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Section 16 - 510(k) Summary

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Device Name: BiPAP® S/T-D
Common Name: Continuous Ventilator, Passive Exhalation Port, Critical Care

Classification: 868.5895

Predicate Device: BiPAP® (K883825)

Detachable Control Panel (K905540)

Siemens Servo 900 (K81102)

Puritan Bennett 7200 (K823958/B and K833786)

Description of the BiPAP S/T-D System

The BiPAP S/T-D System is a ventilation support system designed to augment a patient's ability to breathe on a spontaneous basis. It is not intended for life support situations. The BiPAP S/T-D System is intended for hospital or institutional use for treatment of obstructive sleep apnea, respiratory failure, or respiratory insufficiency.

The BiPAP S/T- D offers four modes of operation:

- **Continuous Positive Airway Pressure (CPAP)**
- **Spontaneous (S) mode.** The unit cycles between Inspiratory Positive Airway Pressure (IPAP) and Expiratory Positive Airway Pressure (EPAP) in response to the patient rate. The difference between IPAP and EPAP is the delivered pressure support level.
- **Spontaneous/Timed (S/T) mode.** The unit cycles between Inspiratory Positive Airway Pressure (IPAP) and Expiratory Positive Airway Pressure (EPAP) in response to the patient rate. The difference between IPAP and EPAP is the delivered pressure support level.
- **Timed (T) mode.** The unit cycles between Inspiratory Positive Airway Pressure (IPAP) and Expiratory Positive Airway Pressure (EPAP) levels based solely on set breaths per minute (BPM) and %IPAP Time Controls.

The BiPAP S/T-D System provides ventilation support by applying a positive pressure (IPAP) during the inspiratory segment of a breathing cycle, and subsequently cycling to a lower pressure level (EPAP) during the expiratory segment of the cycle for spontaneous breaths. The transition point between inspiration and expiration is sensed by the BiPAP S/T-D System as a function of a decrease in patient flow demand. The BiPAP S/T-D System also senses the transition point between expiration and inspiration. As the patient begins to inhale, the BiPAP S/T-D System senses the increase and transitions from EPAP to IPAP. These points are called the trigger thresholds.

Levels of IPAP and EPAP can be adjusted by the clinician for individual patient requirements. The IPAP control setting is prohibited from being greater than EPAP by design of the control system. IPAP settings are always set equal to or greater than EPAP. By setting IPAP and EPAP levels the same, CPAP therapy is applied. If the EPAP level is set greater than the ambient atmospheric pressure (greater than 0), then a level of positive end expiratory pressure (PEEP) is applied to the patient's airway. The BiPAP S/T-D System is a prescription device. IPAP and EPAP levels are determined by a physician or by a clinician under the direction of a physician.

The BiPAP S/T-D System has the capability of monitoring delivered pressure and adjusting flow as applied to the patient circuit to maintain set IPAP and EPAP pressures. The System is also capable of compensating for air

leakage around the patient interface. Patient interfaces include nasal masks, full face masks covering both the mouth and nose, and a mouthpiece that is used to apply pressures orally.

Each patient interface system uses an exhalation leak to direct the patient's exhaled gasses to the atmosphere. This leak is incorporated either as an accessory valve or bleed port.

Intended Uses of the BiPAP S/T-D System

The BiPAP S/T-D System is intended for hospital or institutional use for treatment of obstructive sleep apnea, respiratory failure, or respiratory insufficiency.

The BiPAP S/T-D System can be used to administer oxygen by using an external oxygen tank and bleeding oxygen into the patient circuit. This therapy is not metered or otherwise regulated. Patient monitoring must be performed to ensure effective administration of oxygen therapy.

The BiPAP S/T-D System is similar to the BiPAP described in K883825, and other continuous ventilators, such as the Siemens Servo 900 and the Puritan Bennett 7200. However, there are specific differences between the BiPAP S/T-D and these traditional life-support ventilators as noted below.

Comparison of the BiPAP to Predicate Devices

The major technical difference between the BiPAP S/T-D System and most continuous ventilators is in the technical approach used to achieve patient support ventilation.

The BiPAP S/T-D System has a self-contained, internal blower assembly to generate airway pressure. Most comparable predicate devices utilize an external pressure source.

The BiPAP S/T-D System is an electromechanically controlled system that controls the pressure applied to the patient based on patient demand, while the flow is adjusted to maintain a set inspiratory and expiratory pressure. Changes between inspiratory phases and expiratory phases are determined by changes in patient flow patterns.

The BiPAP S/T-D System has an electronic mechanism for compensating for leaks around the patient's mask or in the patient circuit supplying positive pressure to the patient. The pressure supplied by the BiPAP S/T-D System is constant within +0.8 to -1.5 cm H_2O in the flow ranges of -60 to 100 Liters per Minute (LPM). (The -60 LPM designation represents patient exhalation into the BiPAP S/T-D patient circuit.) Most comparable continuous ventilators require a

manual operator adjustment to the flow rate control to compensate for leaks in the masks and other areas of the patient circuit.

There are differences in operational characteristics between the BiPAP S/T-D system and predicate devices that are fully compliant with ASTM F 1100-90, the voluntary standard for critical care ventilators:

- The BiPAP S/T-D System provides continuous positive airway pressure (CPAP) and positive pressure ventilation and is indicated for assisted ventilation of adults. This system does not provide mandatory ventilation with guaranteed tidal volume delivery. Patients requiring mandatory ventilation at predetermined tidal volumes are not candidates for pressure support or pressure-limited ventilation.

- The BiPAP S/T-D System requires an intentional leak port, instead of an actively controlled exhalation valve to remove exhaled air from the circuit. Therefore, specific masks and circuits using an intentional leak port are required for normal operation. The pressurized air from the BiPAP S/T-D System causes a continuous flow of air to exhaust from the leak port to flush the exhaled air from the circuit. The machine should be turned on and the intentional leak port should be checked before the mask is applied.

- Pressurized air from the BiPAP S/T-D System causes a continuous flow of air to exhaust from the leak port to flush exhaled air from the circuit. The ability to completely exhaust exhaled air from the circuit is dependent upon the EPAP setting and I:E ratio. At low EPAP settings or with short expiratory times (e.g., high breathing rates) the leak rate through the intentional leak port may be inadequate to clear all exhaled gas from the circuit. Some rebreathing may occur.

- A controlled method for setting and measuring inspired oxygen concentrations cannot be accomplished while using the BiPAP S/T-D System. Instead, oxygen administration is accomplished by using an external low flow oxygen source that is titrated into the mask. At a fixed flow rate of supplemental oxygen, the inspired oxygen concentration will vary, depending on the IPAP and EPAP settings, patient breathing pattern, mask fit and the leak rate. Continuous patient monitoring is recommended while administering oxygen.

- The Airway Pressure Monitor is recommended for use while operating the BiPAP S/T-D System. The Airway Pressure Monitor will monitor proximal airway pressures and provide audible and visual alerts for high and low pressure conditions, and alert the user to a low internal battery, and incidents when the monitor's power switch is inadvertently turned OFF while the BiPAP S/T-D System is in use. Each alarm function should be checked before use by performing the Performance Verification procedure described in Chapter 8 of the Clinical Manual.

- The BiPAP alarm system differs from some ventilators in the following respects:

  > Although the low pressure alarm on the Airway Pressure Monitor will sound in the event of a power failure, the BiPAP System does not have an independent loss-of-power alarm.

  > The Airway Pressure Monitor cannot detect complete or partial obstruction of the exhalation port.

  > The Airway Pressure Monitor will sound if pressures exceed the user-set threshold, but there is no mechanism to relieve excess pressures generated in the event of a ventilator control system failure.

  > The BiPAP's alarms provide indication only while the alarm condition exists. There is no mechanism to retain the alarm message after a transient alarm condition returns to normal.

- Unlike most ventilators, the oxygen inlet (located on the mask) will accept general purpose tubing. Caution must be exercised to ensure that only oxygen is connected to the oxygen inlet.

- The BiPAP System can be set to extreme inverse I:E ratios. Use of such ratios may have adverse physiological consequences and are not recommended.

The BiPAP Systems have been functionally tested to meet their published specifications for applied pressure, patient airflow, under varying environmental conditions. Specifications that were met include:

	BiPAP S/T-D System	**Environmental Conditions**
Pressure Regulation/ Flow Levels	+.8, -1.5 cm H_2O above setpoint over flow rates of -60 to 100 LPM	Nominal 115 VAC 132 VAC. 100 VAC, 72-75° F Nominal 105° F High
Control Accuracy, IPAP and EPAP Settings	±2 cm H_2O of setting in the range of 4 to 20 cm H_2O	Nominal temperature and input voltage
Control Setting Accuracy, Breaths Per Minute (BPM)	±2 BPM over range of 4 to 30 BPM, or ±10 of setpoint, whichever is greater	Nominal temperature and input voltage

Control Setting Accuracy %IPAP	±10% of setpoint measured at 90% and 10% IPAP settings	Nominal temperature and input voltage

Electromagnetic environmental testing, and shock and vibration testing were conducted by independent laboratories to the following National and International Standards for electrical safety for medical devices:

- Canadian Standards Association (CSA) C22.2 125, as tested by CSA.
- UL544 Medical and Dental Equipment Standards, as tested by the City of LA Test Labs.
- German Postal Law Requirements for Conducted and Radiated Emissions per VFG 234/1991, as tested by EMACO for TüV.
- Shock and Vibration testing per IEC 68-2-6 (sinusoidal vibration), IEC 68-2-27 Shock, and IEC 68-34 Random Wide Band Vibration, as tested by East West Labs.
- Shock and vibration for the final packaged configuration per National Safe Transit Association Test Labs.
- Electromagnetic compatibility testing to IEC 601-1-2 for medical electrical equipment. This is a standard that includes IEC 801-1, -2, -3 and CISPIR 14 requirements identified in the FDA Reviewer's Guidance Document. The BiPAP S/T-D System was also tested to MIL-STD-461D and MIL-STD-462D for magnetic field susceptibility. EMI and magnetic field testing was conducted by Canadian Standards Association.
- FCC Class B, Part 15.J Emissions.

Results of the performance testing indicate that the BiPAP S/T-D System will operate within its specifications.

Results of environmental testing indicate that the BiPAP S/T-D System will continue to function after being subjected to shock and vibration, and electromagnetic interference.

Radiation emissions meet the requirement of FCC Class B, Part 15.J.

Clinical Study Summary

Clinical data are presented that verify the suitability of BiPAP Systems for use in treating adult patients with obstructive sleep apnea, respiratory insufficiency, or respiratory failure. These data indicate that the BiPAP System can be used in critical care situations with these patients to manage their acute respiratory condition. Data and analysis presented indicate with a high confidence ($p \leq 0.05$) that there is a statistical basis to indicate that the use of the BiPAP System, like other devices of this type, will help to avoid the need for intubation of these patients.

The clinical data includes 31 adult patients with acute respiratory failure who were enrolled in prospective, randomized, controlled clinical studies to determine, as a primary outcome measure, if the BiPAP System can be used to treat these patients and successfully avoid the need for intubation. Additional data concerning 81 patients enrolled in prospective, non-randomized studies were included to substantiate the conclusions drawn from the controlled studies.

Adverse Effects

Adverse effects identified during the clinical studies include abrasions on the bridge of the nose due to tight fitting masks. These were resolved by readjusting the mask, using foam spacers, or a skin barrier.

There was one report of a patient who had respiratory failure as a result of being taken off of the BiPAP S/T-D System to enable transport to another procedure. It is advised that an alternate method of ventilation be available when patients are transported.

Conclusions

The technical data presented indicate that the BiPAP S/T-D System is compatible with typical environment found in the home and hospital. They have been tested to meet technical safety and performance specifications for medical equipment as established by Canadian Standards Association and IEC.

Clinical data demonstrate that the BiPAP S/T-D System can be used in the hospital environment and other institutional settings to provide ventilation to spontaneously breathing adult patients who suffer from obstructive sleep apnea, are in acute respiratory failure, or have acute respiratory insufficiency.

When used with standard medical care, devices like the BiPAP S/T-D System can help reduce the need to intubate patients with respiratory failure or respiratory insufficiency.