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GP LLC

January 12, 2001

Docket No. – Guidance for Infant/Child Apnea Monitor 510(k) Submissions
Docket Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
(HFA-305)
Rockville, MD 20852

Re: Comments on Draft Guidance for Infant/Child Apnea Monitor 510(k) Submissions

Dear Sir or Madam:

Following are our comments on the above document.

Primary Monitoring Modality

FDA needs to define or at least provide examples of what "special procedures" are acceptable for changing the apnea setting from 20 seconds to some other set point. For apnea monitors utilized in the traditional health care setting is FDA inferring that a rotary dial switch selection (e.g., for set points of say 6, 12 and 20 seconds) is unacceptable?

Signal level from the sensor is not a proper measure. "Signal level from..." should be changed to "performance of...". Also, eliminate "by the monitor manufacturer" as the important point is that a sensor fault alarm should occur when the performance adversely affects proper operation.

Secondary Monitoring Modality

The range for parameters within the ANSI/AAMI EC13-1992 is not intended to cover neonates, premature infants, etc. If they were, the document would not specify "pediatric".

FDA either needs to identify the differences in range or identify to the reader that parameters may be outside this standard for specific patient populations covered by the draft guidance and not covered by this ANSI/AAMI standard.

With regard to the secondary sensor fault alarm, the wording for this feature should be the same as the wording for this feature of the primary monitoring modality.

Audible Status Indicators (alarms)

FDA should not be requiring an audible indicator "for ready", especially in an alarm section.

FDA should utilize the anesthesia alarm scheme for different sound characteristics (e.g., pitch, sound level, time duration, ability to distinguish between audible status indicators).

Remote Alarm

This section does not address remote alarms that have separate batteries within the remote alarm housing itself. Also, the battery back up feature on line power failure doesn't seem to be appropriately placed in this section.

Clinical Testing

I know of no single "reference physiologic parameter" than can be monitored to detect and differentiate central, obstructive and mixed apneas. Hence, the need for two monitoring modalities in these monitors. Change this to 'sufficient reference physiologic parameters to..."

FDA requires the timer setting to be at 10 seconds, while the standard requires 20 seconds.

In one section FDA requires 3 independent investigations, while in another section FDA notes at least one experienced healthcare practitioner should perform independent observation. This is unclear. Does FDA intend three experienced healthcare practitioners, one for each independent investigation, or can the same experienced healthcare practitioner do each of the three independent investigations (making them essentially "dependent").

FDA requires a "statistical analysis" to be provided. Is FDA claiming that the tests it is recommending are statistically significant?

Battery Power

The requirement for battery power backup to activate needs work. Specifically, the caveat "unless the overcurrent protection has activated" needs further explanation. The only time

this caveat should hold is when battery power activation could cause equipment damage, fire, etc. If the overcurrent protection activates and battery power and monitor operation could proceed safely, why should the device shutdown and disallow operation?

A requirement assuring that settings remain the same from line power operation through the fault to battery power operation should be added.

The requirement for audible and visual low battery warning indicators should be revised to include operation on resume of available line power.

The means for silencing the low battery alarm should not be permanent.

Controls Protection

Why are only monitors for home use required to protect controls? Control protection should be provided for all monitors.

Device labeling: General

Add a contact telephone number, online assistance site or other method by which the user can rapidly access assistance.

Healthcare Practitioner Operator Information

Add a statement discussing cardiopulmonary artifact rejection.

Sincerely,

Gary H. Harding
User Co-Chair
AAMI Apnea Monitor Committee

Raymond Huey
Industry Co-Chair
AAMI Apnea Monitor Committee

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