Fisher & Paykel
HEALTHCARE

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510(k) Summary of Safety and Effectiveness Information

Model Number / Name: **HC500 Servo-Controlled Heated Respiratory Humidifier**
Classification Name: Humidifier, Respiratory Gas, Direct Patient Interface - 73 BTT Anesthesiology Devices, 21 CFR §868.5450
Predicate Devices: Fisher & Paykel, MR730 Respiratory Humidifier, K913368
Fisher & Paykel, MR410 Respiratory Humidifier, K913367

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The HC500 is enclosed in a thermoplastic case that features an aluminium heater plate mounted in the top of the unit, with a chamber clamping mechanism. The device indicators, controls and temperature display are located on the front panel. Sockets for a temperature probe and heater wire, and the power switch are on the right side, and a mounting bracket is located on the back of the device. The HC500 measures 135 x 170 x 156mm and weighs 2.8kg without a humidification chamber fitted. It contains a mains transformer and Power and Control printed circuit boards.
The HC500 Servo-Controlled Heated Respiratory Humidifier controls the addition of heat and humidity to respiratory gases delivered through a patient delivery circuit. The humidifier operates in two modes that are individually selected: (1) Non Heated Wire mode, and (2) Heated Wire mode.
In the Non Heated Wire mode, gas temperature and humidity is determined by the heater plate temperature and gas flow rate. The heater plate temperature is set by the control knob, from 45°C to 80°C, and controlled by a thermistor mounted on the heater plate which provides feedback to a software controlled Proportional, Integral, Derivative (PID) algorithm. The airway temperature is monitored by in line temperature probes at the exit of the humidification chamber and at the patient end of the delivery circuit. A high temperature alarm is set to 41°C at the patient end of the delivery circuit. Enabling the alarm turns off the heater element and turns on audible and visual alarm indicators, and the temperature display. In normal operation the patient airway temperature can be displayed on the front panel by pressing and holding the mute button.
In the Heated Wire mode, gas temperature and humidity is determined by controlling the heater plate and a heater wire in the patient delivery circuit. The patient delivery temperature is set by the control knob, from 32°C to 39°C. The heater plate controls the temperature at the output of the humidification chamber and there is a +2°C rise to the patient end of the delivery circuit which is controlled by the heater wire. The temperature rise in the patient delivery circuit minimises rainout in the delivery circuit.

Feedback to the PID software is provided by the heater plate thermistor and the airway temperature probes. If a high temperature (≥ 41°C) alarm is detected at the end of the patient delivery circuit, both heater elements are shut off and the audio and visual indicators and temperature display are turned on for the duration of the alarm. Chamber high temperature alarms are set at ≥ 47°C, and 41°C for longer than 20 minutes. The patient airway temperature is available in the same manner as the non heated wire mode.
The HC500 features a 118°C thermal overheat cut-out on the heaterplate, a back-up electronic over temperature protection circuit, and connection or fault alarms for the temperature probe and heater wire.

The intended use of the HC500 is to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using an artificial ventilation system. This includes use with systems such as portable volume ventilation systems, pressure support ventilation and continuous positive airway pressure (CPAP) devices. These systems may bypass the patient airway (using an endotracheal tube) or use mask ventilation. Providing heat and humidification to these gases counteracts the effects of bypassing the nose, pharynx and trachea, where this function would normally be carried out by the body. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through mask ventilation is similarly beneficial to prevent drying of the patient airways. The HC500 is primarily intended for a home-use situation, typically for patients requiring long-term respiratory assistance of a non-critical nature (ie not requiring hospital or intensive care levels of attention).
To accommodate this more specific intended environment of use of the HC500 from the predicate device, the Operating Manual has been rewritten to clearly detail the responsibilities of the home caregiver and supervising clinician, provide expanded cleaning and maintenance sections, and emphasize safety precautions. The HC500 has been modified to suit home use, with unnecessary features removed, controls simplified and made less liable to inadvertent adjustment.

The technological characteristics of the HC500 are equivalent to the predicate device. The device size, shape, material construction, and location of functional components are all retained in the HC500. All significant components of the HC500 are identical to those used on the MR730 or MR410 predicate devices. These include all enclosure, mounting and chamber retaining components, heater plate assembly, internal chassis and transformer, PCB's, microprocessor, power supply cord and external connectors or sockets, and internal connectors and wiring. The devices both use a nominal 115Vac 60Hz mains supply.
The changes between the HC500 and predicate devices consist of a rearrangement and simplification of available features in order to make these more appropriate for the intended home use of the device. These differences consist of the following items. Element power is reduced to 85W and maximum heaterplate temperature reduced to 100°C, as the reduced maximum flow specification for the HC500 requires less power for equivalent performance. The temperature control range and lower alarm limits have been adjusted to suit a home use environment. A power on indicator is added, and alarm indicators combined on the front display panel. Data

I/O and stand by mode features are removed as are not required in a home use application. The chamber temperature display, chamber offset control, heater wire mode switch and general temperature display features, while still available on the HC500, have been reduced in general accessibility to the user as are expected to be required very infrequently. The heaterplate temperature in non heated wire mode is software controlled, as the MR410 predicate device which uses this mode has electronic control only. The additional safety features of airway temperature monitoring and display, with temperature, connection and fault alarms, have been added to non heated wire operation.

A series of non-clinical tests have been carried out for the HC500 to establish correct operation of the device in mechanical, electrical, software and performance aspects. Mechanical shock, vibration and environmental conditions testing ensures that the HC500 can withstand extreme conditions of use without loss of function or significant physical damage to the unit. The HC500 electrical and hardware characteristics remain equivalent to the predicate devices, and maximum power usage ratings have been established by testing. All electrical safety parameters such as leakage current are within limits set by international design standard. Software changes from the predicate device have been verified through functional tests, which prove correct operation of the features which have had parameters modified for the HC500. Performance testing demonstrates that the device functions as specified under a variety of conditions of use, and with the home respiratory care equipment which the HC500 will be used with. Comparative testing for both heated wire and non heated wire operating modes ensure that performance is equivalent to the predicate devices in terms of delivery of absolute humidity or temperature levels within the specified flow limits of the HC500.

The results of the performance and other testing carried out for the HC500 establish that the device has the same or better safety and effectiveness characteristics over the predicate devices, due to the high level of similarity between these models, and the application of additional safety features not previously available in non heated wire mode use. The HC500 has equivalent or better performance characteristics over the specified range of use for the device, as the reduction in heaterplate power used in heated wire mode is compensated for by the reduced operating flow specification necessary for home use of the device.

signed: _____ date: 14 July 1995

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