SLOVENSKI

PREDSTANDARD

SIST EN 60601-1-8:2004/oprA1:2005

julij 2005

Medicinska električna oprema – 1-8. del: Splošne zahteve za varnost – Spremljevalni standard: Splošne zahteve, preskusi in vodila za alarmne sisteme in medicinsko električno opremo in medicinske električne sisteme

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

ICS 11.040.01; 13.320

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COMMITTEE DRAFT FOR VOTE (CDV)
PROJET DE COMITÉ POUR VOTE (CDV)

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Secretary: USA Secrétaire:		
Also of interest to the following committees Intéresse également les comités suivants TC 62, SC 62B/C/D, TC 66, TC 76, ISO/TC 106/SC 6, ISO/TC 121/SC 1 and SC 3, ISO/TC 150/SC 6, CENELEC/TC 62	Supersedes document Remplace le document 62A/470/DC and 62A/481/MCR	
Functions concerned Fonctions concernées ☒ Safety / Sécurité ☐ EMC / CEM ☐ Environment / Environnement ☐ Quality assurance / Assurance qualité		

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Titre : Amendement 1 à la CEI 60601-1-8 : Appareils électromédicaux – Partie 1-8: Règles générales de sécurité – Norme collatérale: Règles générales, essais et guides pour les systèmes d'alarme dans l'équipement électromédical et les systèmes électromédicaux

Title :Amendment 1 to IEC 60601-1-8: 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

Parallel CENELEC and ISO votes

ATTENTION	ATTENTION
CDV soumis en parallèle au vote (CEI) et à l'enquête (CENELEC)	**Parallel IEC CDV/CENELEC Enquiry**

Note d'introduction

Après avoir pris connaissance des préoccupations relatives à la sécurité soulevées par les commentaires allemands et de la résolution approuvée à la récente réunion du CENELEC/TC 62 de presser le comité technique 62 de la CEI à intervenir rapidement pour traiter du problème, le JWG2 s'est réuni et a établi le présent projet d'amendement. Les Secrétariats ont l'intention de faire avancer le présent amendement dans le but d'obtenir l'approbation des Comités Nationaux et des Organismes Membres en ce qui concerne les changements techniques nécessaires pour régler ce problème et pour éviter l'empêchement de l'harmonisation de la EN IEC 60601-1-8 en Europe. A la lumière du commentaire 8 du 62A/481/MCR, les Secrétariats ont décidé d'accélérer le processus du présent amendement en passant l'étape du Comité.

Le Comité National français nous rappelle la décision prise aux réunions du SC 62A de Francfort en octobre 2003 concernant l'alignement structurel des normes collatérales sur la troisième édition de la CEI 60601-1 et de la priorité donnée à cet alignement. Il est dans l'intention des Secrétariats responsables, avec le présent amendement qui traite de la problématique allemande, de commencer en parallèle le travail de cet alignement. Les secrétariats se proposent de diffuser cette (seconde) édition alignée de la CEI 60601-1-8 dès la clôture du vote du FDIS de la troisème édition de la CEI 60601-1.

Les aspects éditoriaux émanant des Comités Nationaux et des Organismes Membres seront traités au cours de la préparation de la seconde édition pour aligner de manière structurelle la CEI 60601-1-8 avec la troisième édition de la CEI 60601-1. Les aspects techniques émanant d'autres Comités Nationaux ou d'autres Organismes Membres seront traités, soit dans un amendement à la seconde édition, soit, s'ils sont suffisamment importants, dans une future édition de la CEI 60601-1-8.

Introductory note

Taking note of the safety concern raised in the German comments and the resolution passed at the recent meeting of CENELEC/TC 62 urging IEC/TC 62 to take expeditious action to address the issue, JWG2 met and produced this draft amendment. The Secretariats intend to push forward with this amendment with the goal of obtaining approval of the National Committees and Member Bodies for the technical changes necessary to address this issue and eliminate the impediment to harmonization of EN IEC 60601-1-8 in Europe. In light of comment 8 in 62A/481/MCR, the Secretariats have decided to expedite processing of this amendment by omitting the Committee Stage.

The French National Committee reminds us of the decision taken during the SC 62A and TC 62 meetings in Frankfurt, October 2003, concerning the structural alignment of the collateral standards to the third edition of IEC 60601-1 and the priority given to this alignment. It is the intent of the responsible Secretariats to begin work on this alignment in parallel with this amendment that addresses the German issue. The Secretariats intend to circulate this aligned (second) edition of IEC 60601-1-8 following the close of the FDIS ballot of third edition of IEC 60601-1.

Editorial issues raised by National Committees and Member Bodies will be addressed in the process of preparing the second edition to structurally align IEC 60601-1-8 with the third edition of IEC 60601-1. Technical issues raised by other National Committees or Member Bodies will be dealt with in either an amendment to the second edition, or, if sufficiently extensive, in a future third edition of IEC 60601-1-8.

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/XX/FDIS	62A/XX/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result date[1] 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 ISO 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.

[1] The National Committees are requested to note that for this publication the maintenance result date is 2009.

201 * ALARM SYSTEMS

201.1.2 * ALARM CONDITION priority

Replace the existing note [e] in Table 201 with the following:

[e] Where practicable, MEDICAL ELECTRICAL EQUIPMENT with a therapeutic function incorporates 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):

Add the following new note after example 5:

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

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Replace 201.8 with the following:

201.8 * ALARM SIGNAL inactivation states

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 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;
- 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 (see 201.7) OPERATORS 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 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.

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 an ALARM SIGNAL when this state was entered, ceases.

When an ALARM SIGNAL inactivation state is terminated, the ALARM SIGNALS of any current ALARM CONDITION shall cause the re-generation of ALARM SIGNALS.

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 36, in two places in the third paragraph of the subclause, the word:

'sounds' with 'signals'

Replace, on page 36, 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.

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AAA.201.1.2 ALARM CONDITION priority

Add the following as the last paragraph:

MEDICAL ELECTRICAL EQUIPMENT ALARM SYSTEMS are a protective measure used to minimize risks to PATIENT, personnel, and equipment. In certain therapeutic MEDICAL ELECTRICAL EQUIPMENT, a hazardous situation could develop so rapidly, and cause injury or damage so rapidly, that OPERATOR response to even a well-designed ALARM SYSTEM would be too slow. In such MEDICAL ELECTRICAL EQUIPMENT, an automatic system of mitigating the hazardous situation is highly desirable, if not essential. The General Standard and many Particular Standards require such safety mechanisms. It is recognized, however, that no MEDICAL ELECTRICAL EQUIPMENT could have protection against every possible hazard, or in the presence of multiple fault conditions.