

NOV 20 1998

K983981



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November 3, 1998

510(k) Summary

BEAR 1000es Ventilator

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TRADE/PROPRIETARY NAME: BEAR 1000es Ventilator
COMMON/USUAL NAME: Volume Cycled/Pressure-Controlled-Ventilator
CLASSIFICATION NAME: Ventilator, Continuous (Respirator)

ESTABLISHMENT REGISTRATION NUMBER: 2022747

PRODUCT CLASSIFICATION Class II

ANESTHESIOLOGY DEVICE CLASSIFICATION PANEL (73 CBK)

Comparison to Predicate Device;

k912619/A BEAR 1000[®] Ventilator
k901448 Hamilton Veolar, with Leonardo Graphics
k935788 SMARTCATH INTRATRACHEAL CATHETER
now known as the BICORE CP 2000
k900696B CP-100 Pulmonary Monitor

Statement of Indication for Use.

The BEAR® 1000 Ventilator employs both microprocessor and microcontroller technology to yield a simple, compact design. This full-featured package has powerful performance capabilities-in terms of output capability, Sensitivity to patient demand and response time. They render the BEAR® 1000 Ventilator fully capable of ventilating the entire spectrum of patients requiring such support-from the Emergency Room to the ICU, from pediatric patients to adults.

The BEAR® 1000 Ventilator is available in a standard model as well as an upgraded model which includes the fully loaded Enhancement Package. The standard model BEAR® 1000 Ventilator offers the clinician the following ventilatory modes:

- Assist CMV
- SIMV (with or without Pressure Support), and
- CPAP (with or without Pressure Support)

In addition to greater flow and rate capabilities, Enhancement Package offers additional functions such as:

- Pressure Control Ventilation
- Minimum Minute Volume capability
- Pressure Augmentation, and more.
- Smart Trigger
- ES (Esophageal Monitoring)

Any standard model can be upgraded to add the EPI features or any other new option; thus from the outset, the ventilator, has been designed for the 1990's, with future upgrades in mind. Consistent with Bear Medical Systems' philosophy of maintaining an easy-to-use operator interface, this ventilator can be upgraded by replacing the control panel hood. In this manner, not only will all new controls remain as logically arranged as those on the standard ventilator model, but control multiplexing can be held to a minimum. Beyond the above described ventilatory mode capabilities, BEAR® 1000 models offer important features which improve ventilator-patient synchrony and may reduce the work of breathing.

Important among these features is the "demand system" which has long been pioneered by Bear Medical Systems, Inc. This demand system provides additional gas flow in response to patient demand, even in volume-controlled breaths. Such response is termed "Flow end volume augmentation" and it serves to ensure that patients with high or asynchronous demand will not be limited by selected peak flow or tidal volume settings.

Statement of Indication for Use.

The BEAR[®] 1000 Ventilator expands the horizons of this responsiveness through its function called "Pressure Augmentation". Further improving ventilator-patient synchrony is the PRESSURE SLOPE control. This control enables the clinician to tailor, for each patient, the rate of pressure rise during inspiration in any pressure breath, and thereby more closely match ventilatory support to patient demand. Also available in the BEAR[®] 1000 Ventilator, again to improve ventilator-patient synchrony, is a leak makeup system. This system can detect and compensate for very small to rather large leaks. In small leaks, which are more clinically-relevant, this leak makeup system can not only maintain PEEP and avoid AUTOCYCLING, but also maintain consistently sensitive assist trigger levels-even when leaks are intermittent.

Device Design.

The modifications to the Bear 1000[®] Ventilator are minor, and primarily affect only the monitoring capabilities of the system, with the exception of the addition of one alarm. There is no impact to the control functions of the ventilator. These modifications are:

The addition of esophageal and tracheal pressure monitoring. All monitoring is the result of pressure data that is obtained through the esophageal and tracheal catheters and communicated to the Graphic Display via the RS-232 communication port.

The addition of one alarm -- Prolonged Esophageal Pressure.

The addition of one membrane key switch for filling the esophageal catheter balloon with air.

The addition of a bi-directional flow sensor at the patient wye using a presently approved and marketed technology to enhance the flow and volume monitoring capabilities. The bi-directional flow sensor measures inspiratory and expiratory flow that is used in calculating and displaying digital data and various waveforms/loops on the Graphic Display. The user has the option of using either the bi-directional flow sensor or the exhaled flow sensor.

The digital data calculated by and displayed on the Graphic Display has been enhanced to include 17 additional respiratory parameters which are categorically displayed on four user selected pages.

Electronic System Overview:

Electronic Control System (ECS)

The ECS consists of the Control and Monitor PCB's. The Control PCB performs all of the ventilator's higher level functions, while the Monitor PCB scans the membrane touch panels and the seven segment displays. The Control PCB communicates new display information to the Monitor and the Monitor PCB communicates changes in the membrane touch panels to the Control PCB over a parallel eight bit data bus. The ECS also has an RS-232 port, and three analog ports. The RS-232 port is used to communicate the monitor, alarm and control settings to an external device, and send flow and pressure signals in real time to an external graphics display. The analog ports are used to output real time flow, volume and pressure signals.

Control PCB

The Control PCB performs all of the ventilators high level control functions. This is accomplished by computing the desired flow rate, oxygen concentration, and desired valve states every 10 msec and sending them to the Electro/Pneumatic Interface (EPI) via the ECS/EPI-Communication Channel (ECS/EPI-CC). The Control PCB's second major function is to monitor, alarm and display all clinical data, based on the transducer data received from the EPI.

Electro/Pneumatic Interface (EPI)

The major purpose of the EPI is to provide a clear interface from the ECS to the pneumatic hardware. The EPI receives the desired flow rate, oxygen concentration, and valve states every 10 msec from the ECS. Based on this information, the EPI commands each individual valve to its correct position or state.

The second function of the EPI is to read the transducers, digitize their data, and send it to the ECS upon request. The pressure transducers are physically mounted on the EPI to improve signal quality by minimizing the transmission distance of their analog signals.

Power Supply

The power supply converts AC line voltage into the DC voltages used by the system (+5 VDC, +12 VDC & -5 VDC + 7 VDC). It will also provide approximately 150 milliseconds of hold up power in the event of a temporary AC power loss.

Pneumatic System Overview:

Inlet Pneumatic System

The inlet pneumatic system conditions and monitors the air and oxygen supplies entering the ventilator.

Gas conditioning:

The air and O₂ inlet filters remove aerosol and particulate contaminants from the incoming gas supplies.

The air & O₂ regulator-relay combination enables this system to provide balanced supply pressure to the gas blending system. The air regulator reduces the air supply pressure to 18.0 psig and pilots the O₂ relay to track at this same pressure.

In the event the supply air pressure falls below an acceptable level, the Crossover Solenoid opens delivering high pressure oxygen to the air regulator, allowing the O₂ Relay to function. In this mode, O₂ flowing through the air regulator will also allow the inlet pneumatic system to provide sufficient flow of 100% O₂ to the blending system. In the event of an oxygen supply pressure drop below the threshold, the Crossover Solenoid stays closed. The blender slews to 21 % O₂ and regulated air pressure provides sufficient flow of 100% air to the blending system.

Oxygen Blender

The Oxygen Blender (O₂B) is comprised of three major sub-systems, the valve, the stepper motor and the drive electronics. The oxygen blender receives the system air/O₂ from the Inlet Pneumatic System and blends the two gases to the user selected value. The user setting is received by the ECS which commands the EPI to position the blender stepper motor to a pre-calculated position.

PEEP/Exhalation Control System & Exhalation Valve

The exhalation valve in tandem with the PEEP/Exhalation control system closes off the expiratory limb of the patient circuit during an inspiration, so that all gas delivered by the machine will be diverted into the patient. Once the breath is completed the valve is opened so that the patient may exhale. Its second function is to maintain a positive end expiratory pressure (PEEP) during exhalation to a set value. The exhalation valve also acts as a check valve so that the patient can not inspire gas through the expiratory leg of the circuit.

Pneumatic System Overview:

Exhalation Valve:

The exhalation valve regulates all flow out of the patient circuit. Exhaled gases from the patient flow through the patient circuit and into the exhalation valve. If the valve is open, gases flow past the valve seat and continue on to the exhaled flow sensor. Pilot pressure from the PEEP control pump is applied to the balloon diaphragm. The exhalation valve acts as a piloted relief valve, i.e. when patient pressure exceeds the pilot pressure, the diaphragm lifts off the seat and "relieves" the patient pressure. The pressure ratio (Proximal pressure)/(Control pressure) of the diaphragm is approximately 1:1.3.

Safety System (Shut Off Solenoid and Low Pressure Regulator)

The safety system and SOPR valve allow the patient to breath "room air" in the event of a ventilator or power failure. In addition the safety system sets the exhalation valve reference pressure to zero, allowing the patient to exhale unimpeded. Under normal operating conditions the low pressure regulator generates the 2 psig reference pressure necessary to shut the exhalation valve during inspiration, and close the relief port of the SOPR valve. PEEP drops to zero during a power failure.

Advanced Monitoring System overview:

Exhaled Flow Sensor and Advanced Monitoring

Three types of flow sensors are supported: flow sensor at the exhalation valve (also referred to as exhaled flow sensor), adult flow sensor at the wye, and infant flow sensor at the wye. The flow sensor at the exhalation valve is designed to detect only flow in the exhalation direction while both types of flow sensors at the wye are designed to detect flow in both directions. Advanced monitoring consists of tracheal and esophageal pressure sensing.

The exhaled flow sensor measures exhaled flow at the exhalation manifold while both types of flow sensor at the wye measure flow at the circuit wye. The technology used to measure flow with all three types of Low sensors are variable orifice flow sensing. All three types of sensors are based on the Bicore Monitoring Systems disposable flow sensor and are called Varflex type flow sensors.

Advanced Monitoring System overview:

Tracheal monitoring monitors airway pressure on the far side of the endotracheal tube eliminating the resistance of the endotracheal tube. A tracheal catheter is used to measure the tracheal pressure.

Esophageal monitoring monitors pressures in the patient esophagus. Esophageal monitoring provides an accurate representation of pleural pressure and therefore patient effort. The BEAR 1000 monitors both adult and pediatric esophageal pressures. Bicare adult and pediatric esophageal catheters (Balloons) are used for monitoring the esophageal pressure. The BEAR 1000 determines which catheter is connected each time the extension tube is mated to the ventilator. The volume of the balloon is larger for the adult catheter. The BEAR 1000 performs a fill for a duration that would distend the pediatric balloon but not fill the adult balloon. After this fill, the esophageal pressure will be at a maximum for the pediatric catheter but not for the adult.

The system consists of one of any of the three types of flow sensors and a tracheal catheter, an esophageal catheter, internal harness assemblies, pneumatic components, and a printed circuit board (PCB). The Flow Sensor and Advanced Monitoring (FSAM PCB) contains all of the electronics required to perform the monitoring functions. This includes pressure transducers, signal conditioning, analog to digital conversion, solenoids, and support electronics required for data communication.

The FSAM PCB contains a pressure transducer, which converts the pressure drop across the flow sensor to a voltage. The ADC converts this voltage to digital data and communicates it to the EPI.

Two solenoids are used to support flow sensing. The auto zero solenoid is used to cancel time and temperature related drift of the pressure transducer output. Enabling the auto zero solenoid provides the same pressure to both sides of the differential pressure transducer. The analog output value generated at this time is used to offset the zero value stored in the ventilator's memory (EPI characterization EEPROM) at calibration time.

Advanced Monitoring System overview:

The second solenoid used for flow sensing is the purge solenoid, unless the flow sensor is an infant wye type. Purging does not occur if the flow sensor is an infant type at the wye. For the other two types of Varflex flow sensors, periodic purging of the sensor pneumatic lines utilizing fixed volumes of air is used to keep them clear of contamination. The purge solenoid is provided with a 2 psig source of air which is metered into the sense lines as determined by the ventilator control software. Prior to activation of the purge solenoid, the auto-zero solenoid is enabled to protect the differential pressure transducer from most pressure spikes due to an occlusion of the pneumatic lines.

Two solenoids are used to support esophageal pressure monitoring. The source solenoid switches between Negative flow (for balloon evacuation) and positive flow (for balloon filling). An isolated solenoid is used to isolate the balloon from the flow source.

Tracheal Catheter:

The tracheal catheter is a single lumen 4 FR catheter. The catheter is inserted into the side port adapter attached to the patient. The catheter contains a luer lock for securing the catheter in place with the side port adapter. The catheter mates with a tracheal catheter extension tube which mates with the ventilator. The extension tube connector contains two

Esophageal Catheter:

The esophageal catheter is a single lumen 8 FR catheter. The catheter end contains several holes to allow filling and evacuation of the balloon. The catheter mates with an esophageal catheter extension tube which mates with the ventilator. The extension tube connector contains two pins which are electrically shorted allowing the FSAM PCB to detect when the extension tube is connected to the ventilator.

Comparison to Predicate Device

The BEAR 1000es Ventilator is the same as the BEAR 1000 Ventilator (k912619A) with the BICORE monitoring (k935788) (k900696b) technology added. The external additions to the ventilator are three connections on the front bezel and one button to fill the esophageal balloon located on the lower front panel. Internal change are the addition of a Circuit board with the pressure transducers, Software and 17 added features to the Graphic Display Monitor. There is an addition of a prolong esophageal balloon pressure alarm. External connection are used to connect Flow Transducers and various size Catheters identical to that used with the BICORE monitoring systems (k935788) (k900696b).

CLEARED 510(k),

K912619/A BEAR 7 now know as the BEAR 1000 (UNMODIFIED) device.

Comparison to Predicate Device; Hamilton Veolar, with Leonardo Graphics.

k901448 Hamilton Veolar, with Leonardo Graphics

Comparison to Predicate Device; BEAR 1000 Ventilator and Bicore monitors CP-100 and CP-2000.

K935788 SMARTCATH INTRATRACHEAL CATHETER
now known as the BICORE CP 2000

K900696B CP-100 Pulmonary Monitor

Summary of Performance Testing

As a result of the review of the Fault Tree Analysis, a FMEA was done for the Flow PCB and concluded that there are no risk associated with any potential failures of components on the PCB.

The software for the ventilator was qualified by performing formal qualification procedures on a test ventilator. These qualification tests consisted of a Mini-qual, which verifies the ventilator's performance in accordance with the approved Design and Performance Specification, as well as a number of independent tests associated with the verification of the software changes.

Although much of the Graphic Display software is unchanged, many new features have been added. As a result, a complete formal qualification was performed on the Graphic Display. The qualification consisted of a complete verification of all features as specified in the Design and Performance Specification, resulting in software Release 1.03.



NOV 20 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Darryl L. Shelby
Bear Medical Systems, Inc.
1100 Bird Center Drive
Palm Springs, CA 92262

Re: K983981
BEAR 1000es Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: November 3, 1998
Received: November 9, 1998

Dear Mr. Shelby:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

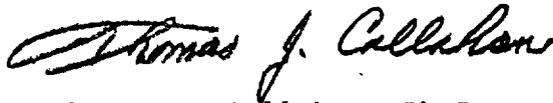
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Darryl L. Shelby

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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Statement of Intended use:
[As required by 21 CFR 807.87(e)]

The BEAR® 1000 Ventilator is fully capable of ventilating the entire spectrum of patients requiring such support-from the Emergency Room to the ICU, from pediatric patients to adults.

The BEAR® 1000 Ventilator is available in a standard model as well as an upgraded model which includes the fully loaded enhancement package. The standard model BEAR® 1000 Ventilator offers the clinician the following ventilatory modes:

- Assist CMV
- SIMV (with or without Pressure Support), and
- CPAP (with or without Pressure Support)

In addition the Enhancement Package offers additional functions such as:

- Pressure Control Ventilation
- Minimum Minute Volume capability
- Pressure Augmentation
- Smart Trigger
- ES (Esophageal Monitoring)

Mark Kramer

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K983981

prescriptions use ✓

OTC _____