K103316

510(k) SUMMARY

Vapotherm Flowrest®

FEB - 8 2011

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

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

Phone: (410) 604 - 0808 extension 209
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Contact Person: Gregory A. Whitney

Date Prepared: November 1, 2010

Name of Device and Name/Address of Sponsor:

Flowrest®

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

Common or Usual Name:

Humidifier, respiratory gas, (direct patient interface)

Classification Name:

Respiratory gas humidifier.
Anesthesiology Panel 868.5450
Class II

Product Code:

BTT 868.5450

Predicate Device:

#	Manufacturer	Trade Name	510(k)
1	Fisher Paykel Healthcare	Airvo Series Humidifier	K092846

Intended Use / Indications for Use:

The Flowrest® delivers warmed humidified high-flow breathing gases. The Flowrest® is intended for treating spontaneously breathing patients who require warmed and humidified high-flow respiratory gases within the homecare, sub-acute and hospital settings.

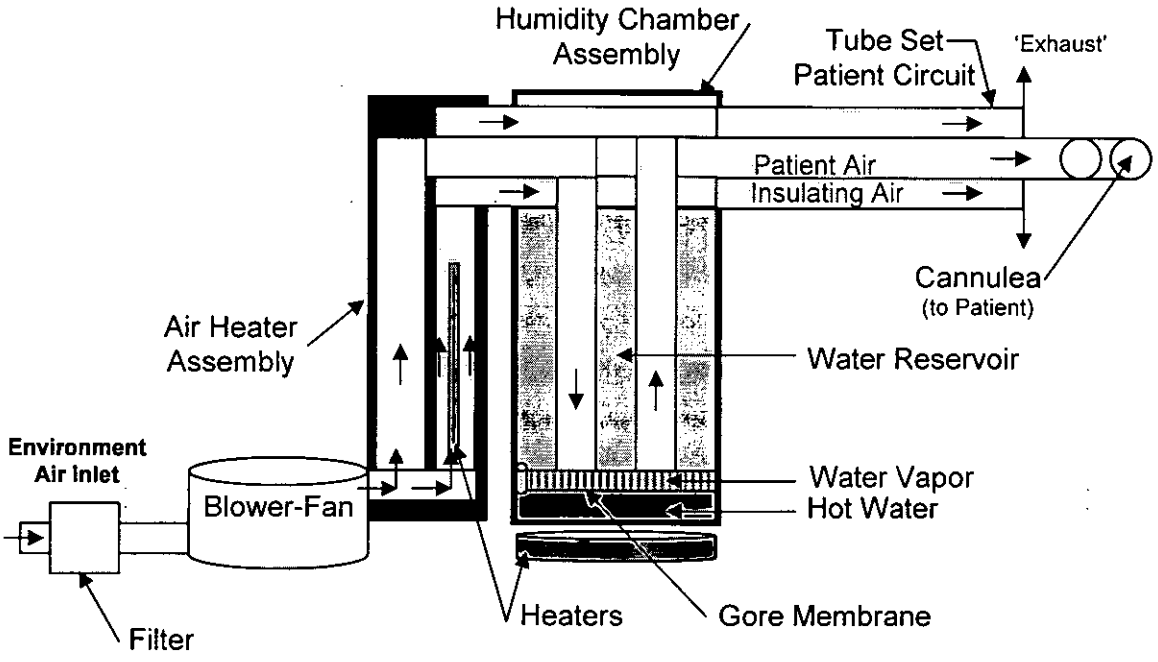
Technological Characteristics:

The Flowrest® is an integrated non-invasive high flow device incorporating a blower, an air flow heater, a heated humidifier, and a dual lumen breathing circuit and cannula. Please refer to the accompanying diagram below. Filtered room air is drawn in through a blower, where it passes a heater. The heated air is split between the inner lumen and outer lumen of the dual lumen breathing circuit. The heated air in the inner lumen passes through a heated humidifier and is delivered to the patient through a cannula. The heated air in the outer lumen passes through the entire length of the breathing circuit and serves to insulate the humidified patient air, thus minimizing condensation and rainout.

The Flowrest® is comprised of two functional, yet integrated components. One is a motorized fan assembly that provides the physician prescribed high flows of heated breathing and insulating gases between 15 and 35 liters per minute. The fan speed is directly related to flow rate and is controlled by software. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second component of the Flowrest® is a heated humidifier. The water is contained in the humidification chamber positioned on a heater plate at the front of the unit. The chamber connects directly to the blower assembly. Air flow from the device passes through the heated humidification chamber, is warmed and humidified and after passing through the breathing circuit, is delivered to the patient through a cannula. The second flow of warm air through the outside lumen of the delivery tube bypasses the humidification chamber through the top of the humidifier chamber. Ambient temperature is monitored in order to reduce humidified patient air condensation. Temperature controls are controlled by software.

Flowrest® Air-Vapor Flow-Path Diagram:



Main Unit:

The main unit houses the blower fan, internal heater, heater plate, display, control panel, and all the electronics that control air flow and temperature. It contains no water and only dry gas pathways, so it requires no internal cleaning or disinfection.

Disposable Components:

The canister assembly contains the distilled water reservoir, gas pathways and humidity cartridge. The insulated delivery tube conveys heated patient gas from the canister to the nasal cannula. Air from the internal heater passes between the insulated tube's inner and outer walls, and keeps the humidified gas from loosing heat and water.

Software Features:

The flowrest software is configured for four types of interface; the patient, the distributor, service, and clinical.

The Flowrest® software control system functions are as follows:

1. The user may or may not be able to adjust the flow and/or temperature settings and the ramp up increase/decrease of the delivered gas, depending on the physician's prescription. A patient may have full access or limited access. The Durable Equipment Supplier has the capability to preset through a secure mode the prescription flow values, temperature values, and ramp up (gradual increase to the full setting value of flow and temperature) through a USB software communication port on the flowrest.

2. The Liquid Crystal Display (LCD) screen will notify the user of reminders when to replace flowrest disposable components, such as, the cannula with tube, delivery tube, water tank, head gear, filter cartridge, ultra fine filter, and pollen filter.

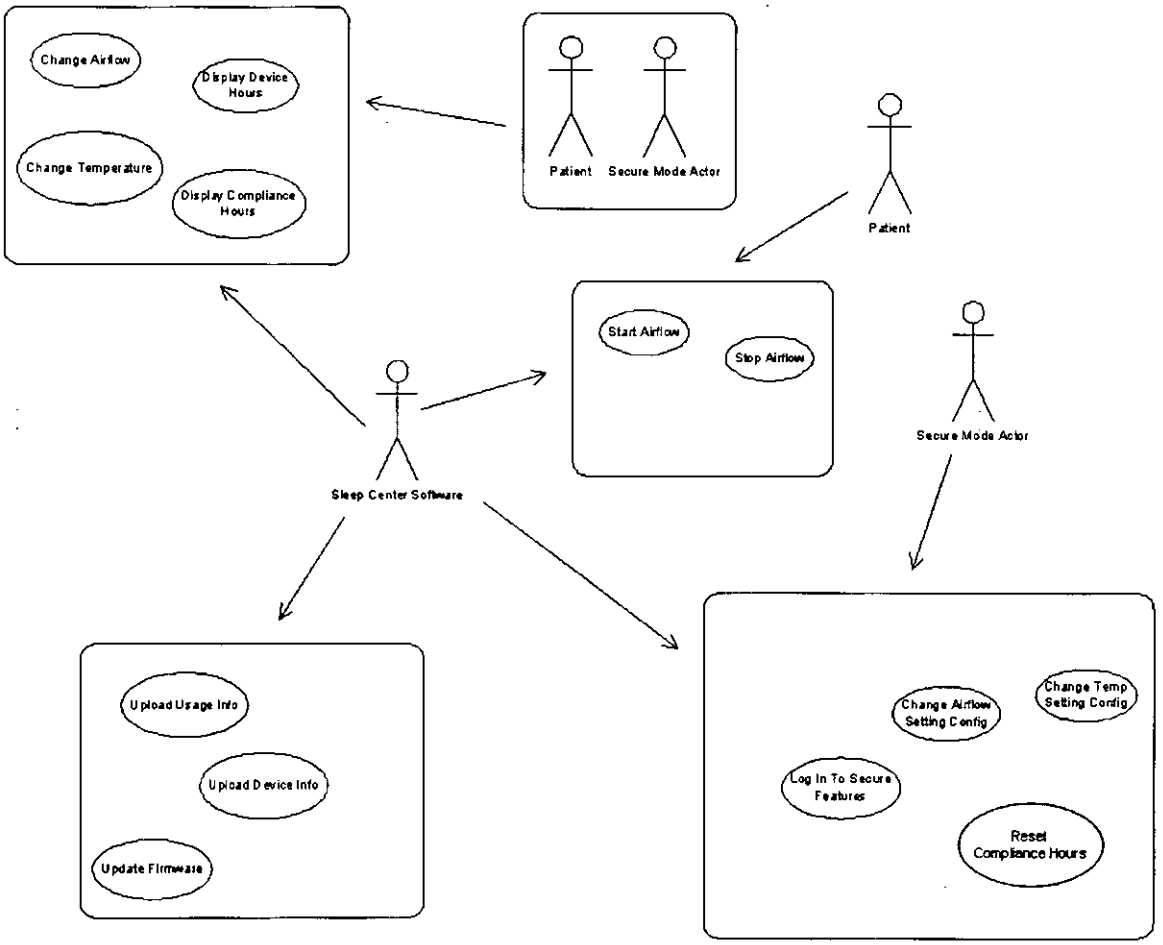
3. The distributor/clinician/service center have access to the amount of time that a patient is continually using the Flowrest®.

4. The service center can access the sum of the time periods during which the Flowrest® is powered on and is in Patient Mode (called "usage hours"). Usage hours primarily monitor the aging of parts, such as the heaters and blower. The service center can us the USB port to upgrade the software.

Note: The patient, distributor, service center, and clinician can only interact with preset software functions and can not access the software code.

5. The Flowrest® provides the ability to operate the system convenient to a clinical technician who may be located in a room away from the device and desires to minimize direct manipulation of the device.

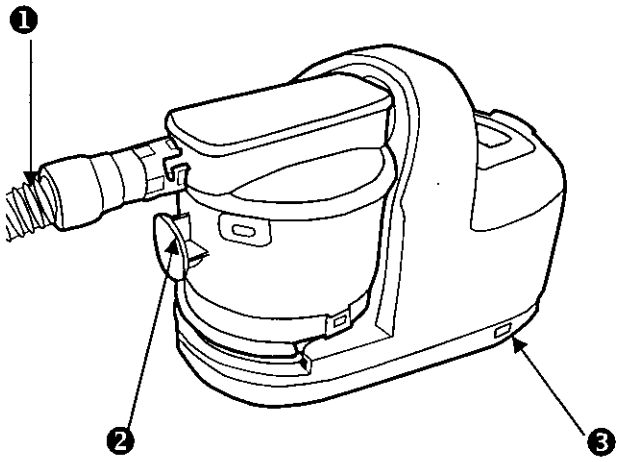
Use Case Overview:



Note: The term "actor" is used to identify a distributor, service, or clinician function that can interact directly with the system.

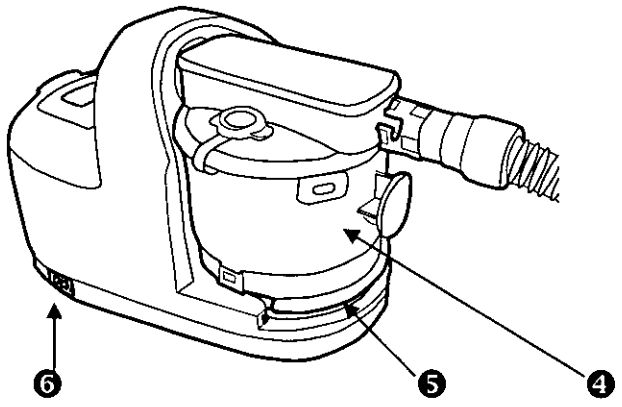
Controls, Indicators & Connections:

LEFT VIEW



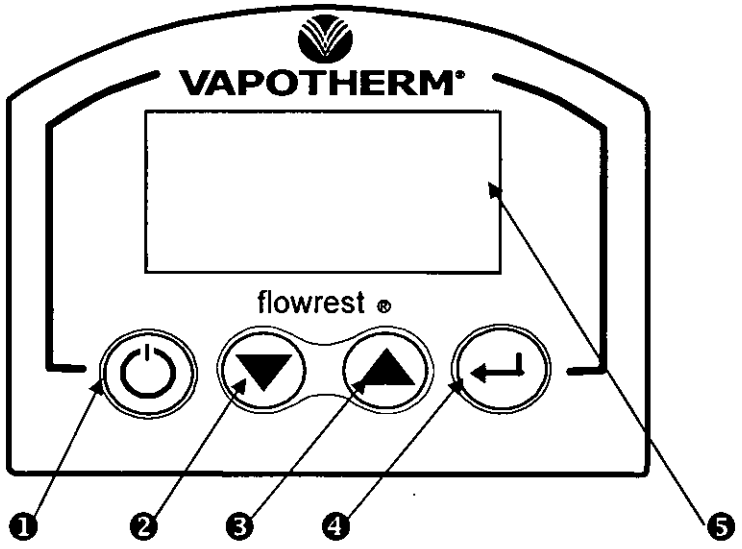
1. **Insulated delivery tube**
2. **Canister handle**
3. **USB port (for clinical/service use only)**

RIGHT VIEW



4. **Canister**
5. **Heater plate**
6. **Power cord inlet**

3.3 MAIN UNIT CONTROL PANEL

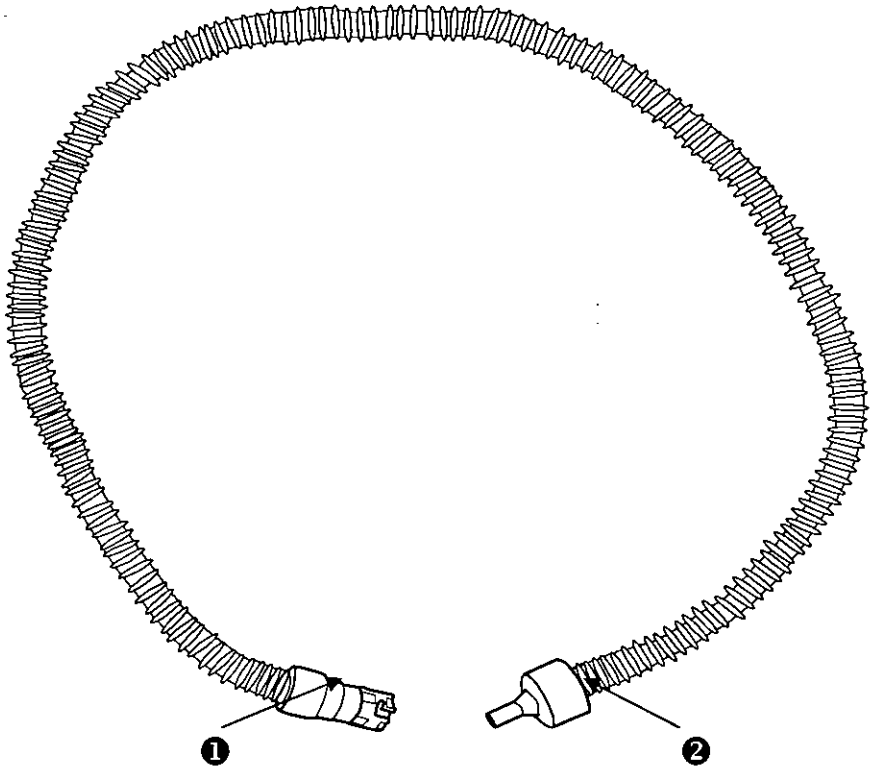


1. **On/Off**
2. **Decrease/Down**
3. **Increase/Up**
4. **Enter/Select**
5. **Liquid crystal display screen**

Patient Interface:

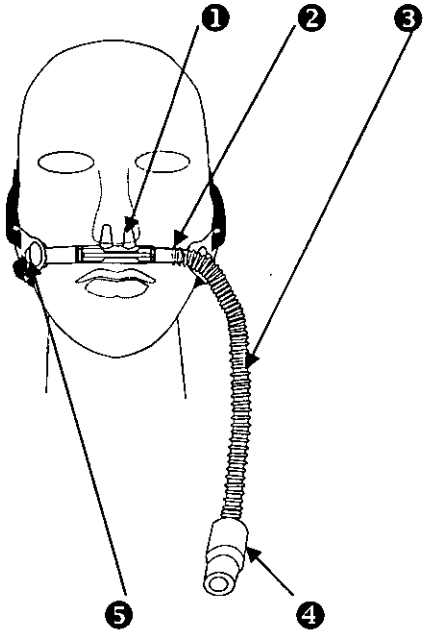
The Flowrest® connects to the patient by a delivery tube, a headset and a cannula.

Delivery Tube



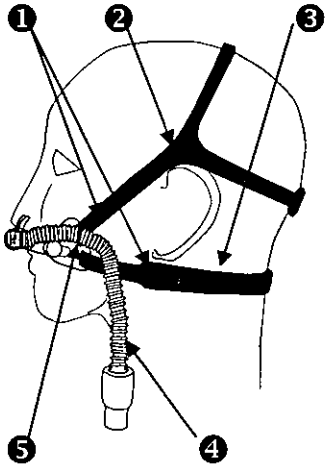
1. **Twist-lock connector**
2. **Swivel connector**

Breathelite™CANNULA FRONT VIEW



1. Nasal Cannula
2. Left/Right Adapter
3. Cannula Delivery Tube
4. Pliable Connector
5. Double Strap Fastener

Breathelite™CANNULA SIDE VIEW



1. Velcro Fastener
2. Head Strap
3. Neck Strap
4. Cannula Delivery Tube
5. Tube Support

Performance Data

The Flowrest® meets the requirements of the following standards:

Number	Standard Title	Description
1	ISO 10993-3:2003	Biological Evaluation of Medical Devices Part 3: -Tests for genotoxicity, carcinogenicity & reproductive toxicity
2	ISO 10993-5:2009	Biological evaluation of Medical Devices – Part 5: Tests for cytotoxicity
3	ISO 10993-10:2010	Biological evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
4	IEC 60601-1-1:2009	General Requirement for Safety Exceptions: 1) Section 5, Does not contain equipment to produce hazardous radiation 2) Section 6, Not to be used with anesthetic mixtures
5	EN 60601-1-2:2007	Medical Electrical Equipment, Part 1: General requirements for safety 2:Collateral standard: Electromagnetic Compatibility – Requirements and Test
6	EN 60601-1-4:2000	Medical Electrical Equipment – Part 1: General Requirements for Collateral Standard: Programmable Electrical Medical Systems
7	IEC 529: IPX1	Drip Proof
8	ISO 8185:2007	Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems, Section 51.101
9	ISO 14971:2007	Medical Devices – Risk Analysis
10	EU Waste Disposal	Directive 2003/12/EC
11	NIOSH Manual of Analytical Methods	Number 0500 Particulates not otherwise regulated
12	EPA Compendium Method TO-15	Determination of VOCs in Air by GC/MS
13	ISO 13495:2003 Medical Devices	Quality Management Systems

In all instances, the Flowrest® functioned as intended and the results observed were as expected.

Substantial Equivalence

The Flowrest® is as safe and effective as the predicate device, the Fisher Paykel Airvo™ Series Humidifier, 510(k) #K092846. The Flowrest® has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device. The minor technological differences between the Flowrest® and its predicate device raise no new issues of safety or effectiveness. Thus, the Flowrest® is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

FEB - 8 2011

Re: K103316
Trade/Device Name: Flowrest®
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: November 5, 2010
Received: November 10, 2010

Dear Mr. Whitney:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Indication for Use Statement

510(k) Number (if known): _____

Device Name: Flowrest®

Indications for Use:

The Flowrest® delivers warmed humidified high-flow breathing gases. The Flowrest® is intended for treating spontaneously breathing patients who require warmed and humidified high-flow respiratory gases within the homecare, sub-acute and hospital settings.

Prescription Use _X_ AND/OR (Part 21 CFR 801 Subpart D)

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)

L Schultz Page __ of __

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

510(k) Number: K103316