SLOVENSKI STANDARD

SIST EN 60601-1-8:2004/A1:2006

01-oktober-2006

Medicinska elektriļ na oprema - 1-8. del: Sploġne varnostne zahteve - Spremljevalni standard: Sploġne zahteve, preskusi in napotki za alarmne sisteme v medicinski elektriļ ni opremi in medicinskih elektriļ nih sistemih (IEC 60601-1-8:2003/A1:2006)

Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2003/A1:2006)

Medizinische elektrische Geräte - Teil 1-8: Allgemeine Festlegungen für die Sicherheit - Ergänzungsnorm: Alarmsysteme - Allgemeine Festlegungen, Prüfungen und Richtlinien für Alarmsysteme in medizinischen elektrischen Geräten und in medizinischen elektrischen Systemen (IEC 60601-1-8:2003/A1:2006)

Appareils électromédicaux - Partie 1-8: Règles générales de sécurité - Norme collatérale: Règles générales, essais et recommandations pour les systèmes d'alarme des appareils et des systèmes électromédicaux (CEI 60601-1-8:2003/A1:2006)

Ta slovenski standard je istoveten z: **EN 60601-1-8:2004/A1:2006**

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-8/A1

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Incorporates Corrigendum October 2006

English version

Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

(IEC 60601-1-8:2003/A1:2006)

Appareils électromédicaux -
Partie 1-8: Règles générales de sécurité -
Norme collatérale:
Règles générales, essais et recommandations pour les systèmes d'alarme des appareils et des systèmes électromédicaux
(CEI 60601-1-8:2003/A1:2006)

Medizinische elektrische Geräte -
Teil 1-8: Allgemeine Festlegungen für die Sicherheit -
Ergänzungsnorm: Alarmsysteme - Allgemeine Festlegungen, Prüfungen und Richtlinien für Alarmsysteme in medizinischen elektrischen Geräten und in medizinischen elektrischen Systemen
(IEC 60601-1-8:2003/A1:2006)

This amendment A1 modifies the European Standard EN 60601-1-8:2004; it was approved by CENELEC on 2006-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CENELEC member.

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

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62A/513/FDIS, future amendment 1 to IEC 60601-1-8:2003, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-1-8:2004 on 2006-04-01.

The following dates were fixed:

– latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2007-01-01
– latest date by which the national standards conflicting with the amendment have to be withdrawn	(dow)	2007-01-01

The contents of the corrigendum of October 2006 have been included in this copy.

Endorsement notice

The text of amendment 1:2006 to the International Standard IEC 60601-1-8:2003 was approved by CENELEC as an amendment to the European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-1-8

2003

AMENDEMENT 1
AMENDMENT 1
2006-03

Amendement 1

Appareils électromédicaux –

Partie 1-8:
Règles générales de sécurité – Norme collatérale: Règles générales, essais et recommandations pour les systèmes d'alarme des appareils et des systèmes électromédicaux

Amendment 1

Medical electrical equipment –

Part 1-8:
General requirements for safety – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

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FOREWORD

This amendment has been prepared by a Joint Working Group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC3: Lung ventilators and related devices, of ISO technical committee 121: Anaesthetic and respiratory equipment.

The text of this collateral standard is based on the following documents:

FDIS	Report on voting
62A/513/FDIS	62A/524/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the amendment has been approved by 17 P-members out of 17 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

This amendment contains a revision to IEC 60601-1-8 (first edition, 2003): *Medical electrical equipment – Part 1-8: General requirements for safety – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*

This amendment deals primarily with requirements for ALARM SYSTEMS that have global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation states and with the requirements for REMINDER SIGNALS.

To meet needs for change which were identified by users of this Collateral Standard, it was necessary to amend the standard before the previously approved maintenance cycle date.

Page 25

201 * ALARM SYSTEMS

201.1.2 * ALARM CONDITION priority

Replace, on page 27, the existing note [e] in Table 201 with the following:

[e] Where practicable, MEDICAL ELECTRICAL EQUIPMENT with a therapeutic function incorporates one or more automatic safety mechanisms to prevent immediate death or irreversible injury caused by the MEDICAL ELECTRICAL EQUIPMENT. See also appropriate Particular Standards.

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201.7 * ALARM SYSTEM security

Replace the parenthetical expression at the end of the first sentence with the following:

(see 201.3.3.1, 201.5.3.1, 201.5.3.2, 201.5.4.1, 201.8.2 b) & c), 201.8.3 b), 201.8.5 and 201.10):

Renumber the existing note as "Note 1" and add the following new note after Example 5:

NOTE 2 Multiple means of restriction can be necessary, e.g., one for the USER and one for each OPERATOR.

201.8 * ALARM SIGNAL inactivation states

Replace the existing subclauses with the following:

201.8.1 * General

Means shall be provided for the OPERATOR to inactivate the auditory, or the visual and auditory, generation of ALARM SIGNALS. Means may be provided to inactivate the generation of other ALARM SIGNALS. Inactivation may apply to an individual ALARM CONDITION, to a group of ALARM CONDITIONS, to the entire ALARM SYSTEM or to any part of a DISTRIBUTED ALARM SYSTEM. The inactivation of the generation of ALARM SIGNALS may be indefinite (i.e., ALARM OFF or AUDIO OFF) or timed (i.e., ALARM PAUSED or AUDIO PAUSED). Flashing visual ALARM SIGNALS specified in 201.3.2.2 may be inactivated by AUDIO PAUSED or AUDIO OFF.

NOTE A group of ALARM CONDITIONS can be predetermined or not.

EXAMPLE 1 All ventilation ALARM CONDITIONS.

EXAMPLE 2 The ALARM SIGNALS of all currently active ALARM CONDITIONS.

If ALARM SIGNAL inactivation applies to an individual ALARM CONDITION or a group of ALARM CONDITIONS, the generation of ALARM SIGNALS from other ALARM CONDITIONS shall be unaffected.

Compliance is checked by inspection.

201.8.2 * REMINDER SIGNALS

The ALARM SYSTEM may be provided with a REMINDER SIGNAL. If an ALARM SYSTEM is provided with a REMINDER SIGNAL:

a) the nature of the REMINDER SIGNAL and the intervals between REMINDER SIGNALS shall be disclosed in the instructions for use;

b) the ALARM SYSTEM shall include a means, accessible only to the USER (see 201.7):
   - to enable and disable the REMINDER SIGNAL; and
   - to configure the maximum REMINDER SIGNAL interval, if adjustment is provided.

c) the ALARM SYSTEM may include a means, accessible only to the USER (see 201.7):
   - to permit designated OPERATORS (see Example 3 in 201.7) to enable and disable the REMINDER SIGNAL;
   - to permit any OPERATOR to enable and disable the REMINDER SIGNAL.

Compliance is checked by inspection.

201.8.3 * Global indefinite ALARM SIGNAL inactivation states

If deemed acceptable by risk assessment with regard to the intended environment of use of the ALARM SYSTEM, a global ALARM OFF or AUDIO OFF may be provided. If an ALARM SYSTEM is provided with a global ALARM OFF or AUDIO OFF, the ALARM SYSTEM shall be provided with:

a) a REMINDER SIGNAL; and

b) means to configure (enable or disable) any global ALARM OFF or AUDIO OFF. Such means shall be restricted to the USER and shall prevent the clinical OPERATOR from changing the configuration in NORMAL USE (see 201.7).

NOTE 1 A global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state affects all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM with multiple PHYSIOLOGICAL ALARM CONDITIONS.

NOTE 2 See also 201.8.2 for requirements for REMINDER SIGNALS.

Compliance is checked by inspection.

201.8.4 * Termination of inactivation of ALARM SIGNALS

Means shall be provided for the OPERATOR to terminate any ALARM SIGNAL inactivation state. An ALARM SIGNAL inactivation state may terminate automatically, when the ALARM CONDITION that was generating the ALARM SIGNAL when this state was entered, ceases.

When an ALARM SIGNAL inactivation state is terminated, the ALARM SIGNALS for any current ALARM CONDITION shall be re-generated.

Compliance is checked by functional testing.

201.8.5 * Indication and access

The ALARM SIGNAL inactivation states AUDIO PAUSED, ALARM PAUSED, AUDIO OFF, and ALARM OFF shall be visually indicated (marked) with the appropriate symbol referenced in Table 205. This indication shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION.

The means of control used to enter one of the ALARM SIGNAL inactivation states may be marked with a symbol referenced in Table 205. If a symbol that is referenced in Table 205 is used, it shall initiate the associated ALARM SIGNAL inactivation state.

The duration of AUDIO PAUSED or ALARM PAUSED, if provided, shall be disclosed in the instructions for use.

If the AUDIO PAUSED or ALARM PAUSED interval is OPERATOR-adjustable, means to adjust the maximum interval shall only be provided to the USER (see 201.7) and means may be provided for the OPERATOR to adjust the interval up to the maximum interval.

Compliance is checked by inspection.

Table 205 – ALARM SIGNAL inactivation states

State	Duration	Visual indication (marking) of state (mandatory) (row of symbol in Table D.201)	Marking of controls (optional)	
			(row of symbol in Table D.201)	(row of marking in Table D.202)
AUDIO PAUSED	Time limited	6	6	1
ALARM PAUSED	Time limited	4 or (4 and 6)	4	2
AUDIO OFF	Indefinite	5	5	3
ALARM OFF	Indefinite	3 or (3 and 5)	3	4

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Annex AAA Rationale and guidance

AAA.2.234 REMINDER SIGNAL (see also AAA.201.8.1)

Replace, on page 75, in two places in the third paragraph of the subclause, the word:

'sounds' with 'signals'

Replace, on page 75, in the forth paragraph of the subclause, the word:

'noise' with 'signal'

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AAA.201.1.2 ALARM CONDITION priority

Delete Example 6.

Renumber Example 7 as Example 6.