



Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care¹

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INTRODUCTION

Medical practice in hospitals is increasingly dependent on equipment for observation and treatment of patients. Sounds and lights are frequently used to indicate the patient's physiological status and the functional state of the equipment. The sounds used are frequently too loud and not sufficiently distinctive, and it is often difficult to identify which item of equipment is signalling. The purpose of this specification is to specify signals, both audible and visual, to be used to draw attention to the fact that equipment has detected a disturbance and to indicate the degree of urgency.

The content of this specification was developed with contributions from clinicians, engineers, applied psychologists, and musicians. Some of the criteria considered during development of the sounds included optimal signal recognition in a relatively noise-filled environment, maximum transmission of information at the lowest practical sound pressure level, ease of learning and retention by operators who have to respond to the various signals, and perceived urgency of the sounds.

1. Scope

1.1 This specification covers defining the characteristics and requirements of electrically generated alarm signals for use with medical equipment intended for use in anesthesia and respiratory care. It does not specify the condition that activates the alarms, nor does it specify the devices used for the production of audible and visual signals. This specification does not address informational sounds produced by devices such as ECG monitors, surgical lasers, and electrocautery units.

1.2 The values stated in SI units are to be regarded as the standard.

2. Referenced Documents

2.1 ISO Standard:

ISO 3744: Acoustics—Determination of Sound Power Levels of Noise Sources—Engineering Methods for Free-Field Conditions Over a Reflecting Plane²

2.2 IEC Standards:²

IEC 651 Sound Level Meters

IEC 73 Colors of Indicator Lights and Push-Buttons³

IEC 601-1 Medical Electrical Equipment—Part 1: General Requirements for Safety³

3. Terminology

3.1 Definitions:

3.1.1 *burst*—a group of pulses with a distinctive rhythm.

3.1.2 *burst amplitude*—the A-weighted sound pressure level of the maximum pulse in the burst measured in decibels.

3.1.3 *burst spacing*—the period of time between the start of the first pulse in one burst and the start of the first pulse in the next burst.

3.1.4 *clearly legible*—the visual attribute of information displayed by the equipment that allows the operator to discern (or identify) quantitative values or functions under a specific set of environmental conditions.

3.1.5 *discriminate*—the ability of an operator to perceive a qualitative difference among visual signals under a specific set of environmental conditions.

3.1.6 *flashing frequency*—the number of light flashes per unit of time.

3.1.7 *high priority alarm*—a combination of audible and visual signals indicating that immediate operator response is required.

¹ This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.15 on Harmonization of Alarms.

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² Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

³ Patterson, R. D., *Guidelines for Auditory Warning Systems on Civil Aircraft*, Civil Aviation Authority (UK) Paper 82017, 1982.

3.1.8 *low priority alarm*—a visual signal, or a combination of audible and visual signals indicating that operator awareness is required.

3.1.9 *medium priority alarm*—a combination of audible and visual signals indicating that prompt operator response is required.

3.1.10 *overall pulse duration*—the time over which the pulse amplitude exceeds 10 % of the maximum amplitude.

3.1.11 *pulse*—a sound having a specific frequency spectrum and specific duration.

3.1.12 *pulse frequency*—the fundamental frequency of the pulse.

3.1.13 *pulse spacing (within a burst)*—the period of time between the start of one pulse and the start of the next pulse.

4. General Requirements

4.1 *High Priority Alarm Signal*—A high priority signal shall have the characteristics given in Table 1.

4.2 *Medium Priority Alarm Signal*—A medium priority signal shall have the characteristics given in Table 1.

4.3 *Low Priority Alarm Signal*—A low priority alarm signal shall have the characteristics given in Table 1.

4.4 When an alarm signal is generated, the cause of the alarm shall be indicated.

NOTE 1—This requirement is satisfied if the monitored variable or condition is identified.

5. Specific Requirements for Audible Signals

5.1 *Sound Quality*— Alarm sounds shall have a fundamental frequency of between 150 and 1000 Hz, based on standard musical pitches, that is, the A440 system ± 1 %. There shall be at least four frequency components ranging from 300 to 4000 Hz. These frequency components shall be related so that they form a distinct sound. These alarms should be nonstartling. Rise times should exceed 15 ms.

5.2 *Sound Intensity*— Alarms that have an adjustable volume shall not be totally silenced by the adjustment, and shall have a minimum setting of 45 dB(A) or greater and a maximum setting of 85 dB(A) or less (peak output at 1 m) from the source in an anechoic chamber. Alarms with fixed intensity shall be between 70 and 85 dB(A) peak output at 1 m. If operator adjustment is provided, the control and its associated indicator shall be marked to indicate an increase or decrease in volume.

5.3 There shall be a visual indication that a high or medium priority alarm audible signal has been disabled.

NOTE 2—The conditions for alarm silencing are specified in the relevant standards for particular devices.

5.4 *Duration of Alarm Sounds*—If the alarm sounds are limited in duration, for example, “power failure alarm,” such limitations shall be disclosed by the manufacturer.

6. Visual Requirements

6.1 All visual signals for alarms shall be clearly legible at a distance of 1 m when tested in accordance with 6.1.1.

6.1.1 The test operator with a visual acuity of one (corrected if necessary), shall be able to read correctly from a distance of 1 m and at an angle of 30° from either side of a line perpendicular to the center of the display or control panel and under an ambient illuminance in the range of 100 to 1500 lx. The test is passed if the test operator can correctly perceive the quantitative value(s) or function(s) displayed by the visual alarm signal(s).

6.1.2 *Rationale*—The ability of an operator to perceive the quantitative information contained in any visual alarm display at a distance of 1 meter was considered by the committee to represent the minimum safety requirement in the operating room environment, or at an ICU bedside.

6.2 An operator shall be able to discriminate between high and medium priority alarm signals at a distance of 4 m when tested in accordance with 6.2.1.

6.2.1 The test operator with a visual acuity of one (corrected if necessary), shall be able to read correctly from a distance of 4 m and at an angle of 30° from either side of a line perpendicular to the center of the display or control panel and under an ambient illuminance in the range of 100 to 1500 lx. The test is passed if the test operator can perceive the high priority and medium priority visual signals, and discriminate between them.

6.2.2 *Rationale*—The ability to see the warning and caution indicators at a distance of 4 meters, and to discriminate between them, is important in large intensive care settings with multiple ventilators and the possibility of multiple simultaneous alarms. The operator can then make a decision as to which alarm to respond to first based on the alarm priority.

6.3 Alphanumeric or computer-generated graphics displays of alarm messages, including centralized alarm displays, are exempt from the color and flashing frequency requirements in Table 1 if the displays meet the requirements in 6.1 and 6.2. However, if an alphanumeric or graphics display of alarm messages does not meet the requirements in 6.1 and 6.2, then an alternate visual method that does meet the requirements in Table 1 shall be employed.

NOTE 3—A single color indicator per category is sufficient to satisfy the requirement in Table 1.

TABLE 1 Alarm Signal Requirements

Alarm Category	Operator Response	Audible Indicators ^A	Indicator Color ^B	Flashing Frequency (Hz) ^C
High priority	Immediate	Not medium or low priority	Red	1.4–2.8 Hz (F_2)
Medium priority	Prompt	Not high or low priority	Yellow	0.4–0.8 Hz (F_1)
Low priority	Awareness	Not high or medium priority	Yellow	Constant (On)

^A See 5.1, 5.2, and Annex A1.

^B See 6.3.

^C Reference to IEC 73.