Section 16
Summary of Safety and
Effectiveness

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Classification Name

Noncontinuous Ventilator

Common/Usual Name

Remote Control

Proprietary Name

Maestro Clinical Remote Control

Predicate Device

Puritan-Bennett Companion 318 Nasal CPAP
Diagnostics System (K910194)

Respironics' REMstar Choice Clinical Remote
Control (K920699)

Predicate Device Information

The technological characteristics of the Maestro Clinical Remote Control (CRC) are substantially equivalent to the predicate devices listed above in terms of design, materials, energy source, and intended use. All three devices are intended for remote operation and monitoring of CPAP devices used in hospital/sleep laboratory settings to treat adult patients who suffer from Obstructive Sleep Apnea (OSA).

Substantial Equivalence

The Maestro Clinical Remote Control is substantially equivalent to remote and instrumentation portions of the Puritan-Bennett Companion® 318 Nasal CPAP Diagnostics System (K910194), and the Respironics REMstar Choice® Clinical Controller (K920699). These predicate devices are remote control and data monitoring devices intended for use with CPAP systems in the diagnosis and treatment of adult Obstructive Sleep Apnea. They are intended to be used by clinicians in hospital (sleep laboratory) environments and are not intended for life support or life-sustaining applications.

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

Intended Use

The Maestro CRC is an optional accessory that provides remote control capabilities when used in conjunction with Respironics Aria CPAP and Virtuoso Smart CPAP Systems and is intended for use by a qualified clinician (any individual trained to perform sleep study diagnoses) in hospital/sleep laboratory settings where adult patients suffering from OSA are diagnosed and treated.

Claims

The Maestro CRC :

- Provides data monitoring capabilities
- Presents alphanumeric and graphical representation of patient data
- Interfaces with a polysomnograph data recording device

Benefit of using the Maestro CRC

The Maestro CRC enables the clinician to control and operate the Aria and Virtuoso Systems from a remote location, assuring that a patient receives uninterrupted sleep, necessary to diagnose and treat OSA. Using the Maestro CRC, a clinician can adjust CPAP device settings and monitor data from a control

room, rather than in the bedroom where these activities could potentially disturb the patient from sleep.

Device Description

The Maestro CRC (Figure 16-1) incorporates a control panel with a display screen and two user keypads (for Function and Setting buttons, respectively) on top. Eight DC signal output ports (five of which are active: two of which will be usable with the Aria and Virtuoso Systems covered in this premarket notification), a power supply connector, and two communications connectors (one of which will be usable with the Aria and Virtuoso Systems covered in this premarket notification) are located on the back of the unit. A contrast adjustment control and a power on/off control accompanied by a Light Emitting Diode (LED) power on indicator are provided on its right side section. An annunciator and microprocessor are contained within the Maestro CRC enclosure. The enclosure measures 9 1/2" x 2" x 7 3/4" (W x H x D).

Note: The three auxiliary DC signal output ports and one auxiliary communications connector are not electrically connected and are, therefore, inactive. The auxiliary ports and connector are for future use and will not be covered in this premarket notification.
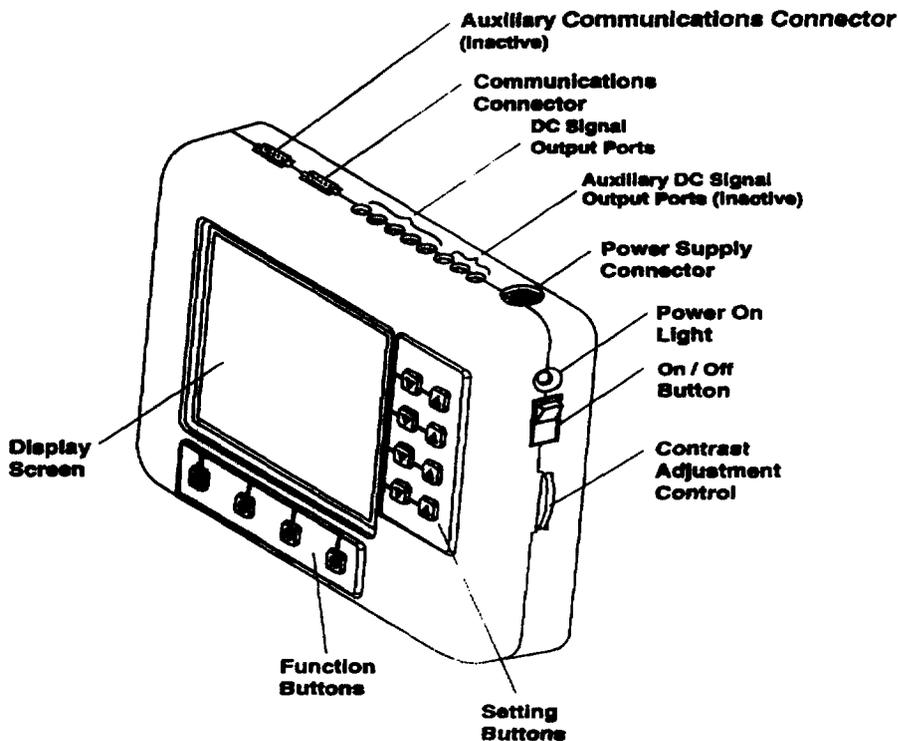

Figure 16-1. Maestro Clinical Remote Control

DC Signal Outputs

The Maestro CRC may optionally be connected by cable to a polysomnograph machine. Data is transmitted as DC signals through the Maestro's DC signal output ports (Figure 16-2). The ports are labeled for their respective signals. The signals are Event Predictor, V_T (Estimated Tidal Volume), $\dot{V}_{est}$ (Estimated Patient Flow), P (Pressure) and $\dot{V}_{leak}$ (Estimated Leak). Only the Event Predictor (for the Virtuoso) and Pressure (for the Aria and Virtuoso) signals are used when the Maestro CRC is connected to the Aria or Virtuoso. The remaining signal outputs are for the Duet and Quartet Systems, and will be covered in a future premarket notification applying to use of the Maestro CRC with these devices. Table 16-1 describes output signals available from the Maestro CRC when connected to the Aria and Virtuoso CPAP Systems.
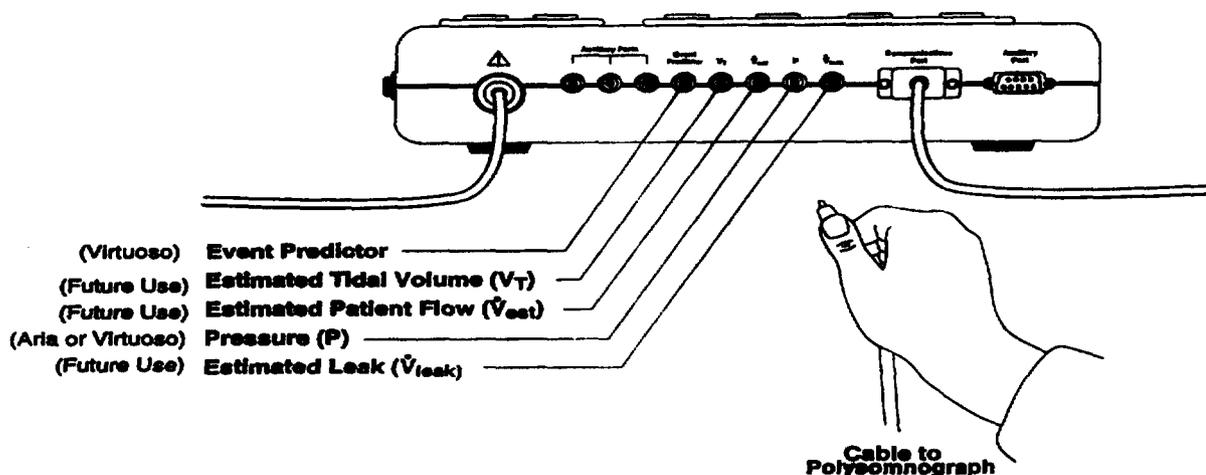

Figure 16-2. DC Signal Outputs

Table 16-1. Signal Outputs

	Event Predictor	V_T	$\dot{V}_{est}$	P	$\dot{V}_{Leak}$
Aria CPAP System	N/A	N/A	N/A	X	N/A
Virtuoso Smart CPAP System	X	N/A	N/A	X	N/A

Note: There is no signal if a cable is connected to an output port that is not applicable to the Aria and Virtuoso devices. The availability of the DC signals from the Maestro CRC to the polysomnograph is a function of the specific CPAP device that is connected to the Maestro CRC. For example, connection to $\dot{V}_{est}$, V_T, and $\dot{V}_{leak}$, when the Maestro CRC is connected to the Aria would result in no DC signal output to the polysomnograph.

Description of Signals

Since this premarket notification addresses use of the Maestro CRC with the Aria and Virtuoso Systems, only the signals applicable to the Aria and Virtuoso Systems (Event Predictor and Pressure) will be discussed.

- Event Predictor - This signal counts the number of recognizable energy patterns created by an unstable airway within one minute. The Event Predictor output signal may provide an early warning that abnormal breathing events are about to occur.

- Pressure (P) - This signal permits continuous recording of the pressure measured at the mask.

Principles of Operation

The Maestro CRC provides remote operation and monitoring of the Aria and Virtuoso Systems. Maestro also provides recording capabilities via outputs that connect to a polysomnograph for data recording. The data recording function is optional. The Maestro CRC can control the connected CPAP device whether or not it is connected to a polysomnograph.

When a patient is receiving therapy from the Aria or Virtuoso CPAP System, patient information/data is sent from the CPAP device to the Maestro CRC's memory. This information is updated at a frequency of 100 Hz. When the clinician uses the keypads to change settings or select functions, the microprocessor selects this information from the appropriate storage area for screen and/or polysomnograph display.

The Maestro CRC does not override or disable the pressure control at the CPAP device and cannot turn the CPAP device on or off. The following features of the Aria and Virtuoso Systems are disabled when connected to the Maestro:

- Auto On - Air flow will no longer automatically turn on when the patient inhales through the connected patient circuit.

- Auto Off - Air flow will no longer automatically turn off when the mask is removed.

- Audible Alerts (Mask Removal indicators) - All alerts will now sound only at the Maestro CRC so that the patient is not disturbed during the study.

- Ramp/Reset Button - Pressures can only be ramped and reset at the Maestro CRC; however, in Virtuoso's Auto-CPAP mode, the Reset Button at the Virtuoso unit will reset the CPAP device during the leak test. Simply, a leak test is a 60 second test that allows the clinician to ensure that there are minimal or no leaks in the patient circuit.

Operations

When using the Maestro CRC, a clinician can perform a number of operations to control and retrieve information from the Aria or Virtuoso System. These operations include the adjustment of settings at the Maestro device while connected to either the Aria CPAP or Virtuoso Smart CPAP Systems. Since this premarket notification addresses only the Aria and Virtuoso Systems, only the operation of functions relating to these devices will be discussed.

CPAP system functions include modes of operation, parameter settings for each mode, and device parameters. Table 16-2 describes the modes available with the Aria and Virtuoso Systems, and a description of the modes follows.

Table 16-2. Modes of the Aria and Virtuoso Systems

	CPAP Mode	Auto-CPAP Mode	Split Night with Auto-CPAP Mode
Aria CPAP System	X	N/A	N/A
Virtuoso Smart CPAP System	X	X	X

CPAP Mode

In the CPAP mode, the Aria and Virtuoso Systems produce fixed continuous positive airway pressure. The clinician can adjust settings to the following parameters in the CPAP mode:

- Therapeutic Pressure
- Minimum Ramp Pressure
- Ramp Time

Auto-CPAP Mode

The Auto-CPAP mode has the ability to automatically determine upper airway instability and automatically generate a minimum pressure necessary to overcome airway collapse within a set pressure range defined by the Minimum Pressure and Maximum Pressure settings. The clinician can adjust settings to the following parameters in the Auto-CPAP mode:

- Minimum Pressure
- Maximum Pressure

Split Night with Auto-CPAP Mode

The term "Split Night" refers to a common sleep laboratory procedure in which a patient is diagnosed for half the night and titrated during the remaining half of the night. In this mode, the Virtuoso will deliver a minimum CPAP pressure for a preset time period referred to as the Delay Time. During Delay Time, the device will monitor and store data, but will not respond to airway instability when CPAP pressure is required. 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. The clinician can adjust settings to the following parameters in the Split Night with Auto-CPAP mode:

- Delay Time
- Minimum Pressure
- Maximum Pressure

The parameter settings for each mode are described below.

Therapeutic Pressure

The Therapeutic Pressure parameter applies only to the CPAP mode. Therapeutic Pressure is defined as the CPAP pressure level set by the clinician. The clinician can increase or decrease Therapeutic Pressure using the Setting Buttons.

Pressure adjustments can be made any time during therapy with a range of 3.0 to 20.0 cm H_2O.

Ramp, Minimum Ramp Pressure, Ramp Time

The Ramp parameter applies only to the CPAP mode. When activated, the Ramp feature initially reduces Therapeutic 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 Therapeutic Pressure allowing the patient to fall asleep more comfortably. The time period required for the pressure to increase from Minimum Ramp Pressure to the Therapeutic Pressure 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 to 20.0 cm H_2O and the Ramp Time can be set from 0 to 45 minutes.

Delay Time

The delay time parameter applies only to the Split Night with Auto-CPAP mode. In this mode, the Virtuoso will deliver a minimum CPAP pressure for a preset time period referred to as the Delay Time. Using the Setting Buttons, this parameter can be set from 30 minutes to 8 hours.

Minimum Pressure/Maximum Pressure

These Minimum Pressure/Maximum Pressure parameters apply only to the Auto-CPAP and Split Night with Auto-CPAP modes. Minimum and Maximum Pressure levels can each be set from 3 to 20 cm H_2O. Minimum Pressure cannot be set higher than the Maximum Pressure setting, and Maximum Pressure cannot be set lower than the Minimum Pressure setting.

Reset

The Reset feature is only operable in the Auto-CPAP and Split Night with Auto-CPAP Modes on the Virtuoso System. When selected, Reset decreases the pressure to the Minimum Pressure setting and begins the self-titrating cycle again.

Maestro Device Parameters

Each Maestro function (Calibration, Mask Removal Indicator, View Graphs) is operable in all modes of the Aria and Virtuoso Systems.

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 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 Mask Removal Indicator uses an audible tone and a visual indicator to provide an alert if the mask, which delivers air pressure from the CPAP unit to the patient, is inadvertently removed or develops a significant leak during therapy. When using the Maestro CRC, all annunciators (visual and audible) are disabled at the CPAP device. The visual indicator is displayed on the Maestro's display screen and the audible tone is sounded through Maestro's annunciator. The audible tone can optionally be deactivated.

The clinician can access the audible settings of the Mask Removal Indicator by pressing the "System Options/Cal" Function Button as indicated by the main 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.

<u>User Operations</u>

Set-up Procedures

The Maestro CRC communicates with the Aria or Virtuoso System by means of a Communications cable that connects the two devices via the RS-232 communication port. Optional connections from the Maestro CRC to a polysomnograph are made through the DC analog outputs that are applicable to the Aria and Virtuoso devices (i.e., Event Predictor and Pressure).

Start-up of the Maestro CRC

The clinician powers the Maestro CRC by turning the power on/off control switch to the on position. The LED adjacent to the power switch illuminates, indicating that the unit is powered, and an audible alert sounds. At start-up, the device performs a self-test, initializes the device software, and displays the start-up screen. An executable control function within the microprocessor manages normal and fault operational states, and identifies which Respironics CPAP System is connected. As the microprocessor completes the self-test and initialization, the Maestro CRC displays the start-up screen for approximately five seconds before the main screen appears.

Using Display Menu Screens

The Maestro CRC Display Screen provides patient information as well as guidance in using the system. The screen also provides messages that keep the operator updated on the therapy being provided. Each menu screen will provide the following information:

- Screen title
- Current mode
- Event Predictor*
- Current use of each Function and Setting Button

*This parameter is only displayed in the Auto-CPAP mode when Maestro CRC is connected to the Virtuoso System.

In addition, a message area is provided in each menu screen for messages and directions that Maestro provides relating to selecting functions, setting parameters, and system status.

Selecting Functions

At the main screen, the clinician can use the Function Buttons located below the Display Screen to select the following Maestro CRC functions: System Options/Calibration, Ramp, View Graphs, and Change Mode. When the clinician selects a function, the appropriate menu appears on the Display Screen.

The Maestro CRC identifies the specific CPAP device model connected and the related functions available for control and display. The Maestro CRC will only provide menus for functions applicable to the CPAP System to which it is connected.
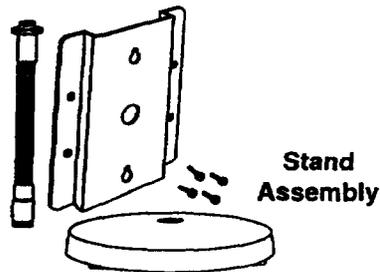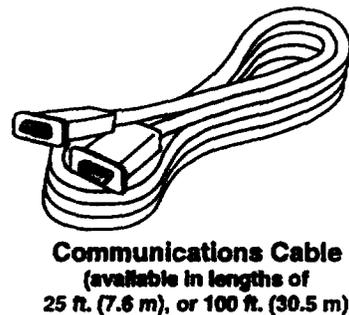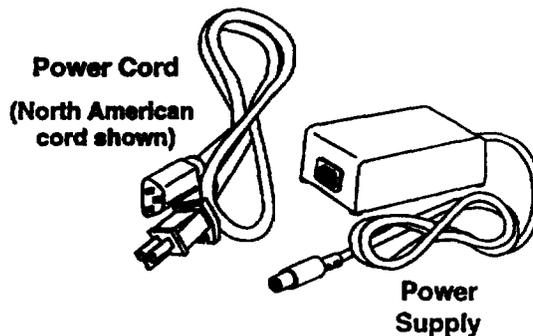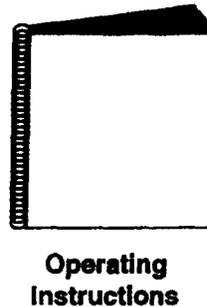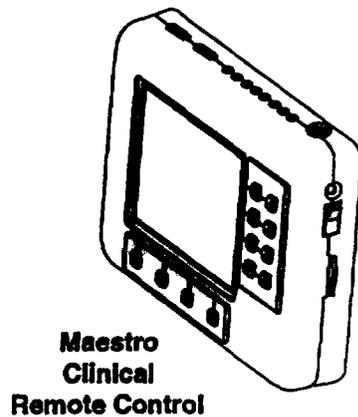
Adjusting Parameter Settings

The Setting Buttons, located at the right of the Display Screen, adjust the device parameter settings within the various function menus. Setting Buttons will relate to the parameters applicable to the current display screen. The menu provides on-screen display of the title for the current parameter of each pair of Setting Buttons.

Accessories

There are no patient interface devices, such as masks, tubing, exhalation ports, or humidifiers, for use with the Maestro CRC. The Maestro CRC comes packaged with the following accessories:

- Communications Cable (available in lengths of 25 ft. or 100 ft.)
- Power Supply (for connection to a 115 V or 230 V AC outlet)
- Power Cord (115 V or 230 V, depending on country of use)
- Operating Instructions
- Stand Assembly for positioning the Maestro CRC unit in a convenient position for viewing and operation

Maestro Clinical Remote Control

Operating Instructions

Power Cord

(North American cord shown)

Power Supply

Communications Cable (available in lengths of 25 ft. (7.6 m), or 100 ft. (30.5 m)

Stand Assembly

Safety and Effectiveness

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

The safety and effectiveness of the Maestro Clinical Remote Control was verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, and Mechanical and Environmental testing. The Maestro CRC 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

The Maestro Clinical Remote Control is intended specifically for use with the Respironics Aria CPAP and Virtuoso Smart Systems that provide Continuous Airway Pressure (CPAP) for the treatment of adult OSA. CPAP devices, with and without remote control, have been on the market since 1984 and have been shown to be effective in treating this disease.

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