SLOVENSKI STANDARD

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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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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)

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
(CEI 60601-1-8:2003)

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 Systemen
(IEC 60601-1-8:2003)

This European Standard was approved by CENELEC on 2003-12-02. CENELEC 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 CENELEC 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 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, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and 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

Ref. No. EN 60601-1-8:2004 E

Foreword

The text of document 62A/424/FDIS, future edition 1 of IEC 60601-1-8, prepared by a Joint Working Group of SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, and SC3, Lung ventilators and related devices, of ISO TC 121, Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-8 on 2003-12-02.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2004-09-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2006-12-01

This European Standard is a collateral standard to EN 60601-1:1990, hereinafter referred to as the general standard.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to
– a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

The numbering of sections, clauses and subclauses of this collateral standard corresponds with that of the general standard.

Clauses, subclauses, tables and figures which are additional to those of the general standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this collateral standard, the following print types are used:
– requirements and definitions: roman type;
– notes, examples, explanations, advice, introductions, general statements and references: smaller roman type;
– *test specifications and guidance in Annex AAA: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Clauses and subclauses for which a rationale is provided in the informative Annex AAA are marked with an asterisk (*).

Annex ZA has been added by CENELEC.

Endorsement notice

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

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 14971	NOTE	Harmonized as EN ISO 14971:2000 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. 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	database	Graphical symbols for use on equipment	-	-
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2 + corr. June	1995 1995		A2 A13	1995 1996
IEC 60601-1-1	2000	Medical electrical equipment Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	2001
IEC 60601-1-6	- [1)]	Part 1-6: General requirements for safety - Collateral standard: Usability	-	-
IEC 60651	1979	Sound level meters	EN 60651	1994
A1	1993		A1	1994
A2	2000		A2	2001
ISO 3744	1994	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane	EN ISO 3744	1999
ISO 7000	1989	Graphical symbols for use on equipment - Index and synopsis	-	-

[1)] To be published.

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Appareils électromédicaux –

Partie 1-8:
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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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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International standard IEC 60601-1-8 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.

It is published as double logo standard.

This first edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety*, hereinafter referred to as the general standard.

This bilingual version (2005-08) replaces the English version.

This standard replaces the following standards:

ISO 9703-1 Anesthesia and respiratory care alarm signals – Part 1: Visual alarm signals

ISO 9703-2 Anesthesia and respiratory care alarm signals – Part 2: Auditory alarm signals

ISO 9703-3 Anesthesia and respiratory care alarm signals – Part 3: Guidance on application of alarms

NOTE This standard is intended to replace other national and regional standards, such as EN 475 Medical devices – Electrically generated alarm signals.

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

FDIS	Report on voting
62A/424/FDIS	62A/432/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. In ISO, the standard has been approved by 16 P-members out of 18 having cast a vote.

The French version of this standard has not been voted upon.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

The numbering of sections, clauses and subclauses of this collateral standard corresponds with that of the general standard.

Clauses, subclauses, tables, and figures which are additional to those of the general standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this collateral standard, the following print types are used:

– requirements and definitions: roman type;

– notes, examples, explanations, advice, introductions, general statements and references: smaller roman type;

– *test specifications and guidance in Annex AAA: italic type; and*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Clauses and subclauses for which a rationale is provided in informative Annex AAA are marked with an asterisk (*).

The committee has decided that the contents of this 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

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are increasingly used in medical practice. ALARM SIGNALS are frequently used to indicate unsatisfactory physiological PATIENT states, unsatisfactory functional states of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM or to warn the OPERATOR of potential hazards to the PATIENT or OPERATOR due to the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM. INFORMATION SIGNALS convey information that is independent of an ALARM CONDITION.

Surveys of healthcare personnel have indicated significant discontent with ALARM SIGNALS. Problems include difficulty in identifying the source of an ALARM SIGNAL, loud and distracting ALARM SIGNALS, and the high incidence of FALSE POSITIVE or NEGATIVE ALARM CONDITIONS [16][1)]. Surveys of manufacturers of medical monitors demonstrated a wide variety of DEFAULT ALARM PRESETS. The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS. See also bibliography.

Safety of PATIENTS depends on the ability of the OPERATOR to correctly discern the characteristics of ALARM SIGNALS. Usability is an important element in the design of ALARM SIGNALS that are readily discernible without being unnecessarily distracting or disturbing. This approach is intended to rationalize the current situation, to reduce confusion by limiting proliferation of ALARM SIGNALS and their control states, and to minimize distraction for other people. This collateral standard was developed with contributions from clinicians, engineers and applied psychologists.

The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for manufacturers of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for particular standards.

The effectiveness of any ALARM SYSTEM depends critically on its implementation by the USER. It is important that the USER configure the ALARM SYSTEM so that an OPERATOR is not able to compromise it.

1) Figures in brackets refer to the bibliography.

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

SECTION ONE – GENERAL

1 * Scope and object

1.201 Scope

This collateral standard specifies requirements for ALARM SYSTEMS and ALARM SIGNALS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.

It also provides guidance for the application of ALARM SYSTEMS.

1.202 Object

The object of this collateral standard is to specify basic safety and essential performance requirements and tests for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent ALARM SIGNALS and consistent control states and their marking for all ALARM SYSTEMS.

NOTE See IEC 60513:1994 [4] for a description of basic safety and essential performance.

This collateral standard does not specify:

– whether any particular MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM is required to be provided with ALARM SYSTEMS;

– the particular circumstances which initiate an ALARM CONDITION;

– the allocation of priorities to a particular ALARM CONDITION; or

– the means of generating ALARM SIGNALS.

1.203 Relationship to other standards

1.203.1 IEC 60601-1

For MEDICAL ELECTRICAL EQUIPMENT, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone;

– "this collateral standard" designates IEC 60601-1-8 alone;

– "this standard" designates the combination of the general standard and this collateral standard.

1.203.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

1.203.3 Normative references

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

IEC 60417-DB:2002[2], *Graphical symbols for use on equipment*

IEC 60601-1:1988 *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability*

IEC 60651:1979 [3], *Sound level meters*
Amendment 1 (1993)
Amendment 2 (2000)

ISO 3744:1994, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Engineering method in an essentially free field over a reflecting plane*

ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

2 Terminology and definitions

For the purposes of this collateral standard, the following definitions apply. [4]

NOTE This collateral standard uses the term "equipment" to mean MEDICAL ELECTRICAL EQUIPMENT or non-MEDICAL ELECTRICAL EQUIPMENT in the context of a MEDICAL ELECTRICAL SYSTEM.

2.201
*** ALARM CONDITION**
state of the ALARM SYSTEM when it has determined that a potential or actual hazard exists

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

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

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[2] "DB" refers to the IEC on-line database.

[3] A consolidated edition (1.2) exists including IEC 60651 (1979), its Amendment 1 (1993) and its Amendment 2 (2000).

[4] An index of defined terms is found beginning on page 153.

2.202
*** ALARM CONDITION DELAY**
time from the occurrence of a triggering event either in the PATIENT, for PHYSIOLOGICAL ALARM CONDITIONS, or in the equipment, for TECHNICAL ALARM CONDITIONS, to when the ALARM SYSTEM determines that an ALARM CONDITION exists

2.203
*** ALARM LIMIT**
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

2.204
ALARM OFF
state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

2.205
*** ALARM PAUSED**
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate ALARM SIGNALS

2.206
ALARM PRESET
set of stored configuration parameters, including selection of algorithms and initial values for use by algorithms, which affect or modify the performance of the ALARM SYSTEM

2.207
ALARM RESET
OPERATOR action that causes the cessation of an ALARM SIGNAL for which no associated ALARM CONDITION currently exists

2.208
ALARM SETTINGS
ALARM SYSTEM configuration, including but not limited to:

– ALARM LIMITS;

– the characteristics of any ALARM SIGNAL inactivation states; and

– the values of variables or parameters that determine the function of the ALARM SYSTEM.

NOTE Some algorithmically determined ALARM SETTINGS can require time to be determined or re-determined.

2.209
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

2.210
*** ALARM SIGNAL GENERATION DELAY**
time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNALS

2.211
ALARM SYSTEM
parts of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS