with §§ 896.22 and 896.23. Apnea monitors intended for use on both infants and older patients may provide duration settings beyond 20 seconds only if special tools or procedures are required to effect those settings.

(c) A sensor fault alarm for determining when the signal level from the primary sensor is outside the range of values specified for proper operation by the monitor manufacturer. When this condition occurs, audible and visual warning status indicators shall be activated within 5 seconds.

## § 896.21 Secondary monitoring modality.

Each monitor shall provide:

- (a) A secondary monitoring modality, which shall incorporate a means for detecting a pathophysiological consequence of apnea that occurs within 60 seconds of the onset of apnea. This modality shall be designed such that values of the critical physiological parameter that are outside the extremes of the monitor's range are not interpreted as being within range. A monitor that includes heart rate monitoring shall meet the requirements of the standard ANSI/AAMI (American National Standards Institute/ Association for the Advancement of Medical Instrumentation) EC13-1983 for pediatric monitors.
- (b) A system of visual and audible warning status indicators designed to activate (alarm) when the measured critical physiological parameter goes above or falls below a selected preset limit. The warning indicators shall be activated within 5 seconds after the measured parameter is outside the range of values specified by the preset limit in accordance with §§ 896.22 and 896.23.
- (c) A control for presetting secondary modality alarm limits.
- (d) A sensor fault alarm for determining when the signal from the sensor for the physiological parameter is outside the range of values specified for proper operation by the monitor manufacturer. When this condition occurs, audible and visual warning status indicators shall be activated within 5 seconds.

## § 896.22 Visual status indicators (alarms).

- (a) Visual status indicators shall be of two visually distinct types:
- (1) Warning indicators shall indicate the need for immediate attention to the patient.
- (2) Ready indicators shall indicate proper operation of the monitor.
- (b) Different colors shall be used to distinguish the two types of visual status indicators as follows:
  - (1) Red for warning indicators; and

(2) Green for ready indicators.

(c) All visual status indicators shall be visible in both a fully illuminated and a darkened room, and shall be located so that they are not obscured from view in the use orientation of the monitor specified by the manufacturer.

(d) Means for disabling any required visual status indicator during operation

shall not be provided.

- (e) Reset controls for visual status indicators shall function such that neither continuous activation nor failure of the reset control will permanently disable the status indicators.
- (f) Warning indicators shall continue being activated until manually reset even if the condition causing indicator activation resolves.
- (g) Visual status indicators shall be subject to the labeling requirements specified in § 896.54.

# § 896.23 Audible status indicators (alarms).

(a) All audible status indicators shall be of two audibly distinct types:

(1) Warning indicators shall indicate the need for immediate attention to the patient.

- (2) Ready indicators if provided shall indicate proper operation of the monitor.
- (b) Different sound characteristics, i.e., pitch, sound level, and time duration, shall be used to distinguish between the types of audible status indicators as follows:
- (1) Warning audible indicators shall sound intermittently at 1-second intervals. Sound level shall be at least 85 decibels at 1 meter for home monitors and 70 decibels for hospital monitors.
- (2) Ready audible indicators if provided shall have distinctly different sound characteristics than paragraph (b)(1) of this section.
- (c) Means for permanently disabling an audible status indicator during operation shall not be provided. Activation of any manual means (reset) for temporarily silencing an audible status indicator shall be accompanied by an automatic realarming of the audible indicator within 2 minutes, and a clear indication of silencing (reset) shall be provided. The audible indicator may automatically reset if the condition causing indicator activation resolves, but any visual status indicator that correlates with a required audible indicator shall continue being activated until manually reset.

(d) Audible status indicator reset controls shall function such that neither continuous activation nor failure of the reset control will permanently disable the status indicators.

#### §896.24 Remote alarm.

- (a) Manufacturers of monitors intended for home use shall provide a remote alarm unit for use with the monitor. The remote alarm unit shall include audible warning status indicators that indicate when a warning status indicator at the site of the patient has been activated and when the unit is unable to detect the status indicator signals from the site of the patient as specified in § 896.23.
- (b) The use of a remote alarm unit shall not disable the status indicators at the site of the patient.
- (c) The remote alarm unit shall have a visual power ready status indicator (pilot light) and an audible power interrupt warning status indicator. If battery operated, the remote alarm unit shall have audible and visual low battery warning status indicators (alarms) that activate when the battery has sufficient charge remaining to supply power to the remote alarm unit for no more than 15 minutes of operation as specified in §§ 896.22 and 896.23.
- (d) If line power operated, battery backup shall be provided that automatically activates within 5 seconds after the power fails for any reason. The battery shall have sufficient capacity, when fully charged, to supply power for normal operation for at least 8 hours.

## § 896.25 Self test.

Monitors shall incorporate a self test, for confirmation by the operator, to operate or exercise all visual and audible status indicators each time the monitor is turned on.

## Subpart C—Electrical Performance Requirements

## §896.30 Battery power.

- (a) All line-powered monitors intended for use in the home shall have a battery power backup which shall, unless the overcurrent protection specified in § 896.32 has activated, automatically activate when the power fails. The monitor shall operate in compliance with the standard within 5 seconds after the battery backup power has activated.
- (b) Monitors intended for use in the home shall have a battery of sufficient capacity, when fully charged, to supply power for normal operation for at least 8 hours.
- (c) Monitors intended for use in the home shall have audible and visual battery depletion warning status indicators that activate when the battery has sufficient charge remaining to supply power for monitor operation in accordance with the standard for at least