

A YX]W]bg_UYY_Hf] bUcdfYa U!%, "XY. Gd`cýbY'nU Hýj Y'nUcgbcj bc`j Ufbcgh]b
V]glj YbY'h^ b] bY`Uglbcgh]! GdfYa `Yj Ub]ghUbXUfX. Gd`cýbY'nU Hýj Yž
dfYg_i ýUb^Y]b`bUdch_]nUUUfa bYg]ghYa Yj`a YX]W]bg_]YY_Hf] b]cdfYa]]b
a YX]W]bg_]YY_Hf] b]`g]ghYa]`f197 * \$ \$ % % , . & \$ \$ * £

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)

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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)

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 (IEC 60601-1-8:2006)

Ta slovenski standard je istoveten z: EN 60601-1-8:2007

ICS:

11.040.01 Medicinska oprema na Medical equipment in general
splošno

SIST EN 60601-1-8:2008**en,fr,de**

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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)**

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

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(IEC 60601-1-8:2006)

This European Standard was approved by CENELEC on 2007-04-11. 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, Bulgaria, 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/519/CDV, future edition 2 of IEC 60601-1-8, 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 Unique Acceptance Procedure and was approved by CENELEC as EN 60601-1-8 on 2007-04-11.

The following date was 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) 2008-02-01

This European Standard supersedes EN 60601-1-8:2004 and its amendment A1:2006 (+ corrigendum October 2006). However, EN 60601-1-8:2004 remains valid until all the parts 2 that are used in conjunction with it have been withdrawn. No date of withdrawal of conflicting national standards (dow) has therefore been fixed. However, when Part 1-8 is used for appliances not covered by a part 2, EN 60601-1-8:2004 is not to be used after 2009-09-12.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

This EN 60601-1-8 was revised to structurally align it with EN 60601-1:2006 and to implement the decision of IEC SC 62A that the clause numbering structure of collateral standards written to EN 60601-1:2006 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in EN 60601-1:2006.

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).

In this collateral standard the following print types are used:

- requirements and definitions: in roman type;
- *test specifications: in italic type. In addition, in Annex A text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTES: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.2.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-8:2006 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/IEC 14971 NOTE Harmonized as EN ISO 14971:2000 (not modified).

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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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60417	Data base	Graphical symbols for use on equipment	-	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
IEC 60601-1-6	2006	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2007
IEC 60651 A1	1979	Sound level meters	EN 60651 ¹⁾	1994
A2	1993		A1	1994
	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	1995
ISO 7000	1989	Graphical symbols for use on equipment - Index and synopsis	-	-

¹⁾ EN 60651 + A1 + A2 are superseded by EN 61672-1:2003 & EN 61672-2:2003, which are based on IEC 61672-1:2002 & IEC 61672-2:2003.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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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

PRICE CODE
CODE PRIX

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**

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.
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International standard IEC 60601-1-8 has been prepared by 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 SC 3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as double logo standard.

IEC 60601-1-8 constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

This second edition cancels and replaces the first edition of IEC 60601-1-8, published in 2003, of which it constitutes a technical revision.

This edition of IEC 60601-1-8 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC Subcommittee 62 A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

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

CDV	Report on voting
62A/519/CDV	62A/537A/RVC

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 18 P-members out of 18 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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).

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

- Requirements and definitions: roman type.
- *Test specifications: italic type. In addition, in Annex A text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.3.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
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- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

A list of all parts of the IEC 60601 series, under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this collateral standard 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

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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 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.

iTeh STANDARD PREVIEW

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.

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

1) Figures in brackets refer to the bibliography.