K012691

ACUTRONIC MEDICAL SYSTEMS	510(k) Summary MONSOON Rev 3	1 of 8

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

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

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DEC 2 0 2002

b. Contact Person: Pius Cavelti

Director Sales / Marketing

c. Date Summary Prepared: September 25, 2002

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Monsoon

b. Classification Name: Ventilator Continuous

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	ACUTRONIC Medical Systems AG
Device:	AMS-1000 Universal Jet Ventilator
510(k) :	K863155
Date Cleared:	8/15/86

Company:	ACUTRONIC Medical Systems AG
Device:	AMS-1020 Heated Jet Humidifier
510(k) :	K863154
Date Cleared:	8/15/86

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

All in one concept:

In the past time, a jet ventilator system consisted of a jet ventilator and a humidifier, both made as individual units in separate enclosures. Now, those components in electronics became smaller and smaller, both units have been put together in one enclosure.

Airway pressure measurement:

One of the key features of the MONSOON is the safety concept to avoid having excessive pressures occurring in the patient's airways. To reach this goal, a high pressure resistant sensor with excellent resolution in the working range of 1 to 200 cmH2O is used.

Bias flow:
Another new feature in airway pressure measurement is the use of a small bias flow going through the airway pressure line, to eliminate the dead-space of the airway pressure line. In addition, the bias flow avoids, bacteria and humidity going back into the machine, creating contamination. If the airway pressure line is occluded, the bias flow makes the pressure rising and the ventilation is stopped immediately.

Display:

A large screen displays the main parameters of ventilation and allows quick information of the anaesthetist about the status of the ventilation. A graphic indication of the airway pressure makes quantitative reading possible and allows quick access for parameter changes. Special functions are activated in menus and displayed on the screen.

Air / Oxygen blender:

The MONSOON has a built in blender, which allows concentrations between 21 and 100 % oxygen. The access for changes is via a knob on the front panel. This parameter is accessible without going into menus, to allow a rapid change in case of emergency. The MONSOON uses an oxygen sensor, which is calibrated each time the unit, is switched on. If the ventilator can't reach the selected FiO2, an alarm message appears on the screen, informing about a problem in the gas supply.

Bypass flow:

The MONSOON has an additional outlet for gas, which can be adjusted from 0 to 70 LPM and a concentration between 21 % and 100 %. This feature allows mask ventilation of the patient for induction in anaesthesia or for emergency ventilation with a manual breathing bag.

Humidification and heating system:

The MONSOON is equipped with a heating and humidification system, controlled by the microprocessor, which automatically adjusts the water injection and temperature of the jet gas. The water supply is based on the minute volume and therefore guarantees an efficient climatisation of the gas. In the MONSOON, the gas is preheated prior the injection of the water and therefore a saturation of the gas is achieved much easier. On the ventilator, all changes affecting the minute volume are controlled by the microprocessor, resulting in a reduction or increase of water injection. The temperature is controlled by a PT-100 temperature sensor and for safety; a thermostatic switch shuts down the heating system in case of a system failure. If the water supply is occluded or the bottle is empty, an alarm message on the screen informs the operator.
The MONSOON has a small roller pump mounted on the right side of the unit, allowing easy access. A standard IV set is used to connect the bottle with the pump inlet.

Microprocessor and Memory:

H8 532 (manufactured by Hitachi) Clock frequency 10MHz

Memory devices:

27C512	(several types available)	64kB EPROM
DS1386	(manufactured by Dallas)	32kB RAM timekeeper external watchdog

Sensors:

200 cmH2O pp-pressure sensor (Honeywell)
monitoring pressure condition in Jet tube sampling rate depending on jet frequency max 2.5 samples per second

200 cmH2O pip-pressure sensor (Honeywell)
monitoring pressure condition 10 ms

72.5 PSI driving-pressure sensor (Honeywell)
monitoring driving pressure sampling rate maximum 200 ms

142 cmH2O differential pressure sensor (Honeywell)
monitoring jet flow in Jet tube sampling rate depending on jet frequency max 2.5 samples per second

142 cmH2O differential pressure sensor (Honeywell)
monitoring bypass flow in Jet tube sampling rate 10 ms

PT 100 temperature sensor (Jumo)
regulates temperature of heating system sampling rate 500ms

EPL 10 Bubble detector (Argus)
water detector sampling rate 100 ms

Fault-Detection:

PP sensor is periodically checked for disconnection, shortcut and defective membrane (period: depending on frequency setting) ***failure results in error message***

PIP sensor is periodically checked for disconnection, shortcut and defective membrane (period: depending on frequency setting) *failure results in error message*

Driving pressure sensor is checked for disconnection & shortcut (period: depending on frequency setting) *failure results in error message*

Differential pressure sensors are periodically checked for disconnection & shortcut (period: depending on frequency setting) *failure results in error message*

Oxygen sensor is periodically checked for disconnection, shortcut and capacity (period: depending on actual regulated difference capacity only in auto calibration mode (startup routine)) *failure results in error message*

Full time gas input detection *failure results in alarm message*

Fully regulated temperature in heating system (timeout and high temperature alarm plus thermostatic HW security) *failure results in alarm message*

Fully regulated oxygen concentration with timeout function *failure results in alarm message*

Water supply is periodically checked *failure results in alarm message*

Alarm functions

General information

In case of an alarm, the MONSOON will display the alarm message on the screen and an acoustic alarm sounds. The acoustic alarm is ceased as soon as the alarm condition is cleared. However, the screen message remains until it is confirmed by pressing the alarm reset button. If you press alarm reset button while the alarm conditions is not cleared, there is an alarm mute for 1 minute activated, which depresses the acoustic alarm for this period. The screen inverses to make the user aware that the alarm mute is active.

The Monsoon has an alarm concept to allow a safe use of the equipment for patient and operator. The following section shows the different alarm types and their sources:

PIP too high:

This alarm is activated if the airway pressure exceeds the set limit. It is only measured if the Proximal Pressure line is connected with the unit and therefore requires double lumen catheters.

PIP disconnect:

This alarm is activated if there was no pressure detected in the Proximal Pressure Line

PP too high:

This alarm is activated if the pressure in the Jet line remains above the set limit for the PP pressure. This alarm is a safety feature for the use of Jet Ventilation with single lumen catheters. It allows a security shut-off of the Jet Ventilator in case of an airway obstruction.

add water:

This alarm is activated when the water-detector in the unit doesn't detect any water.

System alarms

General information

These alarms signal the user a state of improper function of the device. There is no immediate danger to the patient but the device should be replaced and serviced by authorized personal (exception: low level of pressure input).

Specification and characteristics of the *ventilation* alarm

Application:
The ventilation device makes sure that max. oxygen level in the Jet ventilator is below a level of concern. The ventilation is periodically checked for ether disconnect (alarm level 1) or overload (alarm level 2) of the fan. This is an alarm, which cannot be disabled.

Specification and characteristics of the *FIO2 not adjustable* alarm

Application:
The FIO2 not adjustable alarm is evoked as soon as the O2 level can not be adjusted because of any other reason than missing ether O2 or airway pressure. There could be a mechanical problem or a system malfunction of the O2 regulation. If the O2 sensor could not be calibrated this alarm is also set active.

Specification and characteristics of the *temperature* alarm

Application:
The temperature is continuously watched by the controller. This is an alarm, which cannot be disabled. There is another security implied which cuts the heating power off if the temperature still rises above limitation given through software.

Specification and characteristics of the *low O2 pressure* alarm

Application:
The O2 pressure is continuously watched by the controller and goes on if there is not enough pressure on the O2 inlet. This is an alarm, which cannot be disabled. The alarm resets itself if pressure is sufficient.

Specification and characteristics of the *low air pressure* alarm

Application:
The air pressure is continuously watched by the controller and goes on if there is not enough pressure on the air inlet. This is an alarm, which cannot be disabled. The alarm resets itself if pressure is sufficient.

Specification and characteristics of *low bat* alarm

Application:
Battery level is measured and in case of a worn out battery the message "low bat" is displayed next to the time and date. There is no alarm going off because the battery is not used unless the power failure fault. This battery has not a data backup function. In case of "low bat" a replacement of the battery is sufficient.

Specification and characteristics of *Power failure* alarm

Application:
Main-line is less than 95 VAC the beeper on the back panel sounds with interval supplied by battery power. This is an alarm which can not be disabled.

Specification and characteristics of *MAINTENANCE REQUIRED* alarm

Application:
Mistral has an integrated timer function for servicing intervals. After one year, on the display the message "MAINTENANCE REQUIRED" appears. The unit may still be used, however, a service engineer must be called for servicing of the equipment to assure a proper function.

Error functions

Overview

The error message signals a system malfunction. The error messages can be reset by the alarm button but if the malfunction is still detected the message immediately returns to the screen. In any of these cases the Monsoon needs a service.

Type of error	Characteristic
PIP sensor	The PIP sensor is out of range (probably disconnected or defect)
PP sensor	The PP sensor is out of range (probably disconnected or defect)
DP sensor	The DP sensor is out of range (probably disconnected or defect)
O2 sensor is weak	O2 signal is getting to weak replace the sensor

5. Statement of intended use:

The Monsoon Universal Jet Ventilator is designed to use for bronchoscopy and laryngoscopy.

Indication for Use

Jet ventilation applied with the Monsoon Universal Jet Ventilator is useful in airway surgery, as it is performed in thoracic surgery units and ENT surgery. Jet ventilation is the optimal ventilation technique during the application of LASER light, where the presence of an ETT bears the risk for ignition, airway fire and burn injuries. Jet ventilation is useful for the removal of foreign bodies from the airway (e.g. after accidental aspiration of foreign bodies) via rigid bronchoscopes, for supplemental oxygenation during lung surgery (when the operated lung must be recruited for additional oxygenation, but may not be ventilated conventionally for surgical reasons), for surgery of the lower trachea close to the carina (when during the reconstruction phase, no tight airway sealing can be achieved), for radiation therapy of lung metastasis (when the tidal movements of the chest during spontaneous respiration or conventional ventilation would preclude the focusing of the radiation beam onto the target.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Technical feature	AMS-1000/1020	MONSOON	Comment
EEP Limit End Expiratory Pressure Limit	Yes, measured in between the pulses of Jet insufflations. Valve opens during pause to direct pressure on pressure sensor	Yes, measured with a high pressure resistant pressure sensor. Resolution 1 mbar	Due to availability of high pressure resistant sensor, quicker response of the pressure limit = increased patient safety
PIP Limit Peak Inspiratory Pressure Limit	Yes, measured trough proximal pressure line. Purged every 30 minutes to avoid bacterial contamination	Yes, measured through proximal pressure line. Purged continuously to avoid bacterial contamination and to detect occlusion of line.	Quicker response of pressure shut off in case of airway occlusion due to small bias flow in pressure line.
Tidal volume	Yes, averaged over 5 breath	Yes, measures each pulse	Better resolution of volume indication
Minute Volume	Yes, calculated, based on frequency and TV	Yes, calculated, based on frequency and TV	Better resolution and better control of humidity due to improved accuracy of MV
Humidity control	Yes, manually adjusted upon visual control of trachea	Yes, automatically controlled by microprocessor based on minute ventilation	Improved humidity due to automatic adjustment of water amount
Heating control	Yes, manually by operator, based on temperature display	Yes, automatically controlled by microprocessor, based on minute ventilation and flow	Increased patient safety due to servo loop regulation and automatic control of parameters
Bypass flow	No	Yes, adjustable from 5 to 70 LPM	No need for conventional anaesthesia machine for induction
Pressure waveform	No, only numeric display	Yes, backlight display for indication of airway pressure and parameters	Better visualisation of airway pressure as with numerics only
Built-in air-oxygen blender	No. Use of Bird blender	Yes, electronic blender	Compact size without need for external tubings
Oxygen measurement	No. Need of separate oxygen monitor	Yes, with automatic calibration of sensor during start-up procedure	Ease of use.
Peep limit	No	Yes, with visual control on display	Useful for ARDS treatment and if volume controlled ventilation is performed
Inlet pressure controlled by servo valve	No	Yes, if pressure limit is exceeded for more then 3 s, the inlet pressure valves close for patient safety	In case of a jet valve failure, the inlet pressure is shut off automatically to avoid overpressure in the patients lung

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

ACUTRONIC Medical Systems AG
C/O Mr. Terry Torzala
Terry Torzala
P.O. Box 85820
Tucson, Arizona 85754-5820

Re: K012691
Trade/Device Name: Monsoon Universal Jet Ventilator
Regulation Number: 868.5895, 868.5450
Regulation Name: Ventilator Continuous, Respiratory Gas Humidifier
Regulatory Class: II
Product Code: CBK and BTT
Dated: September 25, 2002
Received: September 26, 2002

Dear Mr. Torzala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012691

Device Name: Monsoon Universal Jet Ventilator

Indications For Use:

The Monsoon Universal Jet Ventilator is intended for use during bronchoscopy or laryngoscopy in a hospital or other clinical setting.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K012691

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____