K981971

AUG 24 1998

510(K) SUMMARY

TBird Homecare Volume Ventilator

Bird Products Corporation

Neil Battiste
Regulatory Affairs Manager
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262-6267

760.778.7341 (phone)
760.778.7274 (fax)

June 2, 1998

K981971

General Information

Device Trade Name: **Bird TBird Homecare Ventilator**

Device Common/Classification Name: **868.5895** Continuous Ventilator, 73 CBK

Manufacturing Site: Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262

Reason for Premarket Notification:

This 510(k) Premarket Notification is a modification to an existing device. The intended use of the TBird VS Volume Ventilator is being modified to include homecare applications.

Predicate Device: TBird VS, AVS Volume Ventilator
FDA 510(k) No: K950484

Aquetron LP-10 Volume Ventilator
FDA 510(k) No: K905244

Bear 33 Volume Ventilator
FDA 510(k) No: K841279

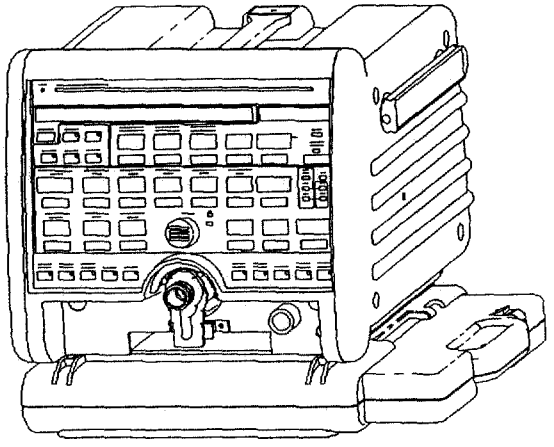
Statement of Indications for Use

The TBird Homecare ventilator is intended to provide continuous or intermittent mechanical ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lbs.), who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive pressure ventilation
- Assist/Control, SIMV, CPAP modes of ventilation

The ventilator is suitable for use in institutional, home, and transport settings. It is not intended for use as an emergency medical transport ventilator

Device Description



The TBird Homecare ventilator employs a revolutionary turbine gas delivery system along with sophisticated microprocessor control to provide support for pediatric to adult patients. Capable of delivering clinically advanced modes of ventilation like Pressure Support with an internal battery or AC power the TBird Homecare has an extensive patient range.

Pneumatic System Overview

The TBird ventilator pneumatic system is an electromechanical system comprised of four major subsystems, each containing several components. These systems include the flow delivery system, the exhalation system, the safety system and the inspiratory hold valve. Individual subsystems are discussed in detail.

Flow Delivery System

This electromechanical system controls all inspiratory flow to the patient. Working under the controller, this system delivers flow to satisfy the criteria for all requested breath types including volume controlled, pressure controlled, and pressure supported. The system is comprised of a turbine, differential pressure transducer, 2 auto-zero valves, and an optical encoder speed transducer. When a breath is initiated, the controller controls the speed of the turbine as required to achieve the commanded flow rate.

The speed and differential pressure transducers signals are used as control inputs to ensure that the proper flow rate is delivered as backpressure varies. Periodically, the auto zero valves are activated to reference both sides of the differential pressure transducer to ambient pressure. The offset is recorded by the controller, and is used as a correction for future pressure measurements. This process compensates for long term and temperature drift. Materials exposed to patient gases include compatible plastics, aluminum, and plated steel.

Exhalation System

The exhalation system controls the flow of gas from the patient's lungs during the exhalation phase. This electromechanical subsystem is comprised of an exhalation valve, flow transducer, differential pressure transducer, airway pressure transducer, and three auto zero solenoid valves. During exhalation, the outflow of the patient gas is regulated by the exhalation valve under the controller to achieve the set PEEP. The exhalation valve is

comprised of an electromagnetic linear actuator operating against a mechanical poppet /seat. Gas flow then travels through the flow transducer. The flow transducer is a variable orifice type, which creates a differential pressure proportional to flow. This differential pressure is transmitted to the differential pressure transducer, which converts the pressure signal to an electrical signal. The controller uses this signal for flow triggering and the exhaled tidal volume monitor. The airway pressure transducer reads pressure in the exhalation leg of the patient circuit. This signal is used as a feedback signal for controlling PEEP, pressure control, pressure support, and various pressure monitors. Periodically, the auto zero valves are activated to reference the differential and airway pressure transducers to ambient pressure. The offset is recorded by the controller, and is used as an offset for future pressure measurements. This process compensates for long term and temperature drift. Materials exposed to patient gases include compatible plastics, aluminum, and stainless steel.

Safety System

The mechanical safety system ensures that the patient can breath spontaneously from room air and that the patient pressure is limited to a maximum value in the event of a ventilator malfunction. This mechanical system consists of a pressure relief valve and a sub ambient relief valve. In the event of a ventilator malfunction that results in high pressure, the pressure is limited by the setting of the relief valve. The relief valve consists of a user adjustable spring loaded poppet acting against a seat.

In the event the ventilator fails to deliver a breath, the patient may inspire spontaneously by drawing room air through the sub ambient relief valve.

Materials exposed to patient gas are aluminum, compatible rubber, and compatible plastics.

Inspiratory Hold Valve

When activated, the inspiratory hold valve blocks flow between the flow delivery system and the patient. This is an electromechanical solenoid valve. This valve is activated during inspiratory hold and maximum inspiratory pressure maneuvers. Materials exposed to patient gases are aluminum and compatible rubber and plastic.

Oxygen Blending System

The optional oxygen blending system is comprised of an O2 Inlet Transducer, five solenoid valves, five flow orifices, an inlet filter, and an accumulator. When a breath is initiated, the turbine draws mixed gas from the accumulator. Filtered air is in turn drawn into the accumulator through the filter. Oxygen is supplied to the accumulator through the solenoids and orifices. The controller opens and closes the valves as required to supply the correct amount of oxygen to satisfy the current O2 setting and flow demand. The O2 delivery is compensated for O2 inlet pressure variations by reading the signal form the O2 inlet pressure transducer. Materials of construction for surfaces exposed to patient gas are compatible plastics, plated steel, and aluminum.

There is also an optional oxygen inlet port which allows for low-flow titration of oxygen into the gas output of this device.

Electronic Overview

The TBird ventilator electronic system is comprised of several subsystems, each containing numerous components. These subsystems include the Display System, the Power System, the Main Controller System, Exhalation, and Flow Delivery systems. Individual subsystems are discussed in detail.

Display System
The Display System is comprised of three Alarm Setpoint Displays, seven Control Setpoint Displays, up to forty-eight Message Display characters, up to twenty-five Discrete Indicators, and a bargraph style Manometer.

Each Alarm Setpoint Display is a 3-or 4 digit group of red 7-segment LED digits which, under software control, shows the present numeric setting of a ventilator alarm.

Each Control Setpoint Display is a 3-or 4 digit group of green 7-segment LED digits which, under software control, shows the present numeric setting of a ventilator control.
The Message Display is a row of dot matrix alphanumeric LED characters which, under software control, show selectable monitored ventilation data with units of measure. This display can also show warning messages, ventilator configuration and setup information, and service and diagnostic prompts.

Each discrete indicator is a small dual color LED which can emit red or green light. Orange or amber colors can be obtained by simultaneous activation of both the red and green emission. These indicators are present in many areas of the control panel, including the battery charge status, power, and patient effort indicators. Most of the indicators are under software control, but a few are under hardwired electronic control.

The manometer is a bargraph-style row of small, dual color, LED indicators which, under software control, are illuminated to indicate the airway pressure. Since each dot is independently controlled and colored, it is possible, under software control, to overlay additional information over the circuit pressure in contrasting colors.

Power System
The Power System conditions and controls energy from the AC line input, the internal battery, and the optional external battery pack. When energy is available from the AC line, the ventilator operates from this source, as well as recharging the internal battery and the external battery (if present). When AC line power is not available, the power system attempts to draw energy from the external battery. If the external battery is not present, or when it becomes depleted, the power system begins to draw energy from the internal battery. The power system uses energy efficient DC-to-DC converter technology to convert energy from the AC line or battery to appropriate voltages and currents to supply power to ventilator components and systems.

Main Controller System

The Main Controller System is comprised of three Pressure Transducers, an Analog-to-Digital Converter, two Digital-to-Analog Converters, the Input-Output Processor, Solenoid Valves, and the Watchdog and Hardware Fault Monitors.

One of the pressure transducers measures the patient circuit pressure. This pressure is an input to the controller. A differential pressure transducer measures the pressure across the turbine. This pressure is also an input to the controller. A second differential pressure transducer is used to measure the flow at the outlet of the exhalation valve. This pressure is also an input to the controller.

Analog to digital converters are used to change the analog pressure signals into measured binary numeric values for use by the microprocessor in the controller.

Digital to Analog converters are used to change the binary numeric commands generated by the microprocessor in the controller into analog signals which drive the turbine and exhalation valve.

The Input-Output Processor is a small microcontroller which, under software control, performs several repetitive tasks such as generating the refresh signals for the display system, cycling the A-to-D converters through a pattern of measurements from the multiple signal sources, and scanning the control panel for pressed buttons. Such repetitive tasks are thereby off loaded from the Main Processor.

The Solenoid Valves and Valve Drivers include the Auto Zero valves which are employed on the Circuit Pressure transducer and on the Turbine Differential Pressure Transducer. These valves allow the controller software to compensate for the long term drift and temperature induced zero shift in the pressure transducers by periodically rechecking the zero pressure readings. Similar solenoid valves are employed in the Oxygen Blending System. The valve drivers for the Auto Zero and Blender valves are similar.

The Main Processor is a 386-type CPU which controls all ventilator functions. All user settings for alarms, controls, ventilation mode, waveform, and monitoried data are stored here and are combined with the measured pressure, flow, and speed data to cause the ventilator to function. The necessary algorithms, formulae, and control functions which define the ventilator behavior are contained in the software program which is executed by the CPU.

The Watchdog Timer and Hardware Fault

Monitors will shut down the ventilator in the event a malfunciton is detected. The Watchdog Timer consists of two timers and a PAL containing a state machine. The Main Controller CPU must communicate with a state machine at intervals within a time window set by the two timers. The CPU must obtain a key from the PAL and send the correct address and data response back to the state machine at each interval. If the response is incorrect, or comes at an invalid time, the Watchdog shuts down the CPU and forces the ventilator hardware to a safe state. The Hardware Fault Monitors check the status of the power supplies to the ventilator

electornics. If any is out of the safe operationg range, the ventilator will shut down and cannot be made to operate until the fault is corrected.

Exhalation System
The electrical portion of the Exhalation System is comprised of the Exhalation Valve Driver Circuitry. The driver converts the low voltage signal output by a D-to-A converter into a controlled constant current which energizes the linear solenoid positioner in the exhalation valve.

Flow Delivery System
The electrical portion of the Flow Delivery System is comprised of a 3 Phase Brushless Motor Driver, and an Optical Speed Transducer.

The 3 Phase Brushless DC Motor Driver converts the low voltage signal output by a D-to-A converter into three controlled currents which energize the three motor phases and cause the motor to create a torque, resulting in motor rotation. The torque generated is a function of current, and therefore of the control voltage from the D-to-A converter. The speed of rotation is monitored by the optical Speed Transducer. The transducer outputs a train of pulses with a frequency proportional to the rotational speed of the motor. This pulse train is a control feedback input to the controller.

Oxygen Blending System
The electrical portion of the optional Oxygen Blending System is comprised of an O2 Inlet Transducer, five Solenoid Valves, and driver circuitry for the solenoid valves.

The Oxygen Inlet Pressure Transducer measures the incoming gas pressure so that the O2 delivery can be compensated for inlet pressure fluctuations.

The Solenoid Valves are energized and deenergized under software control by the Main controller in order to supply the correct amount of oxygen to satisfy the current O2 setting and current gas flow demand.

The driver circuitry translates the binary logic signals presented by the controller to larger voltage and currents suitable for energizing the Solenoid Valves.

Comparison to Predicate Device

Comparison to Predicate Device; TBird VS Volume Ventilator

The TBird Homecare Ventilator is the same device as the TBird VS Volume Ventilator, which was cleared for market under 510(k) K950484. No changes in function or characteristics are being made to this device.

Three modifications to the TBird VS Volume Ventilator have been incorporated into the TBird Homecare Ventilator:

1. Labeling has been modified to incorporate the "TBird Homecare" name and to address the labeling requirements of ASTM F1246 "Electrically Powered Home Care Ventilators, Part 1- Positive-Pressure Ventilators and Ventilator Circuits".

2. Additional shielding has been added to meet the 10V/m susceptibility requirement of the "Draft Reviewer Guidance for Ventilators (July 1995)".

3. An optional oxygen blending system, currently integral to the TBird AVS Volume Ventilator, will be incorporated to provide more precise oxygen delivery.

Comparison to Predicate Devices; Other Homecare Ventilators

The TBird Homecare is not significantly different from the predicate devices, Aequitron LP10 or Bear 33 Volume Ventilator. Both devices deliver air and oxygen mixtures to pediatric through adult patients using pre-defined ventilatory modes. Similar adjustable alarms are used on each device to enhance patient safety.
The TBird Homecare ventilator involves three differences from the currently marketed Aequitron LP10 and Bear 33 Volume Ventilator:

1. the inclusion of Pressure Support mode,
2. the use of flow triggering,
3. a simplified user interface.

First Difference: Pressure Support Mode
The first difference involves the addition of a commonly available mode of ventilation called Pressure Support. Pressure Support mode is available from numerous manufacturers of ventilators. The TBird Homecare ventilator's Pressure support breaths are positive pressure patient breaths in which the ventilator maintains an elevated target pressure during inspiration. Pressure support breaths are always initiated and terminated by the patient and controlled by the ventilator. When the patient initiates a pressure support breath, the ventilator raises the inspiratory flow to meet the patient's demand until the patient airway pressure reaches the target pressure. Once this target pressure is reached, the ventilator adjusts the flow to whatever rate is required to hold the patient at the target pressure. The flow continues to adjust until it reaches 25% of the peak flow obtained. At that point, the ventilator terminates flow, allowing the patient to exhale. The inspiratory time is variable but limited to a maximum of three seconds or two breath periods, whichever is greater.

Pressure support ventilation is used throughout the respiratory care continuum, but it is primarily seen as a weaning tool. Reputable peer review medical journals report pressure supports value as a weaning modality. It is especially valued because it is initiated by the patient and limits the airway pressure. These two factors translate into a mode that allows the patient to control their ventilation and minimizes the potential for barotrauma.

Second Difference: Flow Triggering

The second difference, flow triggering, utilizes another commonly used method of sensing patient effort. Numerous manufacturers of ventilators use flow triggering in their current product offering. The TBird Homecare ventilator's flow trigger is based on a drop in the bias flow – a continuous flow present in the patient breathing circuit. The bias flow can be set from 10 – 20 lpm using the bias flow setting in the TBird Homecare's special functions group. Once the bias flow is set, the ventilator measures the flow passing through the exhalation valve flow transducer. As the patient begins to inspire, the bias flow is diverted from the patient breathing circuit into the patient's lungs. The level of flow is measured at the exhalation valve flow transducer to decrease as the flow is diverted into the lungs. When the patients inspiratory flow rate diverts the bias flow by an amount equal to that of the sensitivity setting on the ventilator, the ventilator delivers a breath.

The predicate devices employ a pressure triggering system. In these systems, the patient must generate a negative pressure within the breathing circuit equal to the amount set on the ventilator's sensitivity setting in order to trigger a breath. In order to accomplish this the patient must inspire some volume of gas from the breathing circuit. This amount can vary depending upon the compliance of the breathing circuit, the humidity of the gas, and overcome any pinhole leaks. Flow triggering eliminates many of these pitfalls. Flow triggering systems reduce the patient's work of breathing. This eliminates an unnecessary fatiguing factor which can cause some patients to become permanently ventilator dependent.

Third Difference: Simplified User Interface

The TBird Homecare ventilator employs a straight-forward single control knob user interface. All of the settable numeric parameters have a small LED window which displays the current value and a corresponding initiation button located directly the window. The user simply needs to press a button to initiate a change, rotate the control knob to change the variable, and confirm the change by pressing the button once more. However, if after initiating a change the user decides to move to another parameter the new value will be engaged upon depressing the new parameters button. The new value will also to put into effect if the ventilator remains untouched for five seconds after changing the parameter. This interface was designed to provide the clinician with an adequate amount of delay time to assess a change prior to its initiation. The need to confirm a change with a second button depression is required when changing a mode of ventilation. A delay period allows the clinician to change any parameters before the new mode and changes are implemented. All of the front panel controls except, monitor select, alarm silence, and manual breath can be temporarily locked out in order to prevent accidental changes.

The predicate device from Aequitron uses a series of knobs for both numeric parameters and modes of ventilation. The clinician initiates a change by rotating the knob to a new value or mode. The Aequitron units do not employ a delay period. A magnetically secured cover deters accidental changes of the parameters by hiding them from plain view.

The Bear 33 Volume Ventilator uses only membrane buttons. A mode is chosen by cycling through the three modes and stopping on the desired one. Numerical parameters are changed by depressing the parameters button while simultaneously depressing either the up or down arrow button. The numeric parameter moves in the desired direction in fixed increments, based on the parameter. All of the buttons default to a locked state after fifteen seconds of rest. Activating the "unlock" button allows the user to change a parameter.

The TBird Homecare Ventilator has the following functional differences as compared to the Aequitron LP10 and the Bear 33:

1. The Aequitron LP10 does not have a peak flow parameter. Peak flow rates are determined by inspiratory time and volume settings. Both the TBird Homecare and Bear units have peak flow settings and internal accumulators. Sudden large flow demands by the patient are more likely to be met by these units reducing sporadic and temporary patient anxiety.

2. The Aequitron LP10 places the pressure relief setting on the front panel. It is used as a limit setting for time cycled pressure limited ventilation. Both the TBird Homecare and Bear units use an internal over pressure relief valve system and recommend its use as a patient system mechanism.

3. The TBird Homecare unit offers a broader range for the high pressure alarm, 5 – 120 cmH_2O. The Aequitron unit's range is 15 – 90 cmH_2O. The Bear unit's range is 10 – 80 cmH_2O.

4. The TBird Homecare unit offers a broader range of control settings and monitors as compared to the Aequetron LP10 and Bear 33.

Summary of Performance Testing

The TBird Homecare Ventilator is the same device as the TBird VS Volume Ventilator. No changes in function or characteristics are being made to this device. Reference 510(k) K950484 for information concerning the TBird VS Volume Ventilator.

As a part of this change in intended use, the TBird Homecare Volume Ventilator has been verified to meet the requirements of ASTM F1246 (1991).

Performance testing verified that the TBird Homecare Volume Ventilator meets it's performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 1998

Mr. Neil Battiste
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262-6267

Re: K981971
TBird Homecare Volume Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: June 2, 1998
Received: June 4, 1998

Dear Mr. Battiste:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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,

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

Enclosures

Statement of Indications for Use

The TBird Homecare ventilator is intended to provide continuous or intermittent mechanical ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lbs.), who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive pressure ventilation
- Assist/Control, SIMV, CPAP modes of ventilation

The ventilator is suitable for use in institutional and home settings.

Mark Neumann

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

✓ FOR PRESCRIPTION USE