Part 2: Auditory alarm signals

ISO 11195, Gas Mixers for Medical Use

ISTA-2A, Ship testing protocol for devices under 150 lbs

VOC TO-15 Volatile Organic Compounds and Particulate Matter PM 2.5

These standards have not been adapted for application to the Precision Flow™. The device that will be tested and the subject of the 510(k) is the Precision Flow™. (b)(4)
(b)(4)
(b)(4) a fully accredited test laboratory, specializing in electrical product safety testing, EMC testing, and benchmark performance testing. Intertek will determine that the Precision Flow™ conforms to the standards. This testing laboratory has the following accreditations:

The Americas		
Organization	**Accreditation Scope**	**Accreditation Criteria**
American Association of Laboratory Accreditation (A2LA)	Accreditation for automotive, building materials, EMC, telecommunications and thermal testing *A2LA testing scopes are site specific; for further details contact A2LA or the Intertek facility.*	ISO/IEC 17025
American National Standards Institute (ANSI)	Accreditation of the ETL Listed and Warnock Hersey certification programs and FCC Telecommunications Body	ISO/IEC Guide 65
Federal Communications Commission (FCC)	Recognition as a TCB to FCC requirements	
Industry Canada	Acceptance as a testing lab for EMI and terminal equipment testing	
International Accreditation Service (IAS) formerly ICBO-ES & National Evaluation Service	Recognition by the International Code Council (formerly BOCA, ICBO &SBCCI) for testing and certification of building materials and gas fueled appliances	Acceptance Criteria 89 supporting ISO/IEC 17025 and Acceptance Criteria 98 supporting ISO/IEC 17020
International Electrotechnical Commission of Electrical Equipment (IECEE)	Approval in the CB Scheme as a National Certification Body and Certification Body Testing Laboratory in the categories of household and similar equipment, electrical equipment for medical use, electronics/entertainment, IT and office equipment and measuring instruments	ISO/IEC Guide 65, ISO/IEC 17025
National Institute of Standards and Technologies (NIST)	US-EU designated Conformity Assessment Body for Telecom & EMC Directives	ISO/IEC 17025
National Voluntary Laboratory Accreditation Program (NVLAP)	Accreditation of Intertek laboratory for Photometry, MIL specifications and Acoustical. NVLAP Lab Code: 100402-0 *NVLAP testing scopes are site specific; for further details contact NVLAP or the Intertek facility.*	ISO/IEC 17025
Occupational Health and Safety Administration (OSHA) Nationally Recognized Testing Laboratory (NRTL)	Recognition of the ETL Listed and Warnock Hersey certification programs	29 CFR 1910.7

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Standards Council of Canada (SCC)	Accreditation as a Testing Organization and Certification Body for electrical appliances, gas-fueled appliances and building materials under the ETL Listing and Warnock Hersey Certification Programs.	ISO/IEC Guide 65, ISO/IEC 17025

Europe

Organization	Accreditation Scope	Accreditation Criteria
International Electrotechnical Commission of Electrical Equipment (IECEE)	Approval in the CB Scheme as a National Certification Body and Certification Body Testing Laboratory in the categories of household and similar equipment, electrical equipment for medical use, electronics/entertainment, IT and office equipment and measuring instruments	ISO/IEC Guide 65, ISO/IEC 17025
SWEDAC	Notified Body for testing to requirements of Low Voltage, EMC, Medical Devices, Machinery and R&TTE Directives	EN 45001, 45011
Department of Trade and Industry; Medicines and Healthcare Products Regulatory Agency (Medical Devices Directive); Department for Environment, Food and Rural Affairs (Boiler Directive) United Kingdom Accreditation Service (UKAS)	Notified/Competent Body for EMC, Low Voltage, Medical Devices, Boiler, Plugs and Sockets, Gas, Toys, Machinery and R&TTE, PED, TPED, and ATEX Directives Accredited Independent Inspection Authority	EN 45001, 45011, NACCB; AU/2/23 ISO/IEC 17020
Zentralstelle der Lander fur Sicherheit (ZLS)	Notified/Competent Body for EMC, Low Voltage, Medical Devices, Toys and Machinery Directives	ISO/IEC 17025, EN 45011

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Declaration of Conformity

The Vapotherm Precision Flow™ will conform to the following areas prior to offering the device to the US market.

1. Vapotherm will demonstrate that the Precision Flow™ conforms to the relevant requirements of the Volatile Organic Compounds and Particulate Matter PM 2.5 Test Methods.

2. Vapotherm will demonstrate that the Precision Flow™ conforms to the relevant requirements of the electromagnetic compatibility and mechanical/environmental testing recommendations as listed above.

3. Vapotherm will demonstrate that the Precision Flow™ conforms to the correction of the software anomalies as listed in submission section 16, Software.

4. Vapotherm will demonstrate (1) that the Precision Flow™ conforms to the initial bioburden of the disposable water path and (2) how the new pathway will perform in comparison to a cleared humidifier with regards to the growth of organisms when water is added to the system for an extended period of time. The protocols for the tests are found in submission section 18, Performance Testing.

(b)(6)

William Robert Storey
President and CEO
Vapotherm, Inc.

10/4/07
Date

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10. EXECUTIVE SUMMARY

The Company's Executive Summary is provided in this section.

Executive Summary

The following is a concise summary of the submission. Additional details are provided in the appropriate sections.

DEVICE DESCRIPTION

Precision Flow™'s intended use/indications for use, technological characteristics, and principles of operation are described below.

A. Intended Use/Indications for Use

Precision Flow™ is indicated for use in adding warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

B. Technological Characteristics

The Precision Flow is comprised of several components. As compared to the cleared Vapotherm 2000 devices (K000401, K013486, and K042245), the Precision Flow has the following major components that are either new or modified:

- A disposable water path module;
- An integrated air/oxygen blender; and
- An integrated oxygen sensor.

The new device features a disposable Vapor Transfer Cartridge ("VTC"), which is essentially identical to the existing component on the company's cleared devices. The only minor difference is the modification of the VTC to add right angle end connections. In addition, the main unit of the Precision Flow has been designed in order to accommodate the modified components. This main unit monitors the activities of the disposable water path module by use of non-contact sensors and contains a motor to drive the fluid flow.

The details of each of the major modifications to the Vapotherm 2000 devices are as follows:

1. Disposable Water Path Module

The most significant modification is the newly designed disposable water path module, which has been designed so that the entire assembly, including the module, VTC, tubing, and connector is designed for use with a single patient only for up to 30 days of treatment. This design replaces the humidification/water pathway used in the Vapotherm 2000i and 2000h which featured internal components that required disinfection. The Precision Flow disposable water path module incorporates all the necessary elements to isolate the water pathway from the main unit and is composed of the following subcomponents:

- A water tank;
- A heater transfer plate (the heating element is part of the main unit);
- A water circulating impellor (the motor stator is part of the main unit and turns the impellor magnetically);
- An air venting diaphragm;
- Non-contact monitoring sensor interfaces;
- A separately attached disposable VTC (which is essentially identical to the comparable component on the company's cleared devices); and
- A separately attached disposable water delivery tube.

The disposable water path has a number of features that minimize the potential for contamination. Initially, the path itself is manufactured in clean conditions and is intended for use with a single patient, eliminating the potential for cross-contamination. The water from the sterile waterbag enters the disposable water path module water tank, flows through the pump impellor and the VTC, through the delivery tube to the patient and completes the closed circuit back to the water tank.

At no time does the sterile water that feeds the system come into contact with the air pathway that is contained in the main unit. Furthermore, the disposable water pathway is closed and completely isolated from the main unit. Specifically, there are no

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"hard" connections as sensors from the main unit are not integrated into the disposable water path and the path's impellor is magnetically coupled to the unit's motor.

2. Integrated Blender

Previous models of the Vapotherm device used external independent flow meters and a gas blender to allow the operator to make adjustments to the flow rate and the proportion of oxygen/air mixture delivered. The Precision Flow has an internal gas mixing feature (blender) which provides precise mixing of medical grade air and oxygen via proportional solenoids (mass flow sensors) that measure the oxygen and air flows and solenoids that control the flows. When the clinician sets the desired percent oxygen and the desired flow rate, the mass flow sensors and oxygen analyzer in combination verify that the blender gas mixture is correct and make the required adjustments in proportion of oxygen and air to meet the desired settings. Gas, consisting of oxygen and air, is supplied to the unit from wall, cylinder, or compressor sources. There are standard gas specific DISS gas fittings to assure proper connection to the unit.

3. Integrated Oxygen Sensor

The previously cleared Vapotherm 2000 products verified the composition of the delivered gas mixture with an external oxygen sensor. The Precision Flow contains an oxygen sensor that is identical to a legally marketed device, the Maxtec $MaxO_2$ CU (K063488). This analyzer is located in the main unit and provides the user with a readout of the delivered and supplied oxygen concentration, and the percentage of oxygen thereby eliminating the need for an external analyzer. The analyzer itself is a galvanic, partial pressure sensor that is specific to oxygen. The only purpose of the monitor is to provide information on the delivered gas mixture to the user. The Precision Flow oxygen sensor automatically calibrates to the 100% oxygen source each time the unit is powered up and every 24 hours thereafter.

C. PRINCIPLES OF OPERATION

In actual operation, the Vapotherm Precision Flow warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 0.5 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently. The main unit and

disposable components of this device function as a system to accomplish this intended use as follows:

1. **Main Unit:**

   - The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

   - Sensors in the main unit monitor gas pressure, water level, and water temperature. There are also sensors to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed.

   - An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

2. **Disposable Components:**

   - **Vapor Transfer Cartridge:** In this cartridge, blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

   - **Triple-lumen Heated Delivery Tube:** The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize condensation. A proprietary nasal cannula, also optimized to minimize rainout, is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

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- **Disposable Water Path Module:** The module houses a water reservoir for the water from the sterile water bag, pump, connections for the VTC and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the VTC where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the sterile water bag to replace evaporative losses in the VTC. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

D. COMPARISON TO PREDICATES

In Section 12 we discuss the proposed device and compare it to the predicate devices. Rather than repeat this comparison in the Executive Summary we refer the reviewer to the appropriate sections of this submission.

The Precision Flow™ is substantially equivalent to the predicate devices because:

1. Indications

- Identical to Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)
  - Warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 0.5 to 40 lpm.
- Identical to Bird Air/Oxygen Bender (K911962)
  - Provides precise mixing of medical grade air and oxygen
- Identical to Maxtec Oxygen Sensor (K063488)
  - Verifies the oxygen composition of the delivered air/oxygen gas mixture

2. Technology

- Humidification technology is identical to Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)
- Blender technology similar to Bird Blender (K911962)
- Oxygen analyzer technology identical to Maxtec (K063488)

3. Materials-

The materials in the gas and fluid pathway are identical to the predicate devices as listed in Section 15.

4. Environment of Use

Identical to the Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)

5. Patient Population

Identical to the Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)

6. Differences between the Precision Flow™ and the Predicates

- Separated the internal water path and converted the device to an external disposable single patient module
- Integrated the air/oxygen mixing function from an external device to an internal blender, similar to the Bird Blender (K911962)
- Integrated the oxygen monitoring function from an external in-line oxygen analyzer, similar to the Maxtec (K063488); and
- Added alarms and indicators to be more user friendly

It is our view that there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

7. Summary of Performance Testing

We will perform testing to demonstrate the safety and effectiveness of the Precision Flow™. The tests included testing the device over the range of flow rate, oxygen concentration, gas source pressures, and temperatures.

Conclusions

We believe that based upon the performance testing and comparison to legally marketed predicate devices (for indications for use, technology, and performance) we will demonstrate that the Precision Flow™ is substantially equivalent in safety and effectiveness to the predicate devices.

11. DEVICE DESCRIPTION

The Company's Device Description is included in this section of the submission.

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11. DEVICE DESCRIPTION

Precision Flow™'s intended use/indications for use, technological characteristics, and principles of operation are described below.

A. Intended Use/Indications for Use

Precision Flow™ is indicated for use in adding warm moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

B. Technological Characteristics

The Precision Flow is comprised of several components. As compared to the cleared Vapotherm 2000 devices (K000401, K013486, and K042245), the Precision Flow has the following major components that are either new or modified:

- A disposable water path module;
- An integrated air/oxygen blender; and
- An integrated oxygen sensor.

The new device features a disposable Vapor Transfer Cartridge ("VTC"), which is essentially identical to the existing component on the company's cleared devices. The only minor difference is the modification of the VTC to add right angle connections. In addition, the main unit of the Precision Flow™ has been designed in order to accommodate the modified components. This main unit monitors the activities of the disposable water path module by use of non-contact sensors and contains motors to drive the fluid flow

The details of each of the major modifications to the Vapotherm 2000 devices are as follows:

1. Disposable Water Path Module

The most significant modification is the newly designed disposable water path module, which has been designed so that the entire assembly, including the module, VTC, tubing, and connector is designed for use with a single patient only

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for up to 30 days of treatment. This design replaces the humidification/water pathway used in the Vapotherm 2000i and 2000h which featured internal components that required disinfection. The Precision Flow disposable water path module incorporates all the necessary elements to isolate the water pathway from the main unit and is composed of the following subcomponents:

- A water tank;
- A heater transfer plate (the heating element is part of the main unit);
- A water circulating impellor (the motor stator is part of the main unit and turns the impellor magnetically);
- An air venting diaphragm;
- Non-contact monitoring sensor interfaces;
- A separately attached disposable VTC (which is essentially identical to the comparable component on the company's cleared devices); and
- A separately attached disposable water delivery tube.

The disposable water path has a number of features that minimize the potential for contamination. Initially, the path itself is manufactured in clean conditions and is intended for use with a single patient, eliminating the potential for cross-contamination. The water from the sterile waterbag enters the disposable water path module water tank, flows through the pump impellor and the VTC (a distance of approximately 19.5 inches), through the delivery tube to the patient and completes the closed circuit back to the water tank (7 feet out and 7 feet back).

At no time does the sterile water that feeds the system come into contact with the disposable water path. Furthermore, the disposable water pathway is closed and completely isolated from the main unit. Specifically, there are no "hard" connections as sensors from the main unit are not integrated into the disposable water path and the path's impellor is magnetically coupled to the unit's motor.

2. Integrated Blender

Previous models of the Vapotherm device used external independent flow meters and a gas blender to allow the operator to make adjustments to the flow rate and the proportion of oxygen/air mixture delivered. The Precision Flow™ has an internal gas mixing feature (blender) which provides precise mixing of medical grade air via proportional solenoids (mass flow sensors) that measure the oxygen and air flows and solenoids that control the flows.

When the clinician sets the desired percent oxygen and the desired flow rate, the mass flow sensors and oxygen analyzer in combination verify that the blender gas mixture is correct and make the required adjustments in proportion of oxygen and air to meet the desired settings. Gas, consisting of oxygen and air, is supplied to the unit from wall, cylinder, or compressor sources. There are standard gas specific DISS gas fittings to assure proper connection to the unit.

3. Integrated Oxygen Sensor

The previously cleared Vapotherm 2000 products verified the composition of the delivered gas mixture with an external oxygen sensor. The Precision Flow contains an oxygen sensor that is identical to a legally marketed device, the Maxtec $MaxO_2$ CU (K063488). This analyzer is located in the main unit and provides the user with a readout of the delivered and supplied oxygen concentration, and the percentage of oxygen thereby eliminating the need for an external analyzer. The analyzer itself is a galvanic, partial pressure sensor that is specific to oxygen. The only purpose of the monitor is to provide information on the delivered gas mixture to the user. The Precision Flow oxygen sensor automatically calibrates to the 100% oxygen source each time the unit is powered up and every 24 hours thereafter.

C. PRINCIPLES OF OPERATION

In actual operation, the Vapotherm Precision Flow warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 0.5 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently. The main unit and disposable components of this device function as a system to accomplish this intended use as follows:

1. Main Unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours thereafter.

- Sensors in the main unit monitor gas pressure, water level, and water temperature. There are also sensors to detect air leaks

- into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed.

- An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

2. Disposable Components:

- **Vapor Transfer Cartridge:** In this cartridge, blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- **Triple-lumen Heated Delivery Tube:** The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize condensation. A proprietary nasal cannula, also optimized to minimize rainout, is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- **Disposable Water Path Module:** The module houses a water reservoir for the water from the sterile water bag, pump, connections for the VTC and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the VTC where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the sterile water bag to replace evaporative losses in the VTC. Air is purged to the atmosphere from the circulation via a hydrophobic filter membrane.

D. Precision Flow™ System Requirements

The Precision Flow™ System Requirements document is provided following this page.

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Vapotherm Precision Flow ™ Hyperthermic Humidification System System Requirements Specification

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666

DOCUMENT NAME:	Vapotherm Precision Flow ™ System Requirements
REVISION:	New
REVISION DATE:	August 1, 2007

1CC1

ABSTRACT AND AUTHORIZATION

Abstract:

(b)(4)

REVISION HISTORY

(b)(4)

LIST OF ITEMS "TO BE DECIDED / TO BE RESOLVED" (TBD/TBR)

(b)(4)

1. Introduction

(b)(4)

2. Intended Use

Precision Flow™ is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

3. Purpose

(b)(4)

4. Scope

(b)(4)

5. Audience

(b)(4)

6. Definitions

(b)(4)

7. References

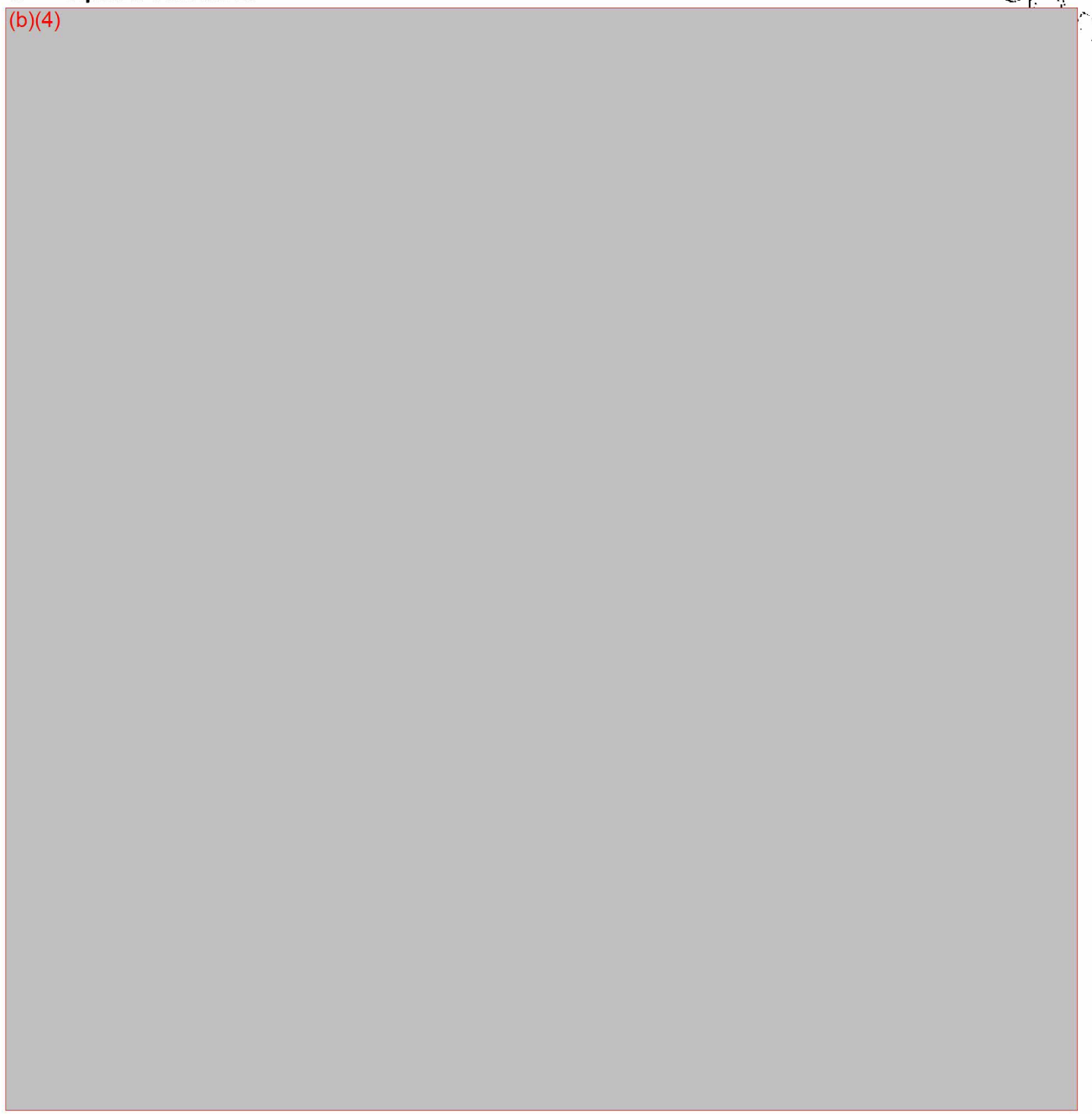
(b)(4)

8. Compliance Notation

(b)(4)

9. **Required Standards**

(b)(4)



10. Physical/Mechanical Characteristics

(b)(4)

11. Electrical Characteristics

(b)(4)

12. Operation and Performance

(b)(4)

13. User Interface

(b)(4)

14. Device Alarms and Cautions

(b)(4)

15. Environmental Criteria

(b)(4)

16. Labeling

(b)(4)

17. Reliability/Serviceability

(b)(4)

12. SUBSTANTIAL EQUIVALENCE

The Company's Substantial Equivalence to predicate devices is provided in this section.

12. SUBSTANTIAL EQUIVALENCE

As explained in detail below, the Precision Flow™ is substantially equivalent to other legally marketed Respiratory Gas Humidifiers, Air/Oxygen Blenders, and Oxygen Analyzers. Specifically, the Precision Flow™ is substantially equivalent to the Vapotherm 2000i and 2000h, the Bird Blender, and the Maxtec Oxygen Analyzer. As explained in more detail below, the Precision Flow™ has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate devices. A substantial equivalence chart comparing the similarities and differences between the Precision Flow™ and its predicate devices is provided below. Labeling and promotional material for the predicate devices is provided below. As also explained in more detail below, minor differences in the technological characteristics between the Precision Flow™ and the identified predicate devices do not raise new questions of safety or efficacy.

1. Intended Use/ Indications for Use

The Precision Flow™ is indicated for use in adding warm moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

The Vapotherm 2000i and 2000h are indicated for use in adding warm moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. The Bird Microblender is intended to provide a precise method of mixing medical grade air and oxygen to a pre-selected oxygen concentration. The Maxtec Oxygen Sensor is intended to verify the composition of oxygen in an air/oxygen mixture.

In other words, the Precision Flow™ has the same intended use as its predicate devices. Thus, the Precision Flow™ satisfies the first criteria for a finding of substantial equivalence.

2. Technological Characteristics

The Precision Flow is comprised of several components. As compared to the cleared Vapotherm 2000 devices (K000401, K013486, K042245), the Precision Flow has the following major components that are either new or modified:

- A disposable water path module;
- An integrated air/oxygen blender; and
- An integrated oxygen sensor.

The new device features a disposable Vapor Transfer Cartridge ("VTC"), which is essentially identical to the existing component on the company's cleared devices. The only minor difference is the modification of the VTC to add right angle end connections. In addition, the main unit of the Precision Flow has been designed in order to accommodate the modified components. This main unit monitors the activities of the disposable water path module by use of non-contact sensors and contains a motor to drive the fluid flow.

The details of each of the major modifications to the Vapotherm 2000 devices are as follows:

A. Disposable Water Path Module

The most significant modification is the newly designed disposable water path module, which has been designed so that the entire assembly, including the module, VTC, tubing, and connector is designed for use with a single patient only for up to 30 days of treatment. This design replaces the humidification/water pathway used in the Vapotherm 2000i and 2000h which featured internal components that required disinfection. The Precision Flow disposable water path module incorporates all the necessary elements to isolate the water pathway from the main unit and is composed of the following subcomponents:

- A water tank;
- A heater transfer plate (the heating element is part of the main unit);
- A water circulating impellor (the motor stator is part of the main unit and turns the impellor magnetically);

- An air venting diaphragm;
- Non-contact monitoring sensor interfaces;
- A separately attached disposable VTC (which is essentially identical to the comparable component on the company's cleared devices); and
- A separately attached disposable water delivery tube.

The disposable water path has a number of features that minimize the potential for contamination. Initially, the path itself is manufactured in clean conditions and is intended for use with a single patient, eliminating the potential for cross-contamination. The water from the sterile waterbag enters the disposable water path module water tank, flows through the pump impellor and the VTC, through the delivery tube to the patient and completes the closed circuit back to the water tank.

At no time does the sterile water that feeds the system come into contact with the air pathway that is contained in the main unit. Furthermore, the disposable water pathway is closed and completely isolated from the main unit. Specifically, there are no "hard" connections as sensors from the main unit are not integrated into the disposable water path and the path's impellor is magnetically coupled to the unit's motor.

B. Integrated Blender

Previous models of the Vapotherm device used external independent flow meters and a gas blender to allow the operator to make adjustments to the flow rate and the proportion of oxygen/air mixture delivered. The Precision Flow has an internal gas mixing feature (blender) which provides precise mixing of medical grade air and oxygen via proportional solenoids (mass flow sensors) that measure the oxygen and air flows and solenoids that control the flows. When the clinician sets the desired percent oxygen and the desired flow rate, the mass flow sensors and oxygen analyzer in combination verify that the blender gas mixture is correct and make the required adjustments in proportion of oxygen and air to meet the desired settings. Gas, consisting of oxygen and air, is supplied to the unit from wall, cylinder, or compressor sources. There are standard gas specific DISS gas fittings to assure proper connection to the unit.

C. Integrated Oxygen Sensor

The previously cleared Vapotherm 2000 products verified the composition of the delivered gas mixture with an external oxygen sensor. The Precision Flow contains an oxygen sensor that is identical to a legally marketed device, the $MaxO_2$ CU (K063488). The oxygen sensor is procured from the Maxtec Company. This analyzer is located in the main unit and provides the user with a readout of the delivered and supplied oxygen concentration, and the percentage of oxygen thereby eliminating the need for an external analyzer. The analyzer itself is a galvanic, partial pressure sensor that is specific to oxygen. The only purpose of the monitor is to provide information on the delivered gas mixture to the user. The Precision Flow oxygen sensor automatically calibrates to the 100% oxygen source each time the unit is powered up and every 24 hours thereafter.

3. Principles of Operation:

In actual operation, the Vapotherm Precision Flow warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 0.5 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently. The main unit and disposable components of this device function as a system to accomplish this intended use as follows:

A. Main Unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

- Sensors in the main unit monitor gas pressure, water level, and water temperature. There are also sensors to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed.

- An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

B. Disposable Components:

- **Vapor Transfer Cartridge:** In this cartridge, blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- **Triple-lumen Heated Delivery Tube:** The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize condensation. A proprietary nasal cannula, also optimized to minimize rainout, is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- **Disposable Water Path Module:** The module houses a water reservoir for the water from the sterile water bag, pump, connections for the VTC and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the VTC where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the sterile water bag to replace evaporative losses in the VTC. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

4. Conclusion

The Precision Flow™ and the Vapotherm 2000i and 2000h, Bird Microblender, and Maxtec Oxygen Sensor have the same intended use and similar indications, technological characteristics and principles of operation. The only technological differences between the Precision Flow™ and its Vapotherm predicates are: (1) an integrated air/oxygen blender; (2) an integrated oxygen sensor; and (3) a

disposable water module. However, the oxygen sensor included in the Precision Flow™ is procured from Maxtec and cleared under K063488. In addition, the air/oxygen blender contained in the Precision Flow™ is similar to the Bird Blender cleared under K911962. No differences between the Precision Flow™ and the identified predicate devices present any new issues of safety or effectiveness. Thus, the Precision Flow™ is substantially equivalent to the Vapotherm 2000i and 2000h, the Bird Microblender, and the Maxtec Oxygen Sensor.

5. Substantial Equivalence Chart

Item	Precision Flow™	Vapotherm™ 2000i and 2000h (K000401, K013486 K042246)	Maxtec Oxygen Analyzer MaxO$_2$ CU (K083488)	Bird Air-Oxygen Blender (K911962)
Product Code	BTT; Respiratory Gas Humidifier BZR; Breathing Gas Mixer	BTT; BTI; Respiratory Gas Humidifier BZR; Breathing Gas Mixer	CCL; BZR; Breathing Gas Oxygen Sensor	BZR; Breathing Gas Mixer
Environment	Hospital or sub-acute institutional settings	Home, hospital or sub-acute institutional settings	Institutional environments where delivery of air/oxygen is required	Institutional environments where delivery of air/oxygen is required
Principles of Operation	Basic membrane type humidifier, hollow fiber cartridge	Basic membrane type humidifier, hollow fiber cartridge	Senses the amount of oxygen present in a mixture of gases	A proportion blending of air and oxygen
Intended Use/ Indications for Use	The Precision Flow™ is intended to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.	The Vapotherm 2000i and 2000h are designed to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. The flow rates may be from 1 to 40 ;liters per minute via nasal cannula.	For continuous monitoring of oxygen levels delivered by medical oxygen delivery equipment & respiratory care	Designed to dispense continuous and precise blend of medical air and oxygen via outlet ports to infant, pediatric, and adult patients. The exact $Fi0_2$ blend of gases corresponds to the dialed in Fractional Concentration of Oxygen setting indicated by the control face.
Components	The device includes: a water pump, and electronic temperature control system, a digital display, a cannula to administer gas to the patient, and a spike to connect to a sealed water bag and an electronic gas blender, and an oxygen sensor.	The device includes: a water pump, and electronic temperature control system, a digital display, a cannula to administer gas to the patient, and a spike to connect to a sealed water bag.	Fast responding, oxygen specific, galvanic sensor	The device includes a balance module, proportioning module, alarm/bypass, outlet ports, and bleed outlet.

Item	PRECISION FLOW™	Vapotherm™ 2000h and 2000i (K000401; K013486 K042245)	Maxtec Oxygen Analyzer MaxO$_2$ CU (K063488)	Bird Microblender (K911962)
Water and gas pathway of Humidifier cartridges	Entirely disposable, removable module, external to unit. No disinfection required.	Partly internal to unit, partly disposable. Internal portion requires disinfection after use. Multiple components and connections.	Not applicable	Not Applicable
Dimensions (l x w x h)	Height: 11.5" (300 mm); width: 8" (2000 mm); depth: 7" (180 mm) excluding IV pole clamp	Height: 11" (280 mm); width: 5.5" (140 mm); depth: 4.5" (114 mm) excluding IV pole clamp	H 3 ½ x W 2 ¼ x D 1 ½ inches	H 3 ½ x W 2 ¼ x D 3 5/8 to 4 ½ inches
Supply Pressure	Medical air and oxygen at inlet pressures between 6 and 70 psi (41-485 KPa)	Medical air and oxygen at inlet pressures between 6 and 70 psi (41-485 KPa)	Not Applicable	30-75 PSIG provided the differential between supply pressures does not exceed 10 PSIG
Max Flow	1-8 lpm via a nasal cannula (Low Flow) 5-40 lpm via a nasal cannula (High Flow)	1-8 lpm via a nasal cannula (Low Flow) 5-40 lpm via a nasal cannula (High Flow)	Not Applicable	≥ 120 lpm @ 60% setting at 50 psig inlet pressures (High Flow)
Humidification	Vapor phase, by transpiration through microporous membrane. Output is at least 95% relative humidity at nasal cannula at a flow rate up to 20 lpm, at least 90% at flow rates from 20-40 lpm, over the full range of operating conditions.	Vapor phase, by transpiration through microporous membrane. Output is at least 95% relative humidity at nasal cannula at a flow rate up to 20 lpm, at least 90% at flow rates from 20-40 lpm, over the full range of operating conditions.	Not Applicable	Not Applicable

13. LABELING

The labeling of the Precision Flow™, including the device's labels, its Operator's Manual and draft promotional materials and the labeling for predicate devices is included in the following section.

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13. LABELING OPERATOR'S MANUAL FOR PRECISION FLOW™

TABLE OF CONTENTS

a. Precision Flow™ Packaging and Labeling

b. Precision Flow™ Operator's manual

c. Precision Flow™ Promotional materials

d. Labeling for Predicate Devices

1. **Vapotherm 2000i**
2. **Bird Microblender**
3. **Maxtec Oxygen Sensor**

a. PRECISION FLOW™ PACKAGING AND LABELING

VAPOTHERM

PRECISION FLOW™ PACKAGING AND LABELING

TABLE OF CONTENTS

1685

10. MI1300 – Nasal Cannula (Infant)
    a. Individual Label
    b. Box Label

11. MI1300B – Nasal Cannula (Intermediate Infant)
    a. Individual Label
    b. Box Label

12. MA1700 – Nasal Cannula (Adult)
    a. Individual Label
    b. Box Label

VAPOTHERM DRAFT

PRECISION FLOW™ – *UNIT & BOX SERIAL LABEL - DRAFT*

August 24, 2007

Description:

The Vapotherm Precision Flow™ Label follows. The serialized label for the device is to be applied to the back of the Precision Flow™ device and is to be located in the upper left hand corner. Every device label is to have one matching box serialized label.

Specification:

The Precision Flow™ Unit label is 2.5 inches by 3.0 inches in overall size. The label is to be printed Black on 2 millimeter white polyester with permanent adhesive backing, with a 1 millimeter clear gloss over-lamination.

2-1/2"

3"

1687

DRAFT

MATCHING BOX LABEL:

The Precision Flow™ Box label is 2.5 inches by 1.0 inches in overall size. The box label serial number is to match the unit serial number. The label is to be printed Black on 2 millimeter white polyester with permanent adhesive backing, with a 1 millimeter clear gloss over-lamination.. The label is to be applied to the outside of the device box, centered in the area on the shortest measured box side.

Packaging:
Labels are to be packaged or bound to prevent damage during shipment. A packing list is to accompany the shipment to reflect Vapotherm's purchase order.

Labeling:
See drawing above for required labeling.

1632

VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(BOX LABEL)

DRAFT

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
[illegible] Canoe Circle
[illegible]ille, MD 21666 USA
[illegible]-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(BOX LABEL)

VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. XX

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(BOX LABEL)

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VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. XX

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Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
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Authorized Representative
RMS-UK, Ltd.
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PF-VTC-Low Rev New

(BOX LABEL)

1690

VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. 1

CE 0297 ⊘ ⚠

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. XX

CE 0297 ⊘ ⚠

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(BOX LABEL)

DRAFT

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. 1

CE 0297 ⊘ ⚠

PENDING

Vapotherm, Inc.
[illegible] Canoe Circle
[illegible]lle, MD 21666 USA
[illegible]3977

Authorized Representative
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28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. XX

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Vapotherm, Inc.
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PF-VTC-Low Rev New

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VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

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PF-VTC-High Rev. New

(INDIVIDUAL LABEL)

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England

PF-VTC-High Rev. New

(BOX LABEL)

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VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
[illegible] Canoe Circle
[illegible]lle, MD 21666 USA
[illegible]-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. XX

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(BOX LABEL)

1692

DRAFT

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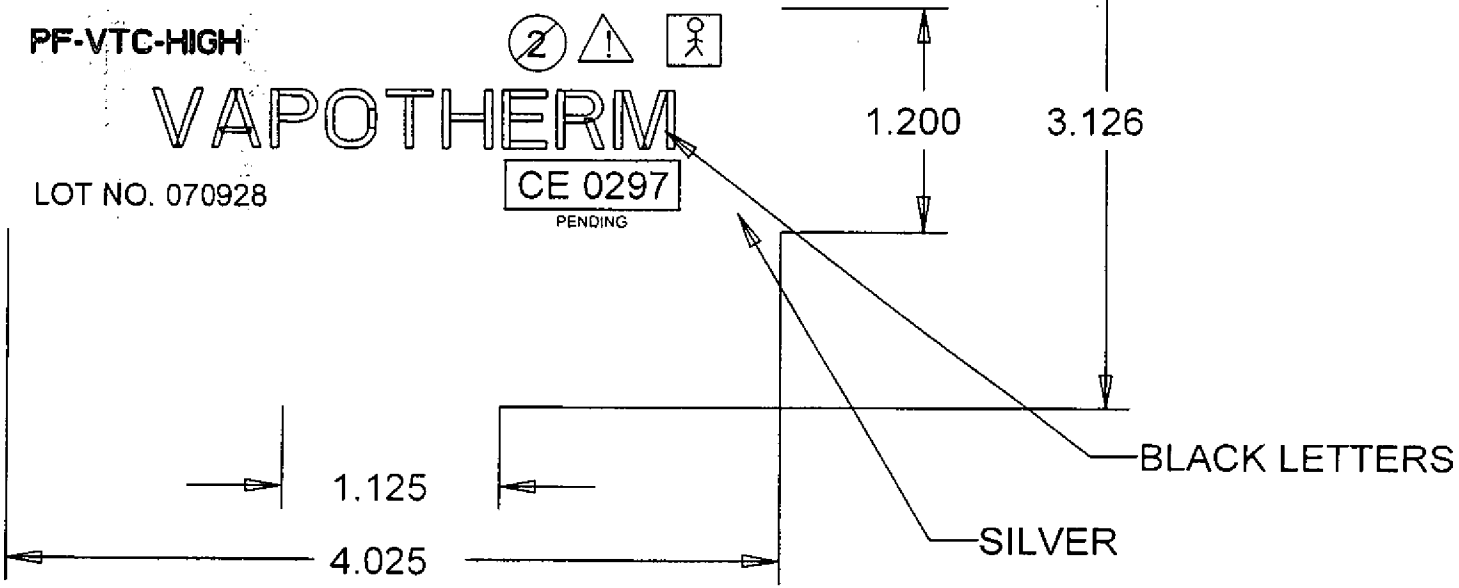

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.XX = ±0.01 ANGLES = ±0.5°
.XXX = ±0.005 DRAFT = ±0.5°

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FILLET AND CORNER RADII: 0.031
DIMENSIONS IN INCHES
DO NOT SCALE DRAWING

ALL DIMENSIONS AFTER FINISH

MATERIAL: MYLAR

FINISH:
COLOR: SILVER/BLACK
TOOL:

DRAWN	DATE
GM	09-10-07
APPROVED BY	DATE

Vapotherm
198 Log Canoe Circle
Stevensville, MD 21666
www.vtherm.com 410-604-3977

TITLE

PF VTC HIGH LABEL

SIZE	DWG. NO.	REV
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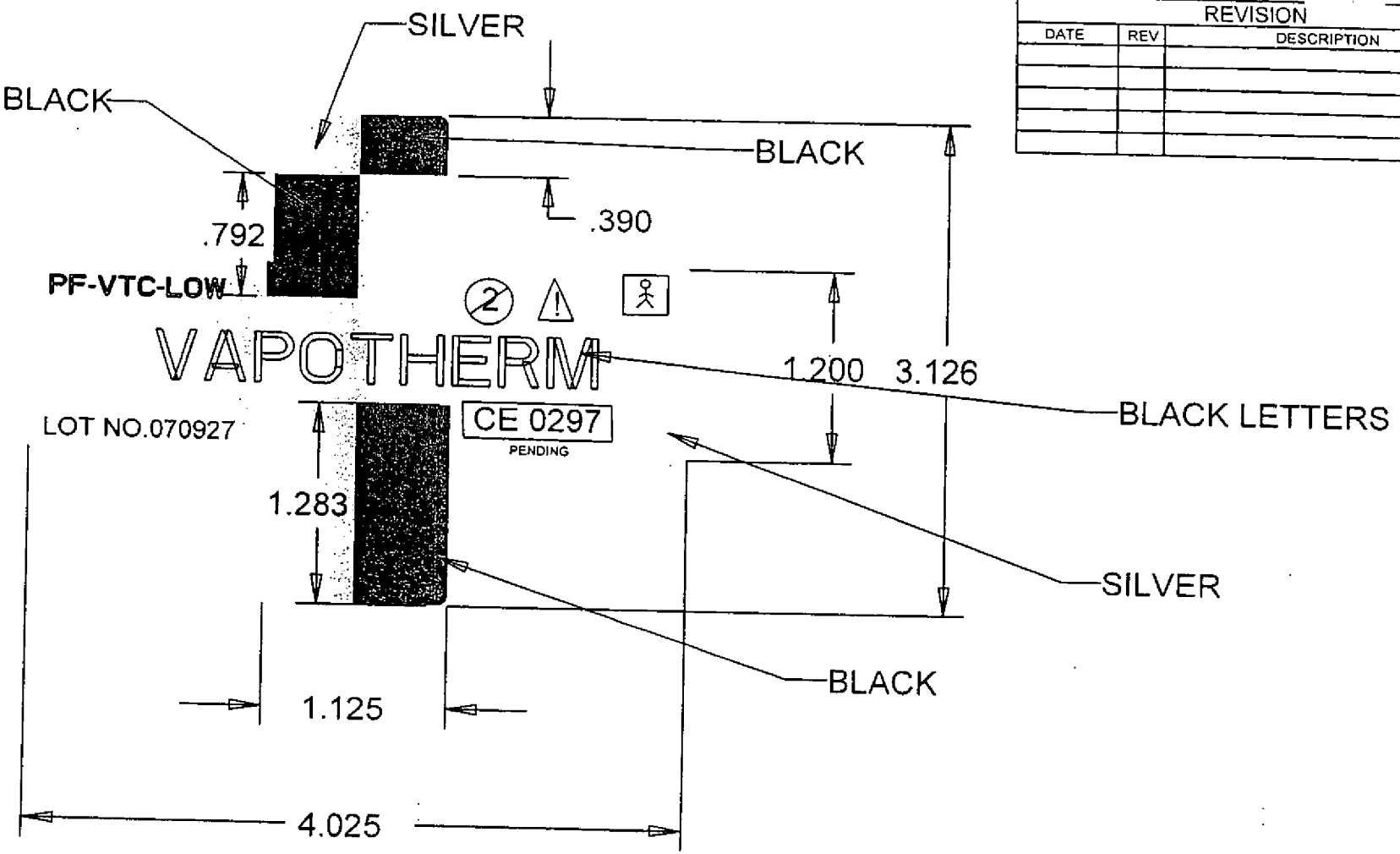
DRAFT



REVISION		
DATE	REV	DESCRIPTION

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UNLESS OTHERWISE SPECIFIED

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.XX = ±0.01 ANGLES = ±0.5 °
.XXX = ±0.005 DRAFT = ±0.5 °

BREAK ALL SHARP EDGES: 0.031
FILLET AND CORNER RADII: 0.031
DIMENSIONS IN INCHES
DO NOT SCALE DRAWING

ALL DIMENSIONS AFTER FINISH

MATERIAL: MYLAR

FINISH:
COLOR: SILVER/BLACK
TOOL:

DRAWN	DATE
GM	09-10-07
APPROVED BY	DATE

Vapotherm
198 Log Canoe Circle
Stevensville, MD 21666
www.vtherm.com 410-604-3977

TITLE

PF VTC LOW LABEL

SIZE	DWG. NO.	REV
A	3010150	1
SCALE 1.000	SHEET 1 OF 1	

DRAFT

VAPOTHERM®

REF. PF- DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-DPC Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. XX

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
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England

PF-DPC Rev. New

(BOX LABEL)

1695

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VAPOTHERM®

REF. PF- DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-DPC Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-DPC Rev. New

(BOX LABEL)

1696

VAPOTHERM®

REF. PF-UKIT-"COUNTRY"

(O2 Sensor, bubble traps, hoses, power cord per country , User Manual, User Guide Guide)

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-UKIT-"COUNTRY" Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

DRAFT

REF. PF-UKIT-"COUNTRY"

(O2 Sensor, bubble traps, hoses, power cord per country , User Manual, User Guide Guide)

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-UKIT-"COUNTRY" Rev. New

(BOX LABEL)

VAPOTHERM®

REF. PF-UKIT-"COUNTRY"
(O2 Sensor, bubble traps, hoses, power cord per country , User Manual, User Guide Guide)

LOT XXXXXXX

QTY. 1

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LOT XXXXXXX

QTY. XX

CE 0297

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198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
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PF-UKIT-"COUNTRY" Rev. New

(BOX LABEL)

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT QTY 1

CE 0297

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England 802361 Rev. D

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT QTY 1

CE 0297

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410-604-3977
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VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT QTY 1

CE 0297

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Stevensville, MD 21666
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Made in U.S.A

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VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT QTY 1

CE 0297

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198 Log Canoe Circle
Stevensville, MD 21666
410-604-3977
Made in U.S.A

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28 Trinity Road, Nailsea, Somerset, BS484NU England 802361 Rev. D

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT QTY 1

CE 0297

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Stevensville, MD 21666
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Trinity Road, Nailsea, Somerset, BS484NU England 802361 Rev. D

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT QTY 1

CE 0297

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Stevensville, MD 21666
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VAPOTHERM®

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REF MN1100A
Nasal Cannula (Premature)

Qty 25

LOT

CE 0297

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410-604-3977
Made in U.S.A

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RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

852361 Rev. E

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

Qty 25

LOT

CE 0297

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

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RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

852361 Rev. E

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

Qty 25

LOT

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

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852361 Rev. E

1700

VAPOTHERM®

REF MN1100B
Nasal Cannula (Neonate)

LOT

QTY 1

CE 0297

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

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VAPOTHERM®

REF MN1100B
Nasal Cannula (Neonate)

LOT

QTY 1

CE 0297

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VAPOTHERM®

REF MN1100B
Nasal Cannula (Neonate)

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VAPOTHERM®

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Nasal Cannula (Neonate)

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REF **MN1100B**
Nasal Cannula (Neonate)

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VAPOTHERM®

REF **MN1100B**
Nasal Cannula (Neonate)

Qty 25

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VAPOTHERM®

REF **MN1100B**
Nasal Cannula (Neonate)

Qty 25

LOT

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852362 Rev. E

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VAPOTHERM®

REF MP1500
Nasal Cannula (Pediatric)

QTY 1

LOT

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QTY 1

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VAPOTHERM®

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Nasal Cannula (Pediatric)

QTY 1

LOT

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Nasal Cannula (Pediatric)

QTY 1

LOT

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Qty 25

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VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

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Made in U.S.A

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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

CE 0297

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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

CE 0297

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VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

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802360 Rev. D

VAPOTHERM®

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Nasal Cannula (Infant) QTY 1

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Nasal Cannula (Infant)

QTY 25

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410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

852360 Rev. E

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant)

QTY 25

LOT

CE 0297

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Made in U.S.A

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VAPOTHERM®

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QTY 25

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VAPOTHERM®

REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

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REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

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Made in U.S.A

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VAPOTHERM®

REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

LOT

CE 0297

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VAPOTHERM®

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Nasal Cannula
(Intermediate Infant) QTY 1

LOT

CE 0297

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410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
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Nasal Cannula
(Intermediate Infant) QTY 1

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Nasal Cannula (Intermediate Infant)

Qty 25

LOT

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Made in U.S.A

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VAPOTHERM®

REF MI1300B
Nasal Cannula (Intermediate Infant)

Qty 25

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Stevensville, MD 21666
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Authorized Representative For The European Union:
RMS UK, Ltd.
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VAPOTHERM®

REF MI1300B
Nasal Cannula (Intermediate Infant)

Qty 25

LOT

CE 0297

Manufactured For:
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Made in U.S.A

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853025 Rev. B

1708

REF MA1700 VAPOTHERM
QTY 1
OT XXXXX
ult Nasal Cannula

CE 0297

Manufactured for:
Vapotherm Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 VAPOTHERM
QTY 1
LOT XXXXX
Adult Nasal Cannula

COPY

CE 0297

Manufactured for:
Vapotherm Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 VAPOTHERM
QTY 1
LOT XXXXX
Adult Nasal Cannula

CE 0297

Manufactured for:
Vapotherm Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 VAPOTHERM
QTY 1
LOT XXXXX
Adult Nasal Cannula

CE 0297

Manufactured for:
Vapotherm Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 VAPOTHERM
QTY 1
LOT XXXXX
Adult Nasal Cannula

CE 0297

Manufactured for:
herm Inc.
g Canoe Circle
ensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
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Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 VAPOTHERM
QTY 1
LOT XXXXX
Adult Nasal Cannula

CE 0297

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Stevensville, MD 21666 USA
Ph: (410) 604-3977

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Label PN 71280, Rev. 05

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Manufactured for:

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Ph: (410) 604-3977

Authorized Representative:
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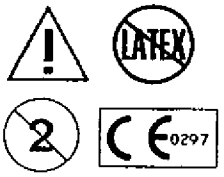
28 Trinity Rd., Nailsea,
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX



LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

Manufactured for:

VAPOTHERM

198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX

LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

Manufactured for:

VAPOTHERM

198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX

LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

Manufactured for:

VAPOTHERM

198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
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28 Trinity Rd., Nailsea,
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX

LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

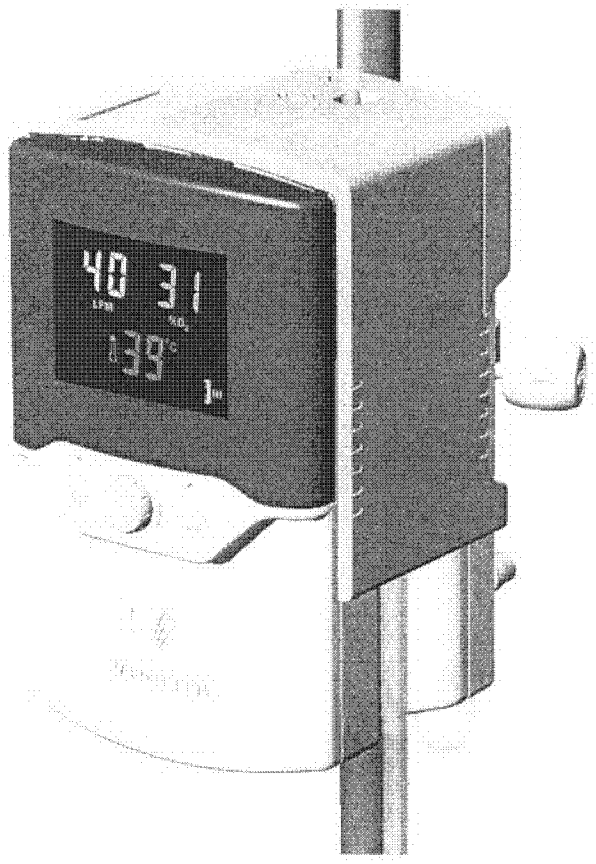
1710

b. PRECISION FLOW™ OPERATOR'S MANUAL

VAPOTHERM®

Precision Flow™

Operator's manual



h12

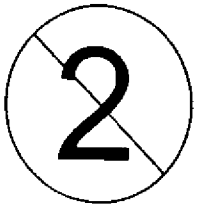
Symbols

Attention: consult manual

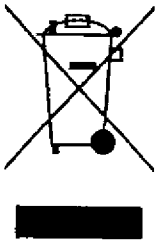
Alternating current

Mute alarms

Run/stop



Single patient use



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1. Indications, Warnings and Cautions:

General Indications & Contraindications.

Primary Indications:

Used to warm and humidify breathing gases, generally prescribed during oxygen therapy where concentrations of oxygen greater than ambient air are utilized to treat symptoms and manifestations of hypoxia

Contraindications:

General:

Any situations in which humidification is contra-indicated (see AARC Clinical Practice Guidelines).

Specific to Nasal Cannula:

Patients with occluded or defective nares should not use the system.

Warnings and Cautions.

A **Warning** indicates that a situation may occur which is potentially harmful to the patient or user.
A **Caution** indicates a condition that may lead to equipment damage, malfunction, or inaccurate operation.
A **Note** indicates a point of emphasis to make operation more efficient or convenient.

Please take the time to familiarize yourself with the warnings, cautions, and notes listed in this manual. They cover safety considerations, special requirements, and regulations.

The user of this product shall have sole responsibility for any malfunction due to operation or maintenance performed by anyone not trained by Vapotherm staff or official training documentation.

When handling any part of the Precision Flow™, always follow hospital infection control guidelines and Standard Precautions. Vapotherm also recommends that users follow the Centers for Disease Control (CDC) publications: *Guidelines for Maintenance of In-Use Respiratory Therapy Equipment* and *Guidelines for Prevention of Nosocomial Pneumonia.*

General warnings:

1. Federal Law (U.S.) restricts the sale of this device to, or by the order of any physician.
2. This device should be used ONLY by a trained operator.
3. This is a humidification device generally used for providing continuous flows of breathing gas. **The Precision Flow™ is not a ventilatory device and should not be used as life support.**
4. Oxygen supports combustion; this device should not be used near or around open flames, oil, or grease, or flammables.
5. Service on the device should only be performed by qualified, certified service technicians.
6. To prevent injury, do not attempt to do any service to the Precision Flow™ while a patient is connected to the device.
7. If the device is damaged or not working properly do not use. Contact Vapotherm or your authorized Vapotherm representative.
8. Do not operate if power cord is damaged.

9. The device should not be turned on and left unattended.
10. Do not use the Precision Flow™ in or around water other than the water bag that feeds the system.
11. Prior to use, machine should be positioned and secured to a sturdy IV pole.
12. Make sure all Patient Delivery Tube connections have been properly secured.
13. The cartridge, disposable module and delivery tube are labeled as **single patient use** only: do not attempt to sterilize or reuse and follow all local and federal regulations for disposal.
14. Failure to utilize sterile water supply or clean gas supply may increase risk of bacterial contamination.
    - The Precision Flow™ utilizes warmed water and can pose a risk for colonization of bacteria and patient infection if proper aseptic technique is not followed.
    - Gas supply is external to the Precision Flow™, but the care giver should confirm the integrity of all respiratory gases utilized to ensure they are free of contamination. Gas supply must be made of clean dry medical grade gas to prevent harm to the patient and prevent damage to the Precision Flow™.
15. To reduce any potential transmission of contaminated water from the system, all assembly and/or disassembly of the unit should take place outside the primary care areas.
16. **The Precision Flow™ is not a Continuous Positive Airway Pressure (CPAP) device.** There are no controls to deliver or monitor airway pressure. The 3000 should not be used to deliver pressure in a closed system.
17. Additional patient monitoring is necessary if the **Precision Flow™** is used to give supplementary oxygen.
18. The **Precision Flow™** is NOT MRI-compatible.

Cautions:

1. Read and understand this manual prior to operating the system
2. Aseptic techniques (including hand washing and avoiding hand contact with connection points) and Standard Precautions should always be followed when handling medical equipment.
3. Standard Precautions should always be followed when coming into contact with patients.
4. Verify that the power source is compatible with the electrical specifications shown on each component. For proper grounding reliability, connect the power cord only to a properly marked hospital grade receptacle. DO NOT USE EXTENSION CORDS. If any doubt exists as to the grounding connection, DO NOT operate the device.
5. **Do not:**
    - immerse the Precision Flow™ in water.
    - steam or gas sterilize the Precision Flow™.
    - wipe with bleach.
6. Flexible sterile water bags are recommended. If rigid or semi-rigid bottles are used, an approved venting bottle cap must be used.

Note:

The Precision Flow™ may be operated with limited performance at gas inlet pressures as low as 2 p.s.i. However, for the full specified range of gas flows and oxygen percentages, both gas inlet pressures must be 40 p.s.i. or above.

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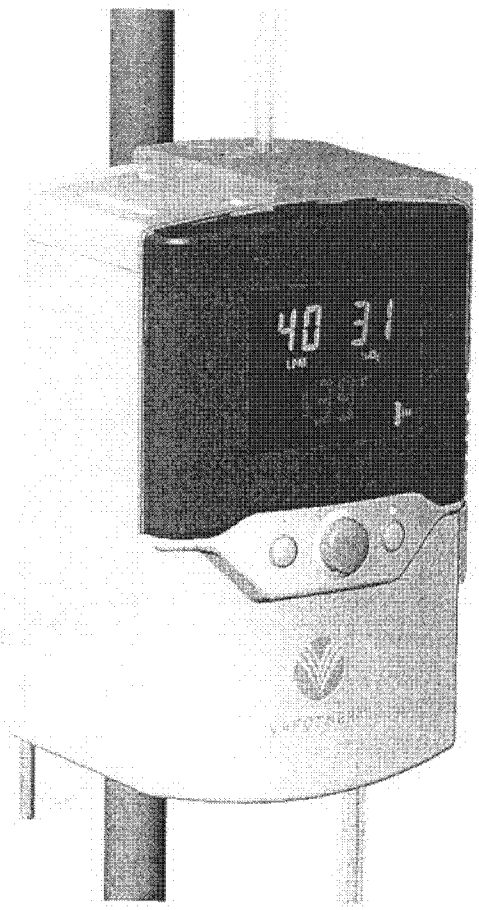
2. Overview

The Precision Flow™ is a system for high flow humidified respiratory therapy by nasal cannula. It incorporates the Vapotherm core humidification technology with an electronic blender and flow controller. The water and gas pathways are both incorporated into a removable, disposable module. The only cleaning and disinfection required is wiping the housing with a an approved disinfectant wipe after use.

Features:



- No disinfection necessary: the water path is detachable and disposable.
- Minimal downtime between patients: less than five minutes to change disposables.
- Built-in oxygen blender
- Built-in electronic flowmeters and controllers
- Self-testing and self-calibrating
- Internal battery backup maintains flow and oxygen percentage for at least 15 minutes if AC power is cut off. Battery recharges in 1-2 hrs.
- All internal sensors self-calibrating and self-monitoring.
- Single button starts and stops the device.
- Temperature, flow and oxygen percentage are adjusted via a single rotary knob on the front panel.
- All values and alarms displayed in a single large color-coded panel.
- Flow range 0.5-40 lpm.
- Oxygen percentage is fully adjustable from 21 to 100% when two 50 psi gas sources are used.
- Inlet gas pressure range is 2-70 psi.
- At low gas inlet pressures maximum flow rate and oxygen percentage settings are automatically reduced to match the inlet pressure.
- Automatically senses cartridge type: maximum flow setting is automatically reduced if low-flow cartridge is installed
- Warm-up time less than five minutes.
- Two levels of alarm indicate low and high priority alarm conditions.
- The water source is a prefilled container of sterile water, connected to the disposable module using a standard spike.
- Easy connection between the delivery tube and disposable module by a simple press and click fitting.
- Universal power requirements- can be used anywhere with only a change of power cord
- Low maintenance: scheduled maintenance for internal components at 3 year intervals, external oxygen sensor replaced annually.

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3. Principles of operation

The Precision Flow™ warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 0.5 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently.

The Precision Flow™ consists of two parts:

1. The **main unit** which contains all the electrical and electronic components including the electronic blender and flow controllers, and sensors for the water pathway. The main unit has no water pathways and the gas pathway contains only dry gas at room temperature, and consequently does not need internal cleaning or disinfection.
2. The **disposable components** comprising the disposable water module, vapor exchange cartridge and heated delivery tube. Conditions in the circulating water and gas streams are sensed remotely via the interface between the main unit and the disposable module.

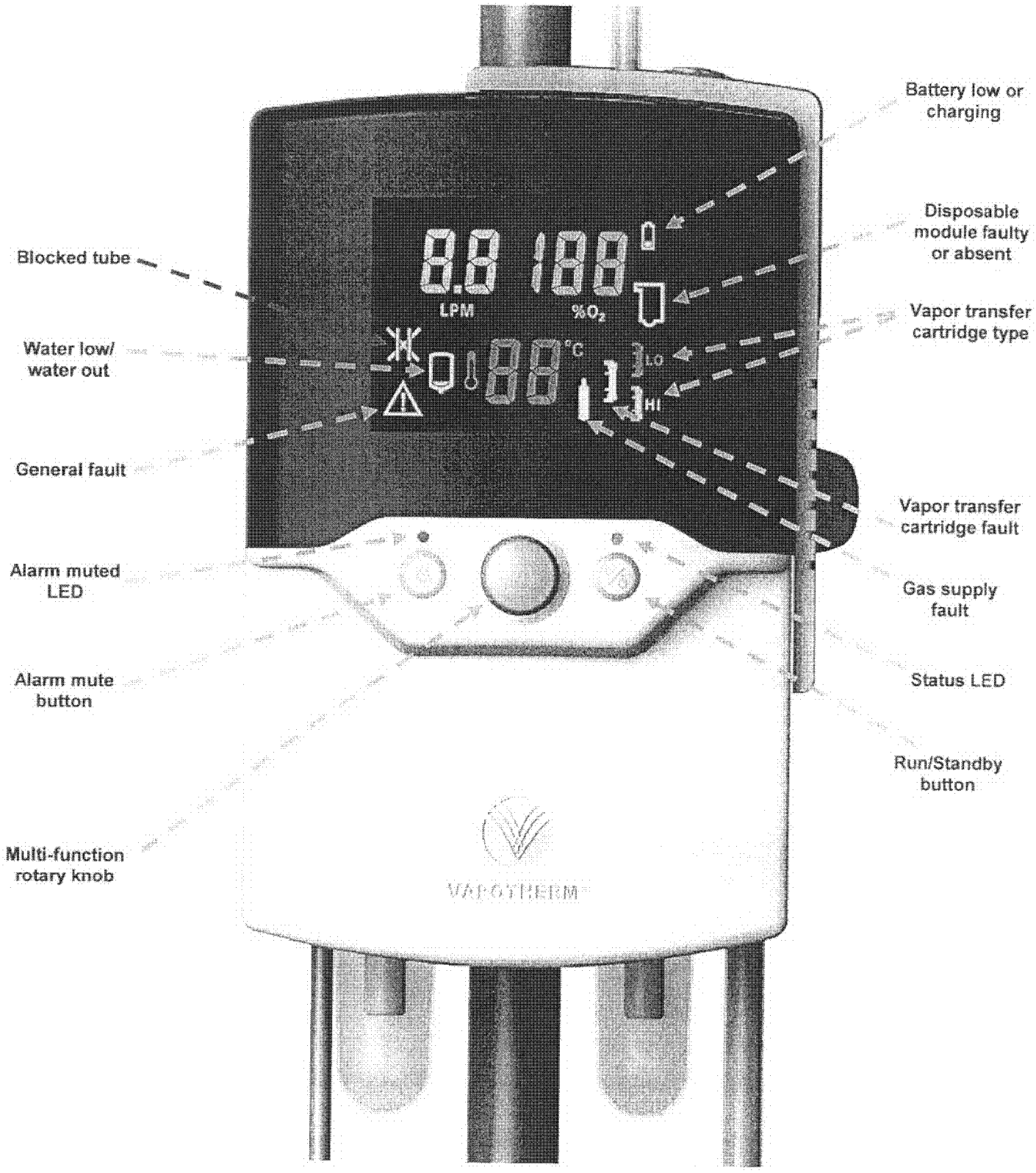
1. Main unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow of each needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.
- Firmware running in the main unit uses sensors to monitor gas pressure, water level and water temperature, and to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed. See Appendix 2 for a description of the firmware states and transitions.
- An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

2. Disposable components:

- Vapor Transfer Cartridge. In the cartridge blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.
  Note: Use ONLY approved cartridges from Vapotherm Inc.
- Triple-lumen heated delivery tube. The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize rain-out. A proprietary short nasal cannula is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nares.
- Disposable module. The module houses a water reservoir, pump, connections for the cartridge and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the Vapor Transfer Cartridge where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the water bag to replace evaporative losses in the Vapor Transfer Cartridge. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

4. External features: (a) Controls and displays



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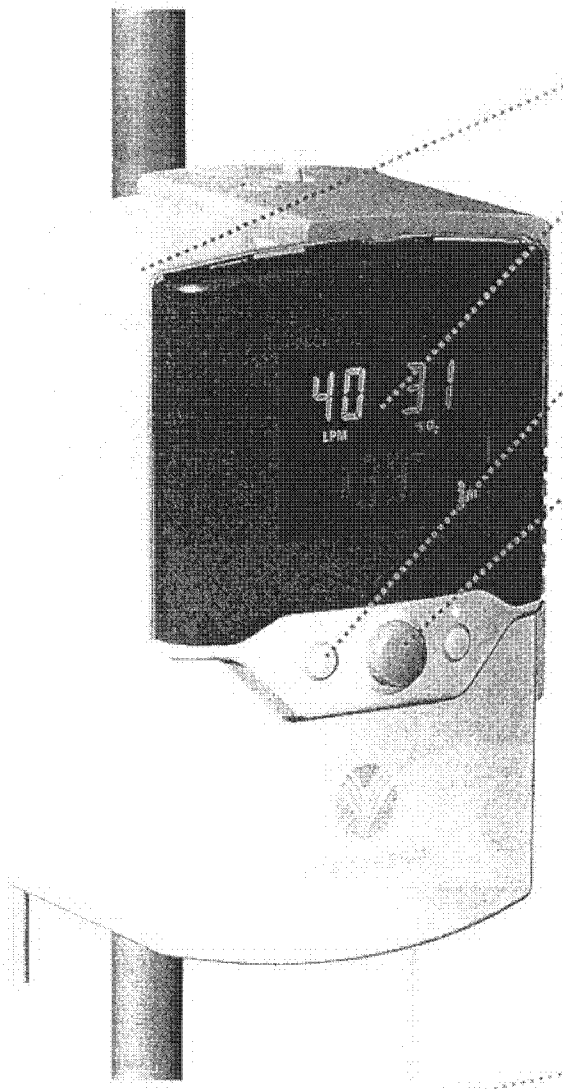
4. External features: (b) front view

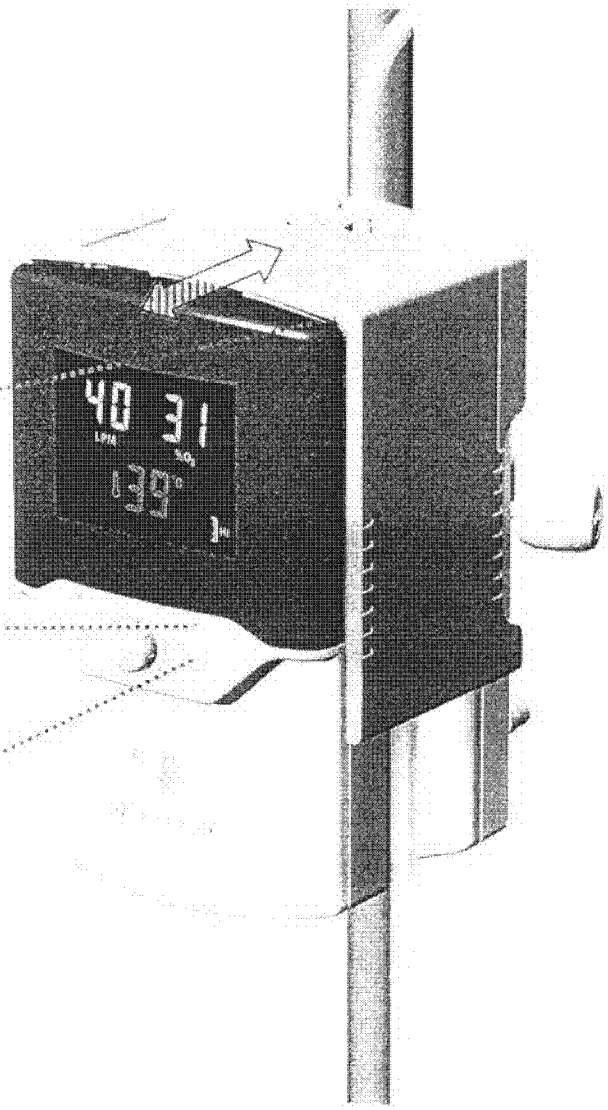


1. Folding carrying handle

2. Multi-function display:
   - Shows set values for oxygen %, flow and temperature
   - Icons indicate alarm conditions

3. Alarm mute:
   - Press to silence alarms for up to 2 minutes
   - LED indicates one or more alarms are muted.

4. Multi-function rotary knob:
   - Press to select which variable to adjust
   - Rotate to adjust to new value
   - Press again to set value

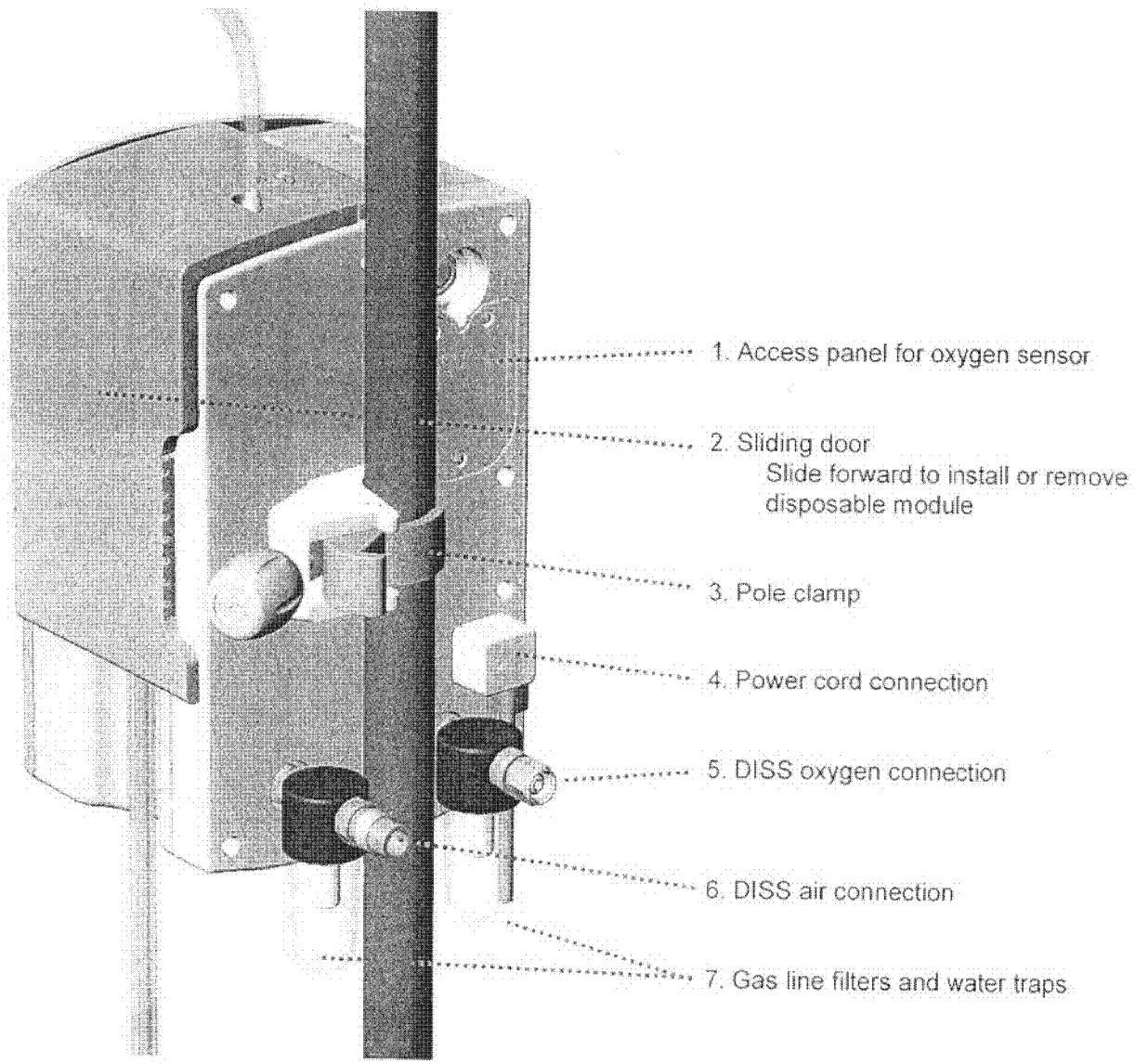


4. Sliding door
   Slides forward to install or remove disposable module

5. Status light:
   Red in standby
   Flashing green when output does not match settings (eg during warmup)
   Steady green when unit is operating normally

6. Run/standby button
   Press to start unit after water and gas are connected

4. External features: (c) rear view



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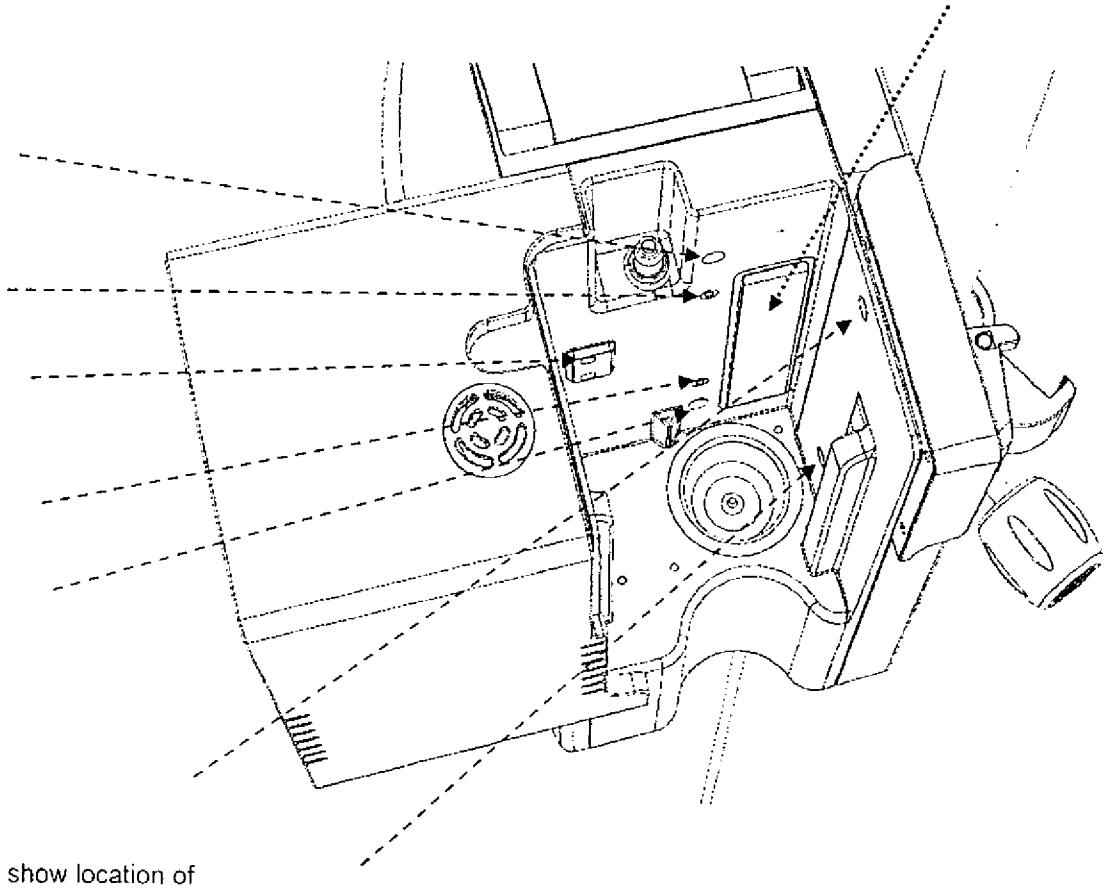
4. External features: (d) docking station for disposable module

Heater plate
WARNING:
May be HOT!



Arrows show location of optical sensor ports.
Do not scratch or scrub the ports. Do not apply organic solvents or bleach.

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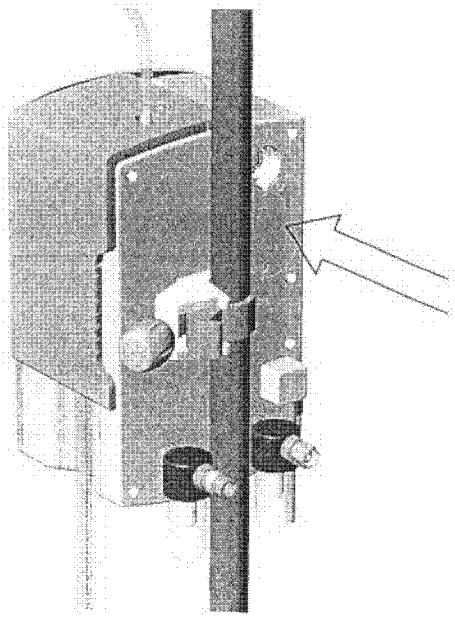
5. Initial assembly.

Certain accessories must be installed in the Precision Flow™ unit before it can be used. These will normally be supplied in a separate package from the main unit as some are country-specific. The power cord plugs into the IEC320-compliant receptacle on the rear panel.

5a. Oxygen sensor installation.

Caution: The oxygen sensor is supplied in a sealed package. Unsealing the package admits oxygen to the sensor which should be replaced 1 year from this date. Do not open the package until the unit is to be used.

Remove three (3) securing screws from the access panel. Pull the panel away from the unit. Insert the threaded end of oxygen sensor into port, and screw into place. Sensor should be hand-tight only- do not use tools. Plug sensor cable into connector. Replace cover. Do not overtighten screws.



5b. Inlet gas filter trap assemblies.

Gas filters and traps are supplied separately and must be installed before first-time use. The filter and trap assemblies have a quick-disconnect fitting which connects to the main unit, and a DISS gas fitting for either an oxygen or an air hose.

Warning: Never attempt to run the Precision Flow™ unit without the inlet gas filters. Particles in the inlet gas flow will cause irreparable damage to the mass flow sensors.

Note: The quick-disconnect tubes for the oxygen and air filters are different sizes, so that they can not be connected incorrectly.

To install the filters:

- Remove any protective tape from the gas inlet connectors at the back of the main unit.
- Push the filter assembly into the correct connector opening until it clicks. The filter should be able to rotate but can not be pulled out.

Removing filter/water trap assembly from main unit:

Note: It is not normally necessary to remove the filter/water trap assemblies, but shipping and packing are easier if the filters are detached first.

To remove:

- press the filter assembly into the main unit
- using forceps or hemostats, hold the locking ring in place against the main unit backplate
- pull the filter assembly straight out.

6. Setting up

Note: Connecting the gas filter and water trap assemblies to the Precision Flow™ unit is described in Appendix 2: Inlet gas filter/ trap assemblies.

6-1. Connect power cord if it is not already in place
6-2. Hang container of sterile water from IV pole hook
6-3. Attach unit to IV pole below lowest point of container.

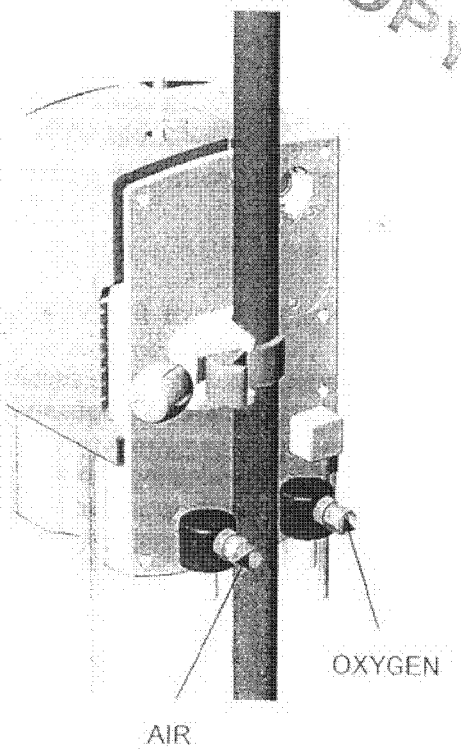
Warning: Unit weighs 12 lbs. It must be securely fixed to a 5-wheel IV pole or stable support to prevent possible injury or damage from falling.

6-4. Connect oxygen and air supply hoses to correct inlets, then connect them to the wall outlets.

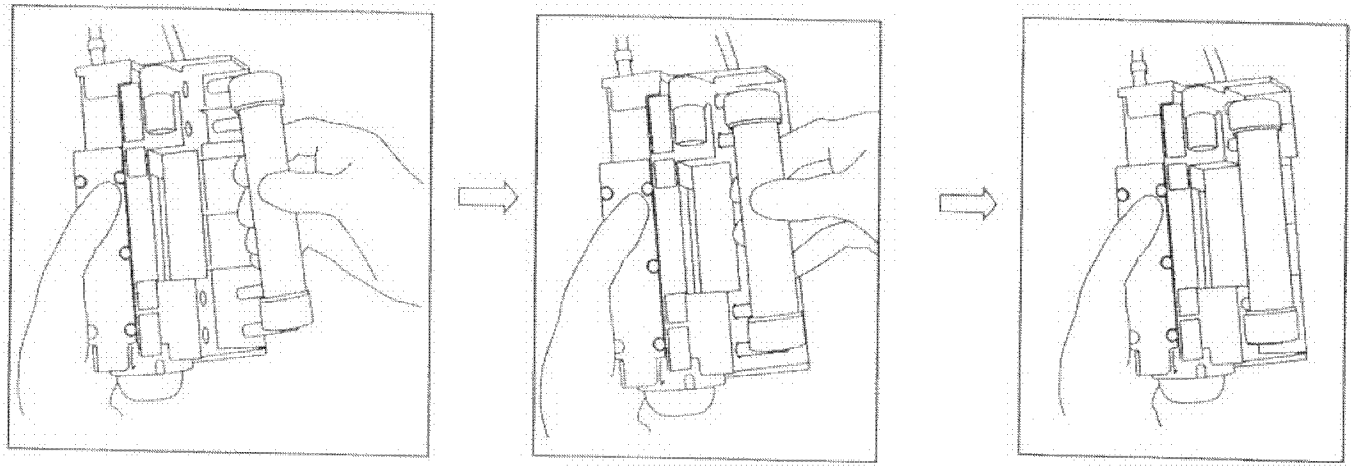
Note: The Precision Flow™ oxygen and air supply inlet fittings are gas-specific to ensure correct connection.

6-5. Open the bags containing the disposable module, cartridge and delivery tube, and assemble them as follows:

6-5-1. Install a high or low-flow vapor transfer cartridge in disposable module as shown. The cartridge may be inserted either way up. Match up the cartridge ports with the module openings and press firmly into place.



Warning: Use high–flow cartridge for flows 5-40 lpm and low-flow cartridge for flows 0.5-8 lpm.



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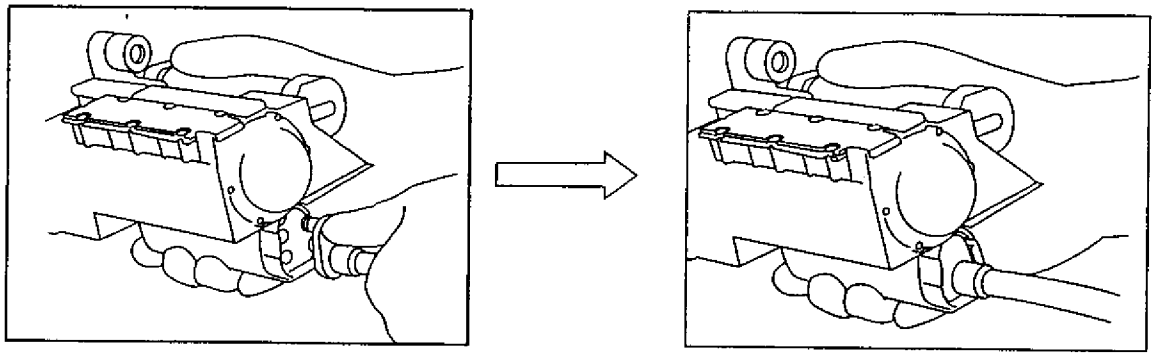
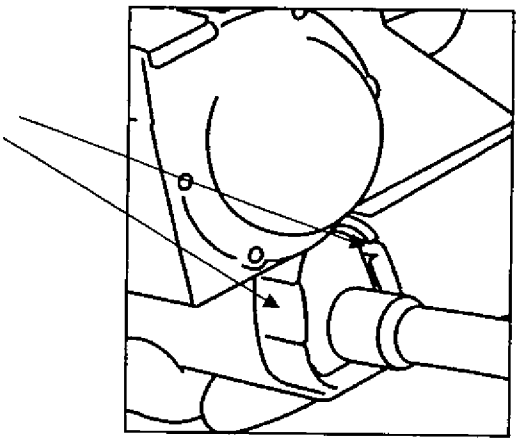
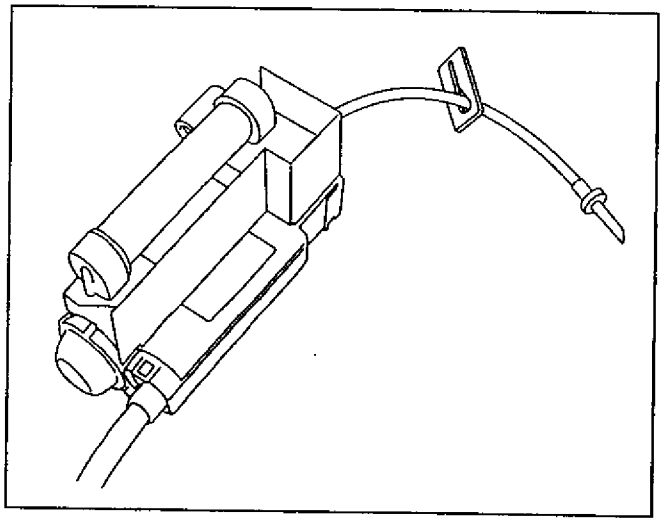
6-5-2. Fit the delivery tube to the disposable module as shown. Press firmly into place.



Insert fully. Both latches must click shut.



Assembled disposable pathway ready for insertion.



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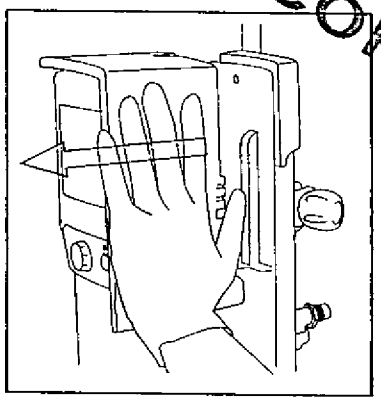
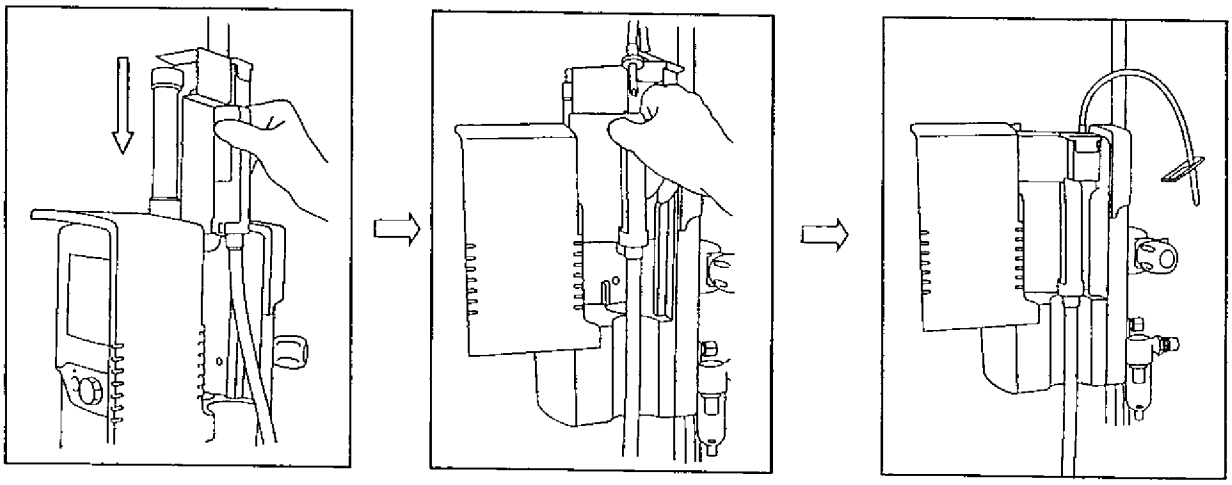
6-6. Inserting disposable assembly:



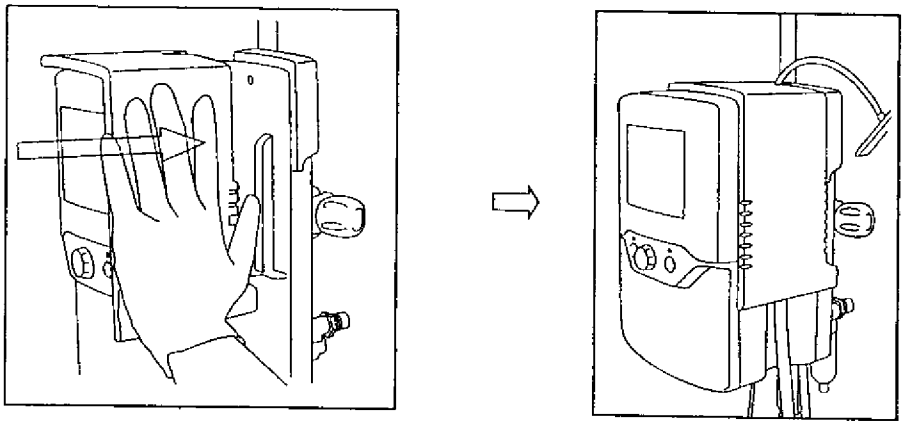
6-6-1. Open door by sliding it forward to expose the docking station.

6-6-2. Hold disposable assembly by its handle, with the delivery tube downwards as shown.

6-6-3. Slide disposable assembly downwards into the docking station until it stops.



6-6-4. Close door by sliding it backwards until it stops.



NOTE: if the sliding door does not close easily, check that the cartridge is installed correctly and the disposable module is fully inserted into the docking station.

CAUTION: DO NOT remove the disposable module while the unit is operating.

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6. Plug in power cord. The Precision Flow™ goes through a self-test:
   - •all icons and numeric displays light up for 10 seconds
   - •internal sensors and control systems are checked
   - •if no faults are detected the unit enters STANDBY mode
   - •"Water Out" icon indicates there is no water in the disposable pathway
   - •status LED is red

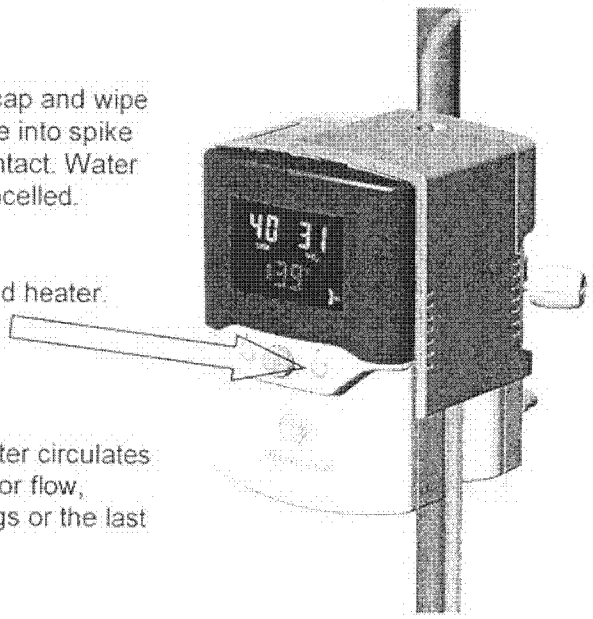
7. Rotate the setting knob in either direction to light up the display in STANDBY mode.

8. Press the Mute button to change between bright and dim display. (This function is only available if no alarms are active.)

9. To connect the sterile water container, remove spike cap and wipe spike with 70-90% isopropyl alcohol. Firmly insert spike into spike port of sterile water container, avoiding direct hand contact. Water flows into the module and the "Water Out" alarm is cancelled.

10. Press Run/Standby button to start gas flow, pump and heater. Press twice if the display is initially blank. The unit beeps while it tests the module and pump (see Notes below).

11. If all tests are passed the unit enters RUN mode. Water circulates and fills the delivery tube. The three numeric displays for flow, temperature and oxygen % display initial factory settings or the last settings used. The Status LED shows green.



NOTES on startup:

- When the Run/Standby button is pressed, the unit enters a detection mode. A **low-priority alarm** sounds and the disposable module icon flashes for approximately five seconds. In this mode the unit inspects the disposable module to confirm that: a cartridge is present; the disposable module is present; and the water level is correct. Power is then applied to the water pump. After five seconds the unit checks that the water pump has started and is running at the correct speed.
- The "low water" icon may flash intermittently until the water system has filled.
- Purging of air bubbles from the circulation can not be seen, because the gas escapes through a membrane, not into the water container.

To adjust settings: See section 6 (Adjustments)
For alarms and troubleshooting: See section 7 (Alarms and warnings)

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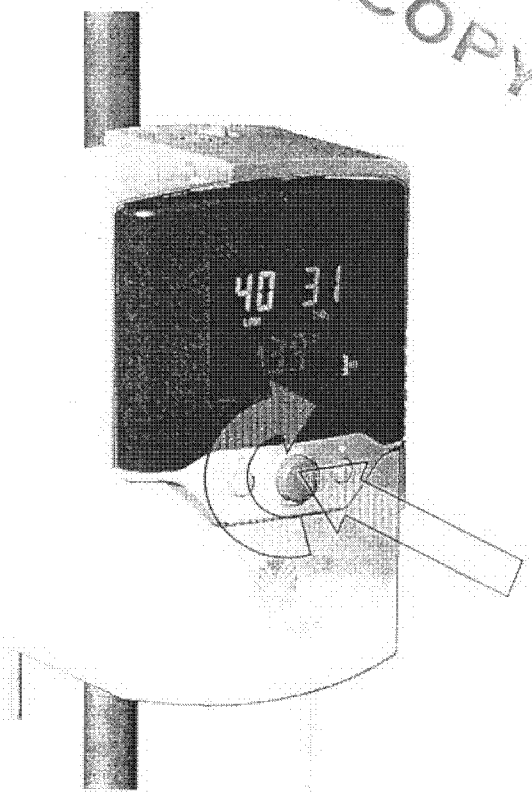
7. Adjustments



Flow, oxygen % and temperature are all adjusted using the rotary knob in the center of the front panel.

7-1. To enter Adjustment mode, press and release the rotary knob. One displayed value will flash to show that it is selected for adjustment. Press the knob repeatedly to cycle the active selection through flow, oxygen % and temperature.

7-2. To change the selected variable, rotate the knob until the desired value is displayed. Press the knob again to enter this value and select the next variable.

7-3. If the knob is not rotated for five (5) seconds, the unit returns to the normal Run mode. To re-enter Adjustment mode, press the knob again.

7-4. Rotating the knob has no effect unless one of the settings has been selected and one of the displayed values is flashing.

NOTES on settings.

- When gas inlet pressures are less than 40 p.s.i the full specified range of flows and oxygen mixtures is not available. The Precision Flow™ system detects the actual inlet pressures and calculates the range of values that can be achieved. An alarm sounds if the operator attempts to make settings outside this range.
- If oxygen is disconnected, the blender setting will be fixed at 21%. If air is disconnected the setting is fixed at 100%. An alarm sounds if the operator attempts to set any other value.
- If a **HIGH-FLOW** cartridge is fitted the flow can not be set below **5 lpm**.
- If a **LOW-FLOW** cartridge is fitted the flow can not be set above **8 lpm**.

NOTES on adjustment:

- If the FLOW setting is rapidly adjusted downward, the temperature display may show a transient increase. This occurs because the heater temperature takes a few seconds to adjust to the lower heat output required for the lower gas flow. The transient temperature increase occurs only adjacent to the heater plate and is not reflected in the temperature of the delivered gas.
- During Warmup the temperature display shows **actual** temperature, not the set value.
- In Run mode the display shows the current **set values** for flow, oxygen % and temperature.
- The rotary knob is sensitive to speed. Rotate quickly for large increments and slowly for small increments.

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8: Connecting to Patient

8-1. Wait for desired set temperature to be reached BEFORE placing the cannula on the end of the Patient Delivery Tube. The flashing green Status LED becomes steady when the set temperature is reached.

8-2. Check water level, temperature display, gas flow rate, and oxygen percentage.

8-3. Size cannula to patient by ensuring that nasal prongs do not fit tightly into nares.

8-4. Attach correct sized cannula for the patient and cartridge onto the delivery tube. Adjust the flow to the desired rate and fit the cannula to the patient. Flow ranges are shown in the table:

Cartridge	Cannula type	Operational flow rates
High Flow	Adult	8-40 lpm
High Flow	Pediatric	5-20 lpm
Low Flow	Premature, neonatal, infant, intermediate infant	0.5-8 lpm

Warnings:

- Always follow aseptic technique (including proper hand washing and avoiding direct hand contact with connection points) when setting up the Precision Flow™ and Standard Precautions when placing on a patient.
- Cannula should not obstruct the nares of the patient.
- Change nasal cannulas when soiled.

Notes:

- The cannula or other interface should be connected to the patient only when the unit has warmed to set temperature.
- Droplets of condensation may appear at the end of patient delivery tube while unit is warming up. This is normal and will stop within a few minutes when set temperature is reached and the cannula is fitted to the patient. If this condition continues refer to trouble shooting section.
- Some condensation of moisture around the nose is possible. In addition, a high moisture level may mobilize mucus from nose and sinuses. Make sure patient has a supply of tissues.

9: Operations: General guidelines.

9-1. Check that water is properly circulating through the machine by making sure the patient delivery tube is warm across the entire length. If good circulation cannot be confirmed, check that the water flow is not obstructed by air bubbles.

9-2. Check that the patient delivery tube will not be occluded by the patient's position or moving bed structures.

9-3. Take precautions to minimize cooling of the unheated cannula by trying to maintain contact with the patient's skin and insulating the exposed portion of the cannula with bedding.

9-4. The sliding cover for the disposable module must be closed during operation.

Note: Condensation in the cannula may occur at flow rates less than 5 lpm (low flow cartridge) or less than 10 lpm (high flow cartridge). To minimize condensation, these general outlines should be followed:

- **If using flow rates less than 5 lpm, do not set the temperature higher than 34°C.**
- The unit should not be in a position where it is cooled (e.g. by an air conditioning outlet).

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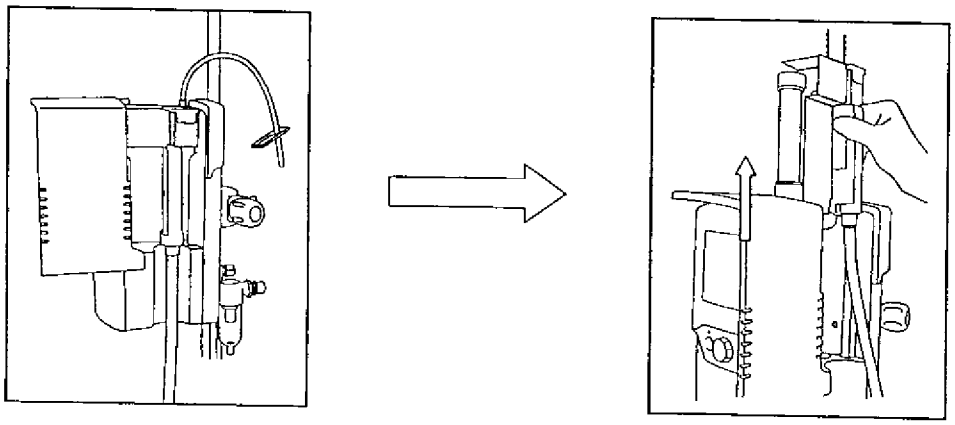
10. Changing the disposable module.

The disposable assembly, consisting of the module, cartridge and delivery tube, is marked for single patient use and must not be re-used. They may be used for up to 30 days on a single patient but must then be replaced.

To change the disposable assembly:

10-1. Shut down the unit by pressing the Run button
10-2. Clamp the water inlet tube attached to the sterile water container.
10-3. Slide the door forward to expose the disposable assembly.
10-4. Lift the assembly out of the Precision Flow™unit and discard in accordance with institutional guidelines.



Warnings:

- **The heater plate in the docking station may be HOT.**
- Universal precautions and aseptic technique must be used in handling the disposable parts.
- There is a risk that bacteria may be present in the water circuit of the old disposable assembly. Do not open or disassemble the disposable parts in a patient care area.

10-5. Wipe down the disposable module docking station with 70-90% isopropyl alcohol wipes
10-6. Open a new cartridge, delivery tube and disposable module
10-7. Fit the cartridge and delivery tube to the module as in Section 5 (Setting up).
10-8. Slide the assembly into the docking station and close the sliding door
10-9. Hang a new sterile water container on the IV pole hook.
10-10. Wipe the spike on the module water inlet tube with 70-90% isopropyl alcohol and insert into spike port of new sterile water container.
10-11. Re-start the unit.

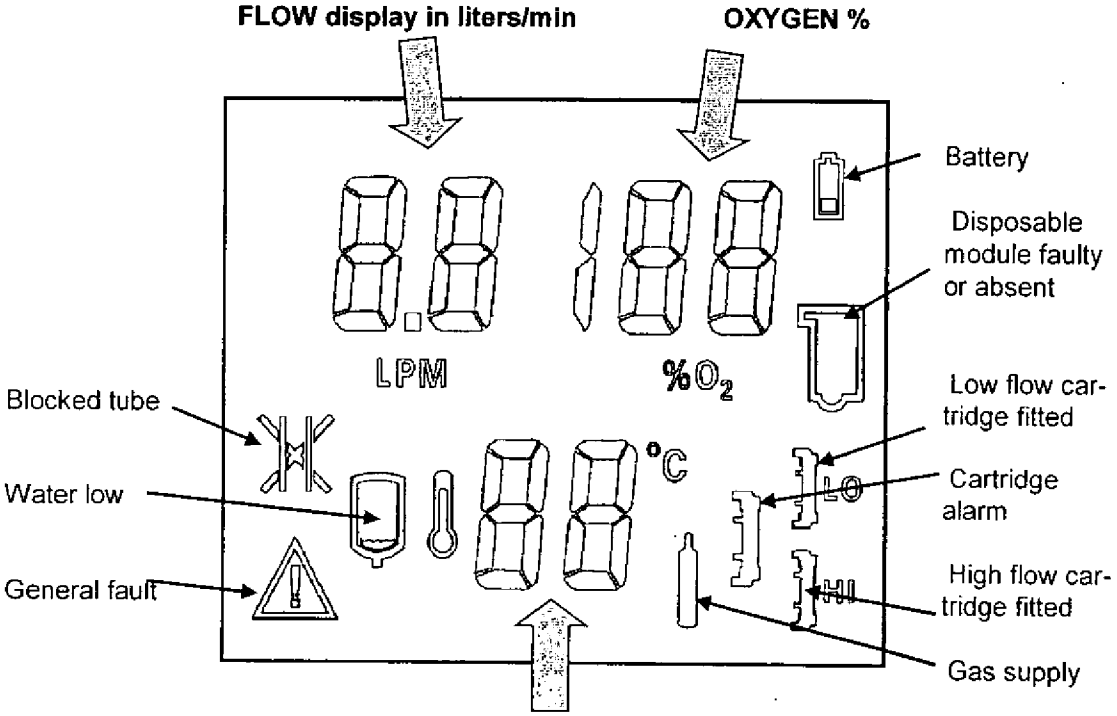
Caution:
The sensor windows in the docking station must not be scratched or damaged. If necessary, clean them only with alcohol wipes (70-90% isopropyl alcohol). **Never use abrasive cleaners, bleach or organic solvents.**

Avoid touching the heater plate. If necessary, clean with alcohol wipes (70-90% isopropyl alcohol).

11. Alarms and Warnings

Fault conditions are indicated by icons displayed on the front panel and by audio signals.

- Unless indicated otherwise, alarms will self-clear when the fault condition is corrected.
- The MUTE button will silence low-priority alarms for 2 minutes and high-priority alarms for 20 seconds.
- A yellow LED above the Mute button indicates that one or more alarms are muted.



ALARM TONE PRIORITIES

- HIGH PRIORITY alarms require immediate attention and are indicated by a CONTINUOUS alarm tone.
- LOW PRIORITY alarms require attention as soon as reasonably possible and are indicated by an INTERMITTENT tone ("beeps") .

Alarm icon	Alarm Priority	Indicates	Cause	Action
General fault	High	Malfunction of sensor or control system	Internal component failure	Cannot be corrected by user: disconnect patient, send unit for service.
Blocked tube	High	High gas pressure at inlet to delivery tube	Obstructed or kinked cannula or delivery tube, or incorrect cannula fitted for flow rate selected	Clear obstruction, check cannula type
Water low (Flashing)	Low	Water level in disposable module is below normal	Low level in water container, or obstructed inlet tube	Replace water container or straighten inlet tube.

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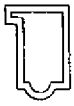
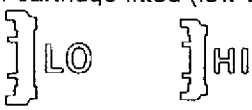
Alarm icon	Alarm Priority	Indicates	Cause	Action
Water out (non-flashing) 	High	No water in disposable module. **Gas flow continues without heating or water circulation.**	Low level in water bag, or obstructed inlet tube.	Disconnect patient. Replace water bag or straighten inlet tube. **Restart unit.**
Disposable module 	High	Disposable module faulty or not detected. Unit will not run.	Disposable module not assembled correctly, defective or not installed.	Install as per instructions. If module is present, remove and replace to reset detector.
Battery charging (flashing) 	None	The internal battery backup is not fully charged. The unit would not run on battery for the full rated time in the event of a power failure. No action is necessary.		
Battery (continuous) 	High	The unit is running in BATTERY mode. Gas flow and blending continues without heat or water circulation.	AC power is disconnected	Reconnect AC power.
Cartridge type	None.	Indicates type of cartridge fitted (low or high flow). **Not an alarm.** 		
Cartridge absent: (Cartridge alarm icon is continuous) 	High	Cartridge not detected. Unit will not run.	Faulty sensor or cartridge not present.	Disconnect from patient. Remove disposable assembly and check cartridge installation. Check reflective label on cartridge. Check that sensor windows are clean.
Cartridge fault (flashing) 	Low	Gas bubbles in water circulation. Unit continues to operate.	Excessive gas diffusion through cartridge fibers.	Disconnect from patient. Shut off unit. Replace disposable water pathway including module, cartridge and delivery tube.
Cartridge fault 	High	Water drops in gas stream. Heating and water circulation are suspended.	Excessive water diffusion through cartridge fibers.	Disconnect from patient. Shut off unit. Replace disposable water pathway including module, cartridge and delivery tube.

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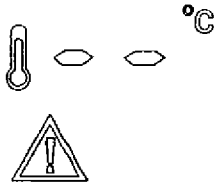
Alarm icon	Alarm Priority	Indicates	Cause	Action
Gas supply (continuous) 	High	Gas supply pressure is outside the range 2-75 psi. Unit will not operate.	Gas supply is disconnected or exhausted.	Check gas supply and correct as necessary.
Gas supply (continuous *and* flow rate numeric display flashes) 	High	Selected flow can not be provided from current gas supply.	Inlet gas pressure too low for selected flow rate.	Increase gas pressure or decrease flow setting.
Temperature display: shows dashes (—) flashing, and General Fault icon 	High	Temperature out of range. Unit will not operate.	Overheating or temperature sensor malfunction.	Cannot be corrected by user: disconnect patient, send unit for service.

NOTE:

Failures in the control or measurement systems for temperature, gas flow, and oxygen percentage will cause a General Fault alarm indicated by this icon. The unit will not operate in this fault condition and must be repaired by an approved service facility.

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12. Shut down

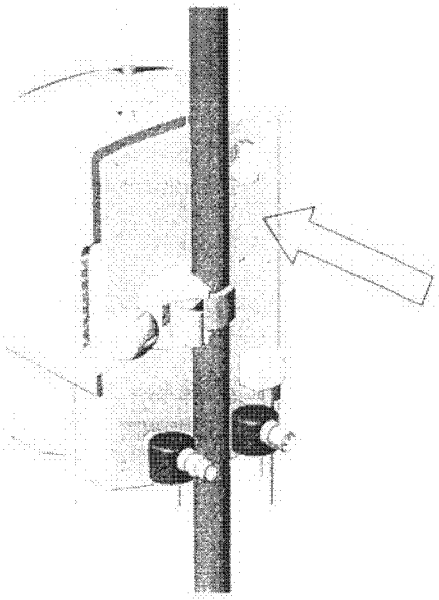
12-1. Press the Run/Standby button.
12-2. Unit will enter Standby mode.
12-3. Clamp the tube from the water container.
12-4. Open the sliding door, remove the disposable module with attached water container, cartridge and delivery tube by sliding upwards out of the docking station.
12-5. Discard all disposables according to hospital guidelines.

CAUTION: Even a fully charged battery will lose its charge over a period of weeks when the unit is not connected to an AC source. It is recommended that the unit is connected to AC for at least two hours once a month to maintain battery charge.

13. Routine maintenance

Oxygen sensor.

The oxygen sensor should be replaced annually. It is accessible by removing a panel at the back of the unit, and can be changed in a few minutes by the user or biomedical engineer.



To replace oxygen sensor:

- Remove three (3) securing screws from the access panel. Pull the panel away from the unit.
- Disconnect the cable connector: grasp with pliers and pull straight back.
- Unscrew the sensor body from its housing. Insert new sensor and screw in.

Caution: sensor should be hand-tight only- do not use tools.

- Plug in cable and replace cover. Do not overtighten screws.
- Apply date label to indicate when replacement is due.

Gas filters and traps.

The traps and gas filters should not require attention if the unit is used with medical-grade gases. However, if particles are visible in the trap, or if the filter appears soiled, the element should be replaced.

To empty trap:

- With gas pressure connected, press the valve pin upwards. Particles in the trap will be forced out.
- Release the pin when the trap is empty.

To change the filter element:

- disconnect the gas line
- unscrew trap bowl counter-clockwise
- unscrew black securing screw and filter element. Do not lose the aluminum washer from above the element
- pull off and discard filter element
- fit new filter element
- re-assemble the filter and trap

No other routine maintenance is required within the first three years of service. There are no other user-serviceable parts. Internal sensors are self-calibrating. Failure to self-calibrate will cause a general fault condition requiring repair.

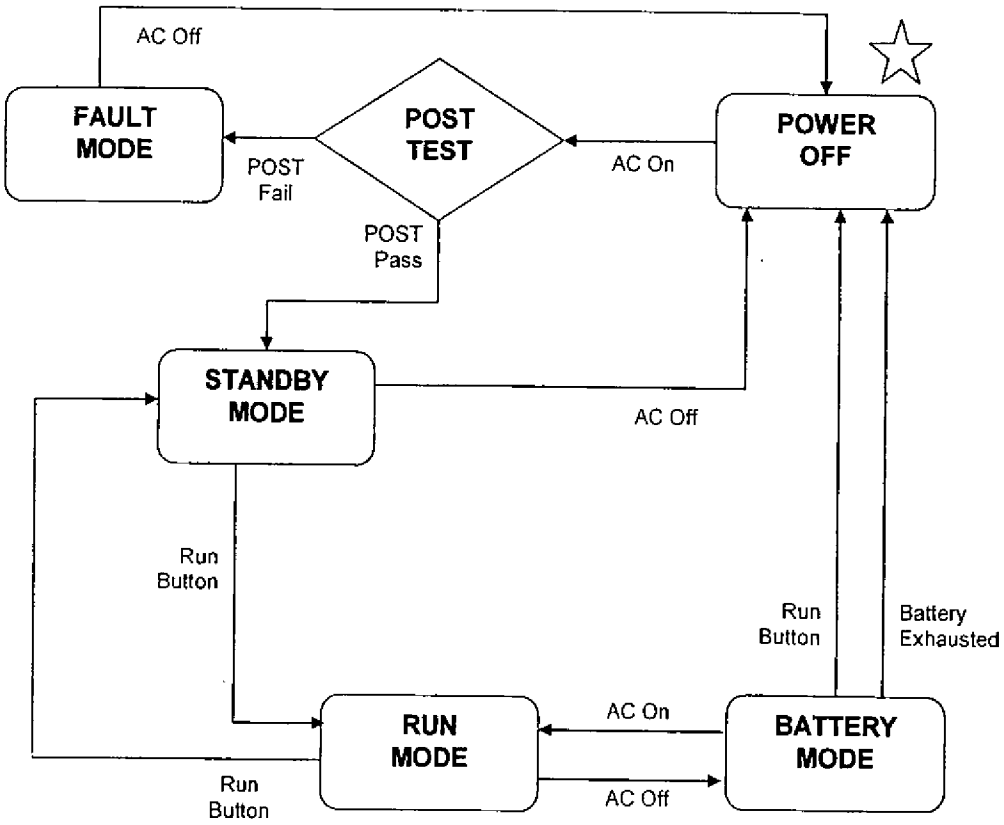
14. Cleaning and disinfection

The entire water pathway is disposable and no disinfection is required. The main unit, including the docking station for the disposable module should be wiped down with 70-90% isopropyl alcohol wipes after use.

CAUTION: do not use bleach, organic solvents or abrasive cleaners.

NOTE: The transparent sensor ports in the module docking station must be clean. The unit will not operate if the sensors do not receive a clear signal.

Appendix: software operating modes.



The diagram illustrates the operating modes for the unit.

- Immediately on connection to AC power a POST (Power-On Self Test) is run to verify proper function of subsystems, sensors and actuators in the 3000 system.
- On successfully completing the POST the unit enters STANDBY unless there is a test failure, when the system alarms, enters FAULT mode and can not be started.
- The 3000 enters RUN mode from STANDBY when the RUN/STOP button is pressed. Normal operation starts. The pump, heater and gas flow proportioning systems start. Sensors and alarms are active and flow, temperature and oxygen % can be set.
- To return to STANDBY, the RUN/STOP button is pressed again.
- If AC power is disconnected when the unit is in RUN mode it enters BATTERY mode. If the battery is fully charged, gas mixing and metering continues for at least 15 minutes, but water is not circulated or heated. When the battery is discharged the unit enters the POWER OFF mode.
- If AC power is disconnected in STANDBY, the unit enters POWER OFF mode.
- If the RUN/STOP button is pressed when in BATTERY mode the unit enters POWER OFF mode.

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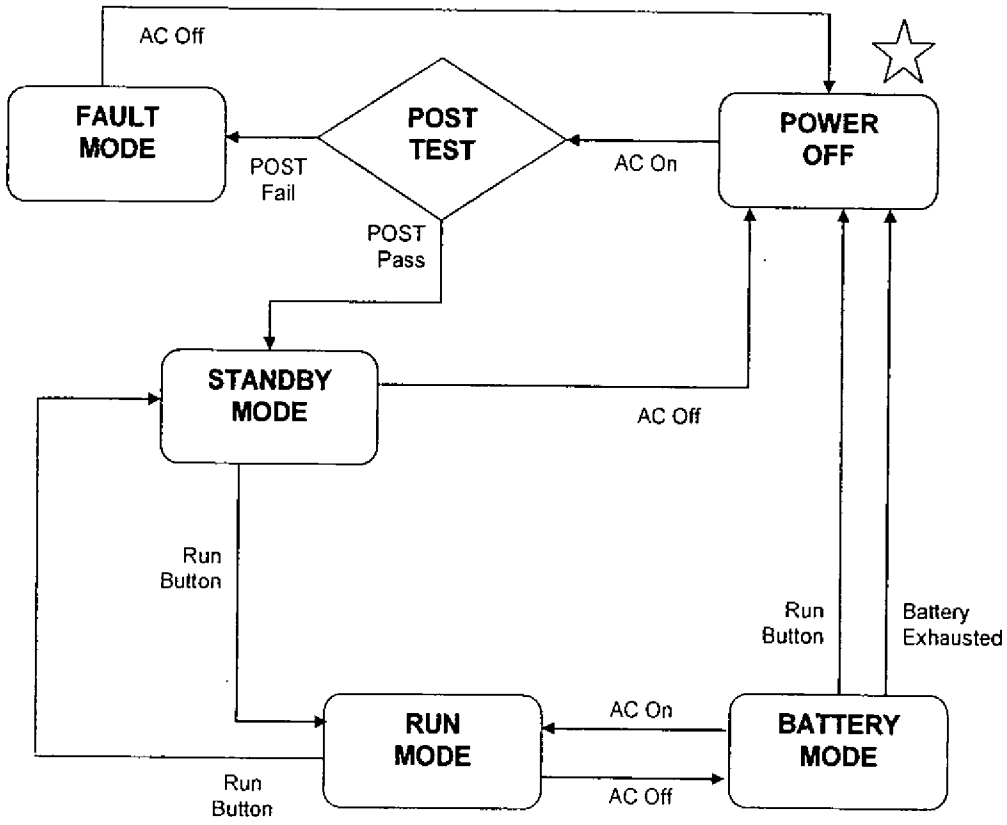
Appendix: software operating modes.



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c. PRECISION FLOW™ PROMOTIONAL MATERIALS

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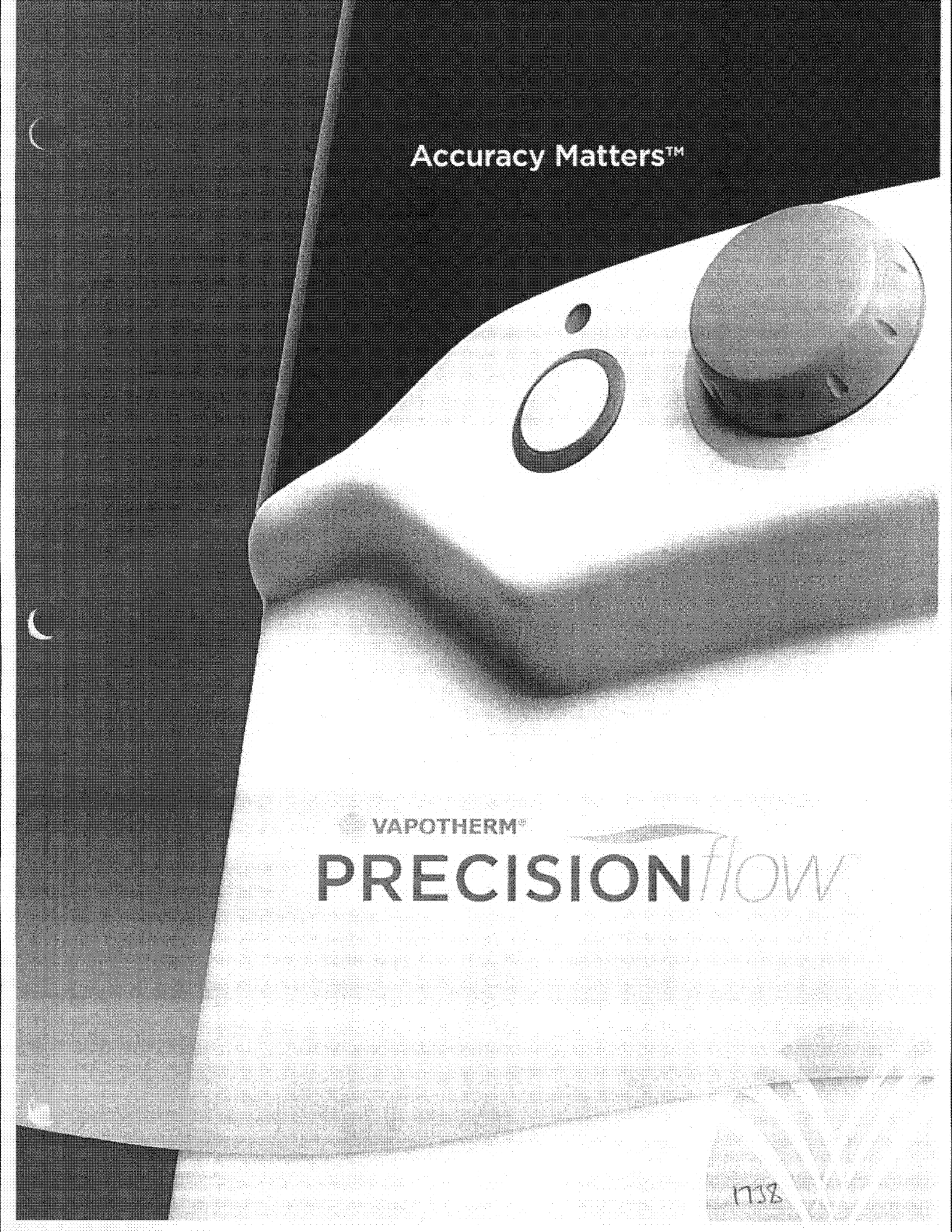
Accuracy Matters™



VAPOTHERM®

PRECISION*flow*

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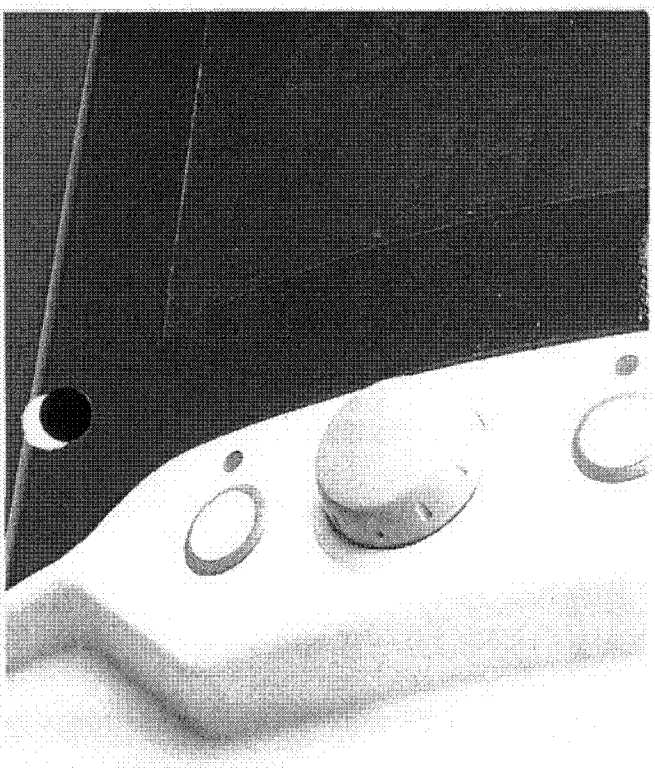
Introducing The Next Generation of
High Flow Oxygen Therapy

VAPOTHERM® PRECISIO

Taking The Technology of High-Flow Oxygen Therapy To The Highest Level of Sophistication.



Vapotherm, the leading innovator of high-flow oxygen therapy takes the science of heating and humidifying breathing gases to a dramatic new level with the creation of PRECISION FLOW™.

PRECISION FLOW™ is a high flow heat and humidification device for the non-invasive delivery of inspired gas flows from 0.5-40 liters per minute.

The unique technology delivers a perfect synchronization of flow, temperature, humidity and oxygen percentage without discomfort without discomfort via nasal cannula.

PRECISION FLOW™ moves beyond conventional humidification, giving the clinician the ability to manage the key factors in gas conditioning to achieve desired outcomes.

PRECISION FLOW™ helps clinicians reach their goal to deliver the maximum respiratory assistance as safely and comfortably as possible. More invasive techniques can result in iatrogenic effects and increased costs. No other High Flow device incorporates these safety features:

- Precise measurement of temperature and flow
- Integrated oxygen blender and back up oxygen sensor
- Disposable patient circuit
- Battery backup

ON flow™

Working with the respiratory community in mind, PRECISION FLOW™ was designed with the clinician in mind, providing easy set up, operation and maintenance including:

- Rapid set up and circuit priming
- Single button control over flow, oxygen percentage and temperature values
- Color-coded, uncluttered display for setting alarms and indicators
- Engineered for reliability and streamlined maintenance

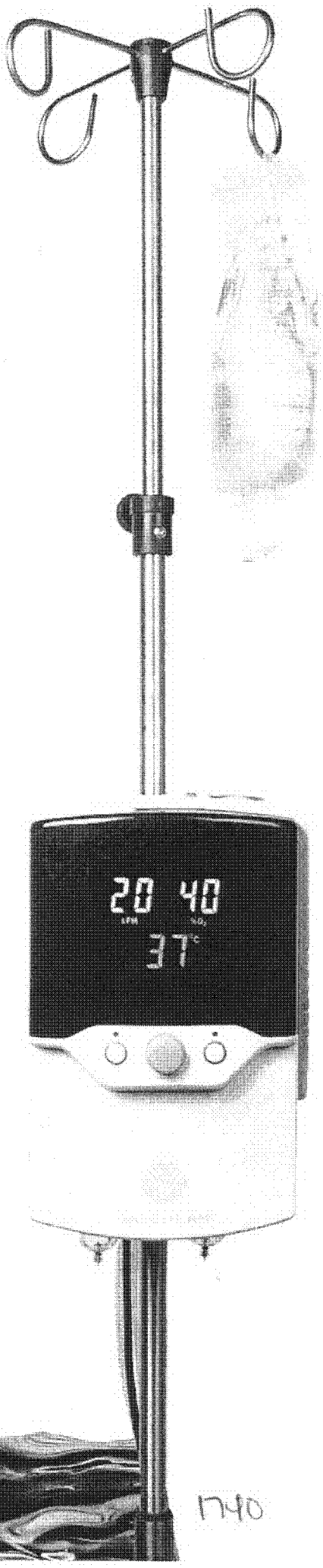
PRECISION FLOW™ allows for the delivery of a broad range of flows at up to 100 % relative humidity, providing effective, well-tolerated treatment for a variety of conditions via nasal cannula.

Care Settings

- Adult Intensive Care
- Pediatric Intensive Care
- Neonatal Intensive Care
- Emergency
- Burn Centers
- Pulmonary Rehabilitation
- Post Operative Care
- Palliative Care

Applications

- Used in Neonatal, Pediatric and Adult Applications



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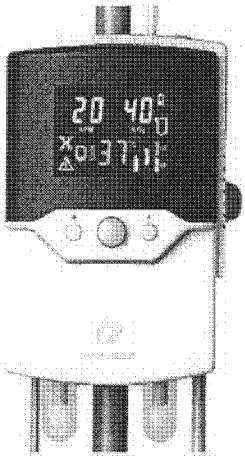
PRECISION

Products and Accessories

PRECISION FLOW DEVICE

The Precision Flow™ is a device designed to heat, humidify and blend medical breathing gases for delivery to the patient. This includes a Start Up Accessory Kit which contains the following: oxygen sensor, air and oxygen hoses and filter traps, electrical cord, Operating Instruction Manual and Quick Reference Guide.



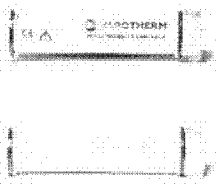
DISPOSABLES

DISPOSABLE PATIENT CIRCUIT

The Disposable Patient Circuit is a single-use item and contains the disposable module with water spike attached and the patient delivery tube.

DISPOSABLE MODULE

Provides the core humidification technology that is placed inside the Disposable Patient Circuit. A Low Flow version is generally used for Neonates and a High Flow version is used for Adult and Pediatric applications.



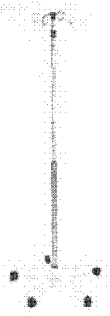
CANNULAS

A series of specially designed cannulas are available for attachment to the Disposable Patient Circuit. Sizes include: Neonatal, Premature, Infant, Intermediate Infant, Pediatric, and Adult.

ACCESSORIES

IV POLE CONNECTOR

The Precision Flow™ device can be attached to the Vapotherm® IV pole.



TECHNICAL SPECIFICATIONS

- Integrated electronic oxygen blender Oxygen percentage is fully adjustable from 21 to 100% when two 50 psi gas sources are used
- Integrated electronic flowmeter
- Inlet gas pressure range is 2-70 psi. At low gas inlet pressures maximum flow rate and oxygen percentage settings are automatically reduced to match the inlet pressure
- Two alarm levels indicate low and high priority alarm conditions. IEC60601-1-8 compliant.
- Internal battery backup maintains flow and oxygen percentage for at least 15 minutes if AC power is cut off

KEY BENEFITS

- No disinfection necessary. Water path is detachable and disposable
- Temperature, flow and oxygen percentage are adjusted via a single rotary knob on the front panel
- Automatically senses cartridge type - maximum flow setting is automatically reduced if low-flow cartridge is installed
- Easy connection between the delivery tube and disposable module by a simple press and click fitting
- All values and alarms displayed in a single large color-coded panel
- Long-life internal parts - no scheduled maintenance required for 3 years except for annual oxygen sensor replacement
- Universal power requirements can be used anywhere with only a change of power cord

VAPOTHERM®
Vapotherm, Inc. • 198 Log Canoe Circle • Stevensville, MD 21666 • 866.827.6843 • www.vtherm.com

d. LABELING OF PREDICATE DEVICES

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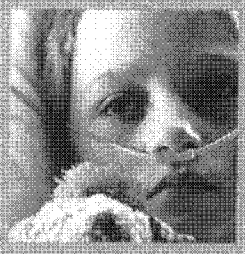
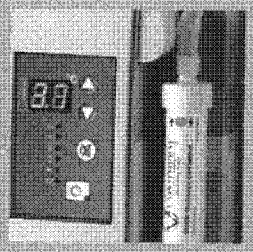
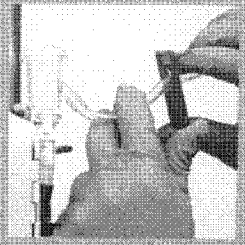
VAPOTHERM







2000i

Operating Instruction Manual

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Contents

Section 1 Indications and Contraindications

Primary Indications:

Used to warm and humidify breathing gases, generally prescribed during oxygen therapy where concentrations of oxygen greater than ambient air are utilized to treat symptoms and manifestations of hypoxia including:

- Documented hypoxemia: decreased PaO_2 in blood below normal range
- Acute care in which hypoxemia is suspected
- Severe trauma
- Acute myocardial infarction

Secondary Indications:

- Managing hypothermia
- Treating bronchospasm caused by cold air

Contraindications:

General:

- Any situations in which humidification is contra-indicated (see AARC Clinical Practice Guidelines)

Specific to Nasal Cannula:

- Patients with occluded or defective nares should not use the system.

Section 2 Definitions, Warnings and Cautions

2.1 Definitions

A **WARNING** indicates that a potentially harmful situation may occur.

A **CAUTION** indicates a condition that may lead to equipment damage, malfunction, or inaccurate operation.

A **NOTE** indicates a point of emphasis to make operation more efficient or convenient.

ASEPTIC TECHNIQUE is practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens. Specifically with respiratory equipment, especially with reference to the Vapotherm 2000i, this includes proper hand washing and avoiding direct hand contact with connection points.

Please take the time to familiarize yourself with the definitions, warnings, cautions and notes listed in this manual. They cover safety considerations, special requirements, and regulations.

The user of this product assumes sole responsibility for any malfunction due to operation or maintenance performed by anyone not trained by Vapotherm™ staff or official training documentation.

When handling any part of the Vapotherm• 2000i, always follow hospital infection control guidelines and Standard Precautions. Vapotherm recommends that users follow the disinfection procedure found in this manual. Vapotherm also recommends that users follow the Centers for Disease Control (CDC) publications: *Guidelines for Maintenance of In-Use Respiratory Therapy Equipment and Guidelines for Prevention of Nosocomial Pneumonia.*

2.2 General Warnings

- Federal Law (U.S.) restricts the sale of this device to, or by the order of any physician.
- This is a humidification device generally used for providing continuous flows of breathing gas. The Vapotherm• 2000i is not a ventilatory device and should not be used as life support.
- This device will not operate without flow.

General Warnings (cont.)

- The Vapotherm 2000i must be disinfected between each patient use and after 30 days of use on the same patient.
- Gas flow delivered by this device is limited to 40 liters per minute. Maximum operational flow rate should not be exceeded.
- Prior to use machine should be positioned and secured to a sturdy IV pole.
- The system includes several disposable elements that are labeled as single patient use only: do not attempt to sterilize or reuse. Follow all local and federal regulations for disposal.
- Oxygen supports combustion; this device should not be used near or around open flames, oil, grease or any flammables or anesthetics.
- Performance verification must be performed prior to use.
- Service on the device should be performed by qualified, certified service technicians ONLY.
- To prevent injury do not attempt to perform any service to the Vapotherm 2000i while a patient is connected to the device.
- If the device is damaged or not working properly do not use. Contact Vapotherm or your authorized Vapotherm representative.
- Do not operate if power cord is damaged.
- The device should not be turned on and left unattended.
- Do not use the Vapotherm 2000i in or around water other than the water bag that feeds the system.
- Failure to utilize sterile water supply or clean gas supply may increase risk of bacterial contamination.
- The Vapotherm 2000i utilizes warmed water and can pose a risk for colonization of bacteria and patient infection if disinfection procedures are not followed.
- Gas flow is external to the Vapotherm, but the care giver should confirm the integrity of all respiratory gases utilized to ensure they are free of contamination.
- Gas supply must be made of clean dry medical grade gas to prevent harm to the patient and prevent damage to the Vapotherm 2000i.
- An oxygen analyzer with alarms must be used when the delivered concentration level is critical. The Vapotherm 2000i does not provide oxygen concentration analysis capability.
- To reduce any potential transmission of contaminated water from the system, all assembly and/or disassembly of the unit should take place outside the primary care areas.
- The 2000i is not a Continuous Positive Airway Device (CPAP). There are no controls to deliver or monitor airway pressure. The 2000i humidifies breathing gases that are delivered externally through standard air/oxygen blender and flowmeter. The 2000i should not be used to deliver pressure in a closed system.

2.3 Cautions

- Verify that the power source is compatible with the electrical specifications shown on each component. For proper grounding reliability, connect the 2000i power cord only to a properly marked hospital grade receptacle. DO NOT USE EXTENSION CORDS. If any doubt exists as to the grounding connection, DO NOT operate the device.
- Do not immerse the Vapotherm 2000i in water. Do not steam or gas sterilize the Vapotherm 2000i.
- Read and understand this manual prior to operating the system.
- The Vapotherm 2000i must be disinfected if the water circuit is opened up by removing or replacing a component.
- Aseptic techniques (including proper hand washing and avoiding direct hand contact with connection points) and Standard Precautions should always be followed when handling medical equipment.
- Standard Precautions should always be followed when coming in contact with patients.

2.4 General Inspection

When unpacking the Vapotherm 2000i system , ensure that the unit is inspected for damage before use. Report any damage or missing parts immediately to your authorized Vapotherm distributor.

When renting a Vapotherm 2000i, customers should require the rental service to provide a certification that the machine has been disinfected before accepting delivery.

The Vapotherm™ 2000h for home use consists of the combination of a 2000i unit and the "Home Care Compressor Kit (Part number HCK200-M)". The HCK-200 Kit consists of an HS-100 Stand, a 5060A Room Air Compressor and Flowmeter assembly.

1. A Vapotherm authorized Durable Medical Equipment (DME) Supplier is responsible for the following:
   - Assembling the 2000i unit and the kit components
   - Instructing the user in their responsibilities for operating the system
   - Providing 1000 ml sterile water bags as needed
   - Routine servicing of the system
   - Removing, replacing, and disposing of the disposable components (Vapor Transfer Cartridge, Vapotherm Spike Set -1 & Delivery Tube) every 30 days
   - Disinfecting of the 2000i unit every thirty days following the procedure found in Section 8.1 – 8.6 of the 2000i Operating Instruction Manual

2. The user/home care provider is responsible for the following:
   - Change nasal cannulas when soiled or excessively wet from secretions. Dispose of properly.
   - Installing and replacing the sterile water bag
   - Avoid liquid spills on the components
   - Do not attempt any repairs. If you have any problems with your Vapotherm 2000i device notify the DME provider immediately

Section 3 About the Vapotherm 2000i

The Vapotherm 2000i warms and humidifies flows of air, oxygen or medical gas blends for delivery to a patient, by nasal cannula or Vapotherm approved interface.Warming and humidification of breathing gas occurs in a Vapor Transfer Cartridge, where air and water are separated by a membrane permeable to water vapor. The membrane consists of microtubules constructed of polysulfone material. The membrane meets HIMA (Health Industry Manufacturers Association) standards on filters for sterilizing liquids and has been shown to effectively exclude bacteria from crossing from the water circulation to the gas flow.

The warmed humidified gas stream reaches the patient via a patented triple lumen Patient Delivery Tube. Humidified gas flow is delivered through the center lumen. The outer lumens contain water which is warmed via an internal heater and propelled through the system via an internal pump (*See schematic, fig. 1).* This maintains breathing gas temperature and minimizes condensation. The final patient interface is a Vapotherm nasal cannula or approved interface configured to minimize resistance and heat loss.

NOTE: The water circuit and gas circuit of the Vapotherm 2000i do not come in contact with each other.

Respiratory gases are supplied to the Vapotherm™ 2000i from an external gas supply, typically through a standard wall-mounted flow meter connected to the hospital medical gas supply. Gas flow rate is controlled by the external flow meter or medical gas blender. There are no flow controls on the Vapotherm™ 2000i. Connections for gas flow and water are made via the rear panel. All Vapotherm 2000i controls are on the front panel of the device.

WARNING: Use of patient interfaces not recommended by Vapotherm may cause safety concerns or affect the performance of the device.

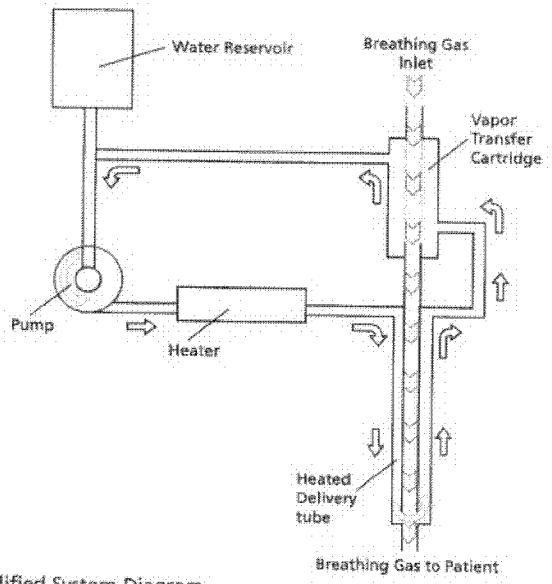


Fig. 1 Simplified System Diagram

Section 4 Set-Up

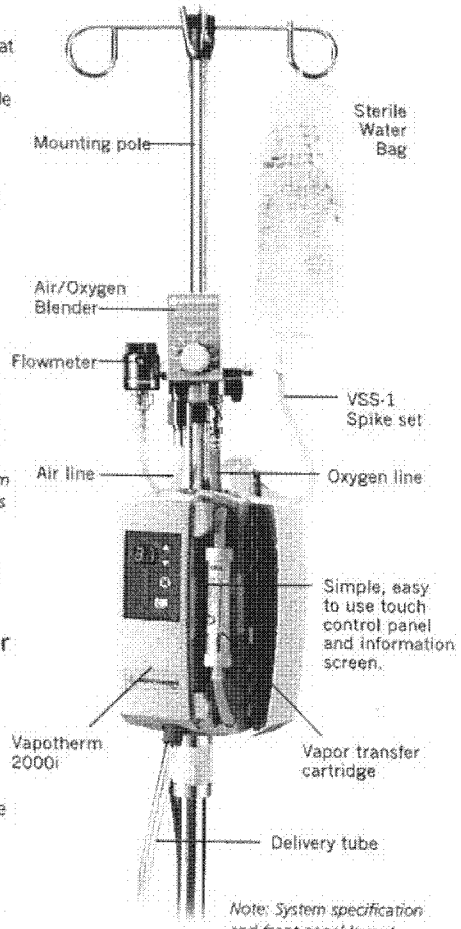
4.1 The 2000i Unit

1. The back of the 2000i has an IV pole clamp that enables IV pole attachment.
2. The unit should be mounted on a sturdy IV pole approximately two feet from the top of the pole to facilitate ease of access and proper flow from sterile water system.
3. If using an oxygen blender, mount the blender above the Vapotherm 2000i on the IV pole.
4. Connect blender hoses into both air and oxygen wall connections.
5. Plug Vapotherm power cord into a hospital wall power outlet.

WARNINGS:
Aseptic technique (including proper hand washing and avoiding direct hand contact with connection points) should always be followed when setting up and operating the Vapotherm 2000i.

The medical gas source is external to the Vapotherm 2000i. Always verify the integrity of the medical gas source and utilize bacterial filters if necessary.

Closed system components (VSS-1, Vapor Transfer Cartridge and Patient Delivery Tube) should not be opened in patient care area.



Note: System specification and front panel layout may vary.

4.2 Selecting the Vapor Transfer Cartridge

Vapotherm provides both a high flow cartridge (VT01-AS) and a low flow cartridge (VT01-BS).

- The high flow cartridge (VT01-AS) should be used with the pediatric cannula with an operational flow range of 5–20 liters per minute (lpm) or with adult sized cannula with an operational flow range of 8–40 lpm.
- The low flow cartridge (VT01-BS) should be used with the neonatal, premature, infant, or intermediate sized cannula with an operational flow range of 1–8 lpm.

WARNINGS:
Do not exceed maximum operational flow rates of 40 lpm for the high flow cartridge (VT01-AS) and 8 lpm for the low flow cartridge (VT01-BS).

Ensure that the correct cartridge is inserted before operating.

4.3 Inserting the Vapor Transfer Cartridge

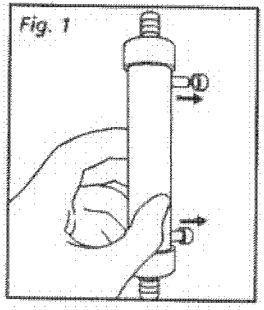
1. The Vapor Transfer Cartridge (VT01-AS or VT01-BS) attaches to the unit by two water and two air connections.
2. When facing the unit, access is via a hinged cover on right side. The cartridge may be fitted in either direction.
3. Date the cartridge.
4. Remove protective caps from luer side ports of cartridge *(Fig. 1)*.
5. Attach lower air tube from Vapotherm 2000i to lower end of cartridge.
6. Insert projecting side ports into matching connections in unit. Press cartridge firmly into place *(Fig. 2)*.
7. Attach upper air tube from Vapotherm 2000i to top of cartridge *(Fig. 3)*. Make sure tubing is not kinked.
8. Close hinged cover. If it does not close easily, check that cartridge is pressed fully into place and that air tubes are not interfering with cover.

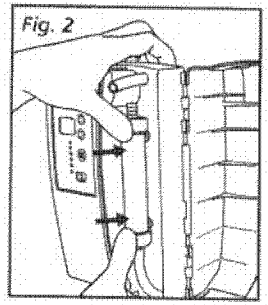
WARNINGS:
The cartridge must be changed between patients and discarded after each use.

If the cartridge is removed, the unit should be disinfected.

If the cartridge is dropped, it should be discarded.

NOTE: Do not remove cartridge from the Vapotherm 2000i without first draining the machine.





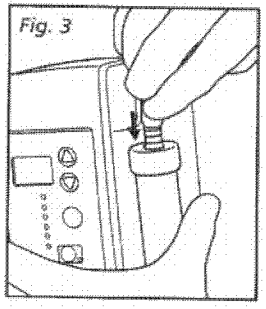
4.4 Inserting the Patient Delivery Tube

1. Insert Patient Delivery Tube into lower portion of the unit by aligning blue tabs on tube with notches on bottom of unit.
2. Firmly press into place *(Fig. 4, see next page)*. Blue lip on tube must be flush with the bottom of unit.
3. Rotate 1/4 turn clockwise and pull slightly downwards to lock into place (Fig. 4, *see next page*).

WARNING: The Patient Delivery Tube is a single patient use item and should be changed with each patient.

If the Patient Delivery Tube is removed from the device for any reason the Vapotherm 2000i should be disinfected following the routine disinfection procedure before returning to service.

CAUTION: Unit will not operate correctly if the Patient Delivery Tube is inserted improperly or not locked into place.



4.5 Vapotherm Spike Set (VSS-1): for connecting Sterile Water Bag

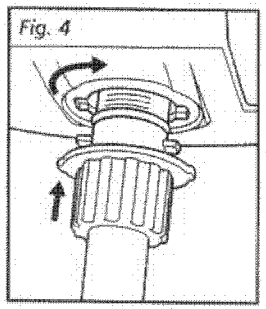
1. Hang a sterile water bag from IV Pole.
2. Connect VSS-1 to the water inlet port on back of unit and make sure it locks into place (Fig. 5).
3. Ensure the VSS-1 is clamped then remove spike cap. Wipe spike with disinfectant wipes, 70-90% isopropyl alcohol.
4. Firmly insert spike into sterile water bag while avoiding direct hand contact with the spike tip and water bag septum.
5. Leave VSS-1 spike set clamped until ready to fill unit.

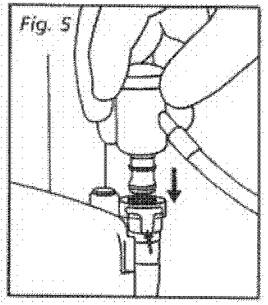
WARNINGS:
The VSS-1 is single patient use item and should be changed with each patient.

If the VSS-1 is removed from the Vapotherm device for any reason the Vapotherm 2000i should be disinfected following the routine disinfection procedure before being returned to service.

CAUTION: Never leave the VSS-1 unclamped when the system is not running.

NOTE: Removing an empty sterile water container does not constitute opening the closed system. New sterile water containers can be spiked using the same VSS-1 without removing the device from service following the procedure above.

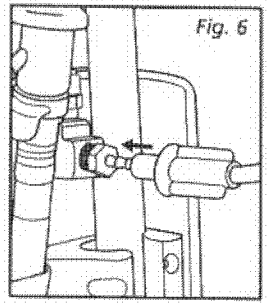




4.6 Connect To A Gas Source

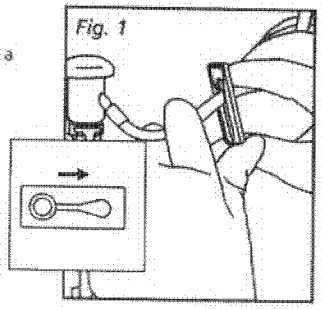
1. Connect a source of air, oxygen or medical gas blender to the gas inlet port of Vapotherm 2000i *(Fig. 6)*. Gas inlet connection is a hose barb that accepts female fitting on a standard 1/4" (6.35mm) oxygen tube.

NOTE: Vapotherm will not operate unless there is gas pressure at gas inlet. With no flow/pressure sensed, a "System Failure" alarm will sound.



5.1 Prepare for Activating the Unit

1. Ensure that the Vapotherm 2000i power cord is plugged into a hospital electrical wall outlet.
2. Unclamp the Vapotherm Spike Set (VSS-1) *(Fig. 1)*.

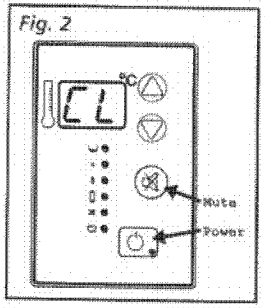


5.2 Turn on Flow

1. If using the high flow cartridge (VT01-AS) flow should be started at least 8 lpm for warm-up.
2. If using the low flow cartridge (VT01-BS) flow should be set to at least 5 lpm for warm-up.
3. Turn on flow.

5.3 Priming the Unit

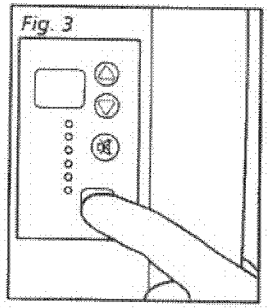
1. Unit should be started in CLEANING MODE "CL" to prime a new Patient Delivery Tube.
2. To place unit in CLEANING MODE, press both the power on and the ALARM SILENCE/MUTE buttons simultaneously *(Fig. 2)*.
3. The display will show "CL" and LED next to cleaning icon will illuminate.
4. Water will begin to circulate and fill the Patient Delivery Tube.
5. Operate in CLEANING MODE until Patient Delivery Tube has been purged of air bubbles.
6. When air has been purged, press POWER to stop system
7. Wait until display blanks.



NOTES:
Pressing both the power and alarm mute buttons will set unit in CLEANING MODE, pressing only the power button sets unit in NORMAL mode.

Water is not being heated in CLEANING MODE: the purpose of this mode is to fill the outer lumens of the Patient Delivery Tube with water.

Gas flow is highly recommended (but not mandatory) during priming.



5.4 Activate the Unit

1. Press the Power button only, to start in NORMAL MODE *(Fig. 3)*.
2. If not using the Patient Delivery Tube with integrated cannula, do not place cannula on the end of tube until warm up is complete.

5.5 Setting the Temperature and Warm-Up

1. The Vapotherm 2000i displays the actual temperature of the circulating water. Press and release the up or down arrow on the front of the unit to display temperature setting for 3 seconds.
2. To adjust the temperature setting of the Vapotherm 2000i, press and hold the up or down arrow until the desired temperature is displayed in the LED.

NOTES:
The Vapotherm 2000i always defaults to previous set temperature at power up.

The temperature can be set between 33 and 43°C.

5.6 Connecting to Patient

1. Wait for desired operating temperature to be reached **BEFORE** placing the cannula on the end of the Patient Delivery Tube.
2. Check water level, temperature display and gas flow rate.
3. Size cannula to patient by ensuring that nasal prongs do not fit tightly into nares.
4. Attach properly sized cannula that is designed to function with the cartridge installed in the machine onto the delivery tube. Adjust the flow to the desired rate and place the cannula on the patient.
5. Some condensation of moisture around nose is possible. In addition, high moisture level may mobilize mucus from nose and sinuses. Make sure patient has a supply of tissues.

Cartridge	*Cannula Type*	*Operational Flow Rates*
High Flow (VT01-AS)	*Adult*	*8 – 40 lpm*
High Flow (VT01-AS)	*Pediatric*	*5 – 20 lpm*
Low Flow (VT01-BS)	*Premature, neonatal, infant, intermediate*	*1 – 8 lpm*

WARNINGS:
Always follow aseptic technique (including proper hand washing and avoiding direct hand contact with connection points) when setting up the Vapotherm 2000i and Standard Precautions when placing on a patient.

Cannula should not obstruct the nares of the patient.

Change nasal cannulas when soiled.

After start-up, during the normal purging of the Patient Delivery Tube, air will release and appear as bubbles in the bubble trap of the VSS-1. If the Patient Delivery Tube is filled and a stream of continuous bubbles appear in the bubble trap, it may indicate a problem with the cartridge or Patient Delivery Tube and both should be checked or changed.

NOTE:
If using a low flow cartridge (VT01-BS) the flow cannot be decreased below 5 lpm until an appropriate cannula has been attached to the delivery tube.

Droplets of condensation may appear at the end of Patient Delivery Tube while unit is warming up. This is normal and will stop within a few minutes when temperature is reached. If this condition continues refer to trouble shooting section. If the system operates while not connected to a patient, condensation is likely to develop.

5.7 Operations – General Guidelines

1. Check that water is properly circulating through the machine by making sure the Patient Delivery Tube is warm across the entire length.
2. If good circulation cannot be confirmed, check that the water flow is not obstructed by air bubbles.
3. Take precautions to minimize cooling of the unheated cannula by trying to maintain contact with the patient's skin and insulating the exposed portion of the cannula with bedding.
4. Cartridge door should be closed during operation.

NOTE: Condensation in the cannula may occur at low flow rates. To minimize condensation, these general guidelines should be followed:

- *If using flow rates less than 5 lpm, do not set the temperature higher than 34°C.*
- *The Vapotherm unit should not be in a position where it is cooled (eg. by an air conditioning outlet).*

CAUTION: DO NOT EXCEED flows of 8 lpm for VT01-BS and 40 lpm for VT01-AS cartridge.
DO NOT SET flows below 1 lpm for VT01-BS.

WARNING:
Never occlude the nares with cannula.

NOTES:

It may become necessary to disconnect the cannula from the Patient Delivery Tube for short periods, such as when moving a patient out of a radiant warmer. At flow rates less than 5 lpm, cannula disconnection will activate a system failure alarm, requiring a reset. To avoid this alarm, briefly turn off unit by pressing the power key once. The display will show two bars. Disconnect the cannula from Patient Delivery Tube and move the patient, reconnect the cannula, then press the power key once more to restart the unit.

A SYSTEM FAIL (88) alarm will activate if there is insufficient gas pressure in the manifold. If no cannula is fitted, flow rate at startup should be at least 5 lpm. The minimum flow rate for operation is 1 lpm if a neonate, infant or premature-sized cannula is fitted, 5 lpm with a pediatric cannula, and 8 lpm with an adult cannula.

Cannulas are single use patient items, dispose of as necessary or according to your institution's guidelines or when visibly soiled or excessively wet from secretions. Weekly change out is recommended to avoid any hardening of nasal prongs.

An air lock can develop at the pump, preventing normal water flow. Try restarting the unit in cleaning mode.

6.1 General

1. Periodically check for alarm conditions.
2. Unit will shut down if there is no gas flow. However, flow will not be interrupted if unit shuts down or malfunctions for any other reason.
3. Unit will shut down if temperature safety limits are exceeded, or if water level is low for more than 4 mins. However, unheated gas flow will continue.

NOTE: Should a malfunction occur, indicators on the front panel will light and an alarm will sound. If the actions listed here do not correct the problem causing the alarm, the unit should be returned to an approved facility for service.

6.2 Alarms and Troubleshooting

Alarm Indication	Cause	Action
Water low 	Water is not filling system properly	Make sure VSS-1 spike set is open, and the tube is not kinked or blocked by air bubbles.
	Low Water Pressure	Make sure gas and water connections are open, gas can flow to unit, and air has purged from water system: if not, run 'CLEANING MODE'.
	Malfunctioning Water or Gas Pressure Sensor	Send in for service.
System Failure S	Insufficient gas or water pressure.	Make sure the gas and water circuits are open and functional and air has purged from the water circuit if the unit is in normal operating mode.
		Run in "CLEANING MODE".
		Make sure there is correct flow for cartridge flow rates. If using <5lpm with a low flow cartridge, a nasal cannula must be attached.
	Malfunctioning Water or Gas Pressure Sensor	If a component failure return the unit for service.
NOTE: To restart after a system failure, the unit must be reset by a momentary pressure on the Power button. Do not hold the Power button. The alarm will shut off after a delay of about a second, and the unit can then be restarted normally.		
Cartridge 	Water drops in the circuit will cause a cartridge alarm; this does not necessarily mean the cartridge needs to be replaced.	

Alarm indication	Cause	Action
Cartridge 	If the Cartridge Alarm is continuous and air bubbles are rising into the VSS-1 bubble trap or if a flow or water is visible in the tube below the cartridge, then the cartridge has failed.	First disconnect the patient from the unit, shut down unit, drain unit, disinfect unit, replace cartridge, VSS-1 and delivery tube, and follow set up instructions.
	If cartridge alarm is intermittent and there are no bubbles in the VSS-1 bubble trap or no obvious water flow below the cartridge there may be condensation in the system.	Occasional brief alarms due to condensation are not a cause for concern. Try briefly pinching and releasing tube under cartridge to dislodge the drops and/ or decrease set temperature.
High Temperature Alarm 	Malfunction of Temperature Control System.	Shut down system and return for service. *NOTE: A momentary High Temperature alarm may occur when the unit has been switched off and on again. If the temperature then stabilizes, no action is needed.*
Blocked Tube Alarm 	High water or air pressure due to high resistance in water circulation or air outlet; or malfunctioning pressure sensor.	
	Blocked tube alarm due to high WATER pressure will cause a continuous or intermittent tone and alarm light. The flow of breathing gas continues, but is no longer heated.	Check that delivery tube is correctly positioned, rotated clockwise, and pulled into locked position. Check that water is circulating within delivery tube. If alarm persists replace delivery tube and/or cartridge. Disinfect unit prior to replacing components.
	Blocked tube alarm due to high GAS pressure will cause a 5 second alarm tone. If the obstruction persists the system will continue to alarm in 5 sec episodes. Water circulation continues but the heater shuts off.	Find and correct the cause of obstruction. The most common cause is a kink in the nasal cannual or in the prong. Attempting to run the Vapotherm 2000i at very high flow through a patient interface not approved by Vapotherm may also raise the internal pressure sufficiently to trigger a Blocked Tube Alarm.

If further assistance is needed please call your clinical product specialist or local distributor representative.

6.3 Component Change Outs

WARNINGS:

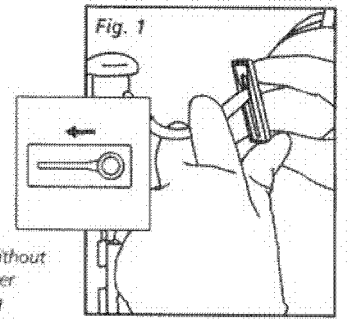
The vapor transfer cartridge, patient delivery tube, and VSS-1 spike set are all single use only and should be discarded after removal from the Vapotherm 2000i.

The Patient Delivery Tube, VSS-1 and Vapor Transfer Cartridge should not be changed or replaced in the patient care area.

The system must be disinfected any time the Vapor Transfer Cartridge, VSS-1 or Patient Delivery Tube are removed.

***NOTE:** The cannula and sterile water source can be replaced without disinfecting the system. As with all respiratory equipment, proper hand washing techniques should be followed before contacting or replacing any patient interfaces.*

Fig. 1

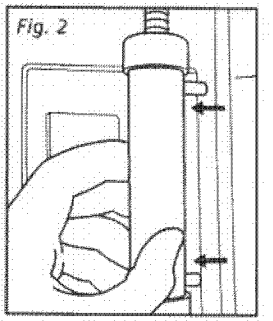


6.3.1 Replacing Vapor Transfer Cartridge

1. Power off unit. Disconnect gas flow.
2. Close clip on VSS-1. *(Fig. 1)*
3. Open hinged cover.
4. Disconnect air tubes from cartridge ends by pressing tubing away from cartridge.
5. Remove cartridge by pulling straight outwards. *(Fig. 2)*
6. Proceed to Section 8.0 and disinfect the Vapotherm® 2000i device before returning the device to service.
7. For set-up please refer to Section 4.3 of the manual.

CAUTION: Do not grip cartridge tubing with sharp instruments.

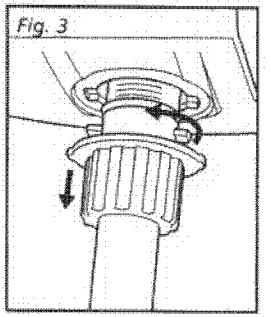
Fig. 2



6.3.2 Replacing the Patient Delivery Tube

1. Power unit off. Disconnect gas flow.
2. To remove tube, push base of tube upwards, rotate 1/4 turn counter clockwise and pull downward. *(Fig. 3)*
3. Proceed to Section 8.0 and disinfect the Vapotherm® 2000i device before returning the device to service.
4. For set-up please refer to Section 4.4 of the manual.

Fig. 3



6.3.3 Replacing the VSS-1 Spike Set

1. Power off unit. Disconnect gas flow.
2. Clamp VSS-1 and remove VSS-1 Spike Set from the water inlet port on the back of the Vapotherm 2000i by releasing the quick connect on the water inlet port.
3. Proceed to Section 8.0 and disinfect the Vapotherm® 2000i device before returning the device to service.
4. For set-up please refer to Section 4.5 of the manual.

Section 7 Removing from Patient and System Shut Down

1. Remove cannula or other interface from patient.
2. Press and release power switch *(Fig. 1)*. Display will show "--"
3. Close clip on VSS-1 *(Fig. 2)*.

NOTE: The system's pump continues to run for 1 minute to allow heater to cool down.

4. After 1 minute, water pump shuts off and numeric display is blank. Unit may now be disconnected from power outlet.
5. Remove unit from patient care area and proceed to disinfection process.

CAUTIONS:
Avoid disconnecting from power or gas sources while machine is operating.

Do not unplug from power source until display is blank.

Fig. 1

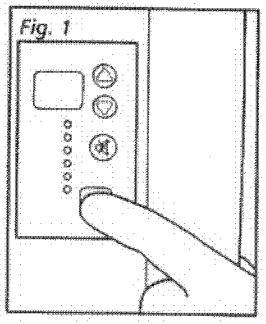
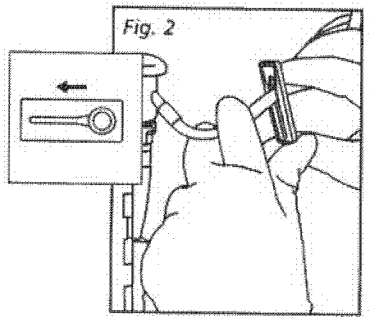


Fig. 2



Section 8 Routine Disinfecting Protocol

8.1 Disinfection Supplies

1. DK-301 (a-e included in kit)
   a. Disinfection Bag A
   b. Disinfection Bag B
   c. Disinfection Tube
   d. Cartridge Bypass Tubes
   e. Y-Spike Assembly
2. Gloves
3. Safety Glasses
4. Disinfectant wipes, 70-90% isopropyl alcohol
5. Approved Disinfectant
6. 1000ml Sterile Water Bag
7. Medical Grade Air Source
8. Standard adult flow meter with oxygen 7ft tubing attached

WARNINGS:
Vapotherm should be disinfected after each patient or every 30 days on a single patient. Do not disinfect in an open patient care area.

The DK-301 disinfection kit is a single use item. Operators should open a new disinfection kit for each disinfection procedure and discard the components at the end of the procedure.

Disinfection Procedure should be performed in a well ventilated area. Use Standard Precautions and aseptic techniques during this procedure.

The Vapor Transfer Cartridge SHOULD NOT be in place when disinfecting the unit.

The Vapor Transfer Cartridge is a single use disposable and must be discarded after each patient use. DK-301 IS NOT designed to disinfect Vapor Transfer Cartridges.

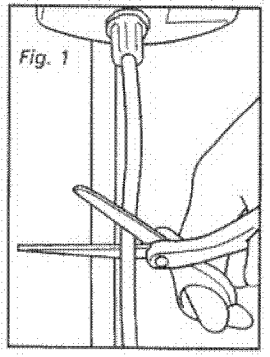
8.2 Pre-Cleaning Process

1. After patient use, it is recommended that the Vapotherm 2000i System remain attached to the IV pole with all the component parts intact.
2. Move the Vapotherm 2000i System to a hospital approved reprocessing area outside the patient care area.

WARNING: The water circuit of the Vapotherm 2000i System is not sterile and can potentially have bacterial contamination. The water circuit of the device should never be opened in a patient care area. Transport the Vapotherm 2000i System to an appropriate area for draining, cleaning and disinfection.

3. Wash hands and put on gloves.
4. Drain the Vapotherm 2000i System in a receptacle by cutting the delivery tube. *(Fig. 1)*
5. Remove and dispose of the delivery tube, cannula, VSS-1 spike set, and sterile water source.
6. Remove and dispose of the vapor transfer cartridge.

Fig. 1



WARNING: The water circuit of the Vapotherm 2000i system has the potential for bacterial growth so standard precautions should be used to open the water circuit. Disposable components should be disposed of in accordance with hospital guidelines and operators should wash their hands after breaking down the device.

8.3 Pre-Disinfection Cleaning and Decontamination

1. Wash hands and put on new gloves.

WARNING: Always use standard precautions when cleaning and disinfecting the Vapotherm 2000i system.

Always use individually wrapped 70-90% isopropyl alcohol disinfectant wipes when wiping down the Vapotherm 2000i and disinfection kit components.

Always use a new disinfectant wipe taken directly from the package or container and ensure that the disinfectant wipe has not dried out before using it on the Vapotherm 2000i device.

2. Wipe exterior casing including inside hinged cover with an approved disinfectant wipe. *(Fig. 2)*
3. Wipe inside and outside of the following connections with an approved disinfectant wipe:
   a. Four cartridge connection ports inside hinged cover (Upper and lower cartridge air tubes and the water connection ports)
   b. Water inlet and air inlet connectors on rear of unit
   c. Delivery tube port on the bottom of unit.

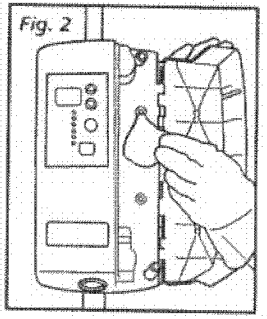


Fig. 2

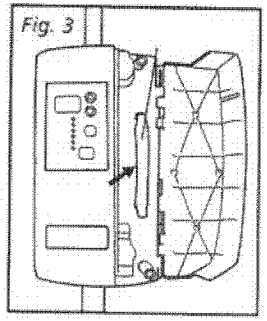


Fig. 3

8.4 Set-up

1. Take the 4 inch bypass tube with 90° barb fittings (Bypass Tube A) and wipe the ends with an approved disinfectant wipe. Press firmly into the inner cartridge connection ports (water circuit). *(Fig. 3)*
2. Take the 6 inch bypass tube with straight barb fittings (Bypass Tube B) and wipe the ends with an approved disinfectant wipe. Insert firmly into outer upper and lower cartridge ports (air circuit). *(Fig. 4)*

WARNING: The By-pass Tubing has been designed to optimize the flow of solutions through the Vapotherm 2000i system. Failure to use the By-Pass Tubing supplied by Vapotherm™, Inc. could lead to improper disinfection and or drying.

3. Close hinged cover.
4. Prepare 200ml of approved disinfectant solution and add it to Bag A with slide clamp closed (see Appendix A – "Disinfection Solutions" for approved disinfection solutions, appropriate concentrations, and required hold times).

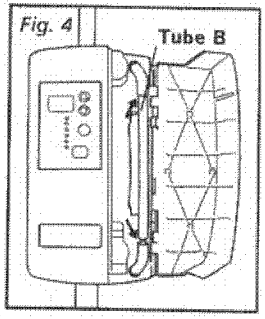


Fig. 4

WARNINGS:

Disinfection solutions, concentrations and hold times in Appendix A have been verified by independent laboratory testing to adequately disinfect the Vapotherm™ 2000i machine when following these instructions. Modifying this procedure or using an alternative disinfection solution, concentration, or hold time could result in inadequate disinfection thereby increasing the risk of contamination.

Always wear gloves when handling disinfectant solutions, work in a well ventilated area, and use an accurate measuring device to ensure the proper concentration of disinfection solution and water.

8.4 Set-up (cont.)

6. Hang Bag A with 200 ml of approved disinfecting solution from IV pole hook.
7. Wipe blue end of disinfection tube with an approved disinfectant wipe. Insert into bottom port of Vapotherm 2000i system. Press firmly into place, rotate 1/4 turn clockwise, and pull down slightly to lock in position. *(Fig. 5)*
8. Wipe the other end of the disinfection tube with an approved disinfection wipe and attach it to the bottom outlet of Bag A. Lock into place. *(Fig. 6)*
9. Suspend Bag B on a separate hook on IV pole. Cap should be firmly closed to minimize potential spilling.
10. Attach Y-Spike Assembly by:
    a. Disinfect wipe male colder fitting end of Y- Spike Assembly and insert it into water inlet port on the back of the Vapotherm 2000i system. Lock into place. *(Fig. 7)*
    b. Disinfect wipe the O, bushing connector end of the Y-Spike Assembly. Attach connector to the air inlet connector port on the back of the Vapotherm 2000i system. *(Fig. 8)*
    c. Disinfect wipe the spike end of the Y-Spike Assembly and insert into bottom outlet of Bag B until it comes to a stop.

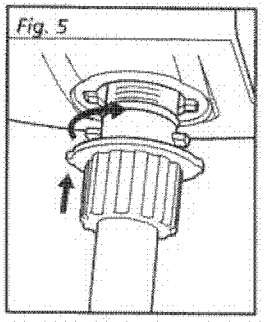


Fig. 5

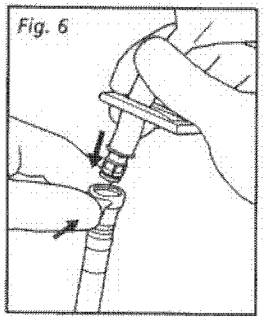


Fig. 6

WARNING: If spike is not properly inserted, it may cause disinfectant to leak creating a potential safety risk. The spike should be inserted into Bag B up to the ridge at the bottom of the spike. Do not insert the spike past the ridge at the bottom of the spike.

NOTE: If the spike is inserted too far into Bag B it will be difficult to remove, do not insert the spike past the ridge at the bottom of the spike. If the spike is hard to remove from Bag B rotate the spike while removing it to make it easier.

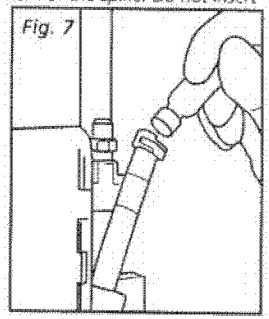


Fig. 7

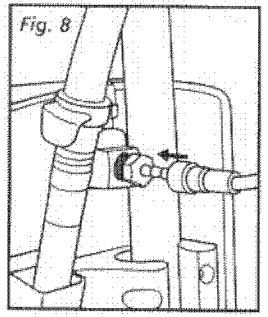
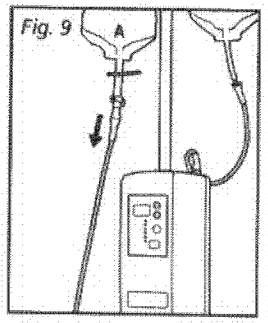
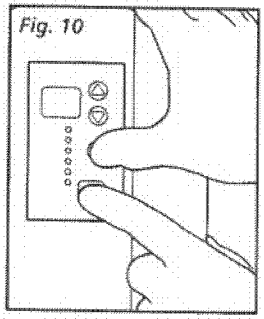
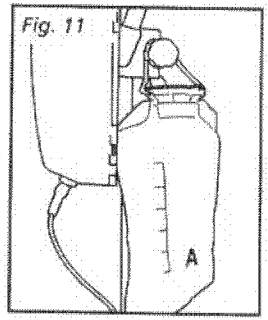


Fig. 8

8.5 Disinfect Gas and Water Circuits







1. Open clamp on Bag A. Disinfectant will start to drain from Bag A through the unit and into Bag B. *(Fig. 9)*
2. When disinfectant has stopped draining into Bag B, clamp Bag A.

NOTE: Not all contents from Bag A will drain into Bag B.

3. Start the Vapotherm 2000i system in cleaning mode by pressing the Mute and Power buttons at the same time *(Fig. 10)*. Disinfectant will circulate through gas and water circuits. Run unit in cleaning mode for the required hold time given in Appendix A for the disinfection solution used.

WARNING: Operating the Vapotherm 2000i system in cleaning mode for less than the required hold time may not adequately disinfect the machine and could lead to contamination of the air and water circuits thereby increasing the risk of infection.

4. After circulating disinfection solution through the machine for the appropriate hold time, turn the Vapotherm 2000i off by pressing the power button.
5. Unclamp and lower Bag A and hang onto Vapotherm i.v. pole clamp knob. *(Fig. 11)*
6. The disinfectant that was contained in reservoir Bag B, has circulated through the unit, and the circulated disinfectant solution drains into Bag A for collection and disposal.
7. Hang 1000 ml of pre-packaged sterile water on i.v. pole.
8. Loosen cap on Bag A to allow air to vent out of the bag as sterile water fills the bag.

WARNING: The disinfection procedure has been specifically designed to use 200 ml of disinfection solution and 1000 ml of sterile water. Bag A is designed to hold 1200 ml of solution. Using larger than the recommended volumes during disinfection or rinsing could cause a spill of diluted disinfection solution.

9. Close the clamp on Bag B, remove the spike, and discard the Bag B in accordance with all applicable regulations and institutional guidelines.
10. Wipe spike with an approved disinfectant wipe and firmly insert into the spike port of a prepackaged sterile water bag. Confirm that water is flowing.
11. Immediately start the Vapotherm 2000i in cleaning mode by pressing the Mute and Power buttons at the same time. (Fig. 10)
12. Run the cleaning mode to circulate the sterile water through the Vapotherm 2000i system until all the water has drained from the sterile water bag. Immediately turn off the system.

CAUTION: Running the system dry can damage the water pump.

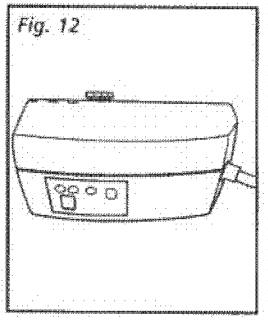
13. Clamp tubing and close cap on Bag A and disconnect the bag from the disinfectant tube.

WARNING: Failure to clamp off or close the cap of Bag A firmly before disconnecting it from the disinfection tube could cause diluted disinfection solution to spill.

8.5 Disinfect Gas and Water Circuits (cont.)

14. Leave all DK-301 tubing connected to the Vapotherm system.
15. Dispose contents of Bag A in accordance with all applicable regulations and institutional guidelines.

8.6 Drying



1. Ensure that the Disinfectant Tube, Cartridge Bypass Tubes and the Y-Spike Assembly are all in place.

CAUTION: In order to dry the Vapotherm 2000i system, the Disinfectant Tube, Bypass Tubes and the Y-Spike Assembly must all be connected to the Vapotherm 2000i system.

2. Remove the spike from the empty sterile water bag and wipe with an approved disinfectant wipe.
3. Insert spike from Y-Spike Assembly into standard oxygen tubing.
4. Set flowmeter to 15 lpm.
5. Take the Vapotherm 2000i system and position the system flat on its side opposite the cartridge door for 2 minutes. *(Fig.12)*
6. After 2 minutes attach the Vapotherm® 2000i device back on the IV Pole and continue to dry at 15 lpm for 25 minutes.
7. After a minimum of 25 minutes, disconnect the disinfection tube, the cartridge By-Pass tubing and Y-spike assembly and close the door to the cartridge area for storage. Discard all components of the DK-301 kit in accordance with all applicable regulations and institutional guidelines.
8. Wipe down exterior casing with disinfectant wipe.
9. Place a sticker over the cartridge access door to certify that the device has been disinfected.
10. Log the disinfection procedure on a Vapotherm 2000i Disinfection Log Sheet or in a similar log approved by your institution. Appendix B has a Sample Disinfection Log. The Disinfection Log can be accessed and printed out at www.vtherm.com.
11. Place the system in a clean plastic cover and seal the end by tying a knot or a clip.
12. The system is now ready for use or storage.

CAUTION: Do not set the flowmeter above 35 lpm or start the drying process without the disinfecting tube in place. This can cause damage to the pressure transducers in the Vapotherm 2000i system.

WARNING:

Gram (-) bacteria can grow in moist environments. The Vapotherm 2000i system should not be stored with visible water remaining in the device.

Vapotherm should be disinfected after each patient or every 30 days on a single patient. Do not disinfect in an open patient care area.

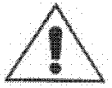
The DK-301 disinfection kit is a single use item and must be discarded after the disinfection procedure.

9.1 Specifications

Dimensions:	Height 11" (280 mm), width 5.5" (140 mm), depth 4.5" (114 mm) excluding IV pole clamp.
Weight:	Less than 6 lbs (2.7 kg) without water reservoir.
Vapotherm spike set:	Works with sterile water bags up to 2000 ml bag.
Circulating water volume	<100 ml. (excluding Patient Patient Delivery Tube).
Mounting:	Rear mounted clamp fits standard IV pole or hanger.
Power:	(US) 115 V, 60 Hz, 250 VA (warm up), approximately 80 VA (continuous). (Other versions) 220–240 V, 50–60 Hz, 250 VA (warm up), approximately 80 VA (continuous).
Gas source pressure:	4–50 psi. At high pressures (e.g. hospital wall system) the Vapotherm 2000i must be connected to the gas outlet via a standard medical flowmeter and flow regulator with approved fittings.
Gas flow:	Controlled by external flowmeter. Operating range 1–40 lpm, dependent on cartridge type and patient interface used.
Output gas temperature:	(US) 33–43°C at outlet of the delivery tube, adjustable by front panel settings. (Other versions) 33–41°C.
Humidification:	Vapor phase, by transpiration through microporous membrane. Output is at least 95% relative humidity at nasal cannula at a flow rate up to 20 lpm, at least 90% at flow rates from 20–40 lpm, over the full range of operating conditions.

9.2 Definitions and symbols


Type BF Class 1


Attention Consult Manual


Silence Alarms


Power On/Off


Alternating Current


Single Patient Use

CE 0297

Vapotherm, Inc warrants that the Vapotherm™ 2000i shall be free of defects of workmanship and materials and will perform in accordance with the product specifications for a period of one year from the date of sale by Vapotherm, Inc. If the product fails to perform in accordance with the product specifications, Vapotherm, Inc. will repair, or replace, at its option, the defective materials or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

VAPOTHERM, INC. DISCLAIMS ALL LIABILITY FOR ECONOMIC LOSS, LOSS OR PROFITS, OVERHEAD OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY SALE OR USE OF THIS PRODUCT. THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES.

- Bamford, Owen and Lain, David. Verification of the Bacteriological Filtration Properties of the Vapotherm Cartridge. Respiratory Care November 2004. Vol. 49 No.11
- CDC, Guideline for prevention of nosocomial pneumonia. MMWR 1997:46 (NO. RR-1)
- CDC, Guidance for Isolation Precautions in Hospitals. Garner, Julia. January 1996. Retrieved May 26, 2006, from http://www.cdc.gov/ncidod/dhqp/gl_isolation.html
- Standard Precautions: CDC, Excerpted from Guideline for Isolation Precautions in Hospitals (January 1996) Retrieved May 26, 2006 from http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html

Appendix A – Disinfection Solutions

This appendix lists approved disinfectant solutions and the required hold times necessary to disinfect the Vapotherm 2000i machine using the routine disinfection procedure outlined in the Vapotherm 2000i Manual Rev B, Section 8. The following disinfectants have been independently tested by an ISO compliant FDA registered lab using "good laboratory practices" (GLP):

Manufacturer	Active Ingredients	Trade Name	Concentration	Hold Time*
Minntech Corporation 14605 28th Avenue North Minneapolis, MN 55447 (800) 328-3345	Hydrogen Peroxide 22% and Peracetic Acid 4.5%	Minncare™	1%	10 minutes at 20°C
Maril Products Inc. 320 West 6th Street Tustin, CA 92780 (800) 546-7711	Dimethyl Benzyl Ammonium Chloride 10% and Dimethyl Ethyl Benzyl Ammonium 10%	Control 3™	1%	10 minutes at 20°C

*Section 8 Step 4 of the Vapotherm 2000i Operating Manual requires approved disinfection solutions to be circulated through the device for an appropriate hold time as outlined in this column of Disinfection Appendix A.

WARNINGS:

These disinfectant solutions are designed to be used to disinfect the Vapotherm 2000i machine without the cartridge in place. These disinfectant solutions ARE NOT approved to disinfect the cartridge.

Failure to properly prepare the disinfection solution or circulate the disinfection solution throughout the machine for the appropriate hold time could result in inadequate disinfection.

Disinfectants must be used at proper concentrations. User must confirm solution has been mixed according to disinfectant manufacturers instructions, or used in pre-diluted form.

Solutions must not be used past their expiration dates See disinfectant manufacturer's product labeling for instructions.

Appendix A – Disinfection Solutions (cont.)

Dilution Instructions for preparing a 1% solution of Minncare® and Control III®

Supplies Needed:

- A beaker, graduated cylinder, or container suitable for measuring and mixing 200ml of disinfectant solution

WARNING: Components or instruments that are not part of the DK-301 Kit and are used to mix or pour disinfectant solutions should be either single use components or glassware that has been sterilized, high level disinfected, or pasteurized before use in accordance with your institution's specific disinfection and sterilization procedures.

- 10ml syringe, or pipette, graduated in 1ml increments
- Concentrate Disinfectant
- Minncare® Cold Sterilant EPA Reg No. 52252-4 (22.00% Hydrogen Peroxide, 4.50% Peroxyacetic Acid, 73.50% Inert Ingredients)
- Control III® Disinfectant P/N 10006 (10% n-alkyl dimethyl benzyl ammonium chloride, 10% n-aykyl ethyl benzyl ammonium chloride, 80% inert ingredients)
- 200 ml of sterile water

WARNINGS:
Always follow manufactures recommendations for handling disinfectant solutions.
Always wear Personal Protective Equipment when handing disinfectant solution.

Procedure:

1. Don appropriate Personal Protective Equipment: Safety goggles, gloves, splash apron.
2. Using an appropriate syringe or pipette, draw up 2 ml of undiluted Minncare® (EPA Reg No. 52252-4) or Control III® (P/N 10006) and expel it in a device appropriate for measuring 200 ml of solution.
3. Make up 200 ml of solution by adding sterile water to the measuring device.
4. Close the slide clamp on Disinfection Bag A and pour disinfectant solution into the bag.
5. Close the cap of Bag A firmly, to avoid spills and continue with Step 6 in Section 8.4 of the disinfection procedure (Page 18).
6. Attach to IV Pole and Vapotherm 2000i according to Disinfection procedure and continue to follow Disinfection Protocol.

Appendix B – Sample Disinfection Log

Vapotherm 2000i Machine Serial No.	Hospital ID (If Applicable)	Disinfection Date	Disinfectant Solution & Hold Time	Operator

VAPOTHERM

Supplied by

Vapotherm, Inc.
198 Log Canoe Circle, Stevensville MD 21666
T: (001) 410.604.3977 F: (001) 410.604.3978 www.vtherm.com

PN 8-300068-00 Rev. E
bdc 8369

1757

Manufactured by:
VIASYS Respiratory Care Inc.
1100 Bird Center Drive
Palm Springs, CA 92262-8099
P: 800-231-2466
F: 714-283-2228

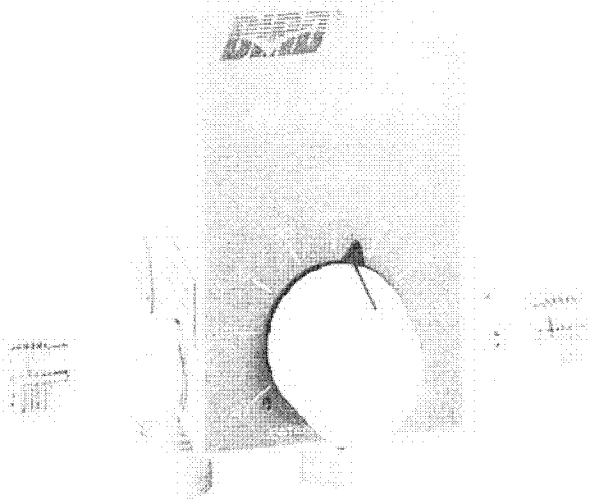
European Authorized Representative:
VIASYS healthcare GmbH
Leibnizstrasse 7
97204 Hoechberg
Germany
P: +49 931 4972-0
F: +49 031 4972-42

VIASYS®
HEALTHCARE

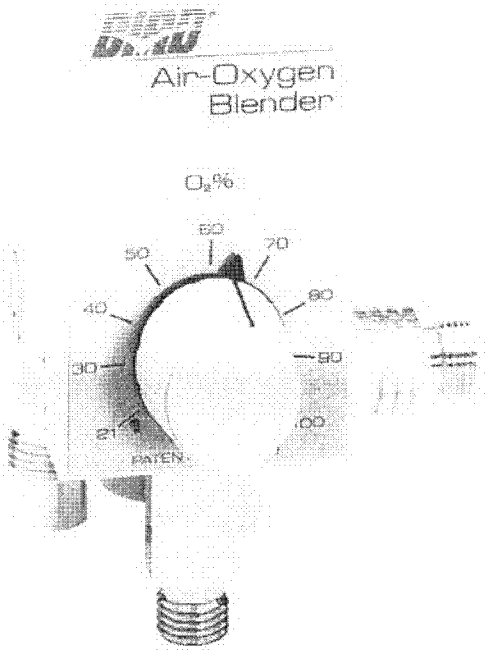
1758

Instruction Manual

Low Flow MicroBlender



High Flow MicroBlender



VIASYS®
HEALTHCARE

L2965-51 Rev B

159

VIASYS Respiratory Care Inc.
1100 Bird Center Drive
Palm Springs, CA 92262-8099

Telephone: (800) 231-2466
Fax: (714) 283-2228

www.viasyshealthcare.com

CONTENTS

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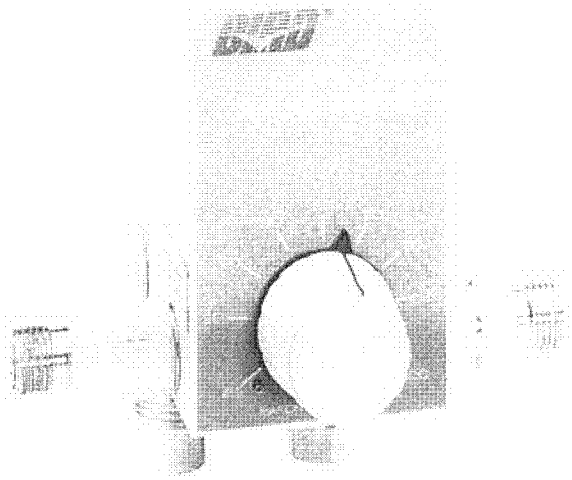
SECTION 1
INTRODUCTION

The MicroBlender is a lightweight, compact, air-oxygen blender that provides precise mixing of medical-grade air and oxygen.

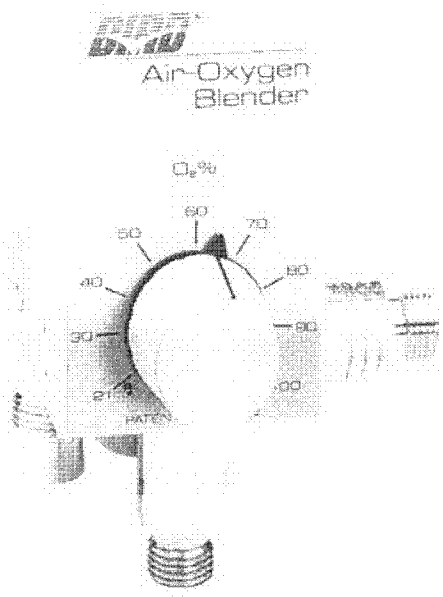
The MicroBlender provides oxygen concentrations from two gas-outlet ports.

The MicroBlender can be used in conjunction with:

- Oxygen hoods
- Resuscitation bags
- Masks
- Transports
- Nasal cannulas
- Treatments



Low Flow MicroBlender



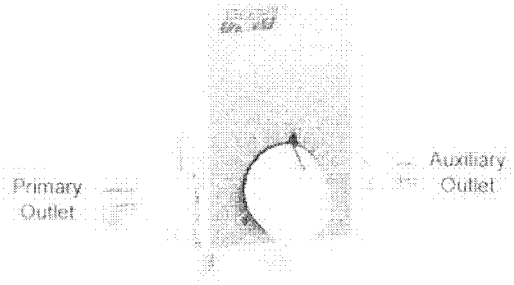
High Flow MicroBlender

h63

SECTION 2
OPERATION OVERVIEW

The MicroBlender provides selection of oxygen concentrations by means of a single control knob located on the front of the unit. Oxygen concentrations ranging from 21 to 100% are available.

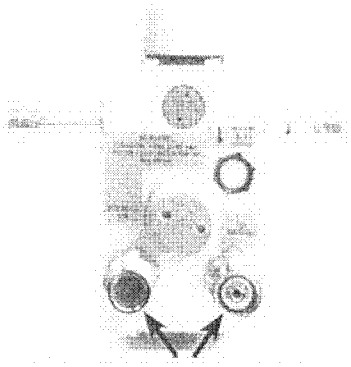
	Outlet	Flow Range	Bleed Flow
Low Flow MicroBlender	Primary, Left Side	3-30 LPM	No Bleed Flow
	Auxiliary, Right Side	0-30 LPM	2.5-3.5 LPM
High Flow MicroBlender	Primary, Bottom	15-120 LPM	No Bleed Flow
	Auxiliary, Right Side	2-100 LPM	10-12 LPM



Low Flow MicroBlender Outlets

GAS INLETS

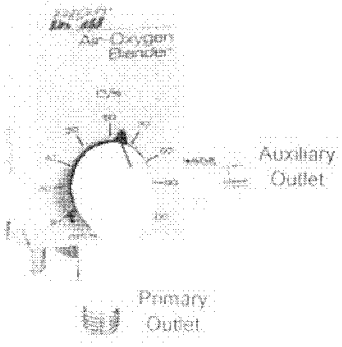
The ports located on either side of the unit allow flexibility for the clinician. The MicroBlender operates by using two 30–75 PSI gas sources that enter the device through DISS or NIST connectors located on the bottom the unit.



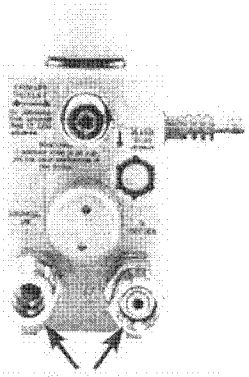
30 - 75 PSI Inlet Connectors

Air and oxygen hoses are connected directly onto the MicroBlender gas inlets.

Each inlet connector incorporates a 30 micron particulate filter. After passing through the filter, the gases travels through duckbill check valves that prevent reverse gas flow from either the air or oxygen supply systems.



High Flow MicroBlender Outlets



30 - 75 PSI Inlet Connectors

The MicroBlender is tested for compliance with ISO 11195E (1995), clause 6, regarding reverse-gas flow as delivered.

BALANCE MODULE

The gases then enter the balance modules, which equalize the operating pressures of the air and oxygen. The diaphragm in the balance module responds to a difference in pressure and directs the movement (stroke) of each poppet contained within the air and oxygen chambers. The movement of each poppet adjusts the amount of gas flowing through the balance module, equalizing the air and oxygen pressures.

PROPORTIONING MODULE

From the balance module, the gases flow into the proportioning module and mix according to the oxygen percentage selected with the MicroBlender control knob. This module consists of a double-ended poppet positioned between two valve seats.

One valve seat controls the passage of air and the other valve seat controls the passage of oxygen into the MicroBlender outlets. At this point, the two gases have been blended according to the oxygen percentage selected by the control knob.

ALARM/BYPASS

The alarm feature provides for an audible alarm if source pressures differ by 20 $\pm$ 2 PSI or more. The primary purpose of the alarm is to audibly warn the operator of an excessive pressure drop or depletion of either source gas. The alarm will also activate when there is an elevation of either source gas resulting in a 20 $\pm$ 2 PSI difference. Should both gas pressures (oxygen or medical air) increase or decrease simultaneously, and a 20 $\pm$ 2 PSI differential is not seen, there will not be an audible alarm. If either source gas pressure drops, the output pressure of the blender will drop similarly, since the source gases are always balanced to that of the lower pressure.

The bypass function operates in unison with the alarm. The alarm bypass poppet communicates directly with the air supply on one end and the oxygen supply on the other.

When the two source gases are near equal in pressure, the alarm bypass poppet is positioned over the bypass channel, blocking the flow of both gases. The poppet will remain seated for unequal pressures up to 20 $\pm$ 2 PSI. Once a 20 $\pm$ 2 PSI difference occurs, the higher gas pressure will overcome the spring force and pressure of the poppet at its opposite end, thus creating a path (air or oxygen) to flow into the alarm channel.

The gas with the higher pressure will also flow directly to the blender outlet port bypassing the Balance and Proportioning Modules. The gas is also directed to the bottom of the unit to the reed alarm, thus creating an audible warning. The oxygen concentration will be that of the gas at the higher pressure. The blender in the alarm/bypass mode will deliver the oxygen (100%) or medical air (21%) until the pressure has been restored to a differential of approximately 6 PSI.

If the blender is set at 21% and the OXYGEN source pressure is reduced enough to produce a 20 $\pm$ 2 PSI or greater differential, the unit may not alarm because it will continue to deliver 21% concentration according to the setting. If the control is moved slightly from the 21% setting, the alarm will sound.

Similarly, if the blender is set to deliver 100% concentration and AIR source pressure is reduced or lost, the unit may not alarm because it will continue to deliver the selected 100% concentration.

If the blender is left connected to source gases but is not being used (i.e., no output flow or bleed flow) the unit will not alarm if a 20 $\pm$ 2 PSI or greater pressure differential develops. If the blender is not in use, an alarm under these conditions will be an unnecessary distraction or nuisance.

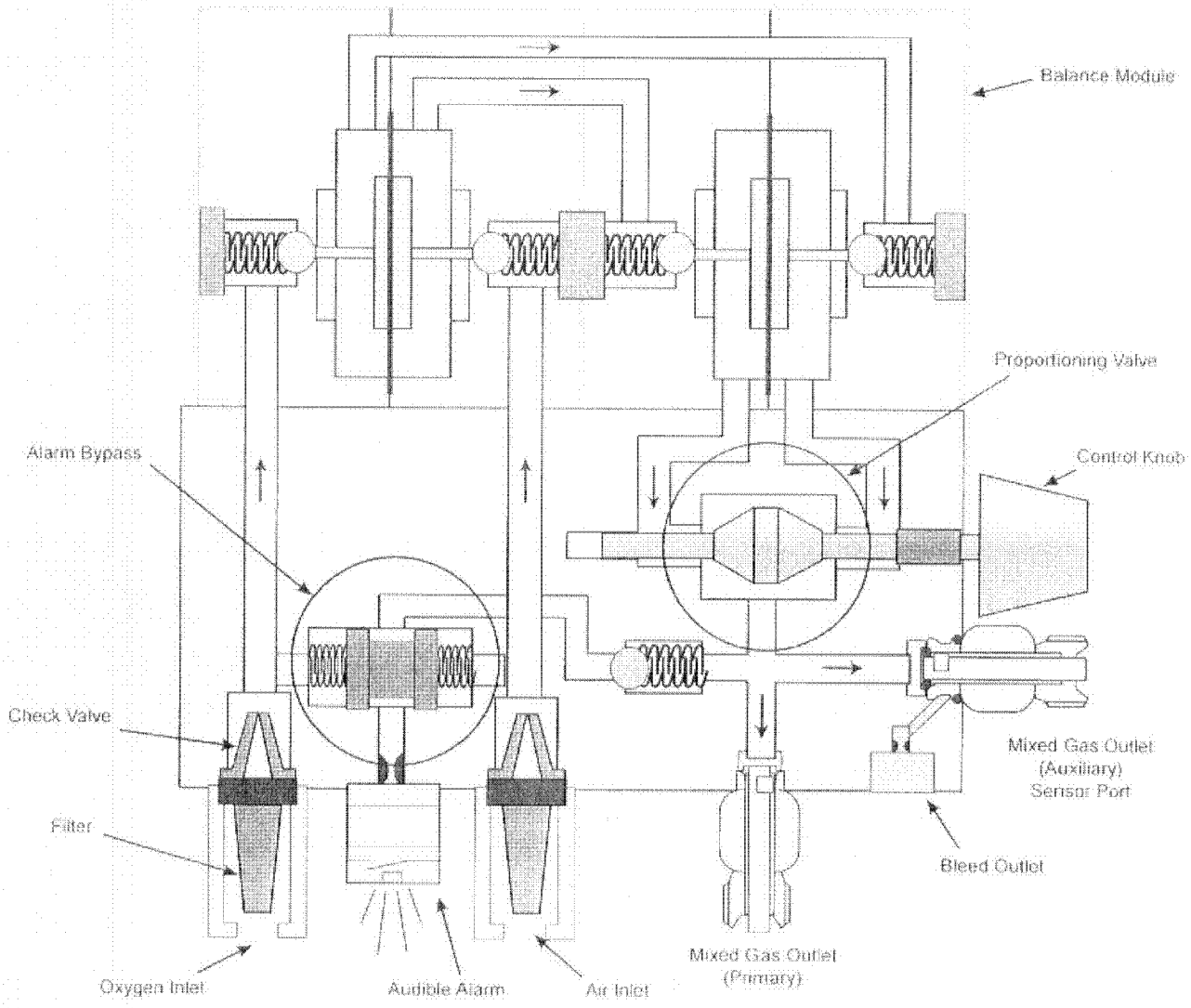
OUTLET PORTS

On the Low Flow MicroBlender, two outlet ports are located on the right and left sides of the MicroBlender and allow low ranges from 0-30 LPM with bleed and 3 - 30 LPM without bleed respectively. On the High Flow MicroBlender, the primary outlet port is located on the bottom of the MicroBlender, and the auxiliary outlet is located on the right side of the MicroBlender, allowing ranges from 15 to 120 LPM without bleed and 2 to 90 LPM with bleed respectively.

BLEED OUTLET

For the Low Flow MicroBlender, when a connection is made to the right side outlet port, for example, when a flow meter is attached, a bleed flow of 2.5- 3.5 LPM is achieved. For the High Flow MicroBlender, when a connection is made to the right side outlet port, a bleed flow of 10-12 LPM is achieved. For both Blenders, the bleed flow exits the unit through a muffler port located on the bottom of the MicroBlender.

High Flow MicroBlender



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SECTION 3
WARNINGS, CAUTIONS, AND NOTES

The MicroBlender should be operated by trained, qualified medical personnel under the direct supervision of a licensed physician. Before clinical application, the following WARNINGS, CAUTIONS and NOTES should be read and understood.

WARNING!
Conditions may exist that could adversely affect the operator or patient.

CAUTION!
Conditions may exist that could damage the MicroBlender or other pieces of equipment.

NOTE
A specific point is made to assist the operator in understanding the equipment.

WARNING!

- If either the air or oxygen gas source fails, the MicroBlender alarm sounds, alerting the clinician that a condition has occurred that may significantly alter the FiO_2 and flow output from the MicroBlender.
- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 20 $\pm$ 2 PSI, the MicroBlender alarm sounds. This condition significantly alters the FiO_2 and flow output from the MicroBlender.
- Always operate the MicroBlender with clean and dry medical grade gases.
- Air Inlet Filter/Water Trap (P/N 07426) is recommended for use with the MicroBlender.
- The patient gas must be monitored with an oxygen analyzer.
- DO NOT steam clean, autoclave, or otherwise subject the MicroBlender to temperatures above 145°F (62°C).
- DO NOT immerse the assembled MicroBlender in liquid decontamination agents.
- Consult a physician for appropriate FiO2 setting.
- DO NOT tape, obstruct, or remove the reed alarm outlet at any time.
- DO NOT occlude or obstruct the bleed port or muffler on the bottom of the MicroBlender.
- Adjustment of the oxygen concentration must be verified using an oxygen analyzer.

CAUTION!

- Always operate air/oxygen blenders with clean and dry medical grade gasses. Contaminant or moisture can cause defective operation. Air used for medical purposes must meet USP compressed air and/or ANSI Z86.1 1973 grade F, and water vapor content must not exceed a blenders dew point of 5°F below the lowest ambient temperature to which the delivery system is exposed. Particulate content must not exceed that which would be down stream of a 15 micron absolute filter.

- Water vapor content of medical air or O_2 supply to the MicroBlender must not exceed 5.63 grams H_2O per cubic meter of non-condensable gas.

NOTE

- Users are advised to use inlet pressure regulators with the MicroBlender to display system pressure.

- Allow equilibration time for FiO_2 changes before analyzing gas.

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SECTION 4
CONTROLS AND ALARMS

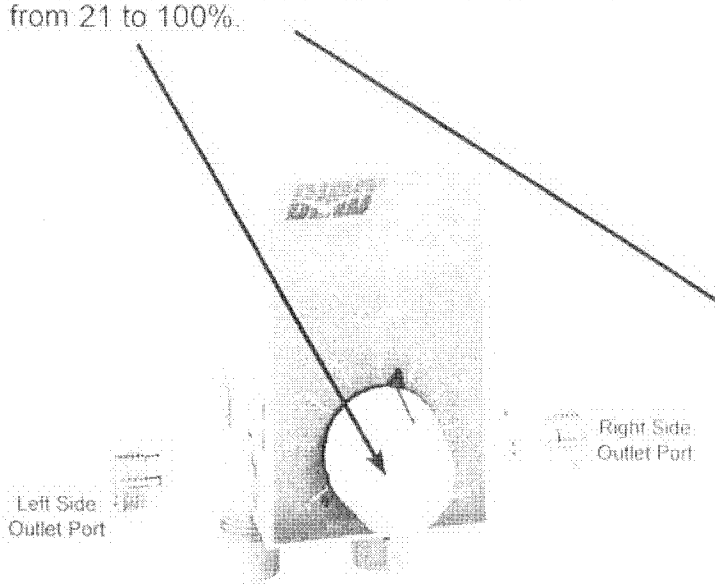
The MicroBlender delivers selected oxygen concentrations through two outlet ports. The outlet ports, although similar in appearance, have different flow range specifications. The two outlet ports provides a choice of flow ranges based on the application desired. Both outlets may be used simultaneously, provided the combined flows do not exceed the rated maximum flow capability of the MicroBlender. The use of a flow meter attached to either or both of the outlet ports may be used to control the flow of mixed gas.

CONTROL KNOB

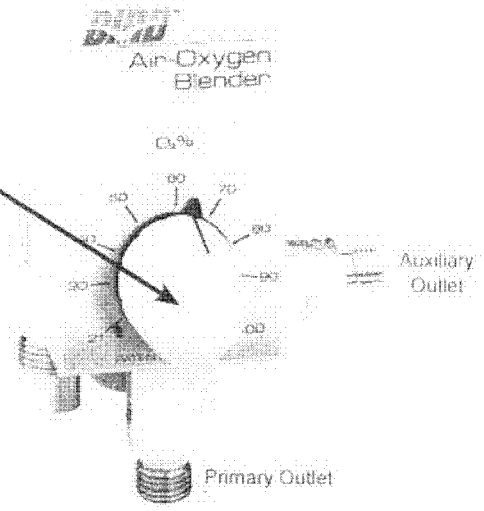
Allows the selection of oxygen concentrations from 21 to 100%.

ALARM

An audible alarm indicates a differential of 20 PSI has been reached between air and oxygen inlet gas pressures.



Front View of the Low Flow MicroBlender



Front View of the High Flow MicroBlender

SECTION 5
PERFORMANCE CHECKS

Before placing the MicroBlender into clinical use, perform the following performance checks.

WARNING!
If the MicroBlender does not function as described below, contact VIASYS Respiratory Care (refer to the company information at the beginning of this manual).

DO NOT use the MicroBlender until correct performance is verified.

Low Flow MicroBlender Alarm / Bypass Check Reverse Flow Check

Adjustment	Response
1. Applying 30 -75 PSIG air/oxygen source gas. Adjust the control knob to 60%	1. Alarm/Bypass* should not activate (if gases are within 20 PSI of each other).
2. Disconnect the 50 PSIG air source from the MicroBlender.	2. Audible alarm. by pass* gas flow starts.
3. Reconnect the 50 PSIG** air source to the MicroBlender.	3. Audible alarm stops; bypass* gas flow stops flowing.
4. Disconnect the 50 PSIG** oxygen source from the MicroBlender.	4. Audible alarm, bypass* gas flow starts.
5. Reconnect the 50 PSIG** oxygen source to the MicroBlender.	5. Audible alarm stops; bypass* gas flow stops flowing.
6. Connect a flow meter and an oxygen analyzer to either outlet port; with the MicroBlender control knob set at 60%, adjust the outlet flow rate to 6 – 8 LPM.	6. Oxygen ana lyzer should read 60 ± 3% when measured from the flow meter outlet.

*Bypass flow should occur whenever the alarm sounds, but this condition can only be verified by measuring O_2 concentrations with an oxygen analyzer.
**Gas supply pressures of 50 PSIG provide optimal performance.

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High Flow MicroBlender Alarm / Bypass Check

Adjustment	Response
1. Connect the 50 +/- 5 PSIG* air/ oxygen source gases. Adjust the control knob to 60%. Connec t the flowmeter to the auxiliary outlet and set the flow to 2 LPM.	1. Alarm/Bypass should not activate.
2. Connect an oxygen flowmeter to the auxiliary outlet to activate the auxiliary bleed and disconnect the 50 PSIG* air source from MicroBlender. **NOTE**: The MicroBlender must be flowing gas for the alarm to activate.	2. Audible alarm
3. Reconnect the 50 PSIG* air source to the MicroBlender.	3. Audible alarm stops. Verify oxygen concentration with an oxygen analyzer.
4. Disconnect the 50 PSIG* oxygen source from the MicroBlender.	4. Audible alarm.
5. Reconnect the 50 PSIG* air source to the MicroBlender.	5. Audible alarm stops. Verify oxygen concentration (57% to 63%) with an oxygen analyzer.
6. Verify that the oxygen flowmeter is set at 2 LPM.	6. Oxygen analyzer should read 57 to 63% when measured from the flowmeter outlet

Reverse Flow Check

1. Connect both gas supply hoses to the inlet connectors.

2. Connect the oxygen hose to an oxygen pressure regulator, and submerge the free end of the air hose in a container of water.

   Do not make a connection to either outlet (so that they remain closed).

3. Slowly adjust the oxygen pressure regulator to increase pressure from 0 to 50 PSIG* while looking for bubbles to rise from the submerged air hose connector.

   The presence of bubbles indicates leakage of the one-way valve and the need for repair.

4. If there is no leakage, disconnect the oxygen from the regulator and submerge the end of the hose in water.

5. Connect the air hose to an air pressure regulator and repeat the procedure. Repair if bubbles are present.

*Gas supply pressures of 50 PSIG provide optimal performance.

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SECTION 6
TROUBLESHOOTING GUIDE

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
Oxygen concentration discrepancy between MicroBlender settings and analyzer.	1. Analyzer out of calibration.	1. Calibrate the analyzer
	2. Flow requirements are below the specified LPM range.	2. Correct the flow. Verify that the correct outlet port is being used. Each outlet port has a different flow range.
	3. Gas supply is contaminated.	3. Correct the contaminated gas supply. If repair is needed, contact VIASYS Respiratory Care
	4. MicroBlender is out of calibration.	4. Contact VIASYS Respiratory Care for repair.
	5. Bleed filter is obstructed, causing reduction of bleed.	5.Contact VIASYS Respiratory Care
	6. Air entrained into circuit by ventilator or accessory device.	6. Correct
Alarm sounding	1. Inlet pressure difference greater than 20 PSI.	1. Correct the pressure difference.
	2. Alarm module is not calibrated properly.	2. Contact VIASYS Respiratory Care for repair.
	3. Inlet gas contamination, alarm module malfunction.	3. Contact VIASYS Respiratory Care for repair.
MicroBlender in bypass - no alarm.	Reed plate improperly installed or damaged.	Contact VIASYS Respiratory Care for repair.
MicroBlender is accurate only when inlet gas pressures are equal.	1. Balance module not functioning properly.	1. Contact VIASYS Respiratory Care for repair.
	2. Both air and oxygen gas sources are below 30 PSIG.	2. Correct the low pressure condition.

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SECTION 7
CLEANING AND STERILIZING

NOTE
User is to consult with the manufacturer of the ETO equipment for aeration time.

- Use an all purpose liquid cleaner on the exterior.
- **Do not** steam autoclave or otherwise subject the MicroBlender to temperatures over 145° F.
- **Do not** immerse the assembled Low Flow MicroBlender in liquid decontamination agents.
- **Do not** use any strong solvent cleaners on labels or markings.

Blenders manufactured by VIASYS Respiratory Care are compatible with ethylene oxide gas sterilization.

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SECTION 8
MAINTENANCE AND SERVICE

CAUTION!
The MicroBlender should only be serviced or calibrated by a VIASYS Respiratory Care trained technician.

CAUTION!
If the MicroBlender does not function as outlined in Section 5, contact VIASYS Respiratory Care for service.

VIASYS Respiratory Care equipment is designed to provide the maximum amount of utilization with a minimum amount of maintenance. When determining the desired frequency of complete overhaul intervals, three variables must be considered:

- Frequency of use
- Cleanliness of compressed air source
- Use of an air inlet filter/water trap

The MicroBlender, like other pieces of health care equipment, will require routine maintenance over a period of time. Before to placing the MicroBlender into clinical use, follow the performance-check guidelines outlined in Section 5.

When using the MicroBlender with a compressed air source, an air inlet filter/water trap (P/N 07426 or equal) is recommended. Contaminants from hospital air lines may compromise the function of the MicroBlender.

Applicable parts used in the MicroBlender have been cleaned and de-greased for oxygen service. All lubricants used during assembly are designed for use in an oxygen enriched environment. Use only VIASYS Respiratory Care specified lubricants when servicing this device.

Elastomer components, such as diaphragms and o-rings, are designed to function satisfactorily for a minimum of two years. The need for cleaning and replacement depends on gas line conditions and is indicated by the MicroBlender not meeting its specified performance. Three years is considered the maximum service interval under the best circumstances.

SECTION 9
PARTS AND ACCESSORIES

Parts and Accessories	
MicroBlender BRACKETS	
Part No.	**Description**
04322	Pole Mount 1 w/ Female Dovetail
05141	Dovetail Bracket, Accepts Built -in Bracket
05213	Dovetail Bracket, Wall Mount Female
09437	Rail Mount Adapter Bracket
OPTIONAL ACCESSORIES	
Part No.	**Description**
00060	Oxygen Supply Hose, 15 ft.
00066	Elbow Adapter 90°
01468	Y-Connector 9/16 – 18 Female and Male Threads for Dual Flow Meters
02899	Air Supply Hose, 15 ft.
03867	Air Supply Hose, 3 ft.
07426	Air Inlet Filter/Water Trap

MS

SECTION 10
EXPLANATION OF ABBREVIATIONS

Air/O_2 - Mixture of Compressed Air and Oxygen

°C - Degrees Centigrade

CGA - Compressed Gas Association

DISS - Diameter Indexed Safety System

°F - Degrees Fahrenheit

FiO_2 - Fractional Concentration of Inspired Oxygen

O_2 - Oxygen

LPM - Liter Per Minute

P/N - Part Number

PSIG - Pounds Per Square Inch Gauge

Do not operate the MicroBlender outside the supply pressure range (30–75 PSIG). Gas supply pressures of 50 PSIG provide optimal performance. The graphs on the following page illustrate typical flow performance characteristics of a representative sample for the Low Flow MicroBlender. The graphs are typical of a representative sample; slight variations among units should be expected.

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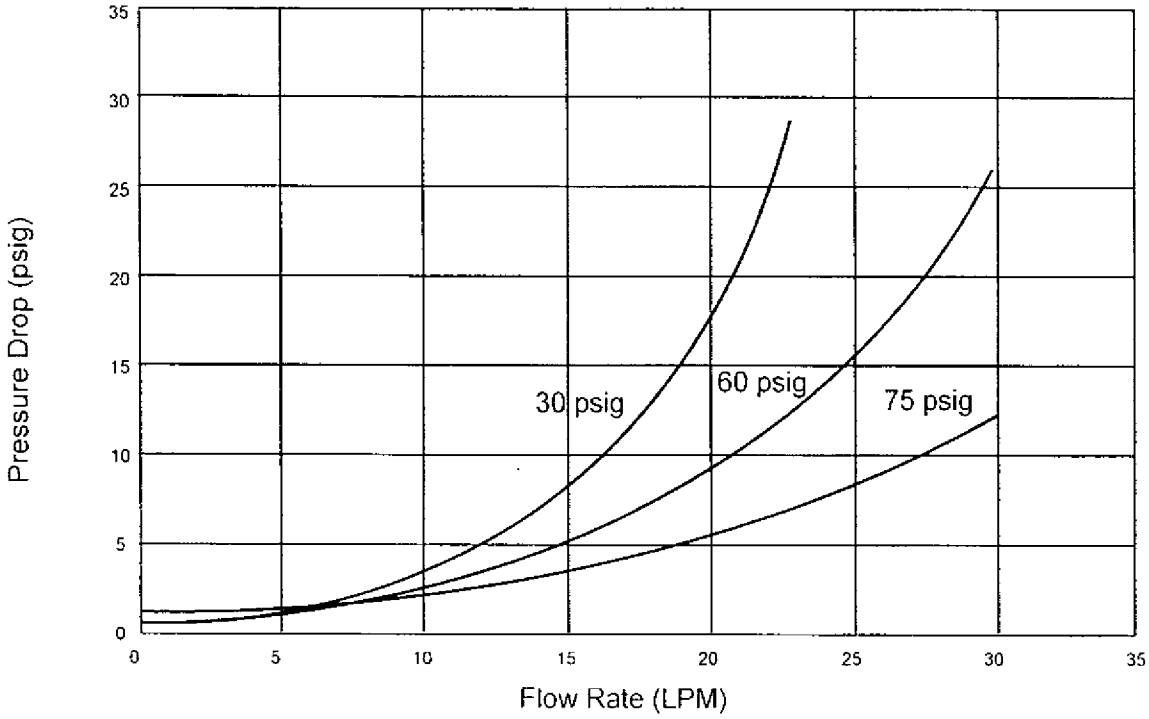
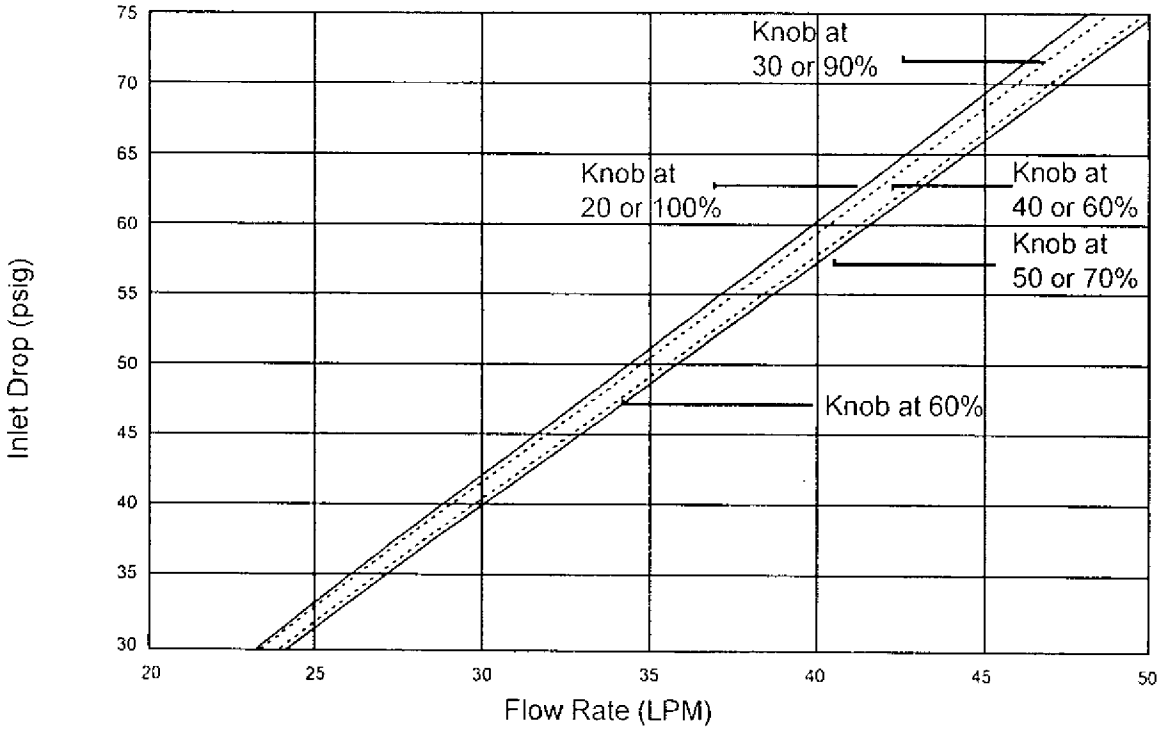


Outlet Pressure Drop at Flow

Note: The graphs are typical of a representative sample; slight variations among units should be expected.



Average Outlet Flow at Various Inlet Pressures

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Gas Supply Pressure	Low Flow	30-75 PSIG (Air and Oxygen must be within 20 PSI of each other)
	High Flow	30-75 PSIG The MicroBlender will maintain stated accuracy at supply pressure, provided the differential between supply pressures does not exceed 10 PSIG. Output flow rate will be diminished if either supply pressures is below 50 PSIG and will be increased if both supply pressures are above 50 PSIG.
Oxygen Concentration Control	Low Flow	21 to 100%
	High Flow	
Outlet Port Flow Ranges		
Auxiliary Outlet	Low Flow	Right Side Outlet 0-30 LPM (Bleed 2.5 -3.5 LPM)
	High Flow	Right Side Outlet 2-100 LPM (Bleed 10 -12 LPM)
Primary Outlet	Low Flow	Left Side Outlet 3-30 LPM (No Bleed)
	High Flow	Bottom Port 15-120 LPM (No Bleed)
Maximum available flow at 60% setting with 50 PSIG both inlets	Low Flow	>30 LPM
	High Flow	>120 LPM
Accuracy	Low Flow	With inlet gases within 17 PSIG , and each gas pressure greater than 30 PSIG (but less than 75 PSIG). The FiO_2 remains constant within ±1% of set value (total set point error is ±3% full scale).
	High Flow	With inlet gases within 10 PSIG and each gas pressure greater than 30 PSIG but less than 75 PSIG; +/-3% of full scale over the stated flow ranges
Stability	Low Flow	±1% (for a fixed concentration setting when operated within specified flow and supply pressure limits)
	High Flow	O_2 concentration shall not vary form a set -point by more than ±1.0 O_2% if either the upstream pressure of the output flow rate is changed within its range specified herein
Alarm/Bypass Activation	Low Flow	When inlet gas pressures differ by 20 PSI ± 2 PSI
	High Flow	

mg

Alarm Sound Generator	Low Flow	Reed Alarm
	High Flow	
Alarm Sound Intensity	Low Flow	80 dB minimum at 1 foot
	High Flow	80 dB minimum at 1 foot
Alarm/Bypass Reset	Low Flow	When inlet gas pressure differential is 10 PSI or less
	High Flow	When inlet gas pressure differential is 6 PSI or less
Pressure Drop	Low Flow	Less than 6 PSI at 50 PSIG inlet pressures and 10 LPM flow rate
	High Flow	Less than 6 PSI at 50 PSIG inlet pressures and 40 LPM flow rate
Weight	Low Flow	2.75 lb. (1.25kg)
	High Flow	
Dimensions (Excluding Fittings)	Low Flow	Height: 3 1/2 in. (8.9cm) Width: 2 1/4 in. (5.8cm) Depth: 3 5/8 in. (9.2cm)
	High Flow	Height: 3 1/2 in. (8.9cm) Width: 2 1/4 in. (5.8cm) Depth: 4 ½ in. (11.5cm)
Note: Product specifications are subject to change without notice.		

SECTION 12
WARRANTY

THE PRODUCTS OF VIASYSHEALTHCARE INC. (VIASYS HEALTHCARE HEREIN) ARE WARRANTED TO BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP AND TO MEET THE PUBLISHED SPECIFICATIONS.

The liability of VIASYS Respiratory Care under this warranty is limited to replacing, repairing or issuing credit, at the discretion of VIASYS Respiratory Care, for the parts that become defective or fail to meet published specifications during the warranty period; VIASYS Respiratory Care will not be liable under this warranty unless (A) VIASYS Respiratory Care is promptly notified in writing by Buyer upon discovery of defects or failure to meet specifications; (B) the defective unit or part is returned to VIASYS Respiratory Care, transportation charges prepaid by Buyer; (C) the defective unit or part is received by VIASYS Respiratory Care for adjustment no later than four weeks following the last day of the warranty period; and (D) VIASYS Respiratory Care's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Any authorization of VIASYS Respiratory Care for repair or alteration by the Buyer must be in writing to prevent voiding warranty.

VIASYS Respiratory Care warranties as hereinabove set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by VIASYS Respiratory Care or its agents in connection with Buyer's order of the products furnished hereunder.

LIMITATIONS OF LIABILITIES

In no event shall VIASYS Respiratory Care be liable to Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder. This warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment or parts.

This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by VIASYS Respiratory Care or authorized for use in writing by VIASYS Respiratory Care, or if the equipment is not maintained in accordance with a prescribed schedule of maintenance.

The warranty stated above shall extend for a period of one year from date of delivery, with the following exceptions:

1. Electrical components for remote monitoring of physical variables such as temperature, pressure, oxygen saturation or flow are warranted for ninety (90) days from date of receipt.

2. Elastomeric components and other parts or components subject to deterioration over which VIASYS Respiratory Care has not control are warranted for sixty (60) days from date of receipt.

The foregoing is in lieu of any other warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of VIASYS Respiratory Care

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NOTES

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maxtec

premier o2 solutions

ABOUT US
MAXO2 ANALYZERS
HANDI
SCUBA KITS
REPLACEMENT O2 SENSORS
MINOLTA PULSOX
ACCESSORIES

MACHINE SHOP CUSTOMER SERVICE MANUFACTURING

Maxtec, Your Premier Solutions for O2 Analysis

Maxtec®, Inc is committed to consistent superior quality, timely delivery and responsiv all aspects of oxygen analysis, oxygen delivery, goods and services resulting in excep to all stakeholders

Hours of Availability

Maxtec is available from 7am - 5pm MST. Please feel free to contact us during those l customer support or to place an order.

Contact Information

800.748.5355
801.266.5300 (intl.)
801.270.5590 (fax)

sales@maxtecinc.com

6526 South Cottonwood Street
Salt Lake City, Utah 84107

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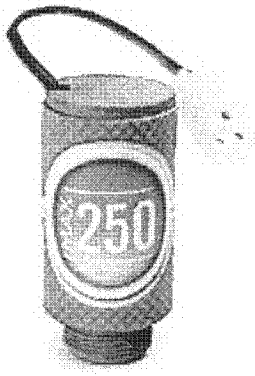
MAX-250

Part Number: see below



24 month warranty

Replacement For:

- Maxtec [OM-25A]
- Mercury Medical [10-103-11]
- Pacifitech [PT-250]
- Teledyne [R29MED]

- Specifications
- Cross-Reference Chart
- Serial Number Chart

Part Numbers

Max-250 Medical
R125P01-002
Max-250 Industrial/Scuba
R125P01-003

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14. STERILIZATION AND SHELF LIFE

The Precision Flow™ is not sold sterile, nor is it intended to be sterilized by the user. The Operator's Manual states on page 18 that the user wipe down the main unit with 70-90% isopropyl alcohol wipes after use. The Operator's Manual is provided in section 13.

The Precision Flow™ does not have a labeled shelf life.

15. BIOCOMPATIBILITY

The Company's biocompatibility statement is included in this section of the submission.

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15. BIOCOMPATIBILITY

The biocompatibility of the Precision Flow™ is based on FDA's clearance of the Vapotherm 2000i and 2000h that contains tissue contact materials for similar uses. The materials are commonly used by respiratory medical device manufacturers and are composed of FDA recognized medical device suitable materials. The following table lists the materials that composed the humidification water path:

(b)(4)				(b)(4)		
Outlet Fitting	Spike Snap Cap	Balls	O-rings	Gaskets	Reflectors	Heater Plate
Delivery Tube	Vent Cover	Spike cover			Rotor Cover	
Spike Tube Set	Spike					
	DWP Body					
	Lenses					
	Plugs					
	Pump Cover					
	Rear Air Port					

(b)(4)	(b)(4)
Spike	Air check valve
VTC body & cap	

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(b)(4),Biocompatibility

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16. SOFTWARE

The Precision Flow™ Software System is included in this section.

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17. ELECTROMAGNETIC COMPATABILITY AND ELECTRICAL SAFETY

The Company's Electromagnetic Compatibility and Electrical Safety test methodology and results are provided in this section.

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18. PERFORMANCE TESTING

The Company's performance testing is included in this section of the submission.

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Food and Drug Administrat
Office of Device Evaluatio
Office of In Vitro Diagnost

COVER SHEET MEMORANDUM

From: Reviewer Name — Kymberly Love

Subject: 510(k) Number — K072743/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary / 510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21		✓	
Neonate/Newborn (Birth to 28 days)		✓	
Infant (28 days -< 2 years old)		✓	
Child (2 years -< 12 years old)		✓	
Adolescent (12 years -< 18 years old)		✓	
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21, No special considerations compared to adults => 21 years old)		✓	
Nanotechnology			✓

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC		✓

Regulation Number: 21CFR868.5450 Class*: Class II (two) Product Code: BTT

Respiratory Gas Humidifier (*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: W. Maf for M. Hwbard (Branch Chief) ARDB (Branch Code) 7-16-2008 (Date)

Final Review: (Division Director) 7/17/08 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K072845
S2

Date: July 16, 2008
To: The Record
From: Kimberly Love, Reviewer

Office: HFZ-480
Division: DAGID/ARDB

510(k) Holder: Vapotherm, Inc.
Device Name: Precision Flow
Contact: Jonathan Khan (Hogan & Hartson L.L.P., Washington D.C.)
Phone (b)(6)
Fax (b)(6)
Email (b)(6)

A. Purpose and Submission Summary

(b)(4)

6

B. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription Use has been indicated.)	Appendix K,S2		
Truthful and Accuracy Statement	Section 6		
510(k) Summary	Appendix N, S2		
Standards Form		X	

C. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device provided sterile?		X	
Is the device reusable (not reprocessed single use)? (Device intended for single patient use.) Are "cleaning" instructions included for the end user?		X	

(b)(4)

D. Indications for Use

Indications for Use as stated in Appendix K of Supplement 22:

7

"Precision Flow is intended use to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rate may be from 1 to 40 liters per minute via nasal cannula."

(b)(4)

E. Predicate Device Comparison

Predicate Devices:

Vapotherm 2000h	K013486
Vapotherm 2000i	K000401
Vapotherm 2000i and 2000h	K042245
Bird Blender	K911962
Maxtec	K063488

(b)(4)

8

F. **Labeling**

(b)(4)

G. **Sterilization/Shelf Life/Reuse**

(b)(4)

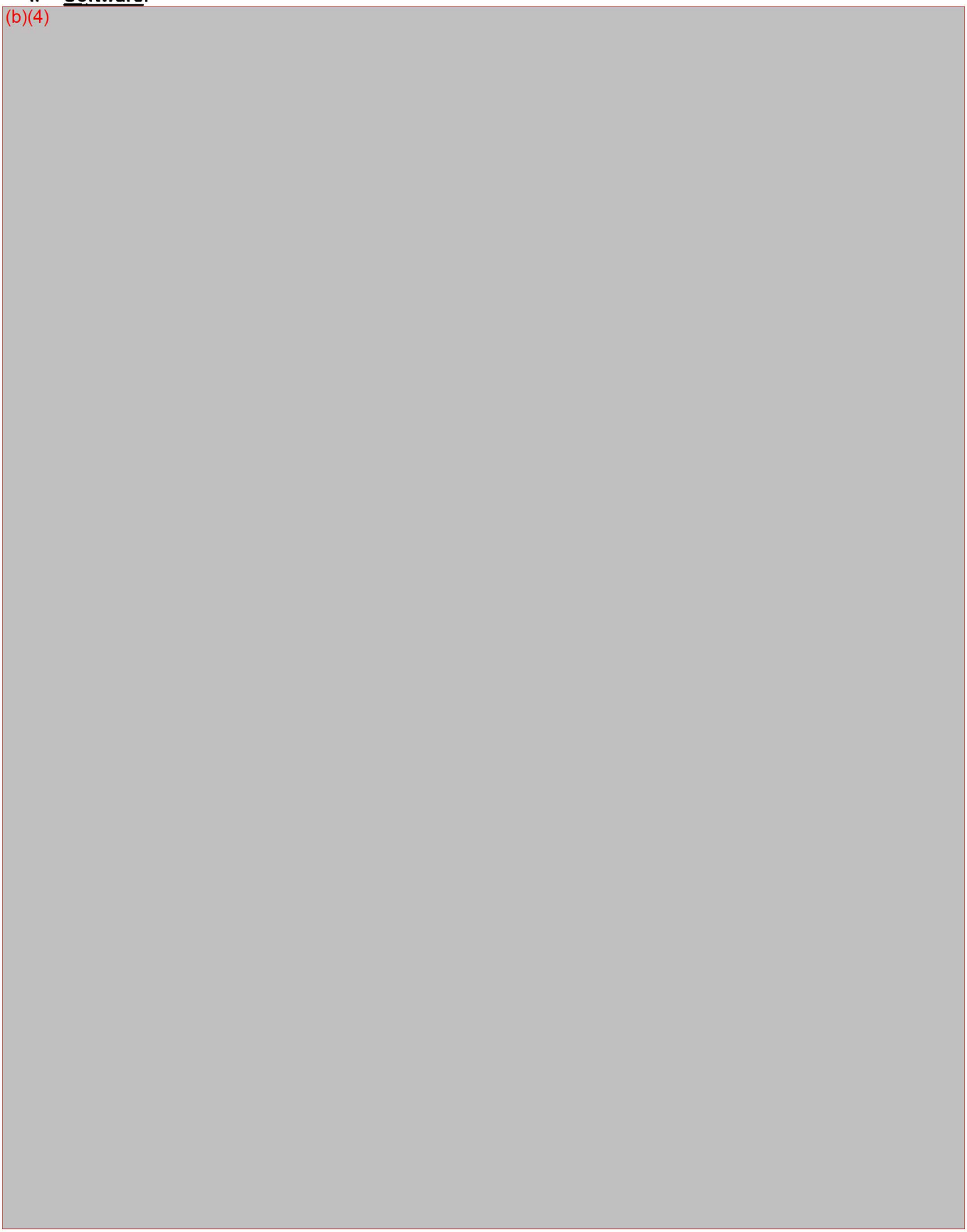
H. **Biocompatibility**

(b)(4)

9

I. **Software**:

(b)(4)



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K. Performance Testing – Bench

(b)(4)

L. Performance Testing – Animal

N/A: No animal studies were conducted in order to demonstrate substantial equivalence of the subject device.

M. Performance Testing – Clinical

N/A: No clinical studies were conducted in order to demonstrate substantial equivalence of the subject device.

N. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE** **Final Decision: SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

Note: See Premarket Notification 510(k) Flowchart Decision Tree for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

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

O. Deficiencies

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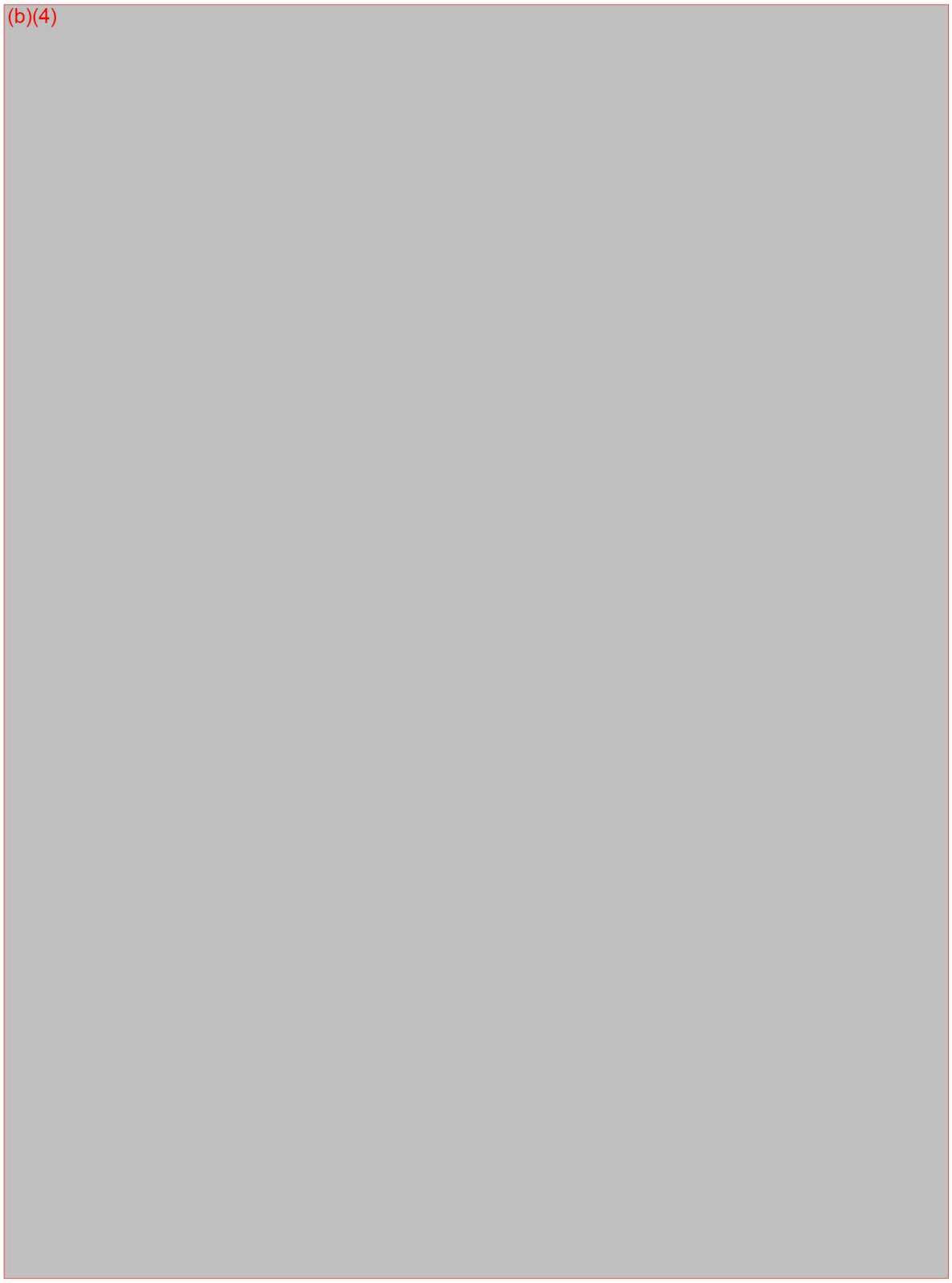

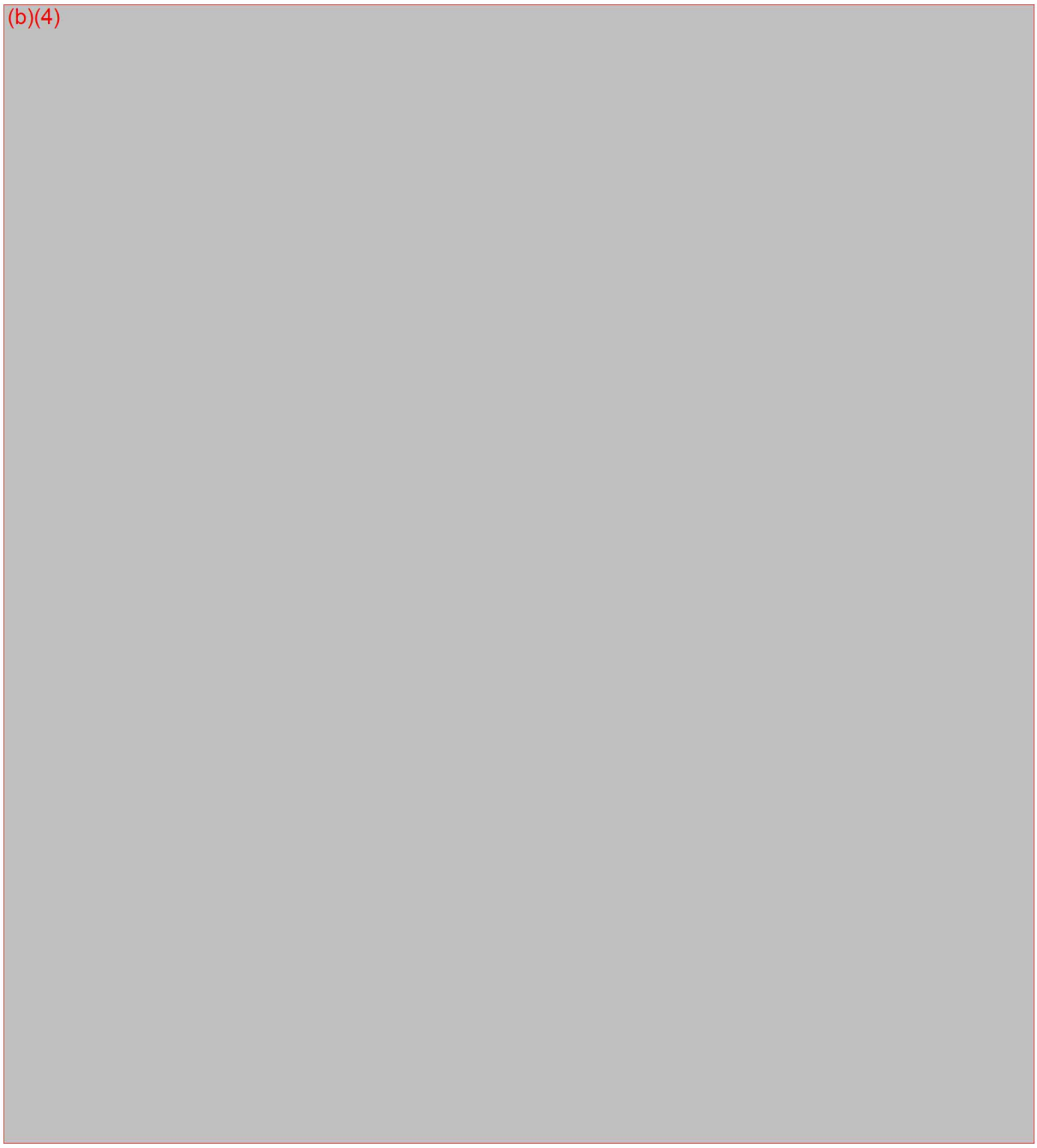
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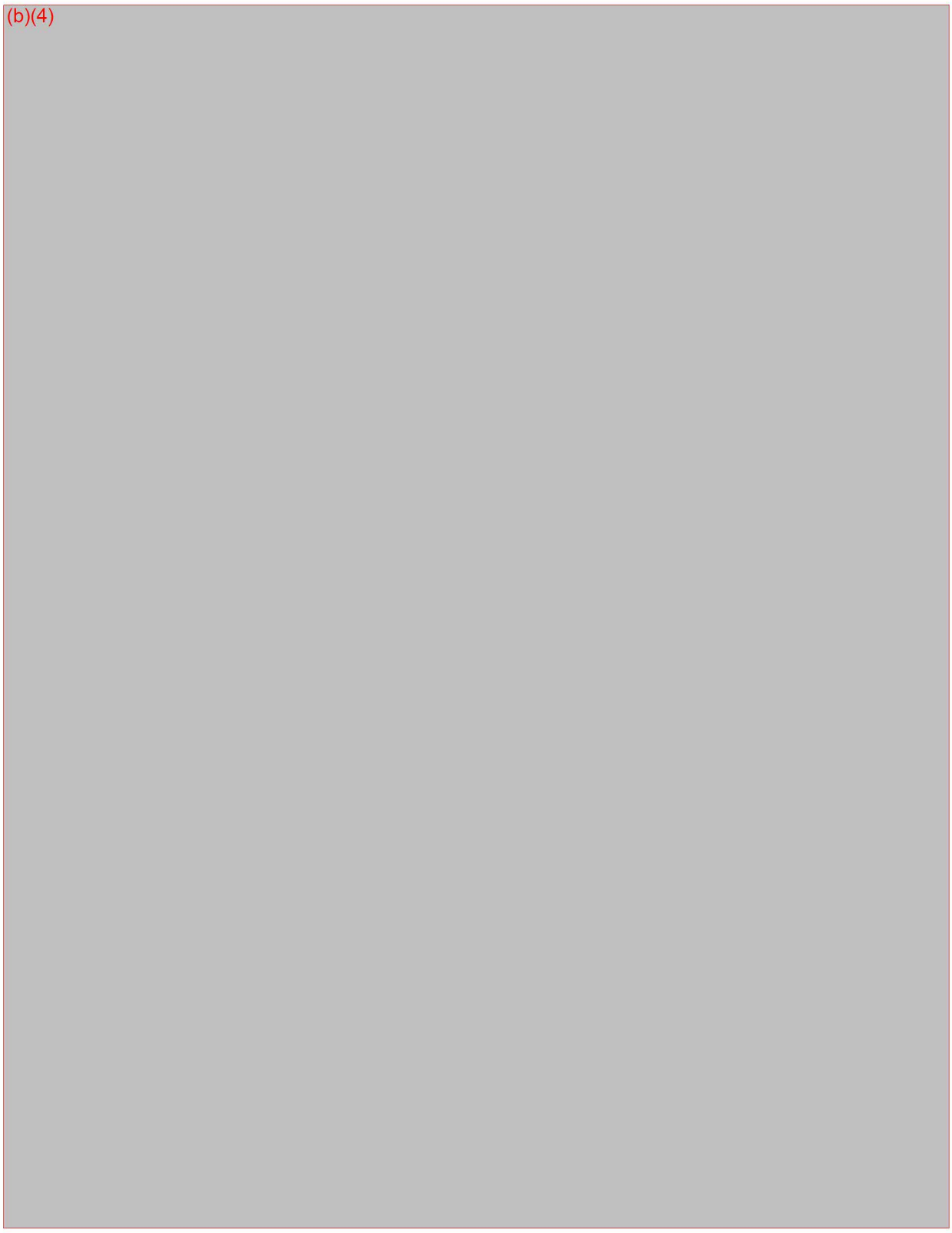

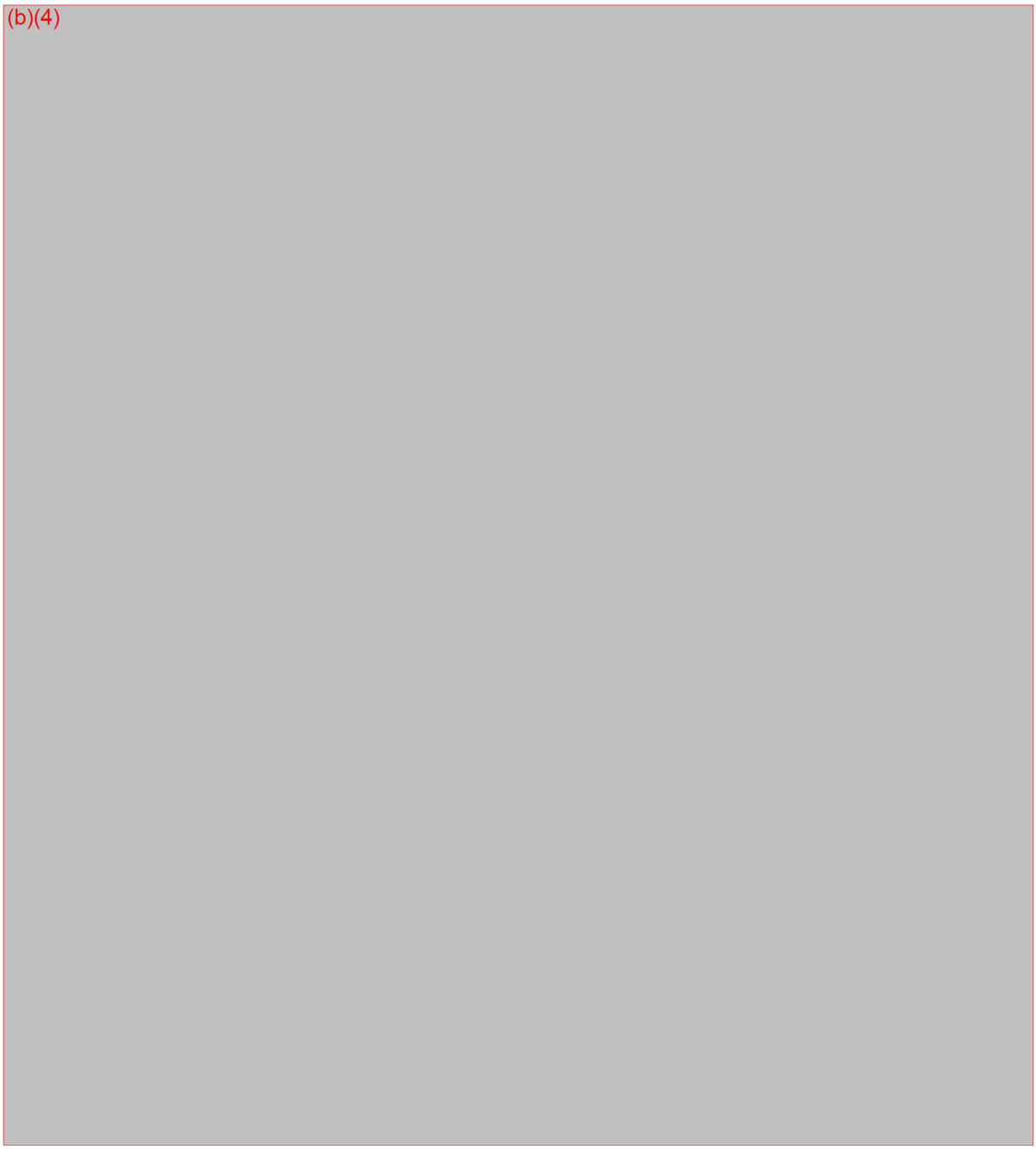

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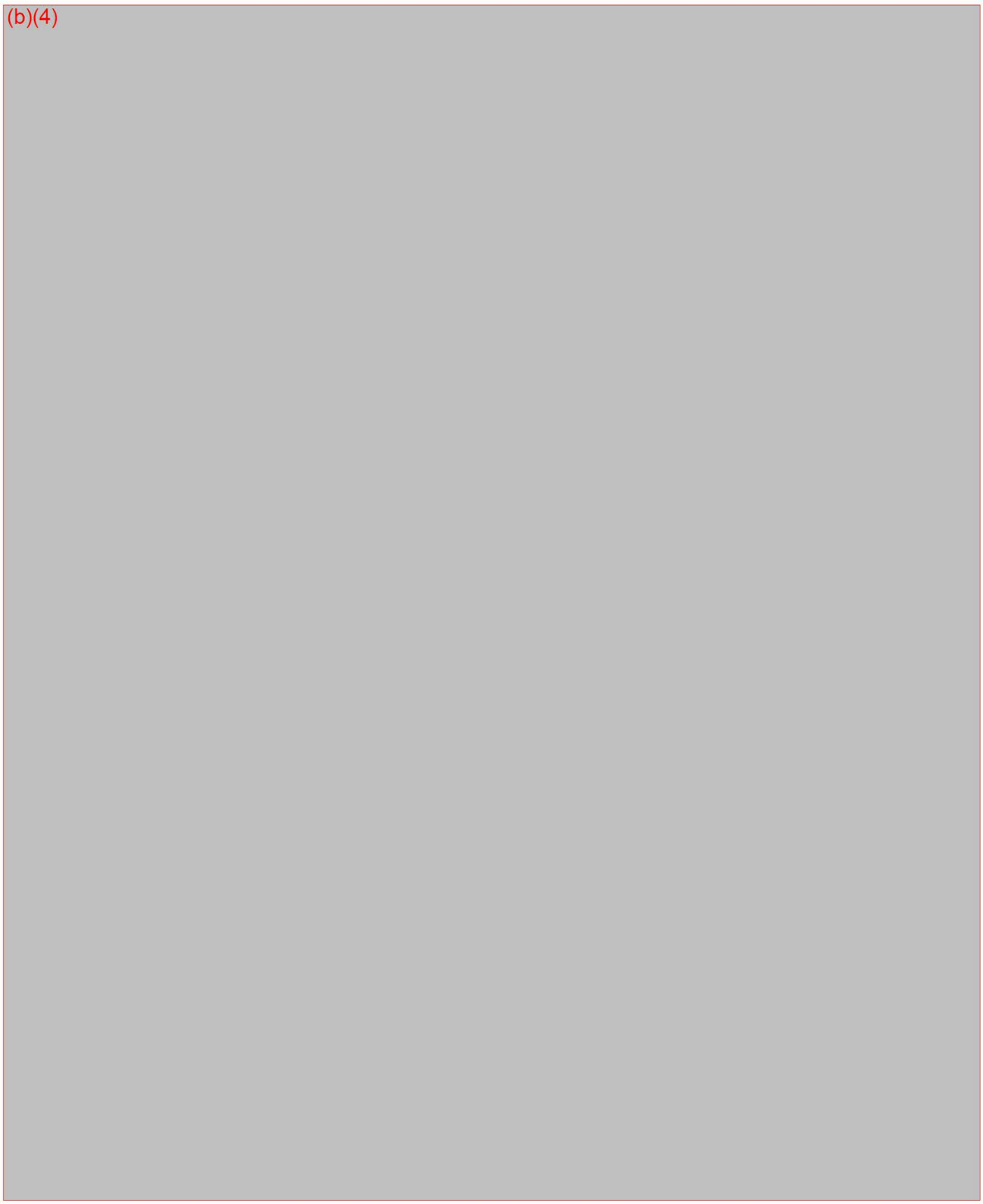
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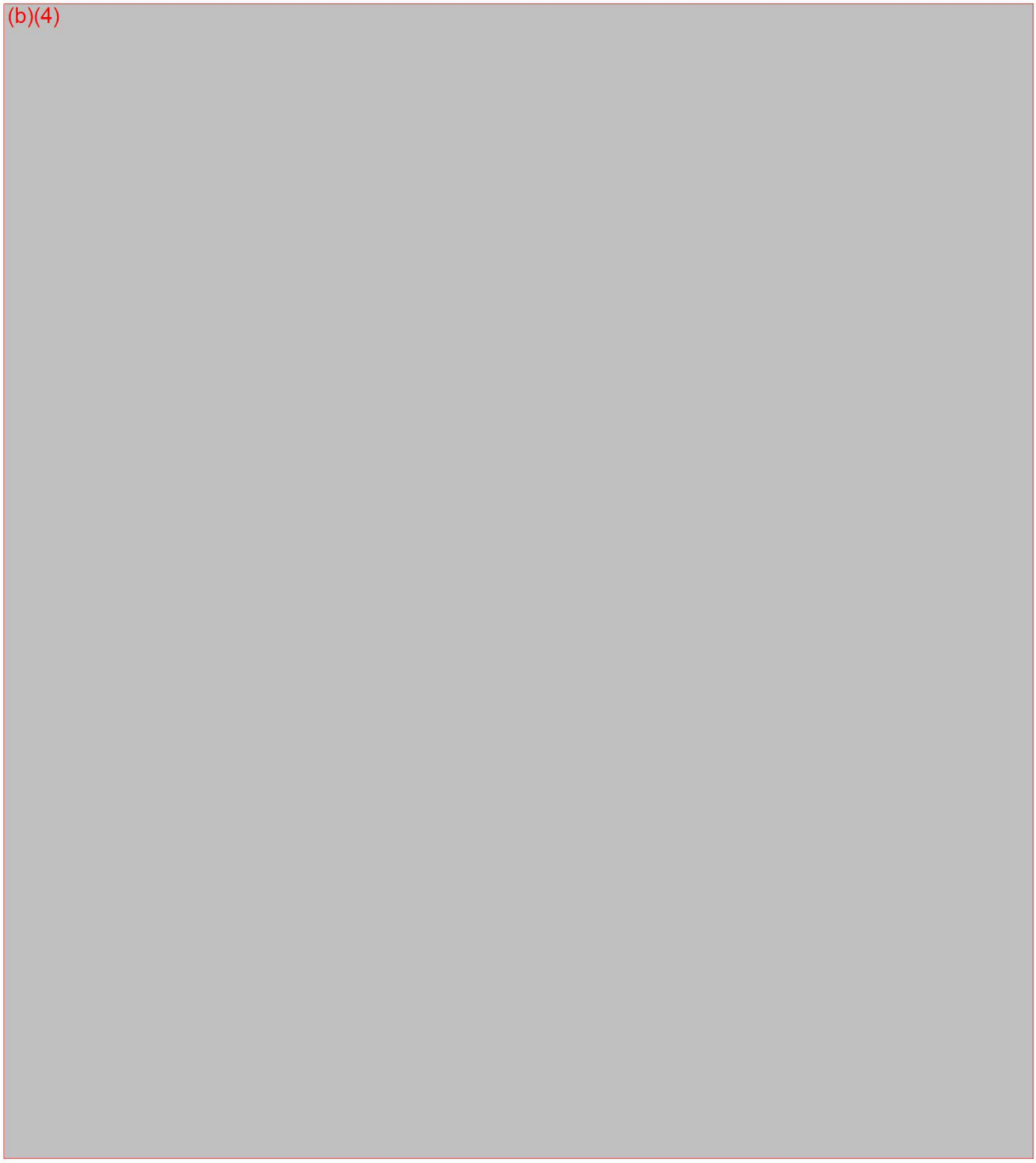

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P. Notes

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Q. Contact History

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R. Recommendation

Upon review of the Precision Flow, I find the devices substantially equivalent to the predicate devices. I recommend substantial equivalence be granted.

This device should be classified as follows:
Regulation Number: 21 CFR 868.5450
Regulation Name: Humidifier, Respiratory Gas (Direct Patient Interface)
Regulatory Class: Class II (Two)
Product Code: BTT

Kimberly G. Love, Lead Reviewer — Date: 07/16/2008

Michael Husband, Branch Chief — Date: 7/16/2008

Love, Kimberly

From: Greg Whitney (b)(6) @vtherm.com]
Sent: Wednesday, July 16, 2008 3:53 PM
To: Love, Kimberly
Subject: Vapotherm, Requested Information
Importance: High
Attachments: VapothermLabTests

Hello Kimberly,

(b)(4)

Best Regards,

Greg Whitney

VAPOTHERM

July 15, 2008

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

Attention: Kimberly Love (HFZ-480)

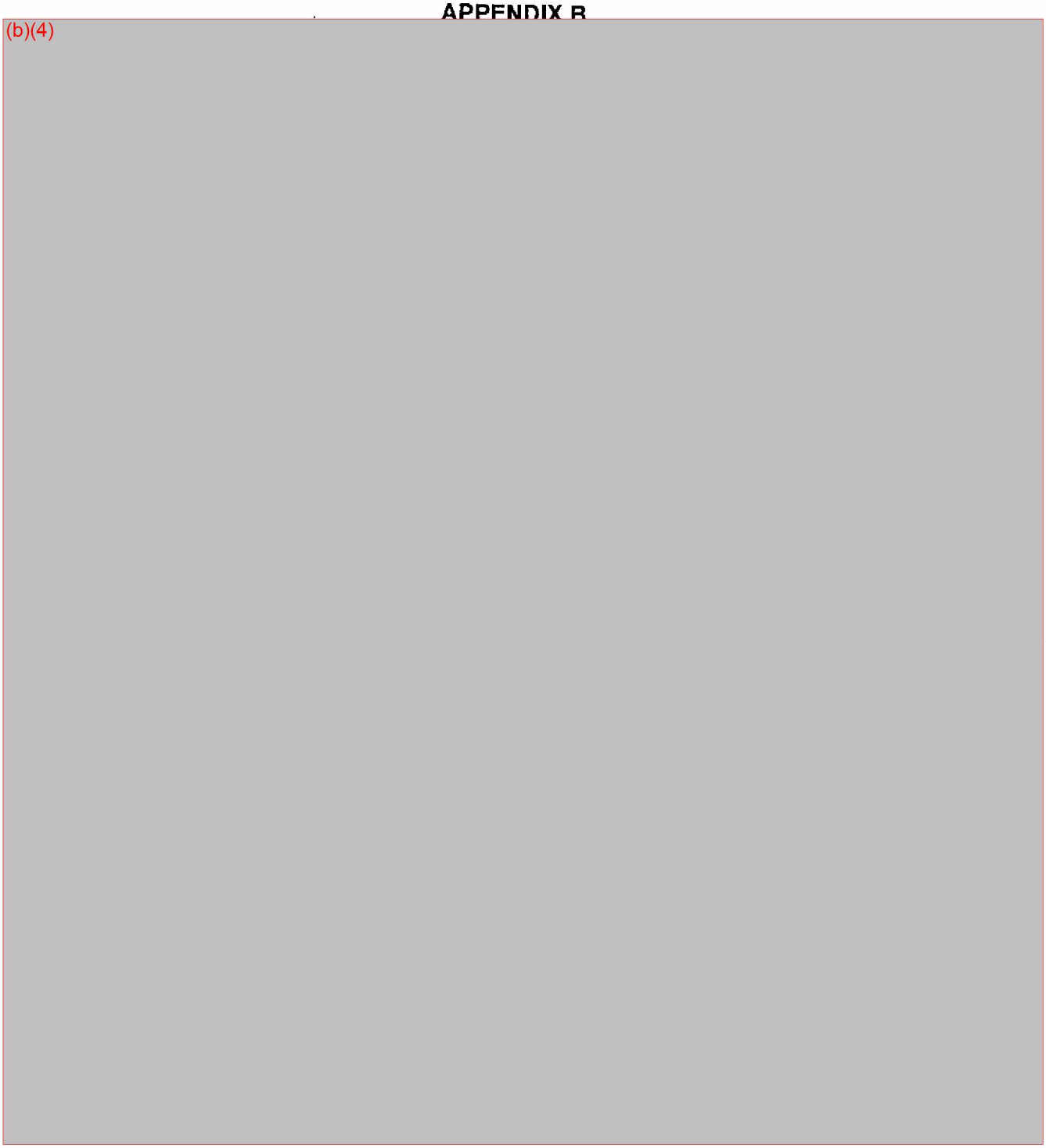
Re: Response to July 14, 2008, Request for Additional Information Regarding Vapotherm, Inc., Precision Flow™

Dear Ms. Love,

(b)(4)

APPENDIX B

(b)(4)



APPENDIX C

(b)(4)

(b)(4)

If you have any additional questions regarding the information provided in this response letter concerning the Precision Flow 510(k) notice, please contact me at the number below or John Smith at Hogan & Hartson L.L.P. (202) 637-3638.

Sincerely,

(b)(6)

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666
410.604.3977 Ext. 109
(b)(6) @vtherm.com

Appendices A-O

ccs: Jonathan S. Kahan, Partner, Hogan & Hartson LLP
(b)(6) Hogan & Hartson LLP
William Robert Storey, President & CEO, Vapotherm, Inc.

32

Appendix A
Table 1
Paragraph #3.1

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Appendix B
Table 2
Paragraph #3.1

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Appendix C
Table 3
Paragraph #3.2

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Appendix D
Table 4
Paragraph #3.2

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Appendix E
Table 5
Paragraph #3.3

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Appendix F
Table 6
Paragraph #3.3

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Appendix G
Table 7
Paragraph #3.4

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Appendix H
No Table
Paragraph #3.5

(b)(4),Sterilization Report

Appendix I
Table 8
Paragraph #3.6

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Appendix J
Table 9
Paragraph #3.7

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Appendix K
Table 1
Paragraph #3.1

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Appendix L
No Table
Paragraph #3.2

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Appendix M
Table 2
Paragraph #3.3

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Appendix N
Table 3
Paragraph #3.4

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Appendix O
Table 4
Paragraph #3.5

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Love, Kimberly

(b)(4)

Thanks.

Kimberly G. Love, LTJG, U.S. Public Health Service
Biomedical Engineer, FDA/CDRH/ODE/DAGID/ARDB
Training Unit Director, Planning Section, PHS-1 RDF
9200 Corporate Blvd.
HFZ-480
Rockville, MD 20850
(240) 276-4251
Email: kimberly.love@fda.hhs.gov

From: Greg Whitney [mailto:(b)(6)
Sent: Monday, July 14, 2008 1:24 PM
To: Love, Kimberly
Cc: Bob Storey
Subject: Vapotherm Laboratory Data

Hello Kimberly,

(b)(4)

Regards,

Greg Whitney

Love, Kimberly

(b)(4)

Thanks.

Kimberly G. Love, LTJG, U.S. Public Health Service
Biomedical Engineer, FDA/CDRH/ODE/DAGID/ARDB
Training Unit Director, Planning Section, PHS-1 RDF
9200 Corporate Blvd.
HFZ-480
Rockville, MD 20850
(240) 276-4251
Email: kimberly.love@fda.hhs.gov

From: Greg Whitney [mailto(b)(6) @vtherm.com]
Sent: Monday, July 14, 2008 1:24 PM
To: Love, Kimberly
Cc: Bob Storey
Subject: Vapotherm Laboratory Data

Hello Kimberly,

(b)(4)

Regards,

Greg Whitney

Love, Kimberly

(b)(4)

Sheila

Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation, Center for Devices and Radiologic Health
9200 Corporate Blvd Room 340H Mail Stop HFZ-480
Rockville, MD 20850
Phone 240-276-3706
Fax 240-276-3789
sheila.murphey@fda.hhs.gov

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Consultation Review

Document Number: K072845/S002
Device Name: Precision Flow™
Sponsor: Vapotherm, Inc.

Reviewer: Sheila A. Murphey, MD
Branch Chief, INCB/DAGID

Date: July 12, 2008

Subject:

(b)(4)

K072845/S001 Response

(b)(4)

131

(b)(4)

(b)(4)

FDA Request 2

(b)(4)

153

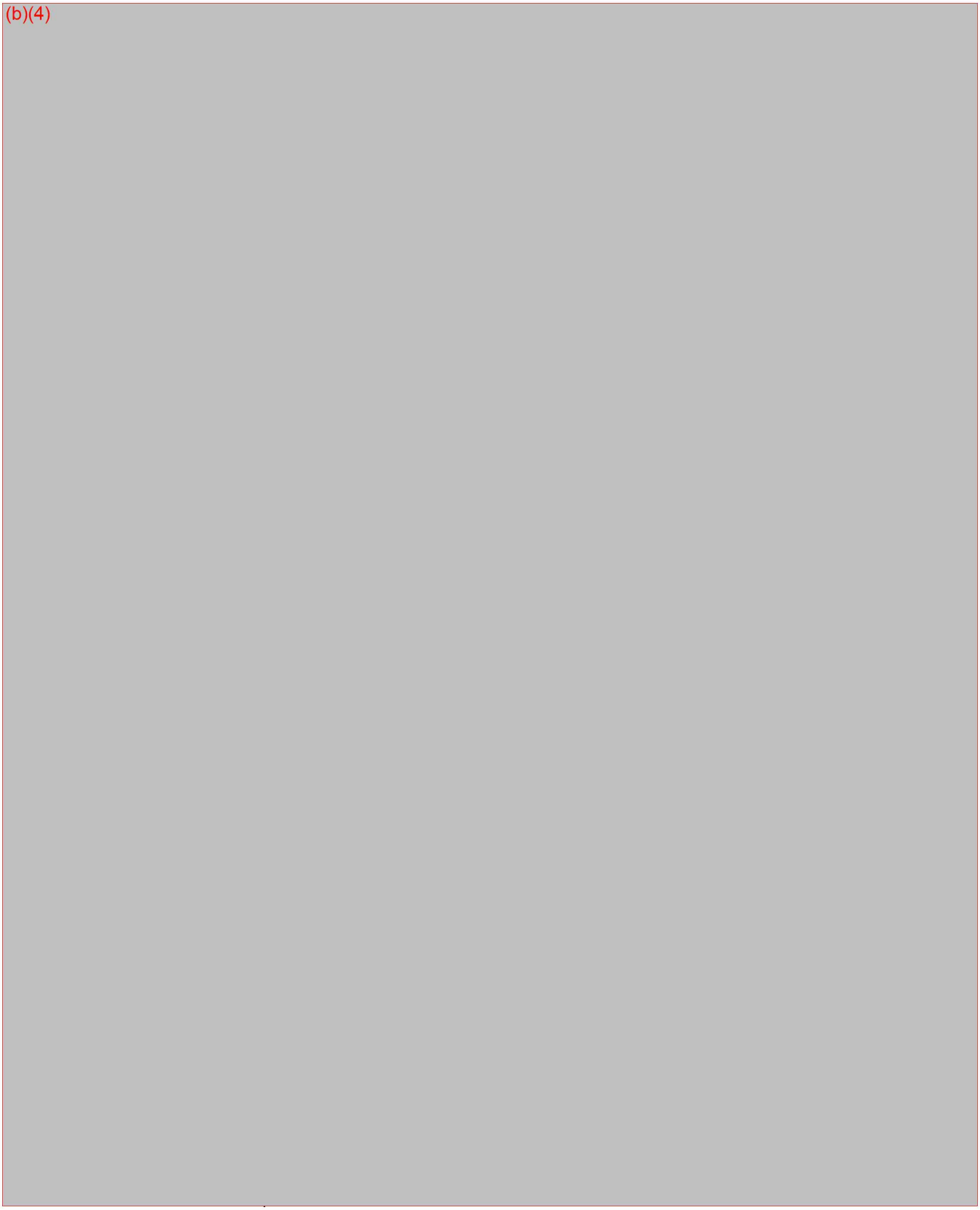
(b)(4)

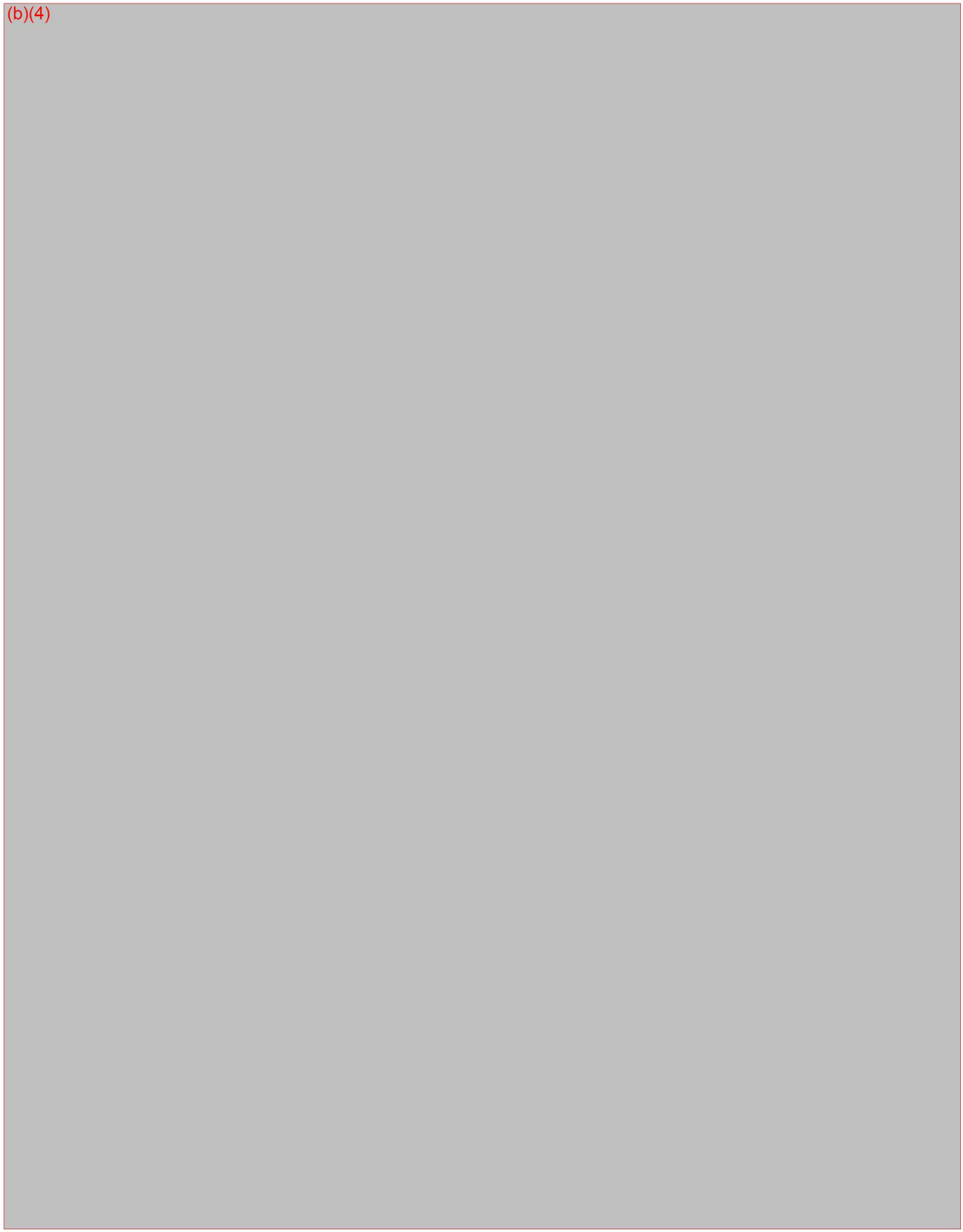
FDA Request 3

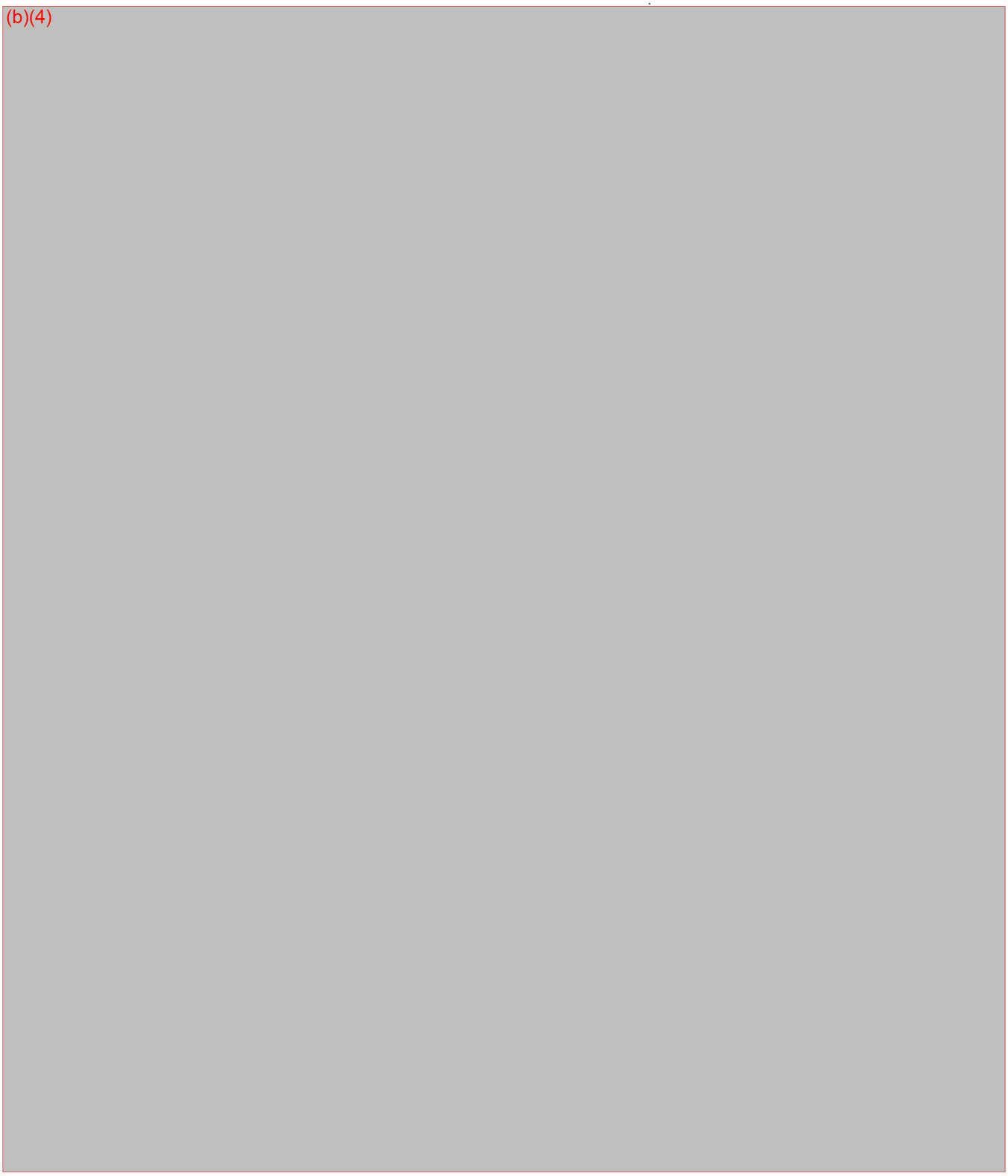
(b)(4)

K072845/S002 Response

(b)(4)

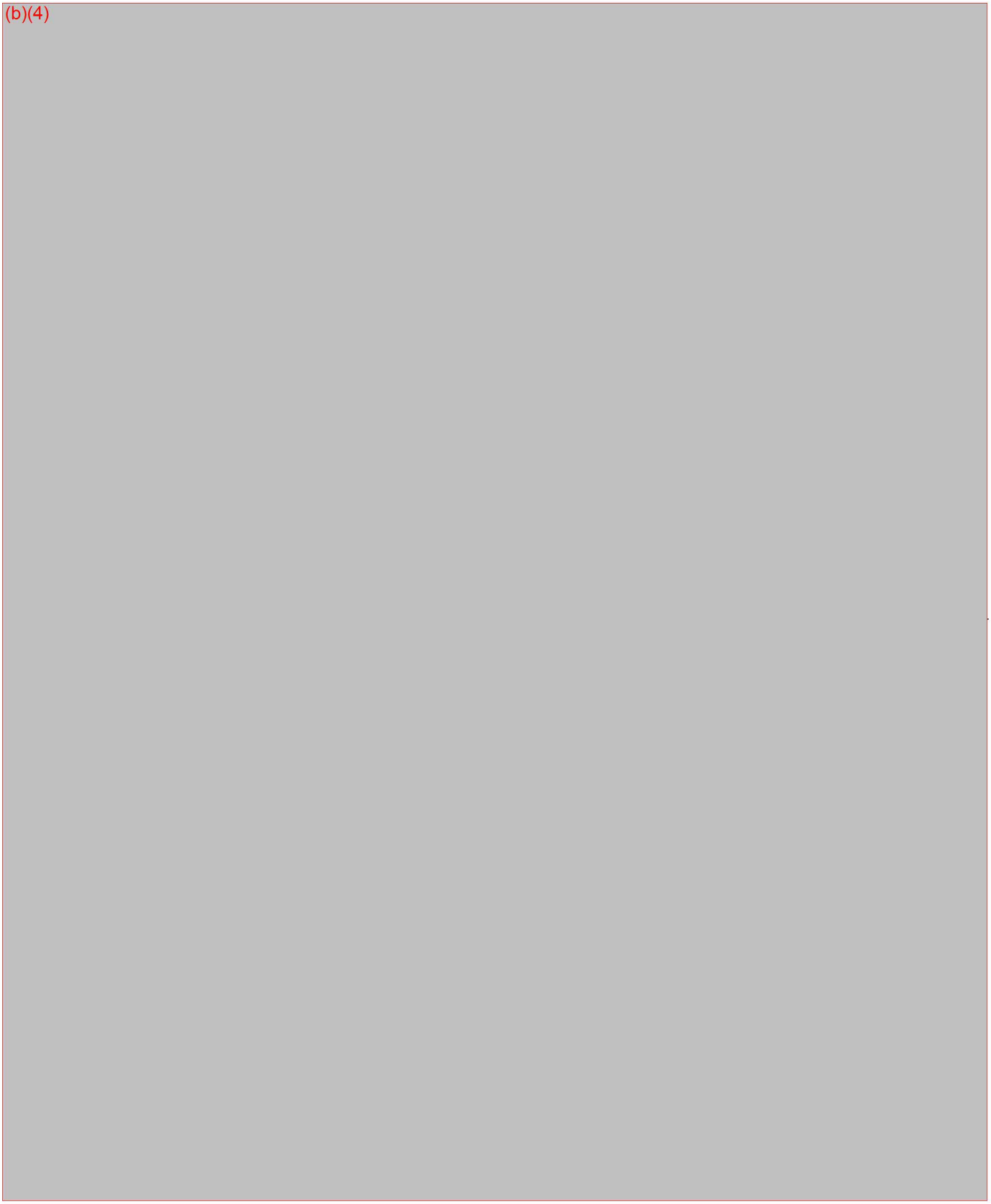

(b)(4)


(b)(4)


(b)(4)

3. Vapotherm Precision Flow Risk Assessment

(b)(4)



(b)(4)

Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
July 12, 2008

Love, Kimberly

From: Greg Whitney (b)(6)
Sent: Thursday, June 19, 2008 9:05 AM
To: Love, Kimberly; Husband, Michael J; Michaud, Ginette; Murphey, Sheila A; (b)(6)
Cc: Kahan, Jonathan S.; (b)(6) b)(6) ; Bob Storey; Lin, Chiu S.
Subject: Presentation for Vapotherm and FDA Meeting
Importance: High
Follow Up Flag: Follow up
Flag Status: Red
Attachments: FDA June 2008 Final.ppt

Good morning,

(b)(4)

Regards,

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666
(410) 604-3977 Ext. 109
(b)(4),(b) @vtherm.com

(b)(4),Meeting Slides

(b)(4),Meeting Slides

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(b)(4),Meeting Slides

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(b)(4),Meeting Slides

(b)(4),Meeting Slides

Love, Kimberly

From: Kahan, Jonathan S. (b)(4), (b)(6)@HHLAW.com]
Sent: Monday, June 16, 2008 8:37 AM
To: Husband, Michael J; Greg Whitney; (b)(6)
Cc: Love, Kimberly; Bob Storey
Subject: RE: today's meeting

Thx Michael. We look forward to hearing back from you regarding rescheduling. As you can imagine, the sooner we can get this back on everyone's calendar, the better. Jon

JONATHAN KAHAN, PARTNER
HOGAN & HARTSON LLP
Columbia Square, 555 Thirteenth Street, NW, Washington, DC 20004
(b)(6)
(b)(6) | http://www.hhlaw.com

From: Husband, Michael J [mailto:michael.husband@fda.hhs.gov]
Sent: Monday, June 16, 2008 8:21 AM
To: Greg Whitney; (b)(6); Kahan, Jonathan S.
Cc: Love, Kimberly
Subject: today's meeting

Gentlemen,

We will need to reschedule the meeting today. The water main break in Montgomery County has shut our building down today. I have received word that Dr. Lin and Dr. Michaud cannot attend already. I will update you as I know more.

Thank you,

Michael Husband

Branch Chief
Anesthesiology and Respiratory Branch
240 276-4224

Protecting and Promoting Public Health

"EMF <HHLAW.COM>" made the following annotations.

This electronic message transmission contains information from this law firm which m
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If you have received this electronic transmission in error, please notify us by tele

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Love, Kimberly

From: (b)(6) @HHLAW.com]
Sent: Monday, June 16, 2008 8:39 AM
To: Husband, Michael J (b)(6) @vtherm.com; Kahan, Jonathan S.
Cc: Love, Kimberly; bstorey@vtherm.com
Subject: Re: today's meeting

Thanks, Michael. We'll look forward to hearing more.

Best regards,

John

John J. Smith, M.D., J.D., Partner
Hogan & Hartson LLP
555 Thirteenth Street, NW
Washington, DC 20004
202.637.3638/202.637.5910(fax)
jjsmith@hhlaw.com

----- Original Message -----
From: Husband, Michael J <michael.husband@fda.hhs.gov>
To: Greg Whitney (b)(6) @vtherm.com>, (b)(6) ; Kahan, Jonathan S.
Cc: Love, Kimberly <Kimberly.Love@fda.hhs.gov>
Sent: Mon Jun 16 08:20:58 2008
Subject: today's meeting

Gentlemen,

We will need to reschedule the meeting today. The water main break in Montgomery County has shut our building down today. I have received word that Dr. Lin and Dr. Michaud cannot attend already. I will update you as I know more.

Thank you,

Michael Husband

Branch Chief
Anesthesiology and Respiratory Branch
240 276-4224

"EMF <HHLAW.COM>" made the following annotations.

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Love, Kimberly

From: Greg Whitney [(b)(6) @vtherm.com]
Sent: Tuesday, June 03, 2008 2:28 PM
To: Love, Kimberly
Subject: RE: FDA Response to (b)(4) Regarding 510(k) K

Hello Kimberly,

Thank you for the response. We will examine it and prepare a response.

Regards,

Greg

From: Love, Kimberly [mailto:Kimberly.Love@fda.hhs.gov]
Sent: Tuesday, June 03, 2008 1:55 PM
To: Greg Whitney
Cc: Husband, Michael J; Murphey, Sheila A
Subject: FDA Response to (b)(4) Regarding 510(k) K

Dear Mr. Whitney:

(b)(4)

Sincerely,

Kimberly G. Love, LTJG, U.S. Public Health Service
Biomedical Engineer, FDA/CDRH/ODE/DAGID/ARDB
Training Unit Director, Planning Section, PHS-1 RDF
9200 Corporate Blvd.
HFZ-480
Rockville, MD 20850
(240) 276-4251
Email: kimberly.love@fda.hhs.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

FDA Response to Vapotherm Bioburden Testing Proposal

K072845

Date: June 3, 2008
To: The Record
From: Kimberly Love, Biomedical Engineer

Office: ODE
Division: DAGID/ARDB

510(k) Holder: Vapotherm, Inc.
Device Name: Precision Flow
Contact: Greg Whitney (Vapotherm, Inc.)
Phone: (410) 604-3977 x109
Fax:
Email: (b)(6) @vtherm.com

I. Background

(b)(4)

II. Purpose

(b)(4)

III. Vapotherm Proposal

(b)(4)

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(b)(4)

(b)(4)

Kimberly Love

Kimberly Love, Lead Reviewer

06/03/2008

Date

Love, Kimberly

From: Murphey, Sheila A
Sent: Tuesday, June 03, 2008 12:41 PM
To: Love, Kimberly; Husband, Michael J
Subject: RE: Final Comment regarding Vapotherm (b)(4)

Dear Kimberly and Mike,

This looks fine to me.

Thanks,

Sheila

Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation, Center for Devices and Radiologic Health
9200 Corporate Blvd Room 340H Mail Stop HFZ-480
Rockville, MD 20850
Phone 240-276-3706
Fax 240-276-3789
sheila.murphey@fda.hhs.gov

From: Love, Kimberly
Sent: Tuesday, June 03, 2008 10:19 AM
To: Husband, Michael J; Murphey, Sheila A
Subject: Final Comment regarding Vapotherm (b)(4)

Mike and Sheila:

(b)(4)

(b)(4)

Thanks.

Kimberly G. Love, LTJG, U.S. Public Health Service
Biomedical Engineer, FDA/CDRH/ODE/DAGID/ARDB
Training Unit Director, Planning Section, PHS-1 RDF
9200 Corporate Blvd.
HFZ-480
Rockville, MD 20850
(240) 276-4251
Email: kimberly.love@fda.hhs.gov

Love, Kimberly

From: Greg Whitney [(b)(6)]@vtherm.com]
Sent: Tuesday, May 20, 2008 5:12 PM
To: Love, Kimberly
Subject: Precision Flow Bioburden Review
Importance: High

Hello Kimberly,

I tried contacting you by telephone yesterday and left a voice message. It has been some time since you told me that Dr. Murphey was reviewing Bob Storey's email of April 22nd. Have you heard anything about the review and when do you think we will hear the final results? We are concerned that the review is taking this long to complete. Please call me at (410) 604-3977 Ext. 109 so we can discuss the issue.

Beat regards,

Greg Whitney
Vapotherm, Inc.

Love, Kimberly

From: Greg Whitney [(b)(6) y@vtherm.com]
Sent: Wednesday, May 07, 2008 4:47 PM
To: Love, Kimberly
Cc: (b)(6) @vtherm.com
Subject: Official Correspondent
Follow Up Flag: Follow up
Flag Status: Red

Hello Kimberly,

I will be the official correspondent for Vapotherm. All correspondence should be directed through me.

Thanks again for our conversation today.

Regards,

Greg Whitney

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Love, Kimberly

From: Greg Whitney (b)(6) @vtherm.com]
Sent: Wednesday, May 07, 2008 11:24 AM
To: Love, Kimberly
Subject: (b)(4)

Good Morning Kimberly,

I have been trying to get in touch with you by telephone. I would like to talk to you about where we are concerning the (b)(4) . Also, would you like to have the replies to FDA requests four through ten to process ahead of the (b)(4) reply?

Regards,

Greg Whitney
(410) 604-3977 X-109
(b)(6) @vtherm.com

Love, Kimberly

From: Greg Whitney [(b)(6) @vtherm.com]
Sent: Thursday, May 01, 2008 3:16 PM
To: Love, Kimberly
Subject: Summary of telephone discussion
Follow Up Flag: Follow up
Flag Status: Red
Attachments: Summary of April 28.08PhoneDiscussion.doc

Hello Kimberly,

As a follow up to our telephone discussion, please see the attached file.

Regards,

Greg Whitney

VAPOTHERM

Date: May 1, 2008

To: Ms. Kimberly Love

From: Greg Whitney

Subject: Summary of Telephone Conference Dated April 28, 2008

Thank you for the time that you spent reviewing the Vapotherm approach to satisfy the FDA request for additional information for the Precision Flow™. You input was very valuable to enable Vapotherm to prepare an adequate reply to FDA requests four through eleven. In an effort to maintain clear communications, I have prepared a short summary of the output of our discussion. Vapotherm will provide the following information for each request:

(b)(4)

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(b)(4)

If the outcome of our discussion is not described adequately above, please contact me at the telephone number below to clarify the issue. We are appreciative of your inputs to help us to assure that we are answering the additional information requests accurately to their intent.

Regards,

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666
(410) 604-3977 Ext. 109
(b)(6) @vtherm.com

Love, Kimberly

From: Bob Storey (b)(6) @vtherm.com]
Sent: Tuesday, April 22, 2008 3:33 PM
To: Lin, Chiu S.; Michaud, Ginette; Murphey, Sheila A; Husband, Michael J; Love, Kimberly
Cc: Kahan, Jonathan S.; (b)(6) ; Greg Whitney; (b)(6)
Subject: Follow-up to Vapotherm's April 18 Conference Call
Follow Up Flag: Follow up
Flag Status: Red

To Kimberly Love (with copies to April 18th conference call participants):

Dear Ms. Love,

(b)(4)

(b)(4)

Regards, Bob

Bob Storey
President & CEO
Vapotherm, Inc.
(b)(6)
www.vtherm.com

mail message by mistake, please notify the sender.

Love, Kimberly

From: (b)(6) @HHLAW.com]
Sent: Friday, April 18, 2008 10:34 AM
To: Lin, Chiu S.; Michaud, Ginette; Murphey, Sheila A; Husband, Michael J; Love, Kimberly
Cc: Bob Storey; Kahan, Jonathan S.; (b)(6)
Subject: Vapotherm FDA Response ppt.PPT
Attachments: Vapotherm FDA Response.ppt

Dear Dr. Lin,

In preparation for today's conference call (12:00 Noon-1:00 P.M. EDT) with FDA and Vapotherm representatives, please find attached a set of PowerPoint sides that the company will follow in making its presentation regarding the Precision Flow device.

We look forward to talking with you soon.

Best regards,

Jonathan Kahan

JONATHAN KAHAN, PARTNER
HOGAN & HARTSON LLP
Columbia Square, 555 Thirteenth Street, NW, Washington, DC 20004
direct +1.202.637.5794 | tel +1.202.637.5600 | fax +1.202.637.5910
jskahan@hhlaw.com | http://www.hhlaw.com

VAPOTHERM

FDA and Vapotherm Conference Call

April 18, 2008

(b)(4),Meeting Slides

(b)(4),Meeting Slides

(b)(4),Meeting Slides

(b)(4),Meeting Slides

(b)(4),Meeting Slides

(b)(4),Meeting Slides

(b)(4),Meeting Slides

Love, Kimberly

From: Love, Kimberly
Sent: Tuesday, April 15, 2008 11:25 AM
To: 'Greg Whitney'
Subject: FDA and Vapotherm Teleconference scheduled for Friday, April 18, 2008 at Noon.

Mr. Whitney:

Below is the call-in information for our teleconference scheduled for Friday, April 18, 2008 from Noon until 1 PM (EDT).

Toll Free Number: (b)(5)
Pass Code:

FDA Attendees: Dr. Chiu Lin (Division Director, DAGID), Dr. Ginette Michaud (Deputy Division Director, DAGID), Dr. Sheila Murphey (Infection Control Branch Chief), Mr. Michael Husband (ARDB Chief), and Ms. Kimberly Love (Lead Reviewer).

Please let me know if you have any additional questions or concerns.

Thank you and we look forward to speaking with you this Friday.

Kimberly G. Love, LTJG, U.S. Public Health Service
Biomedical Engineer, FDA/CDRH/ODE/DAGID/ARDB
Training Unit Director, Planning Section, PHS-1 RDF
9200 Corporate Blvd.
HFZ-480
Rockville, MD 20850
(240) 276-4251
Email: kimberly.love@fda.hhs.gov

Love, Kimberly

From: Murphey, Sheila A
Sent: Wednesday, April 09, 2008 1:22 PM
To: Marion, Jill; Hitchins, Victoria M.; Husband, Michael J; (b)(6) ; Fischer, Robert A; Flack, Marilyn N
Cc: Pressly, Nancy A.; Hoang, Quynh T.; Love, Kimberly; Lin, Chiu S.; Michaud, Ginette; MacFarland, William C
Subject: RE: Vapotherm Report Received

Dear Ms. Jill,

(b)(4)

Thanks,

Sheila

Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation, Center for Devices and Radiologic Health
9200 Corporate Blvd Room 340H Mail Stop HFZ-480
Rockville, MD 20850
Phone 240-276-3706
Fax 240-276-3789
sheila.murphey@fda.hhs.gov

From: Marion, Jill
Sent: Wednesday, April 09, 2008 12:59 PM
To: Hitchins, Victoria M.; Husband, Michael J; Murphey, Sheila A; (b)(6) ; Fischer, Robert A; Flack, Marilyn N
Cc: Pressly, Nancy A.; Hoang, Quynh T.
Subject: Vapotherm Report Received

Dear Vapotherm team,

(b)(4)

Thank you.

Jill Marion
Biomedical Engineer
Medical Product Surveillance Network (MedSun)
FDA/CDRH/OSB/PSS
Phone: 240-276-2285

Fax: 240-276-2280

From: Marion, Jill
Sent: Wednesday, April 09, 2008 10:13 AM
To: Fischer, Robert A
Cc: Swayze, Sonia C.; Gross, Thomas P.; Love, Kimberly; MacFarland, William C; Flack, Marilyn N; Medicus, Jennifer R; Hoang, Quynh T.; Engleman, Donna; Yustein, Aron S; James, Angela
Subject: Vapotherm- more information from hospital

Hi Bob,

(b)(4)

Thanks.

Jill Marion

Biomedical Engineer
Medical Product Surveillance Network (MedSun)
FDA/CDRH/OSB/PSS
Phone: 240-276-2285
Fax: 240-276-2280

From: Fischer, Robert A
Sent: Wednesday, April 02, 2008 1:02 PM
To: Engleman, Donna; Marion, Jill
Cc: 'ajames@S-3.com'; Swayze, Sonia C.; Gross, Thomas P.; Love, Kimberly; MacFarland, William C; Flack, Marilyn N; Medicus, Jennifer R; Hoang, Quynh T.
Subject: RE: Vapotherm PHN-- Just FYI, Julie

(b)(4)

Robert (Bob) Fischer, MSN, RN

Nurse Consultant Anesthesia, Otolaryngology, and Central Venous Catheter Devices; and Unretrieved Device Fragments (UDFs)
Product Evaluation Branch II
Division of Post Market Surveillance
Office of Biometrics and Surveillance

FDA/Center for Devices and Radiological Health (CDRH)
1350 Piccard Drive (HFZ-520)
Rockville, Maryland 20850
(240) 276-3417 (Office)
(240) 276-3301 (FAX)

From: Engleman, Donna
Sent: Wednesday, April 02, 2008 12:39 PM
To: Marion, Jill
Cc: (b)(6)
Subject: FW: Vapotherm PHN-- Just FYI, Julie

From: Marders, Julia A
Sent: Wednesday, April 02, 2008 12:25 PM
To: Engleman, Donna
Cc: Flack, Marilyn N
Subject: Vapotherm PHN-- Just FYI, Julie

FDA Public Health Notification: Precautions in Using the Reintroduced Vapotherm®> 2000i [Respiratory Gas Humidifier] System

(You are encouraged to copy and distribute this notification.)

Date: February 1, 2007

Previous Publications:

December 20, 2005 (http://www.fda.gov/cdrh/safety/122005-vapotherm.html)

October 27, 2005 (http://www.fda.gov/cdrh/safety/102705-vapotherm.html)

Dear Health Care Practitioner:

Vapotherm, Inc. has reintroduced the 2000i [Respiratory Gas Humidifier] System. This system was recalled in 2005 due to possible contamination with *Ralstonia* spp. cultures.

In an earlier publication (see above), FDA noted that premature neonates, immunocompromised patients and those with underlying respiratory illness (such as cystic fibrosis) or malignancy may be at particularly high risk for infection if exposed to breathing gases from a contaminated Vapotherm® device. Though the specific cause for Ralstonia spp. has not been identified, Vapotherm, Inc. has been interacting with the CDC and FDA in updating the Operating Instruction Manual and implementing additional corrective actions to minimize the risk to patients. The FDA continues to monitor the device and encourages you to report any problem. In addition, the FDA recommends that you **take the following steps before using the reintroduced device:**

- Confirm that your base unit has been disinfected by Vapotherm, Inc. as part of the recall corrective plan, or send your unit back to Vapotherm, Inc. (198 Log Canoe Circle, Stevensville, MD 21666) to undergo the manufacturer's disinfection process.
- Discard all **used** Vapor Transfer Cartridges.
- Discard all **used** disinfection kit components and all **opened** disinfection kits.
- Contact your distributor to exchange **unopened** Vapor Transfer Cartridges with product codes VT01-A and VT01-B for new ones with product codes VT01-AS and VT01-BS.
- Obtain the latest 2000i Operating Instruction Manual and closely follow the revised instructions. Note especially that:
    - Each new Vapor Transfer Cartridge is for a **single patient-use and must be discarded after 30 days of use**.
    - Each disinfection kit, including all components in the kit, is for a **single use and must be discarded after one use**.
    - Only **sterile water** is to be used in the device.

The 2000i Operating Instruction Manual can be obtained by contacting Vapotherm, Inc. by phone at 410-604-3977 or 866-827-6843, by fax at 410-604-3978, or by emailing info@vtherm.com.

History

In August 2005, a Pennsylvania healthcare facility reported isolation of *Ralstonia* spp. in cultures obtained from several patients using the Vapotherm® 2000i. Surveillance conducted by the CDC identified additional institutions that have recovered *Ralstonia* spp. from clinical specimens or Vapotherm® devices. In response, Vapotherm, Inc. issued new infection control procedures to reduce the risk of infectious disease transmission on October 13, 2005. This information was published in the October 21, 2005, issue of a CDC MMWR (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5441a5.htm).

CDC's evaluation of a Vapotherm® 2000i, subjected to the chlorine dioxide disinfection protocol provided by the manufacturer, showed that the method may not achieve

sustained bacterial control. On October 27, 2005, the FDA published a Preliminary Public Health Notification (http://www.fda.gov/cdrh/safety/102705-vapotherm.html) informing the health care community of these events. CDC updated the October 21, 2005, MMWR on November 4, 2005, with details of the CDC's evaluation (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5443a4.htm).

Reports to the FDA and the CDC from more than two dozen hospitals in 16 states indicated that some Vapotherm® devices were colonized by *Ralstonia spp.* The bacteria were cultured from used Vapotherm® cartridges, from Vapotherm® devices that were disinfected according to the original instructions for use, and from devices disinfected according to newly issued instructions provided by the firm. The bacteria were also isolated from patients exposed to Vapotherm® devices. Cultures of unused Vapotherm® cartridges performed at two hospitals also yielded Ralstonia. However, cultures of other unused cartridges from some of the same lots performed by the cartridge manufacturer, by the FDA, and by CDC did not reveal any organisms. CDC updated the November 4, 2005 MMWR on December 20, 2005, (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5450a4.htm) with these new reports. On the same day, the FDA updated the Preliminary Public Health Notification (http://www.fda.gov/cdrh/safety/122005-vapotherm.html) to recommend the use of alternative devices.

Though the specific cause for Ralstonia spp. has not been identified since the firm's introduction of the 2005 infection control procedures, Vapotherm, Inc. has been interacting with the CDC and FDA to developing additional preventative measures to minimize the risk to patients.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of Vapotherm® 2000i [Respiratory Gas Humidifier] System, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to Vapotherm® 2000i [Respiratory Gas Humidifier] System that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at http://www.fda.gov/medwatch/report.htm.

FDA Contact

If you have questions about this notification, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 240-276-3357 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at http://www.fda.gov/cdrh/safety.html . You can also be notified through e-mail each time

a new Public Health Notification is added to our web page. To subscribe to this service, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDACDRH_10.

Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

Updated February 1, 2007

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kimberly Love

Subject: 510(k) Number K072845/S1

To: The Record

Please list CTS decision code AT

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: for (Branch Chief) ARDB (Branch Code) 3/31/08 (Date)

Final Review: (Division Director) (Date)

Rev. 5/30/07

425

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K072845
S001

Date: March 31, 2008
To: The Record
From: Kimberly Love, Reviewer

Office: HFZ-480
Division: DAGID/ARDB

510(k) Holder: Vapotherm, Inc.
Device Name: Precision Flow
Contact: Jonathan Khan (Hogan & Hartson L.L.P., Washington D.C.)
Phone: (b)(6)
Fax: (b)(6)
Ema(b)(6)HLaw.com

A. Purpose and Submission Summary

(b)(4)

B. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription Use has been indicated.)	S001, Appendix C, Section 4		
Truthful and Accuracy Statement	Section 6		
510(k) Summary	S001, Appendix C, Section 5		

426

	Yes	No	N/A
Standards Form		X	

C. **Device Description**

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device provided sterile?		X	
Is the device reusable (not reprocessed single use)? (Device intended for single patient use.) Are "cleaning" instructions included for the end user?		X	

(b)(4)

D. **Indications for Use**

Indications for Use as stated under Section 4 of the original submission:

"Precision Flow is intended use to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rate may be from 1 to 40 liters per minute via nasal cannula."

Prescription use has not been indicated. A new form has been requested. **See Deficiency A1 under Section O.**

E. Predicate Device Comparison

Predicate Devices:

Vapotherm 2000h	K013486
Vapotherm 2000i	K000401
Vapotherm 2000i and 2000h	K042245
Bird Blender	K911962
Maxtec	K063488

(b)(4)

F. Labeling

(b)(4)

G. Sterilization/Shelf Life/Reuse

(b)(4)

H. **Biocompatibility**

(b)(4)

I. **Software**: Section 16

(b)(4)

predicate device. **See Deficiency A7 under Section O.**

K. Performance Testing – Bench

(b)(4)

L. Performance Testing – Animal N/A

M. Performance Testing – Clinical N/A

N. Substantial Equivalence Discussion Not applicable at this time.

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See Premarket Notification 510(k) Flowchart Decision Tree for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

450

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

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

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

O. Deficiencies

(b)(4)

452

(b)(4)

5. (b)(4)

454

6. (b)(4)

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9. (b)(4)

10.

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c. (b)(4)

d.

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B. (b)(4)

(b)(4)

3.

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5.

(b)(4)

6.

7.

8.

9. (b)(4)

10

P. Contact History

(b)(4)

Q. Recommendation

(b)(4)

Kimberly Love

Kimberly G. Love, Lead Reviewer — Date: 03/31/2008

for Michael Husband, Branch Chief — Date: 3/31/08

ODE INTER DIVISION CONSULT REQUEST

Date: 3/10/2008 **POS Due Date:** 4/26/2008 **DATE REVIEW DESIRED:** 3/24/2008

FROM: Kimberly Love Branch ARDB Phone: 240-276-4251
Branch Chief: Michael Husband Mail Code: HFZ-480

TO: Dr. Sheila Murphey Branch INCB Phone: 240-276-3706

Documents type: 510(k) **DOCUMENT NUMBER:** K072845 Date Received: 2/26/2008
(e.g., IDE, 510(K), PMA)
Device name: Precision Flow

Sponsor name: Vapotherm, Inc.

Does submission need to be returned? ☐ Yes ☒ No

Purpose of submission:

- ☐ New Submission
- ☐ Protocol change
- ☐ New materials
- ☐ New indication(s)
- ☐ Response to deficiency letter
- ☐ Design change
- ☐ Labeling
- ☒ Other (specify) Supplement/Responses

Type of review: Infection Control

Response Needed:

- ☒ Formal signed memo (hard copy)
- ☐ Email Review
- ☐ Informal Comments (by phone or e-mail)
- ☐ Meeting attendance requested / Teleconference
- ☐ Other (Specify):

Comments or Specific Instructions/Questions (attach additional page if necessary):

(b)(4)

Consultation Review

Document Number: K072845/S001
Device Name: Precision Flow™
Sponsor: Vapotherm, Inc.

Reviewer: Sheila A. Murphey, MD
Branch Chief, INCB/DAGID

Date: March 15, 2008

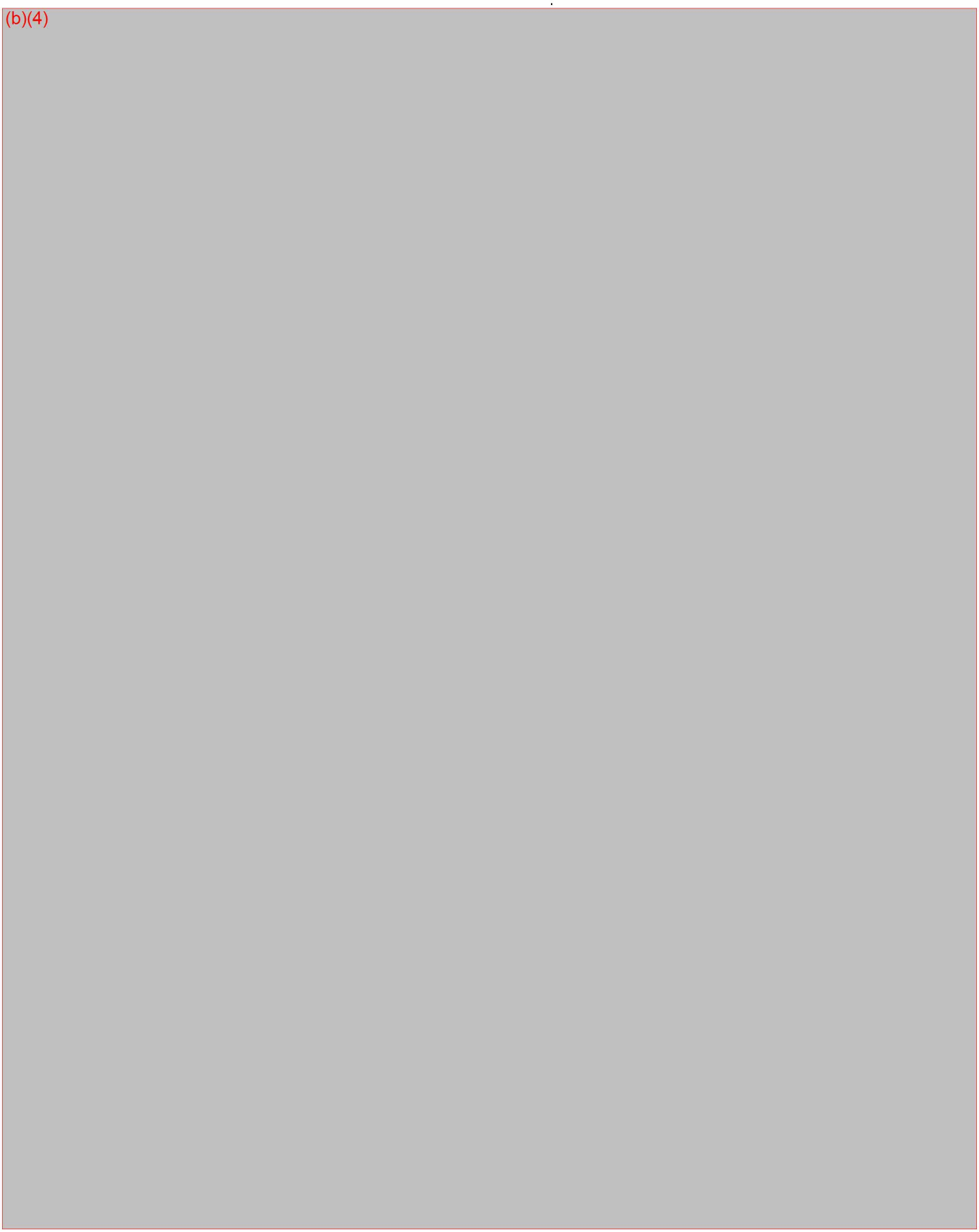
Subject:

(b)(4)

443

(b)(4)

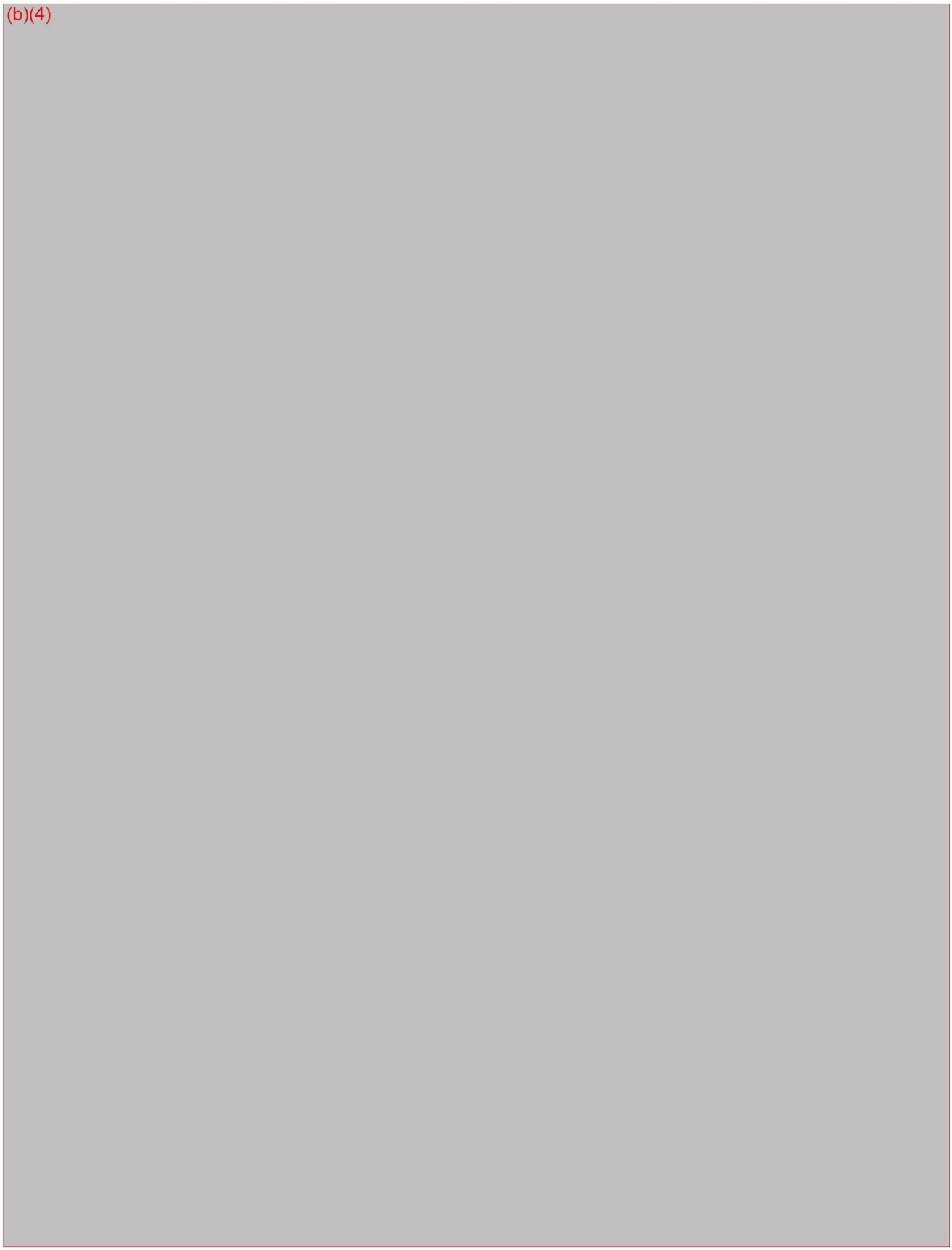
444



44C

(b)(4)

446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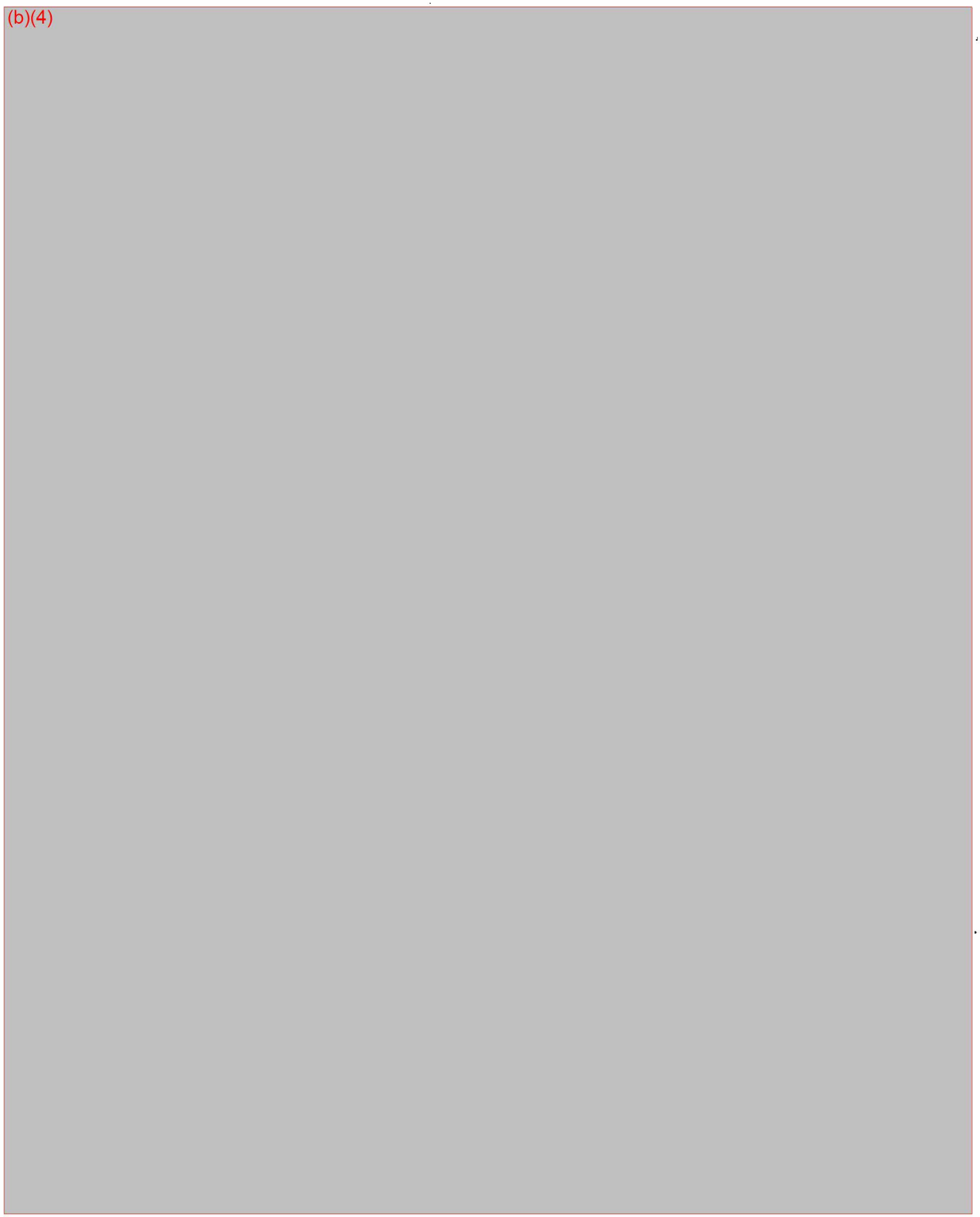
In Summary:

(b)(4)



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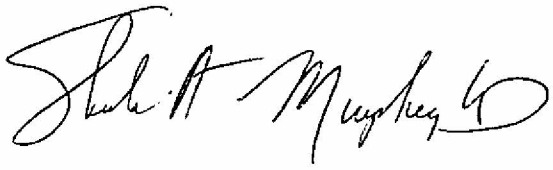

Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
March 15, 2008

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kimberly Love

Subject: 510(k) Number K072845

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ (Branch Chief) ARDB (Branch Code) 11/7/07 (Date)

Final Review: _____ (Division Director) _____ (Date)

Rev. 5/30/07

1598

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			X
5. a. Did the firm request expedited review? (See management.)			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date here: (b)(4)	X	
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

1599

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K072845

Date: November 6, 2007
To: The Record
From: Kimberly Love, Reviewer

Office: HFZ-480
Division: DAGID/ARDB

510(k) Holder: Vapotherm, Inc.
Device Name: Precision Flow
Contact: Jonathan Khan (Hogan & Hartson L.L.P., Washington D.C.)
Phone: (202) 637-5794
Fax: (202) 637-5910
Email: jskahan@HHLaw.com

A. Purpose and Submission Summary

(b)(4)

B. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription Use has not been indicated.)	Section 4		
Truthful and Accuracy Statement	Section 6		
510(k) Summary (Classification and Pro Code are not present.)	Section 5		
Standards Form			X

C. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device provided sterile?		X	

1600

	Yes	No	N/A
Is the device reusable (not reprocessed single use)? (Device intended for single patient use.) Are "cleaning" instructions included for the end user?		X	

(b)(4)

D. Indications for Use

Indications for Use as stated under Section 4 of the original submission:

"Precision Flow is intended use to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rate may be from 1 to 40 liters per minute via nasal cannula."

Prescription use has not been indicated. A new form has been requested. **See Deficiency A1 under Section O.**

E. Predicate Device Comparison

Predicate Devices:

Vapotherm 2000h	K013486
Vapotherm 2000i	K000401
Vapotherm 2000i and 2000h	K042245
Bird Blender	K911962
Maxtec	K063488

1601

(b)(4)

F. **Labeling**

(b)(4)

G. **Sterilization/Shelf Life/Reuse**

(b)(4)

H. **Biocompatibility**

(b)(4)

I. **Software**: Section 16

(b)(4)

1602

(b)(4)

J. **Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

(b)(4)

1603

K. **Performance Testing – Bench**

(b)(4)

L. **Performance Testing – Animal** N/A

M. **Performance Testing – Clinical** N/A

N. **Substantial Equivalence Discussion** Not applicable at this time.

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See Premarket Notification 510(k) Flowchart Decision Tree for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

164

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

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

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

O. **Deficiencies**

(b)(4)

1606

5. (b)(4)

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9. (b)(4)

10.

P. Contact History

(b)(4)

Q. Recommendation

(b)(4)

Kimberly G. Love, Reviewer

11/07/2007
Date

1608

Michael Husband, Branch Chief

Date 11/7/07

Love, Kimberly

From: Husband, Michael J
Sent: Thursday, October 18, 2007 9:44 AM
To: (b)(6)
Cc: 'Kahan, Jonathan S.'
Subject: I070383/S001

John,

(b)(4)

Thank you,

Michael Husband

Love, Kimberly

From: Husband, Michael J
Sent: Thursday, October 18, 2007 9:19 AM
To: Love, Kimberly
Subject: FW: I070379/S1
Follow Up Flag: Follow up
Flag Status: Red
Attachments: Consult on Vapotherm I070379-S1 Precision Flow 10-13-07.doc

(b)(4)

Thank you,

Michael Husband

From: Murphey, Sheila A
Sent: Saturday, October 13, 2007 5:42 PM
To: Husband, Michael J
Subject: I070379/S1

Dear Michael,

(b)(4)

Thanks,

Sheila

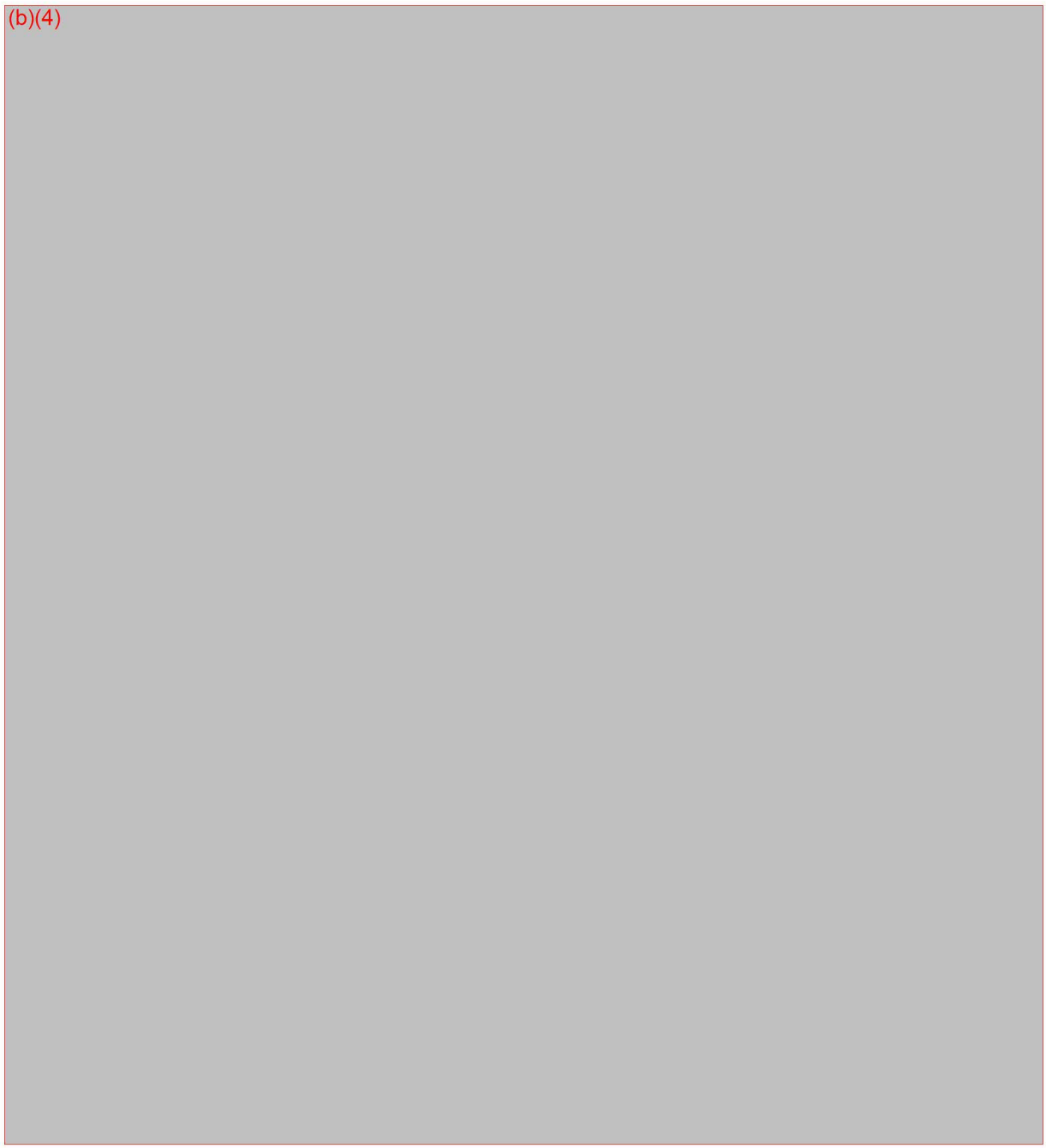
Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation, Center for Devices and Radiologic Health
9200 Corporate Blvd Room 340H Mail Stop HFZ-480
Rockville, MD 20850
Phone 240-276-3706
Fax 240-276-3789
sheila.murphey@fda.hhs.gov

Consultation Review

Document Number: I070379/S001
Device Name: Precision Flow™
Sponsor: Vapotherm, Inc.

Reviewer: Sheila A. Murphey, MD
Branch Chief, INCB/DAGID
Date: October 13, 2007

(b)(4)



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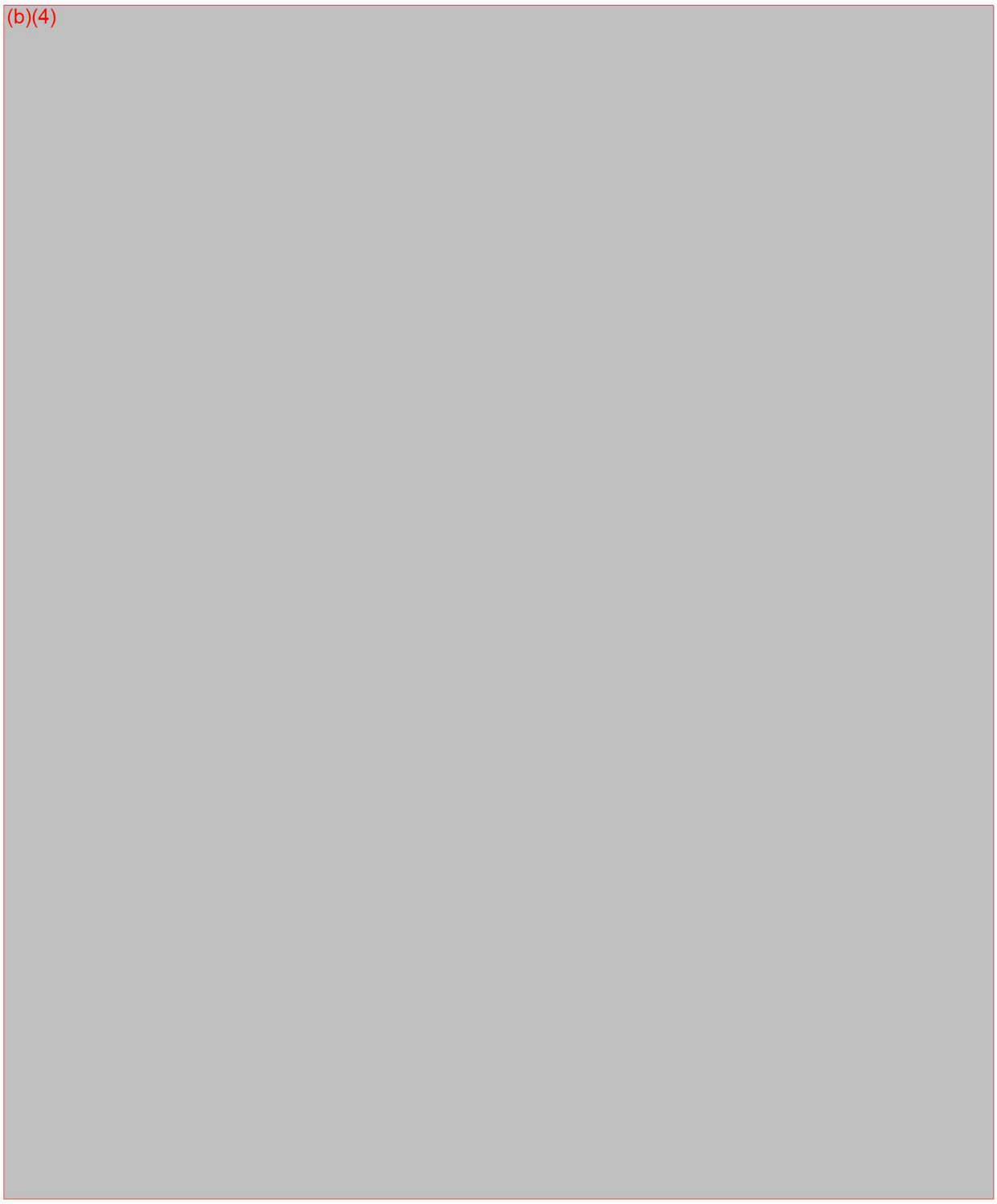
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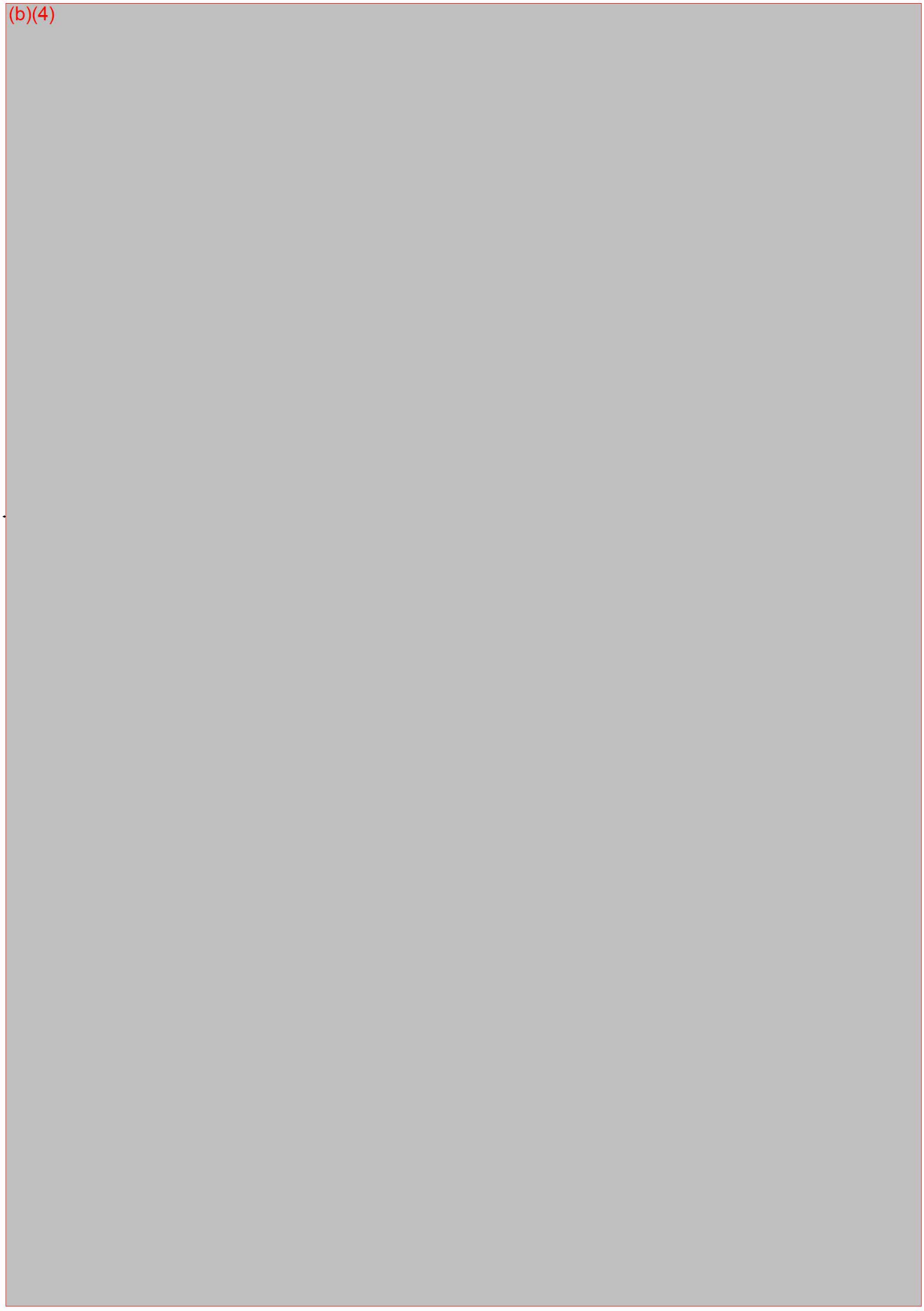
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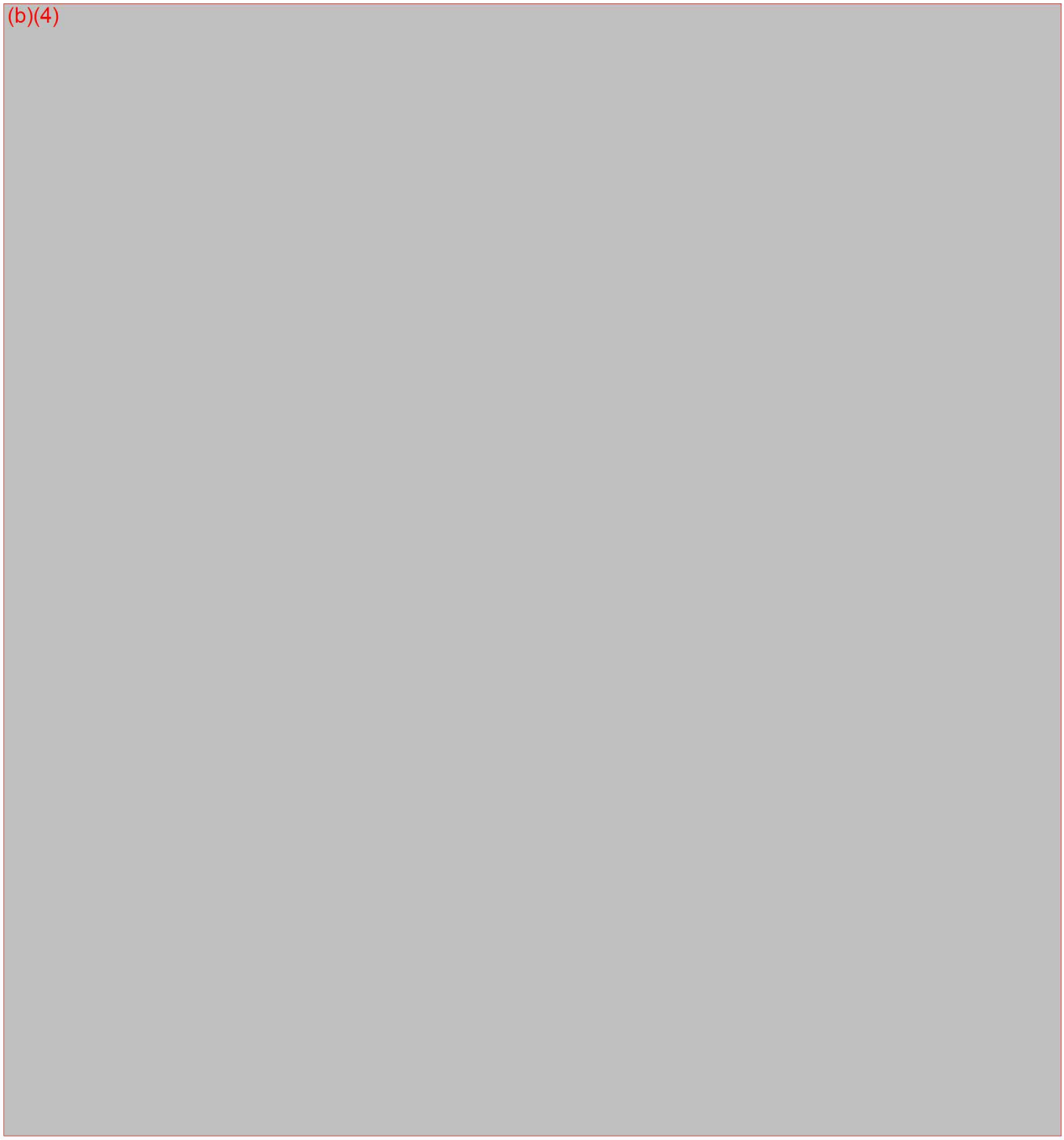
In Summary:

(b)(4)



Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
October 13, 2007

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-40
9200 Corporate Blvd.
Rockville, Maryland 20850

February 26, 2008

VAPOTHERM, INC.
C/O HOGAN&HARTSON L.L.P
555 THIRTEENTH STREET, NW
WASHINGTON, DC 21666
ATTN: JONATHAN S. KAHN

510(k) Number: K072845
Product: PRECISION FLOW

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

K072845/S1

VAPOTHERM

February 21, 2007

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

Attention: Kimberly Love (HFZ-480)

Re: K072845, Trade Name: Precision Flow™
Request for Additional Information (Dated November 8, 2007)

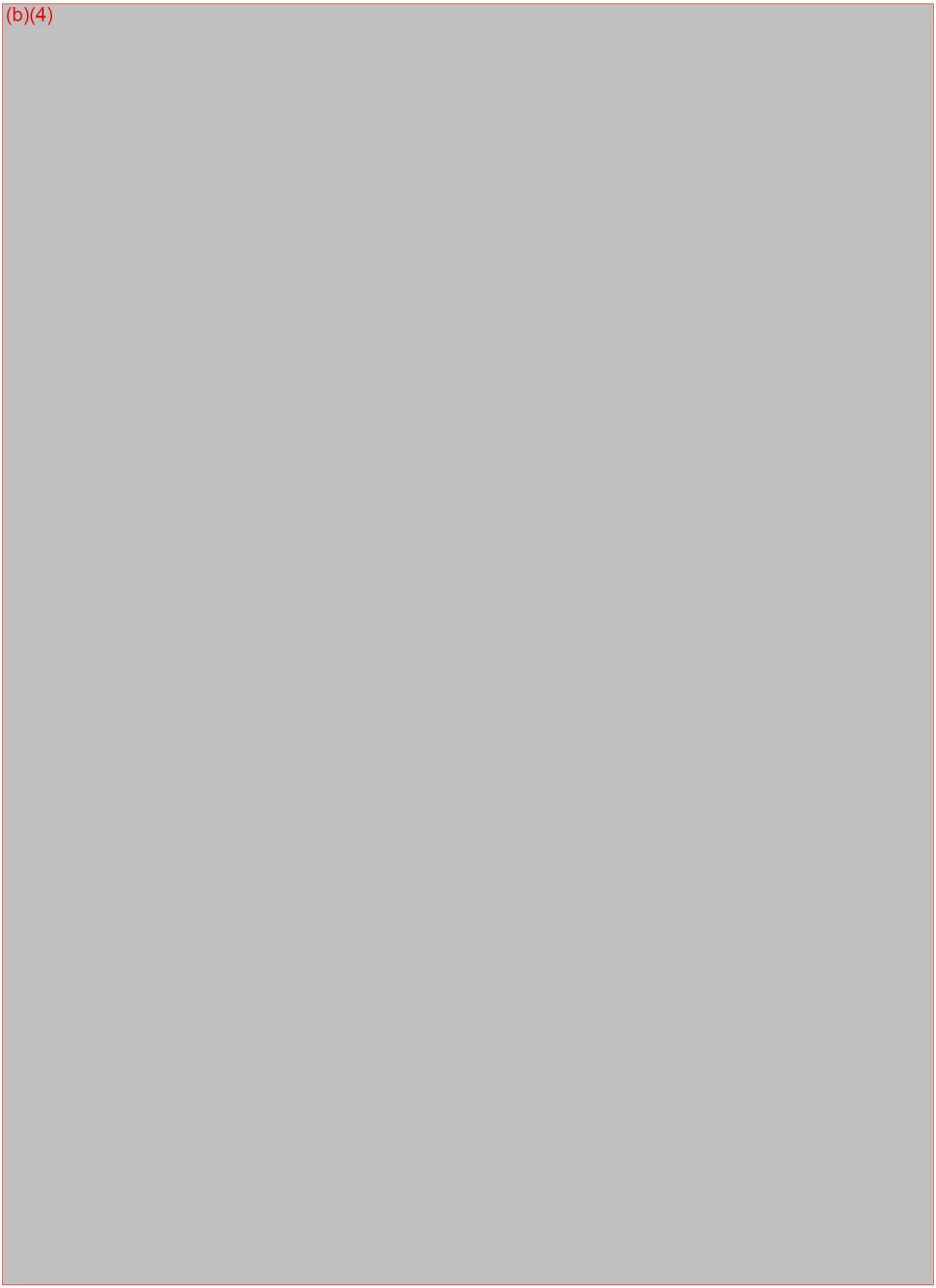
Dear Ms. Love:

The purpose of this letter is to respond to the Food and Drug Administration's ("FDA" or "the agency") letter dated November 8, 2007, requesting additional information regarding Vapotherm, Inc.'s ("Vapotherm" or "the company") 510(k) premarket notification for the Precision Flow™ device (K072845) that was submitted to the agency on October 2, 2007. Specifically, FDA requested additional information concerning ten (10) items regarding the 510(k) described above.

At the agency's request, we are providing the entire 510(k) notice for the Precision Flow that includes the revisions that Vapotherm has made in response to FDA's specific requests. To assist FDA in its review of the revised 510(k) notice, we are including a summary table (matrix) that lists all sections (1-19) of the Precision Flow 510(k) notice and cross reference to the specific changes that Vapotherm has made in addressing the agency's requests (**Appendix A**), as well as the revised 510(k) notice itself (**Appendix C**). In addition, the company has included portions of the labeling from the Vapotherm 2000i and 2000h (K042245) as described in this response (**Appendix B**).

The following section provides Vapotherm's response to each of the items listed in FDA's letter. For convenience, we are restating each of the specific FDA requests for information outlined in the agency's letter dated November 8, 2007, followed immediately by the company's response.

* * *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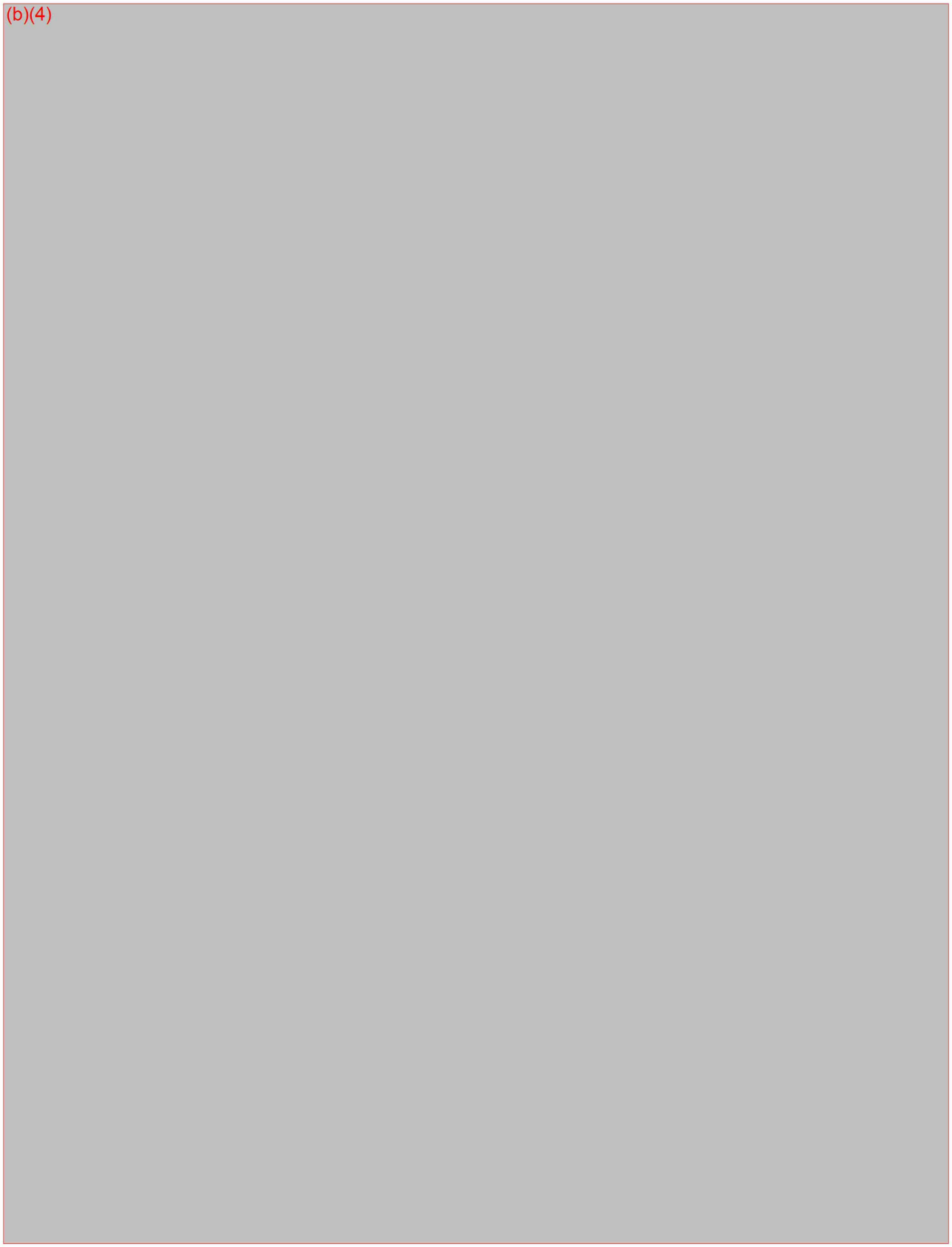
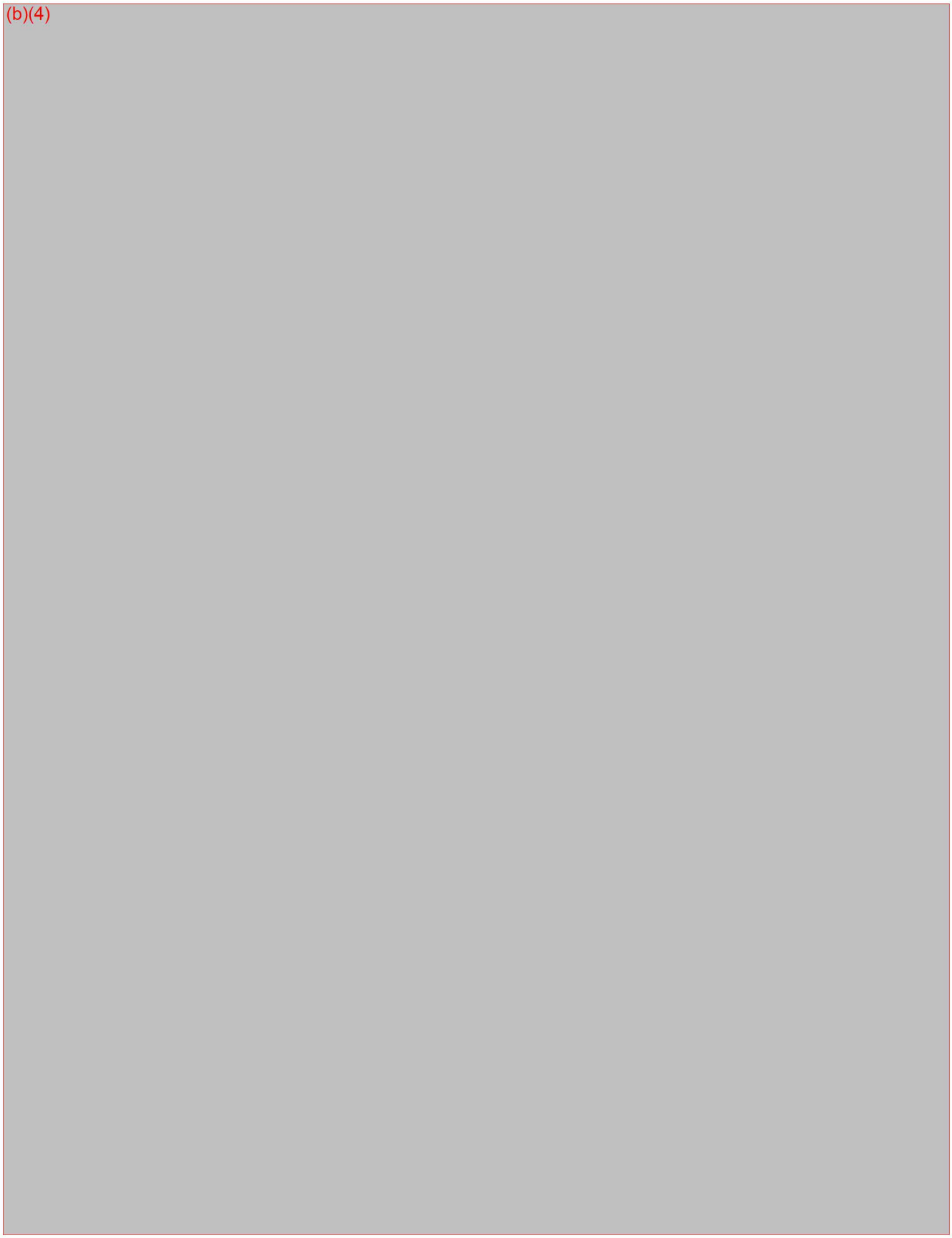
(b)(4)

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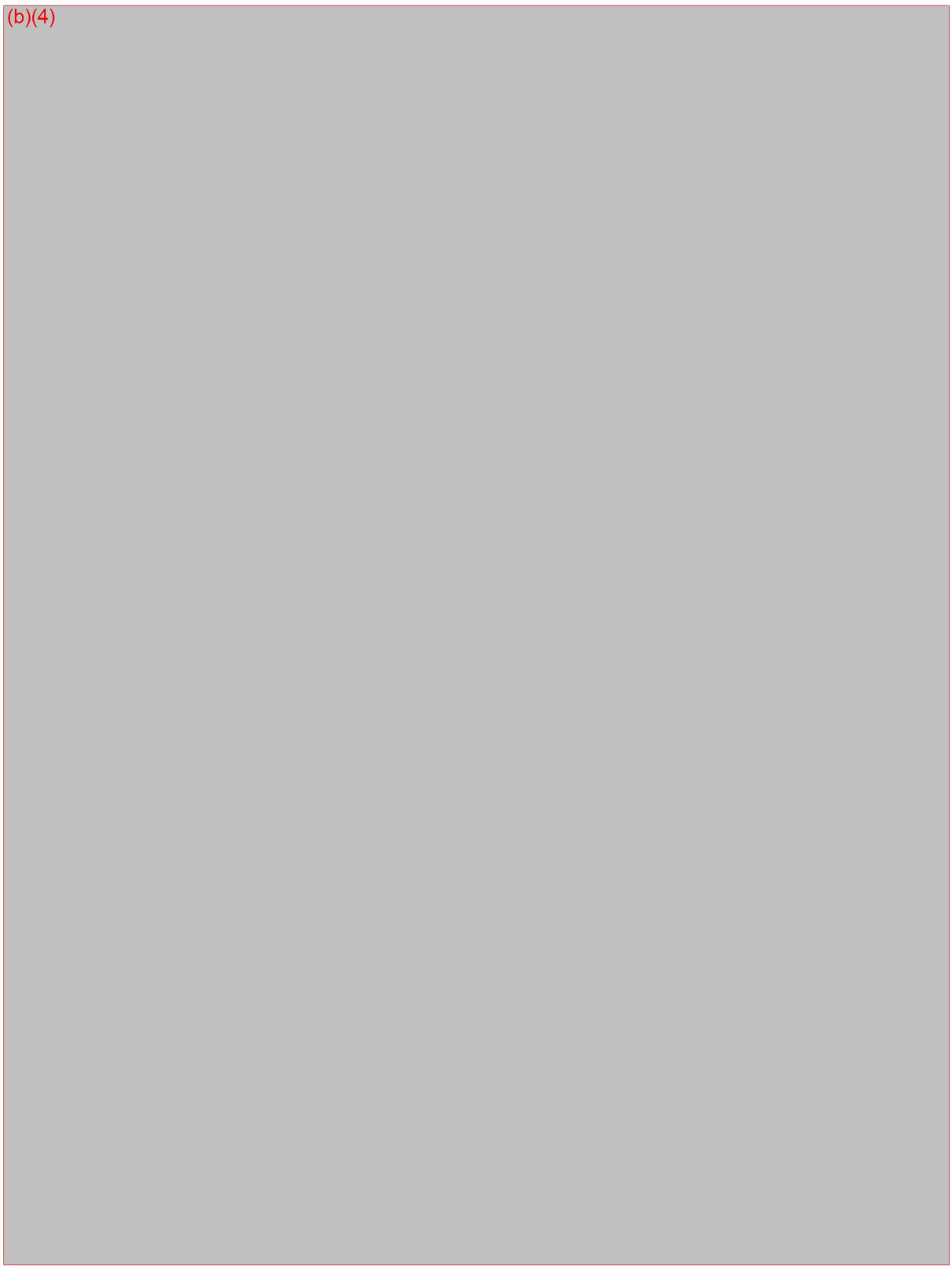

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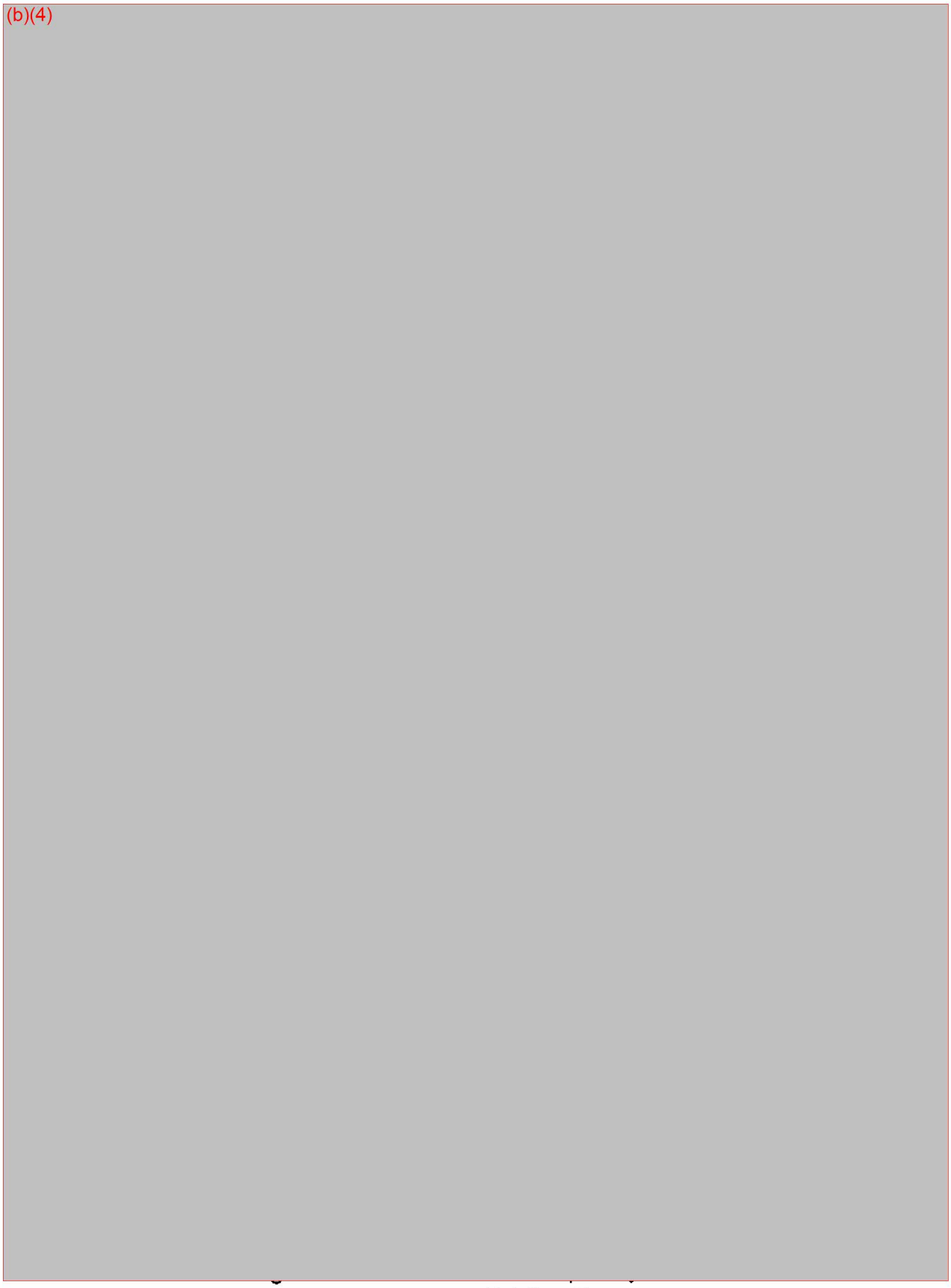
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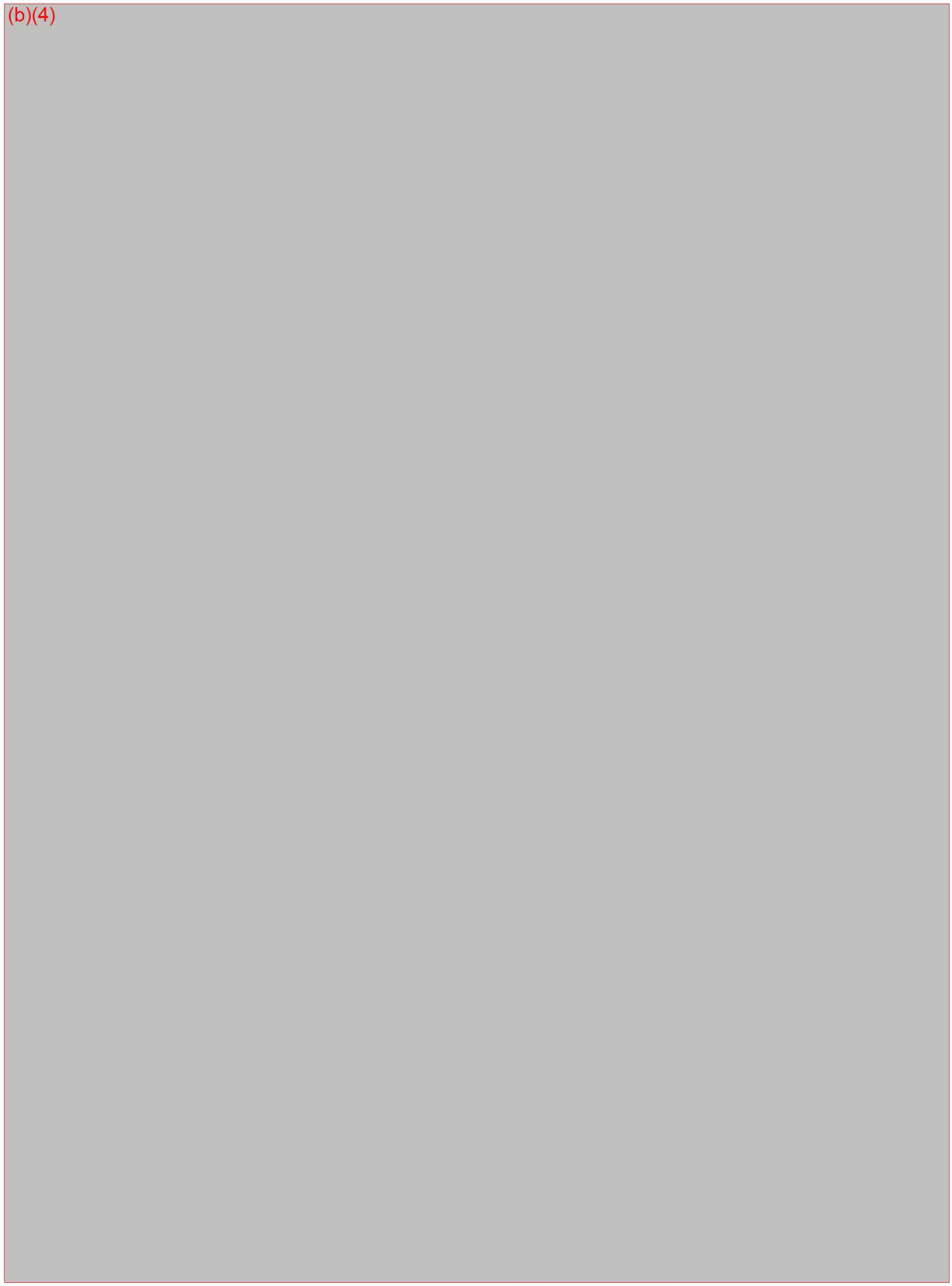

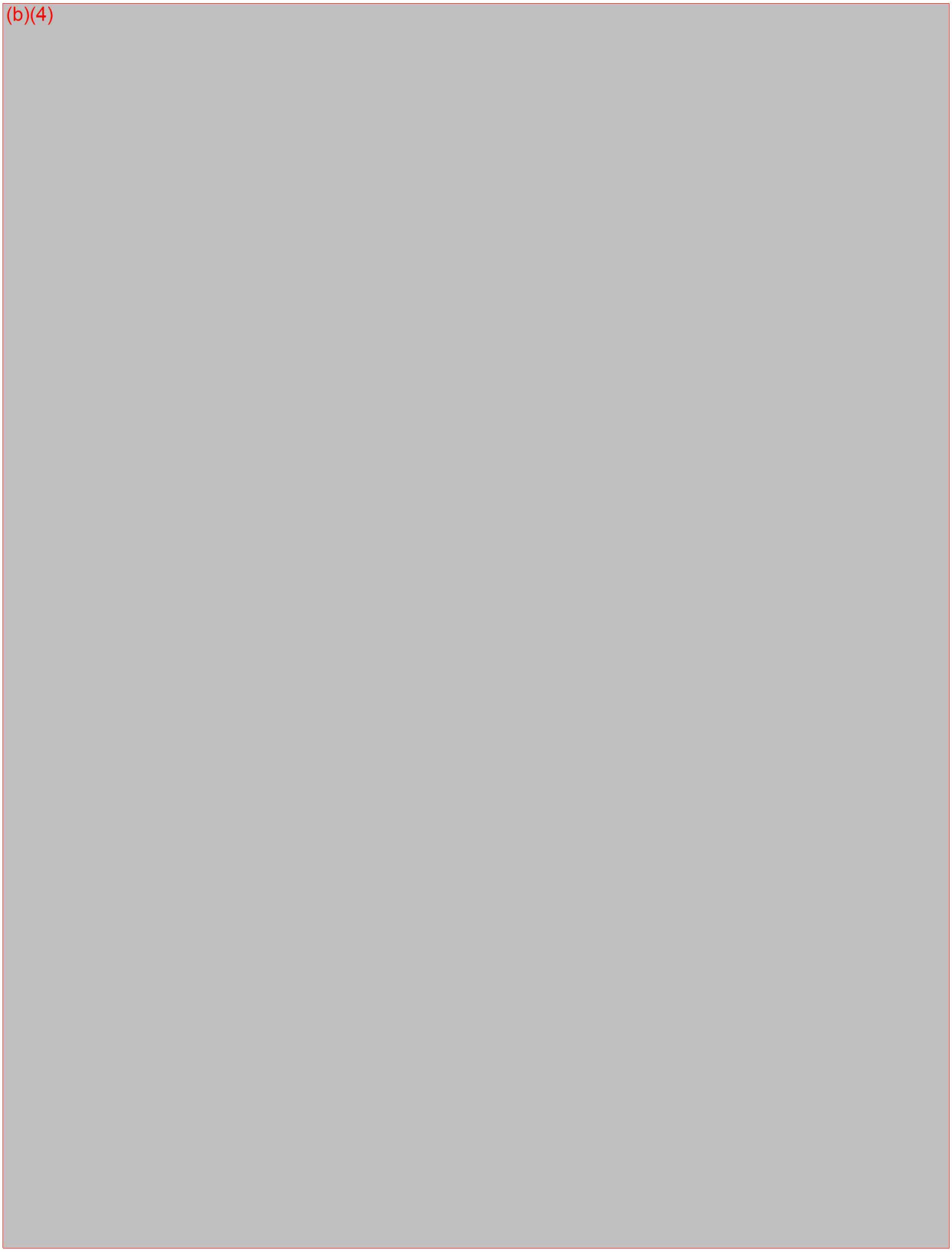
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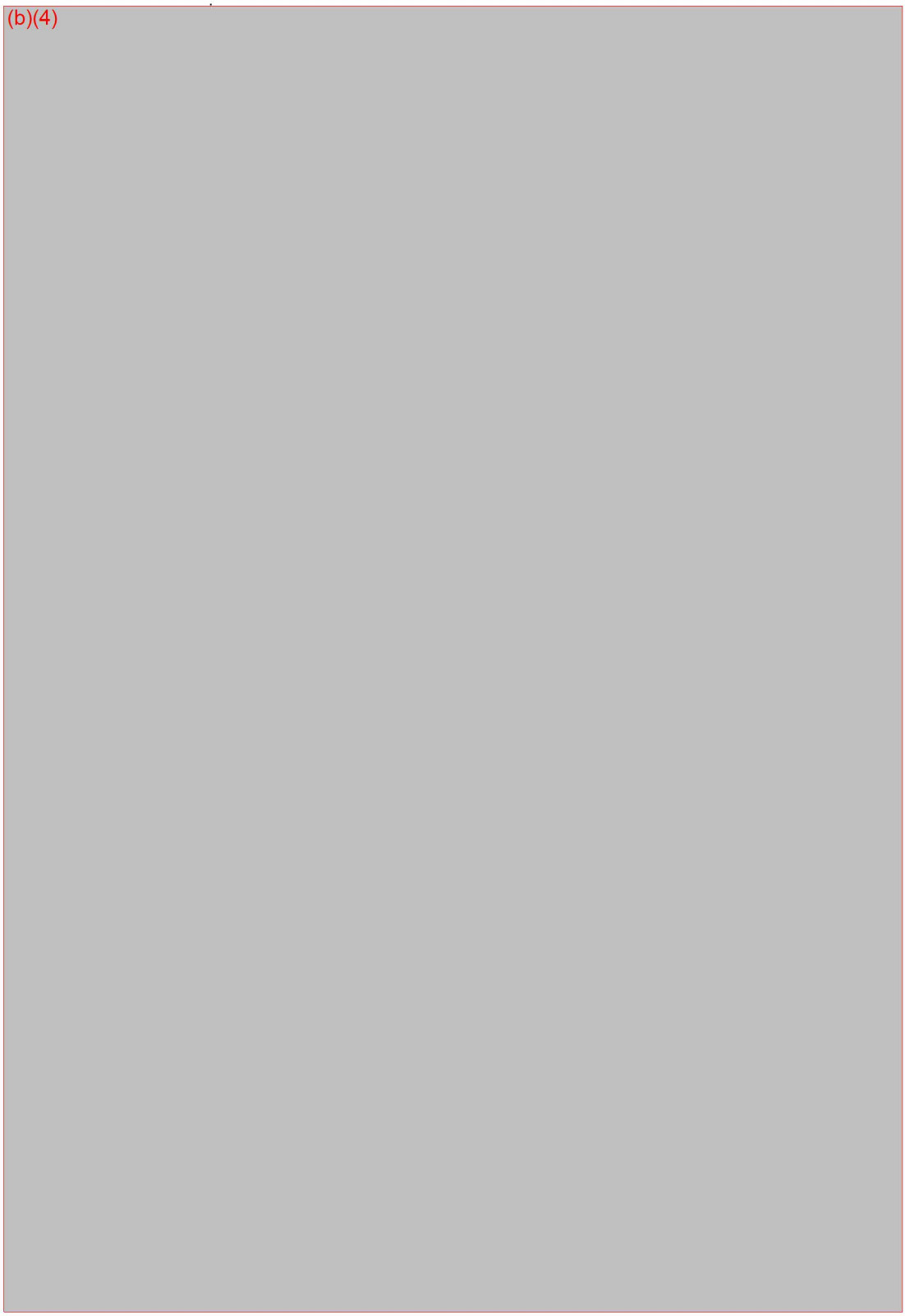
(b)(4)

(b)(4)

Sincerely,

(b)(6)

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666
410.604.3977 Ext. 109
(b)(6)@vtherm.com

Enclosures: (b)(4)

ccs: William Robert Storey, President & CEO, Vapotherm, Inc.
Jonathan S. Kahan, Hogan & Hartson LLP
(b)(6), Hogan & Hartson LLP
ogan & Hartson LLP

Appendix A

FDA Request for Additional Information

Precision Flow™ 510(k) Submission Explanation of Changes

#	510(k) Section	Status	Comments
1	(b)(4)		
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			

463

#	510(k) Section	Status	Comments
12	(b)(4)		
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

464

#	510(k) Section	Status	Comments
26	(b)(4)		
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			
41			
42			
43			
44			
45			

#	510(k) Section	Status	Comments
46	(b)(4)		
47			
48			

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Appendix B

AUG 30 2004

K042245

3.1 Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness
Page 1 of 2
August 16, 2004

Vapotherm, Inc.
108 Log Canoe Circle
Stevensville, MD 21666

Tel – (410) 604-3977
Fax – (410) 974-9707

Official Contact: William Niland, Chairman

Proprietary or Trade Name: Vapotherm™ 2000h and 2000i

Common/Usual Name: Humidifier, Respiratory Gas (Direct Patient Interface)

Classification Name: Humidifier, Respiratory Gas (Direct Patient Interface)

Device: Vapotherm™ 2000h and 2000i

Predicate Devices: Vapotherm™ 2000h, K000401, and 2000i – K013486
Caradyne Guardian – K040862

Device Description:

The Vapotherm 2000i and Vapotherm 2000h are identical and share the concept of humidification by transpiration of water vapor across a membrane by the use of a low or high flow cartridge with membrane bundles. The difference in the cartridges is only the number of membrane bundles included, fewer in the low flow. Both units and cartridges produce a highly humidified air (relative humidity >95%), virtually free of droplets, at body temperature or above at flow rates from 1 to 40 lpm via a nasal cannula. The water content at 41°C is 40-50 mg/liter, about fourfold higher than can be achieved by humidification at room temperature. The unique combination of high flow and high vapor-phase humidity allow an unusually wide range of clinical applications. Applications previously considered impractical because of limited patient tolerance for high nasal flow can now be routine because of the comfort provided by warmth and high humidity.

Indications:

Indicated Use – To add moisture to and to warm breathing gases for administration to patients, including neonates/infant, pediatrics, and adults. The environment of use include – home, hospital or sub-acute institutional settings

Patient Population – For use with neonate/infant, pediatric and adult patients utilizing high flow supplemental air, air/oxygen, or gas mixtures in which humidification would be beneficial.

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 2
August 16, 2004

K042245

Indications: (continued)

Environment of Use – Home, Hospital, Sub-acute Institutions

Contraindications – None

Comparison to Predicate Devices:

	Vapotherm 2000h and 2000i Predicate	Clarification
Attributes		
Indications for use	To add moisture to and to warm breathing gases at high flows with an air or air/oxygen mixture for administration to a patient	Same
Environments of use	Home, Hospital, Sub-acute Institutions, not specified.	Same
Patient Population	For use with any patient utilizing supplemental oxygen in which humidification would be beneficial and with an air or air/oxygen mixture. All patients, non population specific. **Caradyne – Guardian K040862** Neonate / infant	Neonate/infant, pediatric and adult
Contraindications	None	Same
Equipment Design		
No changes		
Technology of humidification		
Membrane type	Basic membrane type humidifier, hollow fiber cartridge	Low flow – 1 - 8 lpm High flow – 5 - 40 lpm

Differences Between Other Legally Marketed Predicate Devices

There are no differences, only clarification of the indicated populations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2004

Vapotherm, Incorporated
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
6329 West Waterview Court
McCordsville, Indiana 46055-9501

Re: K042245
Trade/Device Name: Vapotherm Model# 2000h and 2000i
Regulation Number: 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: August 18, 2004
Received: August 19, 2004

Dear Mr. Dryden:

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. 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/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.3 Indications for Use

510(k) Number: K042245 (To be assigned)

Device Name: Vapotherm 2000h and 2000i

Indications for Use: The Vapotherm™ 2000h and 2000i are designed to add moisture to and to warm breathing gases for administration to patients, including neonates/infant, pediatrics, and adults. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

Environments of use - Home, Hospital, Sub-acute Institutions

Prescription Use XX **or** **Over-the-counter use __**
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K042245

Appendix C

Vapotherm, Inc.

510(k) Premarket Notification

Precision Flow™

February 19, 2008

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland
211666

TABLE OF CONTENTS
Section

MEDICAL DEVICE USER FEE

FDA U.S. Food and Drug Administration Department of Health and Human Services

FAQ UserFees Draft Cover Sheet Previous Cover Sheets Profile Sign Out

Medical Device User Fee

Confirmation

YOUR PAYMENT IDENTIFICATION NUMBER IS: MD(b)(4)

Your Cover Sheet has been submitted electronically. You must print and sign the hard copies. Include one in each copy of your application and include a copy with your payment.

Create Another Cover Sheet

Coversheet

Medical Device User Fee and Modernization Act 1 Fee: $3,404.00

Print/View Final Coversheet

Total:$3,404.00

Applicant Information

Applicant: VAPOTHERM INC
(b)(6)
410-604-3977 109
(b)(6)@vtherm.com

Applicant Contact Information

Submitter: (b)(4)
VAPOTHERM INC
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville,MD 21044
UNITED STATES

Create Another Cover Sheet

Medical Device User Fee
UserFees | Draft Cover Sheet | Order | Profile | Sign Out |

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA | Privacy | Accessibility

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (*if known*)
10 – 3 -07	(b)(4)	K072845

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	☐ Regular (120 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	☒ Original Submission: ☒ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party	☐ Pre-510(K) Meeting ☐ Pre-IDE Meeting ☐ Pre-PMA Meeting ☐ Pre-PDP Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Other (*specify*):

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission Amendment Supplement	☐ Original Submission Amendment Supplement Report Report Amendment	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	☐ 513(g) ☐ 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 Vapotherm, Inc.	Establishment Registration Number (*if known*) 1125759		
Division Name (*if applicable*)	Phone Number (*including area code*) (410) 604-3977		
Street Address 198 Log Canoe Circle	FAX Number (*including area code*) (410) 604-3978		
City Stevensville	State / Province Maryland	Zip/Postal Code 21666	Country USA
Contact Name William Robert Storey			
Contact Title President & CEO	Contact E-mail Address (b)(6) @vtherm.com		

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

Company/ Institution Name Hogan & Hartson L.L.P.	Establishment Registration Number (*if known*) N/A		
Division Name (*if applicable*)	Phone Number (*including area code*) (202) 637-5794		
Street Address 555 Thirteenth Street, NW	FAX Number (*including area code*) (202) 637-5910		
City Washington	State / Province DC	Zip/Postal Code 20004	Country USA
Contact Name Jonathan S. Kahan			
act Title Regulatory Counsel	Contact E-mail Address (b)(6) @HHLaw.com		

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

- ☐ Withdrawal
- Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification;
  - Software/ Hardware
  - Color Additive
  - Material
  - Specifications
  - Other (*specify below*)
- ☐ Location change:
  - Manufacturer
  - Sterilizer
  - Packager
- ☐ Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other (*specify below*)
- ☐ Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other (*specify below*)
- ☐ Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

SECTION D2 REASON FOR APPLICATION – IDE

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

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded indications
- ☐ Change in Technology
- ☐ Other Reason (*specify*):

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SECTION E ADDITIONAL INFORMATION ON 510(k) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	BTI	2	BTT	3	BTT	4	BZR
5	CCL	6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510(k) summary attached
☐ 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	K013486	1	Vapotherm 2000h	1	Vapotherm, Inc.
2	K000401	2	Vapotherm 2000i	2	Vapotherm, Inc.
3	K042245	3	Vapotherm 2000i and 2000h	3	Vapotherm, Inc.
4	K911962	4	Bird Blender	4	Bird Products
5	K063488	5	Maxtec	5	Oxygen Sensor

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Respiratory gas humidifier and/or breathing gas mixer

	Trade or Proprietary or Model Name for This Device		Model Number
1	Precision Flow™	1	Precision Flow™
2		2	

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

1	2	3	4	5	6

Data Included in Submission ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section (*if applicable*)	Device Class
BTT	868.5450	☐ Class I X Class II
BZR	868.5330	☐ Class III ☐ Unclassified

Classification Panel

Anesthesiology

Indications (*from labeling*)

Precision Flow™ is intended to add moisture to and to warm breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

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

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

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name Vapotherm, Inc.		Establishment Registration Number: 1125759			
Division Name (*if applicable*)		Phone Number (*including area code*) (410) 604-3977			
Street Address 198 Log Canoe Circle		FAX Number (*including area code*) (410) 604-3978			
City Providence Stevensville,		State / Province Maryland	ZIP Code 02907 21666	Country USA USA	
Contact Name William Robert Storey	Contact Title President and CEO	Contact E-mail Address bstorey@vtherm.com			

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name (b)(4)		Establishment Registration Number Owner/Operator Number (b)(4)			
Division Name (*if applicable*) (b)(4)		Phone Number (*including area code*) (b)(4)			
Street Address (b)(4)		FAX Number (*including area code*) (b)(4)			
City (b)(4)		State / Province Rhode Island	ZIP Code 02907	Country USA	
Contact Name (b)(4)	Contact Title Head of Quality Assurance and Regulatory Affairs	Contact E-mail Address (b)(4)			

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

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SECTION I	UTILIZATION OF STANDARDS				
Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. IEC 60601-1	Standards Organization: IEC	Standards Title: General Requirements for Safety	Version	Date 1988
2	Standards No. EN 60601-1-2, Group 1, Class A	Standards Organization: EN	Standards Title:	Version	Date
3	Standards No. IEC 60601-1-8	Standards Organization: IEC	Standards Title: General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.	Version	Date 2003
4	Standards No.	Standards Organization	Standards Title:	Version	Date
5	Standards No.	Standards Organization	Standards Title:	Version	Date

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

3. 510(k) Cover Letter

The Company's 510(k) Cover Letter for the Precision Flow™ is provided in this section of the submission.

VAPOTHERM

February 19, 2008

By Messenger

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

Attention: **Document Mail Clerk**

Re: 510(k) Premarket Notification for Vapotherm, Inc.'s Precision Flow™

Dear Charles HO, Ph. D. (HFZ-450)

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), Vapotherm, Inc. ("Vapotherm" or the "Company") is submitting the attached premarket notification ("510(k) Notification") for its Precision Flow™ ("Device") for use in adding warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

The Vapotherm Precision Flow™ is a Class II Respiratory Gas Humidifier, Regulatory Class II (two). The device consists of the following components and accessories:

- Main Unit;
- Disposables: Water module, Vapor Transfer Cartridge, Delivery Tube, Cannula; and
- Accessories: Air/Oxygen Hoses, Gas Filter, Oxygen Sensor, Power Cord, and Mounting Stand

In addition, the Vapotherm Precision Flow™ is identical to the Vapotherm Models 2000i and 2000h (K000401, K013486, and K042245), which have already been cleared for the treatment of any patient utilizing high flow supplemental air or air/oxygen mixtures in which humidification would be beneficial except for some minor technological differences. The primary changes are the addition of an integrated air/oxygen blender, an integrated oxygen sensor, and a disposable water module.

To conform with the Food and Drug Administration's ("FDA" or the "Agency") August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, the principal factors concerning the design and use of the Precision Flow™ are set forth in the following table of FDA questions.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

As explained in more detail in the attached 510(k) notice, the Precision Flow™ is also substantially equivalent to the Maxtec Oxygen Sensor (K063488), and the Bird Microblender (K911962) that the Food and Drug Administration ("FDA") has already cleared for the treatment of any patient utilizing high flow supplemental air or air/oxygen mixtures in which humidification would be beneficial. Vapotherm, Inc. is the primary application submitter for the Precision Flow™.

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Vapotherm, Inc. has submitted the required application fee of $3,404.00. A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

Vapotherm considers its intent to market the Precision Flow™ as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employers, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in the 510(k) notice is sufficient for FDA to find the Precision Flow™ substantially equivalent to its predicate devices for the listed indication. If you have any additional questions regarding the 510(k) notice, please contact me at the above number or John Smith at (202) 637-3638. Upon clearance of the device, please fax the substantial equivalence letter to me at (410) 604-3978.

Sincerely,

(b)(6)

Gregory A. Whitney
VP Regulatory Affairs
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666
410.604.3977 Ext. 109

Attachments

ccs: Jonathan S. Kahan, Partner, Hogan & Hartson LLP
(b)(6) Partner, Hogan & Hartson LLP
William Robert Storey, President & CEO, Vapotherm, Inc.

4. INDICATIONS FOR USE STATEMENT

The Company's Indications for Use Statement for the Precision Flow™ is provided in this section of the submission.

Indications for use

510(k) Number (if known): K072845

Device Name: Precision Flow™

Indications for Use:

Precision Flow™ is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

Precision Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The counter Use ____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(K) SUMMARY

The Company's 510(k) Summary is provided is provided in this section of the submission.

510(k) SUMMARY

Vapotherm, Inc.'s Precision Flow™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

Phone: 410-604-3977
Facsimile: 410-604-3978

Contact Person: Gregory A. Whitney

Date Prepared: October 2, 2007

Name of Device and Name/Address of Sponsor

Precision Flow™

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, Maryland 21666

A. Common or Usual Name

Humidifier, Respiratory Gas (Direct Patient Interface)

B. Classification Name

Humidifier, Respiratory Gas (Direct Patient Interface)
Anesthesiology Panel (868.5450)
Class II

C. Product Code

BTT

D. Predicate Devices

Vapotherm, Inc.	2000i & 2000h	K000401, K0142245, K042245
Maxtec	Oxygen Sensor	K063488
Bird Products	Air-Oxygen Blender	K911962

E. Intended Use / Indications for Use

The Precision Flow™ is intended to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

F. Technological Characteristics

The Precision Flow™ consists of two parts:

The **main unit** which contains all the electrical and electronic components including the electronic blender and flow controllers. All the sensors are located in the main unit. The main unit has no water pathways and the gas pathway contains only dry gas at room temperature, and consequently does not need internal cleaning or disinfection.

The **disposable components** consist of the disposable water module, vapor transfer cartridge and heated delivery tube. Conditions in the circulating water and gas streams are sensed remotely via the interface between the main unit and the disposable module.

1. Main unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow of each needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

- Firmware running in the main unit uses sensors to monitor gas pressure, water level and water temperature, and to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the

type of cartridge installed. An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

2. Disposable components:

- Vapor Transfer Cartridge. In the cartridge blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- Triple-lumen Heated Delivery Tube. The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize rain-out. A proprietary short nasal cannula is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- Disposable Module. The module houses a water reservoir, pump, connections for the cartridge and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the Vapor Transfer Cartridge where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the water bag to replace evaporative losses in the Vapor Transfer Cartridge. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

G. Substantial Equivalence

The Precision Flow™ is as safe and effective as the Vapotherm 2000i and 2000h, the Bird Microblender, and the Maxtec Oxygen Sensor. The Precision Flow™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Precision Flow™ and its predicate devices raise no new issues of safety or effectiveness. Performance data will demonstrate that the Precision Flow™ is as safe and effective as the predicate devices. Thus, the Precision Flow™ is substantially equivalent.

6. TRUTHFUL AND ACCURATE STATEMENT

The Company's signed Truthful and Accurate statement is included in this section of the submission.

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 C.F.R. § 807.87(k))

I certify that, in my capacity as President and CEO of Vapotherm, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the Precision Flow™ are truthful and accurate and that no material fact has been omitted.

(b)(6)

(Signature)

William Robert Storey
(Typed Name and Title)

President and CEO
Vapotherm, Inc.

Vapotherm, Inc.
(Company)

February 19, 2008
(Date)

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7. PREMARKET NOTIFICATION

CLASS III CERTIFICATION AND SUMMARY

(As Required by 21 CFR § 807.94)

The proposed device, Vapotherm Precision Flow, is not claiming equivalence to a Class III device, therefore the summary and certification is not required.

8. FINANCIAL DISCLOSURES

Vapotherm is not submitting clinical data in support of this 510(k) notice. For this reason, FDA's regulation regarding clinical investigators' financial interests and arrangements, i.e., 21 C.F.R. § 54.4, do not apply. Thus, the Company is not providing a disclosure or certification to the absence of any disclosable financial interests or arrangements.

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

The Company's Declarations of Conformity and Summary Reports are included in this section of the submission.

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

No performance standards or special controls have been developed under Section 514 of the FDC Act for Humidifier, Respiratory Gas (Direct Patient Interface). No special controls apply.

Consistent with FDA's guidance document entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000), Vapotherm has included this statement that the Precision Flow™ will comply with the following recognized consensus standards instead of providing the test reports demonstrating compliance with these standards:

ISO 8185-1; Requirements for Medical Humidifiers with exceptions:

- Section 1: Canister or wick type humidifier not applicable
- No external temperature sensors
- Section 6: Anesthetic mixtures not applicable
- Section 8.1: Water temperature is monitored, not gas temperature
- Section 8.2: Water temperature may deliver gas temperature up to 43° C
- Section 10: Delivery tube not applicable

IEC 60601-1; General Requirements for Safety with exceptions:

- Section 5: Device can not produce hazardous radiation
- Section 6: Anesthetic mixtures not applicable

EN 60601-1-2, Group 1, Class A

IEC60601-1-8, General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

UL 2601-1

CSA 22.2

IEC 529; IPX1 Drip Proof

ISO 9703-1, Anesthesia and respiratory care alarm signals -- Part 1: Visual alarm signals

ISO 9703-2, Anesthesia and respiratory care alarm signals -- Part 2: Auditory alarm signals

ISO 11195, Gas Mixers for Medical Use

ISTA-2A, Ship testing protocol for devices under 150 lbs

VOC TO-15 Volatile Organic Compounds and Particulate Matter PM 2.5

These standards have not been adapted for application to the Precision Flow™. The device that will be tested and the subject of the 510(k) is the Precision Flow™. The Testing Laboratory is Intertek (ETL) Testing Services NA, Inc, located at 70 Codman Hill Road, Boxborough, MA 01719, a fully accredited test laboratory, specializing in electrical product safety testing, EMC testing, and benchmark performance testing. Intertek will determine that the Precision Flow™ conforms to the standards. This testing laboratory has the following accreditations:

The Americas		
Organization	**Accreditation Scope**	**Accreditation Criteria**
American Association of Laboratory Accreditation (A2LA)	Accreditation for automotive, building materials, EMC, telecommunications and thermal testing *A2LA testing scopes are site specific; for further details contact A2LA or the Intertek facility.*	ISO/IEC 17025
American National Standards Institute (ANSI)	Accreditation of the ETL Listed and Warnock Hersey certification programs and FCC Telecommunications Body	ISO/IEC Guide 65
Federal Communications Commission (FCC)	Recognition as a TCB to FCC requirements	
Industry Canada	Acceptance as a testing lab for EMI and terminal equipment testing	
International Accreditation Service (IAS) formerly ICBO-ES & National Evaluation Service	Recognition by the International Code Council (formerly BOCA, ICBO &SBCCI) for testing and certification of building materials and gas fueled appliances	Acceptance Criteria 89 supporting ISO/IEC 17025 and Acceptance Criteria 98 supporting ISO/IEC 17020
International Electrotechnical Commission of Electrical Equipment (IECEE)	Approval in the CB Scheme as a National Certification Body and Certification Body Testing Laboratory in the categories of household and similar equipment, electrical equipment for medical use, electronics/entertainment, IT and office equipment and measuring instruments	ISO/IEC Guide 65, ISO/IEC 17025
National Institute of Standards and Technologies (NIST)	US-EU designated Conformity Assessment Body for Telecom & EMC Directives	ISO/IEC 17025
National Voluntary Laboratory Accreditation Program (NVLAP)	Accreditation of Intertek laboratory for Photometry, MIL specifications and Acoustical. NVLAP Lab Code: 100402-0 *NVLAP testing scopes are site specific; for further details contact NVLAP or the Intertek facility.*	ISO/IEC 17025
Occupational Health and Safety Administration (OSHA) Nationally Recognized Testing Laboratory (NRTL)	Recognition of the ETL Listed and Warnock Hersey certification programs	29 CFR 1910.7

Standards Council of Canada (SCC)	Accreditation as a Testing Organization and Certification Body for electrical appliances, gas-fueled appliances and building materials under the ETL Listing and Warnock Hersey Certification Programs.	ISO/IEC Guide 65, ISO/IEC 17025

Europe

Organization	Accreditation Scope	Accreditation Criteria
International Electrotechnical Commission of Electrical Equipment (IECEE)	Approval in the CB Scheme as a National Certification Body and Certification Body Testing Laboratory in the categories of household and similar equipment, electrical equipment for medical use, electronics/entertainment, IT and office equipment and measuring instruments	ISO/IEC Guide 65, ISO/IEC 17025
SWEDAC	Notified Body for testing to requirements of Low Voltage, EMC, Medical Devices, Machinery and R&TTE Directives	EN 45001, 45011
Department of Trade and Industry; Medicines and Healthcare Products Regulatory Agency (Medical Devices Directive); Department for Environment, Food and Rural Affairs (Boiler Directive) United Kingdom Accreditation Service (UKAS)	Notified/Competent Body for EMC, Low Voltage, Medical Devices, Boiler, Plugs and Sockets, Gas, Toys, Machinery and R&TTE, PED, TPED, and ATEX Directives Accredited Independent Inspection Authority	EN 45001, 45011, NACCB; AU/2/23 ISO/IEC 17020
Zentralstelle der Lander fur Sicherheit (ZLS)	Notified/Competent Body for EMC, Low Voltage, Medical Devices, Toys and Machinery Directives	ISO/IEC 17025, EN 45011

10. EXECUTIVE SUMMARY

The Company's Executive Summary is provided in this section.

Executive Summary

The following is a concise summary of the submission. Additional details are provided in the appropriate sections.

DEVICE DESCRIPTION

Precision Flow™'s intended use/indications for use, technological characteristics, and principles of operation are described below.

A. Intended Use/Indications for Use

Precision Flow™ is indicated for use in adding warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

B. Technological Characteristics

The Precision Flow is comprised of several components. As compared to the cleared Vapotherm 2000 devices (K000401, K013486, and K042245), the Precision Flow has the following major components that are either new or modified:

- A disposable water path module;
- An integrated air/oxygen blender; and
- An integrated oxygen sensor.

The new device features a disposable Vapor Transfer Cartridge ("VTC"), which is essentially identical to the existing component on the company's cleared devices. The only minor difference is the modification of the VTC to add right angle end connections. In addition, the main unit of the Precision Flow has been designed in order to accommodate the modified components. This main unit monitors the activities of the disposable water path module by use of non-contact sensors and contains a motor to drive the fluid flow.

The details of each of the major modifications to the Vapotherm 2000 devices are as follows:

1. Disposable Water Path Module

The most significant modification is the newly designed disposable water path module, which has been designed so that the entire assembly, including the module, VTC, tubing, and connector is designed for use with a single patient only for up to 30 days of treatment. This design replaces the humidification/water pathway used in the Vapotherm 2000i and 2000h which featured internal components that required disinfection. The Precision Flow disposable water path module incorporates all the necessary elements to isolate the water pathway from the main unit and is composed of the following subcomponents:

- A water tank;
- A heater transfer plate (the heating element is part of the main unit);
- A water circulating impellor (the motor stator is part of the main unit and turns the impellor magnetically);
- An air venting diaphragm;
- Non-contact monitoring sensor interfaces;
- A separately attached disposable VTC (which is essentially identical to the comparable component on the company's cleared devices); and
- A separately attached disposable water delivery tube.

The disposable water path has a number of features that minimize the potential for contamination. Initially, the path itself is manufactured in clean conditions and is intended for use with a single patient, eliminating the potential for cross-contamination. The water from the sterile waterbag enters the disposable water path module water tank, flows through the pump impellor and the VTC, through the delivery tube to the patient and completes the closed circuit back to the water tank.

At no time does the sterile water that feeds the system come into contact with the air pathway that is contained in the main unit. Furthermore, the disposable water pathway is closed and completely isolated from the main unit. Specifically, there are no

"hard" connections as sensors from the main unit are not integrated into the disposable water path and the path's impellor is magnetically coupled to the unit's motor.

2. Integrated Blender

Previous models of the Vapotherm device used external independent flow meters and a gas blender to allow the operator to make adjustments to the flow rate and the proportion of oxygen/air mixture delivered. The Precision Flow has an internal gas mixing feature (blender) which provides precise mixing of medical grade air and oxygen via proportional solenoids (mass flow sensors) that measure the oxygen and air flows and solenoids that control the flows. When the clinician sets the desired percent oxygen and the desired flow rate, the mass flow sensors and oxygen analyzer in combination verify that the blender gas mixture is correct and make the required adjustments in proportion of oxygen and air to meet the desired settings. Gas, consisting of oxygen and air, is supplied to the unit from wall, cylinder, or compressor sources. There are standard gas specific DISS gas fittings to assure proper connection to the unit.

3. Integrated Oxygen Sensor

The previously cleared Vapotherm 2000 products verified the composition of the delivered gas mixture with an external oxygen sensor. The Precision Flow contains an oxygen sensor that is identical to a legally marketed device, the Maxtec $MaxO_2$ CU (K063488). This analyzer is located in the main unit and provides the user with a readout of the delivered and supplied oxygen concentration, and the percentage of oxygen thereby eliminating the need for an external analyzer. The analyzer itself is a galvanic, partial pressure sensor that is specific to oxygen. The only purpose of the monitor is to provide information on the delivered gas mixture to the user. The Precision Flow oxygen sensor automatically calibrates to the 100% oxygen source each time the unit is powered up and every 24 hours thereafter.

C. PRINCIPLES OF OPERATION

In actual operation, the Vapotherm Precision Flow warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 1.0 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently. The main unit and

disposable components of this device function as a system to accomplish this intended use as follows:

1. **Main Unit:**

   - The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

   - Sensors in the main unit monitor gas pressure, water level, and water temperature. There are also sensors to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed.

   - An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

2. **Disposable Components:**

   - **Vapor Transfer Cartridge:** In this cartridge, blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

   - **Triple-lumen Heated Delivery Tube:** The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize condensation. A proprietary nasal cannula, also optimized to minimize rainout, is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- **Disposable Water Path Module:** The module houses a water reservoir for the water from the sterile water bag, pump, connections for the VTC and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the VTC where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the sterile water bag to replace evaporative losses in the VTC. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

D. COMPARISON TO PREDICATES

In Section 12 we discuss the proposed device and compare it to the predicate devices. Rather than repeat this comparison in the Executive Summary we refer the reviewer to the appropriate sections of this submission.

The Precision Flow™ is substantially equivalent to the predicate devices because:

1. Indications

- Identical to Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)
  - Warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 0.5 to 40 lpm.
- Identical to Bird Air/Oxygen Bender (K911962)
  - Provides precise mixing of medical grade air and oxygen
- Identical to Maxtec Oxygen Sensor (K063488)
  - Verifies the oxygen composition of the delivered air/oxygen gas mixture

2. Technology

- Humidification technology is identical to Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)
- Blender technology similar to Bird Blender (K911962)
- Oxygen analyzer technology identical to Maxtec (K063488)

3. Materials-

The materials in the gas and fluid pathway have been qualified by the biocompatibility tests found in Section 15.

4. Environment of Use

Identical to the Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)

5. Patient Population

Identical to the Vapotherm 2000i and 2000h (K000401, K013486, & K0142245)

6. Differences between the Precision Flow™ and the Predicates

- Separated the internal water path and converted the device to an external disposable single patient module
- Integrated the air/oxygen mixing function from an external device to an internal blender, similar to the Bird Blender (K911962)
- Integrated the oxygen monitoring function from an external in-line oxygen analyzer, similar to the Maxtec (K063488); and
- Added alarms and indicators to be more user friendly

It is our view that there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

7. Summary of Performance Testing

We have performed testing to demonstrate the safety and effectiveness of the Precision Flow™. The tests included testing the device over the range of flow rate, oxygen concentration, gas source pressures, and temperatures. Please see Section 19, "Performance Testing, Claims".

Conclusions

We believe that based upon the performance testing and comparison to legally marketed predicate devices (for indications for use, technology, and performance) we have demonstrated that the Precision Flow™ is substantially equivalent in safety and effectiveness to the predicate devices.

11. DEVICE DESCRIPTION

The Company's Device Description is included in this section of the submission.

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11. DEVICE DESCRIPTION

Precision Flow™'s intended use/indications for use, technological characteristics, and principles of operation are described below.

A. Intended Use/Indications for Use

Precision Flow™ is indicated for use in adding warm moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

B. Technological Characteristics

The Precision Flow is comprised of several components. As compared to the cleared Vapotherm 2000 devices (K000401, K013486, and K042245), the Precision Flow has the following major components that are either new or modified:

- A disposable water path module;
- An integrated air/oxygen blender; and
- An integrated oxygen sensor.

The new device features a disposable Vapor Transfer Cartridge ("VTC"), which is essentially identical to the existing component on the company's cleared devices. The only minor difference is the modification of the VTC to add right angle connections. In addition, the main unit of the Precision Flow™ has been designed in order to accommodate the modified components. This main unit monitors the activities of the disposable water path module by use of non-contact sensors and contains motors to drive the fluid flow

The details of each of the major modifications to the Vapotherm 2000 devices are as follows:

1. Disposable Water Path Module

The most significant modification is the newly designed disposable water path module, which has been designed so that the entire assembly, including the module, VTC, tubing, and connector is designed for use with a single patient only

for up to 30 days of treatment. This design replaces the humidification/water pathway used in the Vapotherm 2000i and 2000h which featured internal components that required disinfection. The Precision Flow disposable water path module incorporates all the necessary elements to isolate the water pathway from the main unit and is composed of the following subcomponents:

- A water tank;
- A heater transfer plate (the heating element is part of the main unit);
- A water circulating impellor (the motor stator is part of the main unit and turns the impellor magnetically);
- An air venting diaphragm;
- Non-contact monitoring sensor interfaces;
- A separately attached disposable VTC (which is essentially identical to the comparable component on the company's cleared devices); and
- A separately attached disposable water delivery tube.

The disposable water path has a number of features that minimize the potential for contamination. Initially, the path itself is manufactured in clean conditions and is intended for use with a single patient, eliminating the potential for cross-contamination. The water from the sterile waterbag enters the disposable water path module water tank, flows through the pump impellor and the VTC (a distance of approximately 19.5 inches), through the delivery tube to the patient and completes the closed circuit back to the water tank (7 feet out and 7 feet back).

At no time does the sterile water that feeds the system come into contact with the disposable water path. Furthermore, the disposable water pathway is closed and completely isolated from the main unit. Specifically, there are no "hard" connections as sensors from the main unit are not integrated into the disposable water path and the path's impellor is magnetically coupled to the unit's motor.

2. Integrated Blender

Previous models of the Vapotherm device used external independent flow meters and a gas blender to allow the operator to make adjustments to the flow rate and the proportion of oxygen/air mixture delivered. The Precision Flow™ has an internal gas mixing feature (blender) which provides precise mixing of medical grade air via proportional solenoids (mass flow sensors) that measure the oxygen and air flows and solenoids that control the flows.

S12

When the clinician sets the desired percent oxygen and the desired flow rate, the mass flow sensors and oxygen analyzer in combination verify that the blender gas mixture is correct and make the required adjustments in proportion of oxygen and air to meet the desired settings. Gas, consisting of oxygen and air, is supplied to the unit from wall, cylinder, or compressor sources. There are standard gas specific DISS gas fittings to assure proper connection to the unit.

3. Integrated Oxygen Sensor

The previously cleared Vapotherm 2000 products verified the composition of the delivered gas mixture with an external oxygen sensor. The Precision Flow contains an oxygen sensor that is identical to a legally marketed device, the Maxtec $MaxO_2$ CU (K063488). This analyzer is located in the main unit and provides the user with a readout of the delivered and supplied oxygen concentration, and the percentage of oxygen thereby eliminating the need for an external analyzer. The analyzer itself is a galvanic, partial pressure sensor that is specific to oxygen. The only purpose of the monitor is to provide information on the delivered gas mixture to the user. The Precision Flow oxygen sensor automatically calibrates to the 100% oxygen source each time the unit is powered up and every 24 hours thereafter.

C. PRINCIPLES OF OPERATION

In actual operation, the Vapotherm Precision Flow warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 1.0 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently. The main unit and disposable components of this device function as a system to accomplish this intended use as follows:

1. Main Unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours thereafter.

- Sensors in the main unit monitor gas pressure, water level, and water temperature. There are also sensors to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed.

- An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

2. Disposable Components:

- **Vapor Transfer Cartridge:** In this cartridge, blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- **Triple-lumen Heated Delivery Tube:** The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize condensation. A proprietary nasal cannula, also optimized to minimize rainout, is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- **Disposable Water Path Module:** The module houses a water reservoir for the water from the sterile water bag, pump, connections for the VTC and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the VTC where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the sterile water bag to replace evaporative losses in the VTC. Air is purged to the atmosphere from the circulation via a hydrophobic filter membrane.

D. Precision Flow™ System Requirements

The Precision Flow™ System Requirements document is provided following this page.

Vapotherm Precision Flow ™ Hyperthermic Humidification System System Requirements Specification

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666

DOCUMENT NAME:	Vapotherm Precision Flow ™ System Requirements
DOCUMENT NO:	(b)(4)
REVISION:	
REVISION DATE:	February 20, 2008

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ABSTRACT AND AUTHORIZATION

Abstract:

(b)(4)

REVISION HISTORY

(b)(4)

LIST OF ITEMS "TO BE DECIDED / TO BE RESOLVED" (TBD/TBR)

(b)(4)

1. Introduction

(b)(4)

2. Intended Use

Precision Flow™ is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

3. Purpose

(b)(4)

4. Scope

(b)(4)

5. Audience

(b)(4)

6. Definitions

(b)(4)

7. References

(b)(4)

8. Compliance Notation

(b)(4)

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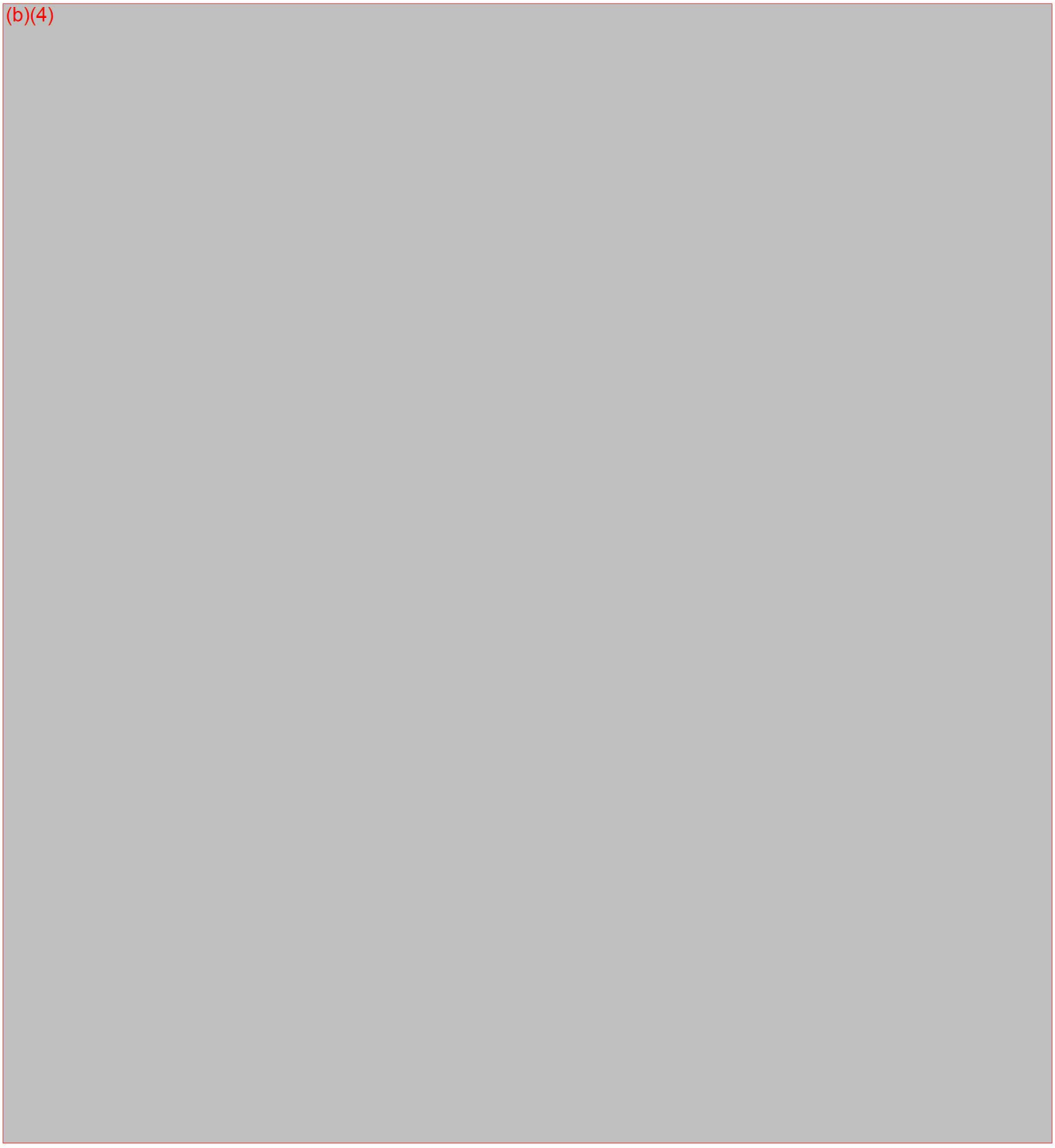
9. **Required Standards**

(b)(4)

10. Physical/Mechanical Characteristics

(b)(4)



(b)(4)

11. Electrical Characteristics

(b)(4)

12. Operation and Performance

(b)(4)

13. User Interface

(b)(4)

14. Device Alarms and Cautions

(b)(4)

15. Environmental Criteria

(b)(4)

16. Labeling

(b)(4)

17. Reliability/Serviceability

(b)(4)

12. SUBSTANTIAL EQUIVALENCE

The Company's Substantial Equivalence to predicate devices is provided in this section.

12. SUBSTANTIAL EQUIVALENCE

As explained in detail below, the Precision Flow™ is substantially equivalent to other legally marketed Respiratory Gas Humidifiers, Air/Oxygen Blenders, and Oxygen Analyzers. Specifically, the Precision Flow™ is substantially equivalent to the Vapotherm 2000i and 2000h, the Bird Blender, and the Maxtec Oxygen Analyzer. As explained in more detail below, the Precision Flow™ has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate devices. A substantial equivalence chart comparing the similarities and differences between the Precision Flow™ and its predicate devices is provided below. Labeling and promotional material for the predicate devices is provided below. As also explained in more detail below, minor differences in the technological characteristics between the Precision Flow™ and the identified predicate devices do not raise new questions of safety or efficacy.

1. Intended Use/ Indications for Use

The Precision Flow™ is indicated for use in adding warm moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer.

The Vapotherm 2000i and 2000h are indicated for use in adding warm moisture to breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. The Bird Microblender is intended to provide a precise method of mixing medical grade air and oxygen to a pre-selected oxygen concentration. The Maxtec Oxygen Sensor is intended to verify the composition of oxygen in an air/oxygen mixture.

In other words, the Precision Flow™ has the same intended use as its predicate devices. Thus, the Precision Flow™ satisfies the first criteria for a finding of substantial equivalence.

2. Technological Characteristics

The Precision Flow is comprised of several components. As compared to the cleared Vapotherm 2000 devices (K000401, K013486, K042245), the Precision Flow has the following major components that are either new or modified:

- A disposable water path module;
- An integrated air/oxygen blender; and
- An integrated oxygen sensor.

The new device features a disposable Vapor Transfer Cartridge ("VTC"), which is essentially identical to the existing component on the company's cleared devices. The only minor difference is the modification of the VTC to add right angle end connections. In addition, the main unit of the Precision Flow has been designed in order to accommodate the modified components. This main unit monitors the activities of the disposable water path module by use of non-contact sensors and contains a motor to drive the fluid flow.

The details of each of the major modifications to the Vapotherm 2000 devices are as follows:

A. Disposable Water Path Module

The most significant modification is the newly designed disposable water path module, which has been designed so that the entire assembly, including the module, VTC, tubing, and connector is designed for use with a single patient only for up to 30 days of treatment. This design replaces the humidification/water pathway used in the Vapotherm 2000i and 2000h which featured internal components that required disinfection. The Precision Flow disposable water path module incorporates all the necessary elements to isolate the water pathway from the main unit and is composed of the following subcomponents:

- A water tank;
- A heater transfer plate (the heating element is part of the main unit);
- A water circulating impellor (the motor stator is part of the main unit and turns the impellor magnetically);

- An air venting diaphragm;
- Non-contact monitoring sensor interfaces;
- A separately attached disposable VTC (which is essentially identical to the comparable component on the company's cleared devices); and
- A separately attached disposable water delivery tube.

The disposable water path has a number of features that minimize the potential for contamination. Initially, the path itself is manufactured in clean conditions and is intended for use with a single patient, eliminating the potential for cross-contamination. The water from the sterile waterbag enters the disposable water path module water tank, flows through the pump impellor and the VTC, through the delivery tube to the patient and completes the closed circuit back to the water tank.

At no time does the sterile water that feeds the system come into contact with the air pathway that is contained in the main unit. Furthermore, the disposable water pathway is closed and completely isolated from the main unit. Specifically, there are no "hard" connections as sensors from the main unit are not integrated into the disposable water path and the path's impellor is magnetically coupled to the unit's motor.

B. Integrated Blender

Previous models of the Vapotherm device used external independent flow meters and a gas blender to allow the operator to make adjustments to the flow rate and the proportion of oxygen/air mixture delivered. The Precision Flow has an internal gas mixing feature (blender) which provides precise mixing of medical grade air and oxygen via proportional solenoids (mass flow sensors) that measure the oxygen and air flows and solenoids that control the flows. When the clinician sets the desired percent oxygen and the desired flow rate, the mass flow sensors and oxygen analyzer in combination verify that the blender gas mixture is correct and make the required adjustments in proportion of oxygen and air to meet the desired settings. Gas, consisting of oxygen and air, is supplied to the unit from wall, cylinder, or compressor sources. There are standard gas specific DISS gas fittings to assure proper connection to the unit.

C. Integrated Oxygen Sensor

The previously cleared Vapotherm 2000 products verified the composition of the delivered gas mixture with an external oxygen sensor. The Precision Flow contains an oxygen sensor that is identical to a legally marketed device, the $MaxO_2$ CU (K063488). The oxygen sensor is procured from the Maxtec Company. This analyzer is located in the main unit and provides the user with a readout of the delivered and supplied oxygen concentration, and the percentage of oxygen thereby eliminating the need for an external analyzer. The analyzer itself is a galvanic, partial pressure sensor that is specific to oxygen. The only purpose of the monitor is to provide information on the delivered gas mixture to the user. The Precision Flow oxygen sensor automatically calibrates to the 100% oxygen source each time the unit is powered up and every 24 hours thereafter.

3. Principles of Operation:

In actual operation, the Vapotherm Precision Flow warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 1.0 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently. The main unit and disposable components of this device function as a system to accomplish this intended use as follows:

A. Main Unit:

- The flow of oxygen and air are measured by mass flow sensors. The operating software calculates the required flow needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting proportional solenoid valves on the gas lines. An oxygen sensor monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.

- Sensors in the main unit monitor gas pressure, water level, and water temperature. There are also sensors to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed.

- An internal battery backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power.

B. Disposable Components:

- **Vapor Transfer Cartridge:** In this cartridge, blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.

- **Triple-lumen Heated Delivery Tube:** The warmed humidified gas passes through the center lumen. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize condensation. A proprietary nasal cannula, also optimized to minimize rainout, is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nose.

- **Disposable Water Path Module:** The module houses a water reservoir for the water from the sterile water bag, pump, connections for the VTC and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the VTC where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the sterile water bag to replace evaporative losses in the VTC. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

4. Conclusion

The Precision Flow™ and the Vapotherm 2000i and 2000h, Bird Microblender, and Maxtec Oxygen Sensor have the same intended use and similar indications, technological characteristics and principles of operation. The only technological differences between the Precision Flow™ and its Vapotherm predicates are: (1) an integrated air/oxygen blender; (2) an integrated oxygen sensor; and (3) a

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disposable water module. However, the oxygen sensor included in the Precision Flow™ is procured from Maxtec and cleared under K063488. In addition, the air/oxygen blender contained in the Precision Flow™ is similar to the Bird Blender cleared under K911962. No differences between the Precision Flow™ and the identified predicate devices present any new issues of safety or effectiveness. Thus, the Precision Flow™ is substantially equivalent to the Vapotherm 2000i and 2000h, the Bird Microblender, and the Maxtec Oxygen Sensor.

5. Substantial Equivalence Chart

Item	PRECISION FLOW™	Vapotherm™ 2000i and 2000h (K000401, K013486 K042245)	Maxtec Oxygen Analyzer MaxO$_2$ CU (K063488)	Bird Air-Oxygen Blender (K911962)
Product Code	BTT; Respiratory Gas Humidifier BZR; Breathing Gas Mixer	BTT; BTI; Respiratory Gas Humidifier BZR; Breathing Gas Mixer	CCL; BZR; Breathing Gas Oxygen Sensor	BZR; Breathing Gas Mixer
Environment	Hospital or sub-acute institutional settings	Home, hospital or sub-acute institutional settings	Institutional environments where delivery of air/oxygen is required	Institutional environments where delivery of air/oxygen is required
Principles of Operation	Basic membrane type humidifier, hollow fiber cartridge	Basic membrane type humidifier, hollow fiber cartridge	Senses the amount of oxygen present in a mixture of gases	A proportion blending of air and oxygen
Intended Use/ Indications for Use	The Precision Flow™ is intended to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.	The Vapotherm 2000i and 2000h are designed to add moisture to and to warm breathing gases from an external source for administration to neonate/infant, pediatric and adult patients in the hospital, sub-acute institutions, and home settings. The flow rates may be from 1 to 40 ;liters per minute via nasal cannula.	For continuous monitoring of oxygen levels delivered by medical oxygen delivery equipment & respiratory care	Designed to dispense continuous and precise blend of medical air and oxygen via outlet ports to infant, pediatric, and adult patients. The exact FiO_2 blend of gases corresponds to the dialed in Fractional Concentration of Oxygen setting indicated by the control face.
Components	The device includes: a water pump, and electronic temperature control system, a digital display, a cannula to administer gas to the patient, and a spike to connect to a sealed water bag and an electronic gas blender, and an oxygen sensor.	The device includes: a water pump, and electronic temperature control system, a digital display, a cannula to administer gas to the patient, and a spike to connect to a sealed water bag.	Fast responding, oxygen specific, galvanic sensor	The device includes a balance module, proportioning module, alarm/bypass, outlet ports, and bleed outlet.

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Item	PRECISION FLOW™	Vapotherm™ 2000h and 2000i (K000401, K013486 K042245)	Maxtec Oxygen Analyzer MaxO$_2$ CU (K063488)	Bird Microblender (K911962)
Water and gas pathway of Humidifier cartridges	Entirely disposable, removable module, external to unit. No disinfection required.	Partly internal to unit, partly disposable. Internal portion requires disinfection after use. Multiple components and connections.	Not Applicable	Not Applicable
Dimensions (l x w x h)	Height: 11.5" (300 mm); width: 8" (2000 mm); depth: 7" (180 mm) excluding IV pole clamp	Height: 11" (280 mm); width: 5.5" (140 mm); depth: 4.5" (114 mm) excluding IV pole clamp	H 3 ½ x W 2 ¼ x D 1 ½ inches	H 3 ½ x W 2 ¼ x D 3 5/8 to 4 ½ inches
Supply Pressure	Medical air and oxygen at inlet pressures between 4 and 70 psi (28-485 KPa)	Medical air and oxygen at inlet pressures between 4 and 50 psi (28-344 KPa)	Not Applicable	30-75 PSIG provided the differential between supply pressures does not exceed 10 PSIG
Max Flow	1-8 lpm via a nasal cannula (Low Flow) 5-40 lpm via a nasal cannula (High Flow)	1-8 lpm via a nasal cannula (Low Flow) 5-40 lpm via a nasal cannula (High Flow)	Not Applicable	≥ 120 lpm @ 60% setting at 50 psig inlet pressures (High Flow)
Humidification	Vapor phase, by transpiration through microporous membrane. Output is at least 95% relative humidity at nasal cannula at a flow rate up to 20 lpm, at least 90% at flow rates from 20-40 lpm, over the full range of operating conditions.	Vapor phase, by transpiration through microporous membrane. Output is at least 95% relative humidity at nasal cannula at a flow rate up to 20 lpm, at least 90% at flow rates from 20-40 lpm, over the full range of operating conditions.	Not Applicable	Not Applicable

13. LABELING

The labeling of the Precision Flow™, including the device's labels, its Operator's Manual and draft promotional materials and the labeling for predicate devices is included in the following section.

13. LABELING OPERATOR'S MANUAL FOR PRECISION FLOW™

TABLE OF CONTENTS

a. **Precision Flow™ Packaging and Labeling**

b. **Precision Flow™ Operator's manual**

c. **Precision Flow™ Promotional materials**

d. **Labeling for Predicate Devices**

1. **Vapotherm 2000i**
2. **Bird Microblender**
3. **Maxtec Oxygen Sensor**

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a. PRECISION FLOW™ PACKAGING AND LABELING

PRECISION FLOW™ PACKAGING AND LABELING

TABLE OF CONTENTS

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10. MI1300 – Nasal Cannula (Infant)
    a. Individual Label
    b. Box Label

11. MI1300B – Nasal Cannula (Intermediate Infant)
    a. Individual Label
    b. Box Label

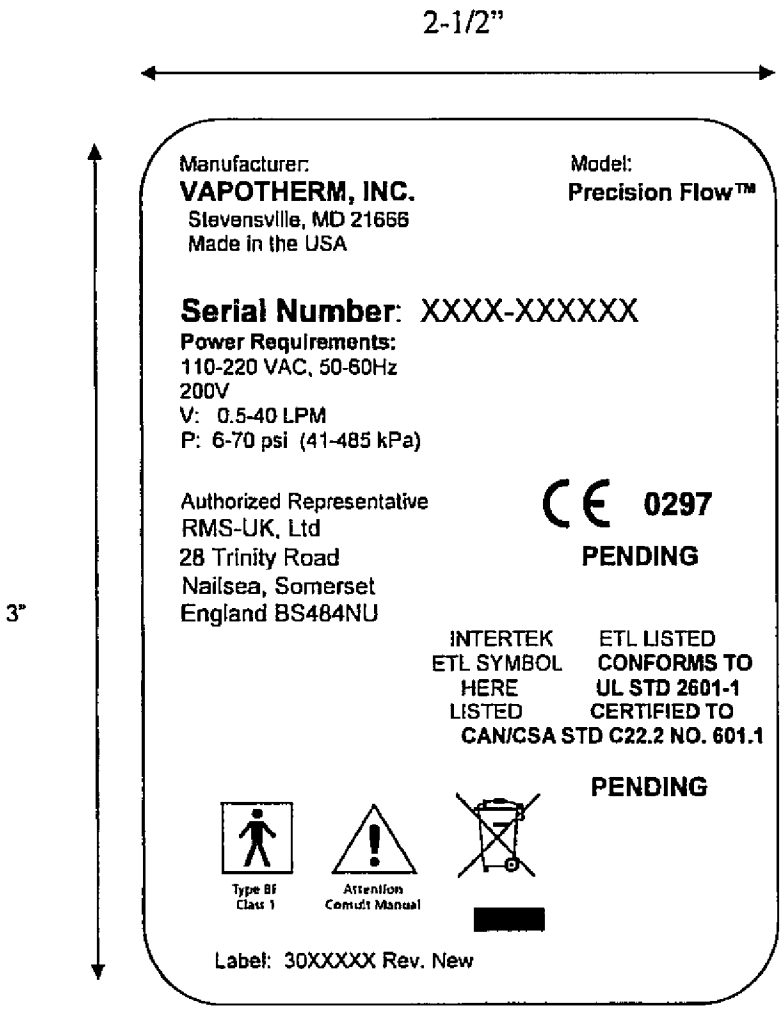
12. MA1700 – Nasal Cannula (Adult)
    a. Individual Label
    b. Box Label

VAPOTHERM DRAFT

PRECISION FLOW™ – *UNIT & BOX SERIAL LABEL - DRAFT*
August 24, 2007

Description:
The Vapotherm Precision Flow™ Label follows. The serialized label for the device is to be applied to the back of the Precision Flow™ device and is to be located in the upper left hand corner. Every device label is to have one matching box serialized label.

Specification:
The Precision Flow™ Unit label is 2.5 inches by 3.0 inches in overall size. The label is to be printed Black on 2 millimeter white polyester with permanent adhesive backing, with a 1 millimeter clear gloss over-lamination.



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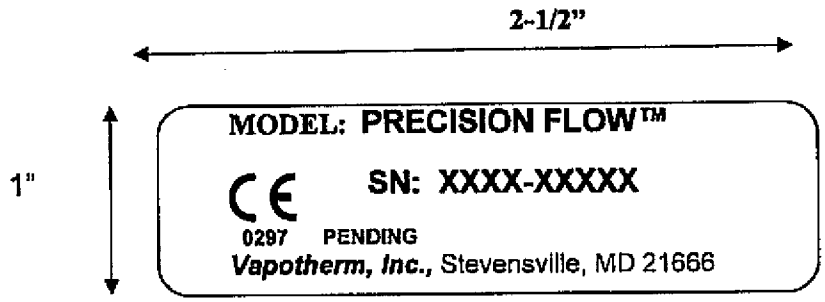
PRECISION FLOW™ – *UNIT & BOX SERIAL LABEL - DRAFT*
August 24, 2007

DRAFT

MATCHING BOX LABEL:

The Precision Flow™ Box label is 2.5 inches by 1.0 inches in overall size. The box label serial number is to match the unit serial number. The label is to be printed Black on 2 millimeter white polyester with permanent adhesive backing, with a 1 millimeter clear gloss over-lamination.. The label is to be applied to the outside of the device box, centered in the area on the shortest measured box side.



Packaging:
Labels are to be packaged or bound to prevent damage during shipment. A packing list is to accompany the shipment to reflect Vapotherm's purchase order.

Labeling:
See drawing above for required labeling.

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VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(INDIVIDUAL LABEL)

VAPOTHERM®

DRAFT

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. XX

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(BOX LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. XX

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(BOX LABEL)

VAPOTHERM®

REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. 1

CE 0297 PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(INDIVIDUAL LABEL)

VAPOTHERM®

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REF. PF–VTC-HIGH

LOT XXXXXXX

QTY. XX

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198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
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28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-High Rev. New

(BOX LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

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PF-VTC-High Rev. New

(INDIVIDUAL LABEL)

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LOT XXXXXXX

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PF-VTC-High Rev. New

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REF. PF-VTC-LOW

LOT XXXXXXX

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PF-VTC-Low Rev New

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LOT XXXXXXX

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PF-VTC-Low Rev New

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VAPOTHERM®

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28 Trinity Road
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PF-VTC-High Rev. New

(BOX LABEL)

VAPOTHERM®

REF. PF-VTC-LOW

LOT XXXXXXX

QTY. XX

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198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-VTC-Low Rev New

(BOX LABEL)

DRAFT

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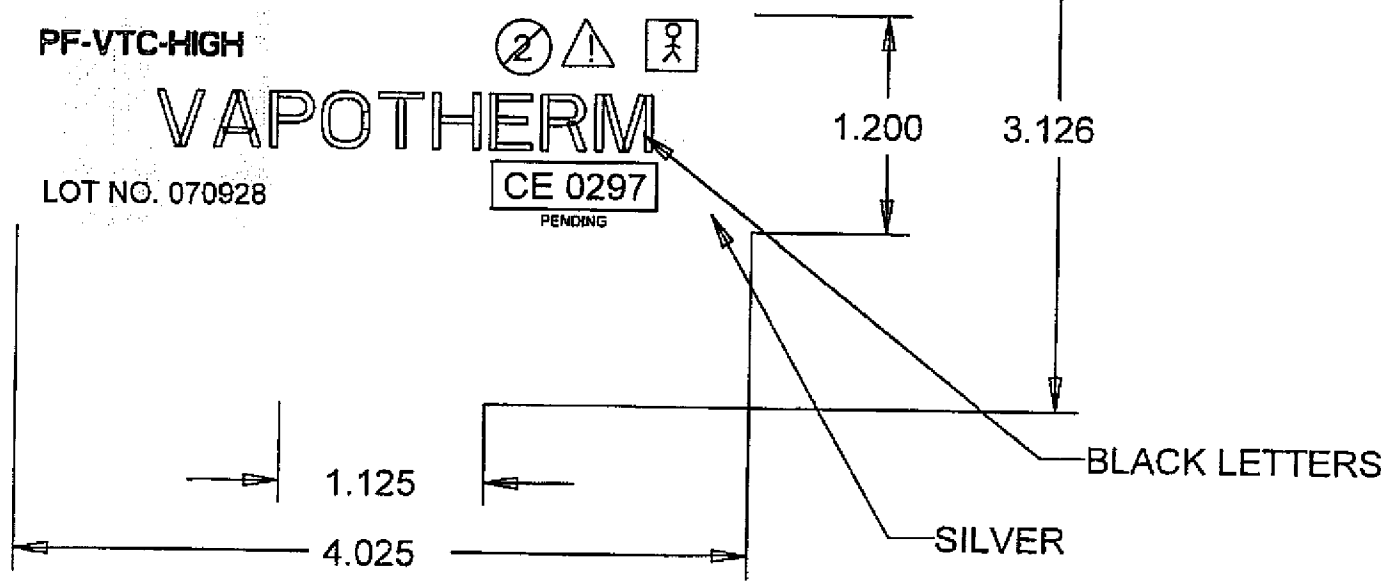

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.XX = ±0.01 ANGLES = ±0.5°
.XXX = ±0.005 DRAFT = ±0.5°

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FILLET AND CORNER RADII: 0.031
DIMENSIONS IN INCHES
DO NOT SCALE DRAWING

ALL DIMENSIONS AFTER FINISH

MATERIAL: MYLAR

FINISH:
COLOR: SILVER/BLACK
TOOL:

DRAWN	DATE
GM	09-10-07
APPROVED BY	DATE

Vapotherm
198 Log Canoe Circle
Stevensville, MD 21666
www.vtherm.com 410-604-3977

TITLE

PF VTC HIGH LABEL

SIZE	DWG. NO.	REV
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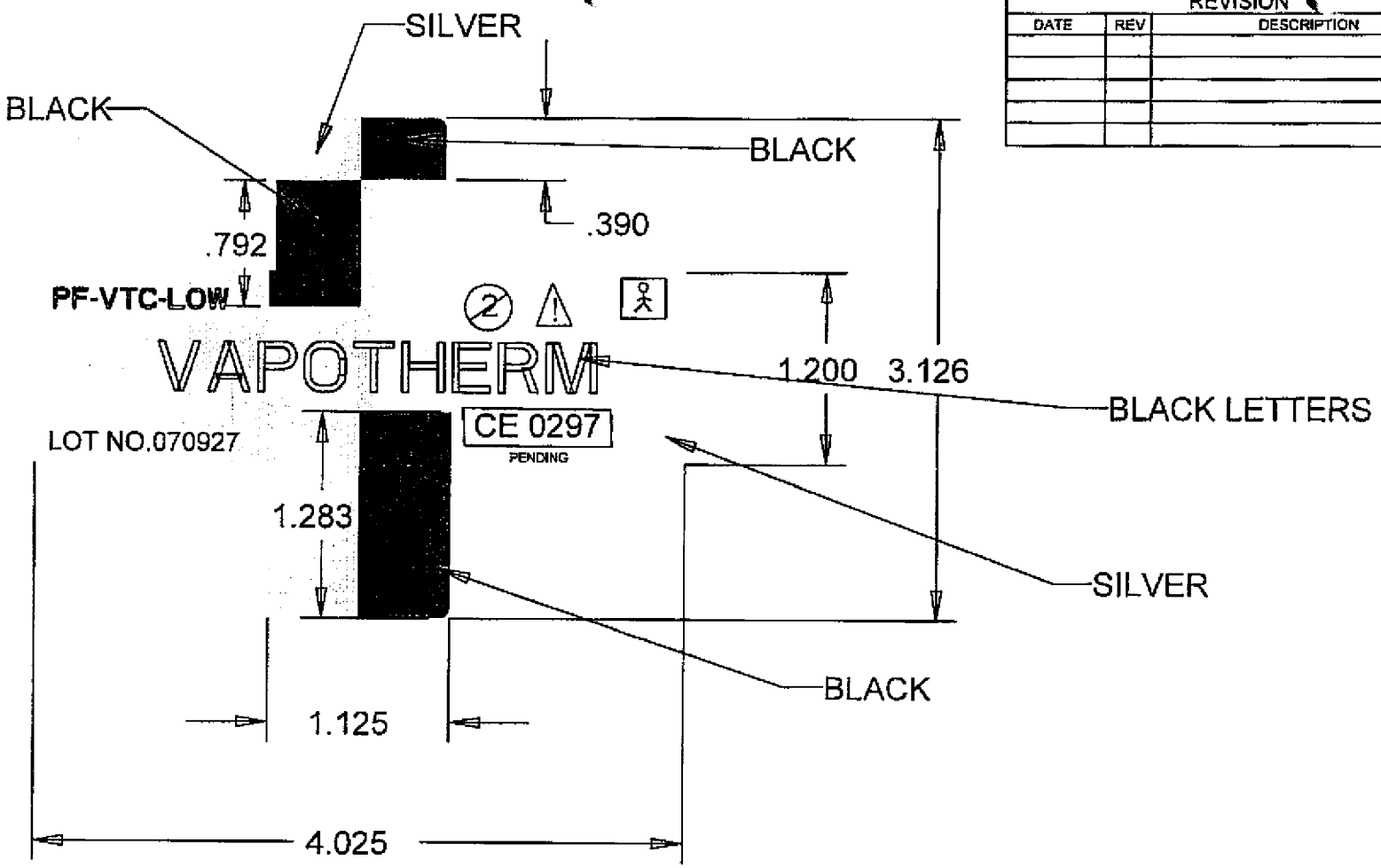
SCALE 1.000	SHEET 1 OF 1	

DRAFT

REVISION		
DATE	REV	DESCRIPTION



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.XXX = ±0.005 DRAFT = ±0.5°

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FILLET AND CORNER RADII: 0.031
DIMENSIONS IN INCHES
DO NOT SCALE DRAWING

ALL DIMENSIONS AFTER FINISH

MATERIAL: MYLAR

FINISH:
COLOR: SILVER/BLACK
TOOL:

DRAWN	DATE
GM	09-10-07
APPROVED BY	DATE

Vapotherm
198 Log Canoe Circle
Stevensville, MD 21666
www.vtherm.com 410-604-3977

TITLE

PF VTC LOW LABEL

SIZE	DWG. NO.	REV
A	3010150	1
SCALE 1.000	SHEET 1 OF 1	

549

DRAFT

VAPOTHERM®

REF. PF- DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-DPC Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
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Authorized Representative
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PF-DPC Rev. New

(BOX LABEL)

550

DRAFT

VAPOTHERM®

REF. PF- DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
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England

PF-DPC Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-DPC
(Disposable Water Path, VSS-1, Tube Set)

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
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28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-DPC Rev. New

(BOX LABEL)

551

VAPOTHERM®

REF. PF-UKIT-"COUNTRY"
(O2 Sensor, bubble traps, hoses, power cord per country , User Manual, User Guide Guide)

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-UKIT-"COUNTRY" Rev. New

(INDIVIDUAL LABEL)

DRAFT

VAPOTHERM®

REF. PF-UKIT-"COUNTRY"
(O2 Sensor, bubble traps, hoses, power cord per country , User Manual, User Guide Guide)

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
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Nailsea, Somerset, BS484NU
England

PF-UKIT-"COUNTRY" Rev. New

(BOX LABEL)

VAPOTHERM®

REF. PF-UKIT-"COUNTRY"
(O2 Sensor, bubble traps, hoses, power cord per country , User Manual, User Guide Guide)

LOT XXXXXXX

QTY. 1

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-UKIT-"COUNTRY" Rev. New

(INDIVIDUAL LABEL)

VAPOTHERM®

REF. PF-UKIT-"COUNTRY"
(O2 Sensor, bubble traps, hoses, power cord per country , User Manual, User Guide Guide)

LOT XXXXXXX

QTY. XX

CE 0297

PENDING

Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
410-604-3977

Authorized Representative
RMS-UK, Ltd.
28 Trinity Road
Nailsea, Somerset, BS484NU
England

PF-UKIT-"COUNTRY" Rev. New

(BOX LABEL)

DRAFT

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT

QTY 1

CE 0297

Manufactured For:
Vapotherm, Inc.
198 Log Canoe Circle
Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

802361 Rev. D

COPY

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT

QTY 1

CE 0297

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Stevensville, MD 21666
410-604-3977
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28 Trinity Road, Nailsea, Somerset, BS484NU England

802361 Rev. D

VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT

QTY 1

CE 0297

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VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT

QTY 1

CE 0297

Manufactured For:
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Stevensville, MD 21666
410-604-3977
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VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT

QTY 1

CE 0297

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VAPOTHERM®

REF MN1100A
Nasal Cannula (Premature)

LOT

QTY 1

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802361 Rev. D

554

VAPOTHERM®

COPY

REF **MN1100A**
Nasal Cannula (Premature)

Qty 25

LOT

CE 0297

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Vapotherm, Inc.
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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

852361 Rev. E

VAPOTHERM®

REF **MN1100A**
Nasal Cannula (Premature)

Qty 25

LOT

CE 0297

Manufactured For:
Vapotherm, Inc.
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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
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852361 Rev. E

VAPOTHERM®

REF **MN1100A**
Nasal Cannula (Premature)

Qty 25

LOT

CE 0297

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Vapotherm, Inc.
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Stevensville, MD 21666
410-604-3977
Made in U.S.A

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852361 Rev. E

555

VAPOTHERM®

REF **MN1100B**
Nasal Cannula (Neonate)

LOT

QTY 1

CE 0297

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
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28 Trinity Road, Nailsea, Somerset, BS484NU England

802362 Rev. D

VAPOTHERM®

REF **MN1100B**
Nasal Cannula (Neonate)

LOT

QTY 1

CE 0297

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VAPOTHERM®

REF **MN1100B**
Nasal Cannula (Neonate)

LOT

QTY 1

CE 0297

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802362 Rev. D

VAPOTHERM®

REF **MN1100B**
Nasal Cannula (Neonate)

LOT

QTY 1

CE 0297

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Nasal Cannula (Neonate)

LOT

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852362 Rev. E

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RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

852362 Rev. E

VAPOTHERM®

REF **MN1100B**
Nasal Cannula (Neonate)

Qty 25

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Authorized Representative For The European Union:
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852362 Rev. E

557

VAPOTHERM®

REF MP1500
Nasal Cannula (Pediatric)

QTY 1

LOT

CE 0297

Manufactured For:
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Stevensville, MD 21666
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Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

803046 Rev. B

VAPOTHERM®

REF MP1500
Nasal Cannula (Pediatric)

QTY 1

LOT

CE 0297

Manufactured For:
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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England

803046 Rev. B

VAPOTHERM®

REF MP1500
Nasal Cannula (Pediatric)

QTY 1

LOT

CE 0297

Manufactured For:
Vapotherm, Inc.
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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
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803046 Rev. B

VAPOTHERM®

REF MP1500
Nasal Cannula (Pediatric)

QTY 1

LOT

CE 0297

Manufactured For:
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VAPOTHERM®

REF MP1500
Nasal Cannula (Pediatric)

QTY 1

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Qty 25

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REF **MP1500**
Nasal Cannula (Pediatric)

Qty 25

LOT

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REF **MP1500**
Nasal Cannula (Pediatric)

Qty 25

LOT

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853046 Rev. B

959

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

CE 0297

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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

CE 0297

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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

CE 0297

Manufactured For:
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Made in U.S.A

Authorized Representative For The European Union:
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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

CE 0297

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Made in U.S.A

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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

LOT

CE 0297

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802360 Rev. D

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant) QTY 1

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REF MI1300
Nasal Cannula (Infant)

QTY 25

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410-604-3977
Made in U.S.A

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852360 Rev. E

VAPOTHERM®

REF MI1300
Nasal Cannula (Infant)

QTY 25

LOT

LATEX

CE 0297

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Made in U.S.A

Authorized Representative For The European Union:
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VAPOTHERM®

REF MI1300
Nasal Cannula (Infant)

QTY 25

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CE 0297

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Made in U.S.A

Authorized Representative For The European Union:
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852360 Rev. E

561

VAPOTHERM®

REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

LOT

CE 0297

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
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28 Trinity Road, Nailsea, Somerset, BS484NU England 803025 Rev. B

COPY

VAPOTHERM®

REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

LOT

CE 0297

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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
28 Trinity Road, Nailsea, Somerset, BS484NU England 803025 Rev. B

VAPOTHERM®

REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

LOT

CE 0297

Manufactured For:
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Stevensville, MD 21666
410-604-3977
Made in U.S.A

Authorized Representative For The European Union:
RMS UK, Ltd.
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VAPOTHERM®

REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

LOT

CE 0297

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410-604-3977
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Authorized Representative For The European Union:
RMS UK, Ltd.
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VAPOTHERM®

REF MI1300B
Nasal Cannula
(Intermediate Infant) QTY 1

LOT

CE 0297

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REF MI1300B

Nasal Cannula (Intermediate Infant)

Qty 25

LOT

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Made in U.S.A

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VAPOTHERM®

REF MI1300B

Nasal Cannula (Intermediate Infant)

Qty 25

LOT

LATEX

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Made in U.S.A

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VAPOTHERM®

REF MI1300B

Nasal Cannula (Intermediate Infant)

Qty 25

LOT

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853025 Rev. B

563

REF MA1700 **VAPOTHERM**

QTY 1

LOT XXXXX

Adult Nasal Cannula

CE 0297

Manufactured for:
Vapotherm Inc.
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Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
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Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 **VAPOTHERM**

QTY 1

LOT XXXXX

Adult Nasal Cannula

CE 0297

Manufactured for:
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Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
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Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 **VAPOTHERM**

QTY 1

LOT XXXXX

Adult Nasal Cannula

CE 0297

Manufactured for:
Vapotherm Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
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Somerset BS484NU
England

Label PN 71280, Rev. 05

REF MA1700 **VAPOTHERM**

QTY 1

LOT XXXXX

Adult Nasal Cannula

CE 0297

Manufactured for:
Vapotherm Inc.
198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU
England

Label PN 71280, Rev. 05

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QTY 1

LOT XXXXX

Adult Nasal Cannula

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Ph: (410) 604-3977

Authorized Representative:
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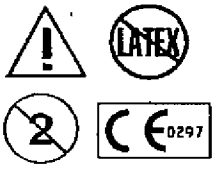
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX



LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

Manufactured for:

VAPOTHERM

198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX

LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

Manufactured for:

VAPOTHERM

198 Log Canoe Circle
Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX

LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

Manufactured for:

VAPOTHERM

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Stevensville, MD 21666 USA
Ph: (410) 604-3977

Authorized Representative:
RMS UK, Ltd.
28 Trinity Rd., Nailsea,
Somerset BS484NU England

REF MA1700
QTY 25
LOT XXXXX

LABEL PN 71282, Rev. 05

Nasal Cannula, Adult

b. PRECISION FLOW™ OPERATOR'S MANUAL

VAPOTHERM®

Precision Flow™

Operating Instruction Manual

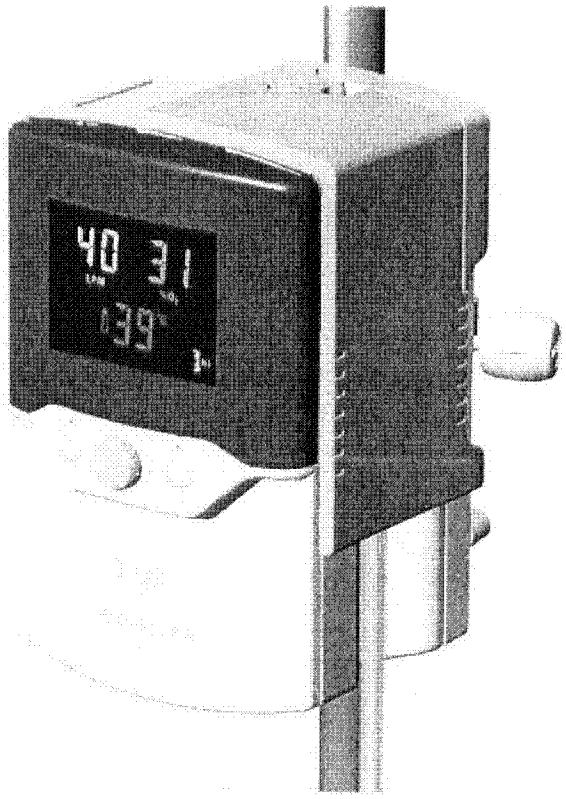
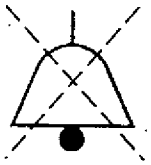


Table of Contents

Symbols

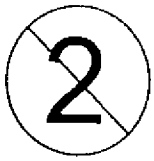
Attention: consult manual

Alternating current

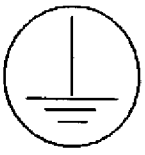


Mute alarms

Run/stop



Single patient use



Protective earth

Do not cover

Type BF Class 1

IPX1

Drip-proof

CE 0297

Vapotherm Inc. has declared that this product conforms with the European Council Directive 93/42/EEC Medical Device Directive when it is used in accordance with the instructions provided in the Operation Manual.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as an unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

For further information contact:

Vapotherm Inc.
198 Log Canoe Circle
Stevensville, MD 21666
USA.

Phone: 410-604-3977
Fax: 410-604-3978
www.vtherm.com

EC REP Authorized Representative:

RMS – UK Limited
28 Trinity Road
Nailsea, Somerset
BS484NV England

Phone: +44-1275-85-88-91
Fax: +44-1275-85-88-91

1. Indications, Warnings and Cautions

General Indications & Contraindications.
Primary Indications:

Used to warm and humidify breathing gases, generally prescribed during oxygen therapy where concentrations of oxygen greater than ambient air are utilized to treat symptoms and manifestations of hypoxia.

Contraindications:

General:
Any situations in which humidification is contra-indicated (see *AARC Clinical Practice Guidelines*).

Specific to Nasal Cannula:
Patients with occluded or defective nares should not use the system.

Warnings and Cautions

A **Warning** indicates that a situation may occur which is potentially harmful to the patient or user.
A **Caution** indicates a condition that may lead to equipment damage, malfunction, or inaccurate operation.
A **Note** indicates a point of emphasis to make operation more efficient or convenient.

Please take the time to familiarize yourself with the warnings, cautions, and notes listed in this manual. They cover safety considerations, special requirements, and regulations.

The user of this product shall have sole responsibility for any malfunction due to operation or maintenance performed by anyone not trained by Vapotherm staff or official training documentation.

When handling any part of the Precision Flow™, always follow hospital infection control guidelines and Standard Precautions. Vapotherm also recommends that users follow the Centers for Disease Control (CDC) publications: *Guidelines for Maintenance of In-Use Respiratory Therapy Equipment* and *Guidelines for Prevention of Nosocomial Pneumonia.*

General Warnings

Federal Law (U.S.) restricts the sale of this device to, or by the order of any physician.

This device should be used ONLY by a trained operator.

This is a humidification device generally used for providing continuous flows of breathing gas. The Precision Flow™ **is not a ventilatory device** and should not be used as life support.

Oxygen supports combustion; this device should not be used near or around open flames, oil, or grease, or flammables.

Service on the device should only be performed by qualified, certified service technicians.

To prevent injury, do not attempt to do any service to the Precision Flow™ while a patient is connected to the device.

If the device is damaged or not working properly, do not use. Contact Vapotherm or your authorized Vapotherm representative.

Do not operate if power cord is damaged.

The device should not be turned on and left unattended.

Do not use the Precision Flow™ in or around water, other than the water bag that feeds the system.

Prior to use, the Precision Flow™ should be positioned and secured to a sturdy IV pole with the base of the unit no more than 40" (102cm) above the floor.

Make sure all Disposable Patient Circuit connections have been properly secured.

The cartridge, disposable water path and delivery tube are labeled as **single patient use** only: do not attempt to sterilize or reuse and follow all local and federal regulations for disposal. Outside the USA follow national or international regulations.

Failure to utilize sterile water supply or clean gas supply may increase risk of bacterial contamination.

- The Precision Flow™ utilizes warmed water and can pose a risk for colonization of bacteria and patient infection if proper aseptic technique is not followed.
- Gas supply is external to the Precision Flow™, but the care giver should confirm the integrity of all respiratory gases utilized to ensure they are free of contamination. Gas supply must be made of clean dry medical grade gas to prevent harm to the patient and prevent damage to the Precision Flow™ .

The Precision Flow™ **is not a Continuous Positive Airway Pressure (CPAP) device.** There are no controls to deliver or monitor airway pressure. The Precision Flow™ should not be used to deliver pressure in a closed system.

Additional patient monitoring is necessary if the Precision Flow™ is used to give supplementary oxygen.

The Precision Flow™ **is not MRI compatible**.

The unit is provided with a Hospital Grade power cord. Do not use any other cord. **Do not use extension cords.** For grounding reliability, the cord **must** be connected to an equivalent receptacle marked "Hospital Grade" or "Hospital Only". If any doubt exists as to the grounding connection, **do not** operate the device.

Medical electrical equipment needs special precautions regarding electromagnetic radiation. Portable and mobile RF communications equipment can affect medical equipment and should not be used near the Precision Flow™.

General Cautions

Read and understand this manual prior to operating the system.

Aseptic techniques (including hand washing and avoiding hand contact with connection points) and Standard Precautions should always be followed when handling medical equipment.

Standard Precautions should always be followed when coming into contact with patients.

Do not cover the unit; blocking the vent may damage the unit.

Do not:

- immerse the Precision Flow™ in water.
- steam or gas sterilize the Precision Flow™.
- wipe with bleach.

Flexible sterile water bags are recommended. If rigid or semi-rigid bottles are used, an approved venting bottle cap must be used.

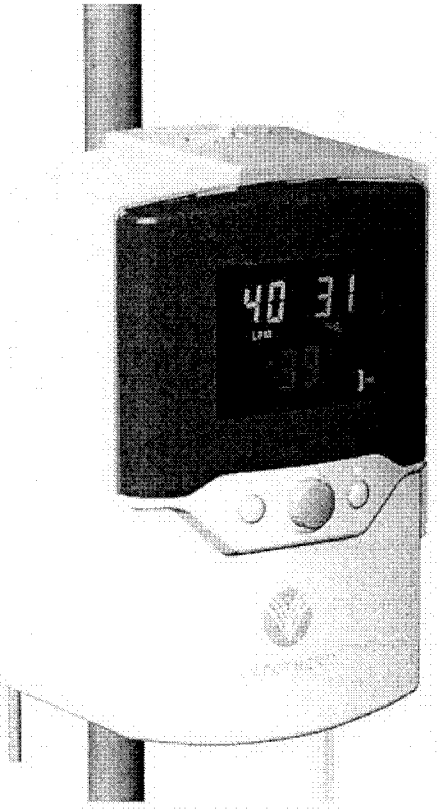
NOTE: The Precision Flow™ may be operated with limited performance at gas inlet pressures as low as 4 psi (28 kPa) However, for the full specified range of gas flows and oxygen percentages, both gas inlet pressures must be 40 psi (276 kPa) or above.

2. Overview

The Precision Flow™ is a system for high flow humidified respiratory therapy by nasal cannula. It incorporates the Vapotherm core humidification technology with an electronic blender and flow controller. The water and gas pathways are both incorporated into a removable, disposable patient circuit. The only cleaning and disinfection required is wiping the housing with an approved disinfectant wipe after use.

Features

- No disinfection necessary: the patient circuit is detachable and disposable
- Minimal downtime between patients: less than five minutes to change disposables
- Built-in oxygen blender
- Built-in electronic flowmeters and controllers
- Self-testing and self-calibrating
- Internal battery backup maintains flow and oxygen percentage for at least 15 minutes if AC power is cut off. Battery recharges in 1-2 hrs.
- All internal sensors self-calibrating and self-monitoring
- Single button starts and stops the device
- Temperature, flow and oxygen percentage are adjusted via a single setting control knob on the front panel
- All values and alarms displayed in a single large color-coded panel
- Flow range 1-40 lpm
- Oxygen percentage is fully adjustable from 21 to 100% when two 40 psi (276 kPa) gas sources are used
- Inlet gas pressure range is 4-70 psi (28-482 kPa)
- At low gas inlet pressures, maximum flow rate and oxygen percentage settings are automatically reduced to match the inlet pressure
- Automatically senses cartridge type: maximum flow setting is automatically reduced if low-flow cartridge is installed
- Warm-up time less than five minutes
- Sterile water is connected to the disposable water path using a standard spike
- Easy connection between the delivery tube and disposable water path by a simple press and click fitting
- Universal power requirements allow use anywhere with only a change of power cord
- Scheduled maintenance for internal components at 3 year intervals, external gas filters replaced at 6-month intervals, external oxygen sensor replaced annually



Precision Flow™

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3. Principles of operation

The Precision Flow™ warms and humidifies a flow of breathing gas for delivery by nasal cannula at flows from 1 to 40 lpm. The unit incorporates an electronic blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently.

The Precision Flow™ consists of two parts:

Main unit

- The *main unit* which contains all the electrical and electronic components including the electronic blender and flow controllers, and remote sensors to monitor the disposable water path. The main unit has no water pathways and the gas pathway contains only dry gas at room temperature, and consequently does not need internal cleaning or disinfection.
- The flow of oxygen and air are measured by *mass flow sensors.* The operating software calculates the required flow of each needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flows accordingly by adjusting *proportional solenoid valves* on the gas lines. An *oxygen sensor* monitors the gas mixture and signals any discrepancy between target and measured percentage. The oxygen sensor is automatically calibrated with oxygen at power-up and every 24 hours.
- *Firmware* running in the main unit uses sensors to monitor gas pressure, water level and water temperature, and to detect air leaks into the water circuit (bubble detector) and water leaks into the gas circuit (droplet detector). Alarms are displayed if any parameters are outside the normal range. Other indicators show low charge in the backup battery, and the type of cartridge installed. ~~See Appendix~~ for a description of the firmware states and transitions.
- An internal *battery* backup will maintain the set flow and oxygen blend for at least 15 minutes without AC power. The battery is not operator replaceable. new

Disposable patient circuit

- The *disposable patient circuit* is comprised of the disposable water path, vapor transfer cartridge and delivery tube. Conditions in the circulating water and gas streams are sensed remotely via the interface between the main unit and the disposable water path.
- *Vapor transfer cartridge.* In the cartridge blended gas passes through the lumens of hundreds of parallel hollow fibers made of a specially developed polymer. Warm water circulates around the fibers and diffuses as vapor through the fiber material into the gas stream flowing through each fiber. Unlike most humidifiers, there is no direct contact between the water and gas streams. The gas stream leaves the cartridge essentially saturated with vapor at the set temperature.
  Note: Use **only** approved cartridges from Vapotherm Inc.
- *Patient delivery tube.* The warmed humidified gas passes through the center of a triple-lumen heated delivery tube. The center lumen is surrounded by two outer lumens carrying warmed water to maintain the temperature of the inner lumen and to minimize rain-out. A proprietary short nasal cannula is connected to the end of the delivery tube and passes the humidified breathing gas to the patient's nares.
- *Disposable water path.* The disposable water path houses a water reservoir, pump, connections for the cartridge and delivery tube, and sensor interfaces to the main unit. Water is pumped past a heater plate through the outer lumens of the delivery tube. Returning water passes through the outer jacket of the specially designed vapor transfer cartridge where some water is lost as vapor to the gas stream. There is no direct contact between water and gas flows. The water then returns to the pump reservoir. Heater power is adjusted continuously to maintain the set temperature. Water flows into the circuit from the water bag to replace evaporative losses in the vapor transfer cartridge. Air is purged to atmosphere from the circulation via a hydrophobic filter membrane.

See Appendix for a description of the software operating modes.

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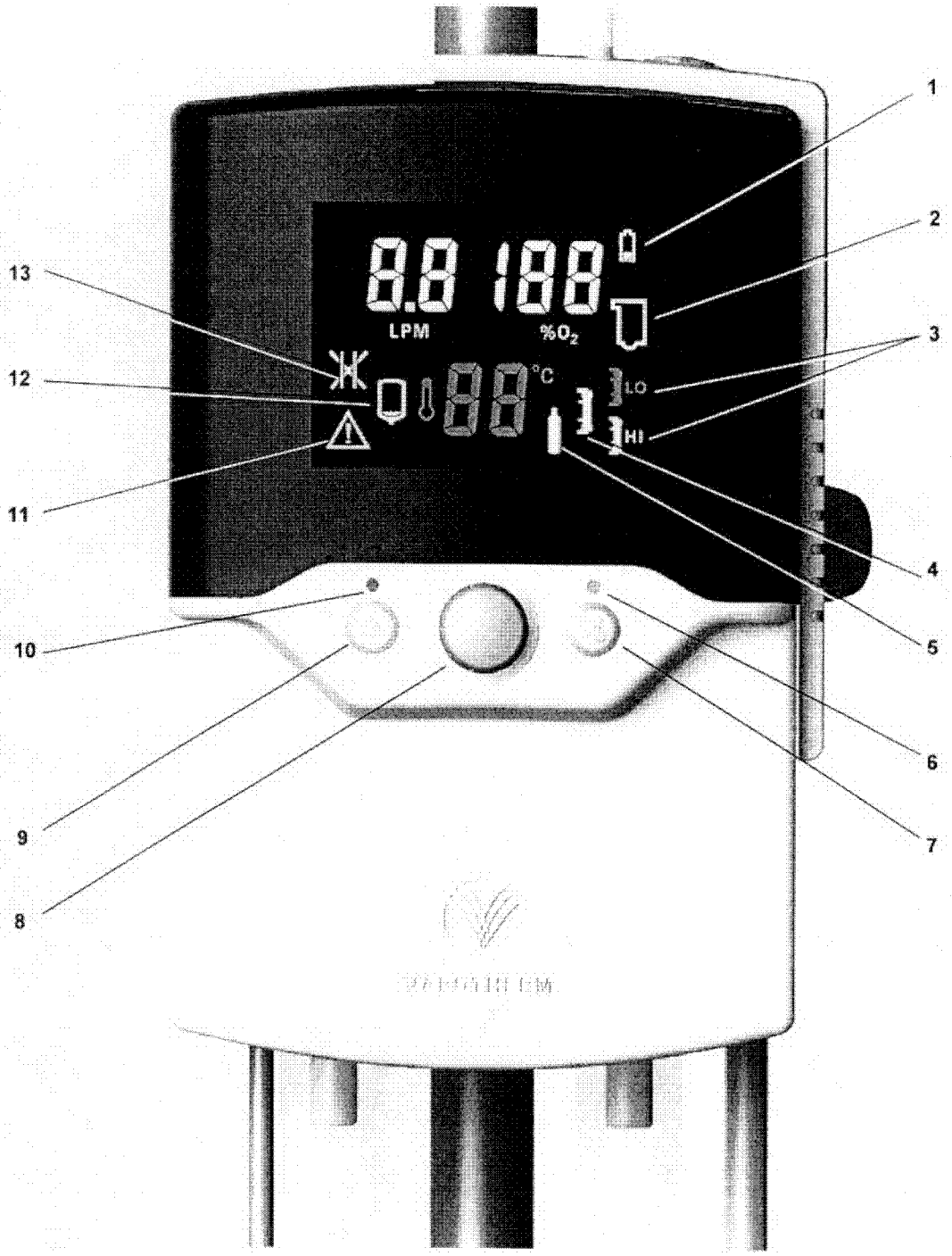
4. Controls , displays & connections



1. Battery low or charging
2. Disposable water path faulty or absent
3. Vapor transfer cartridge type
4. Vapor transfer cartridge fault
5. Gas supply fault
6. Status LED
7. Run/Standby button
8. Setting control knob
9. Alarm mute button
10. Alarm muted LED
11. General fault
12. Water low/water out
13. Blocked tube

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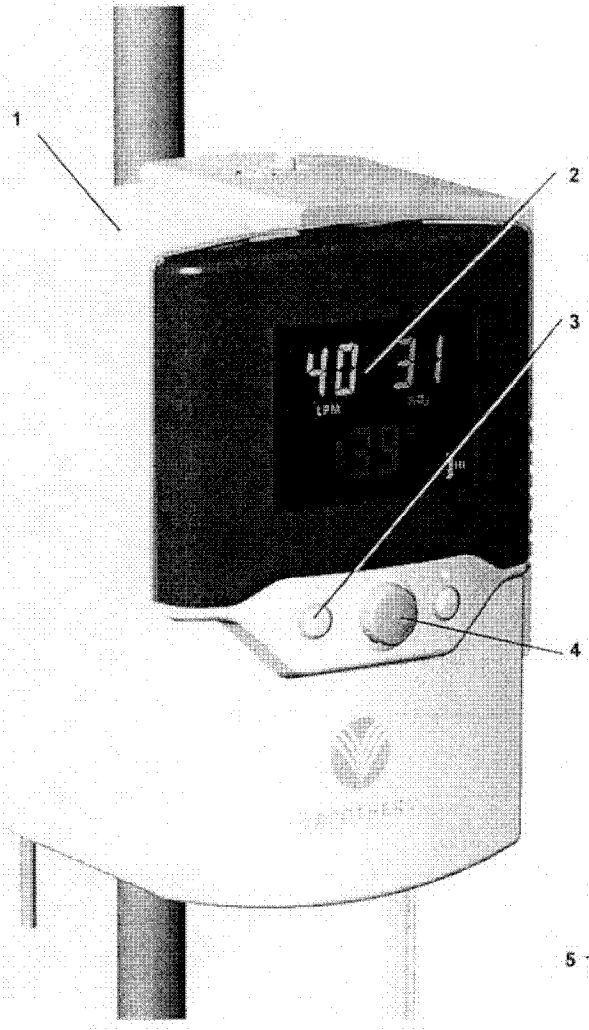
Front view

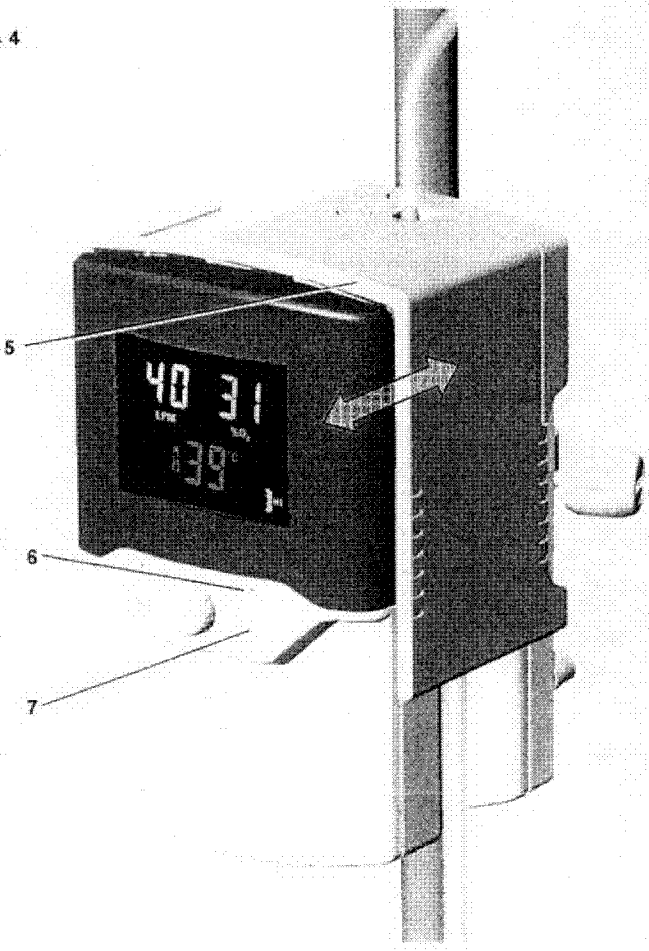


1. Folding carrying handle

2. Multi-function display:
   - Shows set values for oxygen %, flow and temperature
   - Icons indicate alarm conditions

3. Alarm mute:
   - Press to silence alarms for up to 2 minutes
   - LED indicates one or more alarms are muted

4. Setting control knob:
   - Press to select which variable to adjust
   - Rotate to adjust to new value
   - Press again to set value



5. Sliding door:
   - Slides forward to install or remove disposable water path

6. Status light:
   - Amber in standby
   - Flashing green when output does not match settings (e.g. during warmup)
   - Steady green when unit is operating normally

7. Run/standby button:
   - Press to start unit after water and gas are connected

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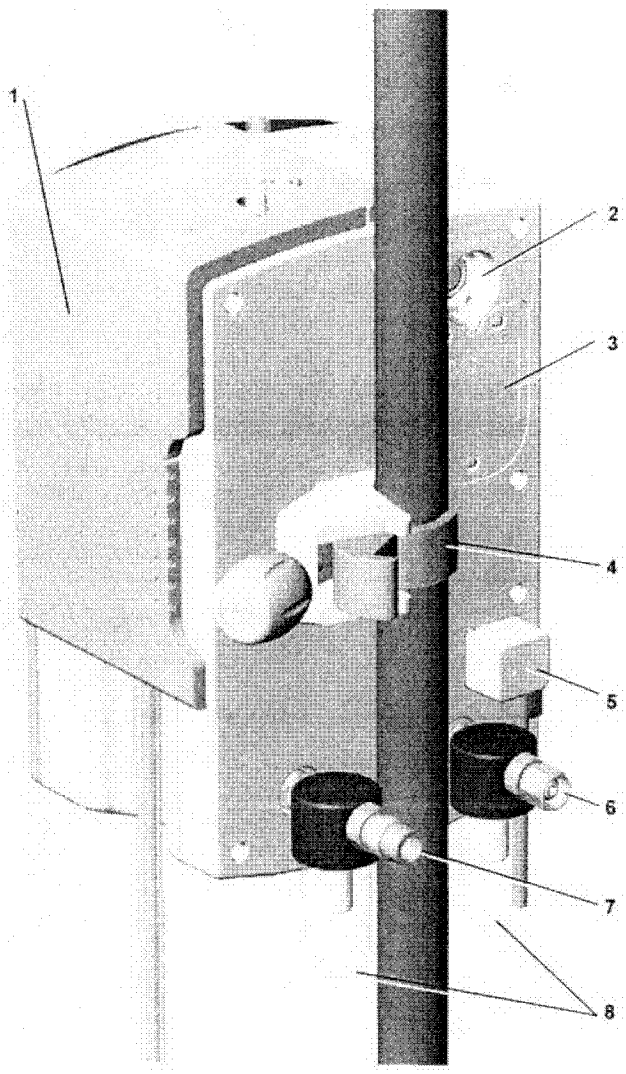
Rear view



1. Sliding door
   - Slide forward to install or remove disposable water path
2. Oxygen bleed vent
3. Access panel for oxygen sensor
4. Pole clamp
5. Power cord connection and fuse holder
6. DISS oxygen connection
7. DISS air connection
8. Gas inlet filters and traps

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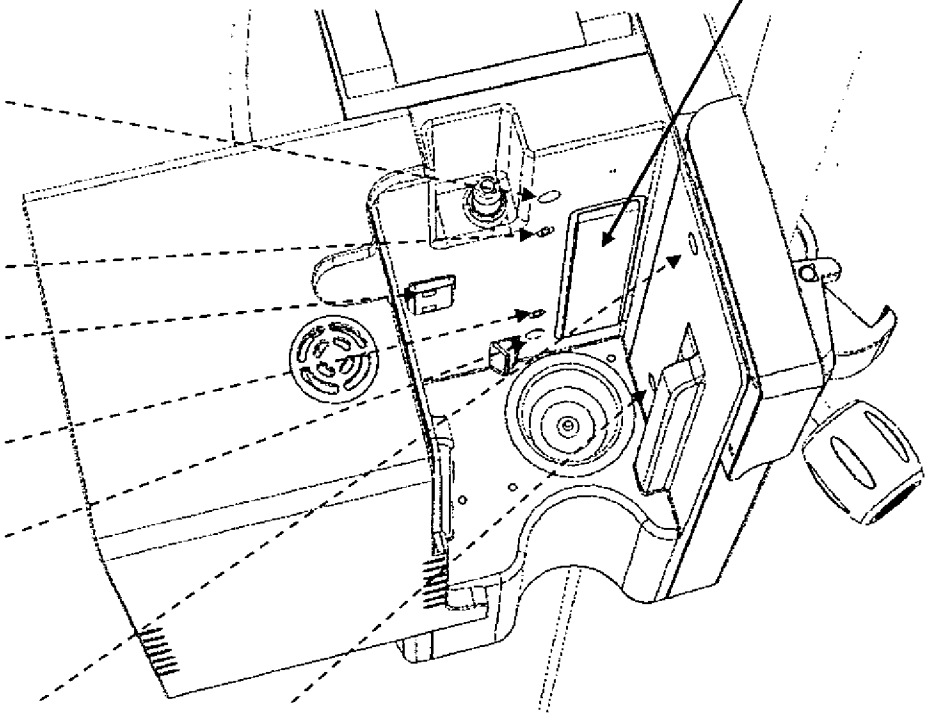
WARNING:
Heater plate
may be hot!

Docking station for disposable water path



Arrows show location of optical sensor ports.
Do not scratch or scrub the ports. Do not apply organic solvents or bleach.

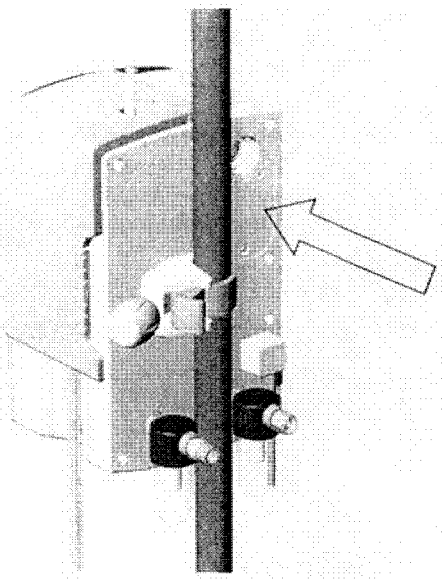
5. Initial assembly

Certain accessories must be installed in the Precision Flow™ unit before it can be used. These will normally be supplied in a separate package from the main unit as some are country-specific. The power cord plugs into the IEC320-compliant receptacle on the rear panel.

5a. Oxygen sensor installation

CAUTION: The oxygen sensor is supplied in a sealed package. Unsealing the package admits oxygen to the sensor which should be replaced 1 year from this date. Do not open the package until the unit is to be used.

1. Remove three (3) securing screws from the access panel. Pull the panel away from the unit.
2. Insert the threaded end of oxygen sensor into port, and screw into place. Sensor should be hand-tight only. Do not use tools.
3. Plug sensor cable into connector. Replace cover. Do not overtighten screws.



Oxygen Sensor Access Panel

5b. Inlet gas filter trap assemblies.

Gas filters and traps are supplied separately and must be installed before first-time use. The filter and trap assemblies have a quick-disconnect fitting which connects to the main unit, and a DISS gas fitting for either an oxygen or an air hose.

Note: The quick-disconnect tubes for the oxygen and air filters are different sizes, so that they can not be connected incorrectly.

WARNING: Never attempt to run the Precision Flow™ unit without the inlet gas filters. Particles in the inlet gas flow will cause irreparable damage to the mass flow sensors.

Installing the gas inlet filters

1. Remove any protective tape from the gas inlet connectors at the back of the main unit.
2. Push the filter assembly into the correct connector opening until it clicks. The filter should rotate but not pull out.

Removing gas inlet filter assembly from main unit

Note: It is not normally necessary to remove the filter and trap assemblies, but shipping and packing are easier if the filters are detached first.

1. Press the filter assembly into the main unit.
2. Using forceps or hemostats, hold the locking ring in place against the main unit backplate.
3. Pull the filter assembly straight out.

6. Setting up

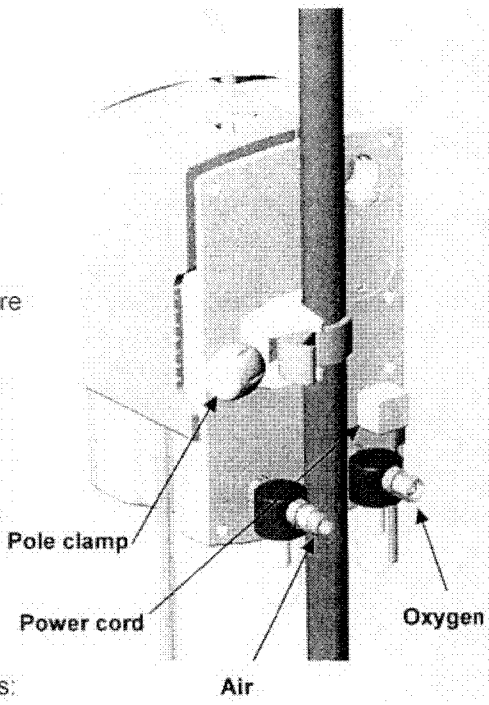
6-1. Connect power cord if it is not already in place.

6-2. Hang the sterile water from IV pole hook.

6-3. Attach the unit to IV pole below lowest point of the sterile water.

NOTE: The Precision Flow™ oxygen and air supply inlet fittings are gas-specific to ensure correct connection.

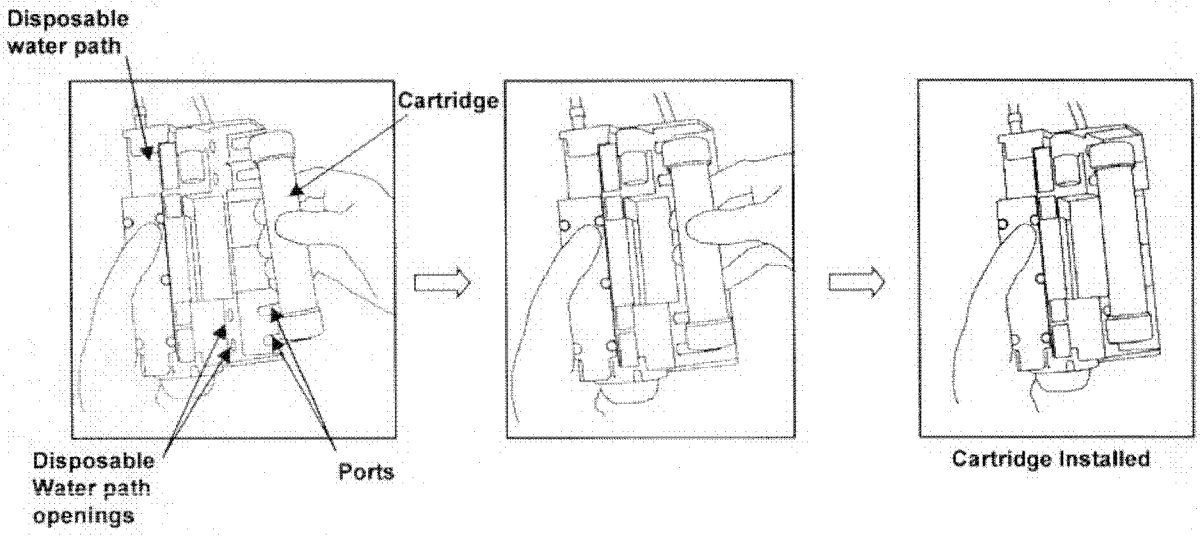
WARNING: Unit weighs 12 lbs.(5.4kg) To prevent possible injury or damage from falling, it must be securely fixed to a 5-wheel IV pole, with the base of the unit not more than 40" (102cm) above the floor. Fixed rail supports may also be used.



6-4. Connect oxygen and air supply hoses to correct inlets, then connect them to the wall outlets.

6-5. Open the bags containing the disposable water path, cartridge and delivery tube, and assemble them as follows:

6-5-1. Install a high or low-flow vapor transfer cartridge in disposable water path as shown. The cartridge may be inserted either way up. Align the cartridge ports with the disposable water path openings and press firmly into place.



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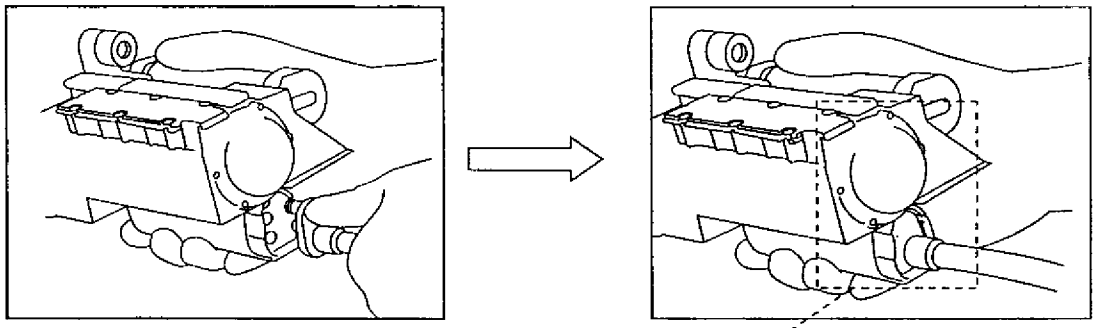
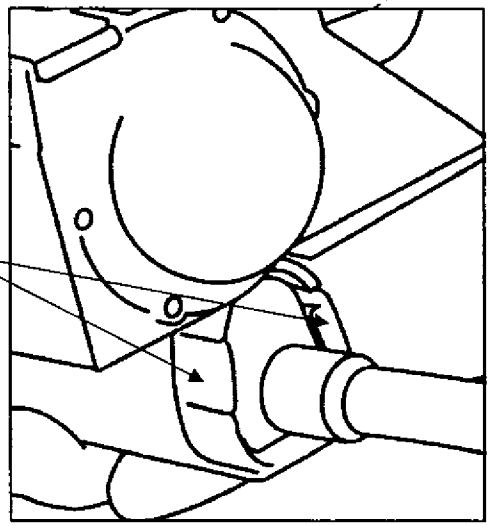
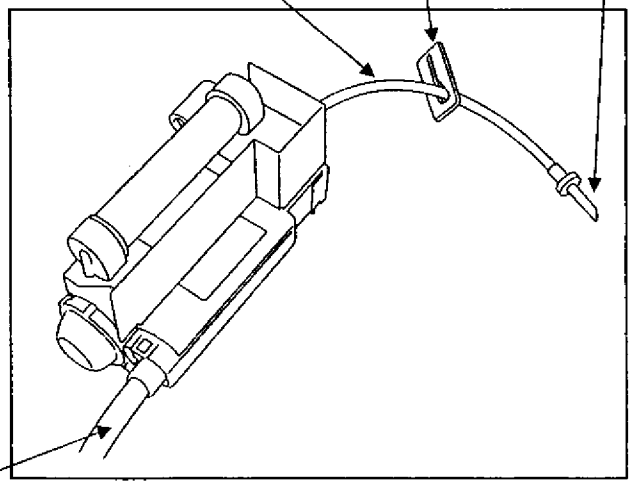
6-5-2. Fit the delivery tube to the disposable water path as shown. Press firmly into place.





Insert fully. Both latches must click shut.



Assembled disposable patient circuit ready for insertion.

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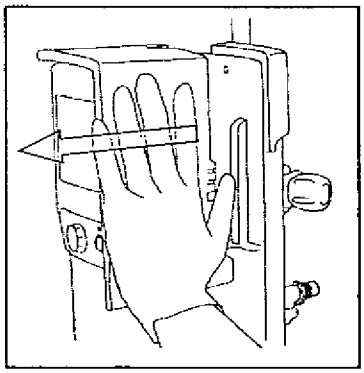
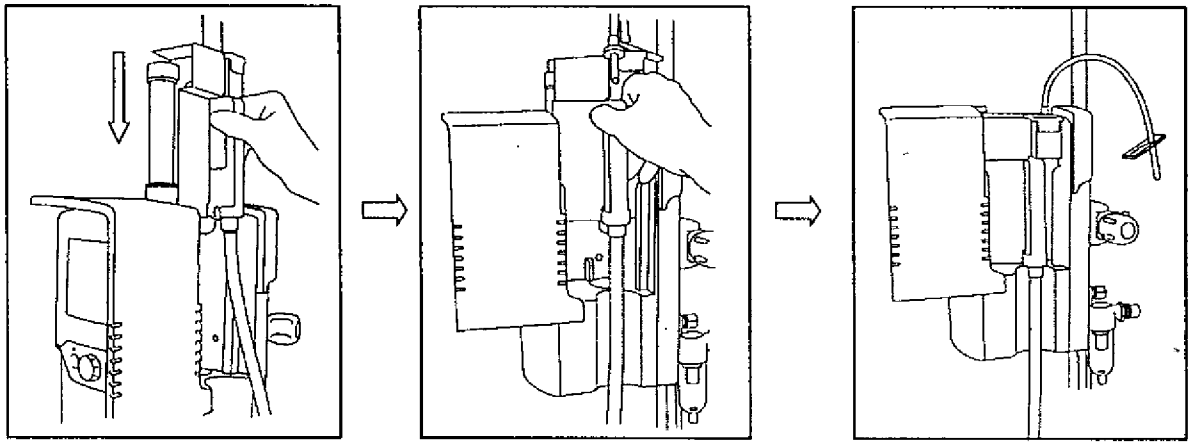
6-6. Inserting disposable patient circuit:

6-6-1. Open door by sliding it forward to expose the docking station.

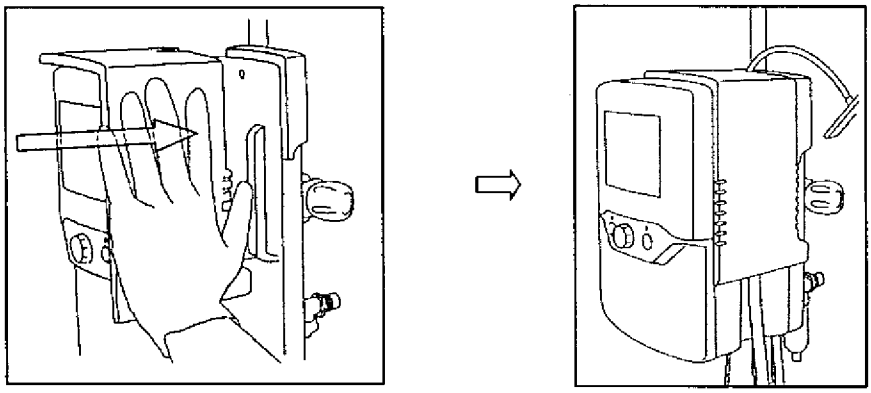
6-6-2. Hold disposable patient circuit by its handle, with the delivery tube downward as shown.

6-6-3. Slide disposable patient circuit downward into the docking station until it stops.





6-6-4. Close door by sliding it backward until it stops.



NOTE: If the sliding door does not close easily, check that the cartridge is installed correctly and the disposable water path is fully inserted into the docking station.

CAUTION: Do not remove the disposable patient circuit while the unit is operating.

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WARNING: Use high–flow cartridge for flows 5-40 lpm and low-flow cartridge for flows 1 -8 lpm.

6-7. Plug in power cord, and check that all the display indicators light. The Precision Flow™ goes through a self-test:

- all icons and numeric displays light up for 10 seconds
- internal sensors and control systems are checked
- if no faults are detected the unit enters STANDBY mode
- "Water Out" icon indicates there is no water in the disposable water path
- status LED is amber

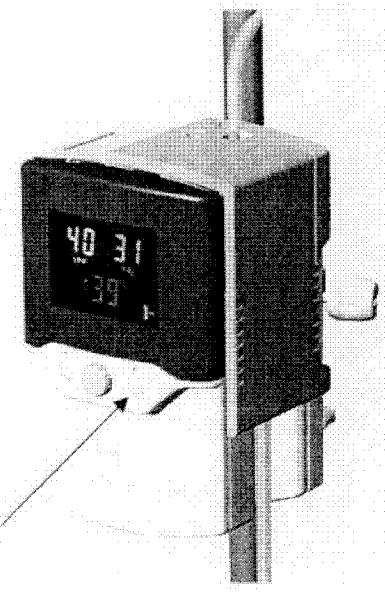
6-8. Rotate the control setting knob in either direction to light up the display in STANDBY mode.

6-9. Press the Mute button to change between bright and dim display. (This function is only available if no alarms are active.)

6-10. To connect the sterile water, remove spike cap and wipe spike with 70-90% isopropyl alcohol. Firmly insert spike into spike port of the sterile water, avoiding direct hand contact. Unclamp the water inlet tube so that water flows into the disposable water path and the "Water Out" alarm cancels.

6-11. Press Run/Standby button to start gas flow, pump and heater. Press twice if the display is initially blank. Check that the unit beeps while it tests the disposable water path and pump (see Notes below).

6-12. If all tests are passed the unit enters RUN mode. Water circulates and fills the delivery tube. The three numeric displays for flow, temperature and oxygen % display initial factory settings or the last settings used. The Status LED flashes then shows continuously green when the unit reaches desired temperature.



NOTES on startup:

- When the Run/Standby button is pressed, the unit enters a detection mode. A prompt sounds and the disposable water path icon flashes for approximately five seconds. In this mode the unit inspects the disposable water path to confirm that: a cartridge is present; the disposable water path is present; and the water level is correct. Power is then applied to the water pump. After five seconds the unit checks that the water pump has started and is running at the correct speed.
- The "low water" icon may flash intermittently until the water system has filled.
- Purging of air bubbles from the circulation can not be seen, because the gas escapes through a membrane, not into the water container.
- Clamp the inlet tube to stop the flow of water into disposable patient circuit whenever the unit is in standby mode.

To adjust settings: See section 7 (Adjustments)
For alarms and troubleshooting: See section 11 (Alarms)

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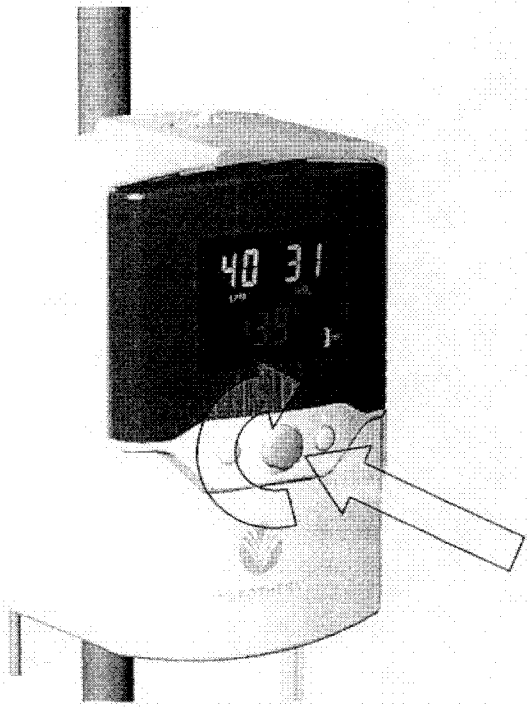
7. Adjustments

Flow, oxygen % and temperature are all adjusted using the setting control knob in the center of the front panel.

7-1 To enter Adjustment mode, press and release the setting control knob. One displayed value will flash to show that it is selected for adjustment. Press the knob repeatedly to cycle the active selection through flow, oxygen % and temperature.

7-2. To change the selected variable, rotate the knob until the desired value is displayed. Press the knob again to enter this value and select the next variable.

7-3. If the knob is not rotated for five (5) seconds, the unit returns to the normal Run mode. To re-enter Adjustment mode, press the knob again. Rotating the knob has no effect unless one of the settings has been selected and one of the displayed values is flashing.



Setting control knob

NOTES on settings:

- When gas inlet pressures are less than 40 psi (276 kPa) the full specified range of flows and oxygen mixtures is not available. The Precision Flow™ detects the actual inlet pressures and calculates the range of values that can be achieved. An alarm sounds if the operator attempts to make settings outside this range.
- If oxygen is disconnected, the blender setting will be fixed at 21%. If air is disconnected the setting is fixed at 100%. An audio signal sounds if the operator attempts to set any other value.
- If a **HIGH-FLOW** cartridge is installed the flow can not be set below **5 lpm**.
- If a **LOW-FLOW** cartridge is installed the flow can not be set above **8 lpm**.

NOTES on adjustment:

- If the FLOW setting is rapidly adjusted downward, the temperature display may show a transient increase. This occurs because the heater temperature takes a few seconds to adjust to the lower heat output required for the lower gas flow. The transient temperature increase occurs only adjacent to the heater plate and is not reflected in the temperature of the delivered gas.
- During Warmup the temperature display shows **actual** temperature, not the set value.
- In Run mode the display shows the current **set values** for flow, oxygen % and temperature.
- The setting control knob is sensitive to speed. Rotate quickly for large increments and slowly for small increments.

8: Connecting to Patient

8-1. Wait for desired set temperature to be reached **before** placing the cannula on the end of the patient delivery tube. The flashing green Status LED becomes steady when the set temperature is reached.

8-2. Check water level, temperature display, gas flow rate, and oxygen percentage.

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8-3. Size cannula to patient by ensuring that nasal prongs do not fit tightly into nares.

8-4. Attach correct sized cannula for the patient and cartridge onto the delivery tube. Adjust the flow to the desired rate and fit the cannula to the patient. Flow ranges are shown in the table:

Cartridge	Cannula type	Operational flow rates
High Flow	Adult	8-40 lpm
High Flow	Pediatric	5-20 lpm
Low Flow	Premature, neonatal, infant, intermediate infant	1-8 lpm

WARNINGS:

- Always follow aseptic technique (including proper hand washing and avoiding direct hand contact with connection points) when setting up the Precision Flow™ and Standard Precautions when placing on a patient.
- Cannula should not obstruct the nares of the patient.
- Change nasal cannulas when soiled.

NOTES:

- The cannula or other interface should be connected to the patient only when the unit has warmed to set temperature (temperature display stops flashing).
- Droplets of condensation may appear at the end of patient delivery tube while unit is warming up. This is normal and will stop within a few minutes when set temperature is reached and the cannula is fitted to the patient.
- Some condensation around the nose is possible. In addition, a high moisture level may mobilize mucus from nose and sinuses. Make sure patient has a supply of tissues.

9. Operations: General Guidelines

9-1. Check that water is properly circulating through the machine by making sure the patient delivery tube is warm across the entire length. If good circulation cannot be confirmed, check that the water flow is not obstructed by air bubbles in the patient delivery tube.

9-2. Check that the patient delivery tube will not be occluded by the patient's position or moving bed structures.

9-3. Take precautions to minimize cooling of the unheated cannula by trying to maintain contact with the patient's skin and insulating the exposed portion of the cannula with bedding.

9-4. The sliding cover for the disposable water path must be closed during operation.

9-5. Check that nothing blocks the vent on the back of the unit.

9.6 For optimum operation, stand facing the front of the unit at a distance that permits you to easily read the display and reach the controls (<1m).

NOTE: Condensation in the cannula may occur in certain ambient conditions at flow rates less than 5 lpm (low flow cartridge) or less than 10 lpm (high flow cartridge). To minimize condensation, these general outlines should be followed:

- If using flow rates less than 5 lpm, it is recommended not to set the temperature higher than 34°C.

10. Changing the disposable patient circuit

The disposable patient circuit, consisting of the disposable water path, cartridge and delivery tube, is marked for single patient use and must not be re-used. They may be used for up to 30 days on a single patient but must then be replaced.

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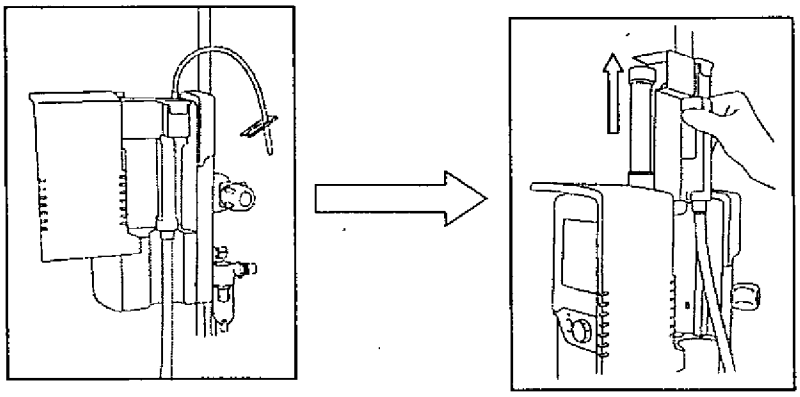
10-1. Shut down the unit by pressing the Run/Standby button.

10-2. Clamp the water inlet tube connected to the sterile water, and disconnect it by pulling out the spike.

10-3. Slide the door forward to expose the disposable water path.

10-4. Lift the disposable patient circuit out of the Precision Flow™ unit and discard in accordance with institutional guidelines.

10-5. Wipe down the docking station with 70-90% isopropyl alcohol wipes.



WARNINGS:

- **The heater plate in the docking station may be hot !**
- Universal precautions and aseptic technique must be used in handling the disposable parts.

10-6. Open a new cartridge, delivery tube and disposable water path.

10-7. Install the cartridge and delivery tube in the water path as described in Section 6 (Setting up).

CAUTIONS:

- The sensor windows in the docking station must not be scratched or damaged. If necessary, clean them only with alcohol wipes (70-90% isopropyl alcohol). **Never use abrasive cleaners, bleach or organic solvents.**

10-8. Slide the disposable patient circuit into the docking station and close the sliding door.

10-9. Hang a new sterile water on the IV pole hook.

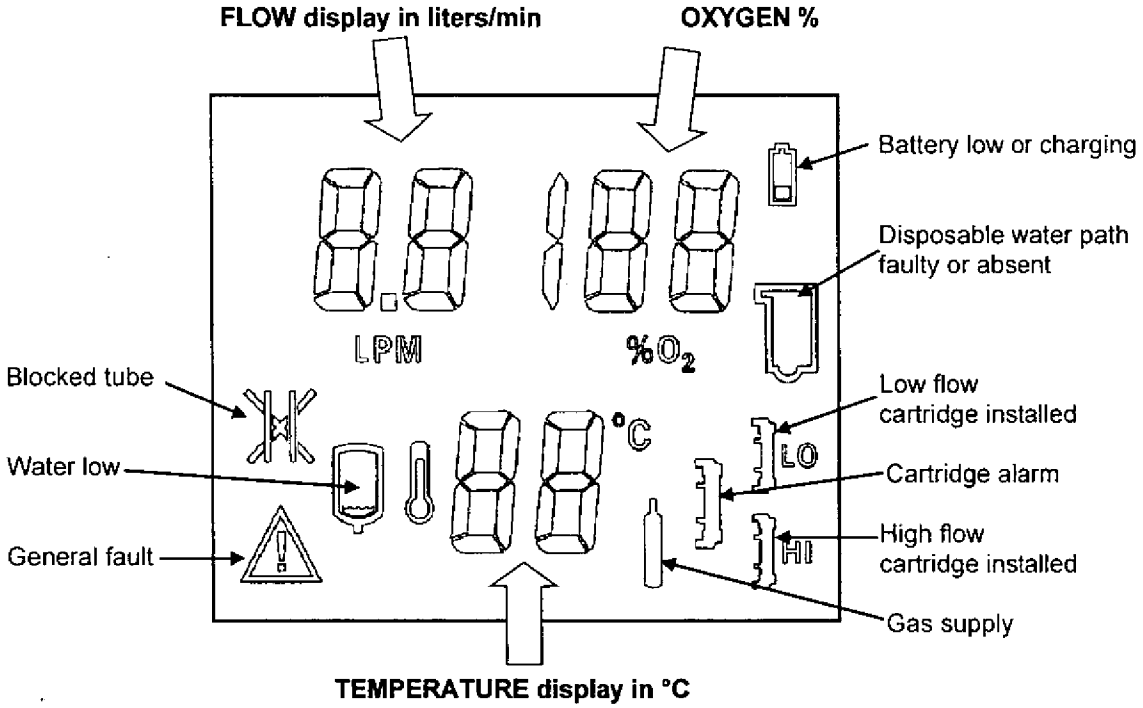
10-10. Wipe the spike on the water inlet tube with 70-90% isopropyl alcohol and insert into spike port of the sterile water.

10-11. Re-start the unit.

11. Alarms

Fault conditions are indicated by icons displayed on the front panel and by audio signals.

- Unless indicated otherwise, alarms will self-clear when the fault condition is corrected.
- The MUTE button will silence low priority alarms for 2 minutes and medium priority alarms for 20 seconds.
- A yellow LED above the Mute button indicates that one or more alarms are muted.



ALARM TONE PRIORITIES

- MEDIUM PRIORITY alarms require immediate attention and are indicated by rapid intermittent tones (fast triple beeps).
- LOW PRIORITY alarms require attention as soon as reasonably possible and are indicated by infrequent intermittent tones (slow double beeps).

In addition to the medium and low alarms, the Precision Flow™ emits the following audio signals:

- single dull tone that sounds when the unit switches from run to standby mode
- single high pitched beep whenever you press the control setting knob
- low pitched buzz when you try to change a setting that cannot be changed or when alarm conditions prevent entering the run mode
- slowly repeating single beep during disposable water path testing

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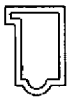
Alarm Table

Alarm Icon	Audio Signal	Indicates	Cause	Action
General fault (flashing) 	Medium Priority	Malfunction of sensor or control system	Internal component failure	Cannot be corrected by user: disconnect patient, send unit for service.
General fault (flashing) % O_2 displays dashes (- -) 	Medium Priority	O_2 sensor fault	Depleted or defective O_2 sensor	Shut off unit. Replace O_2 sensor. **Restart unit.**
Blocked tube (flashing) 	Medium Priority	High gas pressure at inlet to delivery tube	Obstructed or kinked cannula or delivery tube, or incorrect cannula for selected flow rate	Clear obstruction, check cannula type.
Water low (continuous) 	Low Priority	Water level in disposable water path below normal	Low level in sterile water, or obstructed inlet tube	Replace sterile water or straighten inlet tube.
Water out (flashing) 	Medium Priority	No water in disposable water path. Gas flow continues **without heat or water circulation.**	Low level in sterile water, or obstructed inlet tube.	Disconnect patient. Replace water bag or straighten inlet tube. **Restart unit.**
Disposable water path (flashing) 	Medium Priority	Disposable water path faulty or not detected. Unit will not run.	Disposable water path not assembled correctly, defective or not installed.	Install as per instructions. If disposable water path is present, remove and replace to reset detector.
Battery charging (continuous) 	None	The internal battery backup is not fully charged. The unit would not run on battery for the full rated time in the event of a power failure. No action is necessary.		
Battery (flashing) 	Medium Priority	Unit in BATTERY mode. Gas flow continues **without heat or water circulation.**	AC power is disconnected.	Reconnect AC power.
Cartridge fault: (cartridge alarm icon flashes) 	Medium Priority	Cartridge not detected. Unit will not run.	RUN mode: faulty sensor or missing cartridge.	Disconnect patient. Remove patient circuit. Check cartridge installation. Check cartridge reflective label. Check sensor windows are clean.
		Water drops in gas stream. Heating and water circulation are suspended.	Excessive water diffusion through cartridge fibers.	Disconnect patient. Shut off unit. Replace disposable patient circuit including water path, cartridge & delivery tube.

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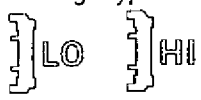
Alarm icon	Audio Signal	Indicates	Cause	Action
Cartridge fault (continuous) 	Low Priority	Gas bubbles in water circulation. Unit continues to operate.	Excessive gas diffusion through cartridge fibers.	Disconnect patient. Shut off unit. Replace disposable patient circuit including water path, cartridge & delivery tube.
		Cartridge not detected.	STANDBY mode: missing cartridge.	Disconnect patient. Remove disposable patient circuit. Check cartridge installation.
Cartridge type 	None	Indicates type of cartridge installed (low or high flow). **Not an alarm.**	Indicates type of cartridge installed (low or high flow). **Not an alarm.**	Indicates type of cartridge installed (low or high flow). **Not an alarm.**
Gas supply (flashing) *and* % O_2 displays dashes (- -) 	Medium Priority	Gas supply pressure outside 4-70 psi (28-482 kPa) range. Unit will not operate.	Gas supply is disconnected or exhausted.	Check gas supply and correct as necessary.
Gas supply (continuous *and* flow rate numeric display flashes) 	Medium Priority	Selected flow can not be provided from current gas supply.	Inlet gas pressure too low for selected flow rate.	Increase gas pressure or decrease flow setting.
Temperature display shows dashes (- -) flashing, & General Fault icon 	Medium Priority	Temperature out of range. Unit will not operate.	Overheating or temperature sensor malfunction.	Cannot be corrected by user: disconnect patient, send unit for service.
Temperature numeric display flashes	Medium Priority	Temperature 2° > set point	User enters set point much lower than previous temperature.	Silence alarm and wait for temperature to drop. Adjust set point.
		Temperature 2° < set point	Very low water temperature after bag replacement.	Silence alarm and wait for temperature to rise. Adjust set point.

NOTE: Failures in the control or measurement systems for temperature, gas flow, and oxygen percentage will cause a General Fault alarm indicated by this icon. The unit will not operate in this fault condition. With the exception of O_2 sensor replacement, the unit must be repaired by an approved service facility.

12. Shut down

12-1. Press the Run/Standby button. Unit will enter Standby mode.

12-2. Clamp the water inlet tube, and disconnect it by pulling out the spike.

12-3. Open the sliding door, remove the disposable water path with cartridge and delivery tube attached by sliding it upwards out of the docking station.

12-4. Discard all disposables according to hospital guidelines.

12-5. Disconnect unit from AC power.

CAUTION: Even a fully charged battery will lose its charge over a period of weeks when the unit is not connected to an AC source. It is recommended that the unit is connected to AC for at least two hours once a month to maintain battery charge.

13. Routine maintenance

Note: The internal backup battery should not require routine replacement and is not user-accessible. Contact Vapotherm for further information.

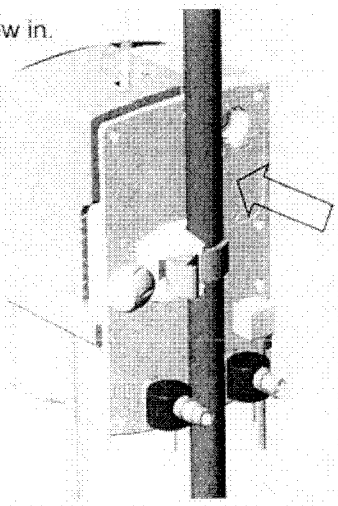
13.a Oxygen sensor

The oxygen sensor (3000127) should be replaced annually. It is accessible by removing a panel at the back of the unit, and can be changed in a few minutes by the user or biomedical engineer. Use only Vapotherm approved parts.

To replace oxygen sensor:

1. Remove three (3) securing screws from the access panel. Pull the panel away from the unit.
2. Disconnect the cable connector: grasp with pliers and pull straight back.
3. Unscrew the sensor body from its housing. Insert new sensor and screw in.
4. Plug in cable and replace cover. Do not over-tighten screws.
5. Apply label to indicate when replacement is due.

CAUTION: Sensor should be hand-tight only. Do not use tools.



Oxygen sensor access panel

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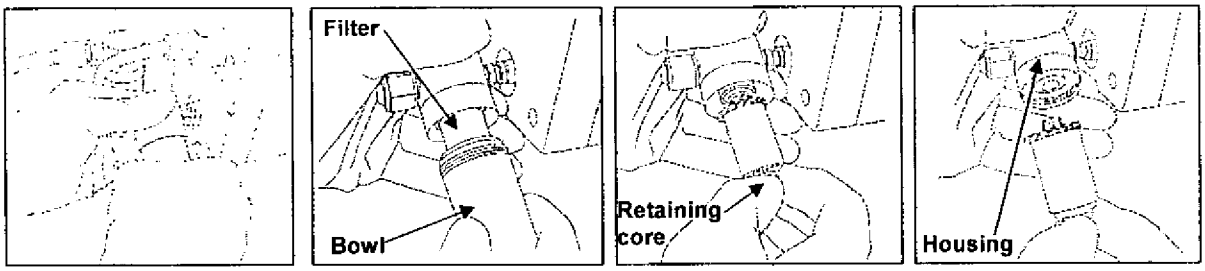
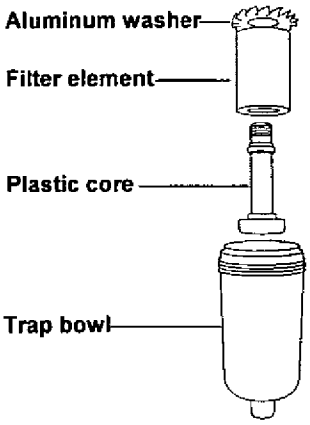
13.b Gas filters and traps

It is recommended that the inlet gas filters be replaced every 6 months.

To change the filter element:



1. Unscrew trap bowl to expose filter element.
2. Unscrew black retaining core to release filter assembly.
3. Pull off and discard old filter element. Install new element by pressing it on to the black plastic retaining core. Use only Vapotherm approved parts. Fit the aluminum washer over the threaded end of the core.
4. Screw the assembled filter element into the housing. Replace the clear plastic trap bowl.



CAUTION: The trap bowl must be screwed tightly into the housing to prevent gas leaks.

13.c Fuses

The mains fuses (two GMA - 3A F250 V, 5 x 20mm) are located next to the power cord inlet. Use a small flat blade screwdriver to pry open the fuse compartment door to access fuses.

No other routine maintenance is required within the first three years of service. There are no other user-serviceable parts. Internal sensors are self-calibrating. Failure to self-calibrate will cause a general fault condition requiring repair.

14. Cleaning and disinfection

The entire patient circuit is disposable and no disinfection is required. The main unit, including the docking station for the disposable water path should be wiped down with 70-90% isopropyl alcohol wipe after use.

NOTE: The transparent sensor ports in the docking station must be clean. The unit will not operate if the sensors do not receive a clear signal.

CAUTION: Do not use bleach, organic solvents or abrasive cleaners.

15. Specifications

PHYSICAL CHARACTERISTICS

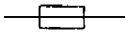
Dimensions:
Height 11.5"(300mm), width 8"(200mm), depth 7"(180mm), excluding IV pole clamp and gas filters.

Weight:
12 lb (5.4 Kg) without disposable patient circuit

Circulating Water Volume:
400 ml approx. including delivery tube and cartridge.

Mounting:
Rear mounted clamp fits IV poles up to 1.5"(38mm) diameter.

Gas Connections:
Standard DISS non-interchangeable fittings for medical air and oxygen.

FUSES: (Qty 2) GMA 3A F250 V 5mm x 20mm 

SYSTEM REQUIREMENTS

Power:
100-240VAC, 50-60Hz, approx. 200VA during warm up, approx. 80VA in steady state (depends on flow rate and temperature).

Back-up power:
(Qty 4) 4.8V nickel-metal hydride AA batteries (not user replaceable).

Gas supply:
Medical air and oxygen at inlet pressures between 4 and 70 psi (28-482 KPa).
NOTE: the full range of flows and oxygen percentage is available only if both gases are present at inlet pressures of at least 40 psi (276 kPa).

Water:
Sterile water in pre-filled sealed container.

PERFORMANCE

Temperature:
Range- 33 to 43°C at exit from the delivery tube, adjustable
Resolution- 1°C
Accuracy- ± 1°C

Warm up time:
± 1°C of 33°C set point < 5 minutes (at ambient 23°C)

Humidification:
>95% at up to 20 lpm; >90% at 20-40 lpm

Oxygen percentage:
Range- 21 to 100% O_2
Accuracy- ± 2%
Resolution- 1%

Flow rate:

Vapor transfer cartridge	Range	Resolution
Low flow	1 - 8 lpm	0.5 lpm
High flow	5 - 40 lpm	1.0 lpm

STANDARDS

Designed to conform to the following standards:

IEC 60601-1
UL60601-01
CSA C.22.2/No. 601.1
AS/NZS 3200.1.2
EN60601-1
ISO 8185

ENVIRONMENTAL

Operating

Ambient temperature: 15-33°C
Ambient relative humidity: 0-90% RH non-condensing
Ambient Pressure: Standard atmospheric – Not to be used in hyperbaric conditions

Storage and Shipping

Ambient temperature: -10 - +50°C
Ambient relative humidity: 20-90% RH

ALARM SOUND PRESSURE RANGES

Medium Priority Alarm

47 dB measured 1m from unit

Low Priority Alarm

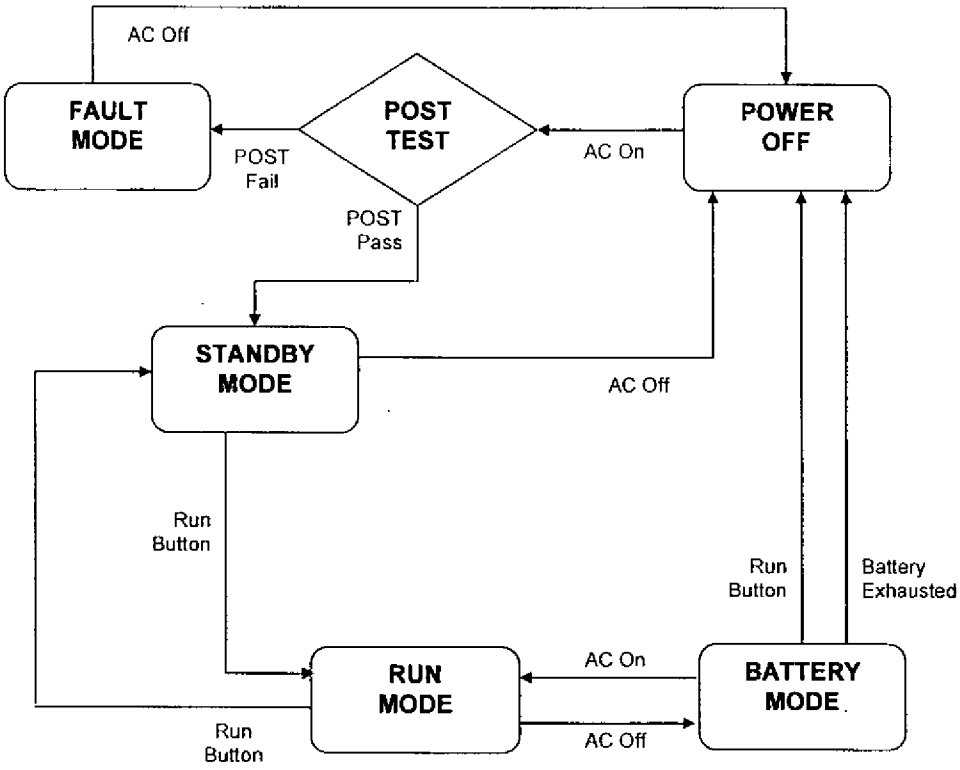
45 dB measured 1m from unit

Appendix

Audio Tone Characteristics

Tone Type	Fo (Hz)	Pulses per Burst	Pulse Spacing (ms)	Pulse Duration (ms)	Inter Burst Interval (s)
Medium Priority	660	3	200	200	2.5
Low Priority	660	2	200	200	18
Run/Stand-By transition	440	1	-	30	-
Encoder Knob press	880	1	-	90	-
User Interface Error	220	1	-	100	-
Self Test	660	5	1000	50	-

Software operating modes



The diagram illustrates the operating modes for the unit.

- Immediately on connection to AC power a POST (Power-On Self Test) is run to verify proper function of subsystems, sensors and actuators in the Precision Flow™.
- On successfully completing the POST the unit enters STANDBY unless there is a test failure, when the system alarms, enters FAULT mode and can not be started.
- The Precision Flow™ enters RUN mode from STANDBY when the RUN/STANDBY button is pressed. Normal operation starts. The pump, heater and gas flow proportioning systems start. Sensors and alarms are active and flow, temperature and oxygen % can be set.
- To return to STANDBY, the RUN/STANDBY button is pressed again.
- If AC power is disconnected when the unit is in RUN mode it enters BATTERY mode. If the battery is fully charged, gas mixing and metering continues for at least 15 minutes, but water is not circulated or heated. When the battery is discharged the unit enters the POWER OFF mode.
- If AC power is disconnected in STANDBY, the unit enters POWER OFF mode.
- If the RUN/STANDBY button is pressed when in BATTERY mode the unit enters POWER OFF mode.

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Guidance and manufacturer's declaration- electromagnetic emissions		
The Precision Flow™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Precision Flow™ should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment- guidance**
RF emissions CISPR 11	Group 1	The Precision Flow™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The Precision Flow™ is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigating measures, such as re-orienting or relocating the Precision Flow™ or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration- electromagnetic immunity	
IEC 60601-1-2:2001+A1:2004 ***EN60601-1-2:2001*** ***AS/NZ3200.1.2:2005***	
Sub Test	**Passed Parameters**
Electro-Static Discharge EN 61000-4-2:1995,+A1:1998, +A2:2001	±6kV Contact discharge ±8kV Air discharge
Radiated RF Susceptibility EN 61000-4-3:2002	80- 2500MHz @ 3 V/m, 1kHz AM 80% modulation
Electrical Fast Transients EN 61000-4-4:2004	±5kV AC mains,
Surges EN 61000-4-5:1995, +A1:2001	±0.5,1kV Line to line ±0.5, 1 2kV Line to protected earth
Line Conducted RF Susceptibility EN 61000-4-6: 1996, +A1:2001	0.15-80MHz @ 3Vrms, 1kHz AM 80% modulation
Power Frequency Magnetics EN 61000-4-8: 1993, +A1:2001	3A/m @ 50/60Hz PASSED
Voltage Dips and Dropouts EN 61000-4-11: 2004	Per Standard

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Warranty

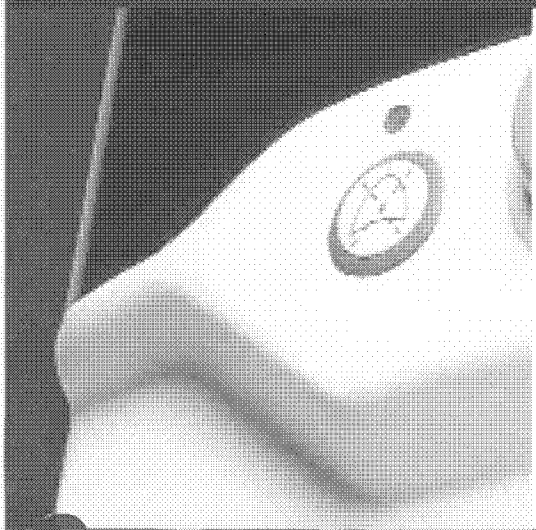
Vapotherm expressly warrants, for a period of one (1) year from the date of purchase by the [Customer] that the Products shall meet the specifications set forth in the applicable official instructions for use provided with each Product (the "Instructions"). The sole remedy for this warranty is that Vapotherm shall repair or, at its option, replace any part or all of any Product that is defective at no cost to the [Customer]. Vapotherm shall pay any shipping charges required in repairing or replacing any part or all of a Product provided that such Product is shipped within three (3) months of the date of retail sale. Thereafter, shipping charges shall be paid by the [Customer]. This warranty does not apply to any patient circuit or hoses supplied with the Product nor does the warranty cover abuse or misuse of the instrument, or damage due to unauthorized servicing. To maintain this warranty, repair may only be performed by Vapotherm or a Vapotherm certified service center. The warranty set forth in this shall become null and void if the Product is opened, otherwise tampered with, or if repairs are attempted by anyone other than Vapotherm, or if the Product is operated by anyone other than trained and duly qualified medical personnel.

EXCEPT AS EXPRESSLY SET FORTH IN SECTION [4.1], VAPOTHERM MAKES NO WARRANTY, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE PRODUCTS OR OTHERWISE IN CONNECTION WITH THIS AGREEMENT, AND HEREBY EXPRESSLY DISCLAIMS ANY OTHER FORM OF WARRANTY, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS STATED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES PROVIDED BY LAW.

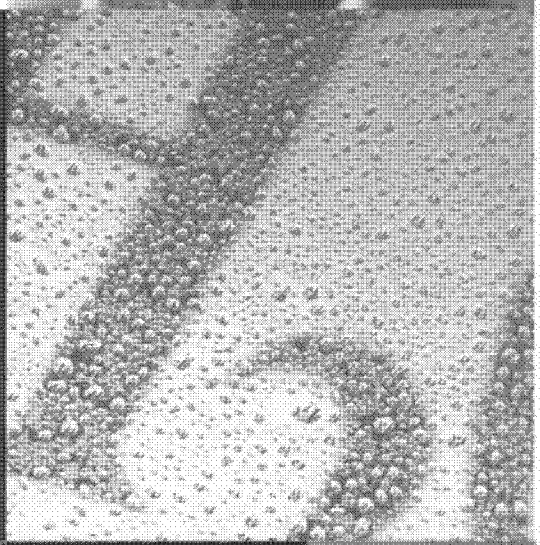
c. PRECISION FLOW™ PROMOTIONAL MATERIALS

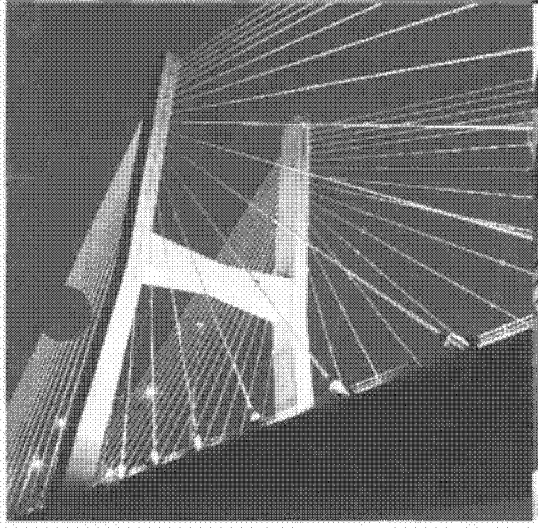
PRECISION*flow*™

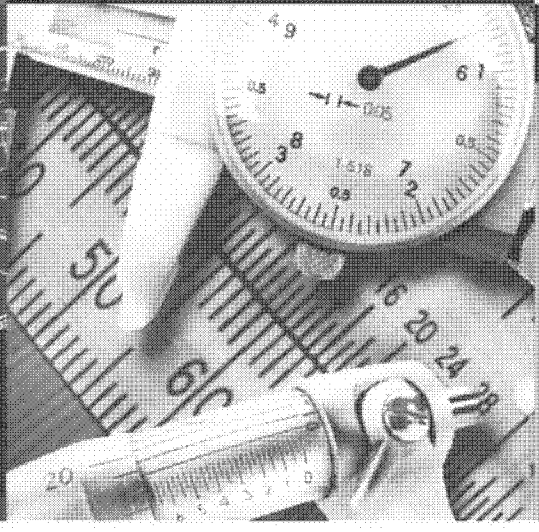
Accuracy matters

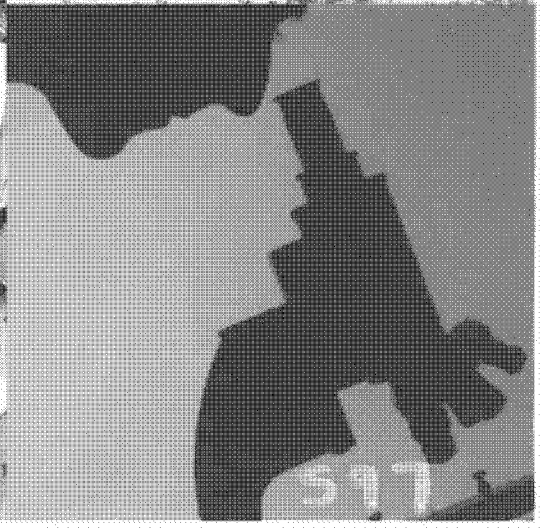


VAPOTHERM®









Introducing The Next Generation of High Flow Oxygen Therapy

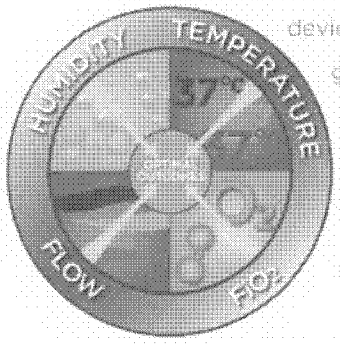
PRECISION*flow*™

Takes The Technology of High Flow Oxygen Therapy To The Highest Level of Sophistication

Vapotherm, the leading innovator of high flow oxygen therapy, takes the science of heating and humidifying breathing gases to a dramatic new level with the creation of PRECISION FLOW.™

INNOVATIVE TECHNOLOGY

PRECISION FLOW™ is a high flow heat and humidification device for the non-invasive delivery of inspired gas flows from 1 to 40 liters per minute.



The technology delivers a perfect synchronization of flow, temperature, humidity and oxygen percentage without discomfort via nasal cannula.

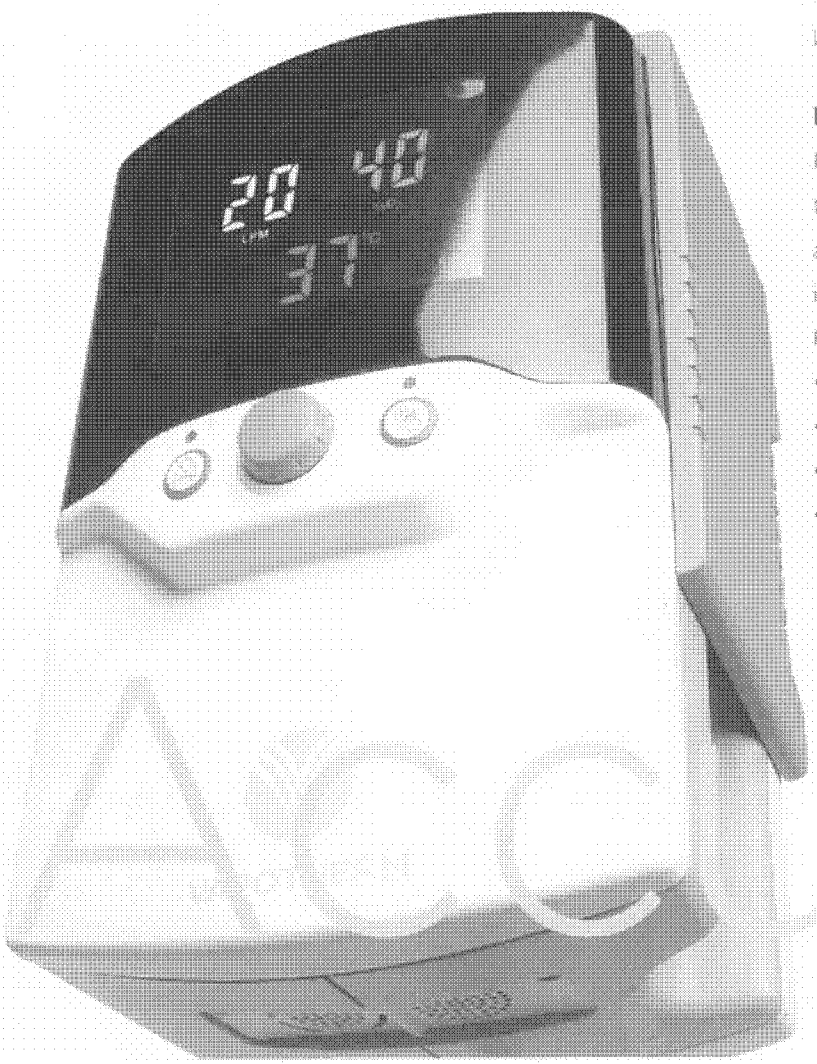
CONTROL THE FACTORS THAT MATTER

PRECISION FLOW™ moves beyond conventional humidification, giving the clinician the ability to manage the key factors in gas conditioning to achieve desired outcomes.

MAXIMUM SAFETY, MINIMAL INVASIVENESS

PRECISION FLOW™ helps clinicians reach their goal to deliver the maximum respiratory assistance safely and comfortably. More invasive techniques can result in iatrogenic effects and increased costs.[1] No other High Flow device incorporates these safety features:

- Precise measurement of temperature and flow
- Built-in oxygen blender and oxygen sensor
- Disposable patient circuit
- Battery backup



Accuracy matters

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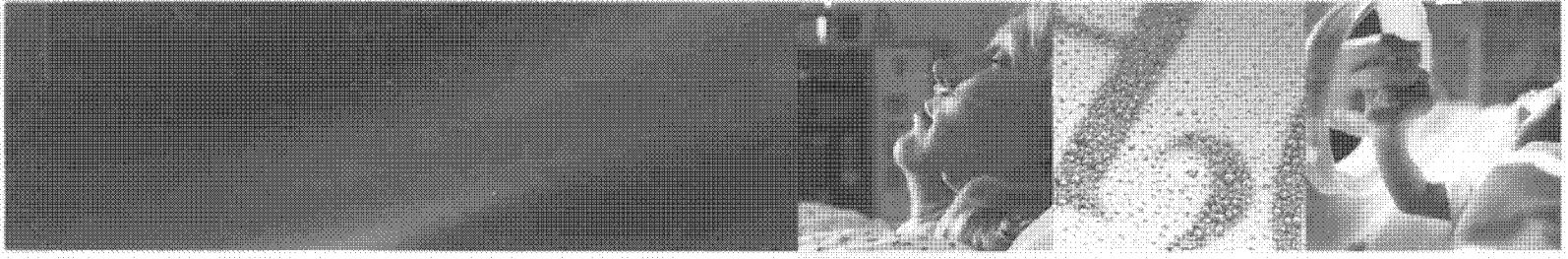


DESIGNED FOR EASE OF USE

Working with the respiratory community, PRECISION FLOW™ was designed with the clinician in mind, providing easy set up, operation and maintenance including:

- Rapid set up and circuit priming
- Single button control for flow, oxygen percentage and temperature values
- Color-coded, uncluttered display for alarms and indicators
- Engineered for reliability and streamlined maintenance

WORKS TO PRECISION IN ANY SETTING

PRECISION FLOW™ allows for the delivery of a broad range of flows at up to 100% relative humidity, providing effective, well-tolerated treatment for a variety of conditions via nasal cannula.

Care Settings

- Adult Intensive Care
- Pediatric Intensive Care
- Neonatal Intensive Care
- Emergency
- Burn Centers
- Pulmonary Rehabilitation
- Post Operative Care
- Palliative Care

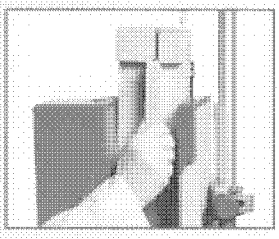
Applications

Oxygenation and Humidification

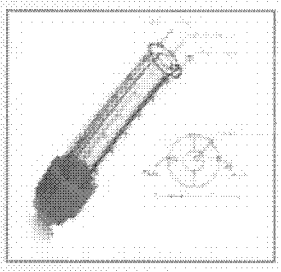
- Used in Neonatal, Pediatric and Adult Applications

(1) Jorge Rites, The use of vapotherm in an NICU: Effects on respiratory support and cost. Respiratory Care 2006; Vol 50 No 8.

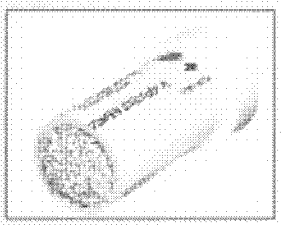
KEY COMPONENTS



Disposable Patient Circuit
No disinfection necessary: the patient circuit is detachable and disposable.

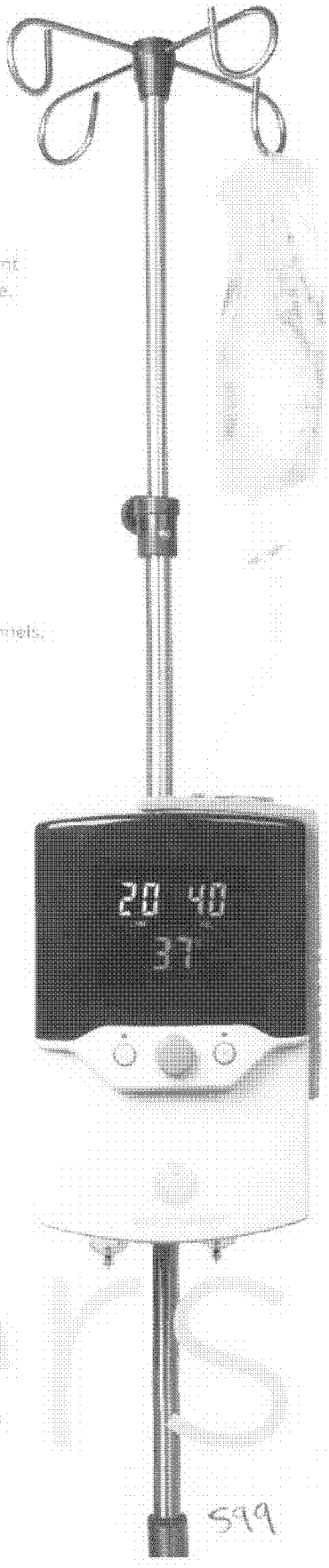


Patient Delivery Tube
Patented triple lumen design, air is surrounded by two water filled channels.



Vapor Transfer Cartridge
Core humidification technology allows molecular water vapor to pass into the gas stream, preventing contact between water source and breathing gas.

Oxygen Blender
Can be used with air or oxygen independently. Does not require a 50 psi source.



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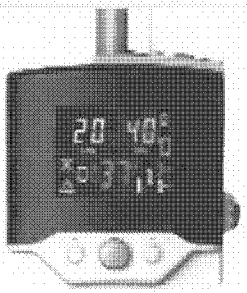
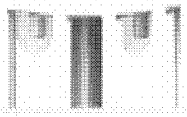
PRECISION*flow*

Products and Accessories

PRECISION FLOW™ DEVICE

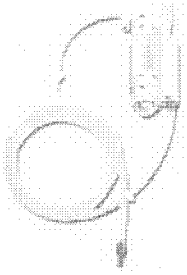


The PRECISION FLOW™ is a high flow device designed to heat, humidify and blend medical breathing gases for delivery to the patient. This includes an Accessory Kit which contains the following: oxygen sensor, air and oxygen hoses and gas inlet traps, electrical cord, Operating Instruction Manual and Quick Reference Guide.

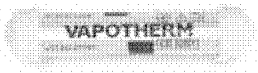


DISPOSABLES

Disposable Patient Circuit

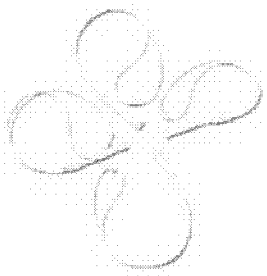


The disposable patient circuit is comprised of the disposable water path, vapor transfer cartridge and delivery tube. The entire disposable patient circuit is available in either High Flow or Low Flow versions.



The Vapotherm Low Flow Cartridge is generally used for neonates and the High Flow Cartridge is used for adult and pediatric applications.

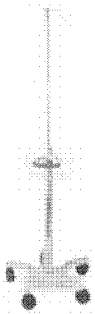
Cannulas



A series of specially designed cannulas are available for attachment to the Disposable Patient Circuit. Sizes include: Premature, Neonatal, Infant, Intermediate Infant, Pediatric, and Adult.

ACCESSORIES

PRECISION FLOW™ Stand



The PRECISION FLOW™ device can be attached to the Vapotherm® IV pole.

TECHNICAL SPECIFICATIONS

- Built-in oxygen blender. Oxygen percentage is fully adjustable from 21 to 100% when two 40 psi (276 kPa) gas sources are used.
- Inlet gas pressure range is 4-70 psi (28-482 kPa). At low gas inlet pressures, maximum flow rate and oxygen percentage settings are automatically reduced to match the inlet pressure.
- Two alarm levels indicate low and medium priority alarm conditions. IEC60601-1-8 compliant.
- Internal battery backup maintains flow and oxygen percentage for 15 minutes if AC power is cut off. Battery recharges in 1-2 hrs.

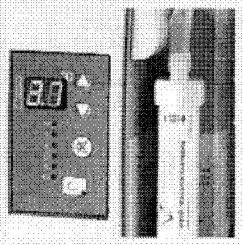
KEY BENEFITS

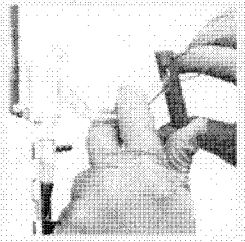
- No disinfection necessary. The patient circuit is detachable and disposable.
- Temperature, flow and oxygen percentage are adjusted via a single setting control knob on the front panel.
- Automatically senses cartridge type — maximum flow setting is automatically reduced if low-flow cartridge is installed.
- Easy connection between the delivery tube and disposable water path by a simple press and click fitting.
- All values and alarms displayed in a single large color-coded panel.
- Scheduled maintenance for internal components at 3 year intervals, external gas filters replaced at 6-month intervals, external oxygen sensor replaced annually.
- Universal power requirements allow use anywhere with only a change of power cord.

Pending FDA Clearance

d. LABELING OF PREDICATE DEVICES

VAPOTHERM





2000i

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Contents

Section 1 Indications and Contraindications

Primary Indications:

Used to warm and humidify breathing gases, generally prescribed during oxygen therapy where concentrations of oxygen greater than ambient air are utilized to treat symptoms and manifestations of hypoxia including:

- Documented hypoxemia: decreased PaO, in blood below normal range
- Acute care in which hypoxemia is suspected
- Severe trauma
- Acute myocardial infarction

Secondary Indications:

- Managing hypothermia
- Treating bronchospasm caused by cold air

Contraindications:

General:

- Any situations in which humidification is contra-indicated (see AARC Clinical Practice Guidelines)

Specific to Nasal Cannula:

- Patients with occluded or defective nares should not use the system.

Section 2 Definitions, Warnings and Cautions

2.1 Definitions

A **WARNING** indicates that a potentially harmful situation may occur.

A **CAUTION** indicates a condition that may lead to equipment damage, malfunction, or inaccurate operation.

A **NOTE** indicates a point of emphasis to make operation more efficient or convenient.

ASEPTIC TECHNIQUE is practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens. Specifically with respiratory equipment, especially with reference to the Vapotherm 2000i, this includes proper hand washing and avoiding direct hand contact with connection points.

Please take the time to familiarize yourself with the definitions, warnings, cautions and notes listed in this manual. They cover safety considerations, special requirements, and regulations.

The user of this product assumes sole responsibility for any malfunction due to operation or maintenance performed by anyone not trained by Vapotherm™ staff or official training documentation.

When handling any part of the Vapotherm 2000i, always follow hospital infection control guidelines and Standard Precautions. Vapotherm recommends that users follow the disinfection procedure found in this manual. Vapotherm also recommends that users follow the Centers for Disease Control (CDC) publications: *Guidelines for Maintenance of In-Use Respiratory Therapy Equipment and Guidelines for Prevention of Nosocomial Pneumonia.*

2.2 General Warnings

- Federal Law (U.S.) restricts the sale of this device to, or by the order of any physician.
- This is a humidification device generally used for providing continuous flows of breathing gas. The Vapotherm 2000i is not a ventilatory device and should not be used as life support.
- This device will not operate without flow.

General Warnings (cont.)

- The Vapotherm 2000i must be disinfected between each patient use and after 30 days of use on the same patient.
- Gas flow delivered by this device is limited to 40 liters per minute. Maximum operational flow rate should not be exceeded.
- Prior to use machine should be positioned and secured to a sturdy IV pole.
- The system includes several disposable elements that are labeled as single patient use only: do not attempt to sterilize or reuse. Follow all local and federal regulations for disposal.
- Oxygen supports combustion; this device should not be used near or around open flames, oil, grease or any flammables or anesthetics.
- Performance verification must be performed prior to use.
- Service on the device should be performed by qualified, certified service technicians ONLY.
- To prevent injury do not attempt to perform any service to the Vapotherm 2000i while a patient is connected to the device.
- If the device is damaged or not working properly do not use. Contact Vapotherm or your authorized Vapotherm representative.
- Do not operate if power cord is damaged.
- The device should not be turned on and left unattended.
- Do not use the Vapotherm 2000i in or around water other than the water bag that feeds the system.
- Failure to utilize sterile water supply or clean gas supply may increase risk of bacterial contamination.
- The Vapotherm 2000i utilizes warmed water and can pose a risk for colonization of bacteria and patient infection if disinfection procedures are not followed.
- Gas flow is external to the Vapotherm, but the care giver should confirm the integrity of all respiratory gases utilized to ensure they are free of contamination.
- Gas supply must be made of clean dry medical grade gas to prevent harm to the patient and prevent damage to the Vapotherm 2000i.
- An oxygen analyzer with alarms must be used when the delivered concentration level is critical. The Vapotherm 2000i does not provide oxygen concentration analysis capability.
- To reduce any potential transmission of contaminated water from the system, all assembly and/or disassembly of the unit should take place outside the primary care areas.
- The 2000i is not a Continuous Positive Airway Device (CPAP). There are no controls to deliver or monitor airway pressure. The 2000i humidifies breathing gases that are delivered externally through standard air/oxygen blender and flowmeter. The 2000i should not be used to deliver pressure in a closed system.

2.3 Cautions

- Verify that the power source is compatible with the electrical specifications shown on each component. For proper grounding reliability, connect the 2000i power cord only to a properly marked hospital grade receptacle. DO NOT USE EXTENSION CORDS. If any doubt exists as to the grounding connection, DO NOT operate the device.
- Do not immerse the Vapotherm 2000i in water. Do not steam or gas sterilize the Vapotherm 2000i.
- Read and understand this manual prior to operating the system.
- The Vapotherm 2000i must be disinfected if the water circuit is opened up by removing or replacing a component.
- Aseptic techniques (including proper hand washing and avoiding direct hand contact with connection points) and Standard Precautions should always be followed when handling medical equipment.
- Standard Precautions should always be followed when coming in contact with patients.

2.4 General Inspection

When unpacking the Vapotherm 2000i system , ensure that the unit is inspected for damage before use. Report any damage or missing parts immediately to your authorized Vapotherm distributor.

When renting a Vapotherm 2000i, customers should require the rental service to provide a certification that the machine has been disinfected before accepting delivery.

The Vapotherm™ 2000h for home use consists of the combination of a 2000i unit and the "Home Care Compressor Kit (Part number HCK200-M)". The HCK-200 Kit consists of an HS-100 Stand, a 5060A Room Air Compressor and Flowmeter assembly.

1. A Vapotherm authorized Durable Medical Equipment (DME) Supplier is responsible for the following:

   - Assembling the 2000i unit and the kit components
   - Instructing the user in their responsibilities for operating the system
   - Providing 1000 ml sterile water bags as needed
   - Routine servicing of the system
   - Removing, replacing, and disposing of the disposable components (Vapor Transfer Cartridge, Vapotherm Spike Set -1 & Delivery Tube) every 30 days
   - Disinfecting of the 2000i unit every thirty days following the procedure found in Section 8.1 – 8.6 of the 2000i Operating Instruction Manual

2. The user/home care provider is responsible for the following:

   - Change nasal cannulas when soiled or excessively wet from secretions. Dispose of properly.
   - Installing and replacing the sterile water bag
   - Avoid liquid spills on the components
   - Do not attempt any repairs. If you have any problems with your Vapotherm 2000i device notify the DME provider immediately

Section 3 Vapotherm 2000i

The Vapotherm 2000i warms and humidifies flows of air, oxygen or medical gas blends for delivery to a patient, by nasal cannula or Vapotherm approved interface. Warming and humidification of breathing gas occurs in a Vapor Transfer Cartridge, where air and water are separated by a membrane permeable to water vapor. The membrane consists of microtubules constructed of polysulfone material. The membrane meets HIMA (Health Industry Manufacturers Association) standards on filters for sterilizing liquids and has been shown to effectively exclude bacteria from crossing from the water circulation to the gas flow.

The warmed humidified gas stream reaches the patient via a patented triple lumen Patient Delivery Tube. Humidified gas flow is delivered through the center lumen. The outer lumens contain water which is warmed via an internal heater and propelled through the system via an internal pump (*See schematic, fig. 1*). This maintains breathing gas temperature and minimizes condensation. The final patient interface is a Vapotherm nasal cannula or approved interface configured to minimize resistance and heat loss.

NOTE: The water circuit and gas circuit of the Vapotherm 2000i do not come in contact with each other.

Respiratory gases are supplied to the Vapotherm™ 2000i from an external gas supply, typically through a standard wall-mounted flow meter connected to the hospital medical gas supply. Gas flow rate is controlled by the external flow meter or medical gas blender. There are no flow controls on the Vapotherm™ 2000i. Connections for gas flow and water are made via the rear panel. All Vapotherm 2000i controls are on the front panel of the device.

WARNING: Use of patient interfaces not recommended by Vapotherm may cause safety concerns or affect the performance of the device.

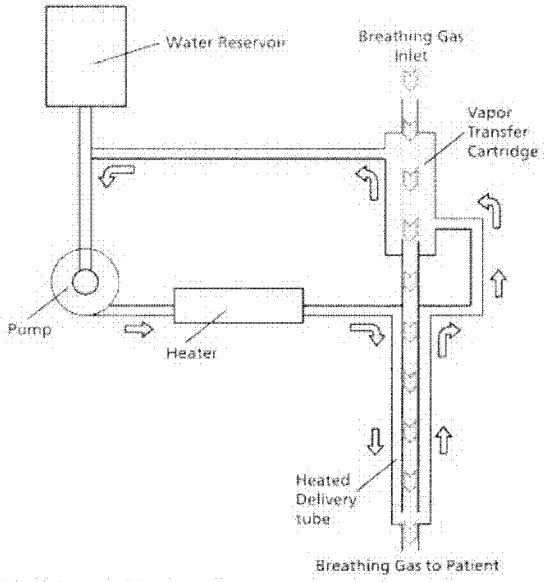


Fig. 1 Simplified System Diagram

Section 4 Set-up

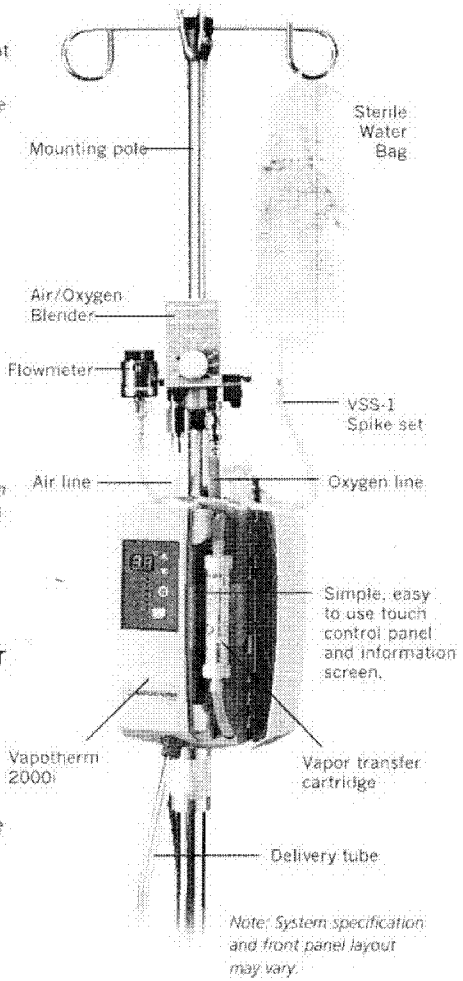
4.1 The 2000i Unit

1. The back of the 2000i has an IV pole clamp that enables IV pole attachment.
2. The unit should be mounted on a sturdy IV pole approximately two feet from the top of the pole to facilitate ease of access and proper flow from sterile water system.
3. If using an oxygen blender, mount the blender above the Vapotherm 2000i on the IV pole.
4. Connect blender hoses into both air and oxygen wall connections.
5. Plug Vapotherm power cord into a hospital wall power outlet.

WARNINGS:
Aseptic technique (including proper hand washing and avoiding direct hand contact with connection points) should always be followed when setting up and operating the Vapotherm 2000i.

The medical gas source is external to the Vapotherm 2000i. Always verify the integrity of the medical gas source and utilize bacterial filters if necessary.

Closed system components (VSS-1, Vapor Transfer Cartridge and Patient Delivery Tube) should not be opened in patient care area.



Note: System specification and front panel layout may vary.

4.2 Selecting the Vapor Transfer Cartridge

Vapotherm provides both a high flow cartridge (VT01-AS) and a low flow cartridge (VT01-BS).

- The high flow cartridge (VT01-AS) should be used with the pediatric cannula with an operational flow range of 5–20 liters per minute (lpm) or with adult sized cannula with an operational flow range of 8–40 lpm.
- The low flow cartridge (VT01-BS) should be used with the neonatal, premature, infant, or intermediate sized cannula with an operational flow range of 1–8 lpm.

WARNINGS:
Do not exceed maximum operational flow rates of 40 lpm for the high flow cartridge (VT01-AS) and 8 lpm for the low flow cartridge (VT01-BS).

Ensure that the correct cartridge is inserted before operating.

4.3 Inserting the Vapor Transfer Cartridge

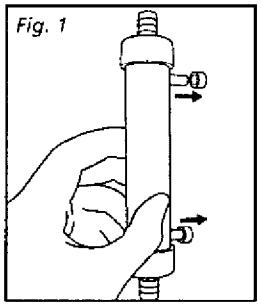


Fig. 1

1. The Vapor Transfer Cartridge (VT01-AS or VT01-BS) attaches to the unit by two water and two air connections.
2. When facing the unit, access is via a hinged cover on right side. The cartridge may be fitted in either direction.
3. Date the cartridge.
4. Remove protective caps from luer side ports of cartridge *(Fig. 1)*.
5. Attach lower air tube from Vapotherm 2000i to lower end of cartridge.
6. Insert projecting side ports into matching connections in unit. Press cartridge firmly into place *(Fig. 2)*.
7. Attach upper air tube from Vapotherm 2000i to top of cartridge *(Fig. 3)*. Make sure tubing is not kinked.
8. Close hinged cover. If it does not close easily, check that cartridge is pressed fully into place and that air tubes are not interfering with cover.

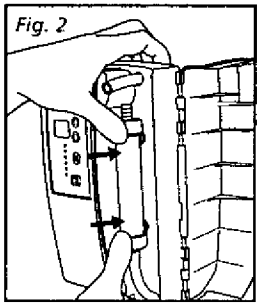


Fig. 2

WARNINGS:
The cartridge must be changed between patients and discarded after each use.

If the cartridge is removed, the unit should be disinfected.

If the cartridge is dropped, it should be discarded.

NOTE: Do not remove cartridge from the Vapotherm 2000i without first draining the machine.

4.4 Inserting the Patient Delivery Tube

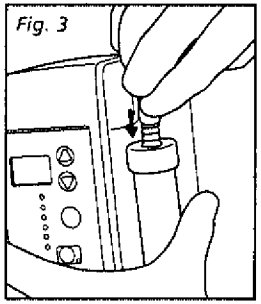


Fig. 3

1. Insert Patient Delivery Tube into lower portion of the unit by aligning blue tabs on tube with notches on bottom of unit.
2. Firmly press into place *(Fig. 4, see next page)*. Blue lip on tube must be flush with the bottom of unit.
3. Rotate 1/4 turn clockwise and pull slightly downwards to lock into place (Fig. 4, *see next page*).

WARNING: The Patient Delivery Tube is a single patient use item and should be changed with each patient.

If the Patient Delivery Tube is removed from the device for any reason the Vapotherm 2000i should be disinfected following the routine disinfection procedure before returning to service.

CAUTION: Unit will not operate correctly if the Patient Delivery Tube is inserted improperly or not locked into place.

4.5 Vapotherm Spike Set (VSS-1): for connecting Sterile Water Bag

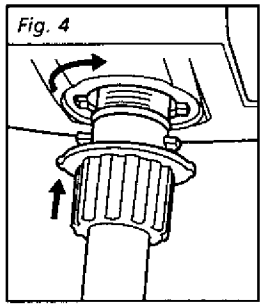


Fig. 4

1. Hang a sterile water bag from IV Pole.
2. Connect VSS-1 to the water inlet port on back of unit and make sure it locks into place (Fig. 5).
3. Ensure the VSS-1 is clamped then remove spike cap. Wipe spike with disinfectant wipes, 70-90% isopropyl alcohol.
4. Firmly insert spike into sterile water bag while avoiding direct hand contact with the spike tip and water bag septum.
5. Leave VSS-1 spike set clamped until ready to fill unit.

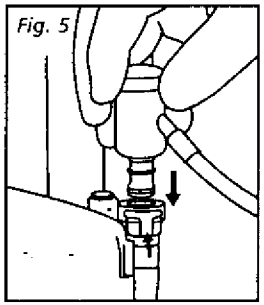


Fig. 5

WARNINGS:
The VSS-1 is single patient use item and should be changed with each patient.

If the VSS-1 is removed from the Vapotherm device for any reason the Vapotherm 2000i should be disinfected following the routine disinfection procedure before being returned to service.

CAUTION: Never leave the VSS-1 unclamped when the system is not running.

NOTE: Removing an empty sterile water container does not constitute opening the closed system. New sterile water containers can be spiked using the same VSS-1 without removing the device from service following the procedure above.

4.6 Connect To A Gas Source

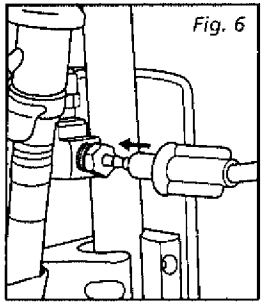


Fig. 6

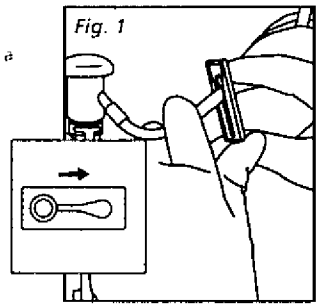
1. Connect a source of air, oxygen or medical gas blender to the gas inlet port of Vapotherm 2000i *(Fig. 6)*. Gas inlet connection is a hose barb that accepts female fitting on a standard 1/4" (6.35mm) oxygen tube.

NOTE: Vapotherm will not operate unless there is gas pressure at gas inlet. With no flow/pressure sensed, a "System Failure" alarm will sound.

5.1 Prepare for Activating the Unit

1. Ensure that the Vapotherm 2000i power cord is plugged into a hospital electrical wall outlet.
2. Unclamp the Vapotherm Spike Set (VSS-1) *(Fig. 1)*.

Fig. 1



5.2 Turn on Flow

1. If using the high flow cartridge (VT01-AS) flow should be started at least 8 lpm for warm-up.
2. If using the low flow cartridge (VT01-BS) flow should be set to at least 5 lpm for warm-up.
3. Turn on flow.

5.3 Priming the Unit

1. Unit should be started in CLEANING MODE "CL" to prime a new Patient Delivery Tube.
2. To place unit in CLEANING MODE, press both the power on and the ALARM SILENCE/MUTE buttons simultaneously *(Fig. 2)*.
3. The display will show "CL" and LED next to cleaning icon will illuminate.
4. Water will begin to circulate and fill the Patient Delivery Tube.
5. Operate in CLEANING MODE until Patient Delivery Tube has been purged of air bubbles.
6. When air has been purged, press POWER to stop system
7. Wait until display blanks.

Fig. 2

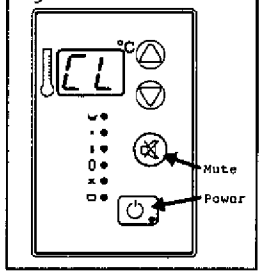
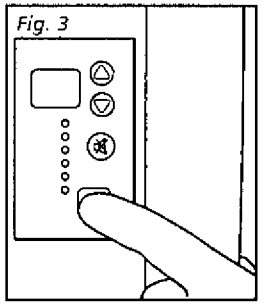


Fig. 3



NOTES:
Pressing both the power and alarm mute buttons will set unit in CLEANING MODE. pressing only the power button sets unit in NORMAL mode.

Water is not being heated in CLEANING MODE: the purpose of this mode is to fill the outer lumens of the Patient Delivery Tube with water.

Gas flow is highly recommended (but not mandatory) during priming.

5.4 Activate the Unit

1. Press the Power button only, to start in NORMAL MODE *(Fig. 3)*.
2. If not using the Patient Delivery Tube with integrated cannula, do not place cannula on the end of tube until warm up is complete.

Section 5 Operation of The Vapotherm 2000i

5.5 Setting the Temperature and Warm-Up

1. The Vapotherm 2000i displays the actual temperature of the circulating water. Press and release the up or down arrow on the front of the unit to display temperature setting for 3 seconds.
2. To adjust the temperature setting of the Vapotherm 2000i, press and hold the up or down arrow until the desired temperature is displayed in the LED.

NOTES:
The Vapotherm 2000i always defaults to previous set temperature at power up.

The temperature can be set between 33 and 43°C.

5.6 Connecting to Patient

1. Wait for desired operating temperature to be reached **BEFORE** placing the cannula on the end of the Patient Delivery Tube.
2. Check water level, temperature display and gas flow rate.
3. Size cannula to patient by ensuring that nasal prongs do not fit tightly into nares.
4. Attach properly sized cannula that is designed to function with the cartridge installed in the machine onto the delivery tube. Adjust the flow to the desired rate and place the cannula on the patient.
5. Some condensation of moisture around nose is possible. In addition, high moisture level may mobilize mucus from nose and sinuses. Make sure patient has a supply of tissues.

Cartridge	*Cannula Type*	*Operational Flow Rates*
High Flow (VT01-AS)	*Adult*	*8 – 40 lpm*
High Flow (VT01-AS)	*Pediatric*	*5 – 20 lpm*
Low Flow (VT01-BS)	*Premature, neonatal, infant, intermediate*	*1 – 8 lpm*

WARNINGS:
Always follow aseptic technique (including proper hand washing and avoiding direct hand contact with connection points) when setting up the Vapotherm 2000i and Standard Precautions when placing on a patient.

Cannula should not obstruct the nares of the patient.

Change nasal cannulas when soiled.

After start-up, during the normal purging of the Patient Delivery Tube, air will release and appear as bubbles in the bubble trap of the VSS-1. If the Patient Delivery Tube is filled and a stream of continuous bubbles appear in the bubble trap, it may indicate a problem with the cartridge or Patient Delivery Tube and both should be checked or changed.

NOTE:
If using a low flow cartridge (VT01-BS) the flow cannot be decreased below 5 lpm until an appropriate cannula has been attached to the delivery tube

Droplets of condensation may appear at the end of Patient Delivery Tube while unit is warming up. This is normal and will stop within a few minutes when temperature is reached. If this condition continues refer to trouble shooting section. If the system operates while not connected to a patient, condensation is likely to develop.

Section 5 Operation of The Vapotherm 2000i

5.7 Operations – General Guidelines

1. Check that water is properly circulating through the machine by making sure the Patient Delivery Tube is warm across the entire length.
2. If good circulation cannot be confirmed, check that the water flow is not obstructed by air bubbles.
3. Take precautions to minimize cooling of the unheated cannula by trying to maintain contact with the patient's skin and insulating the exposed portion of the cannula with bedding.
4. Cartridge door should be closed during operation.

NOTE: Condensation in the cannula may occur at low flow rates. To minimize condensation, these general guidelines should be followed:

- *If using flow rates less than 5 lpm, do not set the temperature higher than 34°C.*
- *The Vapotherm unit should not be in a position where it is cooled (eg. by an air conditioning outlet).*

CAUTION: DO NOT EXCEED flows of 8 lpm for VT01-BS and 40 lpm for VT01-AS cartridge.
DO NOT SET flows below 1 lpm for VT01-BS.

WARNING:
Never occlude the nares with cannula.

NOTES:

It may become necessary to disconnect the cannula from the Patient Delivery Tube for short periods, such as when moving a patient out of a radiant warmer. At flow rates less than 5 lpm, cannula disconnection will activate a system failure alarm, requiring a reset. To avoid this alarm, briefly turn off unit by pressing the power key once. The display will show two bars. Disconnect the cannula from Patient Delivery Tube and move the patient, reconnect the cannula, then press the power key once more to restart the unit.

A SYSTEM FAIL (88) alarm will activate if there is insufficient gas pressure in the manifold. If no cannula is fitted, flow rate at startup should be at least 5 lpm. The minimum flow rate for operation is 1 lpm if a neonate, infant or premature-sized cannula is fitted, 5 lpm with a pediatric cannula, and 8 lpm with an adult cannula.

Cannulas are single use patient items, dispose of as necessary or according to your institution's guidelines or when visibly soiled or excessively wet from secretions. Weekly change out is recommended to avoid any hardening of nasal prongs.

An air lock can develop at the pump, preventing normal water flow. Try restarting the unit in cleaning mode.

Section 6 Alarms, Trouble Shooting and Component Change-Outs

6.1 General

1. Periodically check for alarm conditions.
2. Unit will shut down if there is no gas flow. However, flow will not be interrupted if unit shuts down or malfunctions for any other reason.
3. Unit will shut down if temperature safety limits are exceeded, or if water level is low for more than 4 mins. However, unheated gas flow will continue.

NOTE: Should a malfunction occur, indicators on the front panel will light and an alarm will sound. If the actions listed here do not correct the problem causing the alarm, the unit should be returned to an approved facility for service.

6.2 Alarms and Troubleshooting

Alarm indication	Cause	Action
Water low 	Water is not filling system properly	Make sure VSS-1 spike set is open, and the tube is not kinked or blocked by air bubbles.
	Low Water Pressure	Make sure gas and water connections are open, gas can flow to unit, and air has purged from water system: if not, run "CLEANING MODE".
	Malfunctioning Water or Gas Pressure Sensor	Send in for service.
System Failure **S**	Insufficient gas or water pressure.	Make sure the gas and water circuits are open and functional and air has purged from the water circuit if the unit is in normal operating mode.
		Run in "CLEANING MODE".
		Make sure there is correct flow for cartridge flow rates. If using <5lpm with a low flow cartridge, a nasal cannula must be attached.
	Malfunctioning Water or Gas Pressure Sensor	If a component failure return the unit for service.
NOTE: To restart after a system failure, the unit must be reset by a momentary pressure on the Power button. Do not hold the Power button. The alarm will shut off after a delay of about a second, and the unit can then be restarted normally.		
Cartridge 	Water drops in the circuit will cause a cartridge alarm; this does not necessarily mean the cartridge needs to be replaced.	

Alarm indication	Cause	Action
Cartridge	If the Cartridge Alarm is continuous and air bubbles are rising into the VSS-1 bubble trap or if a flow or water is visible in the tube below the cartridge, then the cartridge has failed.	First disconnect the patient from the unit, shut down unit, drain unit, disinfect unit, replace cartridge, VSS-1 and delivery tube, and follow set up instructions.
	If cartridge alarm is intermittent and there are no bubbles in the VSS-1 bubble trap or no obvious water flow below the cartridge there may be condensation in the system.	Occasional brief alarms due to condensation are not a cause for concern. Try briefly pinching and releasing tube under cartridge to dislodge the drops and/ or decrease set temperature.
High Temperature Alarm	Malfunction of Temperature Control System.	Shut down system and return for service. *NOTE: A momentary High Temperature alarm may occur when the unit has been switched off and on again. If the temperature then stabilizes, no action is needed.*
Blocked Tube Alarm	High water or air pressure due to high resistance in water circulation or air outlet or malfunctioning pressure sensor.	
	Blocked tube alarm due to high WATER pressure will cause a continuous or intermittent tone and alarm light. The flow of breathing gas continues, but is no longer heated.	Check that delivery tube is correctly positioned, rotated clockwise, and pulled into locked position. Check that water is circulating within delivery tube. If alarm persists replace delivery tube and/or cartridge. Disinfect unit prior to replacing components.
	Blocked tube alarm due to high GAS pressure will cause a 5 second alarm tone. If the obstruction persists the system will continue to alarm in 5 sec episodes. Water circulation continues but the heater shuts off.	Find and correct the cause of obstruction. The most common cause is a kink in the nasal cannual or in the prong. Attempting to run the Vapotherm 2000i at very high flow through a patient interface not approved by Vapotherm may also raise the internal pressure sufficiently to trigger a Blocked Tube Alarm.

If further assistance is needed please call your clinical product specialist or local distributor representative.

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Section 6 Alarms, Trouble Shooting and Component Change-Outs

6.3 Component Change Outs

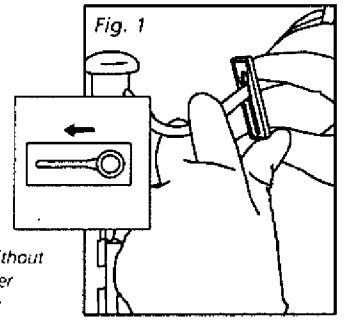
WARNINGS:
The vapor transfer cartridge, patient delivery tube, and VSS-1 spike set are all single use only and should be discarded after removal from the Vapotherm 2000i.

The Patient Delivery Tube, VSS-1 and Vapor Transfer Cartridge should not be changed or replaced in the patient care area.

The system must be disinfected any time the Vapor Transfer Cartridge, VSS-1 or Patient Delivery Tube are removed.

NOTE: The cannula and sterile water source can be replaced without disinfecting the system. As with all respiratory equipment, proper hand washing techniques should be followed before contacting or replacing any patient interfaces.

Fig. 1

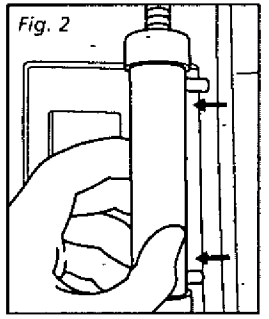


6.3.1 Replacing Vapor Transfer Cartridge

1. Power off unit. Disconnect gas flow.
2. Close clip on VSS-1. *(Fig. 1)*
3. Open hinged cover.
4. Disconnect air tubes from cartridge ends by pressing tubing away from cartridge.
5. Remove cartridge by pulling straight outwards. *(Fig. 2)*
6. Proceed to Section 8.0 and disinfect the Vapotherm 2000i device before returning the device to service.
7. For set-up please refer to Section 4.3 of the manual.

CAUTION: Do not grip cartridge tubing with sharp instruments.

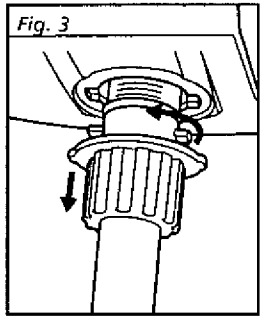
Fig. 2



6.3.2 Replacing the Patient Delivery Tube

1. Power unit off. Disconnect gas flow.
2. To remove tube, push base of tube upwards, rotate 1/4 turn counter clockwise and pull downward. *(Fig. 3)*
3. Proceed to Section 8.0 and disinfect the Vapotherm 2000i device before returning the device to service.
4. For set-up please refer to Section 4.4 of the manual.

Fig. 3



6.3.3 Replacing the VSS-1 Spike Set

1. Power off unit. Disconnect gas flow.
2. Clamp VSS-1 and remove VSS-1 Spike Set from the water inlet port on the back of the Vapotherm 2000i by releasing the quick connect on the water inlet port.
3. Proceed to Section 8.0 and disinfect the Vapotherm 2000i device before returning the device to service.
4. For set-up please refer to Section 4.5 of the manual.

Section 7 Removing From Patient and System Shut Down

1. Remove cannula or other interface from patient.
2. Press and release power switch *(Fig. 1)*. Display will show "--"
3. Close clip on VSS-1 *(Fig. 2)*.

NOTE: The system's pump continues to run for 1 minute to allow heater to cool down.

4. After 1 minute, water pump shuts off and numeric display is blank. Unit may now be disconnected from power outlet.
5. Remove unit from patient care area and proceed to disinfection process.

CAUTIONS:
Avoid disconnecting from power or gas sources while machine is operating.

Do not unplug from power source until display is blank.

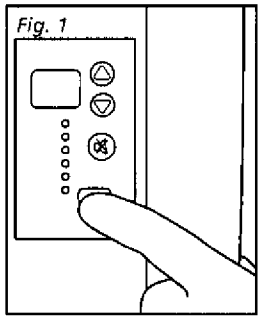


Fig. 1

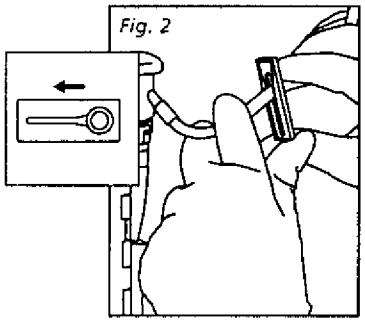


Fig. 2

Section 8 Routine Disinfecting Protocol

8.1 Disinfection Supplies

1. DK-301 (a-e included in kit)
   a. Disinfection Bag A
   b. Disinfection Bag B
   c. Disinfection Tube
   d. Cartridge Bypass Tubes
   e. Y-Spike Assembly
2. Gloves
3. Safety Glasses
4. Disinfectant wipes, 70-90% isopropyl alcohol
5. Approved Disinfectant
6. 1000ml Sterile Water Bag
7. Medical Grade Air Source
8. Standard adult flow meter with oxygen 7ft tubing attached

WARNINGS:
Vapotherm should be disinfected after each patient or every 30 days on a single patient. Do not disinfect in an open patient care area.

The DK-301 disinfection kit is a single use item. Operators should open a new disinfection kit for each disinfection procedure and discard the components at the end of the procedure.

Disinfection Procedure should be performed in a well ventilated area. Use Standard Precautions and aseptic techniques during this procedure.

The Vapor Transfer Cartridge SHOULD NOT be in place when disinfecting the unit.

The Vapor Transfer Cartridge is a single use disposable and must be discarded after each patient use. DK-301 IS NOT designed to disinfect Vapor Transfer Cartridges.

8.2 Pre-Cleaning Process

1. After patient use, it is recommended that the Vapotherm 2000i System remain attached to the IV pole with all the component parts intact.
2. Move the Vapotherm 2000i System to a hospital approved reprocessing area outside the patient care area.

WARNING: The water circuit of the Vapotherm 2000i System is not sterile and can potentially have bacterial contamination. The water circuit of the device should never be opened in a patient care area. Transport the Vapotherm 2000i System to an appropriate area for draining, cleaning and disinfection.

3. Wash hands and put on gloves.
4. Drain the Vapotherm 2000i System in a receptacle by cutting the delivery tube. *(Fig. 1)*
5. Remove and dispose of the delivery tube, cannula, VSS-1 spike set, and sterile water source.
6. Remove and dispose of the vapor transfer cartridge.

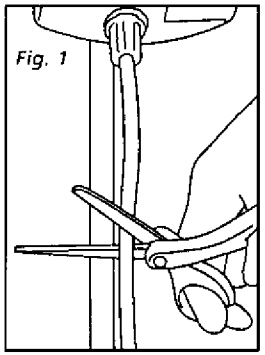


Fig. 1

WARNING: The water circuit of the Vapotherm 2000i system has the potential for bacterial growth so standard precautions should be used to open the water circuit. Disposable components should be disposed of in accordance with hospital guidelines and operators should wash their hands after breaking down the device.

8.3 Pre-Disinfection Cleaning and Decontamination

1. Wash hands and put on new gloves.

WARNING: Always use standard precautions when cleaning and disinfecting the Vapotherm 2000i system.

Always use individually wrapped 70-90% isopropyl alcohol disinfectant wipes when wiping down the Vapotherm 2000i and disinfection kit components.

Always use a new disinfectant wipe taken directly from the package or container and ensure that the disinfectant wipe has not dried out before using it on the Vapotherm 2000i device.

2. Wipe exterior casing including inside hinged cover with an approved disinfectant wipe. *(Fig. 2)*
3. Wipe inside and outside of the following connections with an approved disinfectant wipe:
   a. Four cartridge connection ports inside hinged cover (Upper and lower cartridge air tubes and the water connection ports)
   b. Water inlet and air inlet connectors on rear of unit
   c. Delivery tube port on the bottom of unit.

Fig. 2

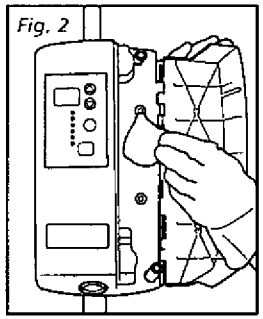
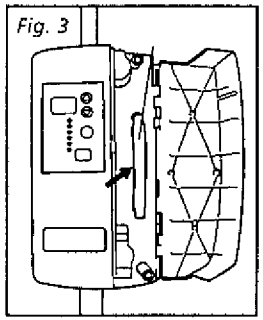


Fig. 3



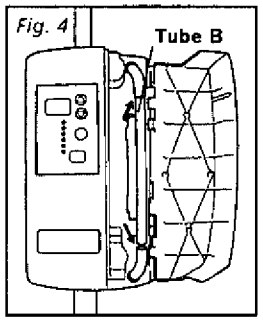
8.4 Set-up

1. Take the 4 inch bypass tube with 90° barb fittings (Bypass Tube A) and wipe the ends with an approved disinfectant wipe. Press firmly into the inner cartridge connection ports (water circuit). *(Fig. 3)*
2. Take the 6 inch bypass tube with straight barb fittings (Bypass Tube B) and wipe the ends with an approved disinfectant wipe. Insert firmly into outer upper and lower cartridge ports (air circuit). *(Fig. 4)*

WARNING: The By-pass Tubing has been designed to optimize the flow of solutions through the Vapotherm 2000i system. Failure to use the By-Pass Tubing supplied by Vapotherm™, Inc. could lead to improper disinfection and or drying.

3. Close hinged cover.
4. Prepare 200ml of approved disinfectant solution and add it to Bag A with slide clamp closed (see Appendix A – "Disinfection Solutions" for approved disinfection solutions, appropriate concentrations, and required hold times).

Fig. 4



WARNINGS:
Disinfection solutions, concentrations and hold times in Appendix A have been verified by independent laboratory testing to adequately disinfect the Vapotherm™ 2000i machine when following these instructions. Modifying this procedure or using an alternative disinfection solution, concentration, or hold time could result in inadequate disinfection thereby increasing the risk of contamination.

Always wear gloves when handling disinfectant solutions, work in a well ventilated area, and use an accurate measuring device to ensure the proper concentration of disinfection solution and water.

8.4 Set-up (cont.)

6. Hang Bag A with 200 ml of approved disinfecting solution from IV pole hook.
7. Wipe blue end of disinfection tube with an approved disinfectant wipe. Insert into bottom port of Vapotherm- 2000i system. Press firmly into place, rotate 1/4 turn clockwise, and pull down slightly to lock in position. *(Fig. 5)*
8. Wipe the other end of the disinfection tube with an approved disinfection wipe and attach it to the bottom outlet of Bag A. Lock into place. *(Fig. 6)*
9. Suspend Bag B on a separate hook on IV pole. Cap should be firmly closed to minimize potential spilling.
10. Attach Y-Spike Assembly by:
    a. Disinfect wipe male colder fitting end of Y- Spike Assembly and insert it into water inlet port on the back of the Vapotherm 2000i system. Lock into place. *(Fig. 7)*
    b. Disinfect wipe the O_2 bushing connector end of the Y-Spike Assembly. Attach connector to the air inlet connector port on the back of the Vapotherm 2000i system. *(Fig. 8)*
    c. Disinfect wipe the spike end of the Y-Spike Assembly and insert into bottom outlet of Bag B until it comes to a stop.

WARNING: If spike is not properly inserted, it may cause disinfectant to leak creating a potential safety risk. The spike should be inserted into Bag B up to the ridge at the bottom of the spike. Do not insert the spike past the ridge at the bottom of the spike.

NOTE: If the spike is inserted too far into Bag B it will be difficult to remove, do not insert the spike past the ridge at the bottom of the spike. If the spike is hard to remove from Bag B rotate the spike while removing it to make it easier.

Fig. 5

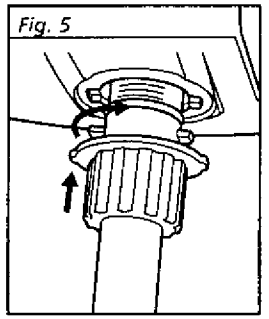


Fig. 6

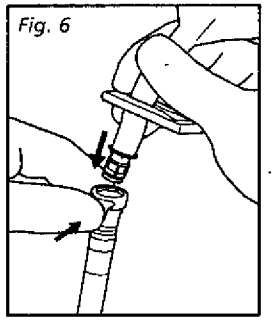


Fig. 7

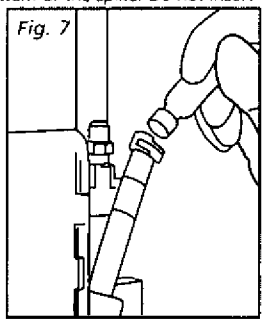
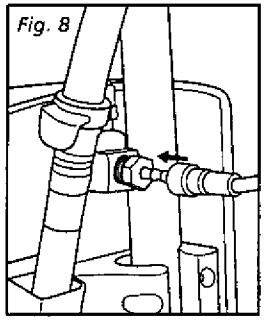


Fig. 8



8.5 Disinfect Gas and Water Circuits

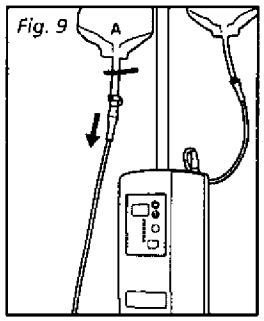


Fig. 9

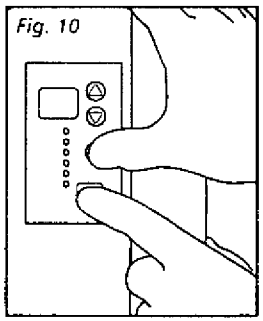


Fig. 10

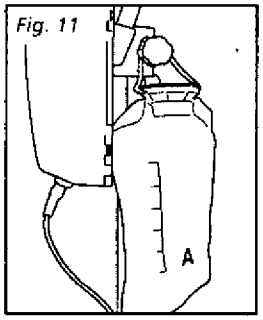


Fig. 11

1. Open clamp on Bag A. Disinfectant will start to drain from Bag A through the unit and into Bag B. *(Fig. 9)*
2. When disinfectant has stopped draining into Bag B, clamp Bag A.

NOTE: Not all contents from Bag A will drain into Bag B.

3. Start the Vapotherm 2000i system in cleaning mode by pressing the Mute and Power buttons at the same time *(Fig. 10)*. Disinfectant will circulate through gas and water circuits. Run unit in cleaning mode for the required hold time given in Appendix A for the disinfection solution used.

WARNING: Operating the Vapotherm 2000i system in cleaning mode for less than the required hold time may not adequately disinfect the machine and could lead to contamination of the air and water circuits thereby increasing the risk of infection.

4. After circulating disinfection solution through the machine for the appropriate hold time, turn the Vapotherm 2000i off by pressing the power button.
5. Unclamp and lower Bag A and hang onto Vapotherm i.v. pole clamp knob. *(Fig. 11)*
6. The disinfectant that was contained in reservoir Bag B, has circulated through the unit, and the circulated disinfectant solution drains into Bag A for collection and disposal.
7. Hang 1000 ml of pre-packaged sterile water on i.v. pole.
8. Loosen cap on Bag A to allow air to vent out of the bag as sterile water fills the bag.

WARNING: The disinfection procedure has been specifically designed to use 200 ml of disinfection solution and 1000 ml of sterile water. Bag A is designed to hold 1200 ml of solution. Using larger than the recommended volumes during disinfection or rinsing could cause a spill of diluted disinfection solution.

9. Close the clamp on Bag B, remove the spike, and discard the Bag B in accordance with all applicable regulations and institutional guidelines.
10. Wipe spike with an approved disinfectant wipe and firmly insert into the spike port of a prepackaged sterile water bag. Confirm that water is flowing.
11. Immediately start the Vapotherm 2000i in cleaning mode by pressing the Mute and Power buttons at the same time. (Fig. 10)
12. Run the cleaning mode to circulate the sterile water through the Vapotherm 2000i system until all the water has drained from the sterile water bag. Immediately turn off the system.

CAUTION: Running the system dry can damage the water pump.

13. Clamp tubing and close cap on Bag A and disconnect the bag from the disinfectant tube.

WARNING: Failure to clamp off or close the cap of Bag A firmly before disconnecting it from the disinfection tube could cause diluted disinfection solution to spill.

8.5 Disinfect Gas and Water Circuits (cont.)

14. Leave all DK-301 tubing connected to the Vapotherm system.
15. Dispose contents of Bag A in accordance with all applicable regulations and institutional guidelines.

8.6 Drying

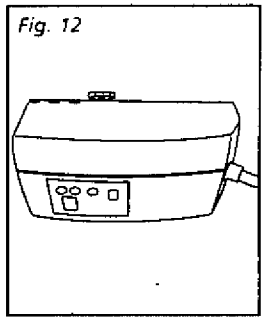


Fig. 12

1. Ensure that the Disinfectant Tube, Cartridge Bypass Tubes and the Y-Spike Assembly are all in place.

CAUTION: In order to dry the Vapotherm 2000i system, the Disinfectant Tube, Bypass Tubes and the Y-Spike Assembly must all be connected to the Vapotherm 2000i system.

2. Remove the spike from the empty sterile water bag and wipe with an approved disinfectant wipe.
3. Insert spike from Y-Spike Assembly into standard oxygen tubing.
4. Set flowmeter to 15 lpm.
5. Take the Vapotherm 2000i system and position the system flat on its side opposite the cartridge door for 2 minutes. *(Fig. 12)*
6. After 2 minutes attach the Vapotherm® 2000i device back on the IV Pole and continue to dry at 15 lpm for 25 minutes.
7. After a minimum of 25 minutes, disconnect the disinfection tube, the cartridge By-Pass tubing and Y-spike assembly and close the door to the cartridge area for storage. Discard all components of the DK-301 kit in accordance with all applicable regulations and institutional guidelines.
8. Wipe down exterior casing with disinfectant wipe.
9. Place a sticker over the cartridge access door to certify that the device has been disinfected.
10. Log the disinfection procedure on a Vapotherm 2000i Disinfection Log Sheet or in a similar log approved by your institution. Appendix B has a Sample Disinfection Log. The Disinfection Log can be accessed and printed out at www.vtherm.com.
11. Place the system in a clean plastic cover and seal the end by tying a knot or a clip.
12. The system is now ready for use or storage.

CAUTION: Do not set the flowmeter above 35 lpm or start the drying process without the disinfecting tube in place. This can cause damage to the pressure transducers in the Vapotherm 2000i system.

WARNING:

Gram (-) bacteria can grow in moist environments. The Vapotherm 2000i system should not be stored with visible water remaining in the device.

Vapotherm should be disinfected after each patient or every 30 days on a single patient. Do not disinfect in an open patient care area.

The DK-301 disinfection kit is a single use item and must be discarded after the disinfection procedure.

Section 9 General Information

9.1 Specifications

Dimensions:	Height 11" (280 mm), width 5.5" (140 mm), depth 4.5" (114 mm) excluding IV pole clamp.
Weight:	Less than 6 lbs (2.7 kg) without water reservoir.
Vapotherm spike set:	Works with sterile water bags up to 2000 ml bag.
Circulating water volume	<100 ml. (excluding Patient Patient Delivery Tube).
Mounting:	Rear mounted clamp fits standard IV pole or hanger.
Power:	(US) 115 V, 60 Hz, 250 VA (warm up), approximately 80 VA (continuous). (Other versions) 220–240 V, 50–60 Hz, 250 VA (warm up), approximately 80 VA (continuous).
Gas source pressure:	4–50 psi. At high pressures (e.g. hospital wall system) the Vapotherm 2000i must be connected to the gas outlet via a standard medical flowmeter and flow regulator with approved fittings.
Gas flow:	Controlled by external flowmeter. Operating range 1–40 lpm, dependent on cartridge type and patient interface used.
Output gas temperature:	(US) 33–43°C at outlet of the delivery tube, adjustable by front panel settings. (Other versions) 33–41°C.
Humidification:	Vapor phase, by transpiration through microporous membrane. Output is at least 95% relative humidity at nasal cannula at a flow rate up to 20 lpm, at least 90% at flow rates from 20–40 lpm, over the full range of operating conditions.

9.2 Definitions and symbols

Type BF Class 1 | Attention Consult Manual | Silence Alarms | Power On/Off | Alternating Current | Single Patient Use

CE 0297

Section 10 Warranty

Vapotherm, Inc warrants that the Vapotherm™ 2000i shall be free of defects of workmanship and materials and will perform in accordance with the product specifications for a period of one year from the date of sale by Vapotherm, Inc. If the product fails to perform in accordance with the product specifications, Vapotherm, Inc. will repair, or replace, at its option, the defective materials or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

VAPOTHERM, INC. DISCLAIMS ALL LIABILITY FOR ECONOMIC LOSS, LOSS OR PROFITS, OVERHEAD OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY SALE OR USE OF THIS PRODUCT. THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES.

- Bamford, Owen and Lain, David. Verification of the Bacteriological Filtration Properties of the Vapotherm Cartridge. Respiratory Care November 2004. Vol. 49 No.11
- CDC, Guideline for prevention of nosocomial pneumonia. MMWR 1997:46 (NO. RR-1)
- CDC, Guidance for Isolation Precautions in Hospitals. Garner, Julia. January 1996. Retrieved May 26, 2006, from http://www.cdc.gov/ncidod/dhqp/gl_isolation.html
- Standard Precautions: CDC, Excerpted from Guideline for Isolation Precautions in Hospitals (January 1996) Retrieved May 26, 2006 from http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html

Appendix A – Disinfection Solutions

This appendix lists approved disinfectant solutions and the required hold times necessary to disinfect the Vapotherm 2000i machine using the routine disinfection procedure outlined in the Vapotherm 2000i Manual Rev B, Section 8. The following disinfectants have been independently tested by an ISO compliant FDA registered lab using "good laboratory practices" (GLP):

Manufacturer	Active Ingredients	Trade Name	Concentration	Hold Time*
Minntech Corporation 14605 28th Avenue North Minneapolis, MN 55447 (800) 328-3345	Hydrogen Peroxide 22% and Peracetic Acid 4.5%	Minncare™	1%	10 minutes at 20°C
Maril Products Inc. 320 West 6th Street Tustin, CA 92780 (800) 546-7711	Dimethyl Benzyl Ammonium Chloride 10% and Dimethyl Ethyl Benzyl Ammonium 10%	Control 3™	1%	10 minutes at 20°C

*Section 8 Step 4 of the Vapotherm 2000i Operating Manual requires approved disinfection solutions to be circulated through the device for an appropriate hold time as outlined in this column of Disinfection Appendix A.

WARNINGS:
These disinfectant solutions are designed to be used to disinfect the Vapotherm 2000i machine without the cartridge in place. These disinfectant solutions ARE NOT approved to disinfect the cartridge.

Failure to properly prepare the disinfection solution or circulate the disinfection solution throughout the machine for the appropriate hold time could result in inadequate disinfection.

Disinfectants must be used at proper concentrations. User must confirm solution has been mixed according to disinfectant manufacturers instructions, or used in pre-diluted form.

Solutions must not be used past their expiration dates See disinfectant manufacturer's product labeling for instructions.

Appendix A – Disinfection Solutions (cont.)

Dilution Instructions for preparing a 1% solution of Minncare® and Control III®

Supplies Needed:

- A beaker, graduated cylinder, or container suitable for measuring and mixing 200ml of disinfectant solution

WARNING: Components or instruments that are not part of the DK-301 Kit and are used to mix or pour disinfectant solutions should be either single use components or glassware that has been sterilized, high level disinfected, or pasteurized before use in accordance with your institution's specific disinfection and sterilization procedures.

- 10ml syringe, or pipette, graduated in 1ml increments
- Concentrate Disinfectant
- Minncare® Cold Sterilant EPA Reg No. 52252-4 (22.00% Hydrogen Peroxide, 4.50% Peroxyacetic Acid, 73.50% Inert Ingredients)
- Control III® Disinfectant P/N 10006 (10% n-alkyl dimethyl benzyl ammonium chloride, 10% n-aykyl ethyl benzyl ammonium chloride, 80% inert ingredients)
- 200 ml of sterile water

WARNINGS:
Always follow manufactures recommendations for handling disinfectant solutions.

Always wear Personal Protective Equipment when handing disinfectant solution.

Procedure:

1. Don appropriate Personal Protective Equipment: Safety goggles, gloves, splash apron.
2. Using an appropriate syringe or pipette, draw up 2 ml of undiluted Minncare® (EPA Reg No. 52252-4) or Control III® (P/N 10006) and expel it in a device appropriate for measuring 200 ml of solution.
3. Make up 200 ml of solution by adding sterile water to the measuring device.
4. Close the slide clamp on Disinfection Bag A and pour disinfectant solution into the bag.
5. Close the cap of Bag A firmly, to avoid spills and continue with Step 6 in Section 8.4 of the disinfection procedure (Page 18).
6. Attach to IV Pole and Vapotherm 2000i according to Disinfection procedure and continue to follow Disinfection Protocol.

Appendix B – Sample Disinfection Log

Vapotherm 2000i Machine Serial No.	Hospital ID (If Applicable)	Disinfection Date	Disinfectant Solution & Hold Time	Operator

VAPOTHERM

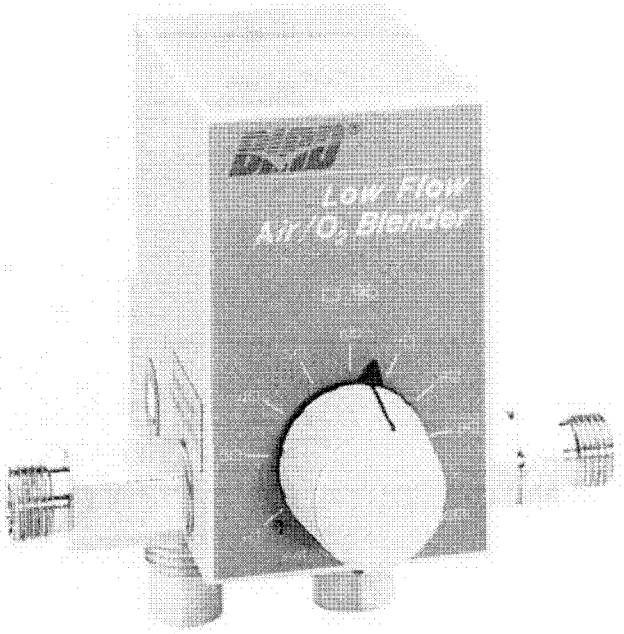
Supplied by

Vapotherm, Inc.
198 Log Canoe Circle, Stevensville MD 21666
T: (001) 410.604.3977 F: (001) 410.604.3978 www.vtherm.com

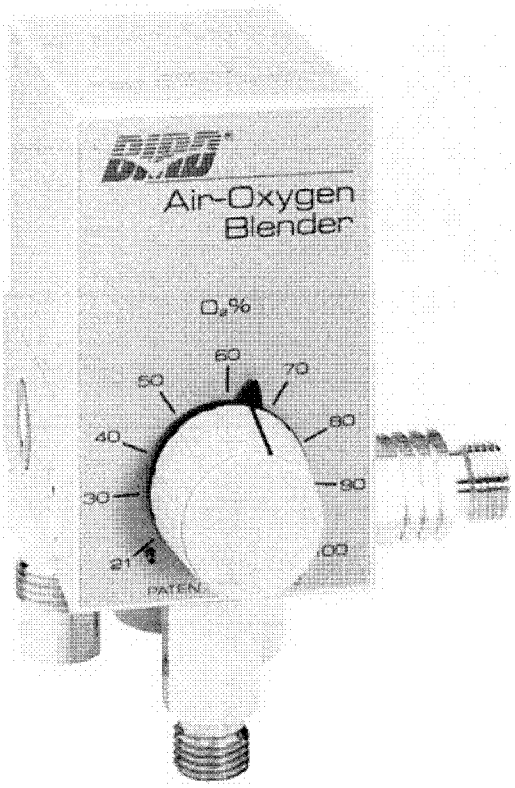
PN 8-300068-00 Rev. E
bdc 8369

Instruction Manual

Low Flow MicroBlender



High Flow MicroBlender



VIASYS®
HEALTHCARE

L2965-51 Rev B

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VIASYS Respiratory Care Inc.
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Palm Springs, CA 92262-8099

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Fax: (714) 283-2228

www.viasyshealthcare.com

CONTENTS

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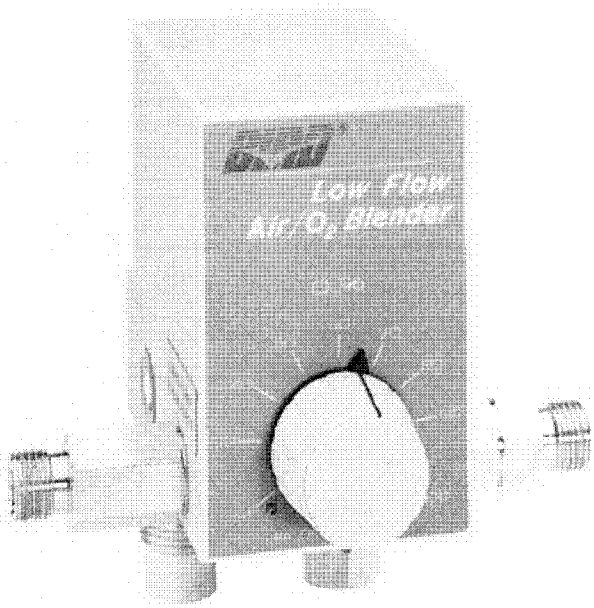
SECTION 1
INTRODUCTION

The MicroBlender is a lightweight, compact, air-oxygen blender that provides precise mixing of medical-grade air and oxygen.

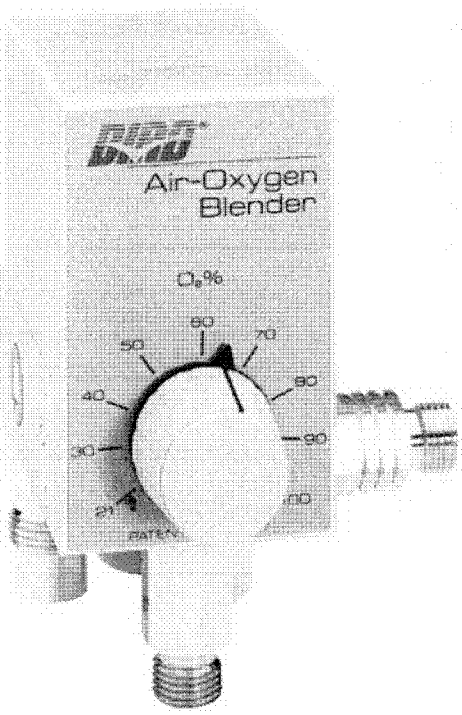
The MicroBlender provides oxygen concentrations from two gas-outlet ports.

The MicroBlender can be used in conjunction with:

- Oxygen hoods
- Resuscitation bags
- Masks
- Transports
- Nasal cannulas
- Treatments



Low Flow MicroBlender



High Flow MicroBlender

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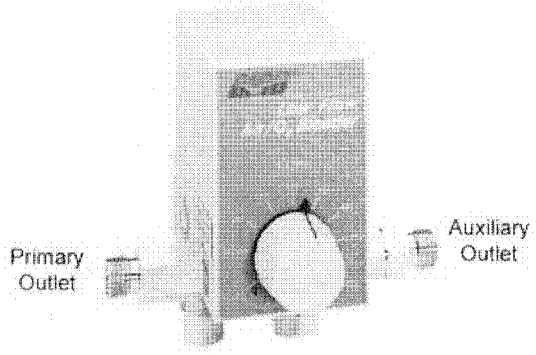
SECTION 2
OPERATION OVERVIEW

The MicroBlender provides selection of oxygen concentrations by means of a single control knob located on the front of the unit. Oxygen concentrations ranging from 21 to 100% are available.

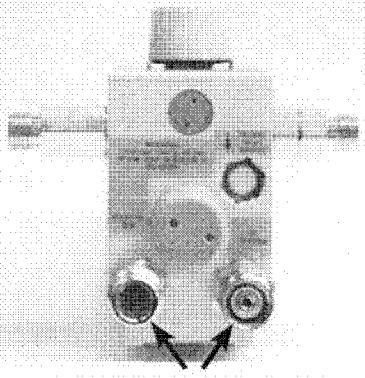
	Outlet	Flow Range	Bleed Flow
Low Flow MicroBlender	Primary, Left Side	3-30 LPM	No Bleed Flow
	Auxiliary, Right Side	0-30 LPM	2.5-3.5 LPM
High Flow MicroBlender	Primary, Bottom	15-120 LPM	No Bleed Flow
	Auxiliary, Right Side	2-100 LPM	10-12 LPM



Low Flow MicroBlender Outlets

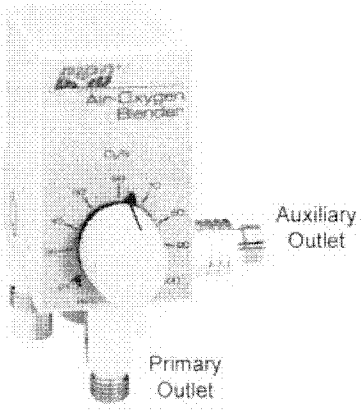
GAS INLETS

The ports located on either side of the unit allow flexibility for the clinician. The MicroBlender operates by using two 30–75 PSI gas sources that enter the device through DISS or NIST connectors located on the bottom the unit.



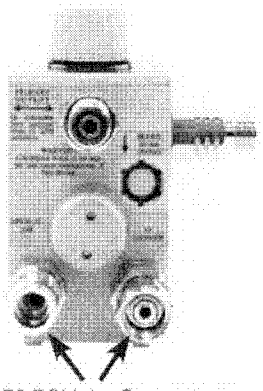
30 - 75 PSI Inlet Connectors

Air and oxygen hoses are connected directly onto the MicroBlender gas inlets.



High Flow MicroBlender Outlets

Each inlet connector incorporates a 30 micron particulate filter. After passing through the filter, the gases travels through duckbill check valves that prevent reverse gas flow from either the air or oxygen supply systems.



30 - 75 PSI Inlet Connectors

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The MicroBlender is tested for compliance with ISO 11195E (1995), clause 6, regarding reverse-gas flow as delivered.

BALANCE MODULE

The gases then enter the balance modules, which equalize the operating pressures of the air and oxygen. The diaphragm in the balance module responds to a difference in pressure and directs the movement (stroke) of each poppet contained within the air and oxygen chambers. The movement of each poppet adjusts the amount of gas flowing through the balance module, equalizing the air and oxygen pressures.

PROPORTIONING MODULE

From the balance module, the gases flow into the proportioning module and mix according to the oxygen percentage selected with the MicroBlender control knob. This module consists of a double-ended poppet positioned between two valve seats.

One valve seat controls the passage of air and the other valve seat controls the passage of oxygen into the MicroBlender outlets. At this point, the two gases have been blended according to the oxygen percentage selected by the control knob.

ALARM/BYPASS

The alarm feature provides for an audible alarm if source pressures differ by 20 $\pm$ 2 PSI or more. The primary purpose of the alarm is to audibly warn the operator of an excessive pressure drop or depletion of either source gas. The alarm will also activate when there is an elevation of either source gas resulting in a 20 $\pm$ 2 PSI difference. Should both gas pressures (oxygen or medical air) increase or decrease simultaneously, and a 20 $\pm$ 2 PSI differential is not seen, there will not be an audible alarm. If either source gas pressure drops, the output pressure of the blender will drop similarly, since the source gases are always balanced to that of the lower pressure.

The bypass function operates in unison with the alarm. The alarm bypass poppet communicates directly with the air supply on one end and the oxygen supply on the other.

When the two source gases are near equal in pressure, the alarm bypass poppet is positioned over the bypass channel, blocking the flow of both gases. The poppet will remain seated for unequal pressures up to 20 $\pm$ 2 PSI. Once a 20 $\pm$ 2 PSI difference occurs, the higher gas pressure will overcome the spring force and pressure of the poppet at its opposite end, thus creating a path (air or oxygen) to flow into the alarm channel.

The gas with the higher pressure will also flow directly to the blender outlet port bypassing the Balance and Proportioning Modules. The gas is also directed to the bottom of the unit to the reed alarm, thus creating an audible warning. The oxygen concentration will be that of the gas at the higher pressure. The blender in the alarm/bypass mode will deliver the oxygen (100%) or medical air (21%) until the pressure has been restored to a differential of approximately 6 PSI.

If the blender is set at 21% and the OXYGEN source pressure is reduced enough to produce a 20 $\pm$ 2 PSI or greater differential, the unit may not alarm because it will continue to deliver 21% concentration according to the setting. If the control is moved slightly from the 21% setting, the alarm will sound.

Similarly, if the blender is set to deliver 100% concentration and AIR source pressure is reduced or lost, the unit may not alarm because it will continue to deliver the selected 100% concentration.

If the blender is left connected to source gases but is not being used (i.e., no output flow or bleed flow) the unit will not alarm if a 20 $\pm$ 2 PSI or greater pressure differential develops. If the blender is not in use, an alarm under these conditions will be an unnecessary distraction or nuisance.

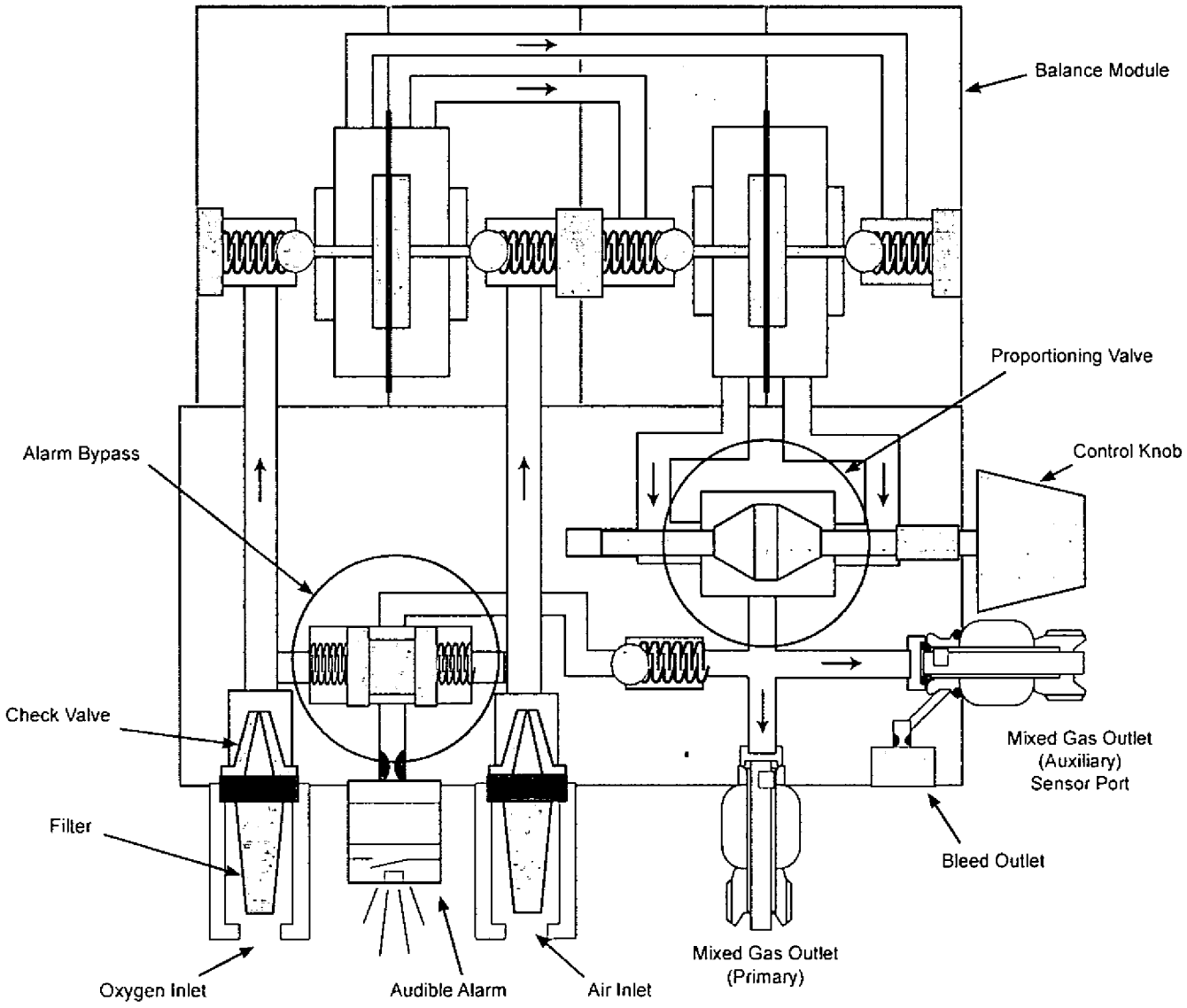
OUTLET PORTS

On the Low Flow MicroBlender, two outlet ports are located on the right and left sides of the MicroBlender and allow low ranges from 0-30 LPM with bleed and 3 - 30 LPM without bleed respectively. On the High Flow MicroBlender, the primary outlet port is located on the bottom of the MicroBlender, and the auxiliary outlet is located on the right side of the MicroBlender, allowing ranges from 15 to 120 LPM without bleed and 2 to 90 LPM with bleed respectively.

BLEED OUTLET

For the Low Flow MicroBlender, when a connection is made to the right side outlet port, for example, when a flow meter is attached, a bleed flow of 2.5- 3.5 LPM is achieved. For the High Flow MicroBlender, when a connection is made to the right side outlet port, a bleed flow of 10-12 LPM is achieved. For both Blenders, the bleed flow exits the unit through a muffler port located on the bottom of the MicroBlender.

High Flow MicroBlender



SECTION 3
WARNINGS, CAUTIONS, AND NOTES

The MicroBlender should be operated by trained, qualified medical personnel under the direct supervision of a licensed physician. Before clinical application, the following WARNINGS, CAUTIONS and NOTES should be read and understood.

WARNING!
Conditions may exist that could adversely affect the operator or patient.

CAUTION!
Conditions may exist that could damage the MicroBlender or other pieces of equipment.

NOTE
A specific point is made to assist the operator in understanding the equipment.

WARNING!

- If either the air or oxygen gas source fails, the MicroBlender alarm sounds, alerting the clinician that a condition has occurred that may significantly alter the FiO_2 and flow output from the MicroBlender.
- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 20 $\pm$ 2 PSI, the MicroBlender alarm sounds. This condition significantly alters the FiO_2 and flow output from the MicroBlender.
- Always operate the MicroBlender with clean and dry medical grade gases.
- Air Inlet Filter/Water Trap (P/N 07426) is recommended for use with the MicroBlender.
- The patient gas must be monitored with an oxygen analyzer.
- DO NOT steam clean, autoclave, or otherwise subject the MicroBlender to temperatures above 145°F (62°C).
- DO NOT immerse the assembled MicroBlender in liquid decontamination agents.
- Consult a physician for appropriate FiO2 setting.
- DO NOT tape, obstruct, or remove the reed alarm outlet at any time.
- DO NOT occlude or obstruct the bleed port or muffler on the bottom of the MicroBlender.
- Adjustment of the oxygen concentration must be verified using an oxygen analyzer.

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CAUTION!

- Always operate air/oxygen blenders with clean and dry medical grade gasses. Contaminant or moisture can cause defective operation. Air used for medical purposes must meet USP compressed air and/or ANSI Z86.1 1973 grade F, and water vapor content must not exceed a blenders dew point of 5°F below the lowest ambient temperature to which the delivery system is exposed. Particulate content must not exceed that which would be down stream of a 15 micron absolute filter.

- Water vapor content of medical air or O_2 supply to the MicroBlender must not exceed 5.63 grams H_2O per cubic meter of non-condensable gas.

NOTE

- Users are advised to use inlet pressure regulators with the MicroBlender to display system pressure.

- Allow equilibration time for FiO_2 changes before analyzing gas.

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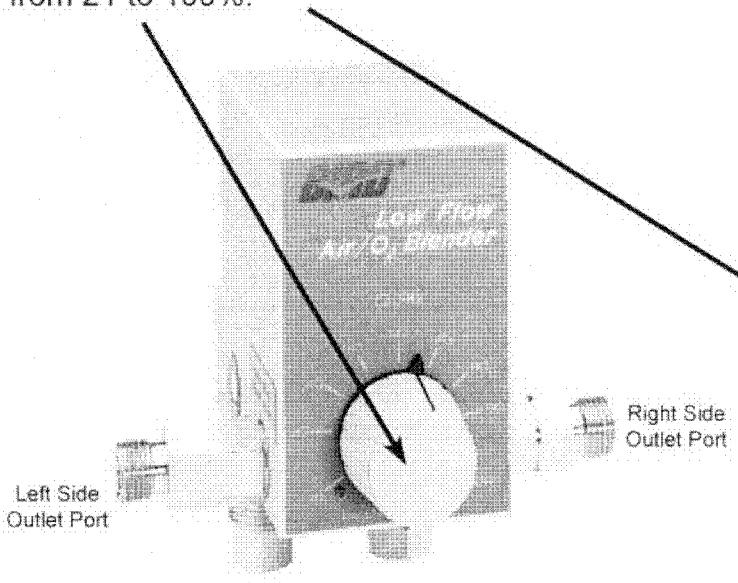
SECTION 4
CONTROLS AND ALARMS

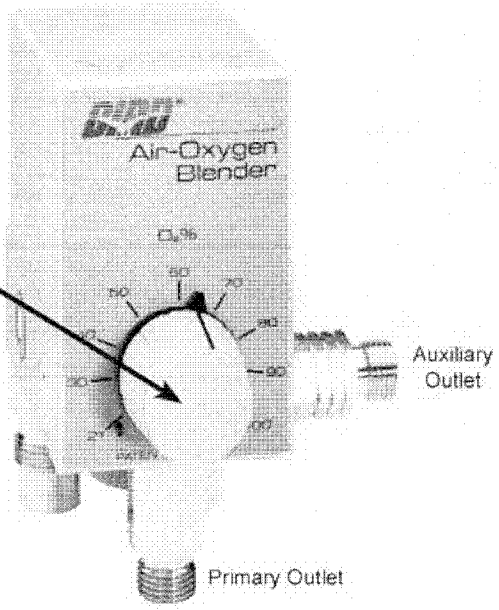
The MicroBlender delivers selected oxygen concentrations through two outlet ports. The outlet ports, although similar in appearance, have different flow range specifications. The two outlet ports provides a choice of flow ranges based on the application desired. Both outlets may be used simultaneously, provided the combined flows do not exceed the rated maximum flow capability of the MicroBlender. The use of a flow meter attached to either or both of the outlet ports may be used to control the flow of mixed gas.

CONTROL KNOB
Allows the selection of oxygen concentrations from 21 to 100%.

ALARM
An audible alarm indicates a differential of 20 PSI has been reached between air and oxygen inlet gas pressures.



Front View of the Low Flow MicroBlender



Front View of the High Flow MicroBlender

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SECTION 5
PERFORMANCE CHECKS

Before placing the MicroBlender into clinical use, perform the following performance checks.

WARNING!
If the MicroBlender does not function as described below, contact VIASYS Respiratory Care (refer to the company information at the beginning of this manual).

DO NOT use the MicroBlender until correct performance is verified.

Low Flow MicroBlender Alarm / Bypass Check Reverse Flow Check

Adjustment	Response
1. Applying 30 -75 PSIG air/oxygen source gas. Adjust the control knob to 60%	1. Alarm/Bypass* should not activate (if gases are within 20 PSI of each other).
2. Disconnect the 50 PSIG air source from the MicroBlender.	2. Audible alarm, by pass* gas flow starts.
3. Reconnect the 50 PSIG** air source to the MicroBlender.	3. Audible alarm stops; bypass* gas flow stops flowing.
4. Disconnect the 50 PSIG** oxygen source from the MicroBlender.	4. Audible alarm, bypass* gas flow starts.
5. Reconnect the 50 PSIG** oxygen source to the MicroBlender.	5. Audible alarm stops; bypass* gas flow stops flowing.
6. Connect a flow meter and an oxygen analyzer to either outlet port; with the MicroBlender control knob set at 60%, adjust the outlet flow rate to 6 – 8 LPM.	6. Oxygen ana lyzer should read 60 ± 3% when measured from the flow meter outlet.

*Bypass flow should occur whenever the alarm sounds, but this condition can only be verified by measuring O_2 concentrations with an oxygen analyzer.
**Gas supply pressures of 50 PSIG provide optimal performance.

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High Flow MicroBlender Alarm / Bypass Check

Adjustment	Response
1. Connect the 50 +/- 5 PSIG* air/ oxygen source gases. Adjust the control knob to 60%. Connec t the flowmeter to the auxiliary outlet and set the flow to 2 LPM.	1. Alarm/Bypass should not activate.
2. Connect an oxygen flowmeter to the auxiliary outlet to activate the auxiliary bleed and disconnect the 50 PSIG* air source from MicroBlender. **NOTE**: The MicroBlender must be flowing gas for the alarm to activate.	2. Audible alarm
3. Reconnect the 50 PSIG* air source to the MicroBlender.	3. Audible alarm stops. Verify oxygen concentration with an oxygen analyzer.
4. Disconnect the 50 PSIG* oxygen source from the MicroBlender.	4. Audible alarm.
5. Reconnect the 50 PSIG* air source to the MicroBlender.	5. Audible alarm stops. Verify oxygen concentration (57% to 63%) with an oxygen analyzer.
6. Verify that the oxygen flowmeter is set at 2 LPM.	6. Oxygen analyzer should read 57 to 63% when measured from the flowmeter outlet

Reverse Flow Check

1. Connect both gas supply hoses to the inlet connectors.

2. Connect the oxygen hose to an oxygen pressure regulator, and submerge the free end of the air hose in a container of water.

   Do not make a connection to either outlet (so that they remain closed).

3. Slowly adjust the oxygen pressure regulator to increase pressure from 0 to 50 PSIG* while looking for bubbles to rise from the submerged air hose connector.

   The presence of bubbles indicates leakage of the one-way valve and the need for repair.

4. If there is no leakage, disconnect the oxygen from the regulator and submerge the end of the hose in water.

5. Connect the air hose to an air pressure regulator and repeat the procedure. Repair if bubbles are present.

*Gas supply pressures of 50 PSIG provide optimal performance.

SECTION 6
TROUBLESHOOTING GUIDE

PROBLEM	POTENTIAL CAUSE	CORRECTIVE ACTION
Oxygen concentration discrepancy between MicroBlender settings and analyzer.	1. Analyzer out of calibration.	1. Calibrate the analyzer
	2. Flow requirements are below the specified LPM range.	2. Correct the flow. Verify that the correct outlet port is being used. Each outlet port has a different flow range.
	3. Gas supply is contaminated.	3. Correct the contaminated gas supply. If repair is needed, contact VIASYS Respiratory Care
	4. MicroBlender is out of calibration.	4. Contact VIASYS Respiratory Care for repair.
	5. Bleed filter is obstructed, causing reduction of bleed.	5.Contact VIASYS Respiratory Care
	6. Air entrained into circuit by ventilator or accessory device.	6. Correct
Alarm sounding	1. Inlet pressure difference greater than 20 PSI.	1. Correct the pressure difference.
	2. Alarm module is not calibrated properly.	2. Contact VIASYS Respiratory Care for repair.
	3. Inlet gas contamination, alarm module malfunction.	3. Contact VIASYS Respiratory Care for repair.
MicroBlender in bypass - no alarm.	Reed plate improperly installed or damaged.	Contact VIASYS Respiratory Care for repair.
MicroBlender is accurate only when inlet gas pressures are equal.	1. Balance module not functioning properly.	1. Contact VIASYS Respiratory Care for repair.
	2. Both air and oxygen gas sources are below 30 PSIG.	2. Correct the low pressure condition.

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SECTION 7
CLEANING AND STERILIZING

NOTE
User is to consult with the manufacturer of the ETO equipment for aeration time.

- Use an all purpose liquid cleaner on the exterior.
- **Do not** steam autoclave or otherwise subject the MicroBlender to temperatures over 145° F.
- **Do not** immerse the assembled Low Flow MicroBlender in liquid decontamination agents.
- **Do not** use any strong solvent cleaners on labels or markings.

Blenders manufactured by VIASYS Respiratory Care are compatible with ethylene oxide gas sterilization.

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SECTION 8
MAINTENANCE AND SERVICE

CAUTION!
The MicroBlender should only be serviced or calibrated by a VIASYS Respiratory Care trained technician.

CAUTION!
If the MicroBlender does not function as outlined in Section 5, contact VIASYS Respiratory Care for service.

VIASYS Respiratory Care equipment is designed to provide the maximum amount of utilization with a minimum amount of maintenance. When determining the desired frequency of complete overhaul intervals, three variables must be considered:

- Frequency of use
- Cleanliness of compressed air source
- Use of an air inlet filter/water trap

The MicroBlender, like other pieces of health care equipment, will require routine maintenance over a period of time. Before placing the MicroBlender into clinical use, follow the performance-check guidelines outlined in Section 5.

When using the MicroBlender with a compressed air source, an air inlet filter/water trap (P/N 07426 or equal) is recommended. Contaminants from hospital air lines may compromise the function of the MicroBlender.

Applicable parts used in the MicroBlender have been cleaned and de-greased for oxygen service. All lubricants used during assembly are designed for use in an oxygen enriched environment. Use only VIASYS Respiratory Care specified lubricants when servicing this device.

Elastomer components, such as diaphragms and o-rings, are designed to function satisfactorily for a minimum of two years. The need for cleaning and replacement depends on gas line conditions and is indicated by the MicroBlender not meeting its specified performance. Three years is considered the maximum service interval under the best circumstances.

SECTION 9
PARTS AND ACCESSORIES

Parts and Accessories	
MicroBlender BRACKETS	
Part No.	**Description**
04322	Pole Mount 1 w/ Female Dovetail
05141	Dovetail Bracket, Accepts Built -in Bracket
05213	Dovetail Bracket, Wall Mount Female
09437	Rail Mount Adapter Bracket
OPTIONAL ACCESSORIES	
Part No.	**Description**
00060	Oxygen Supply Hose, 15 ft.
00066	Elbow Adapter 90°
01468	Y-Connector 9/16 – 18 Female and Male Threads for Dual Flow Meters
02899	Air Supply Hose, 15 ft.
03867	Air Supply Hose, 3 ft.
07426	Air Inlet Filter/Water Trap

SECTION 10
EXPLANATION OF ABBREVIATIONS

Air/O_2 - Mixture of Compressed Air and Oxygen

°C - Degrees Centigrade

CGA - Compressed Gas Association

DISS - Diameter Indexed Safety System

°F - Degrees Fahrenheit

FiO_2 - Fractional Concentration of Inspired Oxygen

O_2 - Oxygen

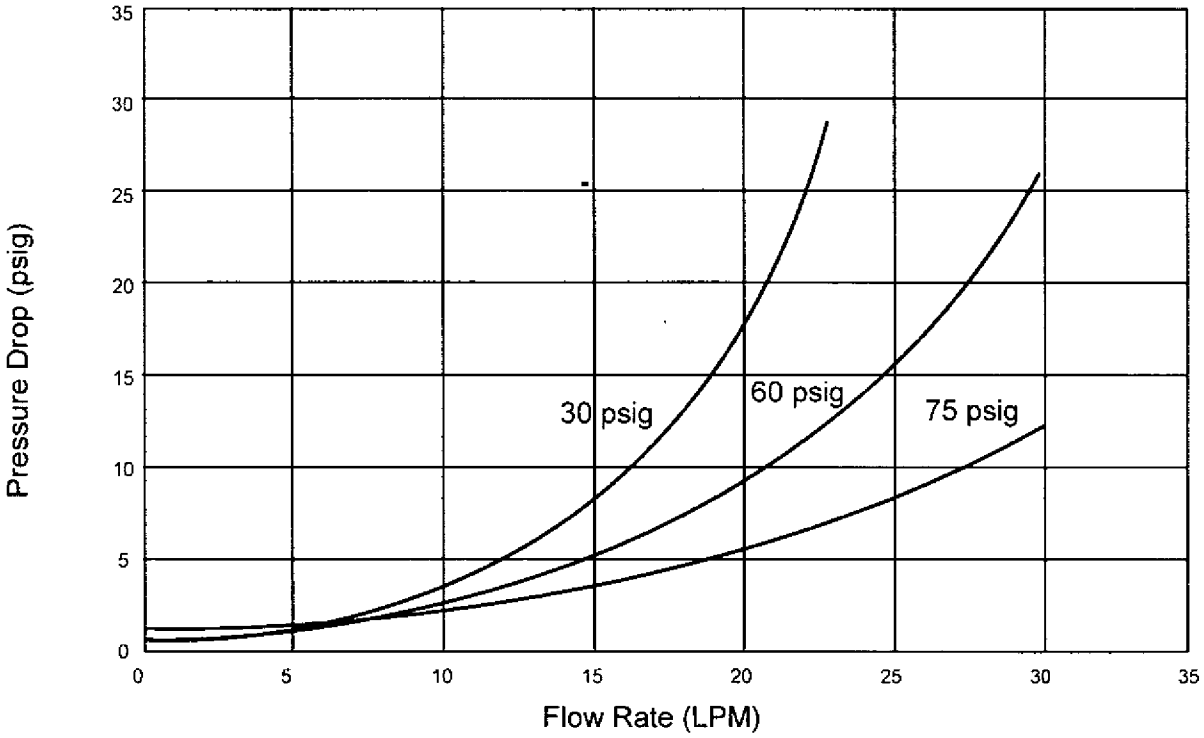
LPM - Liter Per Minute

P/N - Part Number

PSIG - Pounds Per Square Inch Gauge

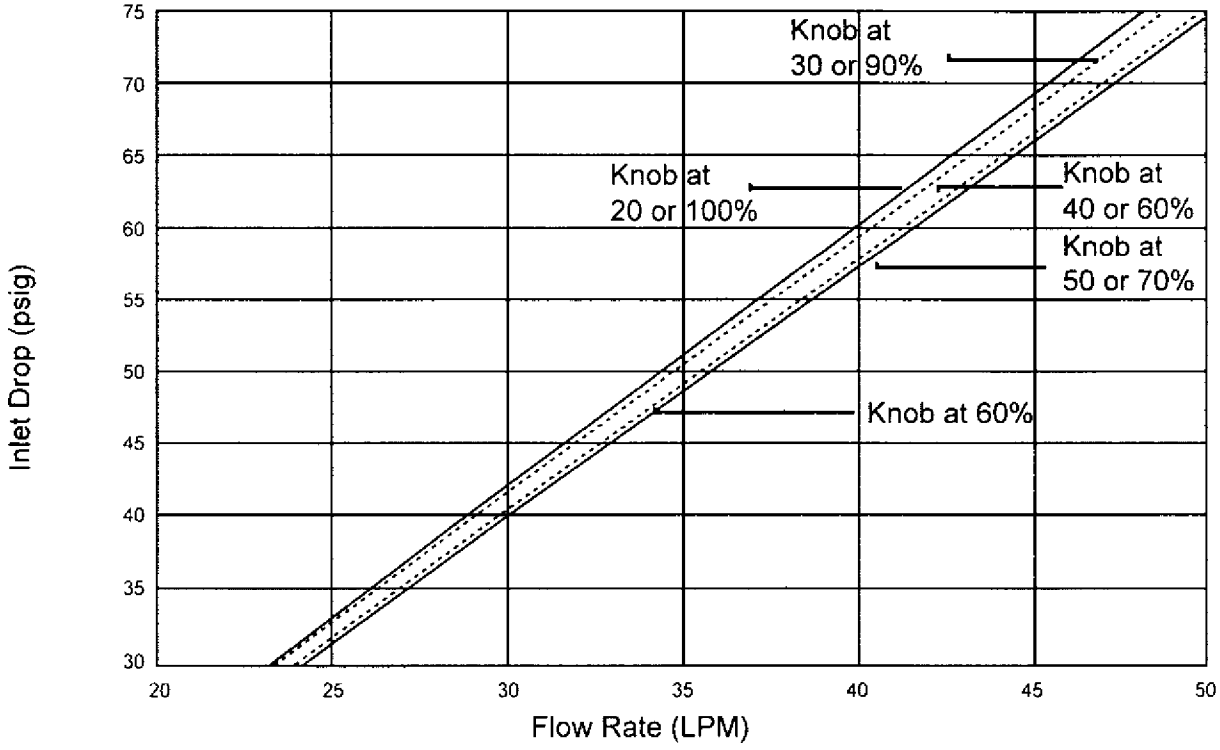
Do not operate the MicroBlender outside the supply pressure range (30–75 PSIG). Gas supply pressures of 50 PSIG provide optimal performance. The graphs on the following page illustrate typical flow performance characteristics of a representative sample for the Low Flow MicroBlender. The graphs are typical of a representative sample; slight variations among units should be expected.

654



Outlet Pressure Drop at Flow

Note: The graphs are typical of a representative sample; slight variations among units should be expected.



Average Outlet Flow at Various Inlet Pressures

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Gas Supply Pressure	Low Flow	30-75 PSIG (Air and Oxygen must be within 20 PSI of each other)
	High Flow	30-75 PSIG The MicroBlender will maintain stated accuracy at supply pressure, provided the differential between supply pressures does not exceed 10 PSIG. Output flow rate will be diminished if either supply pressures is below 50 PSIG and will be increased if both supply pressures are above 50 PSIG.
Oxygen Concentration Control	Low Flow	21 to 100%
	High Flow	
Outlet Port Flow Ranges		
Auxiliary Outlet	Low Flow	Right Side Outlet 0-30 LPM (Bleed 2:5 -3.5 LPM)
	High Flow	Right Side Outlet 2-100 LPM (Bleed 10 -12 LPM)
Primary Outlet	Low Flow	Left Side Outlet 3-30 LPM (No Bleed)
	High Flow	Bottom Port 15-120 LPM (No Bleed)
Maximum available flow at 60% setting with 50 PSIG both inlets	Low Flow	>30 LPM
	High Flow	>120 LPM
Accuracy	Low Flow	With inlet gases within 17 PSIG , and each gas pressure greater than 30 PSIG (but less than 75 PSIG). The FiO_2 remains constant within ±1% of set value (total set point error is ±3% full scale).
	High Flow	With inlet gases within 10 PSIG and each gas pressure greater than 30 PSIG but less than 75 PSIG; +/-3% of full scale over the stated flow ranges
Stability	Low Flow	±1% (for a fixed concentration setting when operated within specified flow and supply pressure limits)
	High Flow	O_2 concentration shall not vary form a set -point by more than ±1.0 O_2% if either the upstream pressure of the output flow rate is changed within its range specified herein
Alarm/Bypass Activation	Low Flow	When inlet gas pressures differ by 20 PSI ± 2 PSI
	High Flow	

K56

Alarm Sound Generator	Low Flow	Reed Alarm
	High Flow	
Alarm Sound Intensity	Low Flow	80 dB minimum at 1 foot
	High Flow	80 dB minimum at 1 foot
Alarm/Bypass Reset	Low Flow	When inlet gas pressure differential is 10 PSI or less
	High Flow	When inlet gas pressure differential is 6 PSI or less
Pressure Drop	Low Flow	Less than 6 PSI at 50 PSIG inlet pressures and 10 LPM flow rate
	High Flow	Less than 6 PSI at 50 PSIG inlet pressures and 40 LPM flow rate
Weight	Low Flow	2.75 lb. (1.25kg)
	High Flow	
Dimensions (Excluding Fittings)	Low Flow	Height: 3 1/2 in. (8.9cm) Width: 2 1/4 in. (5.8cm) Depth: 3 5/8 in. (9.2cm)
	High Flow	Height: 3 1/2 in. (8.9cm) Width: 2 1/4 in. (5.8cm) Depth: 4 ½ in. (11.5cm)
Note: Product specifications are subject to change without notice.		

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SECTION 12
WARRANTY

THE PRODUCTS OF VIASYSHEALTHCARE INC. (VIASYS HEALTHCARE HEREIN) ARE WARRANTED TO BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP AND TO MEET THE PUBLISHED SPECIFICATIONS.

The liability of VIASYS Respiratory Care under this warranty is limited to replacing, repairing or issuing credit, at the discretion of VIASYS Respiratory Care, for the parts that become defective or fail to meet published specifications during the warranty period; VIASYS Respiratory Care will not be liable under this warranty unless (A) VIASYS Respiratory Care is promptly notified in writing by Buyer upon discovery of defects or failure to meet specifications; (B) the defective unit or part is returned to VIASYS Respiratory Care, transportation charges prepaid by Buyer; (C) he defective unit or part is received by VIASYS Respiratory Care for adjustment no later than four weeks following the last day of the warranty period; and (D) VIASYS Respiratory Care's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Any authorization of VIASYS Respiratory Care for repair or alteration by the Buyer must be in writing to prevent voiding warranty.

VIASYS Respiratory Care warranties as hereinabove set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by VIASYS Respiratory Care or its agents in connection with Buyer's order of the products furnished hereunder.

LIMITATIONS OF LIABILITIES

In no event shall VIASYS Respiratory Care be liable to Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder. This warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment or parts.

This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by VIASYS Respiratory Care or authorized for use in writing by VIASYS Respiratory Care, or if the equipment is not maintained in accordance with a prescribed schedule of maintenance.

The warranty stated above shall extend for a period of one year from date of delivery, with the following exceptions:

1. Electrical components for remote monitoring of physical variables such as temperature, pressure, oxygen saturation or flow are warranted for ninety (90) days from date of receipt.

2. Elastomeric components and other parts or components subject to deterioration over which VIASYS Respiratory Care has not control are warranted for sixty (60) days from date of receipt.

The foregoing is in lieu of any other warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of VIASYS Respiratory Care

NOTES

Manufactured by:
VIASYS Respiratory Care Inc.
1100 Bird Center Drive
Palm Springs, CA 92262-8099
P: 800-231-2466
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SCUBA KITS
REPLACEMENT O2 SENSORS
MINOLTA PULSOX
ACCESSORIES

Maxtec, Your Premier Solutions for O2 Analysis

Maxtec®, Inc is committed to consistent superior quality, timely delivery and responsiv all aspects of oxygen analysis, oxygen delivery, goods and services resulting in excep to all stakeholders

Hours of Availability

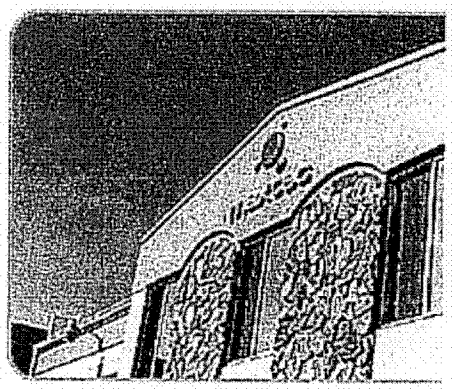
Maxtec is available from 7am - 5pm MST. Please feel free to contact us during those l customer support or to place an order.

Contact Information

800.748.5355
801.266.5300 (Intl.)
801.270.5590 (fax)

sales@maxtecinc.com

6526 South Cottonwood Street
Salt Lake City, Utah 84107



MAX-250

Part Number: see below

24 month warranty

Replacement For:

- Maxtec [OM-25A]
- Mercury Medical [10-103-11]
- Pacifitech [PT-250]
- Teledyne [R29MED]

- Specifications
- Cross-Reference Chart
- Serial Number Chart

Part Numbers

Max-250 Medical
R125P01-002
Max-250 Industrial/Scuba
R125P01-003

14. STERILIZATION AND SHELF LIFE

The Precision Flow™ is not sold sterile, nor is it intended to be sterilized by the user. The Operator's Manual states on page 18 that the user wipe down the main unit with 70-90% isopropyl alcohol wipes after use. The Operator's Manual is provided in section 13.

The Precision Flow™ does not have a labeled shelf life.

15. BIOCOMPATIBILITY

The Company's biocompatibility statement is included in this section of the submission.

15. BIOCOMPATIBILITY

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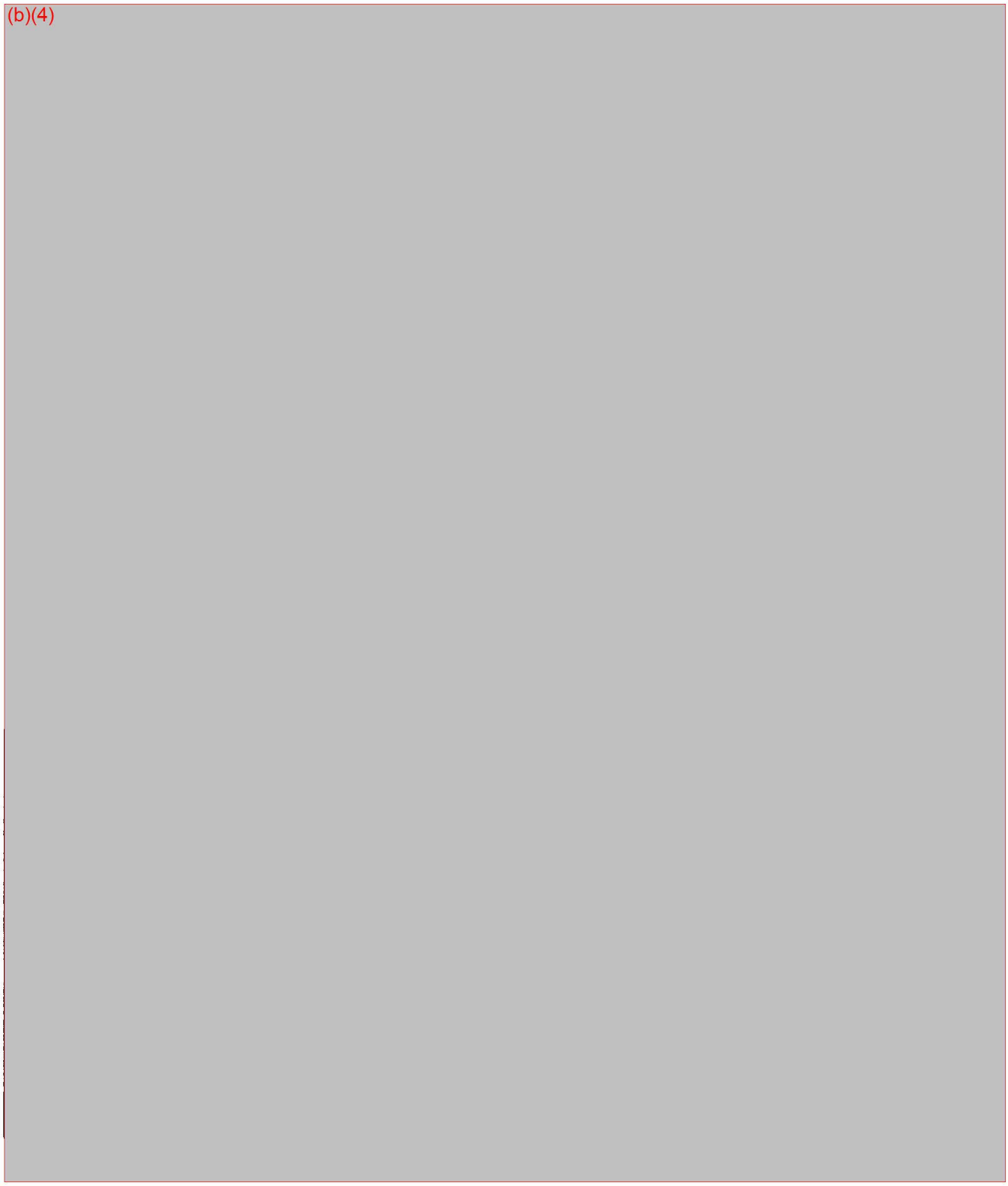

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16. SOFTWARE

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16. SOFTWARE

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