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HEATED HUMIDIFIER REVIEW GUIDE

A. General device descriptions
B. Patient and operator's safety
C. Device specifications
D. Labeling

A. General device descriptions

The humidifiers are usually connected to the inspiratory end of the breathing circuits, with the purpose of maintaining moisture in the patient's airway. These are often microprocessor controlled. The microprocessors monitors the readings from the various sensors and makes the necessary adjustments to maintain a set humidity and temperature. If one or more parameters are out of range, the microprocessor will send a signal to activate the audible or visual alarms.

Note that the humidifier can also be used in conjunction with a servo controller and a heated breathing circuit to reduce condensation of the humidified air in the breathing circuit.

B. Operator and patient safety

The following are the possible adverse effects that may occur when using the device:

1. Burning of patient airway

The major factor is the excessive heat introduced to the patient; however, low humidity and high flow of air can contribute to the problem by drying out the airway and making its lining more susceptible to damage. Although exact parameter for control of operating conditions to avoid injury have not been established, the 510(K)s that were submitted in the past have not exceed the upper limit of 42 degrees C.

2. Electrical shock

Electrical shock to both the patient and the operator can occur if the device is not properly grounded.

3. Water entering the breathing circuit

In humidifiers that has an elevated water supply source, water flows down from the water supply to the heating chamber to be evaporated. If the water supplied is more than the evaporation rate, complications may occur when sufficient water enters the breathing circuit and limits the air passage. The device should have means to prevent this from occuring.

C. Device specifications

1. Operating range

a. Temperature

Air temperature entering the patient can range up to 42

degrees C. If the patient airway temperature is higher, the manufacturer must show a predicate device with the same range of operation or provide data to show that patient safety is not compromised. The temperature at the heating filament, however, can be much higher to compensate for the heat dissipated in the breathing unit. Note that Air flow rate can also influence the rate of temperature loss.

With all the factors that may influence the patient airway temperature (PAT), the sensor at the WYE of the breathing circuit will give the most accurate reading. If the device relies on a sensor located at the humidifier output, the manufacturer may want to include a temperature vs flow relationship on the instruction manual.

b. Humidity
Most humidifier have humidity settings from 0 to 100%

c. Resistance to flow
Does the manufacturer specify the air flow resistance and make necessary precautions to minimize it?

2. Safety features
The device should have means to prevent any possible adverse effects (refer to section B) to the patient and the operator.

a. Audio/visual alarms

Temperature alarm.
-The humidifier should have high and low temperature alarm. If the alarm temperature is settable, make sure that the alarm setting range is within the operating range of the device.
-look into the accuracy of the alarm (i.e. sensitivity and reliability)

Water overflow
-many humidifiers have a hydrophobic barrier that only allows water vapor to enter the breathing circuits. In addition, the humidifiers may have sensors to compare the supply rate with the evaporation rate and alarms the operator if necessary. Look into the reliability of this function and see if the algorithm used is sound (if applicable)

Proper connection alarm
-The humidifier should have an alarm for improper sensor connection

b. Limiting mechanisms
Some devices are designed to limit temperature, power,

currents, etc. so that the device's operating range remain in a safe margin.
-test results may be necessary to show its effectiveness

c. Shut down mechanisms
These mechanisms will cutoff the device or parts of the device to ensure patient safety:
-Microprocessor controlled temperature cut off--Power is cut off when the temperature at the PAT reaches 42 oC.
-Thermal fuse--A mechanical means to disconnect the power delivered to the heating filament if safety temperature is exceeded. Note that the temperature limit can be much higher than 42 oC, and they can vary depending on the design of the humidifier.
-Amperage fuse--The device should have a fuse or a circuit breaker for protection against power surges.

d. Electrical safety
Has the manufacturer made proper design considerations to ensure proper grounding of the device? Does the device comply with industry standards (e.g. UL544)?

3. Software questions
Refer to the software guidance documentation for proper software questions.