



IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

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**

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



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2020 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
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.

IEC online collection - oc.iec.ch

Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

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 18 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC -

webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC online collection - oc.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.



IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

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**

**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

ICS 11.040.01

ISBN 978-2-8322-1032-7

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

REDLINE VERSION

VERSION REDLINE



**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
essentiels – Norme collatérale: exigences générales, essais et guide pour les
systèmes d'alarme des appareils et des systèmes électromédicaux**

CONTENTS

| | |
|---|-----|
| FOREWORD..... | 4 |
| INTRODUCTION..... | 7 |
| INTRODUCTION to Amendment 1 | 7 |
| INTRODUCTION to Amendment 2 | 8 |
| 1 * Scope, object and related standards | 9 |
| 1.1 Scope..... | 9 |
| 1.2 Object | 9 |
| 1.3 Related standards | 9 |
| 2 Normative references | 10 |
| 3 Terms and definitions | 11 |
| 4 General requirements | 18 |
| 5 ME EQUIPMENT identification marking and documents..... | 18 |
| 5.1 Indicator lights and controls..... | 18 |
| 5.2 ACCOMPANYING DOCUMENTS..... | 19 |
| 6 ALARM SYSTEMS..... | 19 |
| 6.1 ALARM CONDITION | 19 |
| 6.2 * Disclosures for INTELLIGENT ALARM SYSTEM | 21 |
| 6.3 Generation of ALARM SIGNALS | 21 |
| 6.4 * Disclosure of delays..... | 29 |
| 6.5 ALARM PRESETS..... | 30 |
| 6.6 ALARM LIMIT | 32 |
| 6.7 * ALARM SYSTEM security | 33 |
| 6.8 * ALARM SIGNAL inactivation states | 33 |
| 6.9 * ALARM RESET | 37 |
| 6.10 * NON-LATCHING and LATCHING ALARM SIGNALS | 37 |
| 6.11 * DISTRIBUTED ALARM SYSTEM AND DISTRIBUTED INFORMATION SYSTEMS ABOUT ALARM CONDITIONS..... | 37 |
| 6.12 * ALARM- CONDITION SYSTEM logging | 42 |
| 6.13 ALARM SYSTEM functions | 44 |
| Annex A (informative) General guidance and rationale..... | 47 |
| Annex B (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS..... | 96 |
| Annex C (normative) Symbols on marking..... | 99 |
| Annex D (informative) Guidance for auditory ALARM SIGNALS | 108 |
| Annex E (informative) Verbal ALARM SIGNALS..... | 110 |
| Annex F (normative) * Reserved melodies for ALARM SIGNALS..... | 112 |
| Annex G (normative) * Auditory ALARM SIGNALS | 113 |
| Annex H (informative) VALIDATION of AUDITORY ICONS | 118 |
| Bibliography..... | 124 |
| Index of defined terms used in this collateral standard..... | 130 |
| Figure 1 – Illustration of temporal characteristics of auditory ALARM SIGNALS | 26 |
| Figure 2 – Functions of a DISTRIBUTED ALARM SYSTEM utilizing a MEDICAL IT NETWORK..... | 39 |
| Figure 3 – Functions of an ALARM SYSTEM..... | 45 |

| | |
|--|------------------|
| Figure A.1 – Graphical representation of components of ALARM SYSTEM delay | 70 |
| Figure G.1 – Illustration of spacing of AUDITORY POINTER | 115 |
| Figure G.2 – Illustration of temporal characteristics of an AUDITORY POINTER | 116 |
| Table 1 – Determination of ALARM CONDITION and assignment of priorities | 20 |
| Table 2 – Characteristics of alarm indicator lights | 22 |
| Table 3 – * Characteristics of the BURST of auditory ALARM SIGNALS | 24 |
| Table 4 – * Characteristics of the PULSE of auditory ALARM SIGNALS | 25 |
| Table 5 – ALARM SIGNAL inactivation states | 36 |
| Table A.1 – Reference interpretation of Table F.1 | |
| Table A.2 – Reference interpretation of Table F.2 | |
| Table A.1 – ALARM SYSTEM output to perceived OPERATOR action | 55 |
| Table A.2 – Examples of ME EQUIPMENT for each category of the SOURCE of an ALARM CONDITION | 95 |
| Table B.1 – Cross-reference of marking | 96 |
| Table B.2 – Cross-reference of ACCOMPANYING DOCUMENTS | 97 |
| Table B.3 – Cross-reference of instructions for use | 97 |
| Table B.4 – Cross-reference of technical description | 98 |
| Table C.1 – Graphical symbols for ALARM SYSTEMS | 99 |
| Table C.1 – Graphical symbols for ALARM SYSTEMS (<i>continued</i>) | 100 |
| Table C.1 – Graphical symbols for ALARM SYSTEMS (<i>continued</i>) | 101 |
| Table C.2 – Alternative ALARM SYSTEM related markings | 107 |
| Table D.1 – Attributes of perceived urgency | 108 |
| Table F.1 – * Equipment encoded auditory ALARM SIGNALS categorized by ALARM CONDITION and priority complying with Table 3 and Table 4 | |
| Table F.2 – * Auditory LOW PRIORITY ALARM SIGNAL complying with Table 3 and Table 4 | |
| Table G.1 – Characteristics of the BURST of the AUDITORY POINTER | 114 |
| Table G.2 – Characteristics of the PULSE of the AUDITORY POINTER | 115 |
| Table G.3 – Characteristics of the AUDITORY POINTER | 116 |
| Table G.4 – * Characteristics of the AUDITORY ICON | 117 |
| Table G.5 – Characteristics of the auditory ALARM SIGNAL | 117 |
| Table H.1 – Performance levels of three AUDITORY POINTERS and seven AUDITORY ICONS based on available data | 119 |

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 itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 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.

This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1-8 edition 2.2 contains the second edition (2006-10) [documents 62A/519/CDV and 62A/537A/RVC], its amendment 1 (2012-11) [documents 62A/824/FDIS and 62A/837/RVD] and its amendment 2 (2020-07) [documents 62A/1392/FDIS and 62A/1407/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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 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.

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 the base publication and its amendments 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 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.

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 publication 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 ~~source~~ origin 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.

INTRODUCTION to Amendment 1

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.

1) Figures in brackets refer to the bibliography.

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:

- "the general standard" designates IEC 60601-1 alone ~~(latest edition~~ including any amendments);
- "this collateral standard" designates IEC 60601-1-8 alone, including any amendments;
- "this standard" designates the combination of the general standard and this collateral standard.