Designation: F 1463 – 93 (Reapproved 1999)

An American National Standard

Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care[1]

This standard is issued under the fixed designation F 1463; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 Plane[2]

2.2 *IEC Standards:*[2]

IEC 651 Sound Level Meters

IEC 73 Colors of Indicator Lights and Push-Buttons[3]

IEC 601-1 Medical Electrical Equipment—Part 1: General Requirements for Safety[3]

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.

3.1.8 *low priority alarm*—a visual signal, or a combination

[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.

Current edition approved Feb. 15, 1993. Published June 1993.

[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.

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 I	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.

ANNEX

(Mandatory Information)

A1. CONSTRUCTION OF PULSES AND BURSTS

A1.1 *Pulses*—A pulse is a small unit of sound lasting from 100 to 1000 ms. It is made from a set of harmonics of which the lowest if the fundamental, that usually gives the pulse its pitch. The harmonic content of a pulse would normally consist of a fundamental frequency and a set of higher component frequencies, known as harmonics. The relationship between the fundamental frequency and a set of higher component frequencies, known as components will produce the timbre, or sound quality, of the pulse. There should be at least four, and preferably more, of these harmonics in the pulse in order to avoid masking by other sounds and to aid localisation by the listener. In order to avoid startle responses, the pulses should have a shaped amplitude envelope, meaning that they do not come on at their loudest level. They should therefore be gated with cosine ramps at the onset and the offset. A200 ms pulse may, for example, possess a "standard" envelope consisting of a 25 ms onset and a 25 ms offset ramp. A "slow onset" ramp placed on a pulse of the same length might have a 175 ms onset ramp followed by a 25 ms offset, and a "slow offset" ramp would have the opposite construction. The pulse is the basic unit of sound from which the burst is constructed.

A1.2 *Bursts*—A burst is a unit of sound typically lasting several seconds, consisting of two or more pulses. These bursts will sound like melodies with a rhythm. Bursts are played at intervals to form a complete warning. The first one or two pulses should be played at a lower level in order to avoid startle reactions. Different bursts are more readily discriminated if their rhythms and pitch patterns differ from one another.

A1.3 *Perceived Urgency*—It is essential that the high priority warning is made to be more urgent than the medium priority warning, which in turn should be made to be more urgent than the low priority warning. This can be achieved by selecting spectral (pulse) characteristics that are known to produce high urgency ratings for high priority warnings, low-urgency pulse characteristics for low priority warnings, and the same principles applied to burst characteristics.

A1.3.1 In general, the pulse characteristics will carry less weight in determining the overall urgency of the warning than the burst characteristics. More emphasis should be placed on producing variation in the burst parameters to alter the urgency of the sounds to achieve their final urgency level.

A1.3.1.1 *Pulses*—The fundamental frequency of the pulse affects urgency; the higher the pitch of the pulse, the more urgent it is judged to be. However, the fundamental should not be so high as to produce annoyance, and the first four harmonics should be below 4 kHz. Thus the fundamental frequency should be below 1000 Hz. The harmonic components also affect the urgency of the pulse. Pulses where the harmonics do not bear an integer relationship to the fundamental are judged to be more urgent than completely harmonic, "musical" pulses. However, a very complex harmonic series will obscure the pitch of the pulse. Amplitude envelopes that are either "standard" or "slow onset" are sometimes judged to be more urgent than those with a "slow offset," although the effect is unclear and the changes in urgency produced are small.

A1.3.1.2 *Bursts*—Both temporal and melodic characteristics affect the perceived urgency of the burst. The temporal characteristics are determined by variations in pulse-to-pulse time, and the melodic characteristics are determined by variations in the fundamental frequency of the pulses.

A1.3.1.3 *Temporal Characteristics*—The primary determinant of the urgency of a burst is its speed, as measured by the pulse-to-pulse interval. Any interval below about 200 ms may be judged to be fairly urgent, although faster speeds may be necessary. Any interval greater than about 350 to 400 ms may be described as less urgent. The rhythm of the burst, determined by varying individual pulse-to-pulse intervals, also affects urgency. Regular rhythms are generally more urgent than irregular rhythms, although some sorts or irregularities, such as decreasing the pulse-to-pulse interval during the burst, can be effective. It is very important also to have different temporal patterns within a warning set in order to reduce confusions between warnings. Repeating a burst more often, or at shorter time intervals, may also increase the urgency of the overall warning.

A1.3.1.4 *Melodic Characteristics*—The pitch contour (pattern of ups and downs, produced by altering the fundamental frequency of individual pulses) can affect the urgency of a burst, but it is probably more useful as a discriminating factor between warnings. Larger pitch ranges (the frequency range from the highest to the lowest pulses in the burst) are more urgent than smaller ranges, and bursts which are musically resolved may sound less urgent than atonal or unresolved bursts. The amplitude envelope of a high priority burst should reach maximum output level after one or two pulses, and should stay at that level. A less urgent burst may be produced by reducing the level of the pulses again towards the end of the burst.

A2. Additional References[4,5]

[4] Patterson, R. D., "Guidelines for the Design of Auditory Warning Sounds," *Proc. Inst. Acoust. 11(5)*, pp. 17–24, 1989.

[5] Edworthy, J., Loxley, S., Geelhoed, E., and Dennis, I., "The Perceived Urgency of Auditory Warnings," *Proc. Inst. Acoust. 11(5)*, pp. 73–80, 1989.