SLOVENSKI STANDARD
SIST EN 475:2000

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Medicinski pripomoļ ki - Elektriļ ne alarmne naprave

Medical devices - Electrically-generated alarm signals

Medizinische Geräte - Elektrisch erzeugte Alarmsignale

Dispositifs médicaux - Signaux d'alarme électriques

Ta slovenski standard je istoveten z: **EN 475:1995**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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English version

Medical devices - Electrically-generated alarm signals

Dispositifs médicaux - Signaux d'alarme électriques

Medizinische Geräte - Elektrisch erzeugte Alarmsignale

This European Standard was approved by CEN on 1995-02-10. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard was prepared by Technical Committee CEN/TC 259 "Medical alarms and signals", of which the secretariat is held by BSI.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

This European Standard shall be given the status of a National Standard, either by publication of an identical text or by endorsement, at the latest by August 1995, and conflicting national standards shall be withdrawn at the latest by August 1995.

This European Standard is related to ISO 9703-1: 1992 and ISO 9703-2: 199x prepared by Technical Committee TC 121 'Anaesthetic and respiratory equipment' of the International Organization for Standardization (ISO), and the contribution of ISO/TC 121 in the preparation of this European Standard is acknowledged.

The Annex A is informative and contains the "Bibliography".

The Annex B is informative and contains the "Rationale".

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0 Introduction

Medical practice in hospitals is increasingly dependent on medical devices for observation and treatment of patients. Auditory signals and lights are frequently used to indicate the patient's physiological status and the functional state of the medical device. The auditory signals used are frequently too loud and not sufficiently distinctive, and it is often difficult to identify which medical device is signalling. The purpose of this European Standard is to specify signals, some of which comprise both auditory and visual components, 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 European Standard 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 auditory signals in order to avoid confusion. Work based on psychoacoustic principles in other environments has contributed to the development of this standard, and auditory signals similar to those specified in this standard have already been incorporated into some medical devices.

Some of the criteria considered during development of the auditory signals 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 auditory signals.

Four signals are specified i.e. high priority, medium priority, low priority and information signals. The high and medium priority auditory signals are acoustically related but are differentiated by their perceived urgency.

1 Scope

This European Standard specifies the characteristics of electrically- generated signals intended for use with medical devices, either individually or as part of a centralized system. This European Standard applies only if a particular device standard makes reference to it. It is expected that requirements for the application of the signals specified in this standard will be included in Particular Standards for particular medical devices.

This European Standard does not specify:

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

b) the conditions that actuate the alarms;

c) the means of generating the signals;

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

e) the allocation of priorities to alarms.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate place in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision for undated references the last edition of the publication referred to applies.

ISO 3744: 1981[1)] *Acoustics - Determination of sound power levels of noise sources - Engineering methods for free-field conditions over a reflecting plane*

[1)] This reference will be replaced, when EN 31201 is published, by reference to EN 31201, 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 standard, the following definitions apply.

3.1 alarm signal: Signal indicating the onset and/or duration of a condition that requires a response by the operator.

3.2 high priority signal; warning signal: Signal indicating that immediate operator response is required.

3.3 medium priority signal; cautionary signal: Signal indicating that prompt operator response is required.

3.4 low priority signal; attention signal: Signal indicating that operator awareness is required.

3.5 information signal: A visual signal or an auditory signal or a combination of both, the purpose of which is to convey physiological or technical information.

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 amplitude increases from 10 % to 90 % of maximum amplitude. (See figure 1).

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

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

3.11 maximum amplitude: Average pulse amplitude during the effective pulse duration.

3.12 effective pulse duration (t_d) : : Time between start of pulse and end of pulse. (See figure 1).

NOTE: Although $t_o = t_r + t_d + t_f$, this standard is written in terms of t_d because it is easier to measure.

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

3.14 pulse frequency (f_o) : : Fundamental frequency of a pulse.

3.15 burst: Group of pulses with a distinctive rhythm.

3.16 pulse spacing (t_s):: Time between the start of one pulse and the start of the next pulse. (See figure 1).

3.17 pulse spacing width (t_w): : Time between consecutive pulses over which the pulse amplitude is below 10 % of the maximum amplitude.

3.18 burst spacing (t_b) : 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).

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

3.20 duty cycle: Percentage of the total on-time of a visual indication with respect to the total period of the cycle.

3.21 flashing frequency: Number of light flashes per unit time.

4 Requirements for signals

4.1 Composition of high priority signal

A high priority signal shall comprise a high priority auditory signal complying with tables 1 and 2 and a simultaneous high priority visual indication complying with table 3.

4.2 Composition of medium priority signal

A medium priority signal shall comprise a medium priority auditory signal complying with tables 1 and 2 and a simultaneous medium priority visual indication complying with table 3.

4.3 Composition of low priority signal

A low priority signal shall comprise a continuously-displayed visual indication. If an indicator light is used, it shall comply with table 3.

If the visual indication is accompanied by an auditory signal, the low priority auditory signal shall comply with table 4 and shall not have the characteristics of the bursts of the high and medium priority auditory signals given in table 1.

4.4 Composition of information signal

An information signal shall consist of an auditory signal or a visual indication, or a combination of both.

If a visual indication other than an alphanumeric display or computer generated graphic display is used, it shall not be red. A green light shall only be used to indicate that the equipment is ready for action.

If an auditory signal is used, it shall not have the characteristics of the bursts of the high or medium priority auditory signals given in table 1.

4.5 Legibility and visibility of visual indications

NOTE: Clause 4.5 applies only to those visual indications associated with alarm and information signals.

4.5.1 Visual indications shall be perceived correctly and discriminated between under the following conditions:

a) the operator having a visual acuity of 1 (corrected if necessary), and;

b) the viewpoint being at a distance of 4 m and at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of display of the visual indication, and;

c) under an ambient illuminance throughout the range of 100 lx to 1500 lx.

4.5.2 When tested as described in 4.5.3, the quantitative value(s) and function(s) displayed by the visual indications or graphic displays shall be correctly perceived by the test operator.

4.5.3 Repeat the test described in 4.5.1, but with the viewpoint at a distance of 1 m.

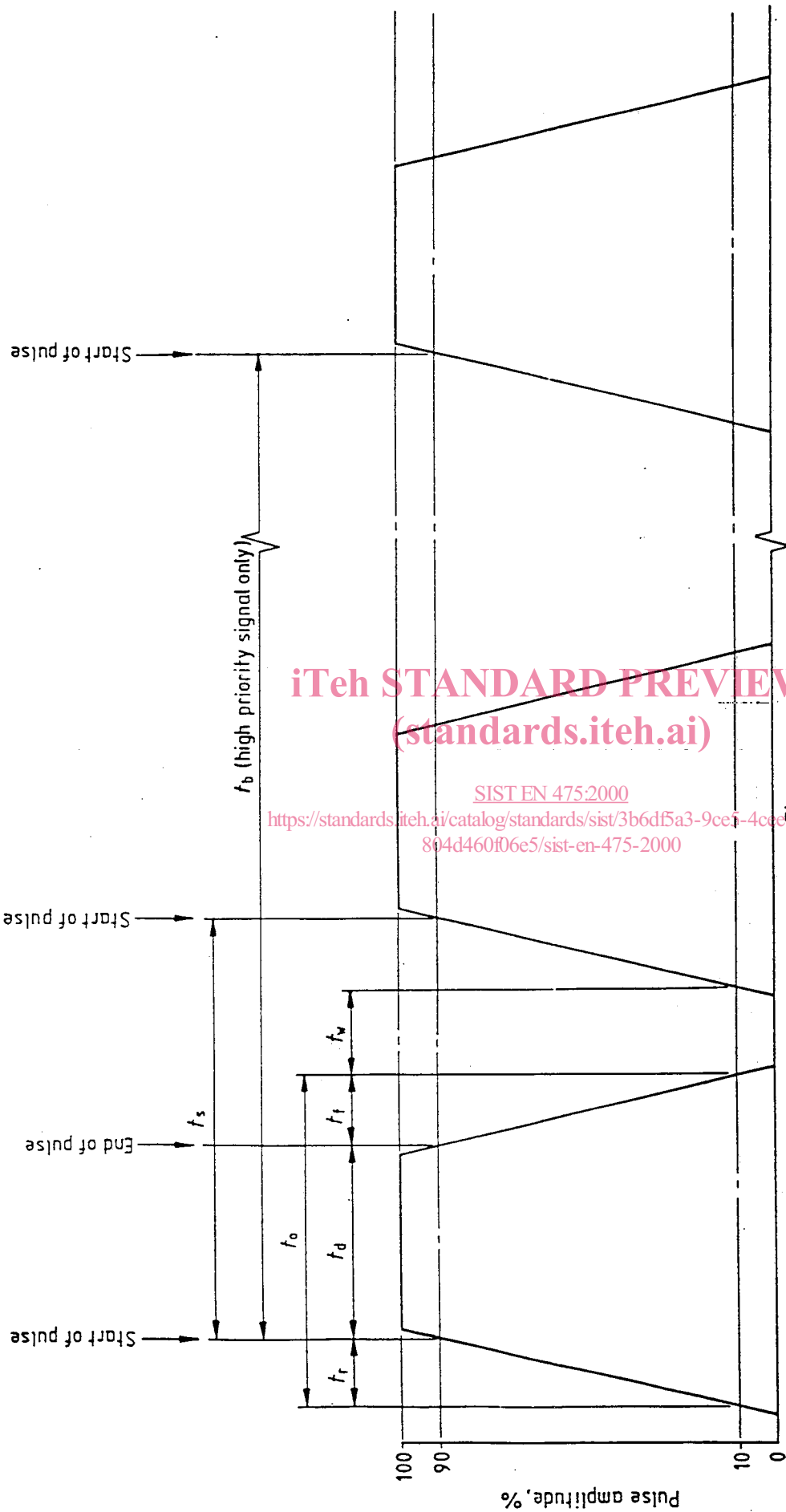

Figure 1: Illustration of temporal characteristics of auditory signals

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

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