INTERNATIONAL STANDARD

ISO 9703-2

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Anaesthesia and respiratory care alarm signals —

Part 2:
Auditory alarm signals

Signaux d'alarme pour l'anesthésie et les soins respiratoires —
Partie 2: Signaux d'alarme auditifs

Reference number
ISO 9703-2:1994(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9703-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 9703 consists of the following parts, under the general title *Anaesthesia and respiratory care alarm signals*:

— *Part 1: Visual alarm signals*

— *Part 2: Auditory alarm signals*

— *Part 3: General requirements*

— *Part 4: Guidance on application*

Annexes A and B of this part of ISO 9703 are for information only.

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Introduction

Medical practice in hospitals is increasingly dependent on medical devices 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 medical device. The sounds used are frequently too loud and not distinctive, and it is often difficult to identify which medical device is signalling. The purpose of this part of ISO 9703 is to specify the auditory component of alarm signals to be used to draw attention to the fact that the medical device has detected a disturbance and to indicate the degree of urgency.

This part of ISO 9703 was developed from contributions from clinicians, engineers and applied psychologists. The approach taken is intended to rationalize the current situation and to limit the proliferation of different sounds, in order to avoid confusion.

Some of the criteria considered during development of the sounds included optimal signal recognition in a relatively noisy environment, maximum transmission of information at the lowest practicable sound pressure level, ease of learning and retention by operators who have to respond to the various signals, and perceived urgency of the sounds.

Two important alarm signals are specified, i.e. high and medium priority signals. The auditory signals are acoustically related, but are differentiated by their perceived urgency. Guidelines are given for the design of a signal of lower priority than that of medium priority, and also for an information signal. Visual components are specified in ISO 9703-1.

NOTE 1 This International Standard is based on discussions held in ISO/TC 121 over a number of years, and on prEN 475, prepared by CEN/TC 259.

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Anaesthesia and respiratory care alarm signals —

Part 2:
Auditory alarm signals

1 Scope

This part of ISO 9703 specifies the characteristics of the auditory component of electrically generated primary alarm systems in anaesthesia and respiratory care, either individually or as part of a centralized system. It applies only if a particular International Standard for a medical device makes reference to it.

This part of ISO 9703 does not specify

a) the medical devices on which these alarms are to be provided;

b) the conditions that actuate the alarms;

c) the means of generating the alarm signals;

d) secondary alarm system characteristics, i.e. alarm systems which are activated in case of a failure in the primary alarm system;

e) the allocation of priorities to alarms.

NOTE 2 It is expected that requirements for the application of the auditory alarm signals specified in this part of ISO 9703 will be included in "Particular Standards" (as formulated in IEC) for the particular medical devices.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9703. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9703 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

ISO 11201:—[1], *Acoustics — Noise emitted by machinery and equipment — Measurement of emission sound pressure levels at the work station and at other specified positions — Engineering method in an essentially free field over a reflecting plane.*

3 Definitions

For the purposes of this part of ISO 9703, the following definitions apply.

3.1 alarm signal: Signal, the purpose of which is to alert the operator to an abnormal condition which, if not immediately or promptly attended to, may develop into a safety hazard.

3.2 information signal: Signal, the purpose of which is to convey physiological or technical information.

1) To be published.

3.3 high priority (warning) alarm: Signal indicating that immediate operator response is required. (ISO 9703-1:1992, definition 2.3)

3.4 medium priority (cautionary) alarm: Signal indicating that prompt operator response is required. (ISO 9703-1:1992, definition 2.4)

3.5 low priority (advisory) alarm: Signal indicating that operator awareness is required. (ISO 9703-1: 1992, definition 2.5)

3.6 pulse: Brief sound having a specific frequency spectrum.

3.7 overall pulse duration (t_o)**:** Time over which the pulse amplitude exceeds 10 % of the maximum amplitude. (See figure 1.)

3.8 rise time (t_r)**:** Time over which the pulse increases from 10 % to 90 % of maximum amplitude. (See figure 1.)

3.9 start of pulse: Point at which the amplitude first exceeds 90 % of the maximum amplitude. (See figure 1.)

3.10 end of pulse: Point at which the amplitude first falls below 90 % of the maximum amplitude. (See figure 1.)

3.11 effective pulse duration (t_d)**:** Period of time between start of pulse and end of the same pulse. (See figure 1.)

NOTE 3 Although $t_o = t_r + t_d + t_p$ this part of ISO 9703 is written in terms of t_d because it is easier to measure.

3.12 fall time (t_f)**:** Time over which a pulse decreases from 90 % to 10 % of maximum amplitude. (See figure 1.)

3.13 pulse frequency (f_p)**:** Fundamental frequency of a pulse.

3.14 burst: Group of pulses with a distinctive rhythm.

3.15 pulse spacing (t_s)**:** Period of time between the start of one pulse and the start of the next pulse. (See figure 1.)

3.16 burst spacing (t_b)**:** Period of time between the start of the first pulse in one burst and the start of the first pulse in the next burst. (See figure 1.)

3.17 repeat time: Period of time between the start of the first pulse of a burst or the first pulse of a double burst and the start of the first pulse of the next burst or the first burst of the next double burst.

4 Requirements for signals

4.1 Auditory alarm signals

Auditory alarm signals shall meet the requirements of tables 1 and 2, unless they are generated by means of different technology, for example voice synthesizing. If a different technology is employed, it shall preclude the possibility of confusion with the auditory signals specified in tables 1 and 2.

4.2 Composition of high priority alarm signal

A high priority alarm signal shall comprise a high priority auditory signal complying with tables 1 and 2, and a simultaneous high priority visual indication complying with ISO 9703-1.

4.3 Composition of medium priority alarm signal

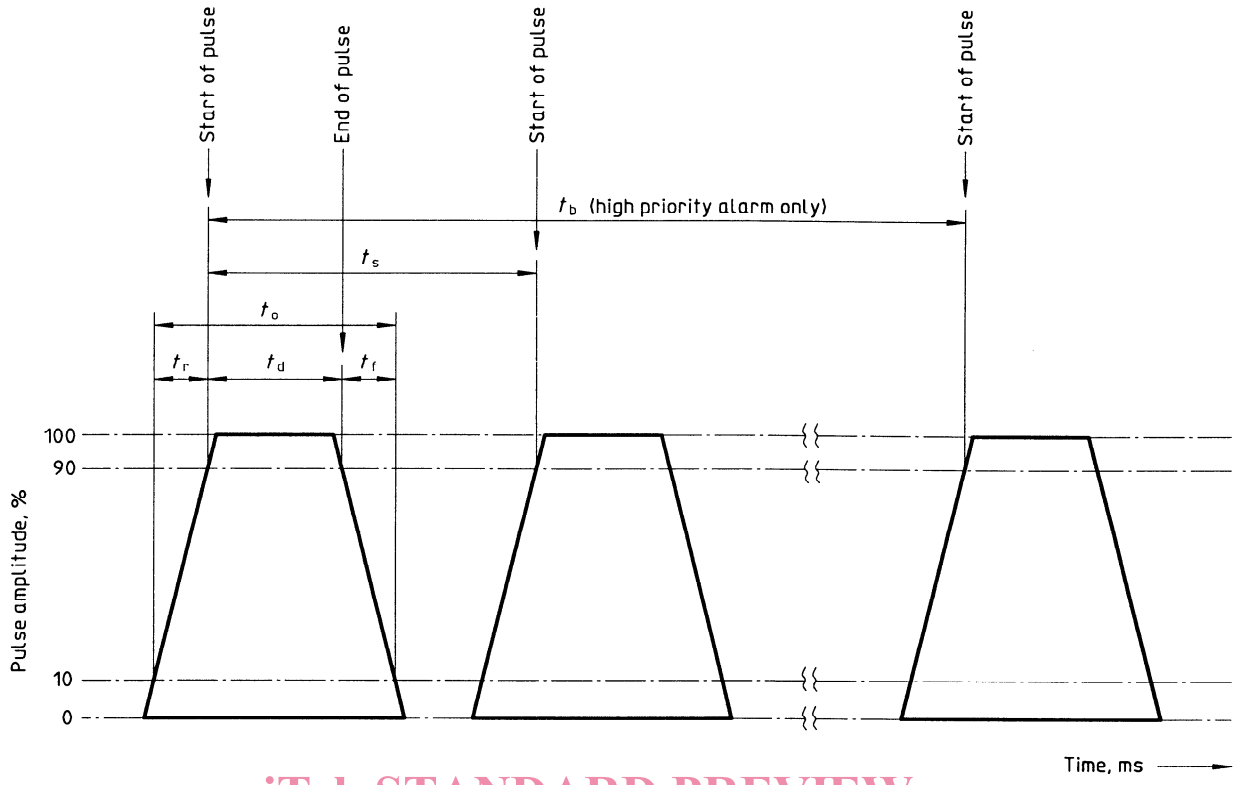
A medium priority alarm signal shall comprise a medium priority auditory signal complying with tables 1 and 2, and a simultaneous medium priority visual indication complying with ISO 9703-1.

4.4 Composition of low priority alarm signal

If one or more levels of low priority alarm signals are employed, their auditory characteristics shall be different from those of high and medium priorities. The sound shall be nonintrusive and nonstartling. Under no circumstances shall the sound pressure level exceed that of a medium priority signal. Both rise time and fall time shall not be less that 40 ms.

4.5 Composition of information signals

If information signals are employed, their auditory characteristics shall be different from that of high and medium priority. The sound shall be nonintrusive and nonstartling. Under no circumstances shall the sound pressure level exceed that of a medium priority signal. Both rise time and fall time shall not be less than 40 ms.



NOTE — This figure is intended to show the designation of temporal characteristics, and does not illustrate any individual auditory signal.

Figure 1 — Illustration of temporal characteristics of auditory signals

Table 1 — Characteristics of bursts

Characteristic	High priority	Medium priority
Number of pulses in burst[1]	5	3
Pulse spacing (t_s) [2] between 1st and 2nd pulses between 2nd and 3rd pulses between 3rd and 4th pulses between 4th and 5th pulses	 x [3] x $2x$ x	 y [4] y NA NA
Burst spacing (t_b)	2 s ± 0,2 s	NA
Repeat time[5]	10 s ± 2,5 s	25 s ± 5 s
Difference in amplitude between any two pulses[6]	10 db(A) max.	10 db(A) max.

1) See table 2 for characteristics of the pulse.

2) $t_s \geqslant t_o$, $t_o = t_r + t_d + t_f$ (to prevent overlap of pulses)

3) Where x is a value between 150 ms and 250 ms

4) Where y is a value between 250 ms and 500 ms

5) Unless otherwise specified in the Particular Standard for a particular medical device.

6) A-weighted sound pressure level measured as described in ISO 3744 and ISO 11201.

Table 2 — Characteristics of pulses

Characteristic	Value
Pulse frequency (f_p) [1]	150 Hz to 1 000 Hz
Number of harmonic components in the range 300 Hz to 4 000 Hz	4 min.
Effective pulse duration (t_d)	150 ms to 200 ms
Rise time (t_r)	10 % to 20 % of t_d
Fall time (t_f)	10 % to 20 % of t_d
Amplitude[2]	45 db(A) to 85 db(A)

1) A change in pulse frequency between the first and last pulse of a burst is permissible. If there is a change, it may be achieved in one or more steps. For the high and medium priority auditory alarm signals, if more than one step is used, the changes in pulse frequency should all be in the same direction.

2) A-weighted sound pressure level measured as described in ISO 3744 and ISO 11201.

Annex A
(informative)

Rationale

A.1 Scope (clause 1)

Those writing a particular standard (see note 2) for a particular medical device should determine whether that device requires alarms, and if so which alarms should be provided. In some instances, their provision may be optional. It is the purpose of this part of ISO 9703 to specify the auditory alarm signals to be used when a particular standard specifies that an alarm be provided. The allocation to an alarm of its urgency category remains a matter for judgement by the manufacturer and/or operator of the device. It is not intended that all, or indeed any, of the auditory alarm signals specified in this part of ISO 9703 need to be incorporated in any particular medical device.

A.2 Requirements for signals (clause 4)

Construction of the auditory signals falls into two discrete phases: the specification of a pulse sound which determines the timbre of the auditory signal, and the specification of a burst of sound. The burst of sound is produced by playing the pulse more than once with, in the case of the high priority auditory signal, a longer interval between the third and fourth pulses. Provision is made for different pulse frequencies. The specification of the pulse involves specifying the spectral components of the sound and the specification of the burst involves specifying the temporal parameters. The specification of the alarm signal involves, for some signals, a combination of the auditory signal and a visual indication.

The auditory signals have been designed with a harmonic content such that their source can be located within rooms, which may reflect sounds from the walls or impede sound as a result of ceiling supports, screens and the like. The frequencies contained in the specified auditory signals will be reflected unequally and, therefore, provide positive means of location. Moreover, the auditory signals are unlikely to be confused with those of common equipment and devices of a nonmedical nature, e.g. doorbells and chimes, telephone annunciators, and personal pagers.

Current alarm sounds are often startling. The specified auditory signals have therefore, been designed to have a gentle onset and offset. Their general characteristics make them instantly recognizable by those who need to be informed by them, but because the auditory signals may be heard by other persons in the vicinity, they are not such as to invoke anxiety in for example other patients, the parents of paediatric patients and visitors.

The specified auditory signals may also be expected to be less jarring to nurses and other attendants than sounds with a sudden onset.

The auditory signals have been designed to have a pattern which is instantly recognizable to the trained respondent, but which will not usually evince anxiety in others. They are not startling and, more important, not persistent. Current sounds are often loud, irritating and all-pervasive: they thus inhibit constructive thought and hinder appropriate response. The response may encompass active intervention or heightened awareness. The specified auditory signals annunciate themselves briefly, and the high priority auditory signal is repeated after a brief interval. They then cease, but if there is no corrective action by the operator or attendant, they are repeated (in 10 s in the case of high priority auditory signals and 25 s in case of medium priority auditory signals). The characteristics of the auditory signal are such that the respondent is not preoccupied with an overwhelming urge to switch off the alarm. The need for nurses and other attendants to escape from the tyranny of current strident and persistent (and often multiple discordant) alarm sounds militates against activation of alarms in the first instance, and against their proper use when activated. A range of amplitudes has been specified so that the appropriate amplitude may be specified in Particular Standards, thereby taking into account the intended use of the medical device, its location, the background sound level, and the need, unless the operator is also the patient (as in many home-care applications), to alert the operator but not the patient.

Subclauses 4.1 and 4.2. It is not intended that the auditory signal should be the only source of this important information. It is necessary for the auditory signal to be backed up or augmented by a visual indication and, when appropriate, by other visual infor-

mation. Attendants, especially nurses, upon hearing undifferentiated alarm sounds have repeatedly to make instant decisions as to whether they should complete a very important patient-oriented task, or abandon it to answer what may or may not be an urgent summons. The provision of high and medium auditory signals enables them to respond to that which is truly urgent while using discretion in other instances.

Subclauses 4.3 and 4.4. It is important that the low priority and information auditory signals, if employed, do not alert the operator in the manner intended only for the high and medium priority auditory signals. In practice, a clear dividing line between what condition should be allocated a low priority alarm signal and an information signal is not easily achievable: therefore, this decision should be made by the manufacturer of the device. As this part of ISO 9703 does not specify any low priority or information auditory signal, if used, they need to be different from those of the high and medium priority signals. It is also recognized that any low priority auditory signal may, or may not, be identical to that of an information auditory signal.

Table 1. The bursts consist of five or three pulses depending on whether the auditory signal is of high or medium priority. The bursts are specified in such a way as to make them distinctive, and ranges of values for some parameters have been given in order that the perceived urgency of the auditory signals may be manipulated if desired.

a) **Distinctiveness.** The temporal pattern (rhythm) of each burst has been specified in order to increase the distinctiveness of the bursts and to allow recognition across a wide range of applications (in table 2) about the pitch contour of the burst, i.e. the pattern of changes in the pulse frequency (f_p) of the individual pulses in the burst.

   The use of a rising pitch contour for the high priority auditory signal and a constant or falling pitch contour for the medium priority auditory signal will confer additional distinctiveness.

b) **Perceived urgency.** The speed, i.e. pulse spacing (t_s) and pulse frequency (f_p), have a strong impact on perceived urgency and can be used to make the high priority auditory signal more urgent than the medium priority auditory signal, particularly if both auditory signals are to be provided on the same medical device. The ranges of values specified allow the high priority auditory signal to be made both faster in speed (decrease in t_s) and higher in frequency (increase in f_p) than the medium priority auditory signal, which will enhance the distinguishability of the two auditory signals on the basis of perceived urgency. The pitch contour also affects perceived urgency, with rising pitch contours being perceived as more urgent than constant or falling pitch contours. Differentiating the auditory signals on the basis of pitch contour will confer appropriate relative urgency in addition to helping to make the auditory signals distinctive.

Table 2. The pulse is the "building block" of the auditory signals. Although many of its features are not discernible on hearing, they are important for psychoacoustic reasons.

a) **Harmonic content.** The pulse frequency (f_p) is within a wide range. The pulse frequency chosen will have an impact on the perceived urgency of the auditory signal (see rationale to table 1). It is specified that at least four harmonic components in the range 300 Hz to 4 kHz are included in the pulse, and this number of harmonic components will aid the hearer in locating the source of the auditory signal. If a high pulse frequency is chosen, care should be taken to include most of the lower harmonics.

b) **Temporal characteristics.** A pulse lasting between 150 ms and 250 ms will convey a definite sense of pulse frequency, while being short enough to allow manipulation of the perceived urgency of the burst (see rationale to table 1). The pulse clearly cannot be longer than the pulse spacing (t_s) otherwise pulses will overlap and distortion may occur. A gradual start to the auditory signal is necessary in order to reduce startle-reactions, and the range specified will allow some choice of rise time (t_r) and fall time (t_f). These times are specified as percentages of the effective pulse duration (t_d). If the rise time were to be less than the minimum specified (which equates to 15 ms) startle-reactions would occur.