

K 96370

SECTION 12
SUMMARY OF SAFETY AND EFFECTIVENESS

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Classification Name Noncontinuous Ventilator

Common/Usual Name CPAP System

Proprietary Name Respironics Quartet Clinical System

Predicate Device(s) Respironics BiPAP S-D System
(K883825 & K905540),
Innovative Medical Systems DPAP
System (K933184).

Predicate Device Information

The technological characteristics of the Quartet Clinical System are equivalent to the predicate devices as listed above in terms of design, materials, energy source, and intended use. These devices provide CPAP, bi-level positive airway pressure, and self-titrating CPAP therapies for the treatment of adult obstructive sleep apnea (OSA).

Testing was performed to demonstrate that the performance of the Quartet Clinical System in its intended environment is as safe and effective as that of the legally marketed predicate devices. The safety and effectiveness of the Quartet

Clinical System was verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environmental Testing. The Quartet Clinical System was found compliant and has been certified to the standards referenced in the "FDA Reviewer Guidance for Premarket Notifications."

Intended Use

The Quartet Clinical System delivers continuous positive airway pressure (CPAP) and bi-level positive airway pressure therapies for the treatment of adult OSA. The Quartet Clinical System is intended for use 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. The device is used in conjunction with masks, headgear, and various combinations of patient circuit accessories.

Claims

General

- Provides four modes of operation.
- Provides data monitoring capabilities.
- Presents alphanumeric and graphical representation of data.
- Interfaces (optionally) with a polysomnograph (an independent data recording device used in sleep laboratories).

CPAP Mode

- Maintains constant pressure within ± 1.5 cm H₂O at patient interface for flows of -35 to +85 L/min during both inspiratory and expiratory phase of the breathing cycle.

Bi-level Mode

- Senses the patient's breathing efforts by monitoring airflow in the patient circuit.
- Increases the pressure at the patient interface upon sensing a patient inspiratory effort.
- Decreases the pressure at the patient interface upon sensing a patient expiratory effort.

- Trigger sensitivity adjusts the trigger cycle variable automatically in response to the patient's respiratory pattern.
- Compensates for most leaks in the patient circuit and at the patient interface.
- Maintains IPAP and EPAP within ± 1.5 cm H₂O at patient interface for flows of -35 to +85 L/min.

Auto-CPAP Mode

- Effective in treating OSA in adult patients; that is, reduces the Apnea Hypopnea Index (AHI) to 10 or fewer events per hour of sleep.
- Reduces the AHI and improves the Arterial Desaturation Index (ADI) for adult OSA patients.
- Improves sleep architecture (percentage of sleep time devoted to the four stages of sleep) for adult OSA patients.
- Maintains CPAP pressure within ± 1.5 cm H₂O at patient interface for flows of -35 to +85 L/min.

Split Night with Auto-CPAP Mode

- Delivers a minimum CPAP pressure for a preset time period (Delay Time).
- Provides an opportunity to study the patient at minimal (non-therapeutic) pressures during the Delay Time.
- Responds to airway instability by increasing or decreasing the pressure to help meet the patient's needs within designated pressure limits (i.e., Auto-CPAP mode) once Delay Time ends.

Contraindications

The Quartet Clinical 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

Note: "Seizures" has previously been inaccurately listed as contraindicated for Respironics CPAP therapy products (refer to the Respironics BiPAP-S/D System labeling, for example). There is no clinical basis for this claim. Consequently, Respironics has corrected the Quartet Clinical System contraindications by deleting "seizures" from the list. This is in keeping with the labeling of other CPAP devices.

Clinical Testing Summary

The Quartet's self-titrating Auto-CPAP mode is the same as that provided in the Respironics Virtuoso Smart CPAP System. Clinical testing information relating to the Auto-CPAP mode is provided in K953930 for the Virtuoso Smart CPAP System. Please refer to that cleared 510(k) for complete information.

Respironics-sponsored clinical studies were conducted with thirty-nine clinical subjects using both manually titrated CPAP and the Virtuoso System's Auto-CPAP mode. In these clinical trials, the Virtuoso system successfully reduced AHI below 10 at a 35% lower average airway pressure than manual CPAP. However, while both the Virtuoso's Auto-CPAP mode and manual titration produced clinically acceptable AHI/ADI improvement (relative to no treatment), the study did show that manually titrated CPAP achieved a statistically significant greater improvement in AHI. The following chart summarizes of the results from that study, provided for comparison purposes:

Therapeutic Factor	Manually Titrated CPAP	Virtuoso System Auto-CPAP
Mean Therapeutic Pressure (\pm SD)	12.99cm H ₂ O (3.67)	8.50cm H ₂ O (3.46)
Average AHI Reduction (\pm SD)	From 51.81 to 6.0 (29.23) (5.03)	From 51.81 to 8.39 (29.23) (6.41)
Average ADI Reduction (\pm SD)	From 61.59 to 11.66 (36.14) (10.59)	From 61.59 to 16.39 (36.14) (19.27)

Bench testing was performed and demonstrated that the Quartet responds to apneic events in the same manner as the Virtuoso and there were no significant differences in the frequency response between the two devices.

Device Description

Purpose and Function

The purposes of the Quartet Clinical System are to:

1. Allow the clinician to choose the appropriate type of therapy (i.e., CPAP therapy, bi-level positive airway pressure therapy, or self-titrating CPAP therapy) for a patient. This allows the clinician to select the appropriate home unit for the patient.
2. Provide information to the clinician to determine if one of the three available types of therapy, successfully treats an adult patient suffering from OSA.
3. Provide information to the clinician to assess the level of sleep disordered breathing via the Maestro CRC's output signals and displays.

The Quartet Clinical System has a number of mode of operation choices to allow the clinician to choose the type of therapy (i.e., conventional fixed-pressure CPAP, bi-level positive airway pressure, or self-titrating CPAP). Each mode is described below.

- **Manual CPAP Titration Mode** - The device delivers a fixed continuous positive airway pressure to the patient throughout the breathing cycle.
- **Bi-level Titration Mode** - The device cycles between IPAP and EPAP in synchrony with the patient's breathing efforts.
- **Auto-CPAP Titration Mode** - The device automatically adjusts and applies the minimum CPAP level to a patient's airway to treat OSA. The Auto-CPAP mode has the ability to determine upper airway instability and generate the minimum pressure necessary to overcome airway collapse within a set pressure range defined by the Minimum Pressure and Maximum Pressure settings.
- **Split Night with Auto-CPAP Titration Mode** - The device delivers a minimum CPAP pressure for a preset time period referred to as the Delay Time. During this time, the device will monitor airway pressure and collect and store data, but will not respond to airway instability. Once the Delay Time ends, the system will automatically respond to airway instability by increasing or decreasing the pressure to meet the patient's needs within designated pressure limits.

Technical Description

The Quartet Clinical System is intended to apply continuous positive airway pressure, known as CPAP, bi-level positive airway pressure, and self-titrating CPAP therapies to adult patients who suffer from OSA. The device can operate on either 115 or 230 Volts AC. As shown in Figure 12-1, the System consists of the Quartet device, a clinical remote control device called the Maestro CRC, and the recommended patient circuit that is used to direct the air to the patient. The tubing, exhalation port, and mask are referred to as the patient circuit.

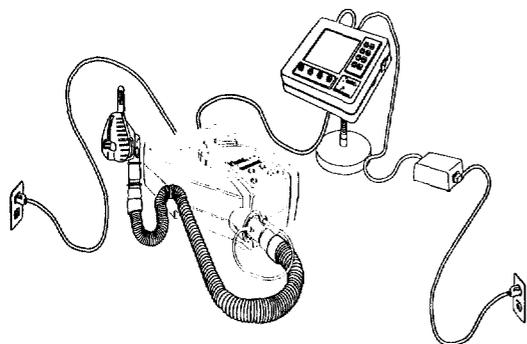


Figure 12-1. The Quartet Clinical System

The primary components of Quartet device are a blower motor assembly and a microprocessor control system. The blower motor is capable of generating positive airway pressures from 3 to 20 cm H₂O. The level of pressure is dependent on motor speed, which is controlled by a microprocessor-controlled feedback system.

Hardware - Quartet Device

The Quartet device is approximately 5.40" 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

- Transformer
- Quartet Main printed circuit board
- Power entry module
- Filter (with or without optional fine filter)
- Filter cap
- Communications connector

Quartet Clinical System Accessories

Maestro Clinical Remote Control

Accessories for the Quartet Clinical 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 Virtuoso Smart CPAP System are also intended for use with the Quartet Clinical System. These accessories have not been modified since the Virtuoso was determined substantially equivalent. Please refer to K953930 for complete accessory information.

An additional accessory intended for use with the Quartet Clinical System is the King Bacteria Filter (K880681). Please refer to that cleared 510(k) for complete information.

The following table lists the patient circuit accessories that are available for use with the Quartet Clinical System, the manufacturer, and the reference number under which each accessory received 510(k) clearance.

Table 12-1. Quartet Clinical System Patient Circuit Accessories

Accessory	Reference 510(k)
Respironics Contour Nasal Mask and headgear	K911856
Respironics Spectrum™ Disposable Full Face Mask and headgear	K936047
Respironics Comfort Flap® Mask Accessory	K883825 (BiPAP System)
Respironics Flexible Tubing Assembly	K883825
Respironics Whisper Swivel® Exhalation Port	K883825
Respironics GEL™ Mask and headgear	K954207

Respironics Monarch™ Mini Mask and headgear	K945938
King Bacteria Filter	K880681

Principles of Operation

CPAP Therapy

The therapeutic effect of CPAP, as provided by the Quartet Clinical System, is stabilization or splinting of the upper airway to prevent an apneic event. OSA is a disorder in which breathing is affected during sleep because the upper airway, in the area of the throat, collapses. The major complications of this disorder are excessive daytime sleepiness, a drop in blood oxygen level during sleep, and potential cardiovascular complications such as high blood pressure. The traditional treatment for this disorder is the application of CPAP. A physician determines the therapeutic pressure level required for effective treatment. Pressure is applied through a mask and helps keep the airway open, just as a small amount of pressure in a balloon keeps the balloon inflated. Patients requiring CPAP therapy are not at any risk if therapy stops during treatment, as patients are able to continue breathing spontaneously.

Patients are typically prescribed CPAP therapy based on diagnostic testing in a clinical environment such as a sleep lab, which can involve measurements of sleep level, respiratory effort, airflow, oxygen saturation, leg movements, and EKG. This data is analyzed to determine if CPAP treatment is appropriate. Patients diagnosed with OSA are connected to the Quartet Clinical System and monitored throughout the night using standard polysomnography to determine the device settings required for effective treatment of the disease. The results of the sleep studies are recorded. The physician uses the recorded information to prescribe the patient CPAP device that will best treat the patient. Patients are then referred to a therapist or a home care provider who prepares the CPAP device for the patient. Preparation includes setting up the device with the settings indicated by the physician. The therapist or home care provider instructs the patient on how to use the device.

Air Pressure Delivery of the Quartet Device

When the Quartet 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

12-2 shows the Quartet device and the patient circuit (six-foot, 3/4 inch I.D. tube and a patient interface/nasal mask.)

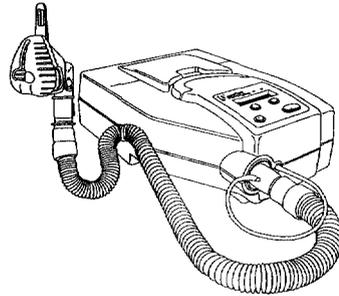


Figure 12-2. The Quartet Device and Patient Circuit

Therapy can be provided by a single level (CPAP and Auto-CPAP modes) or two levels (Bi-level mode) of positive pressure.

The Quartet System applies CPAP to adult patients suffering from OSA and incorporates four titration modes; a CPAP mode, a Bi-level mode, an Auto-CPAP mode, and a Split Night with Auto-CPAP mode.

Controls and Functions

During patient therapy, a clinician uses the Maestro CRC to control and retrieve information from the Quartet device. These operations include the adjustment of settings at the Maestro CRC while connected to the Quartet device.

The Maestro CRC provides the clinician with the capability of setting the mode of operation, pressure settings, pressure ranges and various operational parameters of the Quartet device. The Maestro CRC also provides data monitoring capabilities, alphanumeric and graphical representations of patient data, and 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 Quartet device whether or not it is connected to a polysomnograph.

Selecting Functions

The clinician can use the Function Buttons located below the Maestro CRC Display Screen to select the following functions:

The device function buttons allow the Quartet Clinical System to perform the following:

- Calibration - The clinician has the option to send calibration signals to the polysomnograph by pressing the "System Options/Cal" Function Button as indicated by the main menu screen. By pressing the "Calibrate Recorder" Button, the clinician can alternate between the baseline output signals and gain output signals allowing calibration of the polysomnograph.
- Mask Removal Indicator - The clinician can access the audible settings of the Mask Removal Indicator of the Maestro by pressing the "System Options/Cal" Function Button as indicated by the main menu screen. Using the Setting Buttons, the clinician can activate or deactivate the audible tone and adjust its volume.
- View Graphs - The clinician can view patient profile screens at any time during therapy by pressing the View Graphs Function Button indicated by the main screen. With this function, graphs and messages relating to patient profile data (Pressure Profile and Event Predictor Profile) are shown on the display screen. The graphs represent the pressure applied to the patient for the past hour or eight hours.
- Ramp - Ramp is applicable to both CPAP and Bi-Level modes. It is used if a physician prescribes ramp for a patient.

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 indicated by the main screen. Using the Setting Buttons, the Minimum Ramp Pressure can be set from 3.0 cm H₂O to the CPAP setting in CPAP mode, and 4.0 cm H₂O to the EPAP level in Bi-level mode, and the Ramp Time can be set from 0 to 45 minutes. • Change Mode - The mode settings for the Quartet Clinical System are:

- CPAP mode
- Bi-level mode
- Auto-CPAP mode
- Split Night with Auto-CPAP mode

Adjusting Parameter Settings

The Setting Buttons, located at the right of the Display Screen, adjust the device parameter settings for the various functions.

The parameter settings are:

CPAP mode:

- Therapeutic Pressure
- Minimum Ramp Pressure
- Ramp Time

Bi-level mode:

- IPAP
- EPAP
- Minimum Ramp Pressure
- Ramp Time

Auto-CPAP mode:

- Minimum Pressure
- Maximum Pressure

Split Night with Auto-CPAP mode:

- Delay Time
- Minimum Pressure
- Maximum Pressure

Software Control System - Quartet Clinical System

The Quartet Clinical System includes both the Quartet device and the Maestro CRC, which are both software-driven. This section contains a detailed functional description of the Software Control System for both devices.

Quartet Device Software

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

- Apnea Prediction (Auto-CPAP Mode)
- Bi-level Pressure Control (Bi-level Mode)
- Blower Time Logger
- Pressure Control
- Pressure Error Calculation
- Pressure Mediator
- Sensor Module
 - Flow Sensor Function
 - Motor Speed Voltage & Valve Voltage
 - Pressure Sensor Function
 - Snore Sensor Function
- Stored Parameters
- Therapy Menu
- User Interface
- Watchdog Timer

Maestro CRC Software

The purpose of the Maestro CRC software is to control the monochrome LCD, the five DC outputs to the recording device, and the serial communications port. 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 Quartet device. The Maestro CRC will receive data via the serial communications port from the Quartet device.

Safety and Effectiveness

Testing was performed to demonstrate that the performance of the Quartet Clinical System in its intended environment is as safe and effective as that of the legally marketed predicate devices.

The safety and effectiveness of the Quartet Clinical System was verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, and Mechanical and Environmental testing. The Quartet Clinical System was found compliant and has been certified to the following standards referenced in the "FDA Reviewer Guidance for Premarket Notifications."

- IEC 601-1: General Requirements Safety of Medical Electrical Equipment;
- IEC 801-1: Electromagnetic Compatibility for Industrial Process and Measurement and Control Equipment. Part 1;
- IEC 801-2: Electrostatic Discharge Requirements;
- IEC 801-3: Radiated Electromagnetic Field Requirements;
- IEC 801-4: Electrical Fast Transients/Burst Requirements;
- CIPSR 11: Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific, and Medical Equipment;
- CISPR 16: CISPR Specification for Radio Interference Measuring Apparatus and Measurement Methods;
- IEC 68-2-6: Basic Environment Test Procedures. Part 2: Tests. Test Fc and Guidance: Vibration (Sinusoidal);
- IEC 68-2-27: Basic Environment Test Procedures. Part 2: Tests. Test Ea and Guidance: Shock;
- IEC 68-2-37: Basic Environment Test Procedures. Part 2: Tests. Test Fdc: Random Vibration Wide Band - Reproducibility Low;
- MIL-STD-461D: Requirements for Control of Electromagnetic Interference Emissions and Susceptibility;
- MIL-STD-462D: Measurements of Electromagnetic Interference Characteristics; and
- MIL-STD-810E: Environmental Test Methods