ELEKTRILISED MEDITSIINISEADMED. OSA 1-8: ÜLDISED NÕUDED ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE. KOLLATERAALSTANDARD: ELEKTRILISTES MEDITSIINISEADMETES JA -SÜSTEEMIDES KASUTATAVATELE ALARMSÜSTEEMIDELE ESITATAVAD ÜLDNÕUDED, KATSETAMINE JA JUHISED

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 + IEC 60601-1-8:2006/A1:2012 + IEC 60601-1-8:2006/A2:2020)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-8:2007 +A1+A11+A2:2021 sisaldab Euroopa standardi EN 60601-1-8:2007 ja selle muudatuste A1:2013, A11:2017 ja A2:2021, ja paranduse AC:2010 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-8:2007 +A1+A11+A2:2021 consists of the English text of the European standard EN 60601-1-8:2007 and its amendments A1:2013, A11:2017 and A2:2021 and its corrigendum AC:2010.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 31.07.2007, muudatused A1 22.03.2013, A11 10.03.2017 ja A2 16.07.2021.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 31.07.2007, for A1 22.03.2013, A11 10.03.2017 and A2 16.07.2021.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud püstkriipsuga teksti vasakul veerisel. Muudatusega A11 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud topeltpüstkriipsuga teksti vasakul veerisel. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦A2⟩ ⟨A2⟩. Parandusega AC lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦AC⟩ ⟨AC⟩. Muudatuse A1 parandusega AC:2014 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦AC2⟩ ⟨AC2⟩. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by a vertical line in the left margin of the text. The start and finish of text introduced or altered by amendment A11 is indicated in the text by a double vertical line in the left margin of the text. The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags ⟦A2⟩ ⟨A2⟩. The start and finish of text introduced or altered by corrigendum AC is indicated in the text by tags ⟦AC⟩ ⟨AC⟩. The start and finish of text introduced or altered by amendment A1 corrigendum AC:2014 is indicated in the text by tags ⟦AC2⟩ ⟨AC2⟩. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.01

[Blank page]

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-8 + A1+ A11 + A2

July 2007, March 2013, March 2017, July 2021

ICS 11.040.01

Supersedes EN 60601-1-8:2004 + A1:2006

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 + IEC 60601-1-8:2006/A1:2012 + IEC 60601-1-8:2006/A2:2020)

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 + IEC 60601-1-8:2006/A1:2012 + IEC 60601-1-8:2006/A2:2020)

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 + IEC 60601-1-8:2006/A1:2012 + IEC 60601-1-8:2006/A2:2020)

This European Standard was approved by CENELEC on 2007-04-11. Amendment A1 was approved by CENELEC on 2013-01-02. Amendment A11 was approved by CENELEC on 2017-01-07. Amendment A2 was approved by CENELEC on 2020-08-27. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendments 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 European Standard and its Amendments A1, A11 and A2 exist 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 60601-1-8:2007 E + EN 60601-1-8:2007/A1:2013 E + EN 60601-1-8:2007/A11:2017 E + EN 60601-1-8:2007/A2:2021 E

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
– [AC] latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2014-01-2012 [AC]

This European Standard supersedes EN 60601-1-8:2004 and its amendment A1:2006 (+ corrigendum October 2006). [AC] *deleted text* [AC]

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.

Amendment A1 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 h as 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)	[AC2] 2018-12-31 [AC2]

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.

Amendment A11 European foreword

This document (EN 60601-1-8:2007/A11:2017) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2018-07-01
• latest date by which the national standards conflicting with this document have to be	(dow)	2020-01-07

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.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

A2 Amendment A2 European foreword

The text of document 62A/1392/FDIS, future IEC 60601-1-8/A2, 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 approved by CENELEC as EN 60601-1-8:2007/A2:2021.

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) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-1-8:2006/A2:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 80001-1	NOTE	Harmonized as EN 80001-1
ISO 9000:2015	NOTE	Harmonized as EN ISO 9000:2015 (not modified)

A2

IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

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 60601-1-8:2006-10+AMD1:2012-11+AMD2:2020-07 CSV(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

ISBN 978-2-8322-8720-0

CONTENTS

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.
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.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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;

– “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 (*).

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

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.

AMENDMENT A1 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.

AMENDMENT A2 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 3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo amendment.

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

FDIS	Report on voting
62A/1392/FDIS	62A/1407/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 15 P members out of 15 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.

NOTE The attention of users of this document 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 ⟦A2⟩ origin ⟨A2⟧ 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 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.

INTRODUCTION TO THE AMENDMENT A1

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.

INTRODUCTION TO AMENDMENT 2

The second edition of IEC 60601-1-8 was published in 2006 and amended in 2012. Since the publication of IEC 60601-1-8:2006+A1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the third edition of IEC 60601-1-8, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 20 items were presented to the National Committees present. All 20 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-8.

The "short list" of issues was documented in the design specification for Amendment 2. As IEC 60601-1-8 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 2. JWG 2 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-8:2006, the style in force at the time of publication of IEC 60601-1-8 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

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

1 * Scope, object and related standards

1.1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

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

It also provides guidance for the application of ALARM SYSTEMS.

1.2 Object

The object of this collateral standard is to specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and tests for ALARM SYSTEMS in ME EQUIPMENT and ME 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.

This collateral standard does not specify:

– whether any particular ME EQUIPMENT or ME 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.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, 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:

– A2 "the general standard" designates IEC 60601-1 alone, including any amendments;

– "this collateral standard" designates IEC 60601-1-8 alone, including any amendments; A2

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

1.3.2 Particular standards

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

2 Normative references

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.

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
Amendment 2:2020

deleted text

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
Amendment 1:2020

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

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012+A2:2020, IEC 62366-1:2015+A1:2020, and the following definitions apply.

NOTE 1 The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 2 An index of defined terms is found beginning on page 124.

3.1
*** ALARM CONDITION**
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.

3.2
*** 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

3.3
*** ALARM LIMIT**
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION