SLOVENSKI STANDARD

SIST EN 60601-1-8:2008/A1:2014

01-februar-2014

Medicinska električna oprema - 1-8. del: Splošne zahteve za osnovno varnost in bistvene tehnične lastnosti - Spremljevalni standard: Splošne zahteve, preskušanje in napotki za alarmne sisteme v medicinski električni opremi in medicinskih električnih sistemih - Dopolnilo A1 (IEC 60601-1-8:2006/A1:2012)

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

Medizinische elektrische Geräte - Teil 1-8: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Alarmsysteme - Allgemeine Festlegungen, Prüfungen und Richtlinien für Alarmsysteme in medizinischen elektrischen Geräten und in medizinischen elektrischen Systemen

Appareils électromédicaux - Partie 1-8: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux

Ta slovenski standard je istoveten z: **EN 60601-1-8:2007/A1:2013**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1-8:2008/A1:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-8/A1

March 2013

ICS 11.040.01

English version

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

(IEC 60601-1-8:2006/A1:2012)

Appareils électromédicaux - Partie 1-8: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux (CEI 60601-1-8:2006/A1:2012)

Medizinische elektrische Geräte - Teil 1-8: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Alarmsysteme - Allgemeine Festlegungen, Prüfungen und Richtlinien für Alarmsysteme in medizinischen elektrischen Geräten und in medizinischen elektrischen Systemen (IEC 60601-1-8:2006/A1:2012)

This amendment A1 modifies the European Standard EN 60601-1-8:2007; it was approved by CENELEC on 2013-01-02. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62A/824/FDIS, future edition 1 of IEC 60601-1-8:2006/A1, prepared by SC 62A, "Common aspects of electrical equipment used in medical practice", of IEC/TC 62, "Electrical equipment in medical practice" and ISO SC 3, "Lung ventilators and related devices" of ISO/TC 121, "Anaesthetic and respiratory equipment" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-8:2007/A1:2013.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2013-10-02
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-01-02

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60601-1-8:2006/A1:2012 was approved by CENELEC as a European Standard without any modification.

Replace *the Annex ZA of EN 60601-1-8:2007 by the following:*

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60417	Data-base	Graphical symbols for use on equipment	-	-
IEC 60601-1 + corr. December + corr. December + A1	2005 2006 2007 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + A11	2006 2010 2011
IEC 61672-1	2002	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	2003
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
ISO 3744	2010	Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Engineering methods for an essentially free field over a reflecting plane	EN ISO 3744	2010
ISO 7000	-	Graphical symbols for use on equipment	-	-

IEC 60601-1-8

Edition 2.0 2012-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

Appareils électromédicaux –
Partie 1-8: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC 3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/824/FDIS	62A/837/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 standard has been approved by 19 P-members out of 21 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability 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 TO THE AMENDMENT

The second edition of IEC 60601-1-8 was published in 2006. Since its publication, an issue has been identified with respect to pulse and burst testing. In addition, issues have been raised by IEC/62D/MT 22, *Electromedical diagnostic and patient monitoring equipment*, during implementation of alarm system requirements in particular standards within their scope of work.

At the Brussels meeting, IEC/SC 62A accepted a proposal, based on ISO/TC 121/SC 3 Resolution Orebro 6, to develop the 1st amendment to IEC 60601-1-8:2006 to address the issues identified above. IEC/SC 62A – ISO/TC 121/SC 3 Joint Working Group 2, *Alarms*, was reactivated as a maintenance team to develop this amendment.

Foreword

Add the following note at the end of the Foreword:

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

1.2 Object

In the first paragraph, change the print type of the defined terms "basic safety" *and* "essential performance" *to small caps.*

1.3.1 IEC 60601-1

Replace the existing first dash with:

– "the general standard" designates IEC 60601-1 alone (latest edition including any amendments);

2 Normative references

Replace the introductory paragraph with:

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Replace the normative references for IEC 60417 and IEC 60601-1 with the following:

IEC 60417, *Graphical symbols for use on equipment.* Available from: <http://www.graphical-symbols.info/equipment>

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

Delete the normative references for IEC 60601-1-2, and IEC 60601-1-6.

Replace the normative reference to IEC 60651:1979 and its Amendment 1 (1993) and Amendment 2 (2000) with the following:

IEC 61672-1:2002, *Electroacoustics – Sound level meters – Part 1: Specifications*

Add the following normative reference:

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

Replace the normative references for ISO 3744:1994 and ISO 7000:1989 with the following:

ISO 3744:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering methods for an essentially free field over a reflecting plane*

ISO 7000, *Graphical symbols for use on equipment.* Available from: <http://www.graphical-symbols.info/equipment>

3 Terms and definitions

Replace the existing first paragraph with the following:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012 and IEC 62366:2007, and the following terms and definitions apply.

3.1
*** ALARM CONDITION**

Replace the existing definition with the following:

state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

Add the following new definition:

3.37
*** ACKNOWLEDGED**
state of an ALARM SYSTEM initiated by OPERATOR action, where the auditory ALARM SIGNAL associated with a currently active ALARM CONDITION is inactivated until the ALARM CONDITION no longer exists

NOTE 1 ACKNOWLEDGED only affects ALARM SIGNALS that are active at the time of the OPERATOR action.

NOTE 2 ACKNOWLEDGED can terminate after a predetermined time interval has elapsed.

6 Alarm systems

6.1 ALARM CONDITION

6.1.2 * ALARM CONDITION priority

Replace the existing title and text of this subclause including Table 1 with the following:

6.1.2 * Determination of ALARM CONDITIONS and assignment of priority

For each HAZARDOUS SITUATION where the MANUFACTURER has chosen to use an ALARM SYSTEM as a means of RISK CONTROL, the MANUFACTURER shall assign an ALARM CONDITION and its priority using Table 1.

For HAZARDOUS SITUATIONS where the onset of potential HARM is delayed and the potential result of a failure to respond is discomfort or minor reversible injury, the MANUFACTURER may determine that no ALARM CONDITION is required. In such cases, the MANUFACTURER may implement an INFORMATION SIGNAL.

NOTE Not all LOW PRIORITY ALARM CONDITIONS require prompt notification of the OPERATOR. On this basis an auditory ALARM SIGNAL or repeating auditory ALARM SIGNAL can be omitted, when appropriate, since the OPERATOR is expected to check the ME EQUIPMENT at intervals. In the event that the OPERATOR does not check the ME EQUIPMENT in a timely fashion, the ALARM CONDITION should escalate from LOW PRIORITY to MEDIUM PRIORITY or HIGH PRIORITY, and can additionally increase the sound pressure level of the related auditory ALARM SIGNALS, as appropriate.

The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups.

Compliance is checked by inspection of the instructions for use and RISK MANAGEMENT FILE.

Table 1 – Determination of ALARM CONDITIONS and assignment of priorities

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY ALARM CONDITION [e]	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION
Reversible injury	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION
Discomfort or reversible minor injury	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION, no ALARM CONDITION or INFORMATION SIGNAL

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under “prompt”.

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

6.3.2 * Visual ALARM SIGNALS

6.3.2.2 Characteristics of visual ALARM SIGNALS

Restructure the content of this subclause by creating two new subclauses as follows:

6.3.2.2.1 * 4 m (distant) visual ALARM SIGNALS

Under this subclause place the existing text of 6.3.2.2 through Table 2.

In the second paragraph delete the last sentence reading "Alternatively, this indication may be generated by some other type of visual display or device".

6.3.2.2.2 1 m (OPERATOR’S POSITION) visual ALARM SIGNALS and INFORMATION SIGNALS

Under this subclause place the remainder of the existing text of 6.3.2.2.

Renumber Notes 4 through 7 as Notes 1 through 4.

In Note 3, replace "IEC 60601-1-6" with "IEC 62366".

Replace the last paragraph before the compliance test with the following:

Visual INFORMATION SIGNALS, if provided, shall be correctly perceived as different from HIGH PRIORITY or MEDIUM PRIORITY visual ALARM SIGNALS at a distance of 1 m from the ALARM SYSTEM or from the OPERATOR’S POSITION.

NOTE 5 It is recognized that visual INFORMATION SIGNALS and visual ALARM SIGNALS can sometimes contain identical or similar information.

6.3.3 * Auditory ALARM SIGNALS

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

Replace the first paragraph, including items a) and b), with the following:

If an ALARM SYSTEM is provided with auditory ALARM SIGNALS:

a) all auditory ALARM SIGNALS shall be priority encoded;

b) of HIGH PRIORITY, the HIGH PRIORITY auditory ALARM SIGNALS shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

c) of MEDIUM PRIORITY, the MEDIUM PRIORITY auditory ALARM SIGNALS shall convey a higher level of urgency than the LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

d) the ALARM SYSTEM shall have at least one set of ALARM SIGNALS that

– meets the requirements of Table 3 and Table 4; or

– is generated by means of different technology (e.g., voice synthesizing of verbal ALARM SIGNALS) and is VALIDATED (e.g., by clinical or simulated clinical USABILITY testing).

Table 3 – * Characteristics of the BURST of auditory ALARM SIGNALS

Replace the existing fifth row of the table with the following:

Where: x shall be a value between 50 ms and 125 ms, y shall be a value between 125 ms and 250 ms, the variation of x and y within a BURST shall not exceed ± 5 %, and MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$. The INTERBURST INTERVAL (t_b) for HIGH PRIORITY auditory ALARM SIGNALS shall not be greater than the INTERBURST INTERVAL for MEDIUM PRIORITY auditory ALARM SIGNALS which shall not be greater than the INTERBURST INTERVAL for LOW PRIORITY auditory ALARM SIGNALS.

Table 4 – * Characteristics of the PULSE of auditory ALARM SIGNALS

In the fourth row, replace the value "20 %" with "40 %".

Replace the existing sixth row of the table with the following:

NOTE 1 The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY. NOTE 2 In practice, the RISE TIME should not be less than 10 ms to prevent mechanical speaker noise.

Replace the first paragraph after Figure 1, including items c) through h) and Notes 1 and 2, with the following:

If the ALARM SYSTEM is additionally provided with other sets of auditory ALARM SIGNALS, the following shall apply:

e) the other auditory ALARM SIGNALS shall be VALIDATED, e.g., by clinical or simulated clinical USABILITY testing;

f) means shall be provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM PRESET; and

g) means may be provided to store a set of auditory ALARM SIGNALS in any ALARM PRESET.

NOTE 1 See also Annex D.

NOTE 2 Attention is drawn to IEC 62366.

Replace the compliance paragraph with: