EESTI STANDARD EVS-EN 475:1999

Meditsiiniseadmed. Elektriliselt genereeritud häiresignaalid

Medical devices - Electrically-generated alarm signals

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 475:1999 sisaldab Euroopa standardi EN 475:1995 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 475:1999 consists of the English text of the European standard EN 475:1995. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standard määrab kindlaks elektriliselt genereeritud signaalide parameetrid, mis on ette nähtud kasutamiseks meditsiiniseadmetes kas üksikult või tsentraalse süsteemi osana. Standard kehtib vaid siis, kui üksikseadme standard sellele viitab. On eeldatud, et nõuded signaalide rakendamiseks, mis on kindlaks määratud käesolevas standardis, sisalduvad tulevikus eristandardites üksikute meditsiiniseadmete jaoks.	**Scope:**

ICS 11.040.01

Võtmesõnad: elektriline aparatuur, helisignaalid, hoiatussüsteemid, meditsiiniaparatuur, määratlused, parameetrid, tabelid (andmed), valgussignaalid

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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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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".

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

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.