K964363

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SECTION 12

SUMMARY OF SAFETY & EFFECTIVENESS

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Classification Name	21 CFR 868.5905, 73 BZD
Common/Usual Name	Ventilator, Noncontinuous
Proprietary Name	BiPAP Duet System
Predicate Device	Respironics BiPAP S-D System (K883825 & K905540)

Reason for Submission

The BiPAP Duet System is a new device.

Substantial Equivalence

The BiPAP Duet System is substantially equivalent to the Respironics BiPAP S-D System (K883825 and K905540), a bi-level positive airway pressure system with remote control capabilities. Both devices provide CPAP and bi-level positive airway pressure therapies for the treatment of adult OSA.

Testing was performed to demonstrate that the performance of the BiPAP Duet System in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of the BiPAP Duet System was verified through performance related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical, and Environmental Testing. The BiPAP Duet System was found compliant and has been certified to the standards referenced in the "FDA Reviewer Guidance for Premarket Notifications."

General Technical Description

Intended Use

The BiPAP Duet System delivers CPAP and bi-level positive airway pressure therapies for the treatment of adult OSA. The BiPAP Duet System is intended for use in the home and by a qualified clinician (any individual trained to perform sleep study diagnoses) in clinical (hospital or sleep laboratory) settings where adult patients suffering from OSA are diagnosed and treated. When used in clinical settings, the BiPAP Duet System can be used with or without the Respironics Maestro Clinical Remote Control. The BiPAP Duet System is used in conjunction with masks, headgear, and various combinations of patient circuit accessories.

Contraindications

The BiPAP Duet System is contraindicated for the following medical conditions:

- Bullous lung disease
- Pneumothorax
- Pneumomediastinum
- Pathologically low blood pressure
- Severe cardiac arrhythmias
- Susceptible patients with CSF leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or Pneumocephalus
- Sinus or middle ear infection may be temporarily contraindicated
- Coronary Artery Disease

Device Description

Technical Description

The BiPAP Duet System is intended to apply CPAP and bi-level positive airway pressure therapies to adult patients who suffer from OSA. The device can operate on either 115 - 120 Volts AC or 230 - 240 Volts AC. The System consists of the BiPAP Duet device and the recommended patient circuit that is used to direct the air to the patient. The tubing, exhalation port, humidifier (if needed), and mask are referred to as the patient circuit. Also, the Maestro CRC can be used in clinical settings to provide control from a remote location. The Maestro CRC also provides data monitoring capabilities, alphanumeric and graphical representations of patient data, and recording capabilities via DC outputs that optionally connect to a polysomnograph for data recording.

The primary components of the BiPAP Duet device are a blower motor assembly and a microprocessor control system. The blower motor is capable of generating positive airway pressures from 4 to 20 cm H_2O. The level of pressure is dependent on motor speed and a pressure control valve, which are controlled by a microprocessor-controlled feedback system.

BiPAP Duet Device Hardware

The BiPAP Duet device is approximately 5.45" high by 15.25" long by 8.75" wide. The device is made up of the following components:

- Top, bottom, and rear enclosure sections
- Control panel
- I/O board with LCD screen
- Air outlet, blower motor
- Valve assembly
- Flow transducer
- Air inlet
- Filter (with or without optional fine filter)
- Filter cap
- Transformer
- BiPAP Duet main printed circuit board
- Power entry module
- Communications connector

System Accessories

Maestro Clinical Remote Control

Accessories for the BiPAP Duet System include the Maestro CRC and patient circuit accessories. Please refer to K954572 for complete information about the Maestro CRC.

Patient Circuit Accessories

The patient circuit accessories intended for use with the Solo CPAP System (K961626) are also intended for use with the BiPAP Duet System. The accessories have not been modified since the Solo was determined substantially equivalent. Consequently, the labeling for the accessories used with the BiPAP Duet system will contain the same information as that provided for the accessories in the Solo submission. Please refer to K961626 for complete accessory information.

An additional accessory intended for use with the BiPAP Duet System is the Spectrum™ Reusable Full Face Mask (K961915). Please refer to that cleared 510(k) for complete information.

The patient circuit accessories that are available for use with the BiPAP Duet System and the manufacturer of each accessory are listed below.

- Respironics Contour Nasal Mask and headgear
- Respironics Spectrum™ Disposable Full Face Mask and headgear
- Respironics Spectrum Reusable Full Face Mask and headgear
- Respironics Comfort Flap® Mask Accessory
- Respironics Whisper Swivel® Exhalation Port
- Respironics 6' Reusable Flexible Tubing Assembly
- Respironics 6' Disposable Flexible Tubing Assembly
- Respironics 18" Reusable Flexible Tubing Assembly
- Respironics 18" Disposable Flexible Tubing Assembly
- Respironics Plateau™ Exhalation Valve
- Respironics GEL™ Mask and headgear
- Respironics Monarch™ Mini Mask and headgear
- King Bacteria Filter
- Respironics Passover Humidifier
- Fisher & Paykel Heated Humidifier

A typical patient circuit for the BiPAP Duet System is shown below.

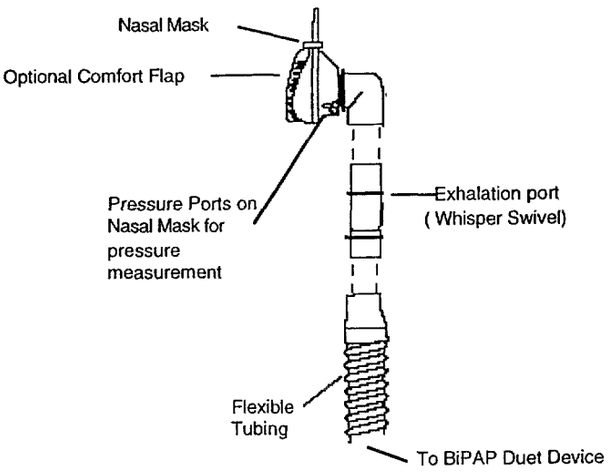

Figure 12-1. Typical Patient Circuit for the BiPAP Duet System

General Principles of Operation

Air Pressure Delivery of the BiPAP Duet Device

When the BiPAP Duet device is in operation, its blower is driven by a high-speed DC motor to supply pressurized air through a patient circuit to the patient. Figure 12-1 shows the BiPAP Duet device and the patient circuit (six-foot, 3/4 inch I.D. flexible tubing, exhalation port, and nasal mask).

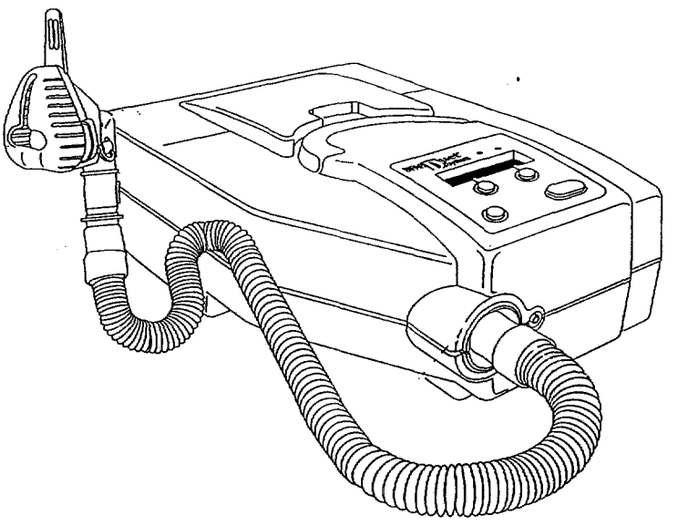

Figure 12-1. The BiPAP Duet Device and Patient Circuit

Pressure Control

The valve is the main control for pressure for the BiPAP Duet device. The energized blower motor draws ambient air through an air filter, pressurizes it, and provides airflow to the patient. The motor speed is fixed based on the inspiratory (IPAP) pressure setting. The airflow path from the blower to the patient circuit flows through a valve assembly that incorporates a valve driver circuit, which employs FET (field effect transmission) circuitry capable of switching the valve control voltage at very fast rates. Valve position is based on IPAP and EPAP settings. The microprocessor controls the valve's position by pulse width modulation (PWM) of one of its I/O lines, which is connected to the FET circuitry.

Pressure is regulated through a combination of valve opening and motor speed to assure that desired pressure is applied to the patient. Closing the valve increases the pressure and opening the valve lowers pressure. When the valve is closed, the majority of the airflow travels from the blower through the valve enclosure to the patient circuit. As the valve is opened, airflow is dumped out the valve to the atmosphere, thereby lowering the pressure delivered to the patient. The amount of airflow dumped out the valve depends on the actual position of the valve. The actual pressure is still sensed by the pressure transducer.

The BiPAP Duet System can sense the patient's breathing efforts by monitoring airflow in the patient circuit. Bi-level therapy is provided by the administration of two (e.g., inspiratory and expiratory) levels of positive pressure. During exhalation the pressure is variably positive or near ambient. The inspiratory level is variably positive and always higher than or equal to the expiratory level.

The airflow path from the blower flows through an enclosed valve and pneumotach to the patient circuit. The BiPAP Duet System monitors the flow and pressure to determine when the patient is inhaling or exhaling. The unit switches between inspiratory and expiratory states and delivers the desired IPAP and EPAP pressure accordingly. Flow and pressure are monitored in order to determine whether the patient is inhaling or exhaling and/or if there are any leaks in the patient circuit. The Inhalation/Exhalation State (IE State), Leak and Estimated Patient Flow are computed based on the flow and pressure signals obtained from the Sensor Module. IE State toggles between the constant values

for Inhalation and Exhalation. Estimated Patient Flow has a range of -120 to 120 L/min with an accuracy of ± 10% at standard temperature and pressure. Leak has a range of 0 to 120 L/min with an accuracy of ± 10% or ± 10 L/min (whichever is greater) at standard temperature and pressure. The Leak value contains both the intentional (exhalation port) and the unintentional (mask) leak values.

Set-Up of the BiPAP Duet System

Once the BiPAP Duet device is plugged into an electrical source, it will perform a self-diagnostic test, test sound the annunciator, and display readiness status via the signal lights. A green light indicates that the system is ready for use; a yellow light indicates a leak detected in the circuit or a System Error. If the system is ready for use, the display screen then shows the System Setup Menu, which allows settings for the leak alert, date, and time. The BiPAP Duet device control buttons, comprising the Pressure On/Off, Ramp, and two user buttons, can be operated within the System Setup Menu to set date and time, and to optionally turn off the audible portion of the leak alert.

Control of the BiPAP Duet System

The clinician can adjust the following parameters for the BiPAP Duet device:

- IPAP
- EPAP
- Minimum Ramp Pressure
- Ramp Time

When IPAP and EPAP are set to different levels (Bi-level mode), the device delivers bi-level therapy. Figure 12-3 shows the applied bi-level pressure settings versus time with Ramp activated when in the Bi-level mode.

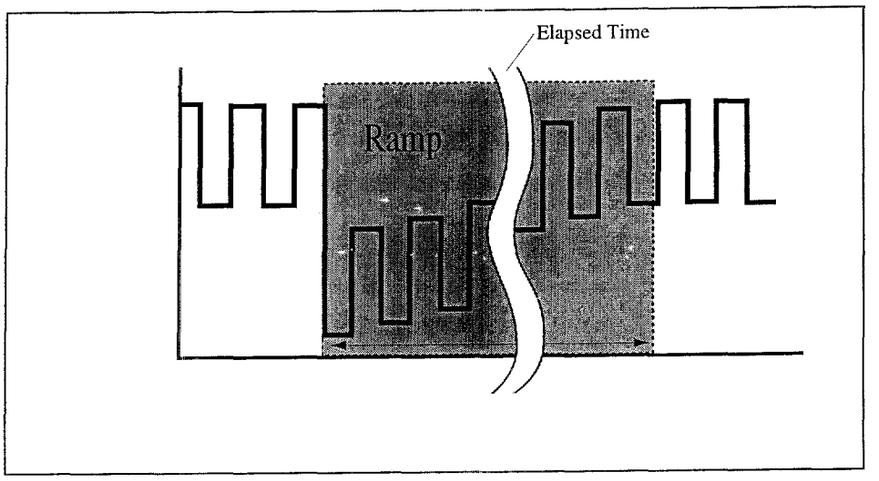

Figure 12-3. Bi-level Mode

The BiPAP Duet device can be set to operate in CPAP mode by setting IPAP equal to EPAP. Figure 12-4 shows the applied Therapeutic Pressure versus time with Ramp activated for the BiPAP Duet System when in the CPAP mode.

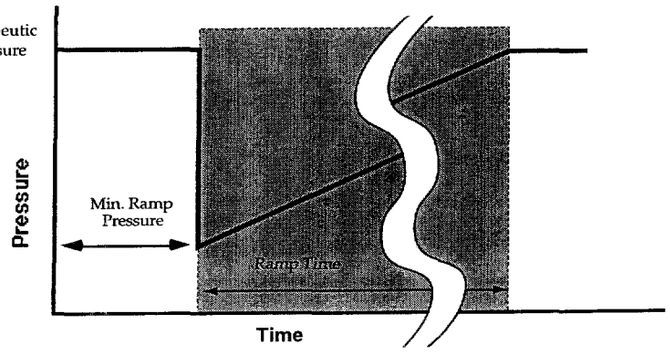

Figure 12-4. CPAP Mode

Therapeutic Pressure

Therapeutic Pressure levels are set for both IPAP and EPAP by the clinician. The clinician can increase or decrease Therapeutic Pressure using the user buttons. Pressure adjustments can be made any time during therapy with a range of 4.0 to 20.0 cm H_2O in Bi-level mode.

NOTE: Although the stated pressure range for IPAP and EPAP pressures is 4.0 to 20.0 cm H_2O, the system will allow a 3.0 cm setting. At some elevations 3.0 cm of delivered presure may not be obtainable. The BiPAP Duet User Instructions notes that a 3.0 cm pressure setting should be verified with a manometer.

Ramp, Minimum Ramp Pressure, Ramp Time

The Ramp parameter applies to both the CPAP and Bi-level modes. When activated, the Ramp feature initially reduces the pressure to the prescribed Minimum Ramp Pressure setting. Minimum Ramp Pressure is the pressure setting to which the device initially drops when Ramp is activated. Ramp incrementally increases to the set Therapeutic IPAP and EPAP Pressures allowing the patient to fall asleep more comfortably. The time period required for the pressure to increase from Minimum Ramp Pressure to the set Therapeutic IPAP and EPAP Pressures is referred to as the Ramp Time.

The clinician can activate the Ramp and set both the Minimum Ramp Pressure and the Ramp Time by pressing the Ramp Function button as indicated by the main screen. Using the user buttons, the Minimum Ramp Pressure can be set

from 4.0 cm H_2O to the EPAP level, and the Ramp Time can be set from 0 to 45 minutes.

Data Monitoring and Recording

When used with the BiPAP Duet System, the Maestro CRC provides data monitoring capabilities, presents alphanumeric and graphical representations of patient data, and provides recording capabilities via DC outputs that connect to a polysomnograph for data recording. The data recording function is optional. The Maestro CRC can control the BiPAP Duet device whether or not it is connected to a polysomnograph.

The following data groups can be monitored and recorded when using the Maestro CRC with the BiPAP Duet System: Event Predictor, V_T (Estimated Tidal Volume), $\dot{V}_{est}$ (Estimated Patient Flow), and P (Pressure).

Description of Signals

- Pressure (P) - This signal permits continuous recording of the pressure measured at the mask.
- Estimated Tidal Volume (V_T) - Determines the amount of air inhaled and exhaled during the breathing cycle. The tidal volume signal should be viewed in conjunction with the estimated patient flow signal to help identify abnormal breathing events and hypoventilation.
- Estimated Patient Flow ($\dot{V}_{est}$) - Determines the flow rate in the patient circuit. This output signal can eliminate the need for a thermistor, thermocouples, or pneumotach within the positive pressure circuit.
- Estimated Leak ($\dot{V}_{leak}$) - Monitors changes in the unintentional leak in the patient circuit.

Software Control System - BiPAP Duet System

Both the BiPAP Duet device and the Maestro CRC are software-controlled. This section contains a summarized functional description of the Software Control System for both devices.

BiPAP Duet Device Software

The BiPAP Duet device software addresses functions relating to the operation of the valve, pressure and flow sensors, and control of the blower motor that generates pressure. The following are some of the high-level software functions that are performed by the BiPAP Duet device:

- Bi-level Pressure Control
- Blower Time Logger
- Pressure Control
- Pressure Error Calculation
- Pressure Mediator
- Sensor Module
  - Flow Sensor Function
  - Motor Speed Voltage & Valve Voltage
  - Pressure Sensor Function
- Stored Parameters
- Therapy Menu
- User Interface
- User Menu
- Watchdog Timer

Maestro Clinical Remote Control Software

The purpose of the Maestro CRC software is to control the monochrome LCD, the DC outputs to the recording device, and the serial communications port when the CRC is attached for use with the BiPAP Duet device. The Maestro CRC software also controls the audible annunciator and processes information from the setting and function buttons, which signal changes to the Maestro CRC and the BiPAP Duet device. The Maestro CRC will receive data via the serial communications port from the BiPAP Duet device.

The Maestro CRC software is described in K954572. Please refer to that previously cleared 510(k) for complete information about the Maestro CRC.